3.

# AN OVERVIEW OF THE EMERGING INTERNATIONAL REGULATORY FRAMEWORK FOR NANOTECHNOLOGY

Meenakshi Chaudhary[1]

## Introduction

Nanotechnology promises new materials and devices that are considered to have profound implications over various industrial sectors. The speedy evolution of nanotechnology and worldwide huge investment in this emerging field has been considered to not only revolutionise diverse industry segments but also to have a considerable impact on human lives. Though, a large number of unregulated nanotechnology products are commercially available, inventive and innovative efforts are on the anvil.

The multidisciplinary dimensions of nanotechnology and its convergence with other cutting-edge technologies promise a new era of technological innovation. Moreover, the economic benefits that this emerging field promises has mobilised both private and public funds in this area from all over the world. The global market of nano-enabled products is expected to reach $4.4 trillion by 2018 (Lux Research 2014), driven by huge investment in health care and electronics sector (Global Industry Analysts, Inc. 2016). The current research in the field of nanotechnology is dominated by the developed countries which focus more on commercialisation of nanotechnology products than on advancing basic research (Baucher et al. 2013: 17).

Nanotechnology tremendous benefits are often commensurate with its unprecedented risks that are unquantifiable due to pervasive uncertainty. A few of the scientific and toxicological findings highlight the myriad risks posed to human health, safety, and environment by nanomaterials. But, the inadequacy of toxicological data underscores the necessity to evaluate the severe implications of nanomaterials. Apart from these

[1] Research Assistant at Indian Society of International Law (ISIL), New Delhi. She holds Ph.D in International Law from Centre for International Legal Studies, Jawaharlal Nehru University, New Delhi and the present article is based on her Ph.D. Thesis. Email: meenakshi.c231@gmail.com

risks, the socio-economic and ethical dimensions of nanotechnology have generated a considerable debate regarding the unprecedented implications of nanotechnology.

Due to enormous benefits and perils of this technology, the need for its effective regulation is being felt. Despite the heterogeneous risks associated with nanotechnology, no international regulatory regime for nanotechnology exists. Despite the fact that many international organisations have identified nanotechnology risks as a matter of considerable concern, international regulatory efforts in this area are limited in scope. This paper explores the nanotechnology and discusses the benefits and risks associated with it to identify the need to regulate it. Finally it provides an overview of the regulatory efforts taken up by the international organizations and institutions and their role in the evolution of international regulatory framework for nanotechnology.

## Understanding Nanotechnology

The concept of nanotechnology was first devised by Richard Feynman in his talk "Plenty of Room at the Bottom". Feynman (1959)'s vision of manipulation of things atom by atom to unravel biology and chemistry conundrums laid the theoretical foundation of nanotechnology. Later on, this idea came to be known as nanotechnology. The term nanotechnology was first coined by Norio Taniguchi of Tokyo University, in 1974, at the International Conference on Production Engineering (Shew 2008). In early 1980s, Scanning Tunneling Microscope (STMs) evolved into Atomic Force Microscopes (AFMs) and these scientific instruments played a crucial role in advancing the research in nanotechnology (Action Group on Erosion, Technology and Concentration 2003: 15-16).

In the early nineties, research in the field of nanotechnology was advancing in a disintegrated manner. The Institute for Molecular Manufacturing established in California US, in 1991, published the first book Nanosystems: Molecular Machinery, Manufacturing, and Computation, which was authored by Drexler. Later, Drexler laid the foundation of the Foresight Institute to make sure that nanotechnology evolve in a productive way (Peterson 1995).

## Definitions

The word "nano" is evolved from the Greek word "nanos" that means "dwarf". One nanometer (nm) is equal to one billionth of a metre. A human hair is roughly 80,000nm in diameter, and a red blood cell is 7000nm across (The Royal Society and the Royal

Academy of Engineering 2004: 5). Nanotechnology deals with the manipulation of infinitesimal materials of about 1-100 nanometres to construct materials possessing novel attributes, devices and heterogeneous systems. Nanotechnology focuses on manufacturing materials having novel properties. For instance, at nanoscale gold is of a different colour, carbon is very strong and inflexible, and silver acts a very effective disinfectant (Action Group on Erosion, Technology and Concentration 2005: 9). These novel materials known as "nanomaterials" and has various commercial applications. These nanomaterials can incorporate nanoparticles or exist without them (Peterson 1995: 5-7).

