
Summary of the workshop on “Issues of Risk in the Regulation of Nanotechnology”

8 January 2010 at TERI, New Delhi

A one day workshop on “**Issues of Risk in the Regulation of Nanotechnology**” was organized by the Science and Technology Area, The Energy and Resources Institute (TERI) on 8th January, 2010. The workshop was a part of an IDRC supported 3 year project on “Capability, Governance and Nanotechnology Developments: a focus on India”. The workshop offered insights on how India might address risks in an appropriate strategy to regulate nanotechnology.

Attended by over 30 experts from diverse fields (toxicologists, scientists and social scientists, technology developers, policy makers, regulators and civil society), the workshop witnessed a comprehensive discussion and debate on environment, health and safety issues as well as social, legal, ethical implications in relation to nanotechnologies, risk governance procedures, national and international efforts in dealing with nanotechnology risks as well as the associated challenges and policy concerns. The workshop was divided into three sessions that drew on presentations delivered on relevant aspects and also included an open discussion. In his opening remarks Dr. Lal described the benefits of nanotechnologies and cautioned that the potential risks of the technology must be understood and managed for society to avail the promise of its applications. In the first session ‘**Governing risks in emerging technologies**’ chaired by Shri. Saha, Dr. Rajan’s talk focused on approaches to risk governance in complex emerging technologies like nanotechnology given the challenges for obtaining risk estimates and consent on safety data. Discussions in the session included the process and strategies through which risks might be managed in the sphere of nanotechnology.

The second session ‘**Understanding risks in nanotechnology**’ dwelled on the nature and extent of multidimensional risks of nanotechnology and was chaired by Prof Gupta. Presentations made by Prof. Saxena centered on environment, health and safety issues while those made by Prof. Haribabu and Dr. Basu focused on social and ethical challenges nanotechnologies pose to society and the diverse perceptions and opinions on technology risk. Prof. Saxena highlighted the characteristics of nanoparticles that influence their toxicity and also described the impact that nanoparticles can have on the human body as a consequence of their uptake. Dr. Basu in his talk argued that the fact-value dichotomy is no more obvious today in techno-scientific disciplines like nanotechnologies and that these technologies are embedded in society rather than it just being viewed as a techno-centric-entity. He further stressed that since the decoupling of science and technology is difficult today, responsibility in practice of techno-sciences must take precedence. Prof. Haribabu described how the idea of risk is conceptualized in social sciences and drew attention to the fact that judgment over acceptable levels of risk and time dimension are two main aspects of risk. He also highlighted the fact that the development of regulatory frameworks for nanotechnology must be done so in a more democratic and transparent manner. The presentations were followed by a discussion on

the gaps and uncertainties prevalent in the understanding of risk, safety as well as socio-ethical implications.

Discussions in the third session '*Addressing nanotechnology risks: status, actors, procedures and policy concerns*' chaired by Dr. Ghosh emphasized the key gaps that exist in being able to address the issues of toxicity and safety in the context of nanomaterials and nanotechnology based applications and urgent need to identify a suitable regulatory response. Prof. Dhawan's presentation described the national and international efforts in risk research and policy and highlighted the paucity of research being undertaken in this area. He also emphasized on the fact that there are only guidance documents and no guidelines available for safety. Dr. Nair in his presentation highlighted that the very characteristics of nanomaterials that make them beneficial for product development and society are in fact those that might pose dangers to human and environmental health. Therefore he argued that society would need to carefully choose how nanomaterials might be tailored for productive applications by identifying and managing the risks. He also suggested that more than the absolute value of risk, a risk-benefit ratio of nanotechnology based applications has to be carefully evaluated. Both Prof. Dhawan's and Dr. Nair's talks also identified key areas where research would be needed to characterize hazards from nanomaterials. Dr. Mokkalapati in his presentation described nanoapplications in the medical and food industry. He also focused on the challenges regulators face at the moment in regulating nanotechnology and the steps that need to be undertaken in areas of risk assessment and standards creation to enable support for developing appropriate regulations. Mr. Takemura on the other hand centered on the strategy undertaken by Japan to address multidimensional risks from nanotechnology. He described the activities undertaken by the government and the work being undertaken in spheres of risk assessment, management, communication, social implications and public engagement.

The last session was devoted to an *Open discussion* chaired by Dr. Rao in which all invitees participated. The session commenced with a presentation by Dr. Srinivas which highlighted key issues in the regulation of nanotechnology and the lessons we can draw from our experience in regulating biotechnologies. A lively debate and dialogue then ensued on the approaches developing countries like India must assume to address environment, health and safety as well as social and ethical concerns. Through the discussions key areas that need attention were identified, especially in context of understanding the toxicological aspects of nanomaterials, risk assessment of applications and capacity building for regulation of nanotechnologies as well as risk communication and public engagement. The need for the development of strong databases for nanomaterial standards and risk research as well as information exchange, public awareness and employing different models of governance were highlighted. The deliberations focused on reconciling the aspects of these various elements in order to draw insights for shaping a responsive policy framework for risk governance and evolving a suitable regulatory strategy.

The conference concluded with a set of recommendations that is presently being drafted and will be forwarded to relevant agencies including, Department of Science and

Technology (DST), Department of Biotechnology (DBT) and the Ministry of Environment and Forests (MoEF) and Ministry of Health and Family Welfare (MoHFW). National and international participants at the workshop included representatives from the Indian Institute of Toxicology Research (IITR); Jawaharlal Nehru University (JNU), Amrita Center for Nanosciences, Indian Council for Medical Research, National Physical Laboratory (NPL), University of Hyderabad, Research Information System for developing countries (RIS), University of California, National Institute of Material Science, Japan, National Institute for Science Technology and Development Studies (NISTADS), All India Institute of Medical Sciences (AIIMS), Centre for Occupational and Environmental Health, World Health Organization (WHO), Centre for Science and Technology of the Non Aligned and Other Developing Countries, Indian Agricultural Research Institute (IARI), International Advanced Research Centre for Powder Metallurgy and New Materials (ARCI), Central Pollution Control Board (CPCB), Aditya Birla Science and Technology Company and some foreign embassies. Policy makers included representatives who had retired from agencies like Department of Science and Technology (DST) and the National Mission on Nanoscience and Technology as well as the Ministry of Environment and Forests (MoEF).

