EJLT European Journal of Law and Technology

How Resilient is India to Nanotechnology Risks? Examining Current Developments, Capacities and an Approach for Effective Risk Governance and Regulation

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Cite as: Deshpande, Sarma, S., 'How Resilient is India to Nanotechnology Risks? Examining Current Developments, Capacities and an Approach for Effective Risk Governance and Regulation', European Journal of Law and Technology, Vol. 2, No.3, 2011

Abstract

Over the last decade the Indian state has strived to establish an adequate foundation for advancing nanotechnology resulting in the expansion of R&D and commercialization of nanoproducts. A greater focus on technology development has meant that India's engagement with the overdue but not less significant risk debate appears to be far behind global discourses. The main focus of the paper is to examine whether India possesses sufficient resilience to avoid or address the environment and health risks that the development of nanotechnologies poses, given its existing capacities. It does so by analyzing the motivations and initiatives by the state to address nanotechnology risks as well as identifying key actors and efforts in the direction of risk appraisal and management. Furthermore it also examines this issue by locating nanotechnology's development in a larger context- that of the existing milieu in India for attending to environment and health issues in general. Based on this analysis it argues that the nation is vulnerable to the potentially adverse impacts of nanotechnology for a variety of reasons given the rapid unfolding of R&D in India and the substantial evidence of risks from specific nanomaterials. The lagging attention to risk regulation, ambiguity in roles and responsibilities, gaps in risk appraisal and governance especially in the capacities to formulate effective legal frameworks in addition to prevailing deficiencies in enforcement of regulations create an environment where India could be especially susceptible to nanotechnology's risks. In conclusion the study suggests that a comprehensive and flexible strategy to address the multidimensional risks is imperative and highlights what could be key elements of such a framework. Mechanisms for inter-agency coordination and inclusive dialogue on risks are highlighted as key measures besides the need to broaden the scope of risk appraisal and management initiatives.

1. Introduction

Post liberalization, India has employed rapid industrialization and embraced the use of emerging technologies- information technology (IT), biotechnologies, and nuclear technology, all of which has resulted in the current growth rate of 8% (GOI, 2011) and significant achievements in domain of science and technology (Schaffer, 2010). Nevertheless these gains have not come about without a price to environment and human health. Industrial and urban pollution has led to environmental problems (Kanchan et al., 2011) and has created public health hazards both in terms of morbidity and mortality as can be seen in the large scale impact of use of the pesticide endosulfan in Kerala for instance (GoK, 2010-11). Significantly, despite their tremendous benefits, environmental challenges and controversies in relation to application of emerging technologies have also surfaced. For instance the unprecedented growth of the IT industry has spawned an e-waste crisis, resulting in soil and ground water contamination besides occupational hazards (CAEP-TERI, 2010). On the other hand the state's approach to regulation of genetically modified (GM) crops in India in the case of Bt Brinjal has been criticized (Shah, 2011) whereas studies on Bt Cotton indicate growing incidence of pest resistance and explosion of non-target pest populations (Karihaloo and Kumar, 2009). [2] Altogether despite a comprehensive legal and policy framework for environmental governance in India there prevails an inadequate understanding of environmental problems and its cumulative implications which, together with underdeveloped mechanisms of environmental management especially in relation to enforcement and compliance, tends to escalate environmental degradation (World Bank, 2006). Therefore India's technological and industrial progress is of concern given that it is outpacing the nations' capacity to address the accompanying environment and health risks.

It is under these circumstances that Indian state seeks to harness the potential of another emerging technology, nanotechnology that whilst promising socio-economic and development gains also presents potential challenges for environmental and human safety (The Royal Society and The Royal Academy of Engineering, 2004). Involvement with nanotechnology is viewed as a strategic advantage by nations given its valuable contribution to diverse sectors with social and economic gains. Therefore notwithstanding resource constraints, India, about a decade ago embarked on a Nano Science and Technology Initiative (NSTI) the culmination of which witnessed the initiation of a larger mission mode program- Nanoscience and Technology Mission (Nano mission), with significantly enhanced funding (TERI Report 2009b). However given that the foundation of nanotechnologies rests on nanomaterials that possess unusual physico-chemical properties, there is growing evidence that the manufacture, use and disposal of some nanoproducts might present potential risks as much as they do pose benefits. Given that the structure (size and shape) and greater reactivity of specific nanomaterials (for instance metals and metal oxides and carbon nanotubes) can enhance exposure potential and elicit unusual or adverse responses, they can display increased 'real hazard potential' over conventional chemicals (Maynard, 2007). Another concern is that existing risk assessment, management or regulatory frameworks may not be adequate to address nanotechnology risks given that they are tailored for conventional chemicals (Renn and Roco, 2006). Serious information deficits reign on the nature of risks due to the diversity of nanomaterials, problems with materials characterization and standardization and the knowledge gaps on hazards, exposures and appropriate regulatory thresholds (Hansen 2009). Since traditional ways of evaluating and regulating risks would need to be reconsidered in the case of nanotechnologies how effectively can this be pursued in the Indian context remains a key question.

On the other hand despite these prevailing uncertainties over a thousand nanoproducts have been commercialized internationally. [3] India too has witnessed the emergence of nanomaterial use in products such as water filters. [4] [5]and other household appliances such as washing machines [6], air conditioners and fridges [7], textiles [8] [9] cosmetics and personal care, paints and therapeutic applications. [10] These products together with the development of more complex nanosystems in the future could create numerous opportunities for environmental, occupational and public exposure to nanomaterials. This has direct ramifications on the intensity of effort that would need to be undertaken to address risks at the national level. Meanwhile just as it has in other countries, (European Commission, 2010) the emergence of nanoproducts in India too could lead to public concerns on aspects like benefits, risks, equity and ethics especially since the nation has witnessed public dispute and debate over such matters in the case of GM technologies. Does India have the capacity to acknowledge and manage risks from rapidly evolving nanosystems, in addition to addressing public concerns?

