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Multi level governance (MLG) framework for nanotechnology

Capability, Governance, and Nanotechnology Developments: a focus on India

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The Energy and Resources Institute

Study team

- Manish Anand
- Indrani Barpujari
- Nidhi Srivastava (co-ordinator)
- Ligia Noronha

Secretarial assistance

M K Bineesan

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For more information

Nidhi Srivastava
T E R I
Darbari Seth Block
IHC Complex, Lodhi Road
New Delhi – 110 003
India

Tel. 2468 2100 or 2468 2111
E-mail nidhis@teri.res.in
Fax 2468 2144 or 2468 2145
Web www.teriin.org
India +91 • Delhi (0) 11

Table of Contents

List of Tables

List of Figures

Preface

The domain of nano science and nanotechnology has witnessed large-scale engagements from both developing and developed nations. This emerging technology due to its complexity, wide applicability and transformative nature needs to be understood holistically and by looking at all the facets that it embodies. Therefore, various dimensions that range from developments across national and international platforms, capacity building initiatives and challenges, opportunities for aiding socio-economic development, multidimensional risk and regulatory imperatives as well as science and society interfaces need to be addressed.

With this background TERI started a three-year project in 2007 ***on Capability, Governance and Nanotechnology Developments: a focus on India*** with support from IDRC, Canada. The project was initiated with the objective of helping policy-makers, industry, and civil society in developing countries to be better positioned to avail of optimal benefits of nanotechnology by increasing the knowledge base available to policy-makers and others involved with nanotechnology developments. The project adopts a nested hierarchical approach to linking national with global research on responsible Nanotechnology.

The report seeks to contribute to a multi level governance (MLG) framework of nanotechnology. Drawing from the discourse on MLG, the report contextualises the issues in nanotechnology governance with reference to India. The study builds upon the diverse and extensive research and stakeholder engagement exercise undertaken as a part of the project over the last three years. The report proposes a multilevel governance framework, which embraces all the vertical and horizontal levels involved in the development, application and regulation of nanotechnology, would enable integration of divergent perspectives and help steer the course towards responsible development of nanotechnology in India.

Executive Summary

Poised to be one of the 'defining technologies' of the 21st century with envisaged breakthroughs in a large number of fields, nanotechnology has fuelled a significant increase in R&D expenditure in all developed countries. Developing countries are also increasingly investing in nanotechnology, in view of its potential to be utilised as a tool to address key development related challenges in sectors like energy, water, agriculture, health, environment and the like. However, the very same attributes which make nanotechnology so unique and endowed with immense potential for both societal benefits and economic gain, also pose questions regarding their safety and carry social, economic, ethical and other implications. This poses considerable challenges for governance of nanotechnology, with the governance framework being required to reconcile the need to provide a nurturing environment for the development of the technology and maximise societal benefits, while addressing the risks and socio-economic implications.

Problems in nanotechnology governance arise from the fact that there is considerable scientific uncertainty regarding the risks to health and environment, the unavailability of metrology tools, the absence of standardized methodologies for risk assessment and management, difficulties in developing regulation in the face of such uncertainty etc. These problems are magnified for developing countries lacking the resources as well as the capacity to engage in risk research, assessment and management and to develop and implement regulation, while being severely constrained by the lack of standards.

The case for multi-level governance in nanotechnology

There has been some realization that rapid technological and scientific developments typical with nanotechnology put governing systems under much strain and requires new conceptions of governance. There is the need to move away from the 'government' approach characterised by a top-down legislative approach, to a 'governance' mode characterized by increased participation and cooperation between the different players and stakeholders. It is in this context that this paper seeks to build the case for the development of a multi level governance framework for nanotechnology in India and suggests ways and means on how to achieve it. Originally developed in the context of developments in EU policy in the 1990s, the concept of multi-level governance (MLG) has since then been accepted in theoretical discourse on governance in general and extended to various issues and jurisdictions. The MLG approach as developed by Marks et.al (1996) is characterized by “the existence of overlapping competencies among multiple levels of governance and the interaction of political actors across those levels”. The key elements of MLG include increased participation of non-state actors in government functions, shift from discrete territorial levels to complex overlapping networks, change in the understanding of the State’s role from command and control to co-ordination, steering and networking and a shift in the way democratic accountability in governance takes place. It can be of two types-vertical and horizontal. The former refers to dispersion of power to jurisdictions at a specific number of clearly defined general purpose jurisdictions-from international to local. On the other hand, horizontal MLG is a scenario where jurisdictions cut across type I territorial scales and are defined in terms of the tasks then perform rather than a generalized approach. Neither type alone is sufficient on its own. Inter-linked, they comprise the framework of MLG together.

The fast pace and large scale of developments, diversity of technologies involved, promise of potential benefits along with limited knowledge about impacts and nature of risks make the fabric of nanotechnology governance more complex with a greater role for a diverse set of actors and stakeholders in this area. This makes governance of nanotechnology difficult through conventional linear approaches and calls for a multi level approach to governance to ensure that technology is developed and contributes towards societal benefits in a responsible manner.

Multi-level governance of nanotechnology in India

A MLG approach for nanotechnology would entail examining both vertical and horizontal aspects across jurisdictions and issues. The level of governments or institutions, which can be included in a multilevel governance framework, is important not only to make the governance inclusive and democratic but because the number of actors determines how complex the framework would be. (Jollands et al, 2009) The report maps the different actors at different levels having a role in governance of nanotechnology, how they interact with each other and how they influence the nanotechnology landscape in India and in medical applications in particular.

At an international level, both political and sub political sites are important for understanding the governance of nanotechnology considering the kind of influence that sub political sites have begun to have and current developments in these sites. Although they may lack effective legitimacy and formal rule making or implementation power, they can be instrumental in shaping the nanotechnology governance frameworks at domestic levels. These include Intergovernmental Forum on Chemical Safety (IFCS), International Standards Organization (ISO), and the International Risk Governance Council (IRGC). Besides these, the role of World Trade Organisation (WTO) and World Health Organization (WHO) would continue to be important in setting rules and laying down guidelines and standards.

The role of national level governments and institutions in India has been studied extensively under the project and described in previous reports as well. At the national level the Ministry of Science and Technology is the nodal ministry for promotion of research and development in the area of technology and administers its functions through three departments – department of science and technology (DST), department of biotechnology (DBT) and department of scientific and industrial research (DSIR). DST, through its Nano Mission has been the most instrumental agency within the government for encouraging nanotechnology development and application through both financial and institutional support.

Other ministries such as those of commerce, defence, information technology etc. are also important for promoting R&D in nanotechnology and building capability. In terms of managing the impacts of nanotechnology and governing the technology's interface with the environment and humans, ministry of health and family welfare, and ministry of environment are the relevant ministries. Central agencies and offices under the two such as Central Pollution Control board, Central Drugs Standard Control Organisation are key national level actors.

At a state level or sub national level, there are state level or zonal implementing agencies, which implement and discharge the different functions of importance to any technology, including nanotechnology. State drug controllers, State Pollution Control Board, State committees look after the regulatory aspects whereas state level institutes, laboratories, institutes, patent controllers work towards strengthening the nanotechnology research and development in India.

In the overall governance framework for nanotechnology, there is a limited role for local authorities. This is ironical as the impact of an emerging technology percolates down to the lowest levels. Drug inspectors and health and sanitation inspectors monitor and operate at local levels also. Local authorities can take *suo motu* action in case of a public nuisance (including risk to environment and human health) being caused by a technology developer or a manufacturing process.

The horizontal dimension of MLG operates at two levels - between actors at same level/within jurisdictions and another based on issues. In a technology governance framework, the three most important issues are that of (i) capability and innovation (ii) risks, and (iii) regulation.

The role of policy instruments in building science, technology and innovation capability is paramount. Innovation in nanotechnology may be conceptualized as the accumulation and diffusion of scientific knowledge in research institutions and firms. Innovative activities involve directly or indirectly a large variety of actors, including: firms, research organizations like universities and public and private research centres, financial institutions, regulatory authorities, consumers. Institutional environment may facilitate the interaction among various actors and the emerging policy options would have to be explored for application of new technologies in the production processes with special focus on institutional environment. New products, processes and services created using nanotechnology involve social, economic, ecologic, political and ethical matters surrounding their emergence. All this needs to be sufficiently addressed in defining the nanotechnology innovation trajectory.

The project acknowledges the existence of multidimensional risks around nanotechnology ranging from environment and health and occupational risks to socio-economic risks. A holistic approach to risks is essential and nanotechnology risks can be best understood in conjunction with its benefits. A technology governance framework should also address the risk of missing an opportunity that the technology can offer. The IRGC framework is the most comprehensive risk governance framework for nanotechnology comprising pre-assessment, risk appraisal, characterization and evaluation of risks, risk management, risk communication. Risk governance therefore would include laws, processes and institutions by which decisions regarding risk analysis, management and communication are taken. It takes into cognizance both the structures (i.e. the actors who participate in the decision making process) and the process (i.e. the procedures that legitimise the decision-making process).

Regulation essentially relates to government action in the form of laws and notifications with the objective of directing private action for a specific purpose or with a certain aim (Brownsword, 2008). Regulation of nanotechnology would therefore aim at both promoting it and governing its impacts. The role of the state is of primary importance in defining regulatory objectives and developing the ambit. A previous report on regulatory challenges under the project provides a detailed review of the regulatory regime for nanotechnology applications divided into the categories or stages of technology development and application – (i) research and development, (ii) production and marketing, (iii) occupational health and safety, (iv) environmental risk management and (v) waste disposal. It can be observed that there are several regulatory instruments across these stages and there are both opportunities as well as gaps within the existing regime for nanotechnology. There exists some level of flexibility within the existing regime to initiate a response to meet challenges related to nanotechnology. However, even to make use of the flexibilities, where available, major steps will have to be taken to put them to use.

Challenges for multi-level governance in nanotechnology

Given that nanotechnology is widespread in its reach and interdisciplinary in nature, it spans issues, domains and stakeholders making it a complex territory for governance. With these characteristics and complexities nanotechnology seems apt for MLG, which itself is going to be more challenging in the case of nanotechnology.

Capabilities, in terms of number of research institutions and organizations, infrastructure, funds, health services delivery at the district and local level remains weak to a large extent. In the multi level governance framework, a greater emphasis needs to be laid at the state and local levels. Downstream engagement, right from the framing of research agenda to developing innovative health products and services, would be an essential pre requisite for effectively governing the health sector.

Nanotechnology development in India is largely a government led initiative, yet the state agenda is marred with a serious lack of coordination at several levels – research, policy and interagency/ governmental. The existing linkages between our S&T institutes under the Ministry of Science and Technology and other S&T institutes under the socio-economic ministries and such others that does not appear to be strong and clearly differentiated. Similarly coordination and linkages between central and state S&T institutes might gain from this learning.

A smooth flow of information is necessary for enabling any governance framework and more so if it is multi level and multi-actor. In the case of nanotechnology with which significant degree of uncertainty is attached given its evolving nature, the staple set of concerns for governance are further amplified. Given that nanotechnology has application potential in various sectors of the economy, development of cross–sectoral policies and clear prioritisation for nanotechnology may be a critical approach to multilevel governance. Credibility of policies and actions is central to a wider acceptance and inclusiveness of governance, which is difficult to obtain in view of differences in opinions and perceptions about benefits and risks of nanotechnology. One way of overcoming the problem of legitimacy is through democratisation of MLG facilitating a dialogue and learning across state and non-state actors.

Way forward: roles and points of interventions for governance of nanotechnology

An institutional framework for nanotechnology in India would, thus, ideally include a range of institutions- research bodies, promotional agencies, planning bodies, nodal ministries, other ministries, regulatory agencies, implementing agencies etc. performing different functions. As a way forward in developing a responsible and inclusive governance of nanotechnology, it is essential to identify the roles for different actors and stakeholders.