There is lack of consensual definition of nanotechnology. Various regulatory agencies and international organisations such as International Standard Organisation (ISO), Organisation for Economic Co-operation and Development (OECD), and European Patent Office (EPO) have drafted and proposed working definitions for nanotechnology for executing policies and strategies in this field (Lovestam et al. 2010: 19). Most of the definitions of nanotechnology are derived from the US National Nanotechnology Initiative that defines nanotechnology as "Nanotechnology is the understanding and control of matter at the nanoscale, at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications."[2] Various definitions of nanotechnology that have been put forwarded by regulatory bodies have emphasised on size i.e. nanoscale as a defining criterion. However, this size limit of nanoscale i.e.1-100nm has generated controversies as it excludes many devices and materials that should come under the definition of nanotechnology (Morrow et al. 2007: 807).

Some argue that a uniform regulatory definition for nanotechnology is not possible, considering the fact that its risks are extremely contextual (Maynard 2011). Definitions are fundamental for the proper functioning of a regulatory framework as they help in identifying the subject-matter and its scope to be regulated. However, in case of an interdisciplinary technology, such as nanotechnology, a regulatory definition would explicitly determine the materials causing risks and need to regulate them. The

[2] The National Nanotechnology Initiative (NNI) is a U.S. Government research and development (R&D) initiative involving the nanotechnology-related activities of 20 departments and independent agencies. The United States set the pace for nanotechnology innovation worldwide with the advent of the NNI in 2000. The NNI today consists of the individual and cooperative nanotechnology-related activities of Federal agencies with a range of research and regulatory roles and responsibilities.

definition should incorporate both size and enhanced properties as they are the determining factors about its novelty.

**Characteristics and Generations**

Nanoscale has been considered as the quintessence of nanotechnology. Nano-sized materials display new physical and chemical properties as compared to large-scale materials. For instance, at nanoscale gold exhibits different colour, carbon becomes very strong and inflexible, and silver turns out to be a very effective disinfectant disinfectant (Action Group on Erosion, Technology and Concentration 2005: 9). Due to its interdisciplinary nature, therefore, nanotechnology is not chasing any clear-cut goals and finite applications (Nordmann 2004).

Nanotechnology uses two modes of manufacturing: bottom-up and top-down. Bottom-up manufacturing process uses a single atom or molecule at a time to construct structures (Cao 2004: 9). Top-down manufacturing disintegrates large compounds into nanoparticles to develop enhanced materials, machines and systems (Scrinis and Lyons 2007: 23).

Nanotechnology products have been divided into four generations: passive nanostructures, active nanostructures, nanosystems, and heterogeneous molecular nanosystems (Bowman and Hodge 2006: 1061). Passive nanostructures were developed after 2000, such as complex scientific tools and nanoparticles used in consumer products. Active nanostructures came out in 2005 including 3d transistors, amplifiers, and drug delivery devices actuators (Renn and Roco 2006: 156). These active passive nanostructures are being used in various industrial sectors such as medicine, aeronautics, electronics, and optics. The third generation nanotechnology products, i.e. nanosytems, developed after 2010, this generation products very comprehensive, intricate, and hypothetical. The fourth generation of nontechnology covers period from 2015 onwards and it will be related to “heterogeneous molecular Nanosystems” (Bowman and Hodge 2006: 1061-1063). These futuristic applications of nanotechnology include complex machines capable of performing complex functions (Malsh 2013: 461-486). However, these applications are in early phases of development and yet to be commercialized.

**Heath, Safety and Environmental Risks**

Despite its promise of remarkable benefits, the potential complex risks generated by this technology warrant serious consideration. Some scientific findings have highlighted the risks that nanoscopic materials could pose to human health, and environment due to their minute form and novel properties (Action Group on Erosion, Technology and Concentration 2005: 13). The uncertainty regarding the magnitude of nanomaterials risks have been amplified by the lack of quantitative information. Nanomaterials can penetrate in human body through various channels, such as lungs, intestine and through skin layers. However, the likelihood of penetration depends upon the size and characteristics of nanomaterials. Therefore, nanoparticles risks to human health are difficult to generalise; these particles have to be assessed individually to determine health risks (Hoet et al. 2004: 12).

Furthermore, some studies have also elucidated that nanoparticles can get accumulated in plants, and can be transferred to consumers. The impact of nanotechnology on human health is contingent on the method of its employment and the risks exhibited by it (Wuger and Cottier 2013: 4). Insufficient knowledge of nanoparticles properties creates difficulty in elucidating their biological and toxicological effects (Oberdörster et al. 2007: 1). The European Commission Scientific Committee on Emerging and Newly Identified Health Risks (2009: 52-56) concluded that the science in regard to risk assessment and risk identification needs to be developed. It suggested that the risks assessment must be done on a case by case basis. The scientific findings about nanomaterials' risks on humans and environment have highlighted the insufficiency of data and contextual nature of their risks. It is essential to develop a strong knowledge base to reduce uncertainty and to promote commercialisation of nanotechnology.

