Regulatory Challenges posed by Nanotechnology Developments in India

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This report is a part of the study on Capability, Governance and Nanotechnology Development: A focus on India. Research under this study has been divided into five work packages – (i) Review of Nanotechnology developments (ii) Understanding multi-dimensional risk (iii) Nanotechnology developments in India (iv) Regulatory framework in place in India. This particular report, primarily deals with the regulatory issues, institutions, mechanisms and functioning imperatives related to nanotechnology in India. Adopting a cradle to grave approach, the research under this section entails examining policy and legal instruments, administrative systems, institutional frameworks, and systems for public and private participation, which already have or are likely to have a bearing upon regulation of nanotechnology.

The research on understanding different dimensions of risks notes that the inherently complex nature of nanotechnology has given rise to a host of uncertainties and risks affecting natural and human systems. It has been noted in various studies that applications of nanotechnology and manufacture and use of nano-materials may pose new challenges for health, environment safety and raise ethical, societal, economic and legal concerns. Although, several of the challenges posed by nanotechnology are not new and have been confronted and addressed at the time of emergence of biotechnology, there are some other challenges, which are new. Given the complexity and possibility of its wide dissemination nanotechnology requires an entirely new paradigm of regulatory approach and charting of new regulatory pathways. Today, nanotechnology is no longer at research stage alone, but entering markets in different forms and through different routes. This raises concerns around a nation’s regulatory preparedness to respond to the exposure of its people and environment to risks.

In India, the government has been playing a central role in promoting nanotechnology research and development, and application. The role of the state is also of prime 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. The government priority at a given point of time will also influence regulatory choices made. The current focus of government action on promotion is evident from the mission mode it has approached under Nano Mission. This focus may get reflected in the way regulations are designed/modified for technology. Similarly, a shift in the focus, say towards risk
management, would translate into regulatory action. Thus the need arises of gaining insights into the origin of such regulations, their implementation techniques, their sustainability and the possibility of change, etc. In this context, we have identified intellectual property rights and risk regulation for detailed analysis for its importance to developing countries.

Although there does not exist a nanotechnology specific regulation currently, there exists a whole range of regulatory instruments that do and will extend to the nanotechnology applications in India. However, given that these instruments have been designed for regulation of different aspects of technology development and commercialisation in general, their adequacy and capacity to address the concerns emanating from nanotechnology development is indeed something that needs an in-depth critical analysis and deliberation.

A regulatory matrix comprising several central Acts, rules and notifications pertaining to intellectual property rights and environment, health and safety for nanotechnology development and applications in India has been developed and categorized under the following broad heads -

- Research and development
- Production and marketing
- Occupational health and safety
- Environmental health
- Waste disposal

An attempt has been made to gauge regulatory flexibility of these instruments in terms of their ambit and substantive rights/obligations/responsibilities to respond to nanotechnology developments and risks emanating therefrom. Although, the project views risks in a heterogeneous manner, including environmental, health, occupational and economic risks, in this report we have chosen to restrict the analysis of regulations pertaining to nanotechnology to essentially those which would directly affect the discipline of risk regulation and also on the issue of patenting in nanotechnology. The rationale for choosing to focus on these two specific aspects of regulation is primarily their importance in the context of developing country priorities of harnessing innovation and risk regulation.

One of the purposes of the analysis of regulatory framework in India was to contribute to the debate on whether nanotechnology regulation requires a new legislation? Can the present regulatory regime address the challenges of this new technology or applications from this technology? What are the components of the current regulatory regime
that will be able to address these new challenges? To what extent modifications need to be made? An analysis of several Acts and associated rules and notifications reveals that at this stage, a nanotechnology specific legislation is not necessary. Most of the challenges and concerns could be addressed by way of either intervention at the level of subordinate legislation or amendments in the existing instruments, or interventions at the level of implementation.

Absence of a nano specific regulation does not imply unregulated nanotechnology. Applications of nanotechnology, owing to their very nature, interaction with other technologies, and extent are subject to several regulations already. However, most of these existing regulations require to be revisited, reviewed and amended before they are able to regulate the risks associated with nanotechnology. In some cases, it is merely about recognizing the distinctness of nanotechnology and potential and uniqueness of risks associated with it. There is ample flexibility available in the environmental legislation to address new challenges emanating from nanotechnology developments. In the interest of regulatory economy, the space available within the existing framework has to be identified, utilized and gaps need to be filled, before proposing a new law.

In India, technology as a means of meeting development needs has enjoyed a privileged position. An important feature in the development of a technology and its governance has been the trend of setting up of individual departments at the level of central government with a view of promotion of specific technologies, e.g., Department of Biotechnology, Department of Atomic Energy and the Department of Information Technology, to provide strategic leadership and guidance for technology development in the specific sectors. Such an institutional arrangement poses the question, whether the existence and functioning of a government department solely dedicated to technology promotion may compromise and to a certain extent limit the regulatory role of ministries/departments that address issues of risk regulation of emerging technologies. The issue of institutional arrangements has implications in terms of determining the regulatory space available for undertaking regulation in the context of emerging technologies like nanotechnology.

A general examination of the overall regulatory institutional framework suggested that the institutional dynamics would depend on which sector and in which form is nanotechnology being applied. In light of the developments and implications, the study carried out a detailed analysis of nanotechnology applications in health sector.
The lack of engagement with the risk assessment and management of nanotechnology is not just an issue of prioritisation of public research funding, the gap is reflected even in the institutional framework that exists. The agencies with a focus on nanotechnology have a clear mandate of technology promotion. Regulatory agencies, which have the function of regulation of health and health products, are not able to lay adequate attention on possible risks emanating from nanotechnology due to a number of factors. Institutionally, Ministry of health and family welfare (MoHFW) is in charge of prevention and control of health related hazards but has not been sufficiently included in the overall nanotechnology regulation governance. MoHFW has been indeed engaged with nanotechnology but that has been primarily through Indian Council of Medical Research (ICMR). Another level, at which the ministry plays an instrumental role, is that of regulating drugs and pharmaceuticals through the Central Drugs Standards Control Organization.

The main challenges faced by regulatory institutions currently, or the ones which are likely to make the task of regulating nanotechnology difficult, relate to the following:

- Regulatory capacity
- Information asymmetry
- Inter-agency coordination
- Overlapping roles and mandates

Another challenge for the regulatory institutions is to keep pace with international developments, in terms of responding, incorporating and even influencing them.

With globalisation, there has been an increasing shift towards greater internationalisation of regulation. This however does not result necessarily in the loss of regulatory competence on the part of the national regulators, but results in shared competences by institutionalising channels of influences - At least in theory. In practice, how does one ensure that this is indeed a two-way process? How does a state respond to developments at international level? What is the optimum level regulatory control to be exercised? To answer these questions, the report maps the key international regulatory sites with a view to track their developments in respect of nanotechnology and understand the linkages underlying the relationship between international sites and national regulatory bodies.

As with the emergence of any new technology, nanotechnology (NT) creates issues, opportunities and concerns in adapting the intellectual property rights (IPR) regime to its particular context. This is to a large
extent magnified in developing and least developed countries, which irrespective of their state of technological advancement, are obliged to confer intellectual property (IP) rights in the new technology. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement obligates all WTO (World Trade Organization) member countries to adopt and enforce minimum standards of intellectual property, with WTO members having to allow patents in all fields of technology. This implies that all WTO members (even least developed countries) are obligated to provide intellectual property rights in the emergent field of nanotechnology.

There has been a growing trend towards the acceptability of international forums/institutions as efficient and effective sites of regime creation. These sites are characteristically sub-political in nature in as much as they lack effective legitimacy and formal rule making power. Still, they have emerged or are emerging as important players in nanotechnology governance. The Intergovernmental Forum on Chemical Safety (IFCS), International Standards Organization (ISO), and the International Risk Governance Council (IRGC) are the three identified sites under the study.

Some of the key components of a responsive nanotechnology regulatory framework are discussed in the report. First and foremost, the regulatory regime for an emerging technology should be dynamic, which is reviewed and revisited from time to time. In the present context, intervention at the level of subordinate legislation or amendments in the existing instruments, or interventions at the level of implementation can be made. Given the stage of nanotechnology development and uncertainties around its risks, regulations should be flexible enough to respond to challenges as and when they arise. A good regulatory framework should take into account the phase of Nanotechnology development and the regulatory intervention should be as per the stage of development and knowledge of risks. The IPR regime should also prepare to re-invent itself for this new technology as the state-of-the-art evolves in the future. There should also be a proper channel of communication amongst the key stakeholders and players so as to facilitate government-people, inter-governmental and intra-governmental communication towards regulation. The inter agency coordination is crucial, not just for filling the informational gaps but also removing the overlaps in regulatory mandates and functions.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADRs</td>
<td>Adverse Drug Reactions</td>
</tr>
<tr>
<td>BIS</td>
<td>Bureau of Indian Standards</td>
</tr>
<tr>
<td>CDSCO</td>
<td>Central Drugs Standards Control Organization</td>
</tr>
<tr>
<td>CII</td>
<td>Confederation of Indian Industries</td>
</tr>
<tr>
<td>CSIR</td>
<td>Council of Scientific and Industrial Research</td>
</tr>
<tr>
<td>DRDO</td>
<td>Defence Research and Development Organization</td>
</tr>
<tr>
<td>DAE</td>
<td>Department of Atomic Energy</td>
</tr>
<tr>
<td>DBT</td>
<td>Department of Biotechnology</td>
</tr>
<tr>
<td>DIT</td>
<td>Department of Information Technology</td>
</tr>
<tr>
<td>DSIR</td>
<td>Department of Scientific and Industrial Research</td>
</tr>
<tr>
<td>DGHS</td>
<td>Directorate General of Health Services</td>
</tr>
<tr>
<td>EHS</td>
<td>Environmental, Health and Safety</td>
</tr>
<tr>
<td>EPA</td>
<td>Environment Protection Act</td>
</tr>
<tr>
<td>GOI</td>
<td>Government of India</td>
</tr>
<tr>
<td>ICT</td>
<td>Information and communication technology</td>
</tr>
<tr>
<td>ICMR</td>
<td>Indian Council of Medical Research</td>
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<tr>
<td>INSA</td>
<td>Indian National Science Academy</td>
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<tr>
<td>IPR</td>
<td>Intellectual Property Rights</td>
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<tr>
<td>IFCS</td>
<td>Intergovernmental Forum on Climate Safety</td>
</tr>
<tr>
<td>IRGC</td>
<td>International Risk Governance Council</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standards Organization</td>
</tr>
<tr>
<td>MoEF</td>
<td>Ministry of Environment and Forest</td>
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<tr>
<td>MoHFW</td>
<td>Ministry of Health and Family Welfare</td>
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<tr>
<td>NT</td>
<td>Nanotechnology</td>
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<tr>
<td>NPP</td>
<td>National Pharmacovigilance Programme</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OHS</td>
<td>Occupational Health and Safety</td>
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<tr>
<td>PSU</td>
<td>Public Sector Undertaking</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>SPCB</td>
<td>State Pollution Control Board</td>
</tr>
<tr>
<td>TRIPS</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
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<tr>
<td>WIPO</td>
<td>World Intellectual Property Organisation</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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Chapter 1: Introduction

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).

There is also a need to make a specific 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 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.

Regulation of Emerging Technologies

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 (biotechnology for instance) 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 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)

Another important issue is what do we exactly mean when we refer to when we use the concept of “technology regulation”? Can a technology \textit{per se} be regulated – not only in terms of its different products/applications but also in terms of the phases of its application, laboratory, factory floor, shop, consumer, etc? Is it possible, realistic or even desirable to consider mono-technology regulatory frameworks that address all aspects and all phases of development of that technology? Although frequently within policy debates constellations of regulations are also loosely referred to as a framework, herein frameworks would refer to a self identifiable structure that would form the individual basis for regulating almost all aspects of technology experimentation, production and application. Worldwide there have been very few examples of technology specific regulatory frameworks, primarily because the technology per se is changing very fast, and therefore regulation which is technology specific faces the challenge of becoming obsolete. Also on the grounds of regulatory economy, the first responsibility of regulators is to always review the robustness of the current operational frameworks to see whether they will be able to address the challenges posed by the new developments and/or to identify key amendments, which would be required to bring the framework into line with current developments (Reynolds, 2003). Given the scale of public resource investment that is required in the framing

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and implementation of a new regulatory framework, operating on the basis of regulatory economy, demands that regulatory solutions are considered on the basis of how cost effective they are. The first task of the regulator is to ask the question that, whether the current regulatory framework can be adapted to deal with the new regulatory challenges that technology development throws up.

Policy Coherent and Regulatory Linkage

As mentioned in the above paragraph, in this report we have chosen to restrict the analysis of regulations pertaining to nanotechnology to essentially those, which would directly affect the discipline of risk regulation and also on the issue of patenting in nanotechnology. (Newberger, 2003) This might seem to be totally de-linked and disparate sectors of regulatory control, however there is essential thread, which provides the connectivity. Both these sectors are important and indeed critical especially for developing countries like India in terms of their importance in enabling them to secure a responsible, sustainable and long-term technology development in such key technologies like biotechnology and nanotechnology. It is in this context that we have chosen to focus on risk regulation and intellectual property rights as two aspects of regulation, which regulators, in developing countries like India would have to master in order to design systems that enable us to reap the benefits of these new technologies, in a sustainable and safe manner (Matsuura, 2006).

Herein a caveat seems pertinent. As mentioned in addition to the fact that both these sectors are critical in the Indian context, there also exist linkages or paths of intervention that could connect the two regulatory sectors in terms of ensuring policy coherence between both. To give an example in the case of health related nano applications, nanotech related changes introduced to medical devices and drugs would have to be recognized as a “new application” in order to trigger the regulatory action. This would need to be in reference with the Patent Act under which introduction of nano related improvements would have to qualify to be a “new use” or demonstrate efficacy to be able to qualify for a patent grant. This kind of a linkage is not only useful but also imperative in developing a coherent policy framework with interlinking regulatory tools in place to delimit the regulatory spillovers that might result from such regulatory overtures.
**Regulatory Culture and Technology**

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).

For all the above reasons 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). The need arises in order to gain a deeper understanding of the origin of such regulations, their implementation techniques, how sustainable are they, the possibility of change, etc. In this sense, locating technology regulations (and for that any sector specific regulation) squarely within the specific national/regional/sub-regional/local context explores the possibility of providing a more organic perspective into the whys and wherefores of regulation.² Specifically in the case of technology regulation, it is important to note that the extensive drive for industrialization that was taken up post-independence in India had a number of economic and social implications, however the most important of them, was that of development of technology. Interestingly however (but not surprisingly – See the national development trajectory in Japan for similarities)³ most of the technology development was driven by indigenisation of foreign technology. Thus adaptation of technology for indigenous needs was the primary aim of the scientific establishment in India and to an extent this continues to be true even in the private sector (witness the burgeoning generics pharmaceuticals sectors).

However, before discussing the nature of technology development, it is important to comment on the agenda of technology development in post-independent India itself.⁴ One of the main architects of the

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technology development map of India was Nehru, who was deeply impressed and driven towards the adaptation of technology for India’s development needs. Consequently, first, technology development (focusing on adoption and adaptation of western scientific breakthroughs) was given a prominent place within the national development agenda. (Ashraf and Belluardo, 1998) Second, the founding fathers of the Indian scientific establishment were given considerable leverage power of a civil servant. (Prakash, 2000) This formed the basis of the tradition of requiring technocrats to be at the helm (and also make up for a majority of the departmental workforce), that continues till today.  

One good illustration of this is the five-year plans that are drawn up by the Planning Commission of the Government of India (henceforth GOI). There have been eleven five-year plans so far and currently we are in the phase of the eleventh five year plan. All the Eleven Five year plans have had reference to a wide range of technology inputs. However one can detect a sea change in the manner in which technology inputs are being addressed. In the case of the first seven five year plans, technology inputs were always discussed in the context of specific industrial or agricultural sectors. From the Eighth five-year plan onwards one notice that technology development per se becomes a national goal and therefore part of state agenda for development. The role of the government became that of technology stewardship. This is not surprising given that, the period of the Seventh and the Eighth five year plan (1985-1989 and 1992-1997) witnessed a spurt of growth and interest in technologies such as ICT and Biotechnology. Thus in privileging technology development as a national goal, the fundamental assumption is that targeted public investment in technology development would ensure that the country would leapfrog within the developmental cycle. Thus from the Eight plan onwards there is an intellectual shift from sector driven technology development to technology driven sectoral demand creation, thus technology in itself becoming the fulcrum on which development of a host of other sectors are dependant.

This privileging of technology was also based on an implicit assumption of the neutrality of technology in terms if it is inert (therefore value
neutral) nature and as only a tool for development. The positing of nanotechnology within the discourse of national development has meant that its regulatory aspects in terms of environment, health and social aspects have faced systematic neglect. The unquestionable importance of the national development agenda and its primal position in the list of national priorities has meant that the government efforts have focused on the development and dissemination of this technology at the cost of risk regulation of potential adverse impacts that may emanate from that technology.