Given the influence of international policies and processes on domestic regimes in an era of globalisation, international forums such as the IRGC, ISO, WHO etc. have an enhanced role to play in developing a governance framework for nanotechnology in India. They need to take the lead in setting guidelines, establishment and enforcement of international standards, and in facilitating a network of information and monitoring, for adoption and amalgamation in domestic policies. Till the time they are adopted by domestic policies, these would serve as useful models for adoption in the form of voluntary measures by companies.

The MLG framework in a way broadens the scope of the government's role from command and control to that of coordination, steering and networking. While continuing to provide support for research and development in nanotechnology, the government should also provide support to greater risk related research and generation of data. Government action should also be directed towards laying down guidelines for researchers and industry, the setting of short-term and medium term agendas and fostering inter-disciplinary research, with a focus on the social, ethical and other implications as well.

The scientific research establishment and academia have a crucial role to play in building capabilities in nano- science and technology in terms of critical mass of trained scientific manpower in the various areas of nanotechnology with ability to create, adopt and apply knowledge. They need to further collaborations with industry for development of innovative products as well as engage in a higher level of coordination and information exchange with other research institutions. They also need to channel the research and infrastructure support received from the government towards nanotechnology developments relevant to the Indian context and problems. The academia can be proactive in setting transdisciplinary centres and studying societal impacts of society and undertake socio-economic studies re nanotechnology.

As R&D in nanotechnology progresses and more products are closer to be manufactured on a commercial basis and launched in the market, the industry needs to be an integral part of the nanotechnology governance framework. This it can do through corporate governance tools such as transparency, which would be useful in building trust of the consumers and providing the required flow of information for devising a regulatory strategy. At a stage when it is not possible to have nano-specific regulations and there is a dearth of nanotechnology related standards, both internationally and domestically, companies can the lead and practise self-regulation by coming up with and adhering to voluntary standards. They are also better positioned to collate and provide knowledge on impacts, occupational hazards, waste disposal etc. for further risk research and policy design.

With regard to the role of civil society in a governance framework for nanotechnology, the diversity of nanotechnology applications makes it difficult to identify the target community within the civil society. This makes the task of engaging with civil society difficult but no less important in case of nanotechnology. Consumer groups and NGOs can be influential in demanding greater transparency, information and serve as a watchdog especially with respect to environmental and health impacts of nanotechnology applications. Prioritisation of research and sectoral focus is another area where civil society can influence policies by articulating the needs of the society and the health areas in need of nanotechnology intervention. Civil society organizations along with other stakeholders in the government, industry and academia can also help remove any misgivings and create an information network to facilitate better public engagement, and to avoid the formation of uninformed or ill-informed public perception and consequent reluctance to accept the technology.

CHAPTER 1 Introduction

About nanotechnology

Nanotechnology, according to Siegel *et al* (1999) refers to the development and application of structures, materials, devices and systems with fundamentally new properties and functions which derive from their size in the range of about 1 to 100 nanometres (nm). At this scale, the physical, chemical and biological properties of materials substantially differ from the properties of individual atoms and molecules or bulk matter, which enable novel applications across a range of sectors and embracing diverse disciplines.

Nanotechnology is poised to be 'one of the defining technologies' of the 21st century, with envisaged breakthroughs including order-of-magnitude increases in computer efficiency, advanced pharmaceuticals, bio-compatible materials, nerve and tissue repair, surface coatings, catalysts, sensors, telecommunications and pollution control (Renn et al 2006). This 'promise' of nanotechnology has fuelled a significant increase in R&D expenditure in all developed countries. Developing countries are also increasingly investing in nanotechnology, in view of its potential to be utilised as a tool to address key development related challenges in sectors like energy, water, agriculture, health, environment and the like. However, the very same attributes, which make nanotechnology so unique and endowed with immense potential for both social benefits and economic gain, also pose questions regarding their safety and have social, economic, ethical and other implications.

Issues in governing nanotechnology

UNESCAP defines governance as the process of decision-making and the process by which decisions are implemented (or not implemented). The term 'governance', according to Lyall and Tait (2005), implies a move away from the 'government' approach characterised by a top-down legislative approach attempting to regulate the behaviour of people and institutions in quite detailed and compartmentalised ways. On the other hand, governance views the process of governing as a joint effort of industrial, public and civil society actors, usually within networks, with the goal of making best use of their respective resources, skills and capabilities for reaching specific ends or purposes (Zurn 2000). According to a white paper of the IRGC on nanotechnology risk governance (Renn et al, 2006), the principles of good governance include participation, transparency, effectiveness and efficiency, accountability, strategic focus, sustainability, equity and fairness, respect for the rule of law, and the need for the chosen solution to be politically and legally realisable as well as ethically and publicly acceptable.

In recent times, the governance of emerging technologies such as nanotechnology offering 'radical new solutions' has engendered considerable political, legal and ethical debates. Fiorino (2006) acknowledges that the growing complexity, dynamics and diversity of our societies, as caused by these rapid technological and scientific developments put governing systems under much strain and requires new conceptions of governance from a one-way to a two-way traffic between the public and the private. While 'governance' of nanotechnology has most often been used in the context of risk considerations, there is a need to view it from a much broader perspective. While governance of risk is imperative, benefits and opportunities also constitute an important aspect and the two always need to be balanced against each other (Weidmer *et al*, 2010). A governance framework for nanotechnology has to address simultaneously the need to provide a nurturing environment for the development of the technology and maximise the societal benefits, while addressing the risks and socio-economic implications.

Technology development

A survey on the existing nanotechnology governance in a number of countries (US, UK, Canada, France, Germany, Ireland, Italy, Japan, South Korea, China) by the IRGC Working Group on Nanotechnology[1] indicates that nanotechnology is an important part of national science and technology agendas particularly within the fields of materials, biology, medicine, electronics, engineering, sensors, aerospace, food quality, environmental monitoring and metrology. The survey also indicates that several countries have set up central research coordination bodies, with many existing research institutions and national ministries prioritising nanotechnology. In order to facilitate collaboration and provide access to tools and materials, nanotechnology centres are being constructed in nearly all of the countries surveyed. According to the results of the survey, governments have also been encouraging collaboration between industry and academia to promote transfer of knowledge to the market sector.

[1] IRGC Working Group on Nanotechnology, 2005, *Survey on Nanotechnology Governance, Vol. A. The Role of Government*, Geneva: IRGC

Though in a nascent stage, policy initiatives in nanotechnology in developing countries like India have an almost exclusive focus on development and applications. Basically a government led initiative; nanotechnology development in India is largely taking place under the aegis of the Nanoscience and Technology Mission under the Department of Science and Technology (DST). The Department of Biotechnology (DBT), Council of Scientific and Industrial Research (CSIR) and the Science and Engineering Research Council (SERC) are the other major government players. Industry participation in NT development is very recent and yet to evolve, with most of the R&D taking place in public funded universities and research institutes.

Risks around technology

The IRGC survey on nanotechnology governance (*op.cit.*) indicates that 'strategic risk governance' is underdeveloped in all the countries, in comparison to technology development. It, however, found that there is acknowledgement in recent times that 'risk' needs to become a focal point. The survey cites some examples of current activity in this direction, which includes a requirement for nanotechnology centres to address issues of risk, establishment of best practices and standards, and the funding of research programmes for both physical and social risks. Developing countries like India exhibit a marked priority towards development and application over understanding and regulating risk in nanotechnology. This could be attributed in some part to the fear of being left behind in the NT race. The scientific establishment in India echoes this sentiment: 'We missed the opportunity during the semi conductor revolution. We should not repeat that with nanotechnology' (cited in Choudhury and Srivastava, 2008).

Problems in evolving a governance framework for nanotechnology are many, the main being to ensure a certain level of safety without acting as an impediment to development and stifling innovation. This is compounded by the fact that there is considerable scientific uncertainty regarding the risks which nanotechnology could pose to health and environment, the unavailability of metrology tools, the absence of standardized methodologies for risk assessment and management, difficulties in developing regulation in the face of such uncertainty etc. These problems are magnified for developing countries lacking the resources as well as the capacity to engage in risk research, assessment and management and develop and implement regulation, while being severely constrained by the lack of standards. Davies (2009) found that most developed countries including the United States have limited regulatory preparedness for nanotechnology and apprehends that this would become more difficult with the next generations of nanotechnology and the already existing gap between capabilities of the regulatory system and nanotechnology developments could only become wider. In the case of developing countries like India, the capabilities are further compromised due to lack of resources, expertise and regulatory mandate.

Apart from the environmental and health impacts, nanotechnology could have major impacts on the existing social, economic and trade milieu of developing countries, which needs to be addressed in a 'responsible' governance framework, but have not been adequately studied till date.

Need for multi level governance

This report seeks to build the case for the development of a multi level governance framework for nanotechnology in India and suggests ways and means on how to achieve it. In view of the challenges posed by the need to reconcile multiple objectives-that of technology development, risk regulation and taking care of socio-economic implications, the scientific uncertainty and the limits in capabilities of the various players, a transparent governance framework characterised by increased participation and cooperation between the different players and stakeholders is the need of the hour. Weidmer (*op.cit.*) observes that effective governance of nanotechnology can only be achieved through a 'proactive and adaptive framework, with a high level of interaction between those who develop, manufacture, sell and regulate NT based products, as well as representatives of civil society and which addresses transboundary issues'. A multilevel governance framework, which embraces all the vertical and horizontal levels involved in the development, application and regulation of nanotechnology, would enable integration of divergent perspectives and help steer the course towards responsible development of nanotechnology in India.

CHAPTER 2 MLG: the conceptual framework

Before we examine the need for multilevel governance in nanotechnology and assessing the different aspects of such an approach and framework, it is important to understand the concept of multilevel governance.

Governance can be broadly described as the body of rules, enforcement mechanisms and corresponding interactive processes that coordinate and bring into line the activities of the involved persons with regard to a common outcome (Fischer, Peterson and Huppert, 2004). According to Florini (2008), the term encompasses but goes beyond governmental functions to include the agenda setting, negotiation, regulatory, implementation and monitoring roles that are sometimes played by businesses or civil society actors. Jolands et al (2009) define governance not as a concept but an approach or perspective to governing process. Given that such an approach involves several actors, issues and interests, it must recognize the existence and importance of overlapping and competing authorities at different scales (Bulkeley, 2005) including 'glocalisation' (Swyngedouw, 2003).

The all-encompassing nature of governance makes it impossible to be restricted to a particular level, region or domain. However, governance has typically had a top-down approach with little interaction across scales. There has been a thrust on multi-actor and multilevel governance as a more inclusive, coherent and participatory option as against a top down approach of governance (Kern and Bulkeley 2009). The concept of multi-level governance tries to weave together all the different scales existing around an issue by actors with different interests and values.

What is multilevel governance?

