



**Keynote by Dr. Françoise D. Roure, Senior Adviser, Ministry of Economy,
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NANOTECHNOLOGY GLOBAL GOVERNANCE AT THE CROSSROADS

**Center for Policy on Emerging Technologies (C-PET)
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Regulating nanotechnology is a topic of increasing government interest, as shown by the fact that the United States – European Union summit on transatlantic methods for handling global challenges, to be convened in 2010, will address explicitly this issue. But for public authorities and deliberative assemblies, designing and implementing a regulatory regime requires a global overview of the foreseeable impacts of emerging technologies at the nanoscale. Before this eventual stage, the concept itself of global governance, meaning to conciliate diverging interests, is at the crossroads, and a shared culture of responsible innovation might be the unifying principle that could guide relevant stakeholders towards a cooperative approach in their search of an appropriate model for regulation.

The issue of nanotechnology global governance and the impacts for countries of the Global South was raised at the United Nations headquarters in May 2008, in a side event of the ministerial meeting of the Commission for sustainable development. This shows the fast track followed by the issue since the first institutional, but informal, event dedicated to this topic. The First International Dialogue on responsible development of nanosciences and nanotechnologies took place in June 2004 in Alexandria, Virginia, thanks to the cooperative vision and the personal courage of Mike Roco, and thanks also to the mediation of the Meridian Institute. Since then, policy makers in many countries of the developed and developing world have taken - or observed - a series of initiatives whose first results were perceptible at the Tokyo meeting of June 2006 where the Second Dialogue took place.



Dr. Françoise D. Roure

The preparatory meeting of the Third Dialogue, held in Cape Town, fixed an agenda directly issued from the consensus achieved at the Tokyo meeting.

Discussion points of the previous meetings were the following:

- Infrastructure
- Industrial property rights
- Fighting the “nano-divide”
- Impact on health and environment
- Responsible development, outreach programs and governance and, last but not least,
- Methodology and assessment, taking into account the concept of **responsible innovation**.

The Tokyo meeting successfully concluded its work by reaching a consensus on the fact that the International Dialogue on responsible research and development of nanotechnology was the only really inclusive place available to address topics of common interest at the level of governments and policy makers.

So, it allowed the process begun in Alexandria to find its path to a third meeting, enabling a closed shop of participants from all the continents to prepare this meeting. The participants at the Third Dialogue preparatory meeting were representatives of South Africa, Japan, the United States and the European Commission (represented by DG Research, assisted, at its requirement, by two experts from Member States, The Netherlands and France). They agreed to focus the discussions of the Third Dialogue on four main topics. Those topics were:

- **Governance:** the proposal should focus on the appropriate global governance model for responsible research and development of nanotechnology
- **societal engagement:** this item was identified as central to bridging the gap between the development of nanotechnology and the involvement of society;
- **bridging the nano-divide** ensuring that developing countries are not left behind in the responsible research and development of nanotechnology and would benefit from it, as well as orientating its pervasive applications according to their own needs; this discussion point would be aimed at creating platforms for meaningful participation by all, including developing countries, and manpower cultivation for nanotechnology development;
- **and enabling means (infrastructure, standardization, intellectual property),** elaborating on the first feedbacks available from diverse existing working parties on nanosafety of manufactured nanoproducts and nanotechnology policy, when and where available (e.g., OECD, WPMN and WPN).

It's over four years now since the first International Dialogue took place, and many stakeholders have witnessed, if not promoted, diverse initiatives coming from all the continents. Those initiatives involve many institutions, including multilateral and intergovernmental ones like IBSA, UNESCO, OECD or ISO, as well as private efforts like those conducted by ICON and IRGC. Many initiatives have already blossomed under the leadership of the European Commission, like the preparation of a code of good conduct and the implementation of observatories, with a special mention to the efforts made to developing joint international research programs on nanomaterials safety, in particular.

Nanotechnology-induced change in the supply side is expected to stimulate innovation in many fields of applications and will have a fundamental impact leading to new products. Russia, Korea, Brazil and Argentina, South Africa, Malaysia, India, Turkey, China, almost all the European Union Member States and the European Commission, most of OECD country members and observers, indeed Japan, Taiwan and Israel, but also countries like Morocco for nanomaterials or Saudi Arabia, have adopted public policies supportive of research and innovation in the field of nanoscience and nanotechnology - some if not most

of them including a precautionary approach as regards health, environment, legal and ethical issues as well as systemic risks in the long run.