Risk governance involves risk assessment, management and communication and in the case of nanotechnology is related to recognizing and finding effective ways to assess, avoid, reduce and control its risks besides making decisions in a transparent and collaborative fashion (Renn and Roco, 2006). On the other hand, regulation although a part of the governance process, relates to command and control approach by the state that is enacted through acts, laws and other incentives devised for a desired outcome or action (TERI Report, 2009a). Overall, the nature of the issues associated with environment and health impacts of nanotechnologies gives rise to multiple and some unique challenges (Hansen, 2009). Indeed, given the seriousness of the issue at hand several countries for instance US, EU and China have introduced programs to understand and address the environment and health concerns emerging from nanotechnologies. [11] International efforts in the realm of risk appraisal, risk governance and regulatory convergence are now common place. [12] Given that different countries could possess differentiated capacities for risk governance and regulation, India's capacity to assess and manage nanotechnology risks must be evaluated. Given the positives, India's engagement with R&D and application development in the nanotechnology domain is necessary. However it is also vital that these benefits are availed in a responsible fashion especially given that India's experience with previous technologies such as asbestos (Allen D and Kazan-Allen L, 2008) and pesticides (Thakur et al., 2008) has revealed that unless adequately governed technology interventions can pose environmental and health consequences.

How is India responding to the environment and health concerns that nanotechnology poses? Are there developments in this direction? What sorts of capacities does India possess to address this issue? Does India possess sufficient resilience to avoid and manage nanotechnology risks? Where do the gaps lie and what challenges does the nation face in addressing the risks? Given that India already confronts considerable challenges in addressing environment, health and safety (EHS) issues what are the possible ways in which it can manage risks from nanotechnology? These are the questions that this present study seeks to examine in the following sections. Section 2 begins by providing a brief overview of the nanotechnology trajectory in India. It then traces the approach the state has taken towards the risk and regulation of nanotechnology and maps the actors and initiatives in this sphere. The third section then deals with the central question of whether and why India might be in danger of the risks from nanotechnology as it assesses the gaps and challenges. Based on this analysis Section 4 presents policy suggestions for a way forward to effectively assess, regulate and govern nanotechnology risks in the Indian context.

2. Nanotechnology policy and developments in India: the nation's approach to risk management and regulation

This section begins with a brief description on the focus of the nation's nanotechnology policy and the way India's nanotechnology trajectory has shaped. Through this lens it examines India's initiatives in managing the risks in nanotechnology, and seeks to explain them in the context of national developments and the state agenda.

2.1 India's Nanotechnology trajectory: state agenda and policy

India's engagement with nanotechnology formally began with the NSTI in 2001 which evolved into a much larger program the Nanomission in 2007 with significantly increased funding (INR 1000 crore or approx. USD 202 million) (TERI Report, 2009b). Despite a decade's involvement the state remains the main driver for nanotechnology R&D and continues to have a strong hold on the direction of its trajectory. Nanotechnology in India is seen as a window of opportunity for leap frogging in terms of technological advancement and industrial competitiveness. More significantly it has been also positioned as an essential tool for in sectors such as energy, water and health which are core to the national development agenda in developing countries (Salamanca-Buentello et al., 2005). This has led the state to aggressively champion the cause for nanoscience and technology R&D and focus on ways to secure industry participation; although the success in the latter has been less than desired. Nevertheless industry participation has emerged with giants such as Darbur and Tata Chemicals undertaking R&D in this sphere together with the arrival of several start-ups such as I CanNano, Panacea Biotech on the scene. Nanobiotechnology, nano-electronics and smart textiles are frontrunners in the R&D domain whereas application development has emerged in the spheres of drug delivery, household appliances as well as textiles and cosmetics.

The Department of Science and Technology (DST), leads the charge of expanding nanotechnology R&D within the country although participation of other agencies such as the Department of Biotechnology, Department of Information Technology (DIT), and Council for Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), has emerged within the niche areas they serve. The focus of the national programs has been to actively promote nanotechnology in the country. Tremendous support for R&D projects to strengthen basic research and technology development exists. Efforts have also been made to improve the infrastructure, develop human resources as well as create international networks for R&D. While special Centers of Excellence' (CoE) for nanoscience and technology based research have been established other institutes entirely dedicated to nanoscience and technology R&D are in the pipeline. The current thrust is to enhance technology development by means of public private partnerships, establishing incubators etc which is being bolstered by efforts of industry associations such as the Confederation of Indian Industry (CII). Besides initiatives at the centre, state-led initiatives to promote nanotechnology are emerging and contributing to the significant expansion of this technology in the country (TERI Report, 2009b).

Clearly the government policy is fueled by the aspiration to be amongst the frontrunners in the nanotechnology domain. The state vision for nanotechnology is articulately captured by Dr. CNR Rao, chairman of the scientific advisory committee to the prime minister and head of the Nanomission Council who said at an interview, 'this is the only field in which we can do something. And if we don't catch up with others in the next 10 years, we may miss the 'nano' bus too. [13] This view has been much voiced amongst scientists and policy makers in response to India's missed opportunity with the semiconductor revolution. In 2007 Dr. Rao proclaimed that India should follow the established models of developed countries and urged the government to provide a better environment for the researchers to achieve greater economic growth for the country especially in the field of nanotechnology. 'There is a huge demand for Nano-materials globally. India should be ideally catering to this global demand in the years to come' he delivered in his vision lecture at the valedictory function of Bangalore Nano, the annual government sponsored international event in 2007.[14]

2.2 State response and motivations for addressing nanotechnology risks

This clear mandate for promotion and support nanotechnology R&D in addition to locating nanotechnology within the development agenda did not permit much space for discourses on nanotechnology risks especially in the early years. So even though the Nanomission evolved as late as 2007 when risk issues were being copiously debated at the international arena, its objectives were devoid of any references to addressing issues of safety. Nevertheless although risk management might have not have appeared to be a priority for the state, it is not to say that initiatives in this sphere were entirely absent. On the contrary studies directed towards safety issues did emerge during NSTI albeit in miniscule numbers. Still while support to risk research has grown, at present it is nonetheless a peripheral activity in the overall portrait of projects funded.