**Social, Economical and Ethical Implications**

Nanotechnology is being projected as a tool to eradicate poverty by addressing sustainable development challenges. Convergence of nanotechnology with other new technologies has the potential to promote social and economic growth. It is this transformative potential of nanotechnology which has driven the developing countries to invest in this highly productive research area. This view has been supported by Task Force on Science, Technology and Innovation of the United Nation Millennium Project Report 2005. Its report states that the innovative field of nanotechnology is likely to be relevant for developing countries as it is very advantageous; uses less labour and resources. Nanotechnology processes can contribute to the sustainable development and can enhance the efficacy of existing technologies (United Nations Millennium Project 2005: 72).

However, some scholars assert that developing countries lack sound social and economic infrastructure necessary to access and reap the benefits of nanotechnology (UNESCO 2006: 17-18). Moreover, the multidisciplinary nature of nanotechnology and huge investments in this field would probable contribute to migration of skilled labour to the developed countries (Invernizzi and Foladori 2005: 110). Nanotechnology applications have the potential to replace raw materials that could also overbalance the commodities markets worldwide (Barker et al. 2009: 257).

Considering the fact that nanotechnology basic research is being aggressively patented, multiplication of patents has constituted fragmented patent landscape (Lemley 2005: 618). This has also generated concerns about access and transfer of nanotechnology to the developing world (Latif 2012: 5-8). Development in the field of nanotechnology trigger concern that it will exacerbate economic and social inequalities between developed and developing countries because of their varied technological capacity to access and utilize nanotechnology, resulting in “nanodivide” (Roco and Bainbridge 2006: 357). Therefore, technological innovation also tends to vary with regard to their commercial significance. Any endeavour to promote developing countries’ access to nanotechnologies must take into account these features (Latif 2012: 5-8).

Though, nanotechnology applications would be instrumental in sorting out sustainable development concerns to some extent, it is not certain whether there benefits will be equally distributed, particularly to the developing world. Access to nanotechnology is likely to be hampered by the lack of social and institutional infrastructure. The lack of capacity building and the vigorous patenting in this field will contribute in augmenting global inequalities.

Some scholars opine that nanotechnologies will raise ethical dilemmas that we have not envisaged (Demissie 2008: 327). Nanotechnology may contribute in highly advance surveillance machines, human enhancement applications thereby endangering the “right to privacy”. For example, a miniscule chip implanted in the body to examine a tumour requires continual observation (Sharma and Chugh 2009: 442). Another ethical issue that the critics are apprehensive of is “grey goo”; self-replicating machines capable of causing havoc (Drexler 1986). In addition, nanotechnology convergence with other technologies boosts research in complex hybrid organisms. These novel research areas give rise to myriad moral issues that demand immediate attention (Sandler 2009: 31). However, most of its ethical concerns are considered as speculative by some, but these issues must be examined to avoid the likelihood of them becoming a reality.

**International Regulatory Efforts in Nanotechnology**

The transnational impacts of the nanotechnology, its unique hazards and its implications stress the need for an international regulation. However, lack of terminology and risk management methodologies; need of comprehensive knowledge of nanotechnology risks not only creates challenges in framing a regulatory policy but also discourage commercialisation of nanotechnology applications (OECD 2013: 14). At international level, harmonized efforts are building up that will intensify the discourse of international regulation of nanotechnology.

International Organisation for Standardisation (ISO), a non-governmental organisation, involved in promotion of international coordination and unification of international standards. It has set up technical committee on nanotechnology (ISO TC/229) which is developing nomenclature and standardizations in this field (Mantovani et al. 2010: 65). The work of the technical committee is divided into four Working Groups (WGs): TC229/JWG1 develops nomenclature and terminology for different nano-related terms; TC229/JWG2 concentrates on establishing measurement and characterisation methods; TC229/WG3 focuses on health, safety, and environmental aspects of nanotechnology; and TC229/WG4 is developing specifications for nanomaterials. It has published several standards in this field. Apart from this nanotechnology specific committee, other ISO committees also deal with nanotechnology aspects while working in their respective fields (Leach 2014: 3-4). So far ISO has published 42 international standards, and various other standards are under development. However, the TC 229 working groups are confronting many challenges due to the scientific uncertainty in this field; knowledge gaps and the lack of skills and the lack of consensus among professionals. In case of an emerging and uncertain field like nanotechnology, standards' validity is inevitable for their global ratification. Moreover, in order for the data to be available, TC work must be conducted in a transparent manner (Forsberg 2012: 733-737). ISO decision-making process is consensus-based and therefore, the procedure for developing standards is taxing and tedious. However, there is a consensus among various stakeholders that the international standardisation organisations would aid significantly in accomplishing nanotechnology promises (Mantovani et al. 2010: 70).