Another feature that must be kept in mind before analysing the regulatory framework is the regulatory block that characterizes most of the private sector in India. Although, regulatory certainty seems to be a more rational and economically stable situation and therefore more desirable, this block can be traced to our own structural history of regulations. A study of the structural and procedural history of most Indian legislations would support the contention that they were developed and implemented from a classic command and control regime – that was itself a remnant of the colonial period. The infamous state control exemplified during the time of license raj further cemented such notions of an interventionist state. (Soo, 2008) Thus since 1991 when the economy was liberalized, deregulation has come to be taken as equivalent of privatisation. Also more generally the term “regulation” is implicitly assumed to mean government intervention and generally meddling with the market mechanisms. In this context it is not surprising that there is widespread opposition to regulatory regimes in general as evidence of needless government activism and therefore something that should be opposed by the industry at most times. 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 in undermining efforts to bolster regulatory oversight of these technologies.

Chapter distribution and subject coverage

The above paragraphs provides an overview of a few important aspects of regulatory dynamics that shape and determine the regulatory space and choice of regulatory tools available and ultimately the nature and

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scope of regulatory framework that will operate vis-à-vis nanotechnology in India. The following chapters address specific aspects of such a regulatory framework. The second chapter extensively analyses a host of legislative instruments and policies (regulatory matrix) in terms of their adaptability to address the new challenges thrown up by nanotechnology developments. Adaptability is measured in terms of first outlining the key provisions within the instrument, then studying their convertibility index and then identifying points of intervention is required to bring them in line with the current requirements. This is followed by the next chapter in which the institutional dynamics of regime formation is studied and structural issues discussed. This involves not only role mapping of stakeholders and current agency landscape but also in providing concrete recommendations that can provide the best case scenario in terms of resource utilization and ensure regulatory ownership across the core group of stakeholders. In the fourth chapter the level of internationalisation of regulation is analysed and a discussion is initiated on the optimal level of international regulatory regime formation on nanotechnology in India. The attempt has not been to find any definitive answers, but to discuss the question in the context of an extensive discussion on the limitations and effectiveness of domestic regulations on technology, given the global and interconnected world that we inhabit. The concluding section of the report discusses in detail the value and feasibility of recommendations emerging from the study and adopted at the National Conference on Nanotechnology and Regulatory Issues, held on 4 January at the Technology Campus, Calcutta University, Kolkata. This is followed by introducing a discussion on few conceptual options for nanotechnology regulation. It discusses framework options or components, that need to be understood and kept in mind throughout the process of regulatory design and implementation.
As discussed in the previous chapter, there are various factors, including the government priority at a given point of time, that influence the regulatory choices made with respect to a technology. Thus the need arises of gaining insights into the origin of regulations, their implementation, their relevance, adequacy, the possibility of change, etc. in the context of nanotechnology development in India.

**Need for a gap analysis**

Although there does not exist a nanotechnology specific regulation currently, it would be incorrect to say that nanotechnology and nano particles cannot be regulated in the absence of such a dedicated regulation. There exists a whole range of regulatory instruments that do and will extend to the nanotechnology applications in India. However, given that these instruments have been designed for regulation of different aspects of technology development and commercialization in general, their adequacy and capacity to address the concerns emanating from nanotechnology development is indeed something that needs an in-depth critical analysis and deliberation. It is imperative to review the framework, as it exists for research on nanotechnology and for products developed using nanotechnology and nano particles.

One of the key questions to address in designing a regulatory framework for technology application is whether at all we need technology specific regulation or regulation of technology is something that needs to be built within the product regulatory regime. In order to be able to arrive at a definitive answer on this, we need to ask a few more questions - Can the present regulatory regime address the challenges of this new technology or applications from this technology? What are the components of the current regulatory regime that will be able to address these new challenges? To what extent modifications need to be made? With this background, the chapter maps the regulatory landscape as it exists and extends to nanotechnology research and application in India.

**Identification of regulatory gaps – methodology and approach**

The project has identified specific aspects of the present regulatory regime, which would be directly applicable to new developments in nanotechnology. An attempt has been made to cover all the main legislation regulating the different phases and features of the entire life
The regulatory mapping and gap analysis is a result of a comprehensive review of policy documents of states, ministries, departments, planning commission, relevant central Acts, rules and notifications applicable and judicial decisions, where relevant. The gaps have been analysed with reference to the Indian scenario, stage of development as well as a comparison with the review of international law and policy with respect to environmental principles, health and safety standards, waste disposal.

The project sees regulatory interventions in any given technology at five main stages of its development and application -

- Research and Development (R&D) and intellectual property rights (IPR)
- Production and marketing
- Occupational health and safety
- Environmental risk management
- Waste disposal

At each of these stages individually and together, there are several concerns that relate to regulation of technology, however, intellectual property rights and risk regulation are two of the main concerns vis-à-vis nanotechnology regulation. An analysis of the IPR regime is pertinent as irrespective of their own technological advancement, all TRIPS member countries are obliged to adopt and enforce minimum standards of intellectual property, in all fields of technology. The challenge particularly for developing countries is not only to adapt the patent system to deal with the new technology, but also to ensure harmonizing between two (often contradictory) imperatives: an enabling, incentive based environment for innovation and at the same time, to deter monopolies and serve the public good. The challenges are compounded particularly in the field of nanotechnology, as it poses some unique problems, both for the inventor as well as from the public good perspective.

On the other hand, the risk approach to regulation is based on the tacit understanding that governments bear the direct and indirect responsibility of protecting their citizens against risks. Most are in agreement that with any new and powerful technology such as

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9 Article 27 (1) of TRIPS provides that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.
nanotechnology, appropriate controls in the form of regulation, must be tailored to address the evolving problems and potential risks of nanotechnology, promote its benefits and attenuate its social and economic upheavals.

This chapter is therefore divided into two parts,

- Intellectual property rights issues in nanotechnology regulation,
- Regulation of risks (EHS) emanating from nanotechnology development and application
As nanotech research is too expensive and complex for small players, nanotech may accelerate the trend towards corporate concentration of power and monopoly formation. Innovations derived from nanoscience are likely to generate intense international competition for patents and a drive to harmonize IPRs across countries. Nanotech is emerging into an already evolving global patent landscape where multinational corporations are attempting to own downstream access rights to enabling technologies. Multinational corporations, universities and nanotech start-ups have already secured numerous patents on essential nanotech tools, materials and processes. Participation in the proprietary nanotech revolution for developing countries is likely to be highly restricted by patent tollbooths, obliging payment of royalties and licensing fees to gain access.

At the domestic level, for a developing country like India, the challenge is to tailor an IP regime for nanotechnology, which while offering the mandated protection under TRIPs, is able to explore the flexibilities within TRIPS to serve developing country interests. For instance, the TRIPs has not defined the patentability requirements, nor has it defined invention, with the effect that a domestic regime is free to interpret these as it wishes. According to Bera (2009: 495), provisions like these allow nations some leeway in tailoring their patent system according to their domestic needs, present state of development and their potential for growth.

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**Nanotechnology Patent Landscape in India and Trends**

A study on *Indian Publications and Patents in Nanotechnology during 1990-2007* (Gupta, 2009) (in foreign patent offices like the USPTO, EPO, JPO etc.) arrived at the following conclusions:

- Intensity of patents grew exponentially between 2001-07.
- Of the total 167 patents, 64 patents (39% of the total patents) are owned by government institutions, 45 patents (27% of the total) by firms in the industry and 10 patents (6% of the total) by academic institutions. There are 37 patents (22% of the total) that are owned by individual inventors. The remaining 5% of the patents are joint patents in collaboration between government institutions or firms from industry.
- The leading contributors from the government sector include laboratories of the Council of Scientific and Industrial Research (CSIR), Defense Research and Development Organisation (DRDO) and
Department of Atomic Energy.

- The academic institutions that have taken patents include the Indian Institute of Science, Indian Institutes of Technology and Jawahar Lal Nehru University.
- Firms like Ranbaxy Laboratories, Stempeutics Research Private Limited, Panacea Biotech Limited and Arrow Coated Products Limited are the leading owners of industry patents.
- Academic institutions have more number of publications than patents while reverse is true for industry.

On the other hand, an e-search at the Indian Patent Office website using the key word ‘nano’ reveal that since 1997, 64 patents have been granted by the Indian Patent Office. About 24 patents are owned by industry, 28 patents by academic and scientific institutions (with CSIR having 16 patents, IITs-7 patents), and the rest by private individuals (list attached as appendix).

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**The IPR Regime in India: Its Implications for Nanotechnology**

In this report, the discussion will be confined to the Patents (Amendment) Act of 2005 and the newly drafted Protection and Utilization of Public Funded Intellectual Property Bill, 2008.

**The Patents (Amendment) Act, 2005**

The main provisions of the Indian Patents Act, which has implications for NT patents are as follows:

**Patentability Criteria**

Section 2 (1)(j) of the Patents Act defines an invention as a ‘new product or process involving an inventive step and capable of industrial application’. It defines an ‘inventive step’ as a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art\(^\text{10}\). Thus, from these provisions, it can be interpreted that any existing knowledge or thing cannot be patented and section 3 (d) further reinforces this by providing a bar to patentability of ‘discoveries’.

Prior to the amendment to the Patents Act in 2005, this provision (section 3(d)) excluded from patentability ‘the mere discovery of any new property or new use for a known substance or of the mere uses of a known process, machine or apparatus unless such known process results in a new product

\(^{10}\) Section 2(ja) of the Patents (Amendment) Act, 2005.
or employs at least one new reactant’. After the 2005 amendment, the section reads as under:

*The following are not inventions within the meaning of this Act,*-

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant...

*Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy*.

According to Mueller (2008: 27-28), section 3(d) serves at least two functions: first, it is designed to discourage patent ‘evergreening’ by prohibiting the grant of a patent on a derivative form of a known substance unless the derivative form has significantly enhanced efficacy. Secondly, it prohibits ‘new use’ patents by expressly providing that mere discovery of any new property or new use for a known substance is not patentable. In Mueller’s view, Section 3 (d) is likely to prove very problematic for the Indian biotechnology companies developing combination vaccines because although such combinations may well be novel but the section creates a presumption against the patentability of combinations and other derivatives of a new substance. The same argument can be advanced that it is likely to pose serious impediments to NT inventors applying for patents in India. According to Raju (2009:17), the nano material may be a combination of many particles or technologies or a nano particle of an existing material and patents for nano structures without substantial difference in character and industrial application could very well not pass the standard of efficacy demanded by section 3 (d). He also points out that the explanation to section 3(d) does not accommodate the new technological development of nanotechnology as it specifically debars patenting of ‘particle size’ unless it may differ significantly in properties with regard to efficacy.

The courts in interpreting section 3(d) have also chosen to take a tough stand on the issue of ‘efficacy’, with this issue being discussed at length by the Madras High Court in the Novartis Case\(^\text{11}\). The Chennai Patent Office

rejected the Novartis’ patent application in 2006 on a medicine for treating cancer on the grounds that it was not innovative enough. The Patent Office said that the new claim was for different forms of the same drug (salt and crystalline) and did not involve any inventive step, hence did not merit a patent.

Section 3(d) and the other patentability requirements under the Indian Patent Law are going to create problems in patenting of NT. The problem is further compounded by the fact that there is very little case law on the matter to guide judicial decisions and that too on a subject, which is not well-known. The challenge for patent applicants in India is to ensure that their patent claims are not for mere reduction in size but that they lead to better ‘efficacy’ and solution of new problems.

While the patentability criteria could create certain problems for the inventor, compounded by the lack of a separate classification for NT in India (to be dealt with later), we also need to look into certain provisions of the Patent Act, which could be employed to counter some of the challenges which NT poses, especially from the public good perspective.

Post-grant Opposition

In the context of some of the problems of the USPTO in terms of lax patent standards and lack of patent examiners’ field-specific knowledge, scholars have suggested that the establishment of a European style post-grant opposition could help to ameliorate some of the problems. Under post-grant opposition systems, third parties (including competitors) can challenge the validity of a patent after it is issued. If they are able to produce evidence that the patented invention lacks novelty or non-obviousness, in light of the prior art, then the Patent Office can amend or revoke the patent. According to Sampat (2003: 52), under such a system, even in the face of limits on patent examiners’ field-specific knowledge of the prior art (or access to prior art databases) (as is the case with NT), low quality patents can be eliminated ex post.

In India, following the 2005 amendment, we have in place a post-grant opposition clause as per which a patent may be opposed post-grant on any of the following grounds, namely:

a) that the patentee or the applicant wrongfully obtained the invention from the opponent or a person from whom the opponent derives title;

b) that the invention was published before the priority date, subject to the limitations on anticipation under section 29 Patents Act, 1970;

c) that the invention was previously claimed in an Indian application
having an earlier priority date;

d) that the invention was publicly known or publicly previously used in India and if an invention relates to a process then it shall be deemed to publicly known or publicly used in India when a product made by that process had already been imported into India before the priority date;

e) that the invention lacks any inventive step over any prior publication or over any prior use in India;

f) that the subject matter of the invention is not patentable under the Patent Act 1970

g) that the disclosure of the invention or the method by which it is to be performed is not sufficient and clear;

h) that the patentee has failed to disclose or has furnished false information regarding foreign applications;

i) that there is no disclosure or wrong mentioning of the source and geographical origin of the biological material used for the invention;

j) that the invention is anticipated by the traditional knowledge in India or elsewhere.

Post grant oppositions can be brought within one year of the grant of the patent.

A provision like the above would ensure that NT patents are not granted for inventions which are not novel or non-obvious. At present, litigation is going on in the Chennai High Court with pharma firm Wockhardt challenging Roche's patented product Pegasys (peginterferon alpha-2a) by stoking the post-grant opposition provision.12

Compulsory Licensing

The Indian Patents Act has quite an elaborate framework for compulsory licensing, which ensures that the public good is served, that the abuse of patent as a monopoly is prevented and to make way for commercial exploitation of invention by an interested person. According to section 84 of the Act, a compulsory license could be granted on a patent after three

years, from the date of grant of that patent, on any of the following grounds:

(a) The reasonable requirements of the public with respect to the patented invention have not been satisfied;

(b) The patented invention is not available to the public at a reasonably affordable price.

(c) The patented invention is not worked in the territory of India.

Compulsory licensing is a highly debated issue in patent law, with some considering it indispensable to fulfilling developing country needs. Others have opposed it on the grounds that it would diminish the purpose of the patent system by reducing inventors’ incentive to develop new technologies by encouraging inventors to keep inventions secret (Thomas, 2007: 357). However, this argument is untenable considering the fact that most patent systems which have compulsory license provisions, give patentees a minimum time period (under Indian Patent Law, it is three years from grant of patent) to exploit their invention before compulsory license may be granted. Compulsory licensing in the context of a new powerful technology like NT, especially in developing countries would help overcome many of the problems associated with patenting and which lead to creation of monopolies. According to many researchers, it has been the observation across all sectors that patent holders tend to refuse to give licenses, license with burdensome restrictions or use their patent to enter secondary markets (Muller, 2008: 68-69). That decreases the economic benefits of patents, may produce market failures, increase research costs and make technological progress difficult. Such problems are likely to be magnified in developing countries.

The compulsory licensing provision in the Indian Patents Act would help mitigate some of these problems. A developing country like Brazil has successfully used not compulsory licensing but just the threat of compulsory licensing to facilitate fairer negotiations with pharmaceutical companies regarding the terms of licensing to Brazilian companies and the prices of drugs in Brazil (Chagti: 2006: 33).

Disclosure Standards

A good counter strategy to tackle the issue of broad claims in nanotechnology is through a strong enablement clause or disclosure standard. The enablement doctrine, as existing in the US requires the inventor to provide sufficient information to enable a person skilled in the relevant art to make and use the claimed invention without ‘undue experimentation’. According to Koppikar et.al. (op.cit.: 6), in
biotechnology, examiners and courts used the enablement doctrine to narrow the scope of overly broad claims. A typical rejection states that the scope of the claim is too broad in relation to the number of examples provided in the specification, given the level of unpredictability in the area of the invention at the time the application was filed. According to Raju (op.cit.: 15), the enablement provision is based on the assumption that the ultimate beneficiary of a patent is not the patentee but instead the public by encouraging the disclosure of the invention. The main objective of the enablement provision is to narrow down the claims, so that the patent thicket problem can be avoided.

While in the U.S., broad claims have been granted, despite the enablement clause, in India, the Patents Act has set down disclosure standards (version of the enablement clause), which could help courts and examiners in rejecting broad claims. Section 10 of the Act provides that a complete specification shall ‘fully and particularly describe the invention and its operation or use and the method by which it is to be performed...’ In addition, it states that the complete specification shall ‘disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection’.

**Experimental Use Exception**

The experimental use exception permits researchers and their institutions to make certain uses of patent inventions for purposes of experiment or research. In the U.S., the courts have given a very narrow interpretation of the experimental use exemption, particularly in Madey v. Duke University14, where the Federal Circuit held that Duke University was not immunized from patent infringement when it used patented research equipment for experimental purposes. Nevertheless, academic researchers have long believed that the scope of the experimental use exception should extend to at least experimentation performed at universities or non-profit institutions.