This attention to risks especially post 2007 could be attributed to various developments - international networking for R&D that has exposed scientists and policy makers to the international risk discourse; invitation for participation in international risk management initiatives; workshops on nanotoxicology and risk regulation [15] [16]; increased awareness amongst some sections of Indian scientists for the need for safety measures at their work places and a feeling that adequate regulations might actually reduce uncertainties promoting increased industry participation. [17] In general however, while there is a growing recognition of the significant risks nanotechnology can pose if the EHS impacts are not addressed, there is a greater awareness that technology development itself could be hampered in the absence of a regulatory response. The halt on the release of Bt Brinjal, due to lack of consensus on the extent of risks and approaches to regulate them, serves as a reminder to this effect. [18] In contrast to Bt Cotton, the only other legally introduced GM crop in India, Bt Brinjal drew even greater protests from a opponents of this technology on environment and health impacts due to its use as a food crop and also since India is the center for biodiversity for brinjal. A rather downstream and recent process of stakeholder and public engagement with this issue by the Ministry of Environment and Forests, a first of its kind in the country resulted in the Minister of that time announcing a halt on the introduction of Bt Brinjal. These events probably reinforced the need to establish a regulatory mechanism for nanotechnology amongst policy makers and therefore in early 2010 the initiative for the creation of a regulatory body for nanotechnology in India was also announced. [19] In fact Dr. Rao who is part of the Nanomission Council, [20]while arguing the need for regulation of nanotechnology in medicine and health did state that 'The reason we had problems with Bt Brinjal is because we don't have a strong regulatory body'. [21]

2.3 Risk appraisal and management efforts for nanotechnology: Examining actors, roles and scope [22]

Support for risk research in the country has mainly come from the DST led programs and otherwise DBT through its support for research on application of nanomaterials in biological sciences. CSIR on the other hand has funded nanotoxicology research at the Indian Institute of Toxicology Research (IITR) since it forms a part of the agency's laboratory network. The project on Nanomaterials and Nanodevices for Application in Health and Diseases supported by CSIR also contributes to testing safety of nano-drugs. Together with the University Grants Commission, CSIR also assists students pursuing doctoral research in nanotoxicology by way of fellowships. ICMR under the Ministry of Health and Family Welfare (MoHFW) also seems to support a few studies on similar issues although it more often encourages studies on application of nanosystems for therapeutics.

There are about 6-7 organizations, mostly state funded that are significantly engaged in nanotechnology related risk research in India. Besides IITR, other key institutions associated with nanotoxicology are the Amrita Center for Nanosciences (ACNS) and National Institute of Pharmaceutical Education and Research (NIPER). IITR, with a mandate for conducting safety evaluations of chemicals and assessing occupational health hazards had created a nanotoxicology group in 2008. Currently it is involved in assessing the in vitro and in vivo toxicity of nanoparticles used in consumer products and in the health sector besides eco-toxicity issues. Their work with international collaborators in EU involves validation of methods for nanomaterial toxicity testing. In 2011 they released a guidance document developed for the safe handling of nanomaterials (Dhawan et al., 2011) at the International Symposium on 'Safe Use of Nanomaterials and Workshop on Nanomaterial Safety: Status, Procedures, Policy and Ethical Concerns', an international event organized by the institute. [23]

The Amrita Institute, a private research organization and an established CoE, on the other hand is pursuing toxicology research for bio-material based nanomedicines besides examining the toxicity of nanomaterials for their use in cancer applications. Aside from these DBT sponsored studies, industry sponsored studies also include toxicity of polymeric encapsulated nanomedicines. This Centre has also developed standardized protocols for nanotoxicity testing. Both IITR and ACNS appear involved in the DST led committee to develop regulations as is IITR through its document on safe use of nanomaterials.

NIPER which hosts the Centre for Pharmaceutical Nanotechnology that was funded with an amount of INR 956 lakhs (approx. USD 1.93 million) by DST in 2006. [24] Its work in investigating and reducing the toxicity of drug delivery systems and associated materials has received funding of INR 3.2 crore. It is also involved in developing standard parameters to test toxicity of nano drug delivery systems as well as regulatory guidelines for their approval. [25][26]. Incidentally the institute was also funded in the area of Regulatory Toxicology for the development of facility with Good Lab Practice-certification for toxicological screening of new chemical entities. [27] Central Drug Research Institute (CDRI) is another institute associated with the development of nano-drug delivery systems, but is involved in rather limited toxicity testing of these systems.

Other institutes working in the sphere of nanotoxicological research are Indian Institute of Chemical Technology (IICT), All India Institute of Medical Research (AIIMS), Jamia Hamdard University and Agharkar Research Institute. IICT, a CSIR laboratory for instance has a Toxicology Unit that has undertaken toxicity evaluation of aluminium oxide, iron oxide and silver nanoparticles besides hosting an international Indo-US workshop. Whereas Hamdard University has investigated the safety of nanoemulsions and nanoformulations, Agharkar Institute has assessed the safety of ayurvedic medicines using nanoparticles. Investigations on the effect of nanomaterials on macrophages have been evaluated at AIIMS [28] and research is being pursued on the toxicity and biocompatibility of specific nanomedicines. Few studies

have also been funded at various institutes such as Jawaharlal Nehru Technological University, St. Johns Research Institute, University of Kerala, Bharatidasan University etc although the extent of their contribution in the national efforts to address risks is unclear. Nonetheless from this support to risk research has emerged India's growing contribution to international publications in the area of risks especially in the realm of nanotoxicology.