Although ISO standards are non-mandatory, yet they are important for providing a substantial knowledge base to substantiate regulatory decisions and are indispensible for appropriate regulation (Ngarize et al. 2013: 133). ISO works in collaboration with other organisations, such as the Organisation for Economic Co-operation and Development (OECD) (Marchant et al. 2012: 193).

OECD has been playing a pivotal role in advancing debate on nanotechnology hazards and encouraging global cooperation and harmonization regarding the risks of nanomaterials. It has two working programmes on nanotechnology: the Working Party on Manufactured Nanomaterials (WPMN) and the Working Party on Nanotechnology (WPN). The WPMN set up in 2006, under the OECD Chemicals Committee, focuses on developing working definitions of nanomaterials for regulatory purposes within the context of health, safety and regulatory concerns. It seeks to encourage cooperation and coordination to harmonize risk assessment frameworks and foster information sharing and dissemination to address risk assessment of nanomaterials. It is working on eight projects (Visser 2007: 330-332). The WPN was established in 2007, and its objective is to provide guidance on regulatory controversies of scientific and technical nature regarding the responsible development of nanotechnology. Some scholars excoriate the work of both the working parties as being recommendatory, merely assisting in information exchange (Falkner and Jaspers 2012: 21). Whereas others believe that OECD has organizational legitimacy in advancing harmonious approaches on nanotechnology regulation. However, the lack of transparency in its process affects its credibility as an institution for devising international regulatory framework for nanotechnology (Falkner et al. 2010: 516).

World Health Organisation (WHO) and Food and Agricultural Organisations (FAO) are focusing on reviewing the national and international activities on risk regulation, and identifying strategies to address potential hazards associated with food safety in nanotechnology products (2013: 4-5). FAO in collaboration with World Health Organisation (WHO), organized several meetings since 2009, on the use of nanotechnology in food and agriculture sectors and potential food safety issues. In 2012, the FAO and WHO adopted a draft paper surveying the national and international initiatives regarding the risk management approaches. In the final report, released in 2013, it outlined that the OECD projects on nanotechnology will contribute in enhancing knowledge of risk assessment procedures particular to nanomaterials. However, it asserted the need of a hostile risk assessment framework for food chemicals in nanotechnology. It stressed that mandatory labelling of nanotechnology products would provide transparency to the consumers, thereby strengthening their public trust in the technology (FAO/WHO 2013: 33-36).

WHO Intergovernmental Forum on Chemical Safety (IFCS), established in 1994, has begun to evaluate nanotechnology safety-related issues[3]. In 2008, in its sixth session, it has adopted the Dakar Statement on Nanotechnology and Manufactured Nanomaterials in 2008, which recognised absence of a comprehensive regulatory framework and called for adoption of a risk management framework based on precautionary approach for nanomaterials. It also entailed international cooperation in information sharing and risk assessment (IISD 2008: 1-12). Its recommendations includes among others: stakeholders' dialogue and risk evaluation and risk management of workers health and safety; international cooperation in information sharing for subsequent users; and development of national codes of conduct (IFCS 2008: 5-8). However, during the negotiations, the demand for global codes of conduct raised by developing countries and non-state actors was turned down by the UK and other European countries. Therefore, the Dakar Statement states that its goal is to consider the possibility of devising universal codes of conduct expediently (IFCS 2008: 5-8). Its recommendations are denounced for being "aspirational in nature", therefore, not of much relevance in context of the nanotechnology regulatory debate (Leary and Pisupati 2010: 238). To deal with the risks of nanomaterials at workplace, WHO is currently focusing on the occupational health and safety risks of nanomaterials and formulating occupational guidelines to safeguard workers (WHO 2014).

The United Nations Educational, Scientific and Cultural Organisation (UNESCO) has been addressing the ethical and political aspects of nanotechnology from an international perspective. Nanotechnology issues were considered during the third session of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)[4] held in Rio de Janeiro in December 2003, and Bangkok in March 2005. In 2004, COMEST noted that the exceptional characteristics of nanotechnology and the considerable challenges in its regulation call for UNESCO's

[3] The Intergovernmental Forum on Chemical Safety (IFCS) was created by the International Conference on Chemical Safety held in Stockholm in April 1994.

