REPORT
International Dialogue on Responsible Research and Development of Nanotechnology

Alexandria, Virginia, United States
17-18 June 2004

Andrew McMillan, NASA
Image on Cover Page: Andrew McMillan, NASA. A 17 nm genetically engineered protein cage called a chaperonin is used to organize nanoparticles into ordered arrays. In this example, gold arrays are formed by first tagging subunits with 1.4 nm nanoparticles and then self-assembling the subunits into the characteristic chaperonin ring structure. Extended ordered arrays can be formed because engineered chaperonins readily form two-dimensional crystals. The ability of the chaperonin to tolerate multiple genetic deletions and substitutions allows both the chemical functionality and the size of the pore leading into the core of the cage to be engineered. By tailoring the pore amino acid sequences, extended arrays of materials in addition to gold can be formed.
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EXECUTIVE SUMMARY

On 17-18 June 2004, a group of experts involved with nanotechnology from twenty-five countries and the European Union met in their individual capacity for an informal dialogue on responsible nanotechnology research and development (R&D). The meeting took place in Alexandria, Virginia, United States. It was sponsored and convened by the National Science Foundation and facilitated by the Meridian Institute. Participants discussed a wide range of topics, and had a chance to discuss several topics in detail during breakout group discussions. The four concurrent breakout group discussions focused on: benefits and risks to the environment; benefits and risks to human health and safety; the socio-economic and ethical implications of nanotechnology; and the special consideration of nanotechnology in developing countries.

The discussions were informal and exploratory in nature and participants covered a broad range of topics. Some of the recurring themes are summarized below. A concrete outcome of the International Dialogue was the agreement that a preparatory group should be formed to explore possible actions, mechanisms, timing, institutional frameworks, and principles for ongoing international dialogue, cooperation and coordination in the area of responsible R&D of nanotechnology. It was proposed that the preparatory group be organized around three large regions (North and South America; Europe and Africa; and Asia and Oceania), and that it should prepare a draft plan of action for continued dialogue and cooperation, as well as a joint declaration and a procedure for its adoption. Some recurring themes during plenary and breakout group discussions included:

- **Nanotechnology and Regulatory Responses** – Participants discussed and expressed divergent views as to whether and to what extent nanotechnology is inherently continuous or inherently disruptive. Those who felt that nanotechnology is inherently continuous suggested that current regulatory systems may be adequate to address the potential impacts of nanotechnology. Those who felt that nanotechnology would yield novel properties that only become evident at the nanoscale, suggested adoption of new, flexible regulatory approaches to quickly respond to developments.

- **Governance**: Participants raised broader issues related to the adequacy of existing organizations, governance tools, and the need for education of the public sector workforce to deal with and address public concerns over a rapidly emerging technology at a global scale.

- **Nanotechnology Applications and Implications** – Participants identified a need for a framework to discuss the possible benefits and risks of nanotechnology. They identified a need to differentiate between categories or types of nanotechnology.

- **Institutional Mechanisms for Ongoing Dialogue** – Participants agreed that there is a clear need for ongoing international dialogue, cooperation and coordination in the area of responsible R&D of nanotechnology. They developed a draft set of operational terms of reference (outlined on page 22) for the formation of a
“preparatory group” to explore possible actions, mechanisms, timing, institutional frameworks, and principles for this dialogue and cooperation.

- **Intention to Coordinate Activities** – Participants called for coordination and sharing of information regarding planned activities related to responsible R&D of nanotechnology. Some of the activities mentioned during the meeting include, but are not limited to: developing a common nomenclature; developing methodologies for risk assessment; exchanging information on human and ecological toxicology studies; studying environmental benefits of nanotechnology; and developing education, training and public awareness programs.

- **Expanding the Dialogue** – Even though many participants thought it was appropriate to begin these discussions with government representatives, they suggested that the discussions should be expanded to include other stakeholders, such as industry and civil society organizations, and that it should include the broadest range of countries, from the more prosperous to the poorest developing countries.
I. INTRODUCTION

Nanotechnology, the study and manipulation of matter on an ultra-small scale, is widely perceived as one of the key technologies of the 21st century. Experts expect that nanotechnology will benefit computing and electronics, medicine, materials and engineering, and the environment. The potential beneficial applications of nanotechnology are numerous, and several products containing manufactured nanomaterials have already reached the marketplace. With the rapid development of the underlying science and practical applications, some civil society groups have expressed concerns about the potential risks that could be associated with nanotechnology.

The International Dialogue on Responsible Research and Development of Nanotechnology (hereafter referred to as the “International Dialogue”) offered the first opportunity for government representatives and other stakeholders from around the world to discuss broad societal issues associated with nanotechnology R&D that are not likely to be adequately addressed by any single country. Dr. Mihail Roco, Senior Advisor on Nanotechnology for the National Science Foundation (NSF), and Chairman of the Subcommittee on Nanoscale Science, Engineering, and Technology (NSET) of the U.S. National Science and Technology Council convened the meeting, which was held in Alexandria, Virginia, United States on 17 – 18 June 2004. The Meridian Institute, a U.S.-based non-profit organization served as the facilitator of the discussions that took place at the meeting.

The International Dialogue brought together governmental representatives from twenty-five countries and the European Union and several international organizations to share information and exchange ideas and points of view in an open and informal setting, and to discuss the role and potential means of international collaboration to support responsible R&D of nanotechnology. The informal setting of the meeting allowed participants to express their individual and personal views, as well as to reflect any official policies or positions of their governments or organizations. This report contains a non-attributional summary of the discussions that took place at the meeting, reflecting the informal nature of the event. See Attachment A for a list of the participants and Attachment B for a copy of the agenda.

II. WELCOME AND OPENING REMARKS

Dr. Mihail Roco opened the meeting and welcomed participants. In describing the timeliness and importance of this meeting, Dr. Roco mentioned that worldwide government investments for research in nanotechnology have exceeded US$ 3.5 billion in 2004, that nanotechnology products are reaching the market and that concerns about the societal implications of nanotechnology are being voiced with increasing frequency. The time is right for this meeting of government representatives to discuss broad societal issues associated with nanotechnology R&D that cannot be addressed by any single country. Dr. Roco suggested that people need to balance the promise of nanotechnology
and the potential negative implications and that an ongoing and expanding dialogue can help foster the responsible R&D of nanotechnology. Dr. Roco proposed that an ongoing dialogue could be organized through an “international consultative board for responsible nanotechnology.” A copy of Dr. Roco’s remarks can be found in Attachment C.

Dr. John Marburger, Director, Office of Science and Technology Policy, Executive Office of the President, also welcomed the participants and provided opening remarks. He referred to nanotechnology broadly as applying to a wide range of science and technology opportunities created by the ability to image, manipulate, and simulate matter at the atomic scale. Dr. Marburger suggested that what distinguishes the new nanoscience from the old chemistry is the increased understanding and technical control of the role of nano-scale structure, but he stressed that nanoscience does not involve new materials. In discussing responsible development, Dr. Marburger suggested that the toxicity of the new forms of materials might differ substantially from older ones. Although this creates a challenge to regulators, Dr. Marburger suggested that the regulatory framework now in existence in the United States is broad enough to cover potential hazards from nano-materials. Dr. Marburger mentioned that the United States has taken pains to incorporate social, health, and environmental issues into its nanotechnology research planning. Existing legislation and procedures, such as those dealing with biotechnology and genetic engineering, will help to address ethical and other issues associated with R&D of nanotechnology. He emphasized that the societal implications of nanotechnology be discussed based on a clear and rational vision of nanotechnology. Dr. Marburger concluded that “if we are to realize the full potential of nanotechnology for our nations, and for the developing nations that can share its benefits, then we are going to have to agree particularly on standards and nomenclature, on issues of intellectual property protections, and on the need for responsible oversight and regulation of hazards that we may discover in these technologies.” A copy of Dr. Marburger’s statement can be found in Attachment D.

Dr. Arden L. Bement, Jr., Acting Director of the National Science Foundation, welcomed participants and offered comments during the group dinner on 17 June 17 2004. Dr. Bement recognized the shared desire to develop nanotechnology responsibly and with a global perspective. He stressed the importance of international exchange as the best way to ensure nanotechnology supports the common good. Dr. Bement mentioned that including the study of societal implications at the very onset of research creates a greater range of choices about how to shape nanotechnology. He briefly described how NSF brings together social, physical and biological scientists to bring a rich confluence of perspectives to bear upon nanotechnology. Dr. Bement suggested that public trust will be a key element in exploring the nanofrontier for the common good, and suggested that dialogue should engage the broader public. Dr. Bement’s comments can be found in Attachment E.
III. SUMMARY OF NATIONAL NANOTECHNOLOGY RESEARCH AND DEVELOPMENT PROGRAMS AND OPENING STATEMENTS

In advance of the meeting, the facilitators distributed a questionnaire that was designed to collect summary level information on the nanotechnology R&D programs in the countries and regions that were invited to participate, as well as information on relevant regulatory systems and the personal views of participants on the subject of responsible R&D of nanotechnology. During the meeting, one participant from each country was asked to verbally describe the breadth and scope of the nanotechnology research development programs in their country and to offer their initial personal views on responsible R&D. The information that was collected through the use of the questionnaires, and verbally presented in a summary form at the meeting, can be found in Attachment F.