Outside the realm of nanotoxicology, there are other groups involved in aspects related to characterization besides research on exposure scenarios and life cycle perspectives as applied to nanomaterials. National Physical Laboratory (NPL) has undertaken studies to characterize engineered nanoparticles for risk assessment. On the other hand a recent study by the author (Deshpande Sarma, 2011) assessed the risks from a nanosilver filter developed in India using life cycle perspectives filter by identified potential silver releases across its life cycle together with exposure pathways for humans and the environment. Overall it is likely the nature and extent of risk research may expand with increased emphasis on risk issues.

Besides the Nanomission led initiative to create a regulatory board to oversee all the nano products that enter the market, risk management efforts in the Indian context have related to the involvement of Bureau of Indian Standards (BIS) at the International Standards Organization Technical Committee, ISO/TC 229 on Nanotechnology which is an international initiative to establish standards on various aspects related to nanotechnology including terminology, metrology and health and safety practices. While some time appears to have passed since the announcement in early 2010, there appear to have been meetings between the members of the committee formed for this purpose, the latest taking place in August 2011. The guidelines developed for the safe handling of nanomaterials (IITR) and protocols for nanotoxicity testing (ACNS) are also being examined for their incorporation in the framework. On the other hand a Nanotechnologies Sectional Committee, MTD 33 was constituted in BIS in 2007 to enable participation at the ISO initiative and to formulate national standards in the field of nanotechnology. NPL a CSIR laboratory that engages in research related to metrology is a large contributor to this effort. The committee is largely represented by research organizations and government departments such as DBT, DIT. While few private corporations are also represented, the sole NGO participation is indirect via a role of an interested party. [29] The MTD 33 has created in parallel to the ISO four national panels on Terminology and Nomenclature, Measurement and Characterization, Health, Safety and Environment as well as on Materials Specification. The activities being undertaken in the area of risk research pertains to investigations on the toxicity of zinc oxide nanomaterials. Other activities include the development of a 'National Standard on use of Atomic Force Microscope for Characterization' and 'Evaluation of Nanomaterials and Electron Microscopic Characterization of Multi-walled Carbon Nanotubes'. India's contribution to ISO is being viewed as a way to build capacity on risk evaluation and management.

Besides these state led initiatives other civil society organizations such as TERI have focused on understanding the regulatory issues and the challenges posed by nanotechnology in India. Dialogues on 'Issues of Risk in the Regulation of Nanotechnology' (January 2010) and 'National Conference on Nanotechnology and Regulatory Issues' (January 2009) have been organized. The former brought together on one platform over 30 experts from diverse fields (toxicologists, scientists and social scientists, technology developers, policy makers, regulators and civil society technology developers), examined the multidimensional nature of nanotechnologies and debated approaches to address these issues in the context of India [30] An important recommendation from the latter was that a new regulation for nanotechnology was unnecessary. It was felt that existing Indian legislations could be applied to regulate nanotechnology in the country however with suitable amendments tailored to suit the nanotechnology. [31] There exists a comprehensive legal framework in India for research and development, industrial production and marketing, environmental protection including waste disposal as well as occupational health and safety. For reasons of regulatory economy and the diversity of nanotechnology applications, it might be appropriate to examine the adequacy of this existing legal framework and identify the space it offers to regulate nanotechnology development and commercialization by way of amendments (TERI Report, 2009a).

3. How resilient is India to potential risks from nanotechnology? Examining issues, capacities and challenges.

The emergence and severity of nanotechnology's risks depends on both the nature of the risks (hazard potential) as well as the capacities to adequately understand and address those risks. While the hazard potential of nanomaterials remains uniform, whether the risks are likely to manifest and to what extent depends on capacities to assess, regulate and govern risks which is context specific and relates here to specific nations. Institutional capabilities, practice and experience besides monetary resources play a key role as does the importance and emphasis that nations lay on understanding and addressing EHS issues. As described in the first section nanotechnologies on account of the nature of their risks could pose such significant challenge to nations pursuing this emerging technology. Yet the capabilities that India possesses to adequately tackle environment and health issues challenges will decide if it's resilient to the risks nanotechnology poses. Added to this the way the nanotechnology trajectory unfolds in the national context is also crucial. I argue here that

despite growing efforts at risk assessment and management, India is still vulnerable to manifestation and amplification of risks from nanotechnology. The following sections analyses the reasons for this.

3.1 Response to the pace of nanotechnology developments in the context of addressing risks

There is no denying that despite a late start government agencies do appear to be more engaged with the issue of managing risks from nanotechnology. However are these efforts adequate to cope with the rapid progress of nanotechnology in India? Nano-products have entered the market. Consumer appliances with nanosilver include four different makes of water filters as well as the washing machine by Samsung that generated wide controversy in the US and Sweden with regards to regulation of nanosilver use. Besides nanotextiles several leading cosmetic brands already use nano versions of chemicals to improve the efficacy of their products. On the other hand numerous scientific institutions are engaged in synthesizing nanomaterials whereas a small but growing number of industrial facilities claim to be producing nanomaterials in bulk quantities etc. [32] [33] In the absence of any regulatory responses or standard guidelines these developments present significant opportunity for environment and health risks. Therefore the state's response to risk although emerging seems slow in face of this rapid succession of events. Despite the announced intention in early 2010 to create a regulatory board for product safety, there neither seems to be information on when this board assumes functioning nor how product, occupational and environmental safety will be ensued in the interim. Dialogue with industry on these issues also appears to be absent. There are other problems as well. For instance while support for nanotoxicology are laudable mechanisms to correlate the outputs of these investigations with the risk sources- either nanomaterial use in existing or in pipeline nanoproducts or in relation to occupational health is under developed. Most risk research in nanomaterials is confined to the realm of academic pursuits and has to reflect real world scenarios and local contexts. On the contrary accidents due to negligence to work place safety during manufacturing of nanomaterials have emerged as observed in the case of lung disease amongst industry workers exposed to nanomaterials in China (Song et al., 2009). [34] In India, Albupax, a nano drug delivery system for cancer was withdrawn from the Indian market in 2009 by The Drug Controller General of India (DGCI) when information on serious side effects including those on the liver surfaced. [35] These circumstances make India vulnerable to nanotechnology risks and illustrate the urgency needed to address nanotechnology risks.