The term multilevel governance, which refers to the exercise of authority and the various dimensions of relations across levels of government (OECD) was developed in the context of developments in EU policy in 1990s. Gary Marks et al (1996) developed an MLG approach characterised by 'the existence of overlapping competencies among multiple levels of governance and the interaction of political actors across those levels' (Marks et al, 1996). Since then, the concept has been accepted in theoretical discourse on governance in general and extended to issues and jurisdictions beyond the European Union. Over the last two decades, the MLG concept has been contextualised in various spheres and jurisdictions. Environmental governance is one such area, where the discourse on decentralization has been complemented with a broader multilevel governance approach. (Bulkeley, 2005; Homeyer & Knoblauch, 2008) With globalisation, there has been a proliferation of jurisdictions and emergence of non-state actors, territorial boundaries have become blurred and the global is more connected to the national and local. This false dichotomy between domestic and international politics is critiqued by component of MLG. (Bache and Flinders, 2004)

In recognition of the fact that externalities of policies and government actions transcend territorial boundaries, and necessarily vary from global to local, MLG seeks to internalize these differences in externalities. To this effect, 'governance must operate at multiple scales in order to capture variations in the territorial reach of policy externalities.' (Marks and Hooghe, 2004) It, therefore, addresses complexity at and between levels going beyond a linear approach to the study of international organizations on national polity and on specific thematic areas. (Stubbs, 2005)

It is not possible to have a universal definition for the concept of MLG but Bache and Flinders (2004) outline key elements of MLG -

- Increased participation of non-state actors in government functions;
- Shift from discrete territorial levels to complex overlapping networks;
- Change in the understanding of the State's role – from command and control to co-ordination, steering and networking;
- Shift in the way democratic accountability in governance takes place.

A multilevel governance framework can operate at both vertical as well as horizontal levels. The former relates to a distribution of functions and responsibilities across different hierarchical jurisdictions - international, national, state and local. The latter is a more complex arrangement where overlapping jurisdictions interact with each other across levels. The interactions among several actors occur horizontally beyond the hierarchy of institutions and could include inter ministerial, inter-departmental, state and non-state interactions. These interactions transcend not only territorial and administrative boundaries but different policy spheres as well.

Bache and Finder (2004) call it the dispersion of central government authority both vertically, and to actors located at other territorial levels and horizontally to non-state actors. Such a scheme is not only more efficient and normatively superior (Marks and Hooghe, 2004) but enjoys greater ownership and acceptability amongst different actors and stakeholders. Given that multilevel governance is capable of capturing and addressing the differences in concerns and stakes across sections, it has the potential to ensure greater societal acceptance and responsible development of emerging technologies.

Dimensions of MLG

As mentioned above, the concept of MLG has evolved since the early 1990s. Even Marks' definition captured this change when it referred to multi-level governance in 2003 as a 'reallocation of authority upwards, downwards and sideways from central states' (Marks and Hooghe, 2004) Thus, it is both vertical and horizontal. While there was some agreement about the need for multilevel governance, but discussions on how it should be done needed further deliberation. Drawing from existing literature on European Union studies, international relations, federalism, local government, Hooghe and Marks set out two types of multilevel governance – type I and type II.

Table 2.1 Two types of MLG

Type I	Type II
general-purpose jurisdictions	task-specific jurisdictions
non-intersecting memberships	intersecting memberships
jurisdictions organized in a limited number of levels	no limit to the number of jurisdictional levels
system-wide architecture	flexible design

Source: Hooghe and Marks 2003

Type I refers to dispersion of power to jurisdictions at a specific number of clearly defined general purpose jurisdictions – from international to local. Conversely, type II is a scenario where jurisdictions cut across the type I territorial scales and are defined in terms of the tasks they perform rather than a generalised approach.

Neither type I nor type II alone is sufficient on its own. Inter-linked, they comprise the framework of MLG together. Schivatcheva (2009) observes that the fluid nature of Type II governance can make coordination amongst actors difficult and hence necessitate a central actor for the purposes of coordination, thereby underlying the need for a type I governance.

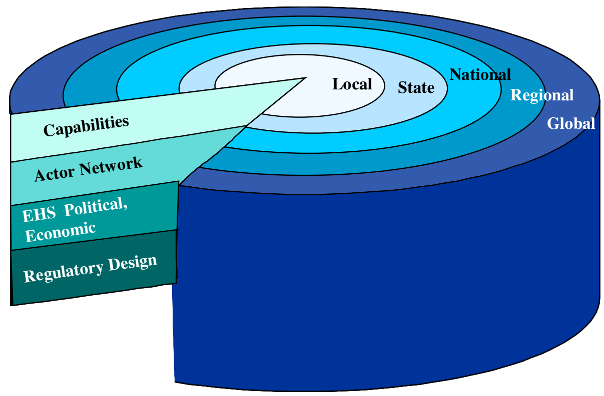

Figure **2.1** Multilevel governance

Source: Adapted from TERI 2009, Nanotechnology Development in India: the need for building capability and governing the technology, Briefing paper

Type I

In a type I model of governance, there are non-intersecting and non-overlapping jurisdictions. There is a nested hierarchical structure, explained by its proponents through a metaphor using Matryoshka dolls, where

> *'every citizen is located in a Russian Doll set of nested jurisdictions, where there is one and only one relevant jurisdiction at any particular territorial scale. Territorial jurisdictions are intended to be, and usually are, stable for several decades or more, though the allocation of policy competencies across levels is flexible.'*

Hooghe and Marks (2004) in Bache and Flinders ed. 'Multilevel Governance' pp. 16

The key characteristics of Type I as defined by Hooghe and Marks are the following –

- the sub-central jurisdictions are multipurpose;
- the memberships of these sub-central jurisdictions do not overlap;
- there are a fixed number of levels of sub-central jurisdictions; and
- the whole system follows one uniform design.

These would, thus, refer to the governments and authorities at international, regional, national, state, local and rural levels where each of the units has a broad ranging, identical powers and responsibilities without any overlaps in the responsibilities for a given territory and population. (Moore, 2003) Here, authority is spread over a flexible and fluid collage of overlapping jurisdictions.

Type II

Type II refers to task-specific specialized jurisdictions, characterised by flexibility, varied scales and no limit on the number of jurisdictional levels and actors. Often there will be intersecting memberships and implementation, given the focus on tasks as against pre-determined territorial limits. Although it departs from type I in its design and scale, it is likely to be rooted in formal legal or institutional frameworks deriving their authority from Type I jurisdictions. (Marks and Hooghe, 2004).

These are illustrated by instances where responsibility for different functions and services are divided amongst institutions with different territorial boundaries and different sub-levels. (Moore, 2003). The Concise Oxford Dictionary of Politics describe it as follows,

> *"in contrast with more traditional forms of decentralization, the number of jurisdictions is not limited, the jurisdictions operate at diverse territorial scales rather than a few levels (even across national borders) and they are task-specific rather than multi-task."*[1]

Bulkeley and Kern (2006) propose another approach to analysing multilevel governance – through the modes of governance. They focus on (i) governance by authority, (ii) by provision, (iii) by enabling provisions and actions, (iv) by self-governance. Jollands et al 2009 have suggested yet another approach to MLG and they identify the following factors integral to its understanding –

- Scope, including the level of inclusion of various levels of government and types of measures taken by the government;
- Structure, including decision making process, nature of participation and accountability; and
- Budgetary and fiscal allocations, including funding asymmetry.

Irrespective of the approach within MLG and the elements of analysis, what is distinct about MLG framework is that it goes beyond movement through a set of nested scales from the local to the national to the international, but local politics can directly access other relevant local actors in the same country and abroad. (Sassen 2003)

With all its proposed benefits, a multilevel governance approach is fraught with several challenges. Literature identifies these limitations as being too descriptive (Bache et al, 1996; Cole)[2]

[1] McLean Iain and McMillan Alistair, 2009, Concise Oxford Dictionary of Politics, OUP: New York
[2] See Bache, George & Rhodes, 1996: pp 312-3. Also see Alistair Cole, Multi-level governance: model or metaphor? Www.univ-paris1.fr/.../Multi-level_governanceEuropean_integration_and_the_State.ppt

and lacking a clear conceptual focus (Peters and Pierre, 2004). Another challenge has been balancing actors and coalitions with structures and instruments of governance. The actor centred approach must deal with relations between state actors at levels as well as relations across sectors (Bache, 2008). These limitations and challenges would have to be addressed while devising MLG framework for any sector, including nanotechnology.

CHAPTER 3 MLG framework for nanotechnology governance in India

Looking for governance rather than government or private industry to assess and manage the implications of nanotechnology provides a broader and more realistic picture about the forces that will shape the future of nanotechnology development.

Renn et al 2006, IRGC White paper on Nanotechnology Risk Governance

Nanotechnology: a case for MLG

Nanotechnology, like any emerging technology ,has promising potential benefits as well as uncertainties about the impact it can have in terms of human health, environment, markets and society. This is what makes most of the new technologies quite contested when released. The uncertainty gets aggravated and becomes an issue of concern in nanotechnology for reasons that make nanotechnology distinct from previous technologies that have been introduced in the society. Paddock (2009) identifies these as the fast pace and large scale of developments, diversity of technologies involved, promise of potential benefits along with limited knowledge about impacts and nature of risks. These factors make the fabric of nanotechnology governance more complex with a greater role for a diverse set of actors and stakeholders in this area. This makes governance of nanotechnology difficult through conventional linear approaches and calls for a multilevel approach to governance to ensure that technology is developed and contributes towards societal benefits in a responsible manner.

Figure 3.1 summarise the vertical and horizontal dimensions (through an actor based approach as well as issue based approach) in multilevel governance of technology.

Weidmer et al (2010) identify the following key obstacles in responsible development of nanotechnologies

- *"Lack of knowledge concerning risks;*
- *Lack of commonly agreed and standardized methodologies to assess and manage nanotechnology-related risks;*
- *Inability of regulation to keep pace with scientific discovery, development and commercialization of nanotechnologies and nano-related products;*
- *Public backlash, resulting from a lack of transparency about the development and use of nanotechnologies".*

These challenges will be difficult to be addressed at any one level or by any one kind of actors, hence requiring a multi governance approach. Governance of technology requires that adequate support for innovation and building capability to research on and develop the technology is provided while it is ensured that any adverse impact that may emanate from it is avoided and kept minimal.

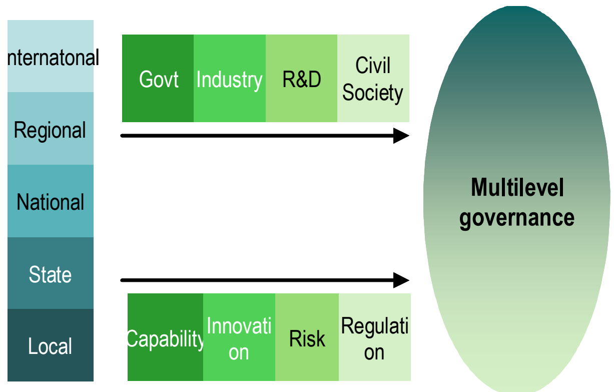

Figure **3.1** Technology governance

Vertical

Vertical dimensions of multilevel governance refer to the interaction amongst different levels of actors. These are marked by clearly defined hierarchical jurisdictions where there is a distribution of powers and responsibilities. The vertical interaction is very similar to the theory of federalism. Multi-level governance systems, however, are more likely to be 'pervasive, almost omnipresent, political units in today's highly complex, ideologically divergent, and increasingly globalized world.' (Stein and Turkewitsch, 2008)

Since nanotechnology is characterised by multiplicity – of disciplines and technologies involved, uses, areas of application, actors and even challenges, it is difficult to study the vertical dimensions without focussing on a given sector. The following sections would make a general comment about the developments, characteristics and challenges but deal particularly with the health sector. Within health, we chose health or medical applications for studying vertical governance patterns on account of its relevance for a developing country like India, investments and interests and direct impact on human health.

In the case of nanotechnology applications in the health sector, a governance framework, including the vertical dimension must aim at both the abovementioned dimensions of technology governance. The levels of governments or institutions, which can be included in a multilevel governance framework, is important not only to make the governance inclusive and democratic but because the number of actors determines how complex the framework would be. (Jollands et al, 2009)

This section would map the different actors at different levels having a role in governance of technology, how they interact with each other and how they influence the nanotechnology landscape in India and in medical applications in particular. (Table 3.1)

International

In a vertical analysis of MLG, governments across levels - from local to provincial to national to international are examined. However, a MLG framework for nanotechnology needs an assessment of subpolitical and apolitical sites as there has been a growing trend towards the acceptability of international forums/institutions as efficient and effective sites of regime creation. Some of the important and active sites are characteristically sub-political[1] in nature in as much as they lack effective legitimacy and formal rule making or implementation power.