The initial statements from participants regarding their personal views on responsible R&D of nanotechnology evidenced a broad range of perspectives and raised a large number of important topics and interesting ideas. Generally, there seemed to be broad recognition that increased international cooperation and coordination will be important and that actions should be taken to ensure the maximization of benefits and minimization of risks. The contributions made at the outset of the meeting also gave everyone a sense that nanotechnology might offer an opportunity to apply the lessons learned from experiences with other technologies. These initial individual contributions are not summarized in this report but they are provided in Attachment F.

IV. DISCUSSION OF RESPONSIBLE RESEARCH AND DEVELOPMENT

Building off of the opening statements, participants discussed several general themes in plenary before breaking into four breakout groups to discuss the following four topics: benefits and risks to the environment; benefits and risks to human health and safety; socio-economic and ethical implications; and nanotechnology in developing countries. A summary of the initial plenary discussion is provided below. The breakout group discussions are summarized in the sections that follow and include comments and questions posed following the small group reports to the full group. Attachment G contains a list of who participated in each breakout group.

A. Initial Plenary Discussion

1. The Nature of Nanotechnology

To start the discussion on the range of potential impacts on society, the group discussed whether and to what extent nanotechnology is inherently continuous or inherently disruptive. Some participants agreed with Dr. Marburger that there is a great deal of continuity, for instance, in nanotechnology’s potential hazards. They felt that the impacts on society that may be similar to those of other technologies and existing policy and regulatory responses are probably adequate to deal with the potential risks and benefits of nanotechnology. Some participants felt that nanotechnology is uniquely defined by its
size, new properties and functions, and capability to manipulate matter at the nanoscale. These participants felt that nanotechnology is by definition the search for and application of novel properties that only become evident at the nanoscale. They felt that these novel properties might make nanomaterials different from materials developed through, for example, traditional “bulk” chemistry applications. Several participants suggested that different types of nanotechnology applications should be distinguished from each other and might be treated differently. For instance, some nano-electronic applications may not be disruptive because they will change gradually and will continue to rely on conventional processes. Other applications, such as the convergence of nanotechnology and biotechnology may be disruptive and might require new regimes that are fast and agile enough to respond to disruption.

Numerous participants stressed that it was important not to think of nanotechnology as a single technology, but rather of a number of both discreet and interrelated technologies, each of which will have their own risk/benefit profile. It was suggested that it would be helpful to develop some sort of a framework within which important distinctions can be made such that the discussion of responsible R&D of nanotechnology does not become overly broad, and result in sweeping but not very meaningful statements and actions.

Governments may have to consider intended and unintended consequences of new nanotechnologies, as well as the possibility that the same technology could be used for both beneficial and harmful purposes. It was acknowledged that such dual-use technologies would present some real challenges in terms of the notion of responsible R&D.

Participants noted the tension between the desire to foster innovation, which may not need a regulatory framework, and the desire to understand and manage potential risks and unintended consequences. Differing views among meeting participants on how to best balance governmental actions to promote innovation that brings about the projected benefits of nanotechnology, and governmental actions to reduce, minimize, or, where possible, eliminate the risks and unintended consequences of nanotechnology was, not surprisingly, the main fulcrum around which much of the discussions revolved during the course of the meeting.

2. Regulatory and Other Responses

Participants discussed a range of possible government regulatory actions to address potential risks of nanotechnology. One participant raised the question as to whether governments should be contemplating a moratorium on nanotechnology. When asked if any country was contemplating a moratorium, none of the participants indicated that they were. The general attitude seemed to be that, aside from the potential benefits that would fail to materialize, there is insufficient knowledge about risks to justify a moratorium. Participants noted, however, that certain civil society groups not represented at this meeting have proposed a moratorium. Several participants suggested that regulation should evolve as information about impacts on the environment, human health and safety, and social structures becomes available. Good information about risks would make it
possible to make changes at the design phase in order to prevent future harmful effects. However, some participants cautioned that a regulatory system should not be unduly prescriptive such that it stifles innovation or causes other problems in the future. Instead, a regulatory system might be based on principles and include components that create adaptive capacity and encourage flexibility as we learn more and more about the benefits and risks associated with discreet forms of nanotechnology. Others felt that it was important that regulations should build public trust by ensuring transparency, credibility and rigor.

A common theme throughout the discussions was the importance participants placed on education and training to prepare the workforce, the public and young generations for the rapid emergence of nanotechnology. Training and education was mentioned as an important aspect of several issues, such as providing public education and information to engender a constructive public debate; allowing all countries to benefit from nanotechnology applications as well as assess and manage potential risks; building a qualified workforce; and preparing government staff for impacts of nanotechnology that might require new policy and/or regulatory approaches.

3. Institutional Mechanisms for Ongoing Dialogue and Action

Participants explored possible venues for continuing the international dialogue on responsible R&D of nanotechnology. Some cautioned that governments may be reluctant to create a new institution, but suggested, for instance, that the G8, the United Nations (UN), or the Organization for Economic Cooperation and Development (OECD) might offer venues. The OECD, for example, has been used as a venue where governments (member and non-member) and other organizations come together to engage in a dialogue.

A participant suggested the formation of a “sherpa” or preparatory group that is representative of all countries to prepare for ongoing dialogue. This suggestion resonated with other participants and, as described more fully below, the development of draft terms of reference for a preparatory group became one of the key outcomes of the meeting.

Several participants reiterated that the international dialogue should discuss specific categories of technologies and place the discussions of potential benefits and risks in specific context. One participant also suggested that it is critical to develop a framework and a logical path to guide the discussions and prevent them from bogging down.

Most participants felt that ongoing dialogue, although important, should not be an end in itself and that this meeting as well as an ongoing dialogue should lead to concrete action. One participant suggested that one form of action could be the development of a code of conduct. Such a code of conduct could include: a commitment from institutional authorities to use public funds for R&D of nanotechnology in a manner that protects the integrity of mankind; the constitution of a high-level scientific advisory board to give advice concerning, among others, risk prevention; and a commitment to treat knowledge
on the impacts of nanotechnology as a public good and share this information. This language, however, led to questions about how to define human dignity and how to reconcile the desire to share information with intellectual property (IP) protection, and led to the suggestion that the international community needs a common nomenclature.

Several participants mentioned that different entities are planning activities that should be considered by a preparatory group, especially as it relates to the need to develop nomenclature and definitions to classify and define nanotechnology.

Some participants mentioned that countries are engaged in a global competition to bring the benefits of nanotechnology to the market. At the same time, it was noted that potential risks associated with nanotechnology could be addressed in common because they affect shared interests. This will require a good understanding of risks, and development of appropriate regulations that do not prevent continued investments and innovation. However, others mentioned that if people agree on the importance of protecting human health and safety, this might lead to added cost due to additional safety precautions. Some participants mentioned that these issues, although important, should not detract from efforts to achieve excellence in and continued funding of basic research. Several participants stressed again the need for a framework, a set of common rules that encourages innovations in a responsible manner.

4. Expanding the Dialogue

An important consideration in future international dialogue should be the position of developing countries, and especially poor and excluded people in developing countries. Several participants stressed the importance of preventing a widening knowledge gap between developed and developing countries, and suggested that the international dialogue and collaboration should help developing countries participate in nanotechnology R&D. Participants suggested that the broadest range of developing countries, from the more prosperous to the poorest, should be included in the dialogue. Participants recognized that economic, social and other conditions vary greatly among developing countries and that these countries may have different needs in terms of responsible nanotechnology R&D.

Companies are rapidly developing products and placing them on the market. Much of the development of nanotechnology will take place in the private sector. Participants suggested that industry should be involved in the international dialogue on responsible development of nanotechnology sooner rather than later. The dialogue could involve industry associations as well as individual companies. However, one participant suggested that industry involvement is more critical for addressing some issues than others (e.g., metrology should be discussed with industry partners). Interactions between governments and industry should be strategic in order to have a long-term impact on nanotechnology. It was suggested that private industry has a strong interest in sharing information on environmental impacts and health and human safety and would be eager to participate in this dialogue.
Several participants mentioned that other groups in society, for instance civil society groups such as environmental organizations, should also be included in the dialogue about responsible R&D of nanotechnology.