In the U.S., the experimental use exception is not enshrined in the patent law and is only a judicially created doctrine applied infrequently and interpreted narrowly. On the other hand, the Indian Patents Act has almost a Bolar-plus provision (experimental use exemption is also known as Bolar exemption in the U.S.), which may prove to be an important liability shield for universities seeking to engage in NT research, without having to wade through patent thickets in the field. Under section 107 (A) of the Indian Act, ‘any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and

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13 Section 10(4)(b).
submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product...shall not be considered as an infringement of patent rights'.

The above discussion illustrates that though NT patents pose a challenge to the Indian Patents Act in terms of its ability to deal with this new technology, nevertheless, it has certain in-built flexibilities to address the issue, in a manner, which reconciles the needs of innovation and societal benefits. The various provisions of the Act can be flexibly interpreted by courts and examiners to serve both interests.

However, more than changes in the legislation *per se*, there is need to bring the whole patent and IPR regime up to date with the latest developments in NT. For instance, novelty and non-obviousness are evaluated against the prior art available, including national and foreign patents, publications and public demonstration or use of inventions. The aforementioned requirement is met through searching of prior art databases by the patent office. Owing to the multidisciplinary nature of nanotechnology inventions, examiners may have a difficult time in performing adequate searches of prior art databases. Further many nanotechnology inventions bridge different fields of applications, the ability of a single examiner or technology group may not be sufficient to determine the novelty of a particular application. Even before going into the provisions of the Indian Patents Act, it needs to be seen whether the Indian IPR regime and its implementation agencies-particularly the Indian Patent Office is equipped to handle nanotechnology and all that it entails in terms of prior art searches and patent examination. While developed countries like U.S.A, European Union and Japan have realized the need to have separate classifications for nanotechnology and imparting training to patent examiners to handle it, India is yet to take any such steps. This creates difficulties not only for the examiner, but also for the inventor.

**Publicly Funded Intellectual Property in Nanotechnology**

A discussion on the Indian IPR regime and nanotechnology will be incomplete without looking to the Indian ‘Bayh-Dole’ Act.

According to Schummer (2007:300-01), nanotechnology is emerging at a time when IPRs and practices have been changed in Western Countries and worldwide with negative side effects in developing countries. One such particularly important trend is this regard, is changing IPR practice at universities following the enactment of the U.S. Bayh-Dole Act of 1980. In his view, while the policy has improved the incomes of universities and evidently, the exclusive knowledge transfer to small local companies and start-ups, it is likely that it has directed publicly funded research to the
needs of local business rather than to the specific needs of developing countries. This trend has already been discussed earlier in this report: here, the discussion would be confined to what implications could be there for nanotechnology in India when the Protection and Utilisation of Public Funded Intellectual Property Bill 2008, introduced in the Rajya Sabha in December 2008 would become law.

Developed on the lines of the Bayh-Dole Act of the U.S., the Bill gives government-funded universities and research institutions the right to patent innovations arising out of public funded research and development. It seeks to provide the necessary boost to the commercialisation of inventions made through government-funded research by passing on the IP rights on the same to the institution responsible for that invention.

The Bill states that the institution will have to report to the government within a stipulated period of time (90 days) about its intention to retain the title of the publicly funded intellectual property. To manage the inventions created and formulate mechanisms for commercial utilisation of the inventions, the university will set up an IP Management Committee (like the Technological Transfer Offices under the Bayh-Dole Act). The Bill determines how the royalty received by the institution will be shared by the inventor, IP cell and the institution.

There has been much controversy surrounding the Bill even before it was introduced in Parliament, owing to the very secretive manner in which the Government has gone about drafting the legislation and getting it approved. The Bill has received the assent of the Union Cabinet without so much as a draft being released to the public and in the complete absence of a debate among stakeholders.

Introduced as a mechanism to encourage the commercialisation of publicly funded research, critics feel that the Bill also has the potential to reduce access to the outputs of publicly funded research, while harming future innovation. The Bayh-Dole, on which it has been modelled, has been under fire for doing very little in increasing public access to the innovation. The Universities Allied for Essential Medicines (op.cit.) point out that the Indian Bayh-Dole Bill replicates and magnifies the mistakes of the US Bayh-Dole Act.

It is apprehended that this Bill will only lead to monopoly over access to technology and hamper academic knowledge generation. Many feel that universities must be allowed to maintain their mission of diffusing knowledge, independent of state and market and without subordinating them to corporate interests.
Another serious flaw of the Indian legislation is that it contains very few provisions to safeguard public access. The U.S. Bayh-Dole Act recognizing the need to ensure public access to publicly funded inventions states that it is necessary to “ensure the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of inventions.” The federal government, however, retains "March-in" rights to license the invention to a third party, without the consent of the patent holder or original licensee, where it determines the invention is not being made available to the public on a reasonable basis. Critics point out that though these rights have never been successfully used, nevertheless, the fact that such provisions have been incorporated testifies to the importance of access in setting public policy. The Indian legislation, unfortunately, does not confer such rights. The only concession to public access is the provision that gives the Indian government the right to refuse title to a research institution receiving the grant within ninety days of learning of the research institution’s intention to retain a patent. Thus, in a marked contrast to the licensing and march-in rights of the Bayh-Dole, which are perpetual and automatic, this provision is available only for a brief, ninety-day window occurring immediately after the research institution announces its intent to retain title to a patent.

Thus, if the Indian Act is to address the problem of patent thickets, broad claims and patenting of upstream, basic research, which NT will give rise to in the future, the least it could do is to incorporate compulsory licensing provisions. The interests of ‘justice and equity’ demands that there is public access to the patented basic research and inventions funded with mostly government funds.

Arguments are also being made that the Bill has been drafted with the assumption that IPR is the best way to promote innovation, which is not always true. There is an increasing realization worldwide that collaboration, networking and sharing of knowledge can be a better business strategy than operating in isolation and appropriating or patenting information (Barpujari, 2008:6). The current intellectual property regime, characterized by the heavily patented nature of knowledge is gradually giving way to a new regime, with greater stress on sharing and collaboration instead of greater protection. ‘Old IP’ is increasingly being replaced by ‘new IP’ as there is a growing realization across the world and across different sectors of the many flaws of the old regime (International Expert Group on Biotechnology, Innovation and Intellectual Property, 2008). The Expert Group also recommends that universities and the scientific community, in keeping with the spirit of this new regime, need to ensure greater access and the use of licensing provisions that make it easy to conduct research and development on products needed by low and middle income countries.
Several definitions are available for the term ‘risk’. While some definitions include only adverse uncertainties, some take a more liberal approach and refer to both positive as well as negative uncertainties. Risk has been defined as an uncertain consequence of an event or an activity with respect to something that humans value (Kates et al. 1985: 21). The Society for Risk Analysis defines risk as ‘the potential for realization of unwanted, adverse consequences to human life, health, property, or the environment; estimation of risk is usually based on the expected value of the conditional probability of the event occurring times the consequence of the event given that it has occurred.’

The project views risks as heterogeneous uncertainty including environmental, health, occupational and economic risks. It even makes a distinction between individual risks and country risks and proposes an inclusive risk governance approach. (See TERI, 2008) In the overall governance of risks emanating from nanotechnology, regulations have a crucial role to play and this chapter examines the regulatory mechanisms in place to address the above-mentioned risks, except social and economic risks.

As mentioned earlier and depicted in the figure above, regulatory interventions for managing risks can be made at different stages of
research and production. Regulations for R &D have been discussed in the preceding section, and following is a discussion on regulations applicable for production and manufacturing, when it comes to market, comes into contact with consumers, public at large and the environment.

**Production and Marketing**

The regulatory framework for production and marketing of any technological application would vary from product to product. Healthcare applications and cosmetics are fast catching up. Other sectors like textiles, paints and chemicals; pesticides, food items, packaging etc are close. The regulatory regime for production and marketing would thus depend on the application. Here, we analyse in detail three separate acts for very different products and sectors – *First*, for drug and cosmetics, since most of the product development is taking place in this sector; *second*, for insecticides and pesticides, because use of nanotechnology for agriculture is being spoken about as a priority area and off late some developments in the field of nano pesticides also has taken place in India\(^\text{15}\); *third*, for food safety, since nano application in food items may have serious ramifications and our food safety legislation is fairly new, thus giving us an opportunity to incorporate nanotechnology related concerns from the start.

**Drugs and Cosmetics Act, 1940**

The Drugs and Cosmetics Act regulates all aspects of drugs and cosmetics pertaining to their import, manufacture, distribution and sale. Any manufacture or sale of drugs has to be in compliance with the standards laid down in the schedule of the Act\(^\text{16}\). A patent or proprietary medicine cannot be sold, unless the true formula or list of active ingredients contained in it along with the quantities thereof is displayed in the prescribed manner on the label or container\(^\text{17}\).

While the inspector is empowered to collect sample, inspect and seize drugs\(^\text{18}\), the central government is empowered even to prohibit manufacture, etc., of drug and cosmetic in public interest\(^\text{19}\). Such a prohibition can be imposed on import of drugs as well where such import is likely to involve any risk to human beings or animals or does not have therapeutic value.\(^\text{20}\)

\(^{15}\) The Indian Agricultural Research Institute has come out with a green nano pesticide – Deccan Herald December 18, 2007; Tamil Nadu Agricultural University is developing nano-herbicide – The Hindu, August 21, 2006

\(^{16}\) Section 16

\(^{17}\) Section 18

\(^{18}\) Section 22

\(^{19}\) Section 26A

\(^{20}\) Section 10(A)
One of the most important provisions of the Act relevant to growing nano based health applications in India is the very definition of “drugs” under the Act. The definition of “drug” includes medical devices. These will thus include gold/silver nano particles for targeted drug delivery, stents, implants, nano ceramics etc.

Although the Act mandates labelling of list of active ingredients, not much progress can be made in terms of bridging the information gaps around the use of nano particles, unless there is consideration of nano particles as either new or modified ingredients. Currently, for patented and proprietary medicine, the prescribed labelling standard format puts no obligation to disclose the use of nano particles as ingredients.

**National Pharmacovigilance Protocol**

The Pharmacovigilance protocol is a post-marketing tool in ensuring the safety of pharmaceutical and related health products. The protocol is designed to collate data, analyse it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public. There is provision for monitoring adverse drug reactions of medicines in order to identify previously unexpected adverse drug reactions or indicate that certain reactions occur more commonly than previously believed. All pharmaceutical companies are required to submit the Periodic Safety Update Reports (PSURs) every 6 monthly for the first 2 years of marketing in India, and annually for the subsequent 2 years.

The Advisory Committee shall assess the regulatory information relating to safety in order to determine what action, if necessary, needs to be taken to improve safe use. Based on the available data, the Advisory Committee shall make recommendations on product label amendments, product withdrawals and suspension. The National Pharmacovigilance Programme (NPP) shall encourage reporting of all suspected drug related adverse events, including those suspected to have been caused by herbal, traditional or alternative remedies. The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a widespread prescribing problem.

The NPP is a voluntary instrument and there is no framework under which the reports of adverse drug reactions can be addressed in a comprehensive manner. Regulatory assessment has been missing in the past studies of

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21 Section 3(b) iv
22 Para 6.1
23 Para 6.2
24 Para 6.4
drug reactions. Another area in which the protocol might be lacking is in terms of a clear conflict of interest. The duty to report adverse drug reactions is on the companies, which are developing and promoting those very drugs. The reporting should be done by a permanent and independent body, rather than being left to the companies earning profit out of the sale of drugs.

The Medical Devices Regulation Bill, 2006

In order to consolidate laws related to medical devices and to establish a Medical Device Regulatory Authority of India for establishing and maintaining a national system of controls relating to quality, safety, efficacy and availability of medical devices that are used in India, the medical Devices Regulation Bill was prepared in 2006 but has not been enacted till date. Prepared by DST, the bill defines ‘Medical device’ as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other article intended by the manufacturer to be used for human beings for the purposes of diagnosis, prevention, monitoring, treatment or alleviation of a disease, injury, or for investigation, replacement, modification, or support of a physiological process, supporting or sustaining life, and control of conception.25

The Bill views risk management as systematic application of policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk; risk being defined as ‘combination of the probability of occurrence of harm and the severity of that harm’.26

It provides for the establishment of a Medical Device Regulatory Authority of India to regulate and monitor the design, testing & evaluation, manufacture, packaging, labeling, import, sale, usage and disposal of medical devices, to ensure availability of safe medical devices for human use in the country.27 It can lay down regulations relating to essential principles of safety and performance of medical devices, and design and manufacturing requirements. One of the main functions of the MDRA is going to be providing for risk-based classification of medical devices. The essential principles governing a MDRA’s actions are as follows28-

- Use of medical devices should not compromise health and safety
- Design and manufacture of medical devices must conform to safety principles
- Medical devices should be suitable for the intended purpose
- Long-term safety must be assured

25 Section 12 (o)  
26 Section 12 z (bb)  
27 Section 13 read with section 35  
28 Section 66 and 67
- Medical devices should not be adversely affected by transport or storage
- Benefits of medical devices must outweigh any side effects

In principle the focus on risk management is commendable but a precautionary approach is not reflected adequately in the functioning of the Bill. Another concern with respect to the Bill is the fact that Drug and Cosmetics Act includes medical devices within the definition of drugs, therefore there will be overlaps and problems, especially in the transition phase for changing the regulatory authority from drug controller to the new medical device regulatory authority. Ministry of health and family welfare may be better equipped to regulate medical devices as compared to the DST, in view of its experience and overall ministerial mandate.

Insecticides Act, 1968

The Insecticides Act was legislated to regulate the import, manufacture, sale, transport, distribution and use of insecticides with a view to prevent risk to human beings or animals. The Act lays down a framework for registration of any new manufacture, import or sale of insecticides/pesticides and obtaining license thereof. A registration Committee is constituted to register insecticide after scrutinizing their formulae and verifying claims made by the importer or the manufacturer, as the case may be, as regards their efficacy and safety to human beings and animals. While making any application for such use, toxicity of the products to human beings, wildlife, aquatic animals has to be disclosed. Any misbranded insecticides can be prohibited from import of manufacture. It is a case of misbranding if -

(i) If its label does not contain a warning or caution which may be necessary and sufficient, if complied with to prevent risk to human beings or animals
(ii) if the insecticide has a toxicity which is higher than the level prescribe or is mixed or packed with any substance so as to alter its nature or quality or contains any substance which is not include in the registration

The Registration Committee can also recommend for a provisional registration upto 2 years, where the insecticide is being introduced for the first time. In nano pesticides, where all the risks are yet to be defined, a provisional registration would be useful as a short to medium term regulatory measure, which ensures promotion of technology while reserving the right to take it off the shelves at a later date, when there are

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29 Section 9 and 13 (1)
30 Section 5(1)
31 Form I, Rule 6
more certainties about the advantages (or lack of it).

The State Government may require a mandatory reporting of all occurrences of poisoning (through the use of handling of any insecticide). Reporting requirement should be mandatory across states and not left for states to notify. Moreover, it should not be restricted to poisoning but any adverse reaction/ effect. Reporting is an important post-marketing tool and in case of merging technologies, when risks may emerge at a later date, such reporting would be helpful.

**Food Safety and Standards Act, 2006**

Safety of food and food products till recently were under the prevention of food adulteration Act. The Food Safety and Standards Act, 2006 was introduced to lay down science-based standards, and to regulate manufacture, storage, distribution, sale and import of food articles to ensure safe and wholesome food. The Act, a fairly comprehensive one with much emphasis on “science based standards”, especially in response to sanitary and phyto sanitary measures agreement and developments at codex, has a number of relevant provisions for regulating use of nanotechnology in food processing and packaging industry.

Under the new Act, “food additive” means any substance not normally consumed as a food by itself or used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food but does not include “contaminants” or substances added to food for maintaining or improving nutritional qualities. Thus, nano particles used in packaging can easily be accommodated into this definition of food additives. Even ingredients refer to any substance, including a food additive used in the manufacture or preparation of food and present in the final product, possibly in a modified form.

Hazard means a biological, chemical or physical agent in food with the potential to cause an adverse health effect. Even risk, under the Act refers to probability of an adverse effect on the health of consumers. However, these terms are only with reference to food articles and do not extend to food packaging and such material.

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32 Section 3 (k), Food Safety and Standards Act, 2006
33 Section 3 (y) FSSA 2006
34 Section 3 (u)
35 Sec 3 (zm)
Under the Act, the food safety authority can prescribe standards determined on the basis of a risk analysis. However exceptions are made for developments with uncertain scientific justifications in the form of provisional measures. It is rare that any Act explicitly incorporates risk assessment in its functioning. FSSA has to take undertake risk assessment based on the available scientific evidence and in an independent, objective and transparent manner, before determining any standards. The State Commissioners are empowered to prohibit in the interest of public health, manufacture, storage, distribution or sale of any article of food.\textsuperscript{36}

The Act may have certain promising provisions but these can be put to use only if there exists a need for great technical expertise and information to make the use of the space that these provisions offer.

This is not restricted to food safety legislation. The above analysis shows that in principle, any new product or application has to go through a procedure for obtaining licences from a designated agency. In order to manage the risks at the very inception, it is at this level that regulatory institutions can be made. However, this requires recognition of nano particles as distinct ingredient (or with different properties) on a substantive level and up-to-date risk assessment and technical know how.