[4] The World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) is an advisory body, established up by UNESCO in 1998. Its authority is to devise ethical principles in several areas: environmental and nanotechnology ethics; ethical issues related to the technologies of the information society; science ethics

attention. To appraise the ethical aspects of nanotechnology from an international dimension (Scholze 2007: 326), a multidisciplinary ad-hoc group was formed in 2005, which drafted a policy plan on nanotechnology and suggested the exigency for ethical education and information regarding research and development policies (UNESCO 2006b: 14-15). In 2006, UNESCO came out with a report Ethics and Politics of Nanotechnology, in which it acknowledged that nanotechnology's novel attributes, might cause hazards on exposure and create difficulties in their regulation. It acknowledges the challenge is to craft specific regulations for nanotechnologies and, concurrently implement existing regulations on the nanotechnology industries (UNESCO 2006a: 13-19). In 2007, COMEST proposed inter alia for ethical guidelines on nanotechnologies and stakeholders' involvement in its ethical dialogue (UNESCO 2007: 3-13). The capacity of UNESCO as transnational fora to regulate various facets of nanotechnology risks is being excoriated on the ground that its objectives does not focus on risk assessment of hazardous chemicals and their transboundary effects (CIEL 2009: 26).

Among these global initiatives, the International Conference on Chemical Management, opened in 2006, is of particular relevance to nanotechnology regulatory discourse. In the same year, it has formed the Strategic Approach to International Chemical Management (SAICM), an autonomous international framework that promotes the chemicals safety at global level. It has been mulling over the international regulation of nanotechnology since the second international conference on chemicals management (ICCM-2) held in 2009. It has adopted a nano-specific resolution II/4 E on Nanotechnologies and Manufactured Nanomaterials to assist developing and transition countries for their productive engagement in responsible development of nanotechnology. It also stressed the exchange of scientific information and to improve public dialogue between governments and various stakeholders in nanotechnology. At the third session of ICCM, held in 2012, nanotechnology was included to the Global Plan of Action and an impetus was provided to nanotechnology policy concerns (IISD 2012: 8-9). SAICM is a global mechanism that aims to mitigate the north-south disparities and favours broad participation of governments and stakeholders. Though, it has not come up with any binding resolution on nanotechnology so far, but it aims to mitigate risks and encourage information sharing and oversight, which are relevant in case of nanotechnologies and nanomaterials (CIEL 2009). To address the specific needs of developing countries and countries with economies in transition, United Nations Institute for Training and Research (UNITAR) is advancing its efforts towards capacity building, developing training materials, and pilot projects (CIEL 2009). UNITAR, operating within the framework of the Inter-Organization Programme for the Sound Management of

Chemicals (IOMC), has completed, since 2009, various pilot projects in developing countries to educate on nano-safety issues and enhance their national institutional capacities to tackle nanotechnology concerns (UNITAR 2012).

The International Risk Governance Council (IRGC) is working actively on risk management of nanotechnology. In 2005, it has proposed a comprehensive risk governance framework that incorporates societal perspective in risk assessment and risk management, and involves stakeholders' participation. The framework sorted the risk-related knowledge to address "complex", "uncertain", and "ambiguous" risks (IRGC 2005: 12-16). IRGC has applied this risk governance model to nanotechnology in a White Paper on Nanotechnology Risk Governance in 2006. It advocated a theoretical framework for nanotechnology risk governance that focuses on all the four generations of nanotechnology. The framework recommends the regulators to separately analyse the two frames while opting for risk regulatory mechanism for nanotechnology. It also tends to combines risk-benefit assessment along with social¸ ethical and economic aspects (IRGC 2006: 12-19). In 2007, IRGC adopted a policy brief 'Recommendations for a global, coordinated approach to the governance of potential risks'. Apart from suggesting the holistic risk governance paradigm, it marked the need to develop harmonized risk assessment methodologies through international cooperation, coordinated by OECD and WTO (IRGC 2007: 15-17). The cyclical nature of the nanotechnology risk governance framework provides room for adaptation. However, the IRGC framework has invited criticism as it hardly focuses on 'metaphysical risks' of nanotechnology. IRGC can contribute significantly as an important forum of information gathering and international coordination on nanotechnology risk regulation.

Other international organisations such as United Nations Environment Programme (UNEP) and International Labour Organisation (ILO) are less dynamic in discussing the regulatory aspects of nanotechnology. Their involvement in nanotechnology debates is limited to guidelines and recommendations. In sum, the efforts to promote international coordination are advancing but in a rather fragmented manner.