A participant warned that the dialogue should be conducted in the broader context of the role of science in society and societal control of science. Focusing exclusively on nanotechnology could result in discussions bogging down in uninformed notions and concerns about risks that are not necessarily real.

**B. Environment Breakout Group Discussion**

One of the four breakout groups took a broad look at the potential benefits and risks to the environment associated with nanotechnology. In addition to a discussion of potential benefits and risks, the group discussed actions that might be taken by the international community to maximize benefits and reduce risks. Group members suggested that a discussion of the environment could include a broad range of topics related to air (e.g., volatile organic compounds emissions), water (e.g., desalination; waste water treatment), soil (e.g., soil fertility and sensors), biological systems, biosphere, weather and climate (e.g., emissions of greenhouse gases), agriculture (e.g., food production), and security (e.g., water and food supplies targeted by terrorist attacks).

Participants recognized that nanotechnology presents opportunities for potential benefits as well as potential risks to the environment. However, they mentioned that there is a lack of hard facts regarding both the potential harmful and beneficial effects. Additional research is needed. One participant suggested that research might look at what is different about nanotechnology that it would require a different response in comparison to existing technologies. Other participants offered that an important difference is that nanoparticles can go anywhere and that, for instance, macrophages do not recognize certain size nanoparticles. These characteristics could have unintended consequences.

**Framework for Discussing Benefits and Risks**

In discussing the key potential benefits and risks to the environment from nanotechnology, the group discussed a framework (see table 1 below) that organizes categories of topics, issues and questions related to the potential environmental risks and benefits of nanotechnology.

**Benefits to the Environment – Some Examples**

In addition to the examples mentioned in the context of this framework, participants mentioned several other specific examples of benefits to the environment that could result from nanotechnology. Several participants mentioned opportunities offered by nanotechnology to combat climate change by enabling economies to switch to hydrogen as a main source of fuel and by making renewable energy sources (e.g., photovoltaics) more efficient. Others mentioned opportunities to reduce energy consumption. For instance, research is being conducted in Japan to develop polymers and metals that can help create super-conducting materials and storage devices that contribute to greater energy efficiency. Energy consumption could further decrease by using better sensors.
Table 1: Framework for Discussing Potential Environmental Benefits and Risks of Nanotechnology

<table>
<thead>
<tr>
<th>Applications (Benefits)</th>
<th>Implications (Risks)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category</strong></td>
<td><strong>Examples of Applications</strong></td>
</tr>
<tr>
<td>Sensors</td>
<td>Sensors for emissions monitoring</td>
</tr>
<tr>
<td>Treatment and/or Remediation</td>
<td>Applications for water desalination and waste water treatment</td>
</tr>
<tr>
<td>Renewable Energy</td>
<td>Applications for efficient hydrogen storage and use, efficient photovoltaic cells and electricity storage</td>
</tr>
<tr>
<td>Catalysis</td>
<td>Applications for improved catalysis to reduce waste compounds</td>
</tr>
<tr>
<td>Green Manufacturing</td>
<td>Applications for cleaner production. This could include green engineering to manufacture nanomaterials in a manner that reduces pollution, but also applying NT to produce other products using a cleaner process</td>
</tr>
</tbody>
</table>

developed with nanotechnology. Participants mentioned that nanotechnology is being used to develop improved coatings that can result in reduced air emissions of volatile organic compounds (VOC). A participant also mentioned that nanotechnology could be used to dramatically increase wireless connectivity, which could reduce the need for face-to-face meetings, thereby reducing the need for transportation.
Risks to the Environment – Need for Risk Assessments

In turning attention to potential environmental risks, participants noted the lack of knowledge regarding potential risks of nanotechnology, and most felt there is a need for risk assessments. Participants suggested that potential exposure in the workplace and potential exposure during research are currently the most likely events that could involve risks. Other potential risks, for instance those resulting from decomposition or change of properties over time, may be longer-term risks. Considering that many nanotechnology applications are still in the developmental stages, and researchers only make very small amounts of material, should risk assessments be conducted now, or would it be more appropriate to do so when commercial applications arise? Many participants felt that governments should promote risk assessments at this early stage of nanotechnology R&D for the following reasons:

- **International corporations are rapidly moving from development to dissemination.** Some products, such as computer displays containing nanomaterials, could be produced in large quantities.
- **Investors are increasingly asking that companies ensure that environmental and ethical standards are met in order to reduce potential liability risks as they develop and distribute new nanotechnology products and applications.**
- **Developing countries have no resources to study toxic effects, but will most likely receive nanotechnology products.**

These reasons make toxicological research both pressing and challenging. Some participants felt that governments have to work now to understand potential risks associated with nanotechnology in order to provide industry and society with solutions for future problems.

In order to promote risk assessments at this early stage, participants felt that funding agencies should require nanotechnology research projects to include an assessment of the environmental, health, social and ethical impacts in order to assess the potential risks associated with the product or method under development. This would promote a balanced, interdisciplinary approach to nanotechnology R&D. Some suggested that the risk studies should be carried out separately from the research on the product and/or technique. This interdisciplinary approach might include an education component. This type of research would help researchers make a product safer as they develop it and would help them think through the multiple applications of their product, which could include environmentally beneficial ones.

One participant mentioned that data from industry studies could be considered as an additional source of data. For instance, DuPont performed a carbon nanotube toxicity study.

Some participants cautioned that there is a lack of uniform scientific research, which suggests a need to develop common standards and methodologies. For research that is...
Currently available, one needs to assess the science behind the study results. For these studies, it will take time to repeat tests and reach broad agreement on the research results.

Several participants suggested that new, fast and secure methods are needed to quickly identify characteristics that would indicate potential toxic effects of new nanomaterials. These methods are needed to keep up with the rapid pace of development of new nanomaterials. They questioned, however, whether it would be possible to develop modeling programs that predict the reactivity of particles. It will be very difficult to develop reliable and useful models due to the complexity of the materials and interactions with their environment. With regards to study methods, one participant suggested that the toxicological effects of nanomaterials should be studied on smaller organisms (e.g., microbes and insects) rather than, for instance, mice and rats. Others suggested that risk assessors should use systems approaches, such as life cycle assessments (e.g., through four phases: extraction, production, use, end of life) and impacts of changes in material flows through the economy.

Participants mentioned that many government agencies have very limited budgets to fund studies to protect the environment and human health, and that whatever safeguards are put in place will be determined, at least in part, by their costs.

Possible Actions by the International Community
Some participants cautioned that international action and coordination should take a sequential approach (e.g., first agree on standards and nomenclature then go to the next step). Participants suggested several possible actions the international community could take in the near term:

- Share hyperlinks to websites with lists of government funded research projects and grantees.¹
- Share hyperlinks to sites with toxicological and ecotoxicological studies. Participants expressed a willingness to create hyperlinks to each other’s sites with toxicological data/risk assessment information.
- Organize an international workshop of grantees that have health and environmental toxicology data. The workshop would allow grantees to share data, map the available data, identify needs for more data, and develop recommendations. Such a meeting could be held periodically.

¹ During the discussion, the following references were provided: an overview of European Commission grants is available at: http://www.cordis.lu/nanotechnology (click on “funded projects and networks”). An overview of U.S. EPA National Center for Environmental Research grants is available at: http://es.epa.gov/hcer/grants/. An overview of U.S. NSF grants is available at http://www.nsf.gov/nano (click on "Solicitations and outcomes" and "Centers"); links to other agencies of the US National Nanotechnology Initiative are available at: http://nano.gov. An overview of UK Engineering and Physical Sciences Research Council (EPSRC) grants is available at: http://www.epsrc.ac.uk/website/index.aspx (click on “grant process checker”; click on “current grant portfolio”).
Some participants also suggested that there could be a shared website or online database with information on research results, toxicological studies and “green” technologies. Others cautioned, however, that such a site would be most valuable if it would only contain studies that meet certain quality standards or criteria to be duly agreed upon. Furthermore, a website would require on-going funding and resources to maintain the website. Perhaps an organization like the G8 could establish a center of information. One participant suggested that interested parties can share information through a listserv and that she manages a listserv that tracks policy-relevant developments in nanotechnology.

Participants mentioned several activities that they will engage in and may be of interest to the group, including: U.S. EPA Grantees Workshop (summer 2004); U.S. EPA Symposium (March 2005 in San Diego); and a review article to be published in the Environmental Science and Technology Journal (March 2005). Participants also mentioned that the European Union and United States are coordinating several activities.

Participants agreed that there seems to be a common interest in sharing information on new technologies, new risk assessments, and new industry applications at this relatively early stage in the development of nanotechnology. They expressed an interest in on-going dialogue, but also stressed the need for action.