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**Occupational health and safety (OHS)**

Although, ‘occupational health risks associated with manufacturing and using nano materials are not yet clearly understood’\textsuperscript{37}, ‘one of the biggest challenges facing firms commercialising nanotechnology innovations today is managing environmental, health and safety (EHS) risks’.\textsuperscript{38} Employers of industries based on or drawing from nanotechnology are exposed to uniquely engineered materials with novel sizes, shapes, and physical and chemical properties. In laboratories and manufacturing units, exposure to nanoparticles occurs mainly through ‘handling nano particles produced for a specific purpose, and through working practices that generate nanoparticles as by-products’. (AIRI and Innovation Society, 2009: 26). To understand the impact of these exposures on health, and how best to devise appropriate exposure monitoring and control strategies, much research is still needed.\textsuperscript{39} Impeding such information, the major anxiety pertains to presence of nano materials in the closed environment of R&D laboratories.

\textsuperscript{36} Section 30 (2)(a)

\textsuperscript{37} National Institute for Occupational Safety and Health (http://www.cdc.gov/niosh/topics/nanotech/ohrisks.html)


\textsuperscript{39} National Institute for Occupational Safety and Health (http://www.cdc.gov/niosh/topics/nanotech/ohrisks.html)
to which scientists and workers are exposed constantly. In India, occupational health and safety is primarily governed by the Factories Act and touched upon by a few more legislation.

Factories Act, 1948

Factories Act is an old piece of legislation enacted for regulating labour in factories. Under the Act, the occupier is under a duty to safeguard health, safety and welfare of all workers while they are at work in the factory. He is also entrusted to ensure that the premises is free from risks to health in connection with the use, handling, storage and transport of articles and substances, and provide for maintenance or monitoring of such risk free working environment.

There are enough opportunities within the Act to address OHS risks from nanotechnology. As mentioned above, at this stage, when all the risks are not yet known, information flow is crucial. The Act specifies provisions for removing the informational gaps, which could lead to occupational health threats. While in general all occupiers have to ensure availability of information, instruction, training and supervision with regard to risks, occupiers of a factory involving any hazardous process is under an obligation to maintain accurate, up-to-date health records of the workers exposed to any chemical, toxic or any other harmful substances. The definition of "hazardous process" is broad enough to encompass any process or activity in relation to an industry specified where, unless special care is taken, raw materials / finished products/ bye- products/ wastes would-- (i) cause material impairment to the health of the persons engaged in or connected therewith, or (ii) result in the pollution of the general environment. Another important feature of the Act is that it recognizes rights of the workers to warn about imminent danger to their lives or health due to any accident and duty on the part of the employer to take remedial actions if satisfied about the existence of such a danger. The Act however lacks in various aspects in its ability to address challenges posed by emerging technologies. It is the designer, manufacturer, importer or supplier of any article who has the responsibility to ensure that the article he is providing in a factory is safe and without risks to the health of the workers. The definition of hazardous process is all-inclusive and wide enough to include nano particles, but it is restricted to industries in the

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40 An occupier is the person who has ultimate control over the affairs of the factory. [Section 2(n)]
41 Whereon ten or more workers are working, and in any part of which a manufacturing process is being carried on. Manufacturing process refers to any altering, repairing, ornamenting, finishing, packing, oiling, washing, cleaning, breaking up, demolishing, or otherwise treating or adapting any article or substance with a view to its use, sale, transport, delivery or disposal. [Section 2 (k), (m)]
42 Section 7(A)(1)
43 Section 7(A) and Section 41C
44 Section 41H
schedule. While the rights of workers to inform about the dangers is recognized, there have to be provisions for training of workers about imminent risks must be provided to enable the workers to exercise their right of warning.

**OHS under other legislation**

There are a few other instruments as well which are applicable for safeguarding occupational health and safety, but unlike, the factories Act, these are not specific legislation for workers safety. The *Manufacture, Storage & Import of Hazardous Chemicals Rules, 1989* promulgated under the Environmental Protection Act, 1986 lays down certain responsibilities of the authorities responsible for manufacture, storage and import of hazardous chemicals. However, it lists only a positive list of hazardous chemicals, which are defined in terms of dosage or content. The classification could recognize risks of nano particles and metals that change properties at nano scale.

*Emergency Planning, Preparedness and Response for Chemical Accidents* are provided for in the 1996 Rules. Even the *Hazardous Material (management, handling and trans boundary movement) Rules 2007*, whereby, occupier is responsible for safe and environmentally sound handling of hazardous waste can be fruitful in maintaining a safe and risk free working environment of places where nano particles are being used in manufacturing processes.

The primary legislation for OHS in India is fairly general and broad. It is broad enough to incorporate any EHS risk within its ambit. However, at the subordinate level, whether, factories law, chemicals or hazardous substances, nanoparticles would have to be separately listed and acted upon.

**Environmental Risk Management**

With the increase in development and greater and wide spread application of nanotechnologies, runs the risk of a noticeable increase in the production and release of manufactured nanoparticles into the environment. Such release could be in the form of direct emission, photochemical formation, accidental spills, and disposal of nano particles. *(AIRI and Innovation Society, 2009: 31)* In terms of human health, the exposure could be through medical intervention, inhalatory, oral and dermal exposure. *(Oberdörster, 2005)* These nanoparticles can be introduced into the atmosphere through fertilizers and remediation. *(TERI. 2008)*

General environmental legislation will be applicable for environmental
hazards flowing from nanotechnology application. However, since environmental laws and policies are broad and generic, there is no specific regulation of nanotechnology or introduction of nano particles in the environment. Therefore, there is a pressing need to look at how equipped the present environmental regime is to protect the public at large from any possible threat that nanotechnology may pose to its environment and health.

Pollution control laws

One of the earliest environment specific legislation of India is the Water Pollution Act. The Act takes within its ambit pollution by way of trade effluents and new discharges. Water is considered polluted when it is rendered harmful or injurious to public health or safety, or to domestic, commercial, industrial, agricultural or other legitimate uses, or to the life and health of animals or plants or of aquatic organisms. Any liquid, gaseous or solid substance discharged from any industry, operation or process, or treatment and disposal system (non-domestic) is treated as a trade affluent. In the context of new and emerging technologies, it is the definition of “new discharge” that deserves attention. Any discharge, which is not, with respect to the nature and composition, temperature, volume, and rate of discharge of the effluent substantially a continuation of a discharge made within the preceding twelve months. The Act has a two tier institutional framework comprising central and state pollution control boards, entrusted with functions like collection and publication of pollution data, laying down standards for and grant permission to establish any industry, operation or process which is likely to discharge trade effluent into a stream. The state board can even take suo motu action for removal of polluting discharge or restrain or prohibit such discharge.

The air pollution Act is also designed on similar lines and the State board has the power to inspect, any control equipment, industrial plant or manufacturing process and to give, by order, such directions to such persons as it may consider necessary to take steps for the prevention, control or abatement of air pollution. However, most of the provisions are applicable in the designated air pollution control areas only.

Environment Protection Act

Environment Protection Act (EPA) is an umbrella legislation under which several notifications and rules have been passed and most environmental

45 Section 2 (e)
46 Section 2 (k)
47 Section 25, Water Pollution Act
48 Sections 21, 24, 25 and 32, Water Pollution Act
49 Sec 17 (1) (e), Air Act
initiatives have been taken. The Act is in the nature of an enabling legislation designed in such a manner that there is space to address any of the environmental concerns by way of subordinate legislation or powers and functions of the designated officials. Even the definitions are broad enough to include as much aspects of environment as possible. Environment includes water, air and land and the inter-relationship which exists among and between water, air and land, and human beings, other living creatures, plants, micro-organism and property; and hazardous substance means any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plant, micro-organism, property or the environment.

Notifications with respect to standards of quality of air, water or soil, concentration limits of environmental pollutants, procedures and safeguards for the handling of hazardous substances etc are within the purview of the central government and has been the basis for many rules and notifications for environment protection. Not only environment protection from pollution, the Act has been used as a tool to regulate technology in the past as well. For instance, regulation of manufacture, use, import, export and storage of genetically engineered organisms or cells has been notified under the EPA. The main issue in this legislation being used for ensuring an environment free from possible risks of nanotechnology is awareness and will at the part of the government and officials. Awareness and recognition about risks associated with nano-particles with the environment protection agencies, standard setting agencies and implementing authorities is of utmost importance to ensure environmental health and safety, whether it is by way of pollution control acts, or the environment protection act.

### Public Liability Insurance Act

The Act provides for a framework for public liability insurance for the purpose of providing immediate relief to the persons affected by accident occurring while handling any hazardous substance. Any injury including permanent total or permanent partial disability or sickness resulting out of an accident has to be compensated for out of the insurance policy, which every owner shall take out, before he starts handling any hazardous substance. However, the Central government, any state government, PSU

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50 Section 2 (a)
51 Section 2 (e)
52 Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms Genetically engineered organisms or cells, 1989
53 Section 2 (ii)
54 Section 4 (1)
or any local authority may be exempted from this requirement of having an insurance policy, if they have any fund to meet a liability.\textsuperscript{55}

Beside environmental legislation, health and safety of humans, plants and animals is sometimes included within the product regulatory regime as well. Such an inclusion is normally with respect to revocation or licences or approvals. For instance, if a pesticide is likely to involve a risk to human being or animals the Government \textit{may} prohibit the sale, distribution or use of the insecticide or batch, in such area, and for such period as specified\textsuperscript{56}. In case of drugs, Central government has the power to prohibit sale, manufacture and distribution in the case of risk to humans and animals on public interest grounds\textsuperscript{57}.

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**Waste Disposal**

Although responsible waste disposal is a part of the overall environmental and health risk management we examine the regulatory framework of waste disposal separately, primarily because, generation and disposal of nano waste is perceived to be a great concern in rapid advancement of nanotechnology. (Breggin and John, 2007)

**Factories Act**

Factories Act, with a view to protect the workers of an establishment, puts a duty on the occupier to make effective arrangements shall be made in every factory for the treatment of wastes and effluents due to the manufacturing process to make them innocuous and for their disposal\textsuperscript{58}

**Hazardous Material (Management, Handling and Trans boundary Movement) Rules 2007**

The 2007 Rules for handling of hazardous waste rules in supersession of 1989 rules can be made applicable to nanotechnology waste, albeit with certain changes in the text and implementation of these rules. “Hazardous waste” has been defined to include any waste, which by reason of its physical, chemical, reactive, toxic, flammable, explosive, or corrosive characteristics causes danger or is likely to cause danger to health or environment, whether alone or in contact with other wastes or substances.\textsuperscript{59}

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\textsuperscript{55} Section 4 (3) 
\textsuperscript{56} Section 27. insecticides act 
\textsuperscript{57} Section 26 DCA 
\textsuperscript{58} Section 12 (1) 
\textsuperscript{59} Section 2 (1)
Under the Rules, the occupier is responsible for safe and environmentally sound handling of hazardous waste. It is mandatory to have the authorization of state pollution control board before generation, processing, treatment, package, storage, transportation, use, collections, destruction, conversion, selling of any hazardous waste.\(^{60}\) Even where, such authorization is granted, the procedure for storage, recycling, processing and reuse of hazardous waste has to be in conformity with the Act.\(^{61}\)

Given the broad scope of the hazardous materials rules, issues in end of life treatment of nano particles and other nano waste can indeed be addressed hereunder. However, this would entail explicit inclusion of nano waste as a hazardous waste. This may require detailed risk assessment and toxicity level study of waste generated out of nanotechnology application. The guidelines for handling of waste has to take into account the characteristics of nano-waste and this too can take place only when there is enough awareness and understanding of the risks on the part of policy makers. Therefore, institutional capacity and coordination is crucial in this regard. The institutional issues have been discussed in detail in the next chapter.

The Bio-Medical Waste (Management and Handling) Rules, 1998

The Rules issued under the EPA enjoins every occupier of an institution generating bio-medical with a duty to take all the steps to ensure that any bio-medical waste\(^{62}\) is handled without any adverse effect to human health and the environment. The rules explicitly lay down that the bio-medical waste shall be treated and disposed of in accordance with the schedules and standards prescribed. Requisite bio-medical waste treatment facilities like incinerator, autoclave, microwave system for the treatment of waste, or, ensure requisite treatment of waste at a common waste treatment facility or any other waste treatment facility too have to be set up by the occupier. \(^{63}\)

The Municipal Solid Wastes (Management and Handling) Rules, 2000

The Municipal Solid Wastes (Management and Handling) Rules, 2000 identifies municipal bodies as the responsible agency for any infrastructure development for collection, storage, segregation, transportation, processing and disposal of municipal solid wastes. “Municipal solid waste” includes all commercial and residential wastes generated in municipal or notified areas in either solid or semi-solid form excluding industrial hazardous wastes but including treated bio-medical wastes. In the context of nanotechnology,

\(^{60}\) Rule 5 (1)  
\(^{61}\) Chapter III  
\(^{62}\) Rule 4; Under the Act, "Bio-medical waste" means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biological  
\(^{63}\) Rule 5 (1) and (2)
one has to revisit this definition and ascertain whether all nano-waste falls under industrial waste or not.

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 legislation, 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. In consideration of the stage at which nanotechnology development is in India, and there is knowledge and certainty about risks and benefits of the same, a technology specific overarching law for nanotechnology may not be desirable or feasible. Because, such a regulation, at least if formulated at this stage would be partial and soon become obsolete. Moreover, the scope of nanotechnology applications is vast, and a lot is still in the domain of uncertain. Therefore, having an existing regulatory framework, which is flexible enough to incorporate concerns of nanotechnology, seems a better option. This approach to regulation involving adaptation of existing sectoral laws to the regulation of nanotechnologies, is popularly referred to as the ‘incremental approach’ and has been widely employed in the European Union and the United states with respect to nanotechnology regulation (European Commission, Health and Consumer Protection Directorate General (2004), Frater et. al. (2006), Davies (2008: v-vi), Franco et.al., (2007) etc.).

This approach does not mean that nothing needs to be done. On the other hand, it involves ‘the launch of a process which uses existing legislative structures (e.g. dangerous substances legislation, classification and labelling, cosmetic legislation etc.) to the maximum, revisits them, and when appropriate only, amends them in order to deal with nanomaterials. It also includes issuing recommendations, commissioning studies, promoting risk assessment throughout the life cycle of a nanotechnology, encouraging actions of existing institutions, supporting observations of nanotechnologies, initiating a minimalist, appropriate and proportionate regulatory intervention and setting up of a framework within which stakeholders can help shape the course of nanotechnologies’ (European Commission, Health and Consumer Protection Directorate General, op.cit.: 24).

In other words, it implies making use of the exiting framework, which allows developing new guidelines, rules and protocols. Coming to the Indian context, even to make use of the flexibilities, depending on the act or rule in question, at least one of the following would have to be done to respond –

- Read into the existing provisions to enable regulation of risks emanating from nanotechnology
- Amendments in primary/parent legislation
- Changes/amendments in subordinate legislation
  - For example, introducing nano particles as a distinct entity alongside other existing chemicals and particles
  - Guidelines for risk assessment or any other action in this regard
  - Make use of monitoring and reporting mechanisms
- Intervene through executive orders
- Use of discretionary powers and duties enjoined upon the designated authorities and implementing agencies.

Besides, a greater emphasis would have to be placed on risk assessment and incorporating them within the regulatory process. The process has to be dynamic and be equipped to address the risks, when they are defined. Till that time, a precautionary approach can be adopted, at least in managing environmental risks, where precautionary principle has already been declared to be a part of law of the land. All the actions listed above can be taken only at the level of regulators, often with the help of research bodies, some at the stage of designing regulations, while others at the stage of executing them. In light of this, the next chapter discusses the institutional dynamics in regulation of nanotechnology development in India.
Chapter 3: Institutional Framework

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

In India, the Ministry of Science and Technology is the nodal ministry for promotion of research and development in the area of technology. With its mandate clearly focusing on promotional aspects of technology, and given the perception and approach towards both development and regulation prevalent in the policy scenario, the ministry of science barely has anything to do with regulation. Regulation of technologies is normally a domain of other agencies, some dedicated and some general regulatory bodies. This chapter elucidates upon the roles different agencies play in development and regulation of technology and where they intersect (or need to).

Technology regulation in India

Chapter 1 discusses the role of technology development in the national development agenda in post-independence India. One of the outcomes of the focus on technology development as part of the state development agenda has been the setting up of individual departments at the level of central government with a view of promotion of specific technologies, thus we have the Department of Biotechnology, Department of Atomic Energy and the Department of Information Technology. The setting up individual departments is to provide strategic leadership and guidance for technology development in the specific sectors like ICT and Biotechnology. In this case therefore the primary objective of the department is to promote and facilitate the development of that technology. In this context the obvious question that arises is to what extent the privileged position of technology development in the state agenda may compromise the regulatory role of the state. More specifically, does the existence and functioning of a government department solely dedicated to technology promotion may compromise and to a certain extent limit the regulatory role of ministries/departments that address issues of risk regulation of emerging technologies. The issue of institutional arrangements has implications in terms of determining the regulatory space available for undertaking risk regulation in the context of emerging technologies like nanotechnology.