International regimes like the WTO would apply to nanotechnology like any other technology, whether it is to do with trade or intellectual property rights. With respect to intellectual property rights, the role of international bodies in shaping the domestic regimes has been rather strong, given the binding commitments under WTO. The role of TRIPs and its influence on the pharmaceutical sector has been discussed and debated extensively across fora.

In case of health, the role of World Health Organization (WHO) is central as it garners acceptance by countries and institutions and hence, there is legitimacy of its definitions, decisions, and directives. One of the founding mandates of WHO is to 'develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products'[2]. To this effect, the Department of Essential Medicines and Pharmaceutical Policies at WHO develops guidelines, builds capacity and promotes medicine safety through pharmacovigilance at global, regional and country level. No action is currently being taken specifically on nanotechnology as yet, except through its intergovernmental forum on chemical safety.

[1] "sub-politics" denotes political decision-making beyond the realms of the formal state and without a clear and unambiguous legal mandate under international law. See Beck, et al (1994) Reflexive Modernization: Politics, Tradition and Aesthetics in the Modern Social Order; Stanford University Press, 13
[2] Article 2, WHO Constitution

The Intergovernmental Forum on Chemical Safety (IFCS), International Standards Organization (ISO), and the International Risk Governance Council (IRGC) are three sites that need special mention for their sub political nature in the context of nanotechnology. Norms emanating from international sub-political sites have earlier had an influential role in domestic regime creation. Given that the Indian domestic regime for nanotechnology is still at a nascent stage and essentially reactive in nature, the deliberations within the aforementioned sites could have considerable influence in the governance of nanotechnology in India. Unlike governmental institutions, these suffer from a democratic deficit, which is so crucial to provide legitimacy to their decisions. These sites, therefore, prefer indirect means of policy implementation through an indirect channel of influence. (TERI.2009)

In today's world where states and actors are connected at multiple co-existing levels, internationalisation of regulation is a concept, difficult to avoid. The influence of this internationalisation could be on account of commitments at international forums, interdependence amongst countries in terms of research, application and markets, increasing acceptability of international standardisation process. We have seen this earlier in the case of food safety regulations. (Chowdhury & Srivastava, 2008)

National

At the national level, the Ministry of Science and Technology is the nodal ministry for promotion of research and development in the area of technology and administers its functions through three departments – Department of Science and Technology (DST), Department of Biotechnology (DBT) and Department of Scientific and Industrial Research (DSIR).

DST has been the most instrumental agency within the government for encouraging nanotechnology development and application through both financial and institutional support. In 2001, a Nano Science and Technology Initiative (NSTI) was launched and as a follow up to it, Nano Mission was set up in 2007. The Department, since engaged with the agenda of promoting nanotech as a thrust area, has declared an investment of 1000 crore INR for five years, beginning 2007 for basic and applied research promotion, infrastructure support, education and international collaboration in this regard. The department provides the secretariat to the Nano Mission Council, which is the highest advisorial policy making body for nanotechnology in India. Besides the Council, the Nano Mission includes two other advisory groups, viz., Nano Applications and Technology Advisory Group and the Nano Science and Advisory Group.

DBT and DSIR too have been supporting some research in nanotech, although not in any organized manner. While DBT has focused essentially on nano-biotech research, most of the nano research funded by DSIR pertains to materials and metals and chemicals.

Institutes and laboratories under the Council for Scientific and Industrial research such as the Central Drug Research Institute and the Indian Toxicological Research Institute are engaged in crucial and specialised research fundamental for nanotechnology governance.

The Ministry of Commerce and Industry and especially the Department of Industrial Policy and Promotion (DIPP), aims at facilitating investment and technology flows in industrial development. The Office of the Controller General of Patents, Designs & Trade Marks is also a part of the DIPP thus making ministry of commerce an important actor in protecting intellectual property rights in the field of nanotechnology and being responsible for addressing the complexities of nanotechnology in the current patent legislation.

Given that most of the R&D and applications are taking place in health sector and products are being launched in the market, the role of the Ministry of Health and Family welfare is very important. However, unlike the Ministry of Science and Technology, there is no special nano programme in the profile of MoHFW. Research in health related applications, including nanotechnology based, is promoted through the Indian Council of Medical Research (ICMR), which has a mandate to direct research funding in areas of national health importance[1]. The Ministry of Health is involved in governance of nanotechnology applications in health sector through its Directorate General of Health Services, under which the Central Drugs Standard Control Organisation (CDSCO) is situated. Health being a state subject is largely in the domain of state governments but a lot of the direction for the same comes from the Centre (See figure 3.3). Institutionally, MoHFW is in charge of prevention and control of health related hazards, but the agenda of MoHFW is already full with issues like providing basic health infrastructure, eradication of diseases like polio, kala azar etc. and check counterfeit drugs to lay priority on nano applications in health sector. Moreover, the current health applications in

[1] Projects primarily dealing with research on nanomaterial use for drug delivery have been funded by the ICMR. See ICMR Annual Report 2006-07, *Appendix IV; Research Fellowships Funded During 2006-07*

nanotechnology are more focused towards curative applications[1] rather than public health.

The Ministry of Environment and Forest deals with environmental impacts or hazards emanating from a new application. Environment being a residuary subject falls in the ambit of the Centre and the Central Pollution Control Board (CPCB) discharges most of the functions relating to prevention and control of pollution, including through hazardous materials.

Central institutes under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers are engaged with advanced studies and research in pharmaceutical sciences, including toxicology. They also have the mandate for conducting programmes on drug surveillance, community pharmacy and pharmaceutical management.

The above discussion and list of national level actors in only indicative. For further insights into institutions and initiatives in nanotechnology, *see* research reports under the project on regulatory challenges and NT developments in India.

Sub-national

At the central level, the Controller General of Patents, Designs & Trade Marks under DIPP is in charge of patents. The legislation and policies on patents are made at the national level (with a great amount of international influence) but patents are filed, examined and granted at one of the four patent offices located in Delhi, Mumbai, Chennai and Kolkatta. State governments also invest in nanotechnology research and development.

Most of the centres of excellence or research institutes working on nanotechnology are funded or supported by the central government. However, states have a role to play in promotion of R&D and providing infrastructure and other required resources for promotion of research and development in the field of nanotechnology. These research institutes and laboratories also provide the institutional support required for discharge of regulatory functions of the state level agencies for health and environment.

The CDSCO is responsible for drugs approval and laying down standards but the implementation takes place at the level of states and union territories. There are thirty-five State Drug

[1] Even the amongst the curative applications, most offer solutions for diseases like cancer, diabetes, cardiac etc rather than malaria, tuberculosis etc.

Controllers[1], which have the primary responsibility of overseeing the regulation, manufacture, sale and distribution (including licensing) of drugs.[2] In their tasks, the SDCs are guided by the CDSCO and aided by government analysts and drug inspectors.

State Pollution Control Boards are the state level authorities under the Environment Protection Act. The SPCBS do not look at nanotechnology applications or health applications. However, any commercial establishment or manufacturing process will have to adhere to standards laid down by the EPA and Hazardous Materials Rules, thereby bringing them under supervision of SPCBS. The State Pollution Control Committees are responsible for granting authorisation for collection, reception, storage, treatment and disposal of bio medical waste.

Sub-state

In the overall governance framework for any technology, either with respect to environmental impact or health impact, there is a limited role for local authorities. This is ironical as the impact of an emerging technology percolates down to the lowest levels. Drug inspectors and health and sanitation inspectors monitor and operate at local levels also. Local authorities can take *suo motu* action in case of a public nuisance (including risk to environment and human health) being caused by a technology developer or a manufacturing process. This of utmost importance as the impact of any technological introduction will be felt locally. Local authorities and stakeholders may not have had a say in the decision making process for development as well as regulation of technology but it is pertinent to note that several products are launched on 'pilot scale' at local or rural levels.

[1] List of State Drug Controllers, http://cdsco.nic.in/html/STATE%20DRUGS1.htm, accessed 14th March 2010.
[2] Section 18 of the DCA, 1940.

Table 3.1 Actor oriented approach to MLG of nanotechnology in health sector in India

	Inter-governmental	Government	Research and academia	Industry	Civil Society
International	WHO, ISO, UNEP, OECD, WTO			ISO	IRGC
Regional	SAARC, ANF		ANF		
National		Planning Commission MST – DST (Nano Mission, SERC) -DBT -DSIR MoHFW – Drugs Controller MoC – DIPP (Controller General of Patents) MoEF Ministry of Labour Others (MoD, MoICT etc.) BIS	ICMR, other Research institutes and laboratories Centres of excellence NIPER IITR INSA	CII, FICCI, ASSOCHAM, Industry associations (*Drugs and Pharmaceutical Manufacturers Association*), companies	e.g., TERI, NISTADS
State		State government departments (health, S&T etc.) Patent controllers State Drug Controllers, State Pollution Control Board, Analysts, Drug Inspectors, Health inspectors Quarantine	Research institutes and laboratories	Technology Promotion Boards, Industry associations, companies	
Local		Drug Inspectors Health inspectors, district administrators		Industry associations, companies	

Horizontal

The horizontal dimension of MLG operates at two levels - between actors at same level/within jurisdictions and another based on issues. (Figure 3.1) In a technology governance framework, the three most important issues are that of (i) capability and innovation (ii) risks, and (iii) regulation.

Capability, technology development and innovation

The role of policy instruments in building science, technology and innovation capability is paramount. Policy instruments comprising of measures aimed at - building institutions and capacities to produce scientific and technological knowledge, and also to recover and upgrade traditional knowledge and techniques; promoting the utilization of the knowledge generated in the country in production and service activities; strengthening the linkages between the supply and demand of knowledge produced; and actions to strengthen science and technology policy making capabilities need to be defined and applied to harness benefit from S&T and successfully engage with emerging technologies (Sagasti 2004). Of late there has been a growing surge in interest in developing countries in engaging with the various policy instruments. Some of the policy instruments available to policy and decision makers to establish science, technology and innovation capabilities in developing countries are enlisted in Table 3.2.

Innovation in nanotechnology may be conceptualized as the accumulation and diffusion of scientific knowledge in research institutions and firms. Innovative activities involve directly or indirectly a large variety of actors, including: firms, research organizations like universities and public and private research centres, financial institutions, regulatory authorities, consumers. Institutional environment may facilitate the interaction among various actors and the emerging policy options would have to be explored for application of new technologies in the production processes with special focus on institutional environment. New products, processes and services created using nanotechnology involve social, economic, ecologic, political and ethical matters surrounding their emergence. All this needs to be sufficiently addressed in defining the nanotechnology innovation trajectory.