C. Human Health and Safety Breakout Group Discussion

This breakout group took a broad look at the potential benefits and risks to human health and safety (HHS) associated with nanotechnology. For the purpose of this discussion, HHS was defined broadly to include medical devices, pharmaceuticals, and worker and consumer exposure issues. The group began by focusing on the following questions:

- What are the key potential benefits and risks to HHS from nanotechnology?
- Are these potential benefits and risks likely to emerge in the short-term (during the next 1-5 years) or the long-term (over 5 years)?
- What are some important actions that might be taken by the international community to enhance the benefits and reduce the risks?

In grappling with this initial set of questions, the group realized it was necessary to find a way to break down the concept of nanotechnology into component pieces. For the purpose of discussing potential benefits and risks to HHS, the group made a distinction between:

A. Nanotechnologies that are intended to improve HHS, such as:
   1. Medical (pharmaceuticals, medical devices, etc.) and cosmetics*
   2. Public health improvements (e.g., water purification)
   3. Bio-sensors

* While it was recognized that cosmetics are typically not intended to improve human health, strictly speaking, they were tentatively included in this category so as to not lose sight of their importance.
B. Nanotechnologies that have unintended consequences or secondary impacts on HHS, including:
   1. Workers
   2. Consumers

Turning its attention back to the initial set of questions, several members of the group suggested it would be helpful to go back to a “first order” question of what is the definition of nanotechnology: Is nanoscience and nanotechnology the search for and application of novel (new and different) properties of matter that are only manifested at the nanoscale? Or is nanotechnology just an evolution of “the same old chemistry” (i.e., the search for and application of well-known properties of matter that are already exhibited at the micro and bulk scales). One participant noted that the philosophy of chemistry is that chemical properties exhibited at the bulk scale are assumed to be the same as those exhibited at the molecular scale. The group agreed that the search for and application of novel properties is the essence of what is referred to as “nanotechnology.” The search for and application of such novel properties is the reason why nanotechnology R&D is segmented from other more traditionally focused R&D programs.

This first order question was important to the group because of the implications it may have for whether new approaches are needed regarding the regulatory systems and related institutions we have in place to protect HHS. One example that was discussed by the group was the Chemical Abstract System (CAS), the internationally recognized system for identifying and naming new chemicals. While this nomenclature system is not a regulatory system per se, it was recognized as an important transparency tool and as a portal into the regulatory system. The discussion noted that the “nomenclature issue” is particularly challenging in that the properties exhibited at the nanoscale are often not static but can be dynamic depending on the size of the nanomaterials – thus resulting in the possibility of hundreds of different entries into CAS for a material that might otherwise be considered the same chemical. Another example mentioned was carbon nanotubes in so far as the material that makes up carbon nanotubes serves as an insulator of electricity at the bulk scale and as a conductor of electricity at the nanoscale.

One participant expressed a view that the existing and widely accepted and utilized protocols for protecting HHS of researchers will probably be adequate in the context of nanoscience and nanotechnology R&D.

With regard to the larger context of the commercialization of nanotechnology, it was suggested that it might be possible to develop a decision-making flow chart that starts with the question of whether the nanomaterial exhibits unique properties and then turn to the question of whether the material is mobile or not (e.g., lead embedded in glass is not as much of a concern to HHS as lead contained in gasoline or paint). Another participant suggested that it might also be important to address the time dimension as well as mobility (i.e., is the material mobile and, if so, for how long?). While there appeared to be agreement that nanotechnology is the search for and application of novel and unique properties, at least one participant expressed a caution that it will be difficult to define and use a “unique properties” test as a trigger for regulatory oversight.
It was also suggested that it might be helpful to do “life cycle case studies” on titanium oxide and carbon nanotubes with the intention of exploring whether they exhibit unique properties that might warrant the need for further evaluation.

One participant raised the issue of the social risk of whether nanotechnology will be seen as socially acceptable given the lack of trust in governance systems and institutions and the general social unease with the introduction of new technologies. Another participant suggested that consideration be given to the development of a voluntary code of conduct, involving and perhaps led by industry and non-governmental organizations. It was noted that some representatives of the insurance and re-insurance industry are beginning to express the need for such a code of conduct. Another suggested that it might be useful to start with a voluntary code of conduct for people who are doing the research.

Some members of the group proposed different types of nanotechnology as requiring relatively more or less urgent attention for evaluating their potential benefits and risks to HHS (e.g., gene targeting DNA as compared to nanomaterials and sensors.) However, it quickly became clear that there were divergent views as to what the priorities should be.

In concluding their discussion, the group did not reach a firm conclusion on whether the sought after novel properties that define nanotechnologies requires novel approaches to ensure transparency and an appropriate level of regulation. However, there appeared to be an emerging consensus that:

- Nanotechnology poses challenges for HHS – both in terms of realizing its full intended potential benefits and reducing its unintended risks;
- Nanotechnology poses challenges for our “current way of doing business,” both in terms of how we conduct R&D, as well as how we regulate the introduction of new technologies into commerce;
- Nanotechnology poses challenges for social acceptability; and
- There is a need for continued dialogue of experts (meetings like this one) as well as with other actors in civil society (such as industry and NGOs).

During the plenary session when the HHS breakout group report was given, several additional points were raised. One participant noted that the amount of the substance a person is exposed to often determines its toxicity. A substance taken in small amounts can be harmless, but in larger doses it could be harmful. Another suggested that research labs should self-regulate for health and safety in the lab space. Still another participant suggested that HHS regulatory efforts should focus first on the health category where the greatest public fear lies: bio/nano – viruses, swarms of nanoparticles, etc. It was suggested that there is an urgent need to clarify the true status of these technologies and to take action to mitigate some of these fears. Finally, it was suggested that we should put nanotechnology in its proper context: by-products from many existing industries pose much higher risks to HHS than do current nanostructures and materials (e.g., welding linked to Alzheimer’s disease). Nanotechnology can be used to reduce the risks from existing industrial processes. Also, we need to put nanotechnology in the context of
human exposure to numerous types and large amounts of naturally occurring and anthropogenic nanostructures and materials.

D. Socio-Economic and Ethical Issues Breakout Group Discussion

The socio-economic and ethical (SEE) issues breakout group identified and discussed a range of topics associated with the anticipated benefits and challenges of nanotechnology. In organizing the conversation, the group decided they would focus on the implications of nanotechnology generally, not just nanotechnology R&D. They also indicated that, in many ways, the SEE work group was addressing the human dimensions of nanotechnology, some of which had been identified in the responses to the questionnaire and discussed in the opening plenary session. This included issues such as, but not limited to: promoting human-well being and human development; the importance of education at all levels for students, researchers, policy makers, civil society, the media and others; participation, trust, and transparency; and dialogue.

Early in the work group conversation, the group took note that while there may be things unique about nanotechnology relative to socio-economic and ethical issues, some socio-economic and ethical dynamics might also be the same as for any new technology. Regardless, the group pointed out that there is clearly one important dynamic that will be important to take into account. This is a recognition that the current societal context in which nanotechnology is emerging is significantly different than the societal context that existed for other significant scientific endeavors of ten, twenty or fifty years ago. Specifically, globalization brings new implications such as: instantaneous worldwide media attention and the use of the Internet for information dissemination (scientific, advocacy, etc). The group noted that there are enhanced expectations about the need for and the manner in which the scientific establishment, governments, and companies interact with the public. There is greater concern about the divide between rich and poor throughout the world, an increasing interest in human development, fairness in access to information and technology, and an even greater expectation of transparency and participation in decisions. Finally, the group recognized that as nanotechnology starts to become the subject of dialogue in society that issues of fact as well as perceptions and values will become an integral aspect of discussions amongst scientists, governments, companies, civil society, policy makers, the media and others.

In considering the implications of the modern day increasingly global context within which nanotechnology is emerging, the group also noted that importance of global market forces and the reality that countries and companies are making investments to gain a competitive advantage. While participants acknowledge the importance of economic competitive forces, they also noted that there appears to be a strong self-interest to find ways to collaborate internationally on issues of common interest such as nomenclature and measurement, collecting risk related information, and promoting dialogue and education.
Within this potential dichotomy of competitive market forces and international cooperation, the work group discussed some of the potential challenges ahead. For example, what could or should be done if one country decides to “opt in” for a particularly controversial technique/product while all others “opt out”? Will that create a push for others to opt in or opt out? Would there be pressure on those who did opt in and what recourse could there be on either side of that issue?

Just as with the opt-in and opt-out dilemma described above, one participant raised the possibility that there could be significant and difficult unintended consequences if a nanotechnology had a dual use application. The product might be restricted for trade or donation for reasons related to its “bad” use, even if it had humanitarian applications with significant potential to improve people’s lives. The issue of dual use and the ethical and socio-economic dimensions of nanotechnology were raised as something that should remain on the global agenda for continued understanding and dialogue.