The Ministry of Science and Technology administers its functions through
three departments – department of science and technology (DST), department of biotechnology (DBT) and department of scientific and industrial research (DSIR). Of these DST is the most important one with the objective of promoting new areas of science and technology and to play the role of a nodal department for organizing, coordinating and promoting S&T activities in India. However, even with respect to promotion, not all technologies fall under the purview of department of science and technology ministry. For instance, there is a separate department within the ministry for biotechnology and information technology is governed by an altogether different ministry for Communications and Information Technology. Given that biotechnology, information and communication technology are the two main new technologies, it is pertinent to take note of the fact that dedicated agencies have been created for both the technologies. To what extent are these dedicated agencies successful in actually promoting and developing the technology is not a subject of this paper but the question that arises and needs to be answered is do we need a separate department for promotion and regulation every time we have a new or emerging technology? And what should be the institutional framework for a technology, which is an enabling technology and would find it being applied across sectors, products and often in concomitance with other existing technologies?

**Institutions for nanotechnology regulation: Agency dynamics**

Currently, DST is the most instrumental wing of government for providing a thrust to nanotechnology development. The Department, engaged with the agenda of promoting nanotech as a thrust area, has declared large investments for basic and applied research promotion, infrastructure support, education and international collaboration under the Nano Mission started in 2007. Speaking at the Indo-US Conclave on nanotechnology in 2006, the then President Dr. APJ Kalam called for mounting ‘a mission mode operation to deliver tangible products to meet our national demand as well as to be beneficial to the other countries’. These views can very well be linked to the vision of the departments under the aegis of Ministry of Science and Technology. Last few years have witnessed a huge investment both in terms of finances and efforts targeted towards nanotechnology development in India. Rupees 1000 crores have been allocated for Nano Mission for a period of five years. A statement, rather caution, made by an eminent scientist and the chairman of the Nano Mission Council captures the mood of the Nanotech situation in India. Speaking at the 93rd Indian Science Congress, Prof CNR Rao said, “If we don’t join the (nano) race, we will be left behind”. It is this fear of being left behind by other countries in the nano revolution that has triggered a single

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64 Dr. A.P.J. Abdul Kalam’s address at the inauguration of the Indo-US Nanotechnology Conclave held on Wednesday, February 22, 2006 at New Delhi. Source: Press Information Bureau, Govt. of India
point agenda for giving a thrust to nanotechnology R&D and application.

Nano Mission is an umbrella programme implemented by DST for capacity building towards overall development of the field of nanotechnology research in India. Of the total proposed outlay of Rs. 19,300 crores for Department of Science and Technology under the XI five-year plan, Rs. 1000 crores have been assigned for the nano mission. There are certain public private initiatives in the form of industry-linked projects under the Mission, half of which are with companies dealing with drugs and pharmaceuticals.\(^{65}\)

Given that nanotechnology is an enabling technology that finds its application at various levels and in different spheres, often in concomitance with other technologies, departments such as DBT and Department of Information Technology (DIT), which have an otherwise dedicated mandate, are also taking a plunge.

Even Defence Research and Development Organization (DRDO) and DSIR too have been fairly proactive in capturing the excitement around nanotechnology. DRDO, which has fullerenes & Nano tubes as one of the thrust areas in Materials research, has developed diagnostics tools for TB and typhoid, by using nanotechnology.\(^{66}\) The chief controller of R&D at DRDO, Mr. A. Sivathanu Pillai recently forecasted that, “Nanotechnology is the science that can ensure sustainability of agriculture and food production and give a solution to water and energy crisis. These two areas would witness an investment of $45 billion per year in nanotechnology research in the next 10 years.”\(^{67}\)

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. Recently, the commerce secretary also has made a public statement emphasizing how ‘India would not be able to do without it (nanotechnology), and Indian companies should be encouraged to get into it at the earliest’. (Economic Times, 2008\(^{68}\))

\(^{65}\) IIT Madras is working with Murugappa Chettiar & Orchid Pharma, University of Hyderabad with Dr. Reddy’s Labs and NIPER, Chandigarh is also working with Pharma industry. Source: Nano Mission


\(^{68}\) Nanotechnology is the future for Indian firms: Commerce Secretary. 25 Mar, 2008, The Economic Times
Industry associations have also joined in the pursuit of promoting nanotechnology in different industrial applications. The Confederation of Indian Industries (CII) launched the nanotechnology initiative in 2002 to bring technologists, scientists, academicians and users on board with a view to forge partnerships for collaborative research and product development, explore the possibilities of Indian industry to take part in these and setting up joint ventures in India. The initiative identifies Bio-nanotechnology, drug discovery and delivery as one of their focus areas. In 2008, it even put together a 10-point action plan aimed at empowering the industry to benefit from commercialization of nanotechnology through programmes on generating awareness, capacity building, technology facilitation and collaborations. Like CII, other industry associations and business promotion organizations such as the Associated Chambers of Commerce and Industry of India (ASSOCHAM) are also looking at pharmaceuticals, FMCG and electronics as focus areas for nanotechnology applications.

These associations and chambers of commerce have been promoting nanotechnology not only at national level but sub national levels as well. In Tamil Nadu, a joint programme of Tamil Nadu Technology Development & promotion Centre (TNTDPC) and CII is building awareness about and facilitating the technology amongst other things. The Tamil Nadu government is proposing a nanotechnology park, on lines of Hsinchu Science Park in Taiwan, for which an investment friendly climate will be provided and public private partnership will be developed. In the state of Kerala, a new centre has been established as the first Government of India-funded initiative for nanotechnology in tissue engineering and stem cell research in India.

Thus, there are several regulatory bodies, research bodies, industry organizations and implementing agencies that together create and manage the regulatory landscape for any technology or its application. All the institutions, irrespective of their role and functions, influence regulation directly or indirectly. For instance, even though DST has a clear mandate of promoting nanotechnology research, application and commercialisation, its actions do impact the manner, in which the overall governance framework is designed and implemented.

Planning Commisision WG On drugs and pharmaceuticals.
69 Confederation of Indian Industries (CII); URL http://cii.in/documents/Technology/page1.pdf
71 ‘Tamil Nadu plans nanotech park’ News item in Business Standard November 07, 2007
Thus 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. The following section focuses on regulatory institutions.

**Role mapping and identifying points of regulatory intervention**

While a number of institutions both public and private, are lead players in nanotechnology, what is noteworthy here, is that all the attention that nanotechnology and its application has received has been focusing on its promotion and not so much on the assessment and management of risks associated with it. It would not be correct to say that there is no institutional framework in place to regulate the development and application of nanotechnology. Notwithstanding the efficacy, products based on nanotechnology, like any other technology, are subject to some regulations or another and fall under the purview of various regulatory institutions, but the real issue is whether their nano characteristics are being regulated or not. *For instance*, nano-based pharmaceuticals are regulated by same agencies as for any other pharmaceuticals; nano pesticides or insecticides would have to get approvals from the Central Insecticides Board and Registration Committee; although at an early stage, food items using nanotechnology for enhancing certain properties would be governed by food safety and standards authority. It is neither possible nor the mandate of this report to do a complete mapping of regulatory institutions and interventions for nanotechnology across sectors and processes. The report purports to look at institutional frameworks of regulation to understand and discuss the issues in effective governance of nanotechnology. In this regard, it examines nano applications in health sector in detail, an important sector, both in terms of the R&D and investments, and the possible risks associated.

The lack of engagement with the risk assessment and management of nanotechnology is not just an issue of prioritisation of public research funding, the gap is reflected even in the institutional framework that exists. The agencies with a focus on nanotechnology have a clear mandate of technology promotion. Regulatory agencies, which have the function of regulation of health and health products, are not able to lay adequate attention on possible risks emanating from nanotechnology due to a number of factors. Institutionally, Ministry of health and family welfare (MoHFW) is in charge of prevention and control of health related hazards but has not been sufficiently included in the overall nanotechnology regulation governance. MoHFW has been indeed engaged with nanotechnology but that has been primarily by way of the research on nanotechnology applications in health sector by Indian Council of Medical
Research (ICMR). Another level, at which the ministry plays an instrumental role, is that of regulating drugs and pharmaceuticals through the Central Drugs Standards Control Organization.

Most of the current and forthcoming research and application of nanotechnology in the health sector are around diagnostics and drug delivery. In India, medical devices such as implants are considered to be drugs and included under the drug regulatory legislation. However, not much progress has been made as yet on regulating nano based drug delivery in particular. Currently, they are regulated by the instruments and institutions for drugs and cosmetics regulation in India.

Regulatory and standard setting institutions

Central Drug Standard Control Organization

CDSCO is the primary drug regulatory authority in the country. It essentially coordinates all the functions relating to quality control of imported drugs, coordination of activities between the state authorities, new drug approvals for drugs manufactured and imported. The approval of new drugs entails examination of the clinical trial reports and checking them for bio-equivalence, etc before granting marketing approval. As discussed above the CDSCO is also the implementing agency for the National Pharmacovigilance Program. In this context, it would be useful if CDSCO pushes for a more intensive program in tracking information on nano applications in the health sector.

CDSCO, although a separate organization, works within the structure of DGHS and its mandate, activities, infrastructure etc. fall under the purview of the directorate. DGHS is the agency overseeing the implementation of the various health programs and schemes and provides technical inputs to the ministry on various aspects of their functioning and implementation and serves as a coordinating agency for all the specialized health related matters including drug regulation and standard setting.

Under the Drug and Cosmetics Act, 1940, state drug controllers are enjoined with the duty to oversee the regulation of drugs within the country. Any manufacturer or importer has to obtain a licence from the state drug controllers depending on the jurisdiction. The licences are approved by the central licence approving authority, i.e. Drug Controller General. Thus the primary responsibility lies with the state controllers.

Bureau of Indian Standards

The Bureau of Indian Standards (BIS) is the chief Standard Setting body in India and sets voluntary standards to indicate the quality of a product. BIS
standards are generally voluntary but some of the BIS standards become mandatory when notified to that effect by the government. It is engaged in formulation of Indian Standards for the 14 sectors including Metallurgical-Engineering. Under this, a sectional committee\textsuperscript{73} has been set up with scope of standardization in the field of nanotechnology. The committee is meant to liaison with Technical Committee 229 of International Standards Organization (ISO) and represents India in the international standard setting process for nanotechnologies. It is crucial that the representatives at international standard setting fora are equipped to voice the concerns of developing countries.

Environment regulatory agencies

Other institutions, which are not exclusive to health sector but are potentially influential, are agencies like environment regulatory bodies. For instance, safe management of nano waste is an important issue in general as well as in the case of nano based health applications. The State Pollution Control Committees are responsible for granting authorisation for collection, reception, storage, treatment and disposal of bio medical waste. Similarly, during the manufacturing process, under the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996, there is a provision for a state and local crisis management group. There is some overlap of functions between centre and state groups for reviewing district off-site emergency plans. Local crisis groups are entrusted with the responsibility to train personnel involved in chemical accident management, but there is no effort towards building the capacity of local actors and stakeholders in this regard. Other institutions like the Central Pollution Control Board, State Pollution Control Board also may play a role in regulation, depending on the over all nature of the process and manufacturing unit. (See Annex 2)

Another kind of institutions, which influence the regulatory framework, is research bodies. Although these per se do not impact regulation, but given their nature, mandate and reach, influence the overall regulatory design of a technology or sector.

Research Bodies

Indian Council of Medical Research

The ICMR under MOHFW is the apex government body engaged with the development and implementation of biomedical research in India. With public health as its key mandate, it invests in research that has been identified as national health priorities, such as, control and management of

\textsuperscript{73} Nanotechnologies Sectional Committee, MTD 33
communicable diseases, fertility control, maternal and child health, control of nutritional disorders, alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, and drug research.

A key question is whether ICMR would invest in R&D with regard to nanotech applications in health in terms of determining the toxicity and other aspects. The possibility of such a development is quite low, as nanotech is a not a national priority in terms of health care. However, in case of environmental and occupational health problems, the potential exposure and toxicity effects of nanotechnology. ICMR is currently funding a few nanotech related health research and there exists a responsibility to ensure that ICMR supported research is in conformity with the occupational health and safety standards. However the larger question is whether the ICMR as a government body is obliged to invest in the toxicity aspects of health related nano products. A look at the recent funding pattern of ICMR seems to suggest that the ICMR is also directing its research funds into projects dealing generally with drug delivery services based on nano particles. This is clearly a good investment strategy but does not contribute anything as such to ICMR’s responsibility towards public health. To reiterate, ICMR’s moral responsibility lies in investing in research that would address public health aspects and in that sense toxicity and other effects of health related nano applications in the market. To this effect, ICMR is planning to set up a nano medicine cell shortly.

Council for Scientific and Industrial Research

Another premier government research body is the Council for Scientific and Industrial Research (CSIR), which was established with the idea of providing scientific industrial R&D for economic, environmental and societal benefits for the people. It has been supporting research in several areas including health and as per the CSIR reports, eleven of the fourteen new drugs developed in independent India are from CSIR. Although no major drug research involving nanotechnology is being carried out under the aegis of CSIR at present, considering the past record of CSIR in drug research, there is a possibility of greater involvement of the Council in nanotech related health applications as well.

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74 For more details see http://www.icmr.nic.in/abouticmr.htm accessed on 25 February 2008.
75 Personal communication with Dr Sitaramaiah Mokkapatti, DDG (SG), Indian Council of Medical Research on March 12th 2009
76 http://www.csir.res.in/External/Heads/csir_faq.htm
77 Most of the nanotechnology related studies under the CSIR relate to metals and metallurgy and chemicals only with occasional studies in other development areas such as water and energy.
Indian National Science Academy (INSA)

INSA seems to be the only government scientific body that has a clear mandate to liaison between science and humanities and has a specific committee set up for drawing ethical guidelines for pursuing Science. The Academy has had a considerable role to play in influencing the overall policy making for technology over the years and it would be worthwhile for it to set up a specific committee on ethical issues involved in nanotech applications in key sectors.

Key challenges for regulatory institutions

Regulatory Capacity

Any regulation is as efficient as those framing it and implementing it. Hence, regulatory capacity is one of the pre requisites of a competent institutional framework. Capacity for formulation of rules, policies and guidelines, as well as implementing it is crucial. As we have seen in the previous section, there are several amendments, initiatives at the level of rules, notifications, schedules etc required for enabling the existing regulatory regime to respond to the challenges posed by nanotechnology. Such interventions would require great amount of technical expertise and foresight on the part of policy makers and regulators.

The implementing agencies 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.78 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 (National Institute of Pharmaceutical Education and Research), under the Ministry of Chemicals and Fertilizers (MoCF) and at the IITR (Indian Institute of Toxicology Research), a CSIR laboratory.

The analysis of IPR issues also highlights the fact that there is a need for providing training to patent examiners and special examiners for handling NT patent applications. Leave alone examiners specially trained to deal with NT applications, but even generally the Indian Patent Office is on the verge of a human resources crisis based on a lack of examiners. As of March 31st, 2007, The Patent Office in all its four branches employed only 171

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78 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.
patent examiners (for all technologies), not including senior staff positions such as Deputy and Assistant Controllers. 79 Again, as of March 31st, 2007, there are only 133 working examiners with technical specialization in fields like agriculture, bio-chemistry, biotechnology, chemistry etc. There is no patent examiner with specialization in nanotechnology. While separate classes exist for chemical patents, food, drug, electrical patents, mechanical, computer/electronics, biotechnology and general, NT patents are not recognized as a separate class of its own right. Building better capacity among patent attorneys to draft NT specific claims as framing of patent claims is crucial in any application but more so in a new technology like NT.

Flow of information

Lack of capacity can also be linked to informational asymmetry. A smooth flow of information is necessary for building institutional capacity and taking regulatory measures. Since the main concerns around nanotechnology are the EHS risks, regulation 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 regulators. 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. Hence, the information amongst agencies, with different mandates, such as DST, DSIR, MoHFW, MoCF 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 favourable to the well being of public at large.

Availability of information is absolutely essential for regulating the intellectual property rights issues in nanotechnology, especially because of the nature of the technology and novelty of the subject. In India, lack of informations access is a problem not only for nanotechnology, which is new, but also for technologies like biotechnology, which has been around for quite some time in India. The Indian Patent Office Journal is published electronically every week, but is not indexed and difficult to search. In this regard, a better indexing and management of prior art databases and drafting of guidelines for examining nano patent applications by the Indian Patent Office should prove to be useful steps in both short term and long term.

Inter-agency coordination

Another related 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 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. 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 within a ministry, this gap is evident. The issues in effective drug regulation have been raised time and again by different committees which have suggested coordination between state units, states to provide personnel, testing facilities and support systems and adoption of post-marketing surveillance. Some of these are in fact covered by the National Pharmacovigilance Protocol, set up with the primary aim of the of creating and managing a database of reports of Adverse Drug Reactions (ADRs) that would form the basis for regulatory decisions for market authorizations of drugs in India. Given that there is still widespread uncertainty as to the health implications of nanotechnology applications, these reporting requirements making it obligatory on the part of the pharmaceutical company marketing lays the foundation for a vigilant and early detection system of any adverse reactions.

Even outside the health sector, nanotechnology applications may raise several health concerns. Risks discussed in work package 2 could be in the nature of occupational health, consumer health and environmental health. Occupational health is the prerogative of Ministry of labour, health is the mandate of ministry of health and family welfare, and environment is governed by the ministry of environment and forest.