This means that, already, **an appropriate model for nanotechnology-induced change should no longer involve leaving a subset of countries behind. An appropriate model for nanotechnology-induced change and the related global and dynamic frame it may design, should not be designed by a subset of countries** deciding in the others' place, if not in their name, because it has too many potential impacts on the international specialization of nano-skills, production, added-value, as well as the conditions of trade and the incentives given to sustainable development.

The International Dialogue has reached the capacity to unify, under a integrated model and frame, the constituent elements of a global nanotechnology governance, that until now have developed separately. This process has the power to shorten dramatically the time to delivering to all stakeholders the low-hanging fruits of nanotechnology, under a responsible, transparent, inclusive, structured governance, in particular in the long expected field of nano-medicine, but might need to be empowered to deliver its potentials.

Four challenges have been addressed at the Third International Dialogue, around the constituent elements **of an appropriate, integrated global nanotechnology public governance. Those challenges for public policy makers are mainly:**

- **1. Designing a global frame for responsible development of nanotechnology**
- **2. Understanding the huge impacts of convergence at the nanoscale**
- **3. Relying on a commonly agreed, ongoing normative assessment methodology**
- **4. Being accountable for the visions, and eventually decisions and measures, taken.**

The first challenge must, by nature, be addressed at a level of synthesis. In my view, the three other challenges deserve being addressed by relevant, specialized experts.

How to address properly those four constituent elements, is *the* real task of the International Dialogue if it wants to play a significant role in improving the quality of public decision-making and meet the requirements of citizens, consumers and actors on the supply side.

The Alexandria process, step by step, leads towards **a major initiative**, which might rely for its implementation on **an intergovernmental, inclusive panel of experts on nanotechnology-induced change (IPNiC), referred to hereinafter as “the Panel.”** The core mission of this Panel would be to providing vision and proposals related to the four building blocks of an integrated model of public global governance on

nanotechnology. This Panel would report to the Intergovernmental International Dialogue on responsible research and development of nanotechnology, and would rely on a set of subgroups led by geographically well-balanced and specialized steering groups.

The first challenge for an appropriate model of nanotechnology governance would be **to design a coherent, global frame, dedicated to preparing public policy** in the following fields:

- establishing a level playing-field for international trade in nano-enabled goods and services;
- adapting the current regulatory frameworks to transformational technologies converging at the nanoscale, towards a predictable, innovation-friendly, regulatory framework; *synchronizing, harmonizing and monitoring* “regional” implementation of the framework;
- filling emerging gaps related to access to the benefits of nanosciences and nanotechnologies;
- strengthening the informed trust of all stakeholders where concerns related to industrial safety emerge;
- implementing the Millennium objectives for/by global governance of nanoscience and nanotechnology.

As the number and the complexity of international transactions and decisions grow in this field as a result of convergent and cross-disciplinary technologies, a framework for global legal authority and transjudicial cooperation is needed.¹ An integrated model of nanotechnology governance, *inspired by the Panel*, would help ensuring the transition between a decision-making process made by a few, to decision-making process involving more stakeholders. Intellectual Property Rights, technology transfers and control, litigation and trials, and the economic models derived from the law, are at stake, as well as **responsible, pervasive innovation** induced by converging technologies at the nanoscale.

The Panel could aim at encouraging in the International Dialogue an *operational* nanotechnology public global governance model, in a useful, practical way dedicated to public policy makers, who carry on their own, non-transferable responsibilities.

The second challenge consists in understanding the huge impacts of nanotechnology and of convergence at the nanoscale.

With respect to networking and data/information sharing, the participants in the Second Dialogue stressed the need to share information and data for sustainable development and

¹ MILLER Sonia E. “Confronting Tomorrow: U.S., E.U. Legal Frameworks Ill-equipped for Technology's Future.” New York Law Journal December 07, 2004 Vol. 232 109

risk/impact assessment, and to rely on databases incorporating scientific data and basic knowledge. For the Panel, designing an *appropriate* global framework would require intelligence of the quickly evolving states of the arts. It necessitates:

- ensuring existing data *sharing*, to the greatest extent possible, following a reasonably and non discriminatory attitude (RAND);
- organizing data for data-mining analysis and synthesis;
- giving incentives for data creation, if necessary (for example, reproducible, standardized test beds for nanoparticles);
- defining relevant, commonly-agreed, published indicators (science and technology indicators, publications indicators, patents indicators), including indicators coming from the social sciences and humanities, and in particular addressing opinions, and gaps between risks and perceived risks;
- helping relevant actors to develop networking (OECD and non-OECD, for example). This might mean connecting observatories in an international network and, if no such observatories are available, promoting their creation. There is such a nano-observatory now going on in the European Union, thanks to the 7th R&D Framework Programme and the responsible vision developed by the Directorate General Research.