3.2 Approach to risk assessment and management of nanotechnology risks

Although support from the government to risk research is apparent and laudable, there is a feeling that the effort is rather fragmented. Given that various agencies DST, DBT, CSIR and ICMR are funding studies related to nanotoxicology, there arises a question of coordination amongst these agencies. Several studies funded across IITR, ACNS, NIPER and other institutes seem to be concentrated particularly on TiO2, ZnO2, silver and gold nanoparticles. Research on drug delivery, nanomedicine and drug safety is also being undertaken by a set of institutions funded by various agencies. There isn't any clarity on how similar or different these studies are terms of objectives, methodologies and outcomes. Hence it is possible that research efforts are being duplicated, a significant problem given constrained resources. Also lacking is a mechanism where the outcomes of the various studies in risk appraisal are reviewed and validated as is the absence of understanding of social implications of nanotechnologies in the context of its risk potential. Besides coordination, concerns on the adequateness of funding, infrastructure and human resources for risk research and risk management have been made. [36]

Beyond these issues there is also a need to probe how the term risk assessment is perceived by both risk researchers and the policy making establishment in the nanotechnology domain. The application of risk assessments is now being recognized for its ability to provide inputs into decision making and there is a growing use of this term to justify the efforts being made to address risks from nanotechnology in India. However, it is unclear whether the difference between toxicology studies (which measures the hazardous nature of the substance) and a broader framework that exists for risk assessment - which develops toxicological data but also encompasses other dimensions of exposure assessments and risk characterization - is appreciated. The danger of using nanotoxicology as a proxy for risk assessment to inform decisions on risk is that risks can either be under or over- estimated due to lack of information on exposures and a biased risk profile. Despite a relatively low hazard potential, a substance could still pose significant risk based on the duration and magnitude of exposure as well as the exposure pathway. So clearly there is a need to broaden the scope of studies undertaken for evaluation of risk from nanotechnologies beyond the discipline of toxicology to cover to adequately characterize them.

Undertaking risk assessment for many nanomaterials all could pose tremendous regulatory burden for underfunded risk management systems like in India. Yet it is unclear if there is awareness in relation to the substantial information on toxicity assessments that already exists or how this might be used for informing national endeavor for risk appraisal and management. Again while participation in ISO's mechanisms by way of BIS is a step in the right direction India has been less pro-active in contributing to other international efforts such as OECD's Working Party on Manufactured

Nanomaterials aimed at building capacities, harmonizing risk management efforts and creating networks. China has assumed an active role in this initiative and the absence of an Indian presence in this risk discourse is worrisome (OECD, 2010; OECD, 2011). [37] Altogether these deficiencies in risk assessment and management might make India more susceptible to nanotechnology risks.

3.3 Capacities within the regulatory system to address risk regulation in nanotechnology

Currently there exist no regulations specific to nanotechnology in any country including India. Owing to regulatory economy and the fact that nanotechnology specific regulations could turn obsolete given rapid evolution of the technology, existing regulatory frameworks must be assessed for their capacity to address the issues put forth by developments in this sphere. Indeed in the Indian context it appears that scope for addressing nanotechnology concerns through existing regulations does exist however only if they are revisited and amended to suit the unique nature of the EHS aspects surrounding this technology. This is imperative so that the existing legal framework is able to accommodate the unusual properties of nanomaterials reflecting an awareness of the unique risks nanotechnologies pose which are distinct from the risks of conventional technologies that Indian regulations cater to presently. The interventions needed could take the shape of amendments within legal instruments besides initiatives at the level of subordinate legislations (rules, notification, schedules) (TERI Report, 2009a). This way the EHS concerns surrounding nanotechnologies might be addressed.

Nanotechnologies would need to be regulated across the spectrum of production, application and disposal as well as across regulatory jurisdictions with regards to sector-wise development and use. Therefore amendments would be needed in a gamut of regulations that span the realm of occupational health and safety, environmental management, waste disposal as well as in the production and marketing, the latter dependent on the specific application being developed. However although this opportunity to address the risks from nanotechnology presents itself, whether it is availed is another matter given the limitations in the functioning of the legal regime in India. It has been observed that although an exclusive regulatory mechanism for nanotechnology might not be preferred, it was most likely that relevant expertise on the technical aspects of risks as well as its legal implications for a regulatory framework are lacking in the Indian context. [38] Therefore an absence of these capacities within the legal system might prevent or prolong the recognition for the need amendments in the existing regulatory framework action in this realm. Since the legal framework in its present form is inadequate to effectively regulate nanotechnology risks in India continuing reliance on this framework for regulation will create greater propensity for risks to emerge.

3.4 Capacities for adequate regulatory implementation and oversight

Severe deficiencies have been observed in capacities to implement and enforce regulations as well as in regulatory oversight which can have serious implications for amplification of nanotechnology risks. For instance the manufacture of nanomaterials and nanoproducts have the potential to generate nanomaterials in waste streams, air emissions and create hazardous waste etc that could lead industrial pollution and environmental risks (Deshpande Sarma, 2011; Mastroianni, 2010;Renn and Roco, 2006). [39] It can also create occupational risks from the handling of nanomaterials and generation of by-products at the units within nanometer range can lead to human exposures (Ostraat, 2010). Prevention or mitigation of these risks necessitates adequate implementation and enforcement of regulatory guidelines like the Environmental Impact Assessments (EIA) [40] and laws related to for instance occupational health and safety (*Factories Act* [41], and Hazardous Waste Management Rules[42]) and pollution prevention (*Acts for Prevention and Control of Pollution for Water* [43] and Air [44]). A vital role is also created for the State Pollution Control Boards (SPCBs), whose main function is the enforcement of national rules and regulations at the local level where industries are established (MoEF, 2011).