The hazardous material rules mandate SPCB approval for generation,

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80 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.
processing, treatment, package, storage, selling of hazardous waste but it is important to make sure that the actions of SPCB and other institutions in coordination with respect to reporting of adverse impacts, latest technologies etc. for safe management of hazardous waste.
Globalisation has had a number of effects on the domestic legal system of nations. There has there been a clear movement upwards in terms of internationalisation of regulatory competencies. This however does not result in the loss of regulatory competence on the part of the national regulators, but results in shared competences by institutionalising channels of influences. However to what extent this co-regulation is equally balanced or two way traffic—so as to speak—will be contingent on how powerful the national regulator is to influence and to an extent co-opt the regulatory international process to reflect its national policy priorities.

However, since level of international influence is an important component in designing or adapting any regulatory framework, following is a brief overview of the landscape of regulatory developments internationally and a comment on the influence these developments will have on the national system. As in the case of domestic regulatory mapping, the chapter looks at international regulations for (i) IPRs and (ii) risk regulation and standardisation.

### Nanotechnology IPRs at international fora

As with the emergence of any new technology, nanotechnology (NT) creates issues, opportunities and concerns in adapting the intellectual property rights (IPR) regime to its particular context. This is to a large extent magnified in developing and least developed countries, which irrespective of their state of technological advancement, are obliged to confer intellectual property (IP) rights in the new technology. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement obligates all WTO (World Trade Organisation) member countries to adopt and enforce minimum standards of intellectual property, with WTO members having to allow patents in all fields of technology. This carries the implication that all WTO members (even least developed countries) are obligated to provide intellectual property rights in the emergent field of nanotechnology.

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82 Knill C and Lehmkuhl (2002); Private Actors and the State: Internationalization and Changing Patterns of Governance. *Governance*, 15, Issue 1, 43. Also see Majore, G (2004) The Internationalization of Regulation: Implications for Developing Countries, Centre on Regulation and Competition (CRC) Working papers 30685, University of Manchester, Institute for Development Policy and Management (IDPM).

83 Article 27 (1) of TRIPS provides that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

84 Least-developed countries have, however, been given an extension until 1 July 2013
Though in its nascent stage, at present, nanotechnology is a very active field internationally, with respect to the number of patent applications. However, the scope of NT is not restricted to patents, but extends to other IPRs as well. In addition to patents, other IP tools like trade secrets, copyright, industrial designs etc. could become increasingly important to inventors and industries dealing with NT. However, patent remains the most preferred form of IPR protection for NT and in this report, the discussions, would be basically centred on patenting of NT.

In the context of IPR protection for new and emerging technologies, the Standing Committee on the Law of Patents of the World Intellectual Property Organisation (WIPO) observed that the patent system constantly faces the question as to whether and how it can adapt itself to new technologies. It says that certain questions are a matter of interpretation of existing laws, for example, whether a new technological creation falls under the definition of ‘invention’ under the applicable patent law. It, however, stresses that the IPR regime should keep in mind the public policy and public welfare perspective in addressing the question as to whether such new subject matter should be covered by patent protection or not. It needs to carefully weigh the consideration in favour of creating a new legal mechanism to protect the creation or adapt and revise the patent law to accommodate the new technology. The Standing Committee admits that there is no one single straight-forward answer to the question.

Apart from the question of adaptability of the patent system to deal with new technologies, patenting of such technology also requires harmonizing between two imperatives. On the one hand, the patent system should be sufficiently rewarding for the inventor, in the absence of which innovation, research and development will be stifled. This is an objective which the domestic patent regime of every country aspires to. At the microeconomic level, IPRS provide a means by which innovators and investors can recover the investment of time and money needed to bring a new product into the market. At the macroeconomic level, intellectual property is expected to promote economic development by encouraging domestic innovation and foreign direct investment (Goans, 2003: 3).

On the other hand, critics argue that patent protection is not likely to

(though initially the transitional period was due to expire in 2006) to provide protection for patents, trademarks, copyright and other intellectual property under the WTO’s agreement. This was following a decision reached by member governments on 29 November 2005 (“Extension of the Transition Period under Article 66.1 for Least Developed Country Members”, Decision of the Council for TRIPS of 29 November 2005), http://www.wto.org/english/news_e/pres05_e/pr424_e.htm (accessed on March 1st, 2009).

contribute to increased growth in countries below a certain threshold in terms of level of development. The debates over protection of intellectual property rights are largely polarized between developed countries, which produce most of the world’s intellectual property and are advocates of strong international protection, and developing countries which perceive that the payment of monopoly rents for the use of intellectual property is detrimental to their development process (Kerr et al., 1999: 203-11).

Thus, the key question which emerges with respect to patenting of new technologies in a developing country like India, is how to achieve a reconciliation between these two conflicting objectives—the need to create an enabling, incentive based environment for innovation and at the same time, deter monopolies and serve the public good, which is actually the ultimate goal of an IPR regime. The challenges are compounded particularly in the field of NT, as NT poses some unique problems, both for the inventor as well as from the public good perspective.

Global Nano IP Landscape and major players

According to the ETC Group (2005: 6), patenting in nanotechnology has acquired a ‘tsunami-like’ strength since the early 1990s and is increasingly growing. Lemley (2005: 1) observed that both universities and companies are rushing to the patent office in record numbers to patent nanotechnology inventions. In his view, this rush to the patent office is so significant that many law firms have established nanotechnology practice groups, and the U.S Patent and Trademark Office (USPTO) has now created a new technology class designed to track nanotechnology product.

According to a report by Lux Research. Inc. (cited in ETC Group, op.cit.: 7), as of April 2005, 3,818 nanotech-related patents were issued by the USPTO between 1985- March 2005, with an additional 1,777 patent applications. According to researchers from the University of Arizona and the U.S. National Science Foundation (ibid.) about 8,630 nanotech-related patents were issued by the USPTO in 2003 alone, an increase of 50% over the previous three years. The top five countries represented were: US (5,228 patents), Japan (926), Germany (684), Canada (244) and France (183). The top five entities winning nanotech-related patents included four multinational electronic firms and one university: IBM (198 patents), Micron Technologies (129), Advanced Micro Devices (128), Intel (90) and University of California (89).

An OECD (Organisation for Economic Co-operation and Development) Directorate report (2007) says that the highest amount of patenting activity in nanotechnology is going on at the USPTO, the EPO (the European Patent Office) and the Japan Patent Office (JPO), which have realized the
need to update their patent regimes to cater to this new technology. According to the same report, which has analysed nanotechnology patent applications at the EPO from 1978 to 2005, the US accounts for about one third of NT patent applications, followed closely by Japan and the EU. Germany, France and the United Kingdom are the leading countries in the European Union. Korea, Switzerland and Canada are also quite ahead in this race to patent NT. The business sector accounts for 80% of the patent applications, followed by government (5%) and higher education (8%) sectors over this period.

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**International Sub-political sites of risk regulation**

There has been a growing trend towards the acceptability of international forums/institutions as efficient and effective sites of regime creation. These sites are characteristically sub-political in nature in as much as they lack effective legitimacy and formal rule making power. The Intergovernmental Forum on Chemical Safety (IFCS), International Standards Organization (ISO), and the International Risk Governance Council (IRGC) are three such sites that have been identified.

This section explores these three sites of regime creation through the theoretical construct of the Beckian notion of sub-politics. The term “sub-politics” denotes political decision-making beyond the realms of the formal state and without a clear and unambiguous legal mandate under international law. We have characterised IFCS, ISO and IRGC as international sub-political sites since these three organizations demonstrate characteristics of emerging international sub-political sites in the context of regulation of nanotechnology. Sub-political sites as compared to the arena of formal politics inherently suffer from a democratic deficit so crucial to provide legitimacy to their decisions. These sites therefore prefer indirect means of policy implementation. Thus another aspect of the impact of these institutions on the formal policymaking process is the indirect channel of influence that they exercise. This section will comment on these channels of influence or linkages and their possibility of influencing the Indian regulatory regime. These sites also illustrate the regulatory competition (Raustiala, 1997) amongst some of the developed countries in advancing their own regulatory norms within the international arena.

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 regulation is still at a nascent stage and essentially reactive in nature, the deliberations within these two sites could have considerable influence in its development and functioning. This per se

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is not problematic, however the concern arises in the context of the inherent structural limitations within these institutional sites coupled with technical and financial capacity deficits confronting developing countries like India, which severely limits and considerably delegitimizes the substantive norms originating from these institutions.87

Following is a theoretical assessment of the identified sites, viz., ISO, IFCS, and IRGC to ascertain their sub-political nature. Herein the norm creating activities of these sites within the field of nanotechnology would also be discussed.

International Organization for Standardization/ ISO

The ISO or the International Organization for Standardization is the premier international organization that is the largest developer of international standards in both goods and services globally. Its own introduction on its website states that it is a network of national standards institutes where adoption of standards is based on consensus (Murphy and Yates, 2008). The ISO is also uniquely public-private in nature given that these national standards institutes sometimes are public institutions in certain countries (for instance in the case of BIS in India) and in others, are largely industry sponsored/supported bodies (ANSI in the USA). Thus the ISO is unique in terms of providing for institutionalised mechanisms for both public as well as private representation.

The ISO has been fairly active in engaging with aspects of material standardization of nanotechnology and has set up a specific technical committee – TC/229 that deals with nanotechnologies. Standardization includes developing standards for terminology and nomenclature, metrology and instrumentation and also health and environment safety practices. The TC/229 includes four working groups; viz. terminology and nomenclature, measurement and characterization, health, safety and environmental aspects of nanotechnologies and material specifications. The committee has published one technical specification on terminology and definitions for nano-objects (ISO/TS 27687:2008) and a technical report on the occupational health and safety aspects of nanotechnologies (ISO/TR 12885:2008). There are thirty-three participation countries and seven have joined as observers. The United Kingdom holds the secretariat and interestingly all the EU nano frontrunners like France, Germany, The Netherlands, UK and some Scandinavian countries88 are members of this

technical committee. China and India also hold membership of this committee.

There are two important aspects of regulatory decision-making within the ISO is that first although consensus is stressed as an important procedural principle that has been adopted by the ISO, however analysis of the final approval process in adopting an international standard provides for a vote of two-thirds majority amongst the technical committee members (supposed to be representing all interested parties) and approval of three fourths (75%) of all the other ISO members. Thus consensus only relates to the process of negotiations between states once the draft standards have been drawn up. Second, the technical committees of the ISO are hosted by the standards organization of a member country, and it is the organization, which forms the secretariat of the technical committee. This essentially gives the member sponsoring the technical committee considerable influence over the functioning and substantive decisions of the committee. In the case of TC/229, amongst the 28 member countries – there is a clear majority of developed countries participating as members.

ISO recognizes the fact that most of the documents by ISO/TC229 will be ‘anticipatory (developed ahead of the technology that act as “change agents” and guide the market) as nanotechnology is still in the early stages of development and evolution.' This is an important aspect as ISO is an internationally recognized and widely acceptable standard. Even the WTO recognizes ISO standards, thereby giving it a mark of approval to be used in trade. Besides, since ISO membership often consists of government or public agencies already in the field of standardization, there is a stronger position that it enjoys with regard to influencing the domestic regimes of countries. In the absence of an already existing framework at a domestic level, countries tend to look at such international sites for guidance and sometimes adoption of standards.

WHO Intergovernmental Forum on Chemical Safety

This is an inter governmental forum set up under the aegis of WHO to develop and promote strategies and partnerships among national governments, inter governmental and non-governmental organizations. It was set up with the primary objective of providing policy guidance, developing strategies in a coordinated and integrated manner and foster...
understanding of issues and promote the requisite policy support to ensure chemical safety.

The forum identifies nanotechnology as a key area of work and has set up a Forum Standing Committee Working Group on Nanotechnology & Nano-materials. At the sixth session of the forum held in September 2008, ethical and other fundamental considerations were discussed beside opportunities and challenges of nanotechnology. The statement issued on Manufactured Nano materials, (IFCS/FORUM-VI/07w) at Dakar, *inter alia*, recommends:

- applying the precautionary principle as one of the general principles of risk management;
- making information on use and risks associated with the lifecycle of manufactured nano materials readily accessible;
- strengthening capacity of civil society to effectively participate in decision making related to manufactured nano materials;
- taking measures to prevent or minimize exposure of workers to nano materials and their releases into the environment; and
- informing users throughout the supply chain about health and safety risks and novel characteristics of manufactured nano materials via Material Safety Data Sheets or other means.

**International Risk Governance Council (IRGC)**

The International Risk Governance Council (IRGC) is an independent international organization set up with the objective of helping the different stakeholders in ‘understanding and management of emerging global risks that have an impact on human health and safety, the environment, economy and society at large.’ This particular site operates on a number of levels by influencing policy decisions through research, developing frameworks, and specific recommendations etc. The mandate of IRGC is risk governance and within that it lays special emphasis on ‘emerging and re-emerging risks’. This focus area assumes special significance for nanotechnology. Being an emerging technology with the risks yet to be spelled out, risk governance is a crucial link in the overall regulatory framework for nanotechnology.

As a sub political site, IRGC aims toward activities which can be explained in terms of agenda setting, where it seeks to assist governments and other stakeholders in policy formulation ‘to anticipate and understand them (risks) and the risk governance options before they become urgent policy priorities’. Thus, one of the main arenas of activities of IRGC is to prepare the policy environment in such a manner that it is forewarned about the future risks such as those emanating from emerging technologies such as
nanotechnology. In fact the council recognizes nanotechnology as a major area for intervention in this regard.

In recognition of the fact that nanotechnology is still an emerging technology which indeed has a 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 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 technology regulation. 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. As IRGC envisages, if ‘opportunities are forgone due to inadequate or inappropriate risk governance, including poor communication... it has potentially catastrophic consequences’.

IRGC is not a network of government representatives or nominees but a group of people who are on the board or sub-council in their individual capacity. Thus it lacks the governmental backing to have a concrete influence, however, it does have the potential to influence and shape policy at country level for two reasons – first, most of the members, even though not from the government are influential in policy formulation at their country level; second, countries like U.K. explicitly recognize the role of IRGC in the field of risk regulation pertaining to nanotechnology.

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.

In the context of nanotechnology, the study identifies questions at two levels i.e. definitional and at the level of functioning. At the definitional
level, the question is - what is the optimum level from which regulatory control should be exercised? This is an essential query because as discussed above, general international law and regulation has witnessed a rapid increase in both the extent and dept of policy competencies. This also applies to the case of technology regulation. We have seen that in the case of biotechnology, the WTO (World Trade Organization), CBD and others emerged as important negotiating forums for debating regulation on biotechnology. In the case of nanotechnology too certain international forums have secured a lead in the colonizing regulatory space vis-à-vis nanotechnology. We use the terms “colonizing” to illustrate two aspects; first, that some of these institutions do not have the legal mandate to address such issues, and in that sense their activities represent a de facto extension of their mandate and second; their activities to an extent pre-empt other organizations from exercising competencies in the same area and also have a dampening effect on national regulatory competencies.

At the functional level, questions that may arise relate to the structure and nature of domestic regulatory institutions in terms of their receptivity to international influences, assuming that there are substantial channels of influence that characterize the national regulatory system. Mapping of international regulatory sites will also provide us with an overview of strategic linkages underlying the relationship between international sites and national regulatory bodies. In this context the Indian system will be scrutinized to understand the possible nature and extent of influence of international sites on the Indian regulatory regime (Chowdhury & Srivastava, 2008).
Chapter 5: Concluding remarks

The report through its detailed analysis of various laws, policies, rules, institutional mechanisms etc. has assessed the regulatory governance framework in place in India that relates to or could relate to nanotechnology. Here are some key observations that the research undertaken so far suggests.93 These observations are followed by a brief discussion on certain options and features that a regulatory framework must incorporate in order to be able to address the concerns around nanotechnology developments and applications in India.

One of the key debates around nanotechnology regulation has been around whether there exists a need for a separate nanotechnology law to regulate the concerns around nanotechnology or not.

A technology which could have risks on human health and environment cannot remain unregulated. At the same time, it is important that legal regulation avoids the harmful effects of nanotechnologies resting on incomplete risk information; without casting the incomplete information in permanent law and the key question is how the regulation can be flexibly adjusted to continuously improved risk identification and assessments (Schummer and Pariotti, 2008.). There is some apprehension that ‘hard’ law developed today in the face of grave uncertainty, may end up regulating the field far beyond the period of the law’s efficacy.

In such a scenario, the incremental approach holds out some promise and offers a reconciliation between the two schools- one advocating no regulation at present given the uncertainty and the other propounding a stand-alone regulation for nanotechnology. An incremental approach and ‘soft law’ provisions will help regulatory approaches to keep pace with developments in technology and changes in society to ensure that regulation becomes a ‘process and not an event’. The European Commission (op.cit.) has pointed out that such an approach will help:

- Avoid preventable risks and hazards, taking practical steps to avoid potential hazards and risks when scientific evidence is not complete and still being assembled;
- Set up a framework within which (a) stakeholders including scientists, industrialists and citizens can participate in shaping the course of

93 These conclusions and recommendations were discussed and largely agreed upon at the National Conference on Nanotechnology and Regulatory issues, organized by TERI and Calcutta University.
nanotechnologies and (b) nanotechnologies can develop safely;

- Monitor the development of nanotechnologies by acquiring and generating the relevant data, keeping the possibility of future regulation in future open and making sure that such regulation would rest on more complete data and a deeper scientific understanding.