The group agreed that in order to move forward with an international dialogue on socio-economic and ethical issues there is a need for a framework that, as explicitly and factually as possible, can make transparent the potential benefits nanotechnology might bring to humanity as well as the risks. The group also noted that it may prove too difficult to develop such an approach at a general level and there is a need to differentiate between different categories or types of nanotechnology, which will have many applications and many types of effects. For some of these effects, current regulations may be sufficient while for others, new approaches might need to be developed. It was suggested that there is a need to establish a framework to facilitate dialogue and that such a framework may need to move to a greater level of detail specific to more focused applications of nanotechnology in order to be productive. Some examples included energy, material, or specific techniques and tools, or products. In addition, in considering whether and how nanotechnology might be regulated in the future, the group noted that any regulatory system would probably need to be flexible because it is likely that continuous adjustments will be needed that we do not yet fully understand.

The group discussed the important role that dialogue will play going forward, especially regarding science and society. The group noted that such dialogue, to be successful and useful, will need to involve a variety of societal actors in different kinds of dialogue such as: scientists, industry, policy makers, civil society, the media, and others. The group also mentioned that different age groups and regions of the world, for example, are likely to be important participants in dialogue on nanotechnology as well. This led to a reiteration of the points raised in the morning plenary that education, including K-12 education as well as university and advanced degree education will be essential to realizing the benefits of nanotechnology, and will contribute to an informed societal dialogue about the balance of benefits and risks.

The group considered just a few of the ethical dimensions that might arise as nanotechnology R&D matures. For example, what are the ethical implications of new life-prolonging technologies or organ or limb replacement tools that can extend life many, many years beyond what is currently possible? The group asked, whether there is
some point at which the use of life-prolonging technologies is no longer considered ethical? The group also noted that some scientists suggest that soon we may be able to know even more about the nature of life itself, including when, and under what conditions life begins and how. Participants indicated that these are only a few examples of the kinds of ethical issues the benefits and challenges nanotechnology may bring to society.

Just before concluding, the group indicated that it might be useful and important to explore what key conditions are necessary to pursue nanotechnology R&D. For example, what types of labs and equipments are needed, what type of knowledge a researcher must have, must the workforce be educated, etc. Understanding this may be an important aspect of how to assist poorer countries in their pursuit of nanotechnology benefits. At the same time, it was pointed out that knowing this may create further ethical and socio-economic questions for society.

At the end of the discussion, the work group members noted that a critical challenge in society’s ability to understand, assess, make explicit, and engage in education and dialogue on the balance of benefits and risks of nanotechnology has a great deal to do with the ability of society to cope with significant complexity. Success may be defined by society’s ability to manage this complexity (e.g., multi disciplinary, multiple ministries, the nature of the science, behavior of products, ethical issues).

The group concluded that while they may have only begun to identify a small portion of the ethical and socio-economic issues associated with nanotechnology, they were confident that finding the balance of managing the benefits and risks would require further international dialogue and collaboration and encouraged further discussion of this topic in the plenary group.

E. Nanotechnology in Developing Countries Breakout Group Discussion

This breakout group discussed whether nanotechnology presents challenges for developing countries that are different than issues associated with other new technologies (e.g., biotechnology, information technology). The discussion, for example, explored whether nanotechnology presents unique issues in regards to R&D capacity, infrastructure, regulatory development, etc. Specifically, the group focused on the following questions:

a. What are the key issues for developing countries associated with nanotechnology R&D?

b. Does nanotechnology raise issues for developing countries that are unique (i.e., issues that have not been seen with the introduction of other new technologies such as biotechnology)? If so, what are they?

c. What are some important actions that might be taken by the international community to address issues regarding nanotechnology that are unique to developing countries?
In discussing key issues for developing countries associated with nanotechnology R&D, the group identified the following list of issues:

- Infrastructure
- Human capacity and policy capacity
- Money
- Intellectual property rights
- Education, both as it relates to academics (i.e., the need to develop university curriculum) and the public
- Trade barriers
- Political context

Based on its limited time together the group concluded, that, by-and-large, the list of issues identified above are not unique to nanotechnology.

Pre-existing gaps in developing countries related to biotechnology and information technology (e.g., lack of infrastructure, human capacity, policies, money, etc.) translate into gaps in the nanotechnology arena because of the linkages between nanotechnology and other new technologies.

Participants noted that societal needs differ between developing and developed countries. For example, in the area of research to address disease, participants noted that the list of high priority research items for developing countries might focus on diseases A, B, and C while developing countries might choose to focus on diseases X, Y, and Z.

While the group concluded that nanotechnology presents a familiar list of issues for developing countries (e.g., lack of capacity, resources, etc.), there are numerous lessons from the introduction of other new technologies that can be applied to nanotechnology, thereby avoiding missteps with nanotechnology.

The group noted the importance of ensuring that a diverse group of stakeholders (e.g., developing countries, NGOs, industry, etc.) are “at the table” when problems and priorities are identified.

Some participants noted that nanotechnology presents an opportunity to think creatively about the role of the private sector in developing countries. For example, with information technology and biotechnology, companies typically donated technologies and services to developing country institutions. With nanotechnology, companies can pursue the development of new products and related services that benefits both the company and developing countries. Specifically, companies and developing countries can work together to develop markets for nanotechnology products. In the plenary session when the workgroup report was presented, one participant commented that the charitable approach taken by companies with biotechnology and information technology is not sustainable, but market-based approaches are sustainable.
Some participants noted that nanotechnology presents an opportunity to think creatively about developing country assets. Several people noted, for example, that developing countries are attractive manufacturing centers because of low labor costs, which make developing countries attractive locations for nanotechnology manufacturing. Manufacturing jobs can raise standards of living and government revenues, which could in turn allow these developing countries to begin investing in nanotechnology R&D.

One participant noted two recent creative initiatives in the biotechnology arena for addressing issues associated with intellectual property rights including the African Agricultural Technology Foundation (AATF) and the Public Intellectual Property Resource for Agriculture (PIPRA). These two relatively new entities help developing country research institutions access patented agricultural technologies from companies and universities. The participant suggested something similar might be appropriate for nanotechnology.

Many members of the group commented on the need for new approaches to training that both encouraged developing country scientists to get trained in developed countries, but return to their native countries when their training was completed.

During these “lessons learned” discussions, participants were repeatedly confronted with terminology and definitional challenges. Specifically, participants questioned one another about the meaning of “developing countries.” Was, for example, the group focused on issues associated with nanotechnology for the more prosperous developing countries (e.g., Brazil, India), the poorest developing countries, poor developing countries, or some combination of these categories? The group acknowledged that the issues would differ depending on which of the categories was the focus of the discussion and, in turn, the strategies to address the issues would also differ. As with the plenary discussion that took place in the morning, the group acknowledged that clarity about the term “nanotechnology” is important, given the breadth and diversity of technologies encompassed by this term.

Due to the time allotted for the breakout session, the group had relatively little time to discuss specific actions that could be taken by the international community to address the issues identified above. One participant made a specific suggestion that donors include specific requirements in funding agreements that would require developing country institutions to use best practices for nanotechnology R&D. At a broader level, the group concluded that more time was needed to discuss this important set of issues associated with nanotechnology and developing countries.

F. Breakout Groups – Common Themes Matrix

In reflecting on the discussions in the breakout groups, David Rejeski, Director of the Foresight and Governance Project of the Woodrow Wilson International Center for Scholars, presented the matrix illustrated on the next page that displays some of the ways risks and benefits were discussed during the breakout sessions as well as a number of possible parameters affecting failure or success.
Figure 1: Nanotechnology Matrix by D. Rejeski, Director of the Foresight and Governance Project, Woodrow Wilson International Center for Scholars

The following two boxes contain a brief explanation of the terms used across the X and Y-axes of this matrix.

**Risks/Benefits**

- **Novelty**: Risk/benefits that arise from the emergence of new properties at a nano-scale level.
- **Systemic**: Risk/benefits arising from systems interactions, such as the convergence of nano, bio, and information technologies. Also see the discussion on emerging systemic risks in the recent OECD study on “Emerging Risks in the 21st Century”.2
- **Social**: Risk/benefits that arise in the social sphere affecting the public acceptance of nanotechnology, technological diffusion, etc. (as distinct from more quantifiable technological risks associated with human exposure, probability of accidents, etc.)

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Failure/Success Modes

- **Resources**: Adequacy of funding and human capital to address emerging nanotechnology issues at national, regional, and international levels.
- **Intellectual**: Development and application of analytical tools and conceptual models needed to deal with emerging challenges of nanotechnology, e.g., new approaches to risk assessment, toxicology paradigms, and technology diffusion models.
- **Governance**: Adequacy of mechanisms such as regulations (environmental, worker safety, consumer protection, and food safety) and bilateral/multilateral agreements to address issues and concerns around nanotechnology. In a larger sense, the adequacy of our existing organizations, governance tools, and public sector workforce to deal with a rapidly emerging technology at a global scale.