Table 3.2 Governance tools to build science, technology and innovation capability

Category	Type of policy instruments	Specific measures
Building science, technology and innovation capabilities in developing countries	Supply side: creating S&T institutions and building research and technology development capacities	Creation and consolidation of all types of S&T institutions, financing of S&T activities, human resource development, S&T foresight and planning, creation of networks of institutions
	Demand side: promoting the utilization of domestic S&T knowledge in production and service activities	Strategic planning of production and service activities, financing of innovation at the firm level, use of the State's purchasing power, technical norms and standards, fiscal incentives to stimulate innovation, promoting export of technology intensive goods

	Linking the domestic supply with the demand for S&T knowledge associated with innovation in the productive system	S&T parks and incubators, technology extension services, engineering design and consulting services, selective recovering and upgrading of traditional techniques, policies to promote technology diffusion between firms, cluster policies to link technology leaders with other firms
	Strengthening S&T policy making	Creation of specialized S&T policy agencies, coordination of national and local initiatives in S&T, organize policy research and foresight centres, provide information to policy makers
Creating linkages between knowledge, technology and production in developing countries and their global counterparts	Establishing linkages with the world scientific research community	Joint research projects, access to international S&T information, remote access to research facilities and equipment
	Obtaining and securing access to external sources of technology	Purchase of technology intensive goods and services, technology licensing agreements, utilize intellectual property regulations, technology scanning and search
	Establishing linkages with the global production system	Direct foreign investment, import and export of equipment and machinery, trade in goods and services, subcontracting in global value chains
Establishing a favorable context and institutional framework for creating an endogenous S&T base	Providing the physical infrastructure for the performance of scientific research, technology development and innovation	Communications facilities, transport infrastructure, reliable energy supply, clean water and sanitation, waste disposal, clean air, appropriate land use regulations
	Establishing institutional arrangements favourable to innovation	Elimination of bureaucratic impediments, transparency, fair and effective regulatory agencies, prevalence of the rule of law, democratic governance
	Creating a stable economic policy framework conducive to long-term thinking in firms and other organizations	Price, interest rate and exchange rate stability, sensible financial and credit policies, prudent fiscal policies, tax arrangements that encourage investment, openness to trade and investment
	Evolving a cultural and social environment that encourages creativity, risk-taking and innovative behaviour	General and scientific education, fair and flexible labour policies, environmental protection, access to information and freedom of the press, poverty and inequality reduction, punish corruption, encourage trust and build social capital, promote values congruent with modern S&T and entrepreneurship

Source: Sagasti 2004

Governance of nanotechnology – capability and innovation

Nanotechnology has been accorded national R&D priority in both developed and developing economies. This is evident from rapidly increasing government investment in R&D in this area. Given its vast application potential in diverse areas, for e.g., health, energy and environment, agriculture, materials etc., nanotechnology forms an important part of national science and technology agendas in these sectors.

In recent years nanotechnology has found a lot of application potential in the healthcare sector. Nanotechnology can contribute significantly to the health care sector by way of addressing the public health concerns like poor sanitation, unsafe drinking water, air and water borne diseases and the like. Further, various bacterial, fungal and viral infections, pulmonary diseases, diarrhoea, liver dysfunction are some very common health related ailments in India. In this regard, nanotechnology provides a viable option to fight these diseases by eliminating the wastage of drug due to targeted delivery and minimization of side effects. This emergent technology can also play a big role in the research area of DNA vaccines. It may also have useful applications in cancer therapy in various directions of diagnostics, imaging and therapeutics. Furthermore, nanotechnology has the potential to provide solutions taking care of the preventive aspects of health care research. For e.g., clean drinking water using nanofilters in rural as well as urban areas can help address one of the most important challenge faced by the poor in the developing world. A domestic water filter that uses metal nanoparticles to remove dissolved pesticide residues believed to be the first product of its kind in the world, has been developed at the Indian Institute of Technology (IIT) Madras.[1]

Providing cost effective technological innovation through R&D has been one of the objectives of the government in India. The Inter-Governmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) constituted at the World Health Assembly, 2006 emphasised the need for promotion and prioritisation of research and development needs and building innovation capabilities in order to address the challenges faced in the health sector in developing countries.

Establishment of research infrastructure in universities and public funded R&D bodies, development of human resources for research and industry has been spurred by government initiatives and policies in the health sector. Manpower development in this area has witnessed an increase over years but still there are concerns regarding the quality. Also the availability of researchers trained specially in nanotechnology remains limited.

Indian firms also demonstrate capability in performing R&D and production of innovative health products. To further broaden their cost-effective manufacturing capabilities, firms have started investing in new manufacturing facilities.

[1] http://www.nanowerk.com/news/newsid=1806.php

Tracking developments in nanotechnology applications in the health sector in India, it could be observed that most of the current initiatives are focused towards the curative aspects of health research (See Box 3.1). However, there has been policy focus in the area of public health research. It is important to note that the wider coverage of public health area necessitates action on the part of several actors and policy-making bodies. For example, research in the area of clean drinking water should not only be in the purview of Ministry of Health and Family Welfare but also of Ministry of Water Resources.

Box 3.1 Nanotechnology applications in health sector in India

Dabur Pharma recently acquired by the Singapore based Fresenius Kabi, is using nanotechnology for a novel cancer drug delivery system. It has used nanotechnology to increase patients' tolerance to the anti-cancer drug Paclitaxel. The company spends more than 10 per cent of its sales of Rs 2,396 crore on R&D and plans to launch other products (using novel drug delivery systems) by 2009-10.

Bharat Biotech is conducting nanotechnology research on products (like oestrogen therapy) reportedly using herbal bases.

The Bangalore-based Velbionanotech, a bio-nanotechnology product development company, has developed nanotech-based treatments for atherosclerosis (arterial plaque), nephrolithiasis (stone in the urinary tract) and diabetes.

The human genome, which remains active in childhood and adolescence, becomes dormant in the late twenties. Using nanotechnology these genes could be reactivated. This helps arrest the process of biological ageing and enables man to fight diseases better. Virtus Techno Innovations has applied for patents not only for a gene repair therapy called Mitsanika, but for various other bio-engineering applications using nanotechnology in the US and a couple of other countries.

Prof. Ramgopal Rao and his team IIT Bombay have developed i-sens, a cardiac diagnostic device that uses nanotechnology for blood analysis The device diagnoses heart conditions, and, importantly, imminent cardiac attacks. It is currently undergoing field trials.

Centre for Pharmaceutical Nanotechnology (CPN) established at National Insitute of Pharmaceutical Education and Research (NIPER) works in the area of Nano-biopharmaceutics: Focus on drug targeting and gene delivery; nanotoxicology
Rinti Banerjee, School of Biosciences & Bioengineering, IIT Bombay, has developed a drug for lung cancer that is inhaled in the form of nano particles through an aerosol spray

Source: Nitya Varadarajan, May 12, 2008, Business Today, Taking baby steps into the nano world. Available at, http://businesstoday.digitaltoday.in/index.php?Itemid=1&id=5150&option=com_content&task=view&issueid=29&sectionid=25

DST is the main body in India providing the financial and institutional support for the promotion of nanotechnology development and application. Beside DST, the Department of Biotechnology have been supporting research in the area of nano-biotechnology. The Department of Scientific and Industrial Research (DSIR) too have been promoting research in materials, metals and chemicals. The Defence Research Development Organization (DRDO) is also engaging with nanotechnology and has come out with diagnostic tools for TB and typhoid using nanotechnology. The governance circuit also reaches beyond the state actors and include non-state actors such as firms, industry associations, civil society etc.

Box 3.2 Activities in nanotechnology research and development in the area of drug delivery, pharmaceuticals and healthcare

- Contract research and new product development, drug delivery systems and pharmaceuticals
- Novel drug delivery systems with nanoparticles and microspheres, anti cancer (oncology) formulations, new chemicals entities peptide, adjacent therapies like cardio protective anti alopecia, vaccines, molecular diagnostics and agrobiotechnology etc.
- Development of new drugs for therapeutic areas
- Innovative bio-informatics and chemo-informatics service provider
- Janis particles, self-assembly and micro structuring, photo catalysis and optical phenomena
- Nano based vast dyeing using less caustic soda
- Nano finish for cotton polyester blends and other speciality nano finish for textiles for rich oxygen finish, anti sectional finish, mosquito repellent fluids etc.
- Development of new anti-asthmatic drugs
- Bio availability and bio equivalence services, clinical trials and research
- Carbon nanotube at ultra low cost
- Nanotribology and genetic engineering

Source: National Foundation of Indian Engineers, 2008, Study on status of nanotechnology in Indian Industry and Academia/R&D Labs, Draft Report

In addition to the government agencies, industry associations have also showed keen interest in the area of nanotechnology health applications. For example, the nanotechnology initiative launched in 2002 by Confederation of Indian Industries (CII) focused at research and development in bio-nanotechnology, drug discovery and delivery by forging partnerships and collaborations. Similarly, the Associated Chambers of Commerce and Industry in India (ASSOCHAM) is trying to explore nanotechnology application potential in the pharmaceuticals, FMCG and electronics sector.

The requirement of establishing specialised centres in the field of performing trans disciplinary research and development of instrumentation and standards to successfully harness the potentials of this emerging technology has been felt and focused upon accordingly. Initiatives are being undertaken to maximise the socio-economic and humanitarian benefits to the local people by bringing science and technology capabilities from around the world into a local ecosystem which engages the local people. For example, Nanobiosym, a US based nanotechnology firm, plans to set up multi-purpose nanotechnology innovation parks, the first of its kind in India and work with leading specialists to bring its cutting edge diagnostic capabilities not only to leading hospitals, healthcare providers, and clinics but also to partners in humanitarian, NGOs and governmental organizations in India involved with health care in rural areas[1].

[1] http://beta.thehindu.com/business/Industry/article56831.ece

Risks associated with nanotechnology

Risk can be defined as 'an uncertain consequence of an event or an activity with respect to something that humans value' (Kates et al. 1985). It refers to both the likelihood of certain consequences from specific activities, and the severity of such effects (Renn 2005). The International Risk Governance Council based in Geneva defines risk as 'the potential for realisation of unwanted, adverse consequences to human life, health, property, or the environment' (Renn 2005).

The project acknowledges the existence of multidimensional risks around nanotechnology ranging from environment and health and occupational risks to socio-economic risks. (TERI 2008) IRGC (2007) classifies the risks associated with nanotechnology into two categories based on the distinction between passive nanostructures and active nanostructures and nanosystems. The former refers to those which are already in the market but are lacking in research on risks that they could pose, including human health, environmental, manufacturing, political and security risks. The latter involve 'genuinely new products and the social, economic and political consequences are expected to be more transformative' and therefore are prone to essential human and environmental risks, societal structure risks and public perception risks (IRGC, 2007). A holistic approach to risks is essential and nanotechnology risks can be best understood in conjunction with its benefits. A technology governance framework should also address the risk of missing an opportunity that the technology can offer.

Currently, the ethical, legal and social aspects of nanotechnology are not in the forefront of the concerns around nanotechnology and its applications. The current focus is on EHS from a nanotoxicological as well as OHS perspective (Weidmer, M et al, 2010). However, parallel approaches emphasizing on building capacity in both scientific methods and sociological approaches to risk assessments must be prioritised.[1]

The risk mapping exercise undertaken as a part of the project environmental, health and occupational risks stress the need for undertaking risk assessment early in nanotechnology research. Exposure pathways to nanotechnology products are multiple, and effectively monitoring them becomes a daunting challenge since these exist along the manufacturing and consumption chain. This has also been highlighted by our study of issues involved in life cycle analysis of nano silver based candle filter. It emphasizes upon the need for studies on the nature and

[1] Stakeholder dialogue on Issues of Risk in regulation of Nanotechnology, organized by TERI on 8th January 2010, New Delhi

degree of nanoparticle exposures from nanoapplications, their toxicity, fate and persistence, simultaneously with technology development (TERI 2008) .Risk concerns in nanotechnology are dominated by complexity, high degree of uncertainty and lack of adequate and clear knowledge about the response of humans to nanotechnology applications (Renn et al 2006).