Apart from international organisations, non-governmental organisations are also actively participating in the regulatory debates, and some have called for a moratorium on research until nano-specific regulations evolve. However, NGOs' demand for stringent regulation of nanotechnology risks and prohibition on their commercialization has not been able to garner governments' support so far (Hodge et al. 2010: 434-438). Though, civil-society groups and international organizations are adhering to a conservative approach towards nanotechnology, the governments are apathetic about its regulatory discourse. However, lack of nano-specific regulations in countries has contributed to the development of soft law mechanism by the industries such as codes of conduct, voluntary reporting scheme, guidelines and risk management systems (Fiorino 2010: 28-34). For example, UK Responsible NanoCode; BASF- Code of Conduct; Nano risk Framework; European Commission Code of Conduct; Responsible Care; Foresight Guidelines. Voluntary initiatives, programmes can be conducive in dissemination of knowledge and development of risk assessment tools to facilitate the policy-making on nanotechnology (Gadekar and Kadam 2014: 226). Therefore concerted efforts are required to promote innovative efforts and the development of global regulatory framework for nanotechnology (Barbier 2011: 242-243).

The novelty of nanotechnology lies in its remarkable characteristics that offer cutting-edge applications. One of the predicaments concerning nanotechnology is complexities involved in defining the concept. However, there is an agreement that manipulation done on the nanoscale i.e 100 nm or less, leads to novel properties. Therefore, size is the predominant factor in the discourse. A regulatory definition of nanotechnology must incorporate both size and remarkable properties as determining criteria. Nanotechnology tremendous benefits are often commensurate with its unprecedented risks that are unquantifiable due to pervasive uncertainty. The lack of risk assessment tools and metrology to unravel the risks of nanomaterials necessitates sound scientific knowledge base and further research.

The potential of nanotechnology applications to promote sustainable development in developing countries cannot be downplayed. It is unlikely that benefits brought by nanotechnology radical applications will be equitably distributed, given that the use of nanotechnology as a techno-fix is contingent on the availability of promising social and institutional frameworks. To avail the benefits of nanotechnology, social and economical aspects need to be integrated in nanotechnology discourse to channel the nanotechnology research in sustainably resolving the problems. In order to pre-empt the technology gap, a nuanced approach to nanotechnology applications must be adapted to encourage sustainable growth in the developing countries. International cooperation is necessary to strengthen and augment the productive capacity of developing countries and to facilitate transfer of nanotechnology.

The transnational impacts of nanotechnology along with its unique hazards and socio-economic dilemmas entail a regulatory policy and that too international. However, the scientific ambiguity regarding its myriad risks, lack of harmonised terminology and risk assessment tools create hurdles in crafting a regulatory oversight for this technology. Several international organisations are involved in regulatory debate of nanotechnology; however, only few are providing meaningful inputs in the process. ISO, OECD, and IRGC are playing an influential role in advancing nanotechnology regulatory debates. Lack of authority and participation of developing countries in these organizational initiatives also raises apprehension about their capacity to address nanotechnology concerns comprehensively at global level. The existing regulatory efforts at international level are fragmented regarding their scope. However, these international efforts are contributing in the development of concrete scientific base to fill knowledge gaps in risk assessment, which are prerequisite for devising regulatory framework for nanotechnology. It is necessary that these organisations must coordinate their risk assessment activities to avoid duplication of effort in nanotechnology risk regulatory process. International organisations should assiduously involve and cooperate in formulating a universal regulatory framework regarding nanotechnology.

**References**

1. Action Group on Erosion, Technology and Concentration (ETC Group) Report (2005), "The Potential Impacts of Nano-Scale Technologies on Commodity Markets: The Implications for Commodity Dependent Countries", South Centre Research Paper no 4, [Online: web] Accessed on 20 December 2014, URL: http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/45/01/southcentre.commodities.pdf

2. Action Group on Erosion, Technology and Concentration (ETC Group) Report (2003), *The Big Down: Technologies Converging at the Nano-scale*, [Online: web] Accessed on 10 March 2014, URL: http://www.etcgroup.org. http://www.etcgroup.org/sites/www.etcgroup.org/files/thebigdown.pdf

3. Barbier, Edward (2011), "The Policy Challenges for Green Economy and Sustainable Economic Development*", Natural Resources Forum.*

4. Barker, Todd F. et al. (2009) "Nanotechnology and the Poor", in Fritz Allhoff and Patrick Lin (eds.), *Nanotechnology and Society: Current and Emerging Ethical Issues*, New York: Springer.