V. CONCLUSION

After hearing the report from the breakout groups in a plenary session, the group decided to stay in a plenary rather than move back into breakout groups as indicated in the agenda for the meeting. During the plenary session, it became clear that the participants agreed there is a clear and urgent need for ongoing international dialogue, cooperation, and coordination in the area of responsible R&D of nanotechnology. An ongoing dialogue should enable and maximize the beneficial contributions of nanotechnologies to society and natural systems as well as address the concerns of the public to reduce risks that may be associated with nanotechnologies. In order to promote an ongoing dialogue, participants spent some time during the final plenary session working on a draft of the operational terms of reference for a “preparatory group”, still informal, that would be formed to further the goal of international dialogue and cooperation.

**Operational Terms of Reference**

**Preparatory Group**

1. The participants support the idea that, in order to reap the full benefits of nanotechnology, there is a need to continue and intensify an international dialogue and cooperation on responsible R&D of nanotechnology to respond to the expectations and concerns of citizens.

2. Such dialogue and cooperation needs structure and the participants agreed to constitute a small preparatory group to explore possible actions, mechanisms, timing, institutional frameworks, and principles for this dialogue and cooperation, which can be accepted by all countries and regions.

3. The preparatory group will prepare a draft plan of action for continued dialogue and cooperation, and a joint declaration, along with a procedure for their adoption. Other countries may join if interested.
4. The preparatory group will be composed of participants from three large regions: North and South America; Europe and Africa; and Asia and Oceania. It will alternate meeting in one of these large regions, with a rotating chairmanship. Every party will cover its own costs and the chair should ensure meeting facilities and the secretariat.

In addition, meeting participants called for action to begin to address priority issues that will help ensure the responsible R&D of nanotechnology. Participants recognized that there are numerous activities that they and others will engage in while the preparatory group forms and completes its tasks. These activities should be considered by the preparatory group as it prepares a plan of action. Some of the activities mentioned during the meeting include, but are not limited to:

- Developing a common nomenclature;
- Developing methodologies for risk assessment;
- Exchanging information on human and ecological toxicology studies;
- Studying environmental benefits of nanotechnology; and
- Developing education, training and public awareness programs.

It was acknowledged that this list may be incomplete and participants were encouraged to share with each other additional information about the scope and nature of the ongoing and already planned activities related to responsible R&D that they are personally involved in.

Participants appreciated the fact that this meeting included mostly government representatives from countries with a broad range of experiences and nanotechnology R&D programs. However, they strongly suggested that future discussions be expanded to include other interested countries that did not participate in the International Dialogue, and, when possible, other stakeholders such as industry and civil society organizations.
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ATTACHMENT B: AGENDA

AGENDA
International Dialogue on Responsible
Research and Development of Nanotechnology
17-18 June 2004

Holiday Inn Hotel and Suites
625 First Street, Alexandria, Virginia, United States
phone number +1-703-548-6300 | fax number +1-703-548-8032

| Meeting Purpose: | To bring together governmental representatives from countries/regions with significant nanotechnology research and development programs to enter into an informal dialogue about how to best ensure such programs are carried out in a responsible manner. |
| Meeting Objective: | To share information and exchange ideas and points of view in an open and informal setting, and to discuss the role and potential means of international collaboration to address responsible development of nanotechnology. |

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9:15 Statements by Participants – An opportunity for one representative from each country/region to make a brief statement and describe to other participants:

- The government programs and agencies in their country/region related to nanotechnology research and development as well as regulation of nanotechnology;
- A general summary and estimate of the public and private sector investments in nanotechnology R&D in their country/region;
- Their personal view on the key issues that need to be addressed in order to ensure that nanotechnology research and development is conducted in a responsible manner.

10:30 Coffee Break

10:45 Continue Statements by Participants

12:00 Lunch Break

13:00 Facilitated Open Dialogue to Identify Key Issues Regarding Responsible Research and Development of Nanotechnology – All Participants

15:15 Afternoon Break

15:45 Breakout Groups to Discuss Key Themes Regarding Responsible Nanotechnology Research and Development

- Environment
- Human Health and Safety
- Socio-Economic and Ethical Issues
- Nanotechnology in Developing Countries

A description of these breakout groups is provided following the agenda.

17:30 Adjourn for the Day

19:00 Bus departs for Le Gaulois

19:30 Group Dinner (no host)
Le Gaulois, 1106 King Street, Alexandria, Virginia

Dinner Remarks by Dr. Arden L. Bement, Jr., Acting Director, National Science Foundation
Friday, 18 June 2004

Location  Holiday Inn Hotel and Suites, Ballroom C and D

8:00  Coffee

8:30  Reports from the Breakout Groups

9:10  General Reactions to Results of the Breakout Group Discussions

9:30  Morning Break

9:45  Breakout Groups – Each group will discuss how to ensure responsible nanotechnology research and development through appropriate action in the following areas:

- Research
- Regulatory Policy
- Education and Training
- Institutional Mechanisms for International Collaboration

Participants return to the same breakout groups as on Day One. Building on the results of the previous day’s discussions and taking into account the results of the other breakout groups, each group will be asked to discuss and identify priorities for research, regulatory policy, and education and training needs. In addition, each group will be asked whether there is a need for greater international collaboration and cooperation and, if so, what institutional mechanisms or approaches might be appropriate.

11:45  Reports from the Breakout Groups and General Reactions

12:15  Review Outcomes of the Meeting

12:45  Closing Remarks

13:00  Adjourn
Description of Breakout Groups to Discuss Key Themes Regarding Responsible Nanotechnology R&D

Environment

This group will take a broad look at the potential benefits and risks to the environment associated with nanotechnology. For the purpose of this discussion, environment should be defined broadly to include air, water, land, and biological systems. This group will focus on the following questions:

a. What are the key potential benefits and risks to the environment from nanotechnology?
b. Are these potential benefits and risks likely to emerge in the short-term (during the next 1-5 years) or the long-term (over 5 years)?
c. What are some important actions that might be taken by the international community to maximize benefits and reduce risks?

Human Health and Safety

This group will take a broad look at the potential benefits and risks for human health and safety associated with nanotechnology. For the purpose of this discussion, human health and safety should be defined broadly to include medical devices, pharmaceuticals, and worker and consumer exposure issues. This group will focus on the following questions:

a. What are the key potential benefits and risks to human health and safety from nanotechnology?
b. Are these potential benefits and risks likely to emerge in the short-term (during the next 1-5 years) or the long-term (over 5 years)?
c. What are some important actions that might be taken by the international community to enhance the benefits and reduce the risks?

Socio-Economic and Ethical Issues

This group will discuss socio-economic issues associated with nanotechnology, as well as ethical issues that may be raised in relation to nanotechnology R&D, with the understanding that ethical issues are rooted in cultural and historical perspectives that differ from region to region. This group will focus on the following questions:

a. What are some of the socio-economic and ethical issues associated with nanotechnology R&D?
b. Does nanotechnology raise socio-economic and ethical issues that are different from those associated with other technologies, such as biotechnology or information technology? If so, what are they?
c. What actions might be taken to address, as needed and appropriate, these issues?
Nanotechnology in Developing Countries

This group will examine and discuss whether nanotechnology presents challenges for developing countries, which are different than issues associated with other new technologies (e.g., biotechnology, information technology). The discussion could, for example, discuss whether nanotechnology presents unique issues in regards to R&D capacity, infrastructure, regulatory development, etc. Specifically, the group will focus on the following questions:

a. What are the key issues for developing countries associated with nanotechnology R&D?

b. Does nanotechnology raise issues for developing countries that are unique (i.e., issues that have not been seen with the introduction of other new technologies such as biotechnology)? If so, what are they?

c. What are some important actions that might be taken by the international community to address issues regarding nanotechnology that are unique to developing countries?
ATTACHMENT C: OPENING COMMENTS BY DR. MIHAIL ROCO

Introduction

On the behalf of NSF, I would like to welcome you at the International Dialog on Responsible Nanotechnology R&D. This is the first meeting of government representatives from over 25 countries dedicated to broad societal issues that cannot be addressed by any single country: How can we prepare our world for the emergence of nanotechnology? How can we use the opportunity? And how can we play the role of our fair brokers in the society? The time is right for this discussion. Worldwide government investments for research in nanotechnology have exceeded $3.5 billion in 2004, nanotechnology products are reaching the market, and concern about the societal implications of this new technology are being voiced with increasing frequency. These concerns must be answered to the public’s satisfaction.