Governance framework for risks

Risk governance is focused on the institutional arrangements of how risk information is collected, analysed and communicated and how risk management decisions are taken (Renn, 2005). Risk governance encompasses all the risk-relevant decisions and actions; is of particular importance in situations where the nature of the risk requires collaboration and coordination between various agencies and stakeholders (no single decision-making authority available); and calls for the consideration of contextual factors such as: (a) institutional arrangements (e.g. regulatory and legal framework and coordination mechanisms such as markets, incentives or self-imposed norms); and (b) socio-political culture and perceptions.][1]

The framework integrates scientific, economic, social and cultural aspects and includes the effective engagement of stakeholders (IRGC 2005). The IRGC framework is the most comprehensive risk governance framework for nanotechnology comprising following steps –

- Pre-assessment
- Risk appraisal
- Characterization and evaluation of risks
- Risk management
- Risk communication

[1] IRGC White paper

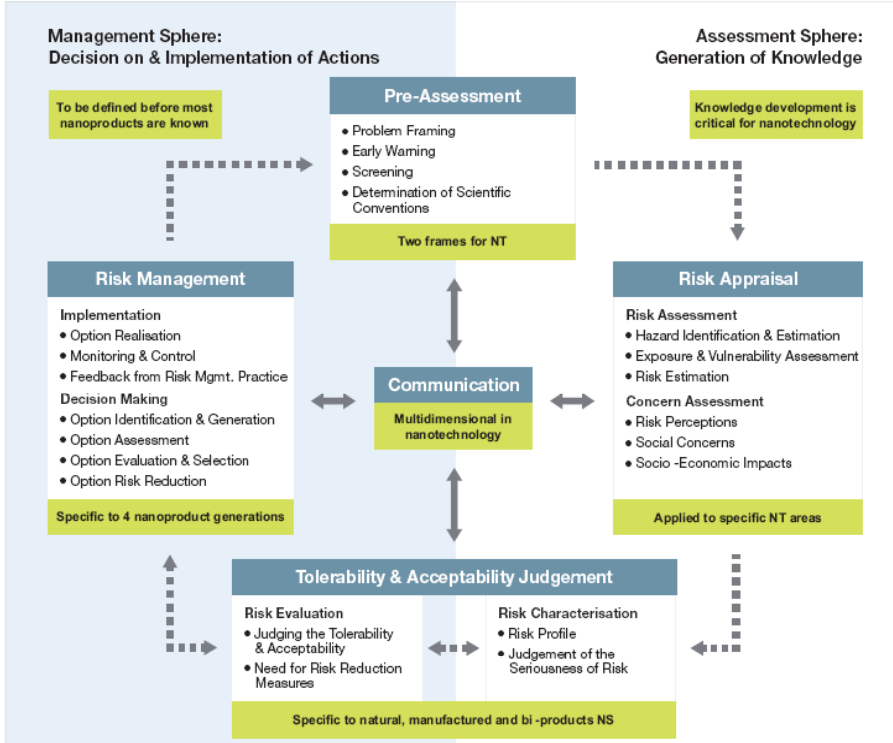

Figure **3.2** IRGC model of risk governance

Source: Renn et al/ IRGC 2006 White paper

Pre assessment requires an understanding and recognition of potential health and environmental risks by giving evidence related to toxicological and ecotoxicological impacts and simulating actual exposure in order to give early warning. Risk appraisal involves (a) risk assessment covering hazard identification, exposure and vulnerability assessment and concern assessment; and (b) assessment of public concerns and opinions in reference to risks. This is followed by characterization based on respect to complexity, uncertainty and ambiguity of risks and its evaluation, which is science based, societal based and conclusive. Along all these steps, risk communication is imperative to ensure that those involved in framing and management of risks have the adequate information and those who are not involved are also informed and engaged (IRGC 2006). Risk governance, therefore, would include laws, processes and institutions by which decisions regarding risk analysis, management and communication are taken. It takes into cognizance both the structures (i.e. the actors who participate in the decision making process) and the process (i.e. the procedures that legitimise the decision-making process). An inclusive risk governance framework would entail democratising science by strengthening the involvement of all the relevant actors and stakeholders. (TERI, 2009; Vivekanandan, 2009; IRGC, 2006)

In recognition of the fact that nanotechnology is still an emerging technology which has the potential to address several needs and demands from various sections of the society, rapid developments are being made in pushing for greater application of nanotechnology across fields and sectors. However, little is being done in terms of formulation or assessment of risks associated with nanotechnology research and application in different fields. Even the governments have been focusing on promotion of nanotechnology application without giving due consideration to the risk aspects of the same.

In view of such a scenario where the formal political agenda[1] is also inclined towards promoting nano applications and meeting their needs through the intervention of new and emerging technologies, there is a clear role for a sub-political site like IRGC which can put risk governance on the table as an agenda that needs to be recognized, discussed and be a part of the overall policy framework for nanotechnology in domestic and international regimes. This does not imply that the advantages being offered by technology are rejected, as that itself would also amount to a loss, therefore, a cautious approach should be taken and a risk governance system should be put in place so as to avail the benefits that a new or emerging technology offers. It is also important that international bodies coordinate in terms of their work on nanotechnology. For instance, ISO has a subcommittee to examine the health and environment safety practices, OECD and IFCS too deal with impacts of nanotechnology. It is important that developments at these fora are in tandem with each other. Thus, besides the inter-level coordination, as discussed in the section on vertical MLG, intra-level coordination forms the core of MLG.

At the national level, the need for this interaction and coordination holds even more weight due to multiplicity of actors and issues of legitimacy. Risks being context specific, there is a pressing need for active risk governance at domestic levels. Risks to environment and human health have been identified as a primary area of concern in need of immediate action, although other risks have been acknowledged. In this respect, a key challenge is knowledge gap vis-à-vis impacts and levels of exposure.[2] To remove this gap, several actors within and outside government will have to coordinate their activities and share knowledge. The agencies of importance include the Department of Science and Technology, the Ministry of

[1] The main government programme for nanotechnology is mission mode and has a clear agenda of promoting nanotechnology in India.
[2] At the stakeholder dialogue on Issues of risk and regulation in nanotechnology, organized under the project, the stakeholders voiced concern about paucity of risk assessment studies and data to aid decision making. See TERI 2010, Summary of proceedings of Workshop on Issues of risks in regulation, January 8th, 2010, New Delhi Web link

Environment and Forests and the Ministry of Health. DST as a nodal agency for R&D and promotion of nanotechnology is responsible for supporting research projects and institutes in the area of nanoscience and nanotechnology. The Indian Institute of Toxiciological Research, which is perhaps the only institute that has taken up nanotoxicology for research institutionally, is also a CSIR institute, hence within the purview of DST. MoEF with its mandate of environment protection and safety has in the past taken a lead in regulation of technology[1] and been implementing environmental safety rules through its pollution control boards. Ministry of Health with its drugs regulatory framework can be instrumental not only in risk management and communication but monitoring and knowledge sharing as well.

Although most of the research is taking place in the public sector, the role of the private sector is growing with more technologies being transferred to companies for commercialisation and products already launched or nearing launch in the market. Through their manufacturing process and marketing, companies can help in risk identification, management and communication. They can provide valuable data with respect to risks to help in risk assessment and devising the appropriate governance strategy. The role of civil society in governance of the EHS risks is limited in comparison to socio-economic risks. In the former, civil society and consumer organisations can, however, be influential in demanding greater transparency, information and serve as watchdogs. However, in case of the latter, civil society and public organisations will be better positioned for risk framing and characterisation too.

Regulating technology

Regulation essentially relates to government action in the form of laws and notifications with the objective of directing private action for a specific purpose or with a certain aim (Brownsword, 2008). Regulation as a legal instrument is also referred to as delegated legislation or subsidiary legislation that is prepared under the aegis of a legislative act for the fulfilment of the objectives of the act. Regulation, therefore, can be variable in nature; ranging from penalty for prohibited acts to that of providing a system of incentives for preferring one kind of action over another. Regulation, therefore, refers to a gamut of both soft (incentive based) and hard options (prohibitions) that direct parties to choose certain course of actions over others (Black, 2001).

[1] Regulation of genetically modified organisms is handled by the ministry of environment

Governance and regulation may overlap in terms of their purpose and impact but there is a clear differentiation between the ambits of regulation and governance. If we could construct a continuum for actions influencing private action with a view to achieving a public goal, regulation would fall within the conservative end of the spectrum while governance would be located on the further more liberal end. A crucial divergence between them is that governance may emanate from both private and public actors (as in the state), whereas only the state has the legal right to regulate. Although there have been instances of what is referred to as “private regulation” (like in the case of supply chain management by private companies), strictly speaking these remain private standards/action with the purpose of influencing a certain target group (Scott, 2004). Thus the source of (legal) regulation can only be the state, whereas governance is a much broader term encompassing a gamut of private and public actions that are aimed towards a specific aim. However the regulatory design can be such that makes the process and implementation inclusive and participatory.

The aim or the specific purpose of government action is usually determined or at least closely aligned with public interest and reflect the public policy goals that are part of the state agenda. Although to a certain extent this is a truism, in particular cases – especially with regard to such contested terrains like emerging technologies the ‘public interest’ dimension in a regulatory action is less clear and may well be contested. In the case of technology regulation, the primary question relates to the nature and pace of growth of technology that in the case of potential environmental and health risks which may result from a particular instance or trajectory of development. In the case of emerging technologies like biotechnology or in this case, nanotechnology, the question is further complicated by aspects like intellectual property rights, access to technology, investment patterns and other issues (Baldi, 2002). The above also illustrates the varied number of arenas that regulation straddles, from risk aspects, product safety issues, and investment and intellectual property rights amongst others. Thus, regulatory framework for a technology will refer to a number of aspects of the production and application of that technology (Susskind, 1996). In the specific case of emerging technologies like biotechnology and nanotechnology, given the potentially adverse health (Moore, 2004) and environmental impacts that could result, the most widely publicized policy discussions have been on the question of risk regulation[1]. Thus,

[1] Fiedler, F and Reynolds, G (1994) Legal Problems of Nanotechnology: An Overview’, 3 S. Cal.
Interdisc. L.J. pp. 593- 595. Also See Hudson, B (2003), Justice in the Risk Society. Sage publications, London, 43-45.

although the regulatory toolkit for technologies are broad and may span a number of sectors seemingly delinked from one another (like intellectual property rights and health for instance), they also reflect the sectoral dynamics that will influence the scope of regulatory action and also the choice of regulatory tool selected by regulators (Wolinsky, 2006)

The role of the state is of primary importance in defining regulatory objectives, developing the ambit and then selecting the tools from the toolkit that would best facilitate the achievement of the objectives. In such a context the regulatory culture at several levels influences the regulatory choices that are often made. Regulatory culture could operate at several levels; viz, industrial policy, emerging technologies, environmental health issues, etc. How the state has in the past addressed these issues through regulation will have an effect on framing the regulatory choices that are made at present. However, one cannot deny that public policy goals are in a constant state of flux in terms of their prioritisation (this process is more acute in the case of developing countries where resources are limited), and,therefore, the government priority at a given point of time will also influence regulatory choices made (Schummer and Baird, 2006). Hence, there is a need to look into issues of regulation and culture while explicating the components of the legal regime and its cumulative regulatory effects (Castro, 2004).

Regulatory governance framework

The 2009 report on regulatory challenges (WP4: D6) under the project provides an extensive review of the regulatory regime for nanotechnology applications in health sector. Regulatory instruments and interventions can be classified into the following categories or stages of technology development and application –

- Research and development
    - (Patents Amendment Act, Public Funded R&D Bill)
- Production and Marketing
    - (Drugs and Cosmetics Act, 1940, National Pharmacovigilance Protocol, Medical Devices Regulation Bill, Insecticides Act, 1968)
- Occupational health and safety
    - o(Factories Act, 1948 and OHS under other legislation)
- Environmental Risk Management
    - (Pollution control laws, Environment Protection Act, Public Liability Insurance Act)
- Waste Disposal
    - (Factories Act, Hazardous Material (Management, Handling and Trans boundary Movement) Rules 2007, Bio-Medical Waste (Management and

Handling) Rules, 1998, Municipal Solid Wastes Rules, 2000)

There are several regulatory instruments across these stages and there are both opportunities as well as gaps within the existing regime for nanotechnology. In some cases, the gaps outweigh the strengths and opportunities of a rule, whereas in some cases, the opposite is true. Our analysis shows that there exists some level of flexibility within the existing regime to initiate a response to meet challenges related to nanotechnology. However, even to make use of the flexibilities, where available, major steps will have to be taken to put them to use.