Numerous surveys published in the fields of toxicity and eco-toxicity indicate that there is a need for research to provide information of the behaviour and fate of the nanoparticles in the environment. Stakeholders' responses generally underline the need to undertake actions in this field. For instance, societal implications, including dialogue and discussions on regulation, were strongly represented in a survey conducted by the European Commission in 2006, even though no specific mention of such implications had been explicitly proposed in the consultation.

The Panel could act as a catalyst for a new kind of network or virtual body, to be demonstrated as a first, accessible and modest step, undertaken separately but simultaneously on a "regional" basis. In particular, multilingualism should be actively promoted in order to allow and boost appropriation and education.

The 3rd challenge consists in designing and setting up a commonly agreed, ongoing assessment methodology of nanotechnology-induced change.

In order to translate intelligence on the state of the art into observation for *monitoring* the responsible development of nanotechnology, the Panel could elaborate and propose a common, dynamic methodology of risks and benefits assessment of dedicated nanotechnology-induced change. The Panel could focus on this methodology, aiming at improving the quality of public policies and private decisions, and rely on scientists from many disciplines as well as other experts. Action could begin with simple, basic objectives, and be open to ongoing improvements. *Voluntary peer reviews*, in particular in the field of

decision-making process, have already been stressed as relevant (by IRGC and transatlantic dialogue PST conference, at least).

The International Dialogue could rely on the proposals made by the Panel to prepare a structured international, institutional (inter-governmental) agreement on this methodology, to be implemented at the global scale and tested on a *voluntary* basis.

This dynamic assessment should rely, as already mentioned, on the relevant public and private initiatives undertaken and would benefit from the following characteristics:

- multi-stakeholders' support, at least public **funding** and involvement, including major international institutions like WHO and UNEP;
- multi-criteria approach (Science and Technology, ELSA²+, educational gap, public security and defence, which are of critical importance for the appropriation of the results by all the stakeholders. "Science and technology indicators" as well as other indicators mentioned "can give insights, for instance, into the stage of maturity of a given technology, and may be used to depict scenarios for future evolution and for decision makers to design an appropriate strategy".³
- Inclusion of demand side and users concerns and requirements (citizen/customer/gender/special interest /handicapped and ill), upstream participation;
- short-term as well as **systemic, long-term approaches** of nanotechnology-induced change.

Giving this Panel the responsibility to design an early warning / early listening process in specific fields, could be an issue of common interest in the short run. This proposal could be extended to a broader scope. It echoes a recommendation made by a German study related to industrial applications of nanomaterials: "A proactive approach should be taken to advance scientific knowledge, develop appropriate monitoring and warning systems, and, if necessary- adjust existing legislation and regulation."⁴

The 4th challenge is to ensure that the International Dialogue is fully accountable for its own, specific responsibility and added-value.

The International Dialogue should be **accountable** for its actions and make them visible

² ELSA stands for ethical, legal and societal aspects.

³ COMPANO R, HULLMANN A. "Forecasting the development of nanotechnology with the help of science and technology indicators". European Commission. 2002 IPO Publishing, 26 April 2002

⁴ VDI Technologiezentrum. August 2004. www.zukuenftegetechnoogien.de

and legible. The Second Dialogue has already made this recommendation. in Tokyo.

Participants to the Second Dialogue required that the proceedings of the meeting be published on the Internet. Many thanks to our Japanese colleagues for the very good report they published in 2006, and their wish to promote it.

This Report stressed that: *“The IDR of N&N should be accountable of its action, fully transparent, in order to strengthen both legitimacy and efficiency. Global support, ‘soft law’ improvement, best practices selection, sharing and dissemination will be inspired by the adequate positioning of the public policy makers, in particular their action in favour of a global framework, provided that the process remains clear, readable, predictable and inclusive. In particular, the benefits of nanosciences and nanotechnologies as enablers deserve being promoted actively, because this part of the assessment is below the medias short-term interest. So the IDR should adopt a balanced approach of risks and benefits and be “results oriented’.”*

The participants to the Third Dialogue, fully aware of the necessity to being accountable and transparent in their actions, took the decision to publish all the contributions as well as the list of participants and a summary of the main results. Those documents are to be published on the European Commission’s website.