In one sense, of course, these concerns are very old. Science and technology have been at the core of human endeavor for as long as we’ve been human. Indeed, human potential and technological development are coevolving, and quality of life has increased tremendously with technological advancements. However, since the antiquity, it has been a perception that technological developments are not friendly to human nature; maybe because of the transforming changes. When the Greek God Prometheus taught humans to use fire and other tools, he also told them that this will bring an “an eternity of torture.”

As old as these concerns are, however, they seem to have particular resonance when it comes to nanotechnology—not least because nanotechnology allows us to work at the very foundation of matter, the first level of organization for both living and manmade systems. The potential benefits are large—and so are the potential risks. For this reason, societal aspects need to be fully considered from the beginning.

Moreover, those aspects need to be considered by humankind as a whole. Nanotechnology knowledge, markets and secondary implications do not have borders. This is a main reason that we are having this meeting. We need to balance the promise of nanotechnology and the potential negative implications. Nanotechnology is still at the beginning and this meeting has a unique opportunity to foster a right start. We need to look to how we distribute the research funds to realize most and equitable results, how the nanotechnology may affect human capabilities, the convergence with other technology, what safety measure to take to address the EHS (Environment, health and safety) concerns, and how to promote international balances and exchanges.

But this meeting is only a beginning. I would like to propose a continuing contact through an “international consultative board for responsible nanotechnology”. This activity may yield a set of principles, structured priorities, and mechanisms of interaction including sharing data on responsible R&D of nanotechnology.
This is an informal dialog, and we have high expectations that important ideas and connection for the worldwide development of the new technology will emerge. I would like to encourage you to look for the broad picture. The shorter-term concerns are EHS in research laboratories and production sites, and nomenclatures and standards. At the same time, we should pay at least same attention to long-term aspects, such as respect to human right to welfare, integrity, dignity and health. Another challenge is a balance and equitable nanotechnology R&D investment, and its integration with other fields of the economy. Environmental protection and improvement, as well new energy sources, may lead to expanding the limits of sustainable development. Responding and interacting with the public, with various countries of the international community and various organizations may be the ultimate test for the successful introduction of nanotechnology.

It is an honor to have this distinguished group of experts advancing the frontiers of human knowledge here.

Mike Roco
Chair, U.S. National Science and Technology Council (NSTC)'s Subcommittee on Nanoscale Science, Engineering and Technology (NSET);
Senior Advisor for Nanotechnology, National Science Foundation (NSF)

Alexandria, 16 June 2004
Good morning. The title of this conference has three words that caught my attention. They are nanotechnology, responsible, and international. I would like to say a few words about each.

Nanotechnology is a buzzword that means different things to different people. I construe it very broadly to apply to a wide range of science and technology opportunities created by the ability to image, manipulate, and simulate matter at the atomic scale. Atomic diameters are a few tenths of a nanometer (billionth of a meter), and the very smallest things we can see with the unaided eye are a few thousand times bigger than this. So within a little box just at the threshold of visibility we can pack about ten to a hundred billion atoms, which is enough to make many interesting structures, including most of the machinery of human cells, which have sizes of order 20,000 nanometers.

I like to illustrate the possibilities of nanotechnology with examples from biology because it is in the structures of life that nature has given us the most interesting demonstrations of the tremendous capabilities of very small scale objects. Early visions of nanotechnology, such as Richard Feynman's famous 1959 talk "There's Plenty of Room at the Bottom", were inspired by examples from biology, and some of the most important developments in nanotechnology today are occurring at the interface between biological and inorganic systems. The immense complexity of biological structures requires huge data processing power simply to store information about where all the atoms are, and retrieve it and visualize it for convenient analysis and simulation. This explains why we speak of information technology, biotechnology, and nanotechnology as the convergent technologies.

Common usage today reserves the word nanotechnology for the realization of these capabilities at the smallest scale in non-biological systems, mostly to distinguish it from biotechnology. The popular image is of scaled down robots with biological complexity made of the structural materials familiar at human scale such as metals, ceramics, etc. It is not clear that such structures are physically possible, but in any case this is certainly not the main thrust of nanotechnology today. The current emphasis is much more on large scale materials with nano-scale structures. This is a branch of chemistry, and we would call it that if we did not have the flashy name "nanotechnology" to describe it. It is not even a particularly new branch of chemistry – after all, chemistry since approximately the time of John Dalton (two hundred years ago) has been about the large scale manifestations of atomic scale phenomena. Many naturally occurring
materials have nano-structure, and metallurgical processes reaching back to prehistoric
times amount to empirical recipes for creating nano-structures within bulk material.

What distinguishes the new nanoscience from the old chemistry is the increased
understanding and technical control of the role of nano-scale structure. We are not
talking about new materials here, but about new processes or new forms of old materials.
This creates a challenge to regulators, because the toxicity of the new forms may differ
substantially from older ones. But neither the scale of the toxic agents nor the nature or
mechanism of toxicities is necessarily new. Chemists have been working for a long time
with nano-scale colloids and aerosols, and regulators have a long history of dealing with
the hazards of asbestos, which breaks into nano-particles, and other air-borne
contaminants. I believe the regulatory framework now in existence in the United States
is broad enough to cover potential hazards from nano-materials, provided, of course, that
the regulatory agencies do their job. The proliferation of new types of material does
create a need for new terminology and methods of classification and characterization, not
only for regulatory purposes, but also to encourage the commercialization of new
materials, processes, and applications.

These observations have a bearing on the issue of the responsible development of
the new nano-capabilities. It is important to keep in mind that the most exotic new nano-
materials are being produced in extremely small quantities under controlled laboratory
conditions, and do not pose a threat to environmental or public health. Non-biological
materials require regulation when they are being produced on industrial scales.
Biological materials require greater surveillance because of their ability to duplicate
themselves or to invade organisms that can -- a feature that nano-entities do not now, and
may never possess despite science fiction scenarios to the contrary. Current research
sponsored within the U.S. National Nanotechnology Initiative includes studies on health
effects of nano-materials. There is great danger of misrepresentation of the results of
these studies because of the huge diversity of nano-materials and processes. No such
study applies to nano-materials in general. Each health effects study is relevant only to
the particular material under the particular circumstances of the clinical procedure in
which it is examined.

Science fiction, some of it quite entertaining as literature, appears to be a major
factor in the public perception of nanotechnology. Unfortunately, the entire field
acquired a cult-like following in the 1990's that includes many engineers and scientists
who have personal visions about the revolutionary possibilities of nanotechnology.
These visions are good for motivating work, but are not scientifically validated. This is a
relatively common phenomenon in science, whose function is to match grand dreams
against the harsh reality of Nature. We need dreams, visions -- and perhaps even fears --
in the first place to drive the arduous business of scientific investigation, but we may not
assume their validity, nor should we act carelessly upon them as we plan to invest
society's scarce resources.

The U.S. has taken pains to incorporate social, health, and environmental issues
into its nanotechnology research planning almost from the beginning. The recent
legislation authorizing the nanotechnology initiative, The 21st Century Nanotechnology
Research and Development Act of 2003, includes provisions related to societal concerns about the responsible development and use of nanotechnology. It requires, for example, that the program ensure "that ethical, legal, environmental, and other appropriate societal concerns, including the potential use of nanotechnology in enhancing human intelligence and in developing artificial intelligence which exceeds human capacity, are considered during the development of nanotechnology ..." The bill also requires 1) the establishment of a research program on these issues, 2) that societal and ethical issues be integrated into all centers established by the program, and 3) that public input and outreach be integrated into the program. A provision to set aside 5% of overall program funding to study societal and ethical issues was defeated during markup of the bill in the House Science Committee, but the proposal indicates how seriously Congress takes these issues. The bill charges a Presidential Advisory Panel with determining and reporting bi-annually to the President whether social and ethical concerns are being "adequately addressed by the program." The bill further requires two studies by the National Research Council, one on the technical feasibility of "molecular self-assembly for the manufacture of materials and devices at the molecular scale," and another on “the responsible development of nanotechnology.” Finally, the bill requires a center focused specifically on societal and ethical issues of nanotechnology.

This is heavy machinery, and indicates an extraordinary level of interest in these issues within Congress. The Act’s language also suggests specific areas of societal and ethical concern that will receive the most attention, at least in the immediate future. My own view of these concerns is first, that they have to be taken seriously, and second, that the scientific community owes the public and Congress a clear and rational vision of nanotechnology that can lead to a productive engagement.