Given the regulatory culture in the country, the term 'regulation' is implicitly assumed to mean government intervention and generally meddling with the market mechanisms. This regulatory block although implicit in most cases, is reflected in regular efforts made by industry organizations to lobby with the government and engage quite vigorously in the rhetoric of technology development and its functionality in national development and consequently in consistently undermining efforts to bolster regulatory oversight of these technologies[1]. Interestingly, this skewed understanding of regulation and its implications is prevalent not only in the industry but amongst government as well. For instance, most of the officials of DST with the mandate of technology promotion were in a state of denial about the potential risks of nanotechnology and the need for regulation. However, recently, the chairman of Nanomission Council announced at the International conference on Nano Science and Technology that a Nanotechnology Regulatory Board will be set up to regulate the industrial nanotechnology products.[2] This appears to be a pre-emptive action to check other ministries from deciding the course of the technology, especially given the recent BT brinjal controversy leading to moratorium on release of BT brinjal in India 'till such time independent scientific studies establish to the satisfaction of both the public and professionals the safety of the product from the point of view of its long term impact on human health and environment.'[3]

The MST (through DST, DBT and DSIR) performs the task of

[1] See Damodaran A for similar argument in the case of biotechnology, Re-Engineering Biosafety Regulations In India: Towards a Critique of Policy, Law and Prescriptions, 1/1 Law, Environment and Development Journal 2005.

[2] 'India to have Nanotechnology Regulatory Board soon' News item in Business Standard; Press Trust of India / Mumbai February 18, 2010. Available on URL http://www.business-standard.com/india/news/india-to-have-nanotechnology-regulatory-board-soon/86186/on

[3] MoEF 2010, Decision on Commercialisation of BT Brinjal; Available on URL http://moef.nic.in/downloads/public-information/minister_REPORT.pdf

promoting technology and ensures that the required technical and financial support for strengthening the research infrastructure to achieve this is provided. Intellectual property rights are key components of an R&D framework, which are administered by the patent controllers office at national (Controller General of Patents and design) and zonal levels (Delhi, Mumbai, Kolkata and Chennai). International influence on regulation at this stage of the regulation is considerable owing to the TRIPs regime and India's obligations thereunder. However, there has been no nano-specific obligation in this regard.

All health applications are governed by the drugs regulatory framework as the current legislation defines 'drugs' broadly enough to include medical devices.[1] The Central Drugs Controller Organization, state controllers and inspectors together regulate the import, manufacture, distribution and sale of drugs in India. The primary powers and responsibilities are distributed amongst these authorities but it is pertinent to note that there are several other actors and stakeholders involved across levels for regulation of health applications. Figure 3.3 describes how the drug regulation is administratively carried out by the office of DGCI and its subordinates, but various national and international actors influence the design and implementation of the regulation.

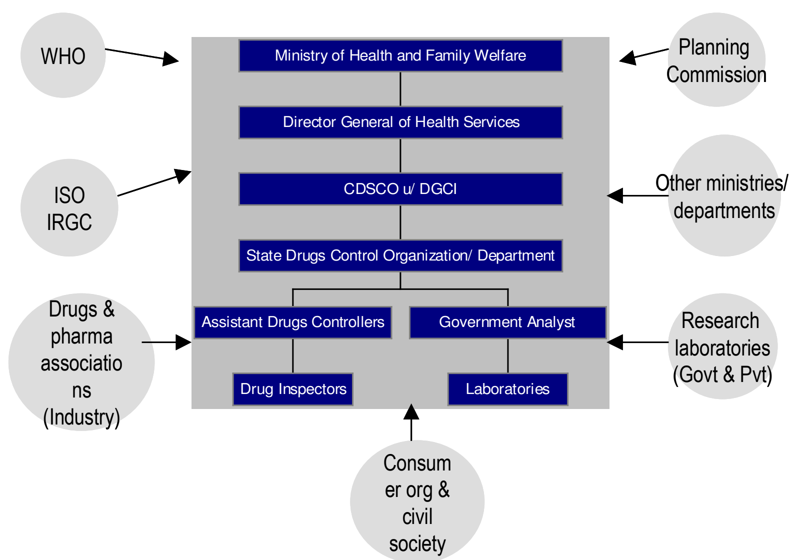

Figure **3.3** Different actors in drugs and pharmaceutical regulation

[1] Section 3(b) iv of the Drugs and Cosmetics Act. Drugs will thus include gold/silver nano particles for targeted drug delivery, stents, implants, nano ceramics etc.

Challenges in implementing multilevel governance framework for nanotechnologies

One of the chief reasons behind the categorisation of nanotechnology as an interdisciplinary technology can be found in technological systems convergence. Given its organic and inorganic applications, nanotechnology is very amenable to convergence processes and hence becomes an enabling technology, making it an important CT initiative.[1] As Nordmann notes, 'From the point of view of nanotechnology, what used to be separate domains of biomedicine, information technology, chemistry, photonics, electronics, robotics, and materials science come together in a single engineering paradigm' (Nordmann 2004). Beside disciplines, there is enormous diversity in the potential applications and, therefore, its reach. Nanotechnology applications are being researched and developed in a wide array of sectors ranging from energy, environment, health, and cosmetics to electronics and consumer goods (*See* Research deliverables 1 and 2). Given that nanotechnology is widespread in its reach and interdisciplinary in nature, it spans issues, domains and stakeholders making it a complex territory for governance. With these characteristics and complexities nanotechnology seems apt for MLG, which itself is going to be more challenging in the case of nanotechnology. This section highlights some of these challenges.

Capability

Capabilities in terms of number of research institutions and organizations in the health sector vary across regions. More concentration of institutions is found at the national level with major cities having large number of research organizations. For example, cities like Bangalore followed by Delhi, Hyderabad, Lucknow, Kolkata, and Mumbai share the largest number of health research organizations. This capability is manifested in terms of these cities having infrastructure facilities, adequate human resource availability and high inflow of funds.

Capabilities in health services delivery at the district and local level remains weak to a large extent. In the multi level governance framework, a greater emphasis needs to be laid at the local level. Downstream engagement, right from the framing of research agenda to developing innovative health products and services, would be an essential pre requisite for effectively governing the health sector.

[1] Technology systems convergence is defined as 'a combination of enabling scientific discoveries (genetics, nanoscience), techniques (informatics, gene splicing), and advances in allied tools (computing power, scanning tunnelling microscopes, robotics) that greatly accelerate the basic sciences involved and their practical applications, across a breathtaking range of subjects, from human health to materials science.' (Whitman 2006:400)

The R&D system is fragmented with a large number of government structures, organizations and programmes existing in India. Besides the institutes under Central Ministries, respective state governments have been actively involved in scientific research and training. However, while, at the central level, there exists several departmental laboratories under professionals; strong and often directed research, both basic and applied, and strong infrastructure, the scenario at the state level is characterised by few labs, multiple goals, often under administrative executive; weak research & infrastructure.

One of the pre requisites of a competent institutional framework is regulatory capacity for formulation of rules, policies and guidelines, and implementing. Any regulatory intervention to achieve the goal of regulation would require great amount of technical expertise and foresight on the part of policy makers and regulators. The implementing agencies, which are usually at the state and local levels, need to be equipped to execute the rules and regulations that are already in place and are formulated from time to time. The agency responsible for regulation of drugs already faces challenges with respect to capacity in terms of even testing of drugs.[1] Considering the lack of capacity for existing drugs with known risks, it is obvious that regulating drugs with risks yet to be known and defined would be an almost impossible task. Further, known capacity for testing nano-particle toxicity exists only at a very few institutes like NIPER and IITR.

Coordination

Nanotechnology development in India is largely a government led initiative, yet the state agenda is marred with a serious lack of coordination at several levels – research, policy and interagency/ governmental. The existing linkages between our S&T institutes under the Ministry of Science and Technology and other S&T institutes under the socio-economic ministries and such others that does not appear to be strong and clearly differentiated. Similarly, coordination and linkages between central and state S&T institutes might gain from this learning.

Diverse capabilities, although weak, and wide variance in governance structure characterized by multiplicity of ministries, local governments, and regulators at various levels (central, state), federal law making institutional structure, existence of a sizeable number of public, private and public-private sector entities coupled with internationalization of R&D is one of the central features of Indian S&T. The huge S&T infrastructure and

[1] As per the Report of the National Commission on Macroeconomics and Health, Ministry of Health and Family Welfare, Government of India 2005, only 17 of the state drug controlling agencies had access to drug testing facilities.

a federated stakeholders related governance structure poses challenge as well as offers opportunities and calls for clear delineation of roles and responsibilities at multiple tiers including at local governments for knowledge generation, its utilization and adaptation.

An outcome of the institutional structure (i.e. the departments' form of agency creation) within the GOI has been the fracturing of regulatory jurisdiction between agencies. Environmental health is an important area of regulation specifically in the context of the potentially adverse impacts of emerging technologies like nanotechnology and biotechnology. However, the division of the regulatory mandate between Ministry of Health and Family Welfare (MoHFW) and the MoEF has made it difficult to provide comprehensive and coherent regulatory cover on the issue of environmental health. In fact, environmental health as a policy discipline is underdeveloped in the Indian context.[1] Thus, the fragmentation of mandates further exacerbates regulatory fissures in situations wherein the state indirectly undermines regulatory overtures by privileging technology within the development agenda of the state by setting up individual state departments with the sole objective of technology promotion and facilitation.

Even outside the health sector, nanotechnology applications may raise several health concerns. Risks discussed in work package 2 of the project could be in the nature of occupational health, consumer health and environmental health. Occupational health is the prerogative of the Ministry of Labour, health is the mandate of the Ministry of Health and Family Welfare, and environment is governed by the Ministry of Environment and Forest.

Uncertainty and information flow

A smooth flow of information is necessary for enabling any governance framework and more so if it is multi level. In the case of nanotechnology with which significant degree of uncertainty is attached given its evolving nature, the staple set of concerns for governance are further amplified. There exists the concern that in a field where debates on nanotechnology (let alone the regulation) are struggling to keep pace with technological advancements, the possibility of abuse by malicious and unstable political elements is ever present. This concern gets exaggerated with a lack of information about the developments, policies/agendas and most important, scientific knowledge about the risks associated with nanotechnology on human health, environment and society.

[1] See for similar conclusions, World Bank (2001) Environmental Health in India: Priorities in Andhra Pradesh, Environmental and Social Development Unit, South Asia Region, 4-6, New Delhi.

Since one of the main concerns around nanotechnology are the EHS risks, governance of which necessitates availability of information, both about the nature and extent of applications as well as the risks associated, it becomes absolutely important that such information is readily available with the governing agencies. This becomes even more crucial because risk and toxicity studies are specialized disciplines, which only a few institutes are equipped to carry out and may be beyond the capabilities of regulatory institutions. There is paucity of data and risk assessment studies to guide the risk governance process at present.[1] Hence, the information amongst agencies, with different mandates, such as DST, DSIR, MoHFW, MoCA and the research institutes should be channelized in a way that each of the these institutions perform their functions and further their mandate in an informed manner.