However it has been observed in India that despite the presence of extensive legislations on paper several problems exist in the implementation and enforcement of the laws (CAEP-TERI, 2010). This will not be without implications for the sustainable development of nanotechnology industries and products in India. For example despite being mandatory, industry still largely remains unaware of the EIA requirements and views it as a 'trivial, check list activity'. [45]There is also insufficient technical capacity to conduct EIAs leading to poor quality EIAs, malpractices and fabricated technical analysis. [46] Again, regardless comprehensive legislation for prevention of air and water pollution, challenges exist with enforcement of these laws. Ill-defined compliance and enforcement requirements, insufficient funds as well as inadequate human and technical capacities have hampered effective post project monitoring by SPCBs. This has meant that compliance with environmental stipulations such as emission limits, pollution mitigation measures etc that are defined during the clearance process is usually lacking since adequately monitoring is missing encouraging industry negligence and malpractice and exacerbating environmental pollution (Paliwal, 2010).

The legislation for occupational safety is comprehensive and obligates industry proprietors to safeguard health of workers by several ways - by declaring known health hazards, facilitating prevention/ minimization of risks, ensure regular monitoring, providing training and monitoring health of workers in case of hazardous processes. However the

laws for occupational health and safety are poorly implemented in local contexts (Planning Commission, 2001). Similar problems with enforcement capacities have also been observed for with enforcement agencies dealing with product safety, for example in the sphere of drugs (United States Pharmacopeia, 2004; National Commission on Macroeconomics and Health, 2005). This could pose serious challenges given the growing use of nanomaterials in applications in these sectors. Therefore in effect for nanotechnology, although amendments could be made in the acts to reflect concerns from nanomaterial processes, the existing shortcomings in the implementation and enforcement of rules and regulations in relation to pollution control, occupational and product safety could make humans and ecosystems would be vulnerable to its risks.

3.5 Institutional frameworks and approach chosen for risk regulation: roles and responsibilities

Problems with addressing EHS issues in India can also be attributed at some level to the fact that these aspects- environmental health, community health and occupational health - are all distributed across the mandates different regulatory agencies. The Ministry of Environment and Forests (MoEF) handles issues related to the environment while the task of addressing human health hazards lies with MoHFW. On the other hand occupational health is dealt with by the Ministry of Labour (MoL). This fragmented mandate has hampered coordination and created information asymmetries restricting a comprehensive and articulate response to EHS challenges (TERI Report, 2009b).

In the case of emerging technologies there has been a preference in India to place regulatory authority with those agencies involved in technology development and promotion. DST leading the regulatory initiative in nanotechnology has been preceded by DBT's involvement in developing regulations for biotechnology. At present neither MoEF nor MoHFW seem involved in the DST led initiative to address regulatory aspects of nanotechnology, although the former has been involved in regulatory affairs in the agriculture biotechnology sector where it called for the moratorium on Bt Brinjal (MoEF, 2010). Furthermore despite the role they play in funding studies on risk, the participation of DBT, CSIR or even ICMR in this effort is also unclear. This continuing ambiguity of the institutional roles and responsibilities in relation to the regulation of EHS impacts of nanotechnologies is especially troubling given the rapid R&D developments as it could hamper effective regulation.

Given the present scenario there are probably two approaches for the way institutional frameworks may be established for regulating nanotechnology in India, both presenting merits and challenges. As it increasingly seems, DST could hold the reigns for regulatory control for nanotechnologies. As DST hosts the Nanomission that at least in theory serves as an umbrella to coordinate the diverse initiatives (in R&D and risk research) by various agencies and also has developed networks with technology developers and industry, its leadership in the regulatory domain could ensure effective coordination between agencies besides facilitating dialogue between technology developers, risk researchers and regulators. However in order for this centralized structure to work DST would need to, as a first step find measures to synchronize interagency efforts currently in the nanotechnology domain, fragmented as they are, and make the functioning of the Nanomission more cohesive by enabling clear channels of communication between stakeholders. The other option is a delegated approach which sees MoST restricted to technology promotion while MoEF, MoHFW and MoL addressing EHS issues according to their mandate. While the merits include harnessing of existing capacities within these institutions to address issues that fall directly within their mandates, there is the danger of regulatory overlap, dis-harmonized efforts besides a feeble response at regulation of nanotechnology risks given the prevailing deficiencies in these institutions.

However beyond the issues of efficiency, a more fundamental question arises in relation to DST's ownership of regulatory authority with regards to nanotechnology. Can an agency devoted to technology development and promotion and which seeks to rapidly expand R&D and product commercialization in the nanotechnology domain effectively assume and administer additional duties as a regulator for environment and health risks? Given the distinct nature of these roles and their dichotomous functions is there a danger for EHS aspects to be marginalized or subverted at levels of decision making when conflicts between technology development and environment or health safety arise. If this indeed occurs the nation would be significantly vulnerable to nanotechnology risks. The experience of DBT's efforts with defining regulation of Bt Brinjal in India does suggest that decision makers must be cautious of the pitfalls this institutional structure creates for transparent and credible regulation. The regulatory effort towards Bt Brinjal has been criticized at various levels- from the severe inadequacies of the biosafety studies submitted by industry, opaqueness of the decision making process, conflict of interest amongst members constituting the decision making body to the ineffective enforcement of regulations during safety trials as well as the inadequacy of the risk assessment framework adopted by DBT given that it does not comply with international guidelines (Shah, 2011)- leading to fears that it would ease the commercialization of genetically modified (GM) Bt Brinjal without adequate safety assessments. Again environmental activists have raised concerns over the Biotechnology Regulatory Authority of India (BRAI) Bill that is in formulation citing it to be pro-industry and without adequate provision for stakeholder consultations, impact assessments, mechanisms for liability and redress or even transparency. [47] Given that nanotechnologies pose unusual risks, serve a wide variety of sectors and also present challenges to risk regulation it is vital that the institutional framework chosen for regulatory function is not only adept but is able to place adequate emphasis on addressing risks so that it is balanced with technology development.