We should begin to construct that clear vision by distinguishing science from science fiction, and emphasizing the strong links of nanotechnology to things we already know a great deal about. While the technologies enabled by atomic scale capabilities are revolutionary, they are not particularly new. Nature has experimented with nanostructures since the earth began to cool four and a half billion years ago, and has blessed us with a rich legacy of examples to stimulate our imaginations. These range from the microstructures of minerals to the intricate molecular mechanisms of life. While it is now possible for us to manufacture structures that do not occur in nature, we are strongly guided by the immense variety of those that do occur. Some of the most important applications of biotechnology are likely to be the tuning up of useful cellular machinery that Nature has not yet had time to evolve to its most efficient form. We have been doing something similar for a century and a half with organic molecules -- dyes, for example, or synthetic fibers -- and Japanese metallurgists were inventing new microstructures over a much longer history to create edged tools and weapons of legendary quality. They were not aware of the nanoscale origins of their products, but they were producing them just the same.

And throughout this long history, society has built up systematic ways of protecting itself against the undesirable consequences of these evolving technologies. During the past half century, in particular -- and as a direct result of growing scientific knowledge -- society has acted through its governmental machinery to establish...
procedures to protect public and environmental health from new materials technology, whether biological, chemical, or radiological. The 25 year old RAC process for example -- (RAC stands for "Recombinant DNA Advisory Committee") -- or a modified version of it recently proposed by an NRC committee chaired by MIT's Gerald Fink, is designed basically to address concerns about new nano-scale phenomena. The Toxic Substances Control Act governing the manufacture and importation of potentially toxic chemicals originated at about the same time as the famous Asilomar Conference that recommended the RAC.

Congress clearly wants to know whether these mechanisms, or reasonable extensions of them, are adequate to respond to concerns about the products of nanotechnology. It is clear that some such products are already covered by existing mechanisms. Can we identify the manner in which new nanotechnology products differ from these older threats? It is important that we do so. I believe the differences are likely to occur in very well-defined areas, and that even in those cases the existing means for addressing threats they may pose to the environment or public health are likely to suffice with relatively little modification or extension.

Recognition of, and emphasis on, the continuity of nano-products with natural or older man-made substances may help us refocus public attention on the most likely short term issues. For many years, biotechnology will remain far ahead of nanotechnology in producing new entities of this sort, and I think it likely that the protective protocols developed for biotechnology will suffice for hazard control. The ethical issues associated with human biological applications of nano-products are the same as with similar applications of "genetically engineered" bio-products. I am not saying we have answered all ethical questions that are raised by such possibilities as sensory enhancement and protracted longevity promoted by these applications, but the idea that there are procedures already in place to deal with these new applications ought to be reassuring.

It is no wonder that developed nations are eager to produce and acquire the technologies that are being spawned by these new atomic scale capabilities, which brings me to the international aspect of today's meeting. As far as I can tell, the science plans for every developed nation and the European Union have a strong "nano" focus. The United States has been a world leader in the development of the underlying science infrastructure for the revolution, and the development of nanotechnology is today a national priority.

Funding for the NNI has more than doubled during the current Administration to about $1 billion, and supports research across ten federal agencies. The Initiative is coordinated through an office established under OSTP and guided by an interagency Nanoscale Science, Engineering, and Technology (NSET) subcommittee of the National Science and Technology Council (NSTC), the S&T interagency coordination umbrella. Congress has asked the President to designate a high level oversight panel composed of non-governmental members, and PCAST, the President's Council of Advisors on Science and Technology, has agreed to take on that task if designated. Last year PCAST identified a Technical Advisory Group of outstanding scientists and engineers to provide expert advice on nanotechnology issues. NSET has established four subgroups to cover
current key areas in which it deemed special attention is desirable: Nanomaterials Environmental & Health Implications; Risk Assessment of Nanomaterials; Industry Liaison; Nanotechnology Standards Nomenclature Development. With respect to this last activity, participating agencies have recently agreed to work with ANSI, the American National Standards Institute, to promote voluntary standards for nanomaterials.

The instrumental and computational infrastructure that provides the new nanoscale capabilities have been built up with federal funding over decades, particularly in the Department of Energy multi-program laboratories, but with significant facilities also at the National Institute of Standards and Technology and NSF-funded university centers. They include electron microscopes, bright x-ray sources, nuclear magnetic resonance devices, mass spectrometers, scanning probe microscopes, and a variety of optical and infrared spectroscopic devices. They also include the inexorably improving power of computation, communication, and data storage capabilities that we lump together under "Information Technology." The development of information technology and its application to nanoscale technologies are today national priorities.

These areas are also R&D priorities for other developed nations, and I expect that the inexorable globalization of technology based economies will lead to many international partnerships and agreements. If we are to realize the full potential of nanotechnology for our nations, and for the developing nations that can share its benefits, then we are going to have to agree particularly on standards and nomenclature, on issues of intellectual property protections, and on the need for responsible oversight and regulation of hazards that we may discover in these technologies. None of these issues is new to nanotechnology, and consequently I am optimistic about the success of our collective venture.

Thank you for inviting me to speak today.
ATTACHMENT E: WELCOME COMMENTS BY DR. ARDEN BEMENT, JR.

Dr. Arden Bement  
*International Dialogue on Responsible Research and Development of Nanotechnology*  
17 June 2004  
*Dinner remarks*  
*Le Gaulois, Alexandria, VA*

Good evening, distinguished colleagues, and a very warm welcome to Alexandria and to Washington. I know you have had a full day of dialogue about the connections between nanotechnology and society, so I will speak briefly, to suggest some context for ongoing discussion. I am very pleased that our nations, which have led investment in this emerging field, are also taking up leadership in exploring the societal implications of this new technology.

Our informal exchanges at this meeting can plant many seeds for collaboration. We may view each other to some degree as economic competitors in developing nanotechnology, but we all stand to benefit by exploring the societal implications together. Our societies share the desire to develop this technology responsibly and with a global perspective. None of us can do that task alone; international exchange is, far and away, the best way to ensure nanotechnology supports the common good—indeed, the only way.

At the National Science Foundation, we began to consider the societal side of our nanotechnology investment early on. You have probably already heard that about 11% of the funding for the U.S. National Nanotechnology Initiative this fiscal year supports study of nanotechnology’s medical, environmental and other broader implications.

At NSF, where social, physical and biological scientists are gathered under one roof, we can bring a rich confluence of perspectives to bear upon nanotechnology. When those who speak languages of different science and engineering disciplines focus on a common problem, they begin to develop a joint vocabulary—building a basis for common understanding.

When we fold in the study of societal implications at the very onset of research, we create a much greater range of choices about how to shape nanotechnology, including exploring the consequences of not developing this frontier field. Understanding nanotechnology *as it emerges* brings the opportunity—to borrow a phrase from NSF social scientist Rachelle Hollander—*to consider “ethics in real time”;* not beforehand or after-the-fact, but right as the science and technology are developing.

- Among NSF-funded efforts to explore nanotechnology’s social implications is a “Nano Bank” being developed at the University of California-Los Angeles. This set of databases will “track in real time the flow of nanoscale science to commerce, and the related socioeconomic impact of commercialization of nanotechnology...”³⁴

  In the short run, such a resource should be of interest to policy-makers, since it can help track the implications of a fast-evolving technology.

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³ Senior Science Advisor, SBE, Div. of Social and Economic Sciences
⁴ Quoted from proposal 0304727, UCLA Dept. of Sociology
Over the longer-term, Nano Bank can trace the impact of steady support for such innovation. A resource offering insights on both time scales should be of interest not only in this country but potentially in collaboration with other nations.

- Another example, from the University of Virginia, is a narrative to “get inside” nanotechnology “in its developmental infancy.” Through in-depth interviews with nano-engineers and scientists at a range of institutions, nano-practitioners’ own narratives will frame the newly forming ethical issues and moral frameworks associated with the research.

- Nano-education is another essential dimension of preparing for and shaping the applications and consequences of nanotechnology. Multidisciplinary teams at universities are creating comprehensive courses on nanotechnology for undergraduate and graduate students that cover the gamut—from principles to ethics to social change. The idea is to equip a new generation not only to carry out nanotechnology research but to deeply appreciate its ramifications.

Dialogue such as the one at this gathering, to address the future of nanotechnology in society, is a vital need, but we must also reach beyond our colleagues in science and engineering to engage the broader public. Public trust, in fact, will be a key element in exploring the nanofrontier for the common good.

One mechanism to promote public involvement in developing nanotechnology policy in this country is the “consensus conference,” a model to foster participation in technology policy that was developed in Denmark. The potential of the Internet to offer similar participation in societal decisions about nanotechnology is also being explored.

In the spirit of popular wisdom which holds that “Timing is everything,” this is a well-timed juncture to share perspectives on the development of nanotechnology. I look forward to hearing about the new connections made at this meeting, which I am confident will benefit us all.
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. Meeting 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

NOTE: The content of meeting participant submissions is provided in separate document “Attachment_F_Responses_and_Background_Info”.

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### ATTACHMENT G: BREAKOUT GROUP ASSIGNMENTS

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<tr>
<th>Environment</th>
<th>Facilitator: Rex Raimond</th>
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