It is clear that knowledge sharing is important for discharge of regulatory functions but it has a greater role in shaping the trajectory of technology development. In the absence of adequate knowledge about risks and impacts, there can be assumptions about both the potential benefits as well as risks. One among the many challenges that can potentially influence the ambit and effectiveness of governance institutions in the future is the polarization of the debate on nanotechnology's benefits and dangers. There is a danger of the debate going the biotechnology way in which the supporters and the critics were arrayed at extreme positions on the issue.

Prioritisation and legitimacy

As nanotechnology has application potential in several sectors, each having different needs operating over divergent timescales and exposed to different market dynamics, countries have also developed or are in the process of developing sector specific strategies and policies.

The TERI report on Conceptual Framework to assess national capabilities to respond to NT developments, observed that in the context of developing countries the role of S&T policy, besides deciding the level of investments and prioritization of sectors, the level of importance attached in engaging with the ethical, legal and societal dimensions – all requiring a substantial amount of funding - would enable a smooth and healthy penetration of nanotechnology within a national boundary. (TERI 2008: D7) Also a critical issue in the policy making process would be the development of capacity in the usage and maintenance of advanced products using cutting edge technologies, such as nanofilters, nano photovoltaic cells and

[1] TERI 2010, Summary of proceedings of Workshop on Issues of risks in regulation, January 8th, 2010, New Delhi

the like. Given that nanotechnology has application potential in various sectors of the economy, development of cross–sectoral policies for nanotechnology may be a critical approach to the capability building process.

Technology development as a state agenda has to an extent meant exclusion of other stakeholders from the decision making and governance process. The considerable leverage given to pioneers of Indian scientific establishment and technocrats has made it difficult for the private sector or civil society to participate in the governance process, which is still government-centric. Recently, the Bt brinjal moratorium may have put civil society at the forefront but it seems like a stand-alone decision. Besides, the legitimacy of that moratorium itself is a subject of debate.

Credibility of policies and actions is central to a wider acceptance and inclusiveness of governance, which is difficult to obtain in view of the divides and differences on basic beliefs vis-à-vis benefits and risks of technology, which itself are rooted in the 'history and symbols of one's culture' and locally constituted perception. (Skogstad, 2002; Beck, 2000) One way of overcoming the problem of legitimacy is through democratisation of MLG facilitating a dialogue and learning across state and non-state actors. In India, traditionally science has enjoyed a privileged position in the state agenda and been approached in a national context, however, gaining credibility and legitimacy for MLG of nanotechnology would entail departing from that stance and democratizing science by strengthening the involvement of four key actors- political, business, scientific and civil society communities.

CHAPTER 4 Way forward: Roles and points of interventions for governance of nanotechnology

Technology is dominated by two types of people: those who understand what they do not manage, and those who manage what they do not understand

Putt's Law

'Governance' refers to the process of decision-making and implementation of those decisions. Unlike a simple analysis of 'government', the process by which decisions are implemented, an analysis of governance looks at both the formal and informal actors involved directly and indirectly in the process. As UNESCAP observes, government is only one of the actors in governance. There are several others that have a role in governance, especially multilevel governance. Table 3.1 in the previous chapter attempts to map some of these on the basis of their level and nature. An institutional framework for nanotechnology governance would ideally include a range of institutions – research bodies, promotional agencies, planning bodies, nodal ministries, other ministries, regulatory agencies, implementing agencies etc performing different functions. (TERI 2009: D5)

There is always a divergence on the question of which level is the most important one in multilevel governance. (Fairbrass and Jordan, 2004) Actors with different objectives and different degrees of political influence may be connected by horizontal links (Forsyth, 2009) and it is this vertical and horizontal interlinkage that makes the interaction between actors complex in MLG.

Multi-level governance refers not only to the 'distribution of authority among national governments and other decision-making authorities on different levels, but also to the interdependence of these different levels' (Homeyer & Knoblauch, 2008). Therefore, there is a need to reflect upon the roles and functions of the different actors involved – both state and beyond state. As a way forward in responsible an inclusive governance of nanotechnology it is essential to identify the roles for different actors and stakeholders, which this concluding chapter seeks to attempt.

International bodies

With globalisation, there has been a gradual increase in the influence of international regimes, organizations and governments on account of commitments at international forums, interdependence amongst countries in terms of research, application and markets, increasing acceptability of international standardisation process. In the case of nanotechnology too, certain international forums such as IRGC, ISO, OECD and IFCS have secured a lead in occupying the governance space.

International agencies like WHO can be influential in setting guidelines and preparing guidance documents for domestic actors with regard to nanotechnology applications in health sector. This could be done by developing, establishing and promoting standards of use and applications in health. With its network at national and sub-national levels, WHO can play an important role in facilitating a network of information and monitoring. An EHS, education, ELSI database can be set up. (IRGC, 2006)

International bodies can foster communication amongst different actors and create collaborations among them. These sites can also help in framing of issues and recommending frameworks to resolve those. Given the influence of international policies and processes on domestic regimes, international bodies such as the ISO must take lead in establishment and enforcement of international standards. Till the time, they are adopted by or amalgamated in domestic policies, these would serve as useful models for adoption in the form of voluntary measures by companies.

Government

Governance implies an approach beyond governments and bringing on board different stakeholders in the decision-making process. However, it does not undermine the role of the government. It in a way broadens the scope of government's role from command and control to that of coordination, steering and networking. The government in a MLG framework has to get into multiple roles. The different wings of the government – planning bodies, legislators, bureaucrats, implementing agencies have to discharge their roles and responsibilities for building capability and innovation, promoting technological development for meeting the needs of the society, regulating the risks associated, allow information flow and public participation in the governance process. Several stakeholder dialogues that TERI has organized over the last three years have reiterated this.

The government should continue providing support for research and development in the field of nanotechnology. However, the role of government should require support for greater risk related research and generation of data in this regard. To aid decision-making, the government can set up a nanotechnology regulatory database. Governments at all levels can be influential in making relevant knowledge accessible. One way of doing so is making information disclosure mandatory – information about use of nanotechnology and nanoparticle through labelling and disclosing information about any adverse impacts that the practitioners or developers of technology become known of.

Taking into account the phase of the technology, government actions should be directed towards laying down guidelines to enable researchers and industry to practise nanotechnology in a manner that keeps the adversities as low as possible. This would, however, require an extensive examination of what tests and assessments should be undertaken for domestically manufactured and imported products. The government could set up an inter-ministerial committee to make short terms and medium term recommendations in this regard. Given the diverse applications, interdisciplinary nature and issues involved, the government must encourage inter-disciplinary and social science research in nanotechnology.

Academia

Nanotechnology R&D in India is largely government driven, with the agenda of promotion of nano science and technology. The scientific research establishment is, therefore, fundamental in building S&T capabilities through creation of a knowledge base in terms of critical mass of trained scientific manpower in various areas of S&T having ability to create, adopt and apply knowledge. Besides preparing a new workforce and expertise in this area, scientific institutions must also be prepared to leverage the existing expertise to be able to harness the potential of nanotechnology in key areas such as health.

As part of the triple helix model of innovation studies, academia need to further collaborations with industry for development of innovative products. They should also channel the research and infrastructure support received from the government, where possible, towards using nanotechnology to find solutions for problems relevant to the Indian context. There is recognition of the need to build endogenous capacity and enhance inter-agency collaborations between domestic academia, firms and government S&T institutions.

Coordination and exchange of information amongst research institutes can best be done at the level of research institutes themselves. This is particularly important in health applications where public institutions, centres of excellence are foraying. It is vital for these to be connected with dedicated drugs research institutes and laboratories like CDRI and NIPER. Besides, institutes dealing with toxicity research should be a part of this network.

Responsible nanotechnology development is not something that can be left to the government or industry alone, but the academia should practice OHS and laboratory safety and be vigilant about risks that may emanate. Institutes dealing with toxicological research and others engaged with nanotechnology development, should generate toxicity date and develop risk assessment methodologies.

The academia can also be proactive in setting up transdisciplinary centres and studying societal impacts of society and undertake socio-economic studies re nanotechnology. Assuming that academia will be impartial in its research and assessment, they are best positioned to educate the society about potential benefits and risks associated with nanotechnology.

Industry

As R&D in nanotechnology progresses and more products are closer to be manufactured on a commercial basis and launched in the market, the role of industries assumes greater significance. Besides, commercialising technologies developed through public funding, there are few companies in India that are engaged in research and product development on nanotechnology. With a stake in development and diffusion of nanotechnology, the private industry needs to be an integral part of the governance framework. The industry can do so through corporate governance tools such as transparency, which can be useful in building trust of the consumers and providing the required flow of information for devising a regulatory strategy.

At a stage when it is not possible to have nano-specific regulations and there is a dearth of nanotechnology related standards, both internationally and domestically, companies can practise self-regulation by coming up with and adhering to voluntary standards. In a globalised world, such practices will ensure a greater consumer acceptance in domestic markets as well as options for international market.

Lack of knowledge about impacts and risks has been identified one of the main challenges with nanotechnology. Industries through risk assessments, pilot launch, post market surveillance are better positioned to collate and provide knowledge on impacts, occupational hazards, waste disposal etc. for further risk research and policy design. Pharmaceutical companies under the pharmacovigilance protocol can play an active role in reporting adverse drug impacts to the regulatory agencies. Moreover, the presence of industry and its contact with the consumers is not restricted to any one jurisdictional level but present at local to international levels, thus making it amenable for it to be a part of the MLG.

Civil society

The role of formal and informal institutions in governance of emerging technologies is getting blurred today. In a society where technologies like nano are being promoted and introduced rapidly, the role of public as mere consumers or recipients needs to be broadened. Visvanathan (2001) notes that public opinion on scientific technological projects is inadequate and there is a need to revisit the notion of citizenship regarding science.

> *'What we need is a role that goes beyond spectatorship or consumption but we also need a notion of participation which sees the citizens as a scientist, a man of knowledge and with technical skills of survival' (Visvanathan, 2001).*

However, in the last decade, there have been at least two instances of legislation being drafted and pushed for with an active and central role for civil society and scientific community. The Biodiversity Act and the Protection of Plant Variety and Farmers Rights' Act are two such examples.[1]

The decision making process at present by-passes public discussion and public participation Therefore, there is need to bring this to the public body at the local level but the real challenge in doing so is the ability to make right decisions at the local level given the complex nature of the technology and its implications.[2] Moreover, things are going to be different in the case of nanotechnology. Civil society is not a homogeneous community but is characterised by enormous diversity. Unlike previous technologies, the target community within civil society is not easy to identify. For example, the farmer community was the primary target community in the biotechnology debate. Nanotechnology applications are so diverse that it is difficult to narrow down to any subset within civil society. This makes the task of engaging with civil society difficult but no less important. Horizontal MLG is more concerned with a 'shift of responsibilities from governmental actors/authorities towards non-governmental actors' (Eckerberg/Joas 2004)

[1] Panel discussion – http://kicsforum.net/kics/KD/040-paneldiscussion,html
[2] TERI, 2007, Capability, Governance and Nanotechnology Developments: a focus on India
Summary report of the Round Table Discussion held at TERI on 8th October 2007

Consumer groups and NGOs can be influential in demanding greater transparency, information and serve as watchdogs especially with respect to environmental and health impacts of nanotechnology applications (IRGC, 2006). Prioritisation of research and sectoral focus is another area where civil society can influence policies by articulating the needs of the society and the health areas in need of nanotechnology intervention.

A flawed public engagement and communication strategy can stifle a technology even before its benefits can reach the public as a result of uninformed or ill-informed public perception and consequent reluctance to accept the technology. Therefore, in order to balance the objectives of technology development and risk governance, civil society organizations along with other stakeholders in the government, industry and academia can help remove any misgivings and create an information network to facilitate public engagement.

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