This holds equally true for a developing country like India, just beginning to engage in nanotechnologies, which will help balance the need to promote research and development as well as build capacity to address risks through a risk-based regulation.

Our analysis suggests that at this stage, a nanotechnology specific legislation is not necessary. Most of the challenges and concerns could be addressed by way of either intervention at the level of subordinate legislation or amendments in the existing instruments, or interventions at the level of implementation.

Absence of a nano specific regulation does not imply unregulated nanotechnology. Applications of nanotechnology, owing to their very nature, interaction with other technologies, and extent are subject to several regulations already. However, most of these existing regulations require to be revisited, reviewed and amended before they are able to regulate the risks associated with nanotechnology. In some cases, it is merely about recognizing the distinctness of nanotechnology and potential and uniqueness of risks associated with it. There is ample flexibility available in the environmental legislation to address new challenges emanating from nanotechnology developments. In the interest of regulatory economy, the space available within the existing framework has to be identified, utilized and gaps need to be filled, before proposing a new law.

A nano-specific law at this juncture, when developments are taking place at a fast pace and both benefits and risks are unfolding at frequent intervals, seems an impractical option. First, when the risks are still being identified and defined, instead of having a separate definite regulation, it is better to ensure that existing regulations are able to address new risks as and when they become known. Second, nanotechnology is applicable across sectors, and stages of production. It is difficult to implement one single law to regulate only nanotech in all the sectors and stages. Third, a nano specific law designed at this stage would soon become obsolete with new developments taking place every day, and toxicity information is still awaited. A regulatory regime has to be flexible enough to deal with different kinds of concerns, whether it is due to the choice of technology, raw materials or process. A good regulatory framework should take into account the phase of Nanotechnology development and the regulatory intervention should be as per the stage of development and knowledge of risks. The IPR regime should also prepare to re-invent itself for this new
technology as the state-of-the-art evolves in the future. Dynamism should be the basis of any regulation of new and emerging technology. In this context, precautionary principle, which has already been adopted in environmental regulation, should be extended to nanotechnology regulation, considering the uncertainties.

Given the stage of nanotechnology development in India and uncertainties around its risks, a robust reporting requirement, especially with respect to adverse reactions, within the regulatory framework is essential. Labelling and mandatory information disclosure are other forms, where regulations can play a role in removing the informational asymmetries that exist at the moment vis-à-vis existence of nano particles and associated risks.

Implementation of laws and rules is crucial for efficacy of any regulatory framework. Therefore, the role of regulatory bodies, especially, state level agencies is critical and it is important to build capacity at sub-national and sub-state levels for the twin task of tracking development and regulatory oversight. Regulatory capacity across departments and levels is key to both designing an effective regulatory framework as well as implementation of the same. This does not necessarily need a separate regulatory authority but an expert committee can be constituted comprising members from concerned departments and ministries.

The different roles and mandates of the ministries and departments in respect of technology promotion and technology regulation have to be clearly and distinctly defined. However, clarity in roles does not mean isolation of activities, instead this clarity has to be developed and executed in close co-ordination. Besides, there is a need for a balancing act by a government agency, such as the Planning Commission.

Options for regulatory framework

It is not possible for one paper to list all the haves and have-nots of a regulatory framework of a technology that is still emerging and risks are still being defined. The process of regulatory governance is a continuing process, which would have several characteristics, including a responsive framework, regulatory flexibility, capacity to implement, information flow, coordination amongst institutions and agencies. Some of these have been discussed along the text of this paper and others need to be looked at in detail by policy makers and the relevant stakeholders. Given the stage of technology development in India and worldwide and the resultant concerns, responses across the globe, the paper puts forward a discussion on three concepts, that would hold merit in the Indian context - regulatory phasing, regulatory flexibility and regulatory interaction.
Regulatory phasing

Brownsworth in *Rights, Regulation and Technological Revolution* discusses the concept of regulatory phasing. Accordingly, regulation can be first phase, second phase, third phase and so on. In the first phase, regulation is meant to control ex ante a particular aspect of practice. In the later phases, this ex ante control is abandoned and operates ex post ‘to compensate for or adjust to the consequences of a practice that cannot be controlled by first phase regulation’. Applying the concept of phasing in formulating a regulatory regime for technology holds merit in the Indian context. Different levels of technology development and knowledge would entail a phased response in terms of regulation to respond to situations and concerns as they evolve.

Regulatory flexibility

Regulatory flexibility refers to ‘the opportunity to propose and apply flexible regulatory approaches based on demonstration of enhanced product knowledge and process understanding’. 94 Since, nanotechnology is an emerging technology, the regulatory actions and instruments to manage the risks should be flexible. A cautious and exploratory approach would be much more feasible and practical at this stage of the technology.

Although the concept of regulatory flexibility is often used only in the context of implementation and enforcement, 95 flexibility is an approach that is key in designing the regime as well. And it is in this respect that the flexibility in regulation of nanotechnology has to be maintained, so as to respond to challenges as they surface.

Regulatory interaction

Any of the abovementioned (or any other) concepts cannot be helpful in an effective regulation, until and unless there is a proper channel of communication amongst the key stakeholders and players. By regulatory interaction, we refer to interaction, exchange of information and concerns between the state and the industry, state and the research community, state and the consumers, state and the civil society. More importantly, the interaction has to take place within the government – between institutes, departments, ministries and units of government, without which the regulatory regime would always be inadequate and little more than a patchwork.


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### Annex I: ‘Nano’ Patents Granted by the Indian Patent Office from 1997 onwards

(Source: Indian Patent Office)

<table>
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<tr>
<th>PATENT NUMBER</th>
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<td>199561</td>
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<td>A method for producing metal oxide particles having nano-sized grains</td>
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<td>A nanoporous receiver element for use in thermal mass transfer imaging and a mass transfer thermal imaging method.</td>
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<td>208589</td>
<td>12/10/2004</td>
<td>Process for preparation of self micro/nano emulsifying systems and compositions thereof</td>
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<td>210596</td>
<td>27/01/2000</td>
<td>Neonanoplasts produced by emulsion technology</td>
<td>M/S. KIMBERLY-CLARK WORLDWIDE, INC</td>
</tr>
<tr>
<td>214524</td>
<td>09/04/2001</td>
<td>&quot;Method for making a nanoporous granular material and a detergent composition&quot;</td>
<td>THE PROCTER &amp; GAMBLE COMPANY</td>
</tr>
<tr>
<td>212665</td>
<td>09/11/2001</td>
<td>&quot;A method for removal of nano-sized pathogens of a size from 20nm to 500nm from water&quot;</td>
<td>THE PROCTER &amp; GAMBLE COMPANY</td>
</tr>
<tr>
<td>210855</td>
<td>02/09/2002</td>
<td>&quot;Nanocapsules and process for its preparation&quot;.</td>
<td>MAINELAB</td>
</tr>
<tr>
<td>209516</td>
<td>11/11/2002</td>
<td>An iron-based rare earth alloy nanocomposite magnet and a method for producing the same</td>
<td>M/S. NEOMAX CO LTD</td>
</tr>
</tbody>
</table>
### Annex II: Overview of Current Regulatory Framework Affecting the Development and marketing of Nano Materials and Nanotechnology Based Application in India

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Legal Instrument</th>
<th>Scope</th>
<th>Strength/Spaces</th>
<th>Gaps</th>
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<tbody>
<tr>
<td>1</td>
<td>Patents Act 1970</td>
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<td>Patentability Criteria</td>
<td>Patentability Criteria</td>
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<td>Section 2 (1)(j) of the Patents Act defines an invention as ‘a new product or process involving an inventive step and capable of industrial application’. It defines an ‘inventive step’ as a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art’. Thus, any existing knowledge or thing cannot be patented.</td>
<td>Patentability criteria may pose serious impediments to NT inventors applying for patents in India. Problem magnified by absence of separate classification for NT patents.</td>
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</table>

According to Section 3(d), the following are not patentable: “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant”.  

A nano material may be a combination of many particles or technologies or a nano particle of an existing material and patents for nanostructures without substantial difference in character and industrial application could very well not pass the standard of efficacy demanded by section 3 (d).

---

*96 The table essentially focuses on health, food and pesticides*
This acts as deterrent to patent 'evergreening' and 'new use' patents.

Explanation to section 3 (d) reads:

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

**Post-grant opposition**

Provision for post-grant opposition facilitates third parties (including competitors) to challenge the validity of a patent after it is issued, if they are able to produce evidence that the patented invention lacks novelty or non-obviousness, in light of the prior art. Ensures that NT patents are not granted for inventions which are not novel or non-obvious.

**Compulsory Licensing**

Section 84 on compulsory licensing that the public good is served, that the abuse of patent as a monopoly is prevented and to make way for commercial exploitation of invention by an interested person. Expected to help overcome many of the problems associated with patenting of NT and which leads to creation of monopolies.

**Disclosure standards**

Examination to section 3(d) does not accommodate the new technological development of nanotechnology as it specifically debars patenting of ‘particle size’ unless it may differ significantly in properties with regard to efficacy.

**Lack of Capabilities**

Indian IPR regime and its implementation agencies-particularly the Indian Patent Office ill-equipped to handle nanotechnology and all that it entails in terms of prior art searches and patent examination.

Shortage of manpower at the IPO.

No special training to patent examiners to handle NT and and lack of special examiners for handling NT patent applications.

Ineffective indexing and management of prior art databases.
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<td>Section 10 of the Act provides that a complete specification shall ‘fully and particularly describe the invention and its operation or use and the method by which it is to be performed...’ In addition, it states that the complete specification shall ‘disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection’. A good counter strategy to tackle the issue of broad claims in nanotechnology.</td>
<td>Experimental Use Exception</td>
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<td>Under section 107 (A), ‘any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product...shall not be considered as an infringement of patent rights’. An important liability shield for universities seeking to engage in NT research, without having to wade through patent thickets in the field.</td>
<td>Experimental Use Exception</td>
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<tr>
<td>Provides the necessary boost to the commercialisation of inventions made through government-funded research by passing on the IP rights on the same to the institution responsible for that invention.</td>
<td>Prior art databases. Lack of guidelines for examining nanopatent applications. Lack of capacity among patent attorneys to draft NT specific claims.</td>
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<td>Public Funded Intellectual Property Bill 2008</td>
<td>Production and Marketing</td>
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<td>Contains very few provisions to safeguard public access, in the form of ‘march-in’ rights or compulsory licensing.</td>
<td>Production and Marketing</td>
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<tr>
<td>2 Public Funded Intellectual Property Bill 2008</td>
<td>Production and Marketing</td>
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<td>3 Drugs and Cosmetics Act 1940</td>
<td>Production and Marketing</td>
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<td>Regulates the import, manufacture, distribution and sale of drugs</td>
<td>Production and Marketing</td>
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<td>Section 3(b). iv - definition of “drug” includes medical devices – include gold/silver nano particles for targeted drug delivery</td>
<td>Production and Marketing</td>
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<tr>
<td>Section 10(A) – “Public Interest Provision” Import prohibition of any drugs and cosmetics which is likely to involve any risk to human consideration that nano particles as either new or modified ingredients</td>
<td>Production and Marketing</td>
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<tr>
<td>Second Schedule – Class 1 Drugs –</td>
<td>Production and Marketing</td>
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</table>
| 4 | Medical Devices Regulation Bill, 2006 | To consolidate laws related to medical devices and to establish the Medical Device Regulatory Authority of India for establishing and maintaining a national system of | Section 12 (o) ‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other article intended by the manufacturer to be used for human beings for the purposes of diagnosis, prevention, monitoring, treatment or alleviation of a disease, injury, or for investigation, replacement, modification, or support of a physiological process, supporting or sustaining life, and control of conception.

12 (z) (cc) - The Bill views risk management as systematic application of policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk;
12 (z)(bb) - risk is a ‘combination of the probability of occurrence of harm and the severity of that harm’.

Drugs and cosmetics Act includes medical devices within the definition of drugs, therefore there will be problems in the phase of transitioning the regulation from drug controller to the new medical device regulatory authority. Ministry of health and family welfare may be better equipped to regulate medical devices, in view of its experience and overall ministerial mandate.

In principle the focus on risk | Patented and Proprietary Medicine – Standard prescribed (Labeling) The formula of list of ingredients displayed in the prescribed manner on the label of the container and such other standards as may be prescribed. (No Obligation to disclose the use of nanoparticles as ingredients). |
controls relating to quality, safety, efficacy and availability of medical devices that are used in India

| Section 13 r/w Section 35 provides for the establishment of a Medical Device Regulatory Authority of India to regulate and monitor the design, testing & evaluation, manufacture, packaging, labeling, import, sale, usage and disposal of medical devices, to ensure availability of safe medical devices for human use in the country. |
| Section 53 An advisory council would *inter alia*, advise the MDRA on selection of standards including that for risk benefit analysis of medical devices; regulations and strategies in the context of emerging areas of scientific advancement and technological developments; and interactions with other regulatory bodies in the country |
| Section 67 - MDRA shall issue regulations relating to essential principles of safety and performance of medical devices, and design and manufacturing requirements. |
| Section 66 – The key essential principles shall be –  
  • Use of medical devices should not compromise health and safety  
  • Design and manufacture of medical devices must conform to safety principles  
  • Medical devices should be suitable for the intended purpose  
  • Long-term safety must be assured  
  • Medical devices should not be adversely affected by transport or storage  
  • Benefits of medical devices must outweigh any side effects |
| One of the main functions of the MDRA is going to be providing for risk based classification of medical devices |

<p>| 5 | National Pharmacovigilal Post-marketing tool | The purpose of the programme is to collate data, analyze it and use the inferences to recommend informed regulatory interventions, | It is a voluntary instrument. |</p>
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<tr>
<th>nce Protocol in ensuring the safety of pharmaceutical and related health products</th>
<th>besides communicating risks to healthcare professionals and the public. Para. 6.1: Shall monitor the adverse drug reactions of medicines in order to identify previously unexpected adverse drug reactions or indicate that certain reactions occur more commonly than previously believed. Para. 6.2: Shall review Periodic Safety Update Reports (PSURs) submitted by pharmaceutical companies. Pharmaceutical companies are required to submit the PSURs of all new chemicals drugs. PSURs shall be expected to be submitted every 6 monthly for the first 2 years of marketing in India, and annually for the subsequent 2 years. Para. 6.4: Assess the regulatory information relating to safety in order to determine what action, if necessary, needs to be taken to improve safe use. Based on the available data, the Advisory Committee shall make recommendations on product label amendments, product withdrawals and suspension. The National Pharmacovigilance Programme (NPP) shall encourage reporting of all suspected drug related adverse events, including those suspected to have been caused by herbal, traditional or alternative remedies. The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a widespread prescribing problem.</th>
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<td>There is no framework under which the reports of adverse drug reactions can be addressed in a comprehensive manner. Regulatory assessment is missing of past studies of drug reactions. Tailored monitoring and reporting of Nano based health applications. Submission of adverse drug reports by companies – clear conflict of interest.</td>
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<th>Food Safety and Standards Act, 2005</th>
<th>Section 3 (k) “food additive” means any substance not normally consumed as a food by itself or used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food but does not include “contaminants” or substances added to food for maintaining or improving nutritional qualities;</th>
<th>Definition of Food Additives can accommodate nano particles used in packaging. FSA is empowered to carry out food safety audits for ensuring compliance. FSA is also empowered to undertake foresight activities in the case of emerging risks. The entire FSA administrative framework is required to undertake public consultations and make regular information disclosure and communication to public bodies like panachayats, consumers and interested parties. – appreciates the differentiation between groups within the public. Food Commissioner is also empowered to prohibit on the basis of public health. Food standards to be determined on the basis of a risk analysis – however exceptions made for developments with uncertain scientific justifications – provisional measures. There is a provision establishing the supremacy of this act over the provisions of any other domestic statute.</th>
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<td>6</td>
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<td>Sec 3 (r) “food safety audit” means a systematic and functionally independent examination of food safety measures adopted by manufacturing units to determine whether such measures and related results meet with objectives of food safety and the claims made in that behalf:</td>
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<td>Sec 3 (u) “hazard” means a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect;</td>
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<td>Sec 3 (y) “ingredient” means any substance, including a food additive used in the manufacture or preparation of food and present in the final product, possibly in a modified form;</td>
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<td>Sec 3 (zm) “risk”, in relation to any article of food, means the probability of an adverse effect on the health of consumers of such food and the severity of that effect, consequential to a food hazard;</td>
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<td>Sec 3 (zz) “unsafe food” means an article of food whose nature, substance or quality is so affected as to render it injurious to health;</td>
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Section 16 – Areas in which FSSA could prescribe standards and its functions includes 
(b)(3)(v) the Food Authority shall search, collect, collate, analyze and summarize relevant scientific and technical data particularly relating to identification of emerging risks; 
(c) promote, co-ordinate and issue guidelines for the development of risk assessment methodologies and monitor and conduct and forward messages on the health and nutritional risks of food to the Central Government, State Governments and Commissioners of Food Safety. 
(g) take all such steps to ensure that the public, consumers, interested parties and all levels of panchayats receive rapid, reliable, objective and comprehensive information through appropriate methods and means 
(j) contribute to the development of international technical standards for food, sanitary and phyto-sanitary standards 

(4) The Food Authority shall make it public without undue delay – 
(a) the opinions of the Scientific Committee and the Scientific Panel immediately after adoption; 
(b) the annual declarations of interest made by members of the Food Authority, the Chief Executive Officer, members of the Advisory Committee and members of the Scientific Committee and Scientific Panel, as well as the declarations of interest if any, made in relation to items on the agendas of meetings; 
(c) the results of its scientific studies; and 
(d) The annual report of its activities; 

Section 18 relates to General Principles that are to be followed in the administration of this act:
(1)(c) where in any specific circumstances, on the basis of assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure appropriate level of health protection may be adopted, pending further scientific information for a more comprehensive risk assessment;

(d) the measures adopted on the basis of clause (c) shall be proportionate and no more restrictive of trade than is required to achieve appropriate level of health protection, regard being had to technical and economic feasibility and other factors regarded as reasonable and proper in the matter under consideration;

(e) The measures adopted shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health being identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment;

(2) The Food Authority shall, while framing regulations or specifying standards under this Act— take into account—

(i) prevalent practices and conditions in the country including agricultural practices and handling, storage and transport conditions; and

(ii) international standards and practices, where international standards or practices exist or are in the process of being formulated.

b) determine food standards on the basis of risk analysis

(c) undertake risk assessment based on the available scientific evidence and in an independent, objective and transparent manner;

(d) ensure that there is open and transparent public consultation, directly or through representative bodies including all levels of panchayats, during the preparation, evaluation and revision of regulation

Section 30: Commissioner of Food Safety of the State
89 Regulatory Challenges posed by Nanotechnology Developments in India

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<td>(2)(a) prohibit in the interest of public health, the manufacture, storage, distribution or sale of any article of food (b) carry out survey of the industrial units engaged in the manufacture or processing of food in the State to find out compliance by such units</td>
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**59: Punishment for unsafe food**

Any person who, whether by himself or by any other person on his behalf, manufactures for sale or stores or sells or distributes or imports any article of food for human consumption which is unsafe, shall be punishable.