3.6 Risk communication and stakeholder engagement

In general efforts at public engagement with respect to impacts of technologies have only been rarely attempted in India and even then led mostly by non-governmental organizations. [48] However state initiated public dialogues and stakeholder consultations has been recently attempted recently in India in the case of the Bt Brinjal although this has been downstream of the technology development cycle (CEE, 2010). Closed door decision making by regulatory authorities, silence on the potential risks and larger impacts of GM technology and evasion at engaging in a two way dialogue with other stakeholders besides technology developers and industry has eroded public trust in the state's ability to ensure fair and responsible development of GM technologies - at least in certain sections of society. It has also led to polarized debates as well as a public backlash that resulted in the moratorium of release of Bt Brinjal in India (Chandran, 2010). Although unlike agri-biotechnology, nanotechnologies are diffused in their applications, a similar situation within the context of nanotechologies is also possible if the government is not forthcoming with public information on products with wide societal use- water filters, other household appliances, textiles and cosmetics which are already out in the market in India-especially if untoward effects do emerge in the future. State driven efforts to engage the public in dialogues on risk and benefits as well as the nature of uncertainties and challenges to risk regulation are absent. Risk communication with industry and R&D institutes also seems to be lacking. This situation could amplify risks of nanotechnologies either indirectly by leading to adverse environment and health outcomes or on the other hand fostering mistrust and polarized debates amongst stakeholders that hampers effective risk management.

4. Policy suggestions for effective risk regulation and governance of nanotechnologies in India

Despite the risks and challenges nanotechnology places before countries, especially those such as India, there are several measures that can be undertaken to reduce the nation's vulnerability to the risks. While a ban on nanotechnology manufacturing or product development is certainly not desired an overall precautionary approach is advised to protect public, occupational and environmental health given the nature and potential magnitude of the risks. Strengthening of current mechanisms for risk assessment, management, regulation is certainly recommended.

A clear strategy is needed for appraising and managing nanotechnology risks and operating under conditions of uncertainty. Foremost,information on potential risk sources- nanoproducts and manufacturing industry as well as volumes of production of nanomaterials must be gathered, maintained and regularly updated. Where risks can be addressed by scientific methods such as risk assessments, these must be undertaken in systematic fashion so that this knowledge informs decision making. Given the regulatory burden the diversity of nanomaterials places, the risk appraisal of nanomaterials used in existing on in-pipeline products could be prioritized. While toxicological and dose response tests must be pursued, attention must be paid to prior and adequate characterization of the nanomaterial properties, use of standard materials and guidelines besides exposure assessments for a comprehensive characterization of risks. Risk evaluation mechanism could also be broadened to apply other techniques such as life cycle methodologies given that they can provide holistic information on the sustainability dimensions of products and processes. Furthermore risk appraisals could also go beyond that of technical risks to ideally include an assessment of stakeholder concerns (Renn and Roco, 2006). Since formal risk assessments might not adequately resolve uncertain and ambiguous positions other approaches such as Scenario analysis and Multi-criteria mapping may be explored (Stirling, 2007). Overall the creation of a formal mechanism that oversees risk appraisals, reviews and validates the outputs of risk research in the country is essential given the growing body of risk research in the country. This committee could also review the substantial studies existing internationally to examine their ability to inform the national strategy and also see if India could address research gaps rather than duplicating research. A public data base of risk assessment studies supported at the national level is needed for better coordination and avoiding duplication of risk assessment efforts. The database could act as an information repository and describe significant outputs or outcomes of national and also international studies so that it informs risk management initiatives. Alternatively both assessment and management capacities could be enhanced by adequate participation at international forums designed for these purposes, where national perspectives and challenges could also be shared.

Mechanisms for occupational and product safety are core to effective risk management. Occupational health and safety is a prime concern, therefore R&D establishments and industry involved with handling nanomaterials or nanoproducts must be compelled to adhere to best practices and safety guidelines. Use of protective gear must be made obligatory and installation of clean rooms wherever applicable must be emphasized (TERI Report, 2008). Since access to equipment for monitoring releases and exposures to nanomaterials might be difficult in India (TERI Report, 2009c), enforcement of these precautionary measures is crucial. To avoid environmental repercussions and as a precautionary measure wastes generated from nanotechnology processes may be mandatorily considered as hazardous at present and treated accordingly. Provision of adequate onsite waste treatment facilities for treating effluents before release into the environment must be ensured and non-compliance penalized (TERI Report 2009c). Mandatory reporting by industry either manufacturing or using nanomaterials could be also be considered. In fact as is the case internationally application of a voluntary code of conduct for nano-industry in India might be advised. Furthermore obligating industry to undertake safety tests for the nano-products developed could facilitate greater consumer safety.

On the other hand attempts at nanoproduct safety especially within the ambit of pharmaceuticals, agricultural chemicals and foods, could be made by extending the *Drugs and Cosmetics Act*, the *Medical Devices Regulation Bill*,*Insecticides Act* and *Food Safety and Standards Act* to reflect the use of nanomaterials in these sectors (TERI Report, 2009a). In the health sector for example the role and capacities of voluntary codes such as National Pharmacovigilance Protocol and institutions like the DGCI could be leveraged (TERI Report, 2009a). Nevertheless since adequate frameworks for safety of other products such as water filters, washing machines etc. in relation to consumer health and environment do not exist, other options for them would need to be examined. As these points suggest amending the existing legislation for ensuring OHS and product safety is crucial and must be considered as a first step in devising adequate risk regulation for nanotechnologies. However given that an absence of adequate implementation and enforcement capacities could amplify risks, risk communication and dialogue with technology developers, industry and industry associations within each sector as well those with broader mandates will be key. Import and export of nanomaterials must also be adequately regulated. [49]

Overall a flexible plan that elaborates on short term and long term goals for risk appraisal and risk management in keeping with the R&D and industry developments in the nation is vital as is a dynamic regulatory framework that adapts to technological advancements. Adequate infrastructural and human capacities must also be established for enabling a comprehensive mechanism that enables effective risk appraisals, responsive risk management and adequate regulatory safety for nanotechnologies. To enable this however greater monetary resources devoted to addressing nanotechnology risks will be required- a challenge given limited resources and existing technological aspirations. Nevertheless given that India seeks to mold itself in line with developed nations in terms of investments in the nanotechnology domain, it is vital that it also in proportion improves its budget for risk research and set up a comprehensive program to assess risks as many of them have or are considering.