5. Baucher, Marie Ange et al. (2013), *Symposium on Assessing the Economic Impact of Nanotechnology : Synthesis Report*, Project Report, Organisation for

Economic Corporation and Development, [Online: web] Accessed on 20 November 2014, URL: http://www.oecd.org/sti/nano/Washington%20Symposium%20Report_final.pdf

6. Bowman, Diana M. and Graeme A. Hodge (2006), "Nanotechnology; Mapping the Wild Regulatory Frontier", *Futures,* 38(1):1060-1073.

7. Cao, Guozhong (2004), *Nanostructures & Nanomaterials: Synthesis, Properties and Applications,* London: Imperial College Press.

8. Center for International Environmental Law (CIEL) (2009), "Addressing Nanomaterials as an Issue of Global Concern", The Center for International Environmental Law, [Online: web] Accessed on 14 January 2015, URL: http://www.ciel.org/Publications/CIEL_NanoStudy_May09.pdf

9. Demissie, Hailemichael Teshome (2008), "Taming Matter for the Welfare of Humanity: Regulating Nanotechnology", in Rogers Brownsword and Karen Young (eds.), *Regulating Technologies: Legal futures, Regulatory Frames and Technological Fixes,* Hart Publishing: Portland.

10. Drexler, K. Eric (1986), "Engines of Creation: The Coming Era of Nanotechnology", [Online: web] Accessed on 26 July 2013, URL: http://e-drexler.com/d/06/00/EOC/EOC_Chapter_1.html#section05of10.

11. Falkner, Robert and Nico Jaspers (2012), "Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap", *Global Environmental Politics*, 12(1): 30-55. [Online: web] Accessed on 15 November 2014, URL: http://personal.lse.ac.uk/falkner/_private/2012_Falkner_Jaspers_RegulatingNanotechnologies.pdf

12. Falkner, Robert et al. (2010), "International Coordination and Cooperation: The Next Agenda in Nanomaterials Regulation", in Graeme A Hodge et al. (eds.), *International Handbook on Regulating Nanotechnologies,* Massachusetts: Edwar Elgar.

13. Feynman, Richard P. (1959), *There's Plenty of Room at the Bottom*, California Institute of Technology, [Online: web] Accessed on 10 March 2014, URL: http://www.its.caltech.edu/~feynman/plenty.html.

14. Fiorino, Daniel J. (2010), *Voluntary Initiatives, Regulation, and Nanotechnology Oversight: Charting a Path,* Woodrow Wilson International Centre for Scholars, Washington, DC: Project on Emerging Nanotechnologies.

15. Food and Agricultural Organisation and World Health Organisation (FAO/WHO) (2013), *State of the Art on the Initiatives and Activities Relevant to Risk Assessment and Risk Management of Nanotechnologies in the Food and Agriculture Sectors*, FAO/WHO Technical Paper, Geneva, [Online: web] Accessed on 21 January 2015,
URL: http://www.fao.org/docrep/018/i3281e/i3281e.pdf

16. Forsberg, Ellen-Marie (2012), "Standardisation in the Field of Nanotechnology: Some Issues of Legitimacy," *Science Engineering Ethics*, 18(4): 719-739.

17. Gadekar, Jyoti M and Kiran D Kadam (2014), "Nanotechnology: Green Innovation", *International Journal of Science and Research*, 3(1): 225-228.

18. Global Industry Analysts, Inc., (2016), *Nanotechnology: A Global strategic Business Report*, [Online: web] Accessed on 12 August 2016, URL: http://www.strategyr.com/pressMCP-1031.asp.

19. Hodge, Graema A. et al. (2010), *International Handbook on Regulating Nanotechnologies*, Massachusetts: Edward Elgar Publishing.

20. Hoet, Peter H.M et al. (2004), "Nanoparticles-Known and Unknown Health Risks", *Journal of Nanobiotechnology,* 2(12): 12.

21. Intergovernmental Forum on Chemical Safety (IFCS) (2008), Sixth Session of the Intergovernmental Forum on Chemical Safety, Dakar, Senegal 15 – 19 September 2008 , Final Report, IFCS/FORUM-VI/07w, [Online: web] Accessed on 15 December 2014, URL:
http://www.who.int/ifcs/documents/forums/forum6/f6_finalreport_en.pdf.

22. International Institute for Sustainable Development (IISD) (2008), "Summary of Sixth Session of the Intergovernmental Forum on Chemical Safety", *Earth Negotiations Bulletin*, 15(160): 1-12.

23. International Institute for Sustainable Development (IISD) (2012), "Summary of the Third Session of the International Conference on Chemicals Management: 17-21 September 2012", *Earth Negotiations Bulletin*, 15(196): 1-16.