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<tr>
<th>7</th>
<th>Insecticides Act 1968</th>
<th>To regulate the import, manufacture, sale, transport, distribution and use of insecticides with a view to prevent risk to human beings or animals</th>
<th>Reporting requirement should be mandatory across states and not left for states to notify. Reporting requirement should not be restricted to poisoning but any adverse reaction/ effect. Reporting is an important post-marketing tool and in case of merging technologies, when risks may emerge at a later date, such reporting would be helpful. In the absence of supporting data, the government can prohibit sale import or manufacture of an insecticide in the interest of public safety only for a maximum of thirty days.</th>
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<td>Section 2 (k) &quot;misbranded&quot; - an insecticide shall be deemed to be misbranded- 1. if its label does not contain a warning or caution which may be necessary and sufficient, if complied with to prevent risk to human beings or animals; 2. if the insecticide has a toxicity which is higher than the level prescribe or is mixed or packed with any substance so as to alter its nature or quality or contains any substance which is not include in the registration</td>
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<td>Section 5 (1) - A registration Committee is constituted to register insecticide after scrutinizing their formulae and verifying claims made by the importer or the manufacturer, as the case may be, as regards their efficacy and safety to human beings and animals</td>
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<td>Form I Rule 6, While making any application for such use, toxicity of the products to human beings, wild life, aquatic animals has to be disclosed</td>
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</table>
Section 9. 3B - Where the Registration Committee is of opinion that the Insecticide is being introduced for the first time in India, it may, pending any inquiry, register it provisionally for a period of two years on such conditions as may be specified by it.

Section 17 - Prohibition of import and manufacture of
1. any misbranded insecticides;
2. any insecticide the sale, distribution or use of which is for the time being prohibited on grounds of public safety;
3. any insecticide except in accordance with the condition on which it was registered;

Section 26 - The State Government may require a mandatory reporting of all occurrences of poisoning (through the use of handling of any insecticide)

Section 27 (1) If the Central Government or the State Government is of opinion, that the use of any insecticide is likely to involve such risk to human being or animals as to render it expedient or necessary to take immediate action then that Government may, by notification in the Official Gazette, prohibit the sale, distribution or use of the insecticide pending investigation into the matter (extendable upto thirty days).

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<th>Occupational Health and Safety</th>
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| **8** | Factories Act 1948 | Law regulating labour in factories | Sec 2 (cb) "hazardous process" means any process or activity in relation to an industry specified in the First Schedule where, unless special care is taken, raw materials used therein or the intermediate or finished products, bye-products, wastes or effluents thereof would - (i) cause material impairment to the health of the persons engaged in or connected therewith, or (ii) result in the pollution of the general environment. | Designer, manufacturer, importer or supplier of any article to ensure that the article is safe and without risks to the health of the workers. There is a clear conflict of interest here. Enjoining the beneficiaries of the trade with this
environment

Sec 7A (1) Every occupier shall ensure, so far as is reasonably practicable, the health, safety and welfare of all workers while they are at work in the factory.

(2) the matters to which such duty extends, shall include- (a) the provision and maintenance of plant and systems of work in the factory that are safe and without risks to health; (b) the arrangements in the factory for ensuring safety and absence of risks to health in connection with the use, handling, storage and transport of articles and substances; (c) the provision of such information, instruction, training and supervision as are necessary to ensure the health and safety of all workers at work; (d) the maintenance of all places of work in the factory in a condition that is safe without risks to health and the provision and maintenance of such means of access to, and egress from, such places as are safe and without such risks; (e) the provision, maintenance or monitoring of such working environment in the factory for the workers that is safe, without risks to health and adequate as regards facilities and arrangements for their welfare at work.

Sec 7B - Designer, manufacturer, importer or supplier of any article for use in the factory shall ensure that the article is so designed and constructed as to be safe and without risks to the health of the workers; and carry out tests and examination and pass all information for ensuring such safety.

Such a designer or manufacturer shall carry out necessary research with a view of the discovery and, so far as is reasonably practicable, the elimination or minimisation of any risks to the health or safety of the workers. (*Article* refers to plants and machineries)

responsibility would make it a difficult proposition.

Hazardous process definition is wide enough to include nanoparticles, but it is restricted to industries in the schedule. Thus the schedule would have to be expanded.

Right of workers is an important empowering tool but pointless in the absence of awareness and knowledge and awareness. Training to workers about imminent risks must be provided to enable the workers to exercise their right of warning.
| 9 | Hazardous Material (management, handling and Trans boundary Movement) Rules 2007 | Handling of hazardous waste rules | Section 2 (l) – hazardous waste – any waste, which by reason of its physical, chemical, reactive, toxic, flammable, explosive, or corrosive characteristics causes danger or is likely to cause danger to health or environment, whether alone or in contact with other wastes or substances

Sec 4(1) occupier responsible for safe and environmentally sound handling of hazardous waste generated in an establishment

Sec 5(1) Authorization of SPCB to be obtained for generation, processing, treatment, package, storage, transportation, use, collections, destruction, conversion, selling of hazardous waste.

Chapter III – procedure for storage, recycling, processing and reuse of hazardous waste has to be in conformity with the Act

Chapter VI – packaging, labeling, and transport of hazardous waste | Guidelines for handling of waste has to take into account the characteristics of nano-waste.

SPCB approval required for generation, processing, treatment, package, storage, selling of hazardous waste; But are actions of SPCB and other institutions in coordination with respect to reporting of adverse impacts, latest technologies etc. for safe management of hazardous waste |
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<tr>
<th>10</th>
<th>DCA Drugs (Control) Act 1950</th>
<th>Section 26 Power of Central govt. to prohibit sale, manufacture and distribution in the case of risk to humans and animals on public interest grounds</th>
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<tr>
<td>11</td>
<td>Manufacture, Storage &amp; Import of Hazardous Chemicals Rules, 1989 U/ Environmental Protection Act, 1986</td>
<td>Rules for manufacture, storage and import of hazardous chemicals</td>
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<td>Lays down certain responsibilities of the authorities responsible for manufacture, storage and import of hazardous chemicals</td>
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<td>Positive list of hazardous chemicals laid down</td>
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<td>Hazardous chemicals in terms of dosage or content laid down. Need for the government to recognize risks of nano particles and metals that change properties at nano scale</td>
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<td>12</td>
<td>The Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996</td>
<td>Emergency planning, preparedness and response for chemical accidents</td>
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<td>Rule 2 (a) &quot;chemical accident&quot; means an accident involving a fortuitous, or Sudden or unintended occurrence while handling any hazardous chemicals resulting in continuous, intermittent or repeated exposure to death, or injury to, any person or damage to any property</td>
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<td>Rule 2 (f) &quot;major chemical accident&quot; means - an occurrence including any particular major emission, fire or explosion involving one or more hazardous chemicals and resulting from uncontrolled developments in the course of industrial activity or transportation or due to natural events leading to serious effects both immediate or delayed, inside or outside the installation likely to cause substantial loss of life and property including adverse effects on the environment;</td>
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<td>Rule 3 - Central Government shall constitute a Central Crisis Group</td>
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<td>Functions of the central crisis group are more with respect to post accident monitoring and evaluation.</td>
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<td>There is some overlap of functions between centre and state groups for reviewing district off-site emergency plans</td>
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<td>Local crisis groups are entrusted with the responsibility to train personnel involved in chemical accident management. However, there is no effort towards building the capacity of</td>
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for management of chemical accidents and state government shall constitute a state equivalent of the same.

Rule 7 - State crisis group to assist the State Government in the planning, preparedness and mitigation of major chemical accidents at a site in the State

| Environmental Health | Prevention, control and abatement of air pollution | "Air pollutant" means any solid, liquid or gaseous substance (including noise) present in the atmosphere in such concentration as may be or tend to be injurious to human beings or other living creatures or plants or property or environment; | These standards are with respect to specified areas only

Sec 22 - No person operating any industrial plant, in any air pollution control area shall discharge or cause or permit to be discharged the emission of any air pollutant in excess of the standards laid down by the State Board

Sec 17 (1) (e) SPCB’s power to inspect, at all reasonable times, any control equipment, industrial plant or manufacturing process and to give, by order, such directions to such persons as it may consider necessary to take steps for the prevention, control or abatement of air pollution;

| Environment Protection Act 1986 | For the protection and improvement of environment | 2 (a) "environment" includes water, air and land and the inter-relationship which exists among and between water, air and land, and human beings, other living creatures, plants, micro-organism and property; | Recognition of nano particles as potential suspended particulate matters |
2 (b) "environmental pollutant" means any solid, liquid or gaseous substance present in such concentration as may be, or tend to be, injurious to environment;

2 (e) "hazardous substance" means any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plant, micro-organism, property or the environment;

Umbrella legislation under which the central government has the power to take measures towards protecting and improving the environment (Sec 4)

Sec 5 (a) - Central government can even order closure, prohibition or regulation of any industry, operation or process

Sec 6 – Notifications with respect to standards of quality of air, water or soil, concentration limits of environmental pollutants, procedures and safeguards for the handling of hazardous substances etc are within the purview of the central government and has been the basis for many rules and notifications for environment protection

| 15 | Public Liability Insurance Act | Public liability-insurance for the purpose of providing immediate relief to the persons affected by accident | 3 (1) liability - Where death or injury to any person (other than a workman) or damage to any property has resulted from an accident
(2) (ii) "injury" includes permanent total or permanent partial disability or sickness resulting out of an accident | 4 (3) The Central Government may, by notification, exempt from taking out an insurance policy
(a) the Central Government;
(b) any State Government, |
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<tr>
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<th>occurring while handling any hazardous substance</th>
<th>4. (1) Every owner shall take out, before he starts handling any hazardous substance, one or more insurance policies</th>
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<td></td>
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<td>(c) PSU</td>
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<td>(d) Any local authority</td>
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<td>[if a fund has been set up to meet any liability]</td>
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<tr>
<td>16</td>
<td><strong>Water (Prevention and Control of Pollution) Act</strong></td>
<td>Prevention and control of water pollution and the maintaining or restoring of wholesomeness of water</td>
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<td>Sec 2 (e) &quot;pollution&quot; means such contamination of water or such alteration of the physical, chemical or biological properties of water or such discharge of any sewage or trade effluent or of any other liquid, gaseous or solid substance into water (whether directly or indirectly) as may, or is likely to, create a nuisance or render such water harmful or injurious to public health or safety, or to domestic, commercial, industrial, agricultural or other legitimate uses, or to the life and health of animals or plants or of aquatic organisers;</td>
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<td>Sec 2 (k) &quot;trade effluent&quot; includes any liquid, gaseous or solid substance which is discharged from any premises used for carrying on any &quot;industry, operation or process, or treatment and disposal system&quot; other than domestic sewage.</td>
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<td>Sec 16 - Functions of CPCB 2 (f) collect, compile and publish technical and statistical data relating to water pollution; 2 (g) lay down, modify or annul, in consultation with the State Government concerned, the standards for a stream; 3) Establish or recognise a laboratory or laboratories.</td>
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<td>Sec 17 - Function of State Board a) plan a comprehensive programme for the prevention, control or abatement of pollution g) lay down, modify or annul effluent standards for trade</td>
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Co-ordination amongst state and central boards

Awareness and recognition about risks associated with nano-particles with the standard setting agencies
(k) to lay down standards of treatment trade effluents to be discharged into any water body and the tolerance limits of pollution permissible in the water of the stream, after the discharge of such effluents;

(l) to make any order for the prevention, control or abatement of discharge of waste into streams or wells; mandating systems for the disposal of sewage and trade effluents or to modify, alter or extend any such existing system or to adopt such remedial measures as are necessary to prevent control or abate water pollution;

(m) to lay down effluent standards

Sec 21 - A State Board shall have power to collect and analyse samples of trade effluent (requirements - notice to the occupier/controller, sample collected in his presence, send one part of sample to recogzd lab and another to the occupier/agent)

Sec 24 (1) (a) no person shall knowingly cause or permit any poisonous, noxious or polluting matter determined in accordance with such standards as may be laid down by the
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<th>No.</th>
<th>Document Reference</th>
<th>Text</th>
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| 17  | G.S.R.384(E), [11/4/1994] - National Ambient Air Quality Standards | National Ambient Air Quality Standard: The levels of air quality necessary with an adequate margin of safety, to protect the public health, vegetation and property  
As per the notification, SPM concentration limit in ambient air |
<table>
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<th>Environmental Impact Assessment Notification-2007</th>
<th>For imposing certain restrictions and prohibitions on new projects or activities, or on the expansion or modernization of existing projects or activities based on their potential environmental impacts</th>
<th>Requirements for EIA are based on land area under operation. Any operation below 50 hectare does not require a mandatory EIA</th>
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</table>
| 18 | The Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996 | Emergency planning, preparedness and response for chemical accidents  
Rule 2 (a) "chemical accident" means an accident involving a fortuitous, or Sudden or unintended occurrence while handling any hazardous chemicals resulting in continuous, intermittent or repeated exposure to death, or injury to, any person or damage to any property  
Rule 2 (f) "major chemical accident" means, an occurrence including any particular major emission, fire or explosion involving one or more hazardous chemicals and resulting from uncontrolled developments in the course of industrial activity or transportation or due to natural events leading to serious effects both immediate or delayed, inside or outside the installation likely to cause substantial loss of life and property including adverse effects on the environment; | Functions of the central crisis group are more with respect to post accident monitoring and evaluation.  
There is some overlap of functions between centre and state groups for reviewing district off-site emergency plans  
Local crisis groups are entrusted with the responsibility to train personnel involved in chemical accident management. However, there is no effort towards building the capacity of local actors and stakeholders in this |
Rule 3 - Central Government shall constitute a Central Crisis Group for management of chemical accidents and state government shall constitute a state equivalent of the same.

Rule 7 - State crisis group to assist the State Government in the planning, preparedness and mitigation of major chemical accidents at a site in the State

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<th>Waste Disposal</th>
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</table>
| 22 | The Bio-Medical Waste (Management and Handling) Rules, 1998 | Rule 3 (5) "Bio-medical waste" means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biological

Biotechnology waste recognized as a separate category of waste. Same should be done for nanotechnology waste or bio nano waste
| Rule 5 (1) Bio-medical waste shall be treated and disposed of in accordance with the schedules and standards prescribed therein. 
| (2) Every occupier shall set up in accordance with the time-schedule in Schedule VI, requisite bio-medical waste treatment facilities like incinerator, autoclave, microwave system for the treatment of waste, or, ensure requisite treatment of waste at a common waste treatment facility or any other waste treatment facility. |

| 23 | The Municipal Solid Wastes (Management and Handling) Rules, 2000 | To regulate the management and handling of the municipal solid wastes |
| | | Rule 3 xv - "municipal solid waste" includes commercial and residential wastes generated in a municipal or notified areas in either solid or semi-solid form excluding industrial hazardous wastes but including treated bio-medical wastes |
| | | Rule 4 - It is the responsibility of the municipal body for any infrastructure development for collection, storage, segregation, transportation, processing and disposal of municipal solid wastes. |
| | | Rule 5 - State governments have the oversight powers |
| | | Rule 6 - CPCB has the monitoring powers |