For all of this and to enable a suitable strategy for risk management and regulation an enlightened approach is necessary. This could be enabled in two ways. First the regulatory board envisioned by the Nanomission could involve an inter-ministerial or an inter-agency committee with participation of MoEF, MoHFW, Central Pollution Control Board and BIS besides DBT, ICMR, and CSIR who contribute to decision making on risk regulation and governance. Expanding their role to assume suitable responsibilities that fall within each of their mandates could be considered. While these members could form the core committee other stakeholders for instance, technology developers, risk researchers (both from the sciences and social science and domains), industry representatives and select non-governmental or civil society organizations could be employed to strengthen the decision making of the committee.

On the other hand although at present none have been undertaken, developing mechanisms to transparently communicate with stakeholders and the public on issues of nanotechnology risks and ways to manage and regulate it is also vital. Furthermore moving away from the science communication paradigm to that of a two way dialogue with stakeholders is necessary given the revolutionary and sometimes controversial nature of the technology. Certainly the ambiguities, uncertainties and social implications in this domain demands that stakeholders and public be adequately engaged in decision making process. This more necessary in developing country contexts due to limited monetary and institutional capacities to address risks, possibilities of disproportionate distribution of benefits and risks and the fact that ethics of public funded research demands this approach.

Obviously public engagement and dialogue does not offer a sure shot panacea to decision making that is challenging. It can fuel more contentious debate and also move away from core issues of environmental and health risk and speak to larger issues- equity, ethics and values. However as the debate on Bt Brinjal in India reveals enabling public dialogue during the course of technology development and engaging with social, ethical and cultural dimensions is as important as pursuing research on technical risks. The rather downstream consultations with stakeholders and public by the then minister of MoEF between January and February 2010 in diverse locations in India revealed apprehensions that ranged from a variety of health and environmental impacts, adequacy of risk appraisal and approval process to other concerns about monopolization of food production by industry, suitability of Bt Brinjal technology in the Indian agricultural context, impact on economic livelihoods of farmers especially small farmers, consumer's the right to choose, loss of traditional varieties, impact on food prices etc. Based on these consultations and others with national and international experts a moratorium was placed on the release of Bt Brinjal in India (CEE, 2010). Clearly given the nature of concerns with nanotechnology democratic participation in decision making will facilitate trust in regulatory institutions and may also prevent polarized debates and public backlash downstream of technology trajectory. Overall such an approach and these measures could improve the preparedness of the state to assess, manage and govern nanotechnology risks increasing its resilience to the manifestation or amplification of EHS risks

5. Conclusion

Developing countries face the dilemma of harnessing the potential of technologies alongside responding to simultaneous concerns of environmental sustainability and human safety - this amidst challenges of limited financial and institutional capacities. In India the outcome of the race for industrial and technological advancement as a means for global competitiveness has invariably been the neglect of EHS and safety issues. Certainly the privileging of technology development in the Indian growth trajectory post independence and its inclusion in the development agenda has in some sense fostered the simplistic equation - the linking of unbridled technological progress with vast socio-economic progress

- without the full appreciation the possible environment, health impacts and its implications for development itself. Again on occasion the aspiration for industrialization and technology self-sufficiency has also been used to justify lethargic responses to the establishment of regulations as reflected in the nanotechnology context. This coupled with poor state responses to evolving EHS issues and limited capacities to ensure regulatory oversight has lead to widespread environment risks and public health hazards. India's engagement with nanotechnology and its potential response to risks emerges in this arduous milieu and is compounded by challenges posed by the nature of the technology itself as it is by the uncertainty in institutional frameworks and capacities for risk regulation and risk governance. Certainly the state appears to have broken the mould in its relatively upstream attempt to address nanotechnology risks as compared to responses to risks from other sources, nevertheless significantly more will be needed if India wants to effectively safeguard its environment and its public from the potentially adverse impacts of nanotechnology.

Given that India's vulnerability to nanotechnology's risks is to an extent due to the deficiencies endemic its approach to risk regulation and governance, changes may necessitated at various levels- perceptions towards risk regulation, designing adequate frameworks for addressing risks, reforming existing institutional capacities and creating democratic and effective approaches for decision making. Undeniably effective approaches to risk regulation and governance in context of nanotechnologies will be beneficial. However it could also possibly have larger implications in that it presents an opportunity for such mechanisms to be implemented across other technologies that exist or might emerge in the future. It also opens a window, a room for discussion for the correction of endemic deficiencies in the way the nation addresses environment and health issues. Hence this opportunity must be availed. The sustainable development of nanotechnologies in India would certainly depend on it as could the shaping of a more sustainable and responsible direction for technology and industrial development which sees a better integration of environment and health issues in its discourse.

Acknowledgement

This research was developed under the IDRC project Capability, Governance and Nanotechnology developments: a Focus on India. It draws on some the ideas described in 'A Report on Risks from a Developing Country Perspective' and 'Report on Regulatory Challenges posed by Nanotechnology Developments in India'. Author thanks Dr. Dhawan, Dr. Nair and Dr. Tikoo for information provided on risk research at their institutes.

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