Indeed, for a better impact, the International Dialogue should adopt multilingualism for its publications, implementing the last breakthroughs in automatic translation and vocal synthesis.

In conclusion, it is in the joint interest of market players as well as citizens to urge policy-makers to providing a clear, integrated frame for an appropriate global governance on nanotechnology induced changes. Despite remaining divisions, global, informal cooperation only is no more an acceptable option. Entering a structured cooperation among public policy-makers is going to take courage and time-consuming investments. This will require full commitment from public policy-makers and international institutions like WHO and UNEP But this deserves to be done.

Many private stakeholders, national or global players, and the financial and insurance sector, have conducted for themselves extensive efforts to establish the global frame that would be most relevant according to their own needs. They are now in a good position to bring an important added-value to the public decision-makers, as the public nanotechnology governance model is at stake. I presume that a constructive, ongoing dialogue among public and private decision-makers must be promoted, in particular in the field of applied research and information sharing related to toxicology and ecotoxicology.

This Third Dialogue has revealed the position where we all stand, which is at the crossroads :

- One option would be for an Intergovernmental Panel is given a mandate to prepare the terms of reference to be proposed in order to secure the relations between the Dialogue and the relevant international institutions identified as having legitimacy to carry on this task, at least the World Health Organisation (WHO/ OMS) and the United Nations Environment Program (UNEP/PNUE), until a UN interagency coordination is established;
- Alternatively, stakeholders must be prepared to facing, and managing, political and societal unrest, with a loss of trust in the ability of public institutions to provide appropriate nanotechnology governance on time, as well as legal uncertainty, both with deep, long-lasting and, unfortunately, predictable consequences on demand and supply sides of the markets.

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This is a revised version of Dr. Roure's keynote presentation given at the C-PET Transatlantic Dialogue on Emerging Technologies at the Society of British Aerospace Companies, London, January 2008.

C-PET

The Center for Policy on Emerging Technologies (c-pet.org) is a nonpartisan think tank based in Washington, DC, with a primary focus on the implications of the key emerging technologies of the 21st century. C-PET's mission is to stimulate broad nonpartisan dialogue, involving civil society, business and finance, and policymakers, on emerging technologies and their social, ethical, and legal implications.

C-PET is developing a global dialogue on the societal dimensions of emerging technologies. The January, 2008 meeting marked the initiation of the Transatlantic Dialogue, with co-sponsorship from the University of Ulster and the Illinois Institute of Technology Center on Nanotechnology and Society, and support from the Wellcome Trust.

Dr. Francoise D. Roure

Françoise Roure, an economist, is the French representative to the International Dialogue on Responsible Development of Nanosciences and Nanotechnologies, also called the *Alexandria process*, since its first meeting in 2004. She has been elected Vice-Chair of the OECD Working Party on Nanotechnology created in May 2007.

She serves as Senior Advisor at the French Ministry of Economy, Finance and Industry. She is member of the National Advisory Board on Information Technologies, and president of its economic and legal section. Co-author of a report on "Nanotechnologies, ethics and industrial foresight" with Professor Jean-Pierre Dupuy (translated in English, Spanish and Japanese). She was a member of the European Commission High Level Expert Group addressing the 2020 Next Technology Wave and contributed to the report on "Converging Nanotechnology, a preliminary risk analysis". She also is a member of the

Panel of the International Risk Governance Council (based in Switzerland) for its survey on nanotechnology governance, and of the Converging Technologies Bar Association.

She has presented several contributions related to nanotechnology governance: "The international nanotechnology economy and public initiatives", "New ethics for nanoscience and the future of information technologies" (published by the European Science Foundation), "Between responsibility and game, converging technologies for a diverse Europe", "Towards an appropriate corporate and public governance of Nano Risks : promoting and strengthening a multilateral approach", "Survey on French nanotechnology governance", "The economics of intangibles and patents : the case of nanotechnologies", "The debate on Nanosciences and Nanotechnologies, or the legitimate trust at stake" and in December 2006 for the France-Stanford Foundation, an essay on "Industrial economics of nanotechnology: hyperchoice and milestones for the manufacturing world at the nanoscale".