24. International Risk Governance Council (IRGC) (2005), *Risk Governance: Towards an Integrative Approach*, White Paper 1, Geneva: International Risk Governance Council, [Online: web] Accessed 12 January 2015, URL:

http://www.irgc.org/IMG/pdf/IRGC_WP_No_1_Risk_Governance__reprinted_version_.pdf

25. International Risk Governance Council (IRGC) (2006), *Nanotechnology Risk Governance*, White Paper 2, Geneva: International Risk Governance Council, [Online: web] Accessed on 14 January 2013, URL: http://www.irgc.org/IMG/pdf/IRGC_white_paper_2_PDF_final_version-2.pdf

26. International Risk Governance Council (IRGC) (2007), *Nanotechnology Risk Governance: Recommendations for a Global, Coordinated Approach to the Governance of Potential Risks*, Policy Brief, [Online: web] Accessed on 25 January 2015, URL: http://www.irgc.org/IMG/pdf/PB_nanoFINAL2_2_.pdf

27. Invernizzi, Noela and G Foladori (2005), "Nanotechnology and the Developing World: Will Nanotechnology Overcome Poverty or Widen Disparities?", *Nanotechnology Law and Business*, 2(3): 1-10.

28. ISO, *ISO/TC 229 Nanotechnologies*, 2005, [Online: web] Accessed on 12 January 2015, URL: http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983

29. Latif, Ahmed Abdel (2012), "Intellectual Property Rights and Green Technologies from Rio to Rio: An Impossible Dialogue?", Policy Brief No. 14, International Centre for Trade and Sustainable Development, [Online: web] Accessed 18 December 2014, URL: http://ictsd.org/downloads/2012/07/intellectual-property-rights-and-green-technologies-from-rio-to-rio-an-impossible-dialogue.pdf

30. Leach, Richard K. (2014), *Fundamental Principles of Engineering Nanometrology*, Oxford: Elsevier.

31. Leary, David and Balakrishna Pisupati (ed.) (2010), *The Future of International Environmental Law*, New York: United Nations University Press.

32. Lemley, Mark A (2005), "Patenting Nanotechnology", *Stanford Law Review*, 58(2): 601-630.

33. Lovestam, Goran et al. (2010), "*Considerations on a Definition of Nanomaterials for Regulatory Purposes*", Reference Report, European Commission Joint Research Centre, Luxembourg: European Union, [Online: web] Accessed on 20 December 2014,

URL: http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf

34. Lux Research (2014), *Nanotechnology Update: Corporations Up Their Spending as Revenues for Nano-enabled Products Increase*, [Online: web] Accessed on 12 February 2015, URL: http://portal.luxresearchinc.com/research/report_excerpt/16215.

35. Malsh, Ineke (2013), "The Just War Theory and the Ethical Governance of Research", *Science Engineering Ethics*, 19(2): 461-486.

36. Mantovani, Elvio et al. (2010), *Developments in Nanotechnologies Regulation and Standards 2010*, Report of the Observatory Nano, [Online: web] Accessed 12 March 2015, URL: http://www.steptoe.com/assets/htmldocuments/ObservatoryNano_Nanotechnologies_Regulation%20and%20Standards_June%202010.pdf

37. Marchant, Gary et al. (2012), "Transnational New Governance and International Coordination of Nanotechnology Oversight", in David Dana (ed.), *The Nanotechnology Challenge: Creating Legal Institutions for Uncertain Risks*, New York: Cambridge University Press.

38. Maynard, Andrew (2011), "Don't Define Nanomaterials", *Nature*, 475(7354): 31.

39. Morrow, K John Jr. et al. (2007), "Recent Advances in Basic and Clinical Nanomedicine", *Medical Clinics of North America*, 91(5): 805-843.

40. Ngarize, Sekai et al. (2013), "The Case for Regulating Nanotechnologies: International, European and National Perspectives", *Review of European Community and International Environmental Law*, 22(2): 131-145.

41. NNI, *What it is and how does it work?*, [Online: web] Accessed on 14 December 2014, URL: http://www.nano.gov/nanotech-101/what

42. Nordmann, Alfred (2004), "Nanotechnology's Worldview: New Space for Old Cosmologies", *IEEE Technology and Society Magazine*, 23(4): 48-54.

43. Oberdörster, Gunter et al. (2007), "Toxicology of Nanoparticles: A Historical Perspective, *Nanotoxicology*, 1(1): 2-25.

44. OECD, *OECD Working Party on Nanotechnology (WPN): Vision Statement*, [Online: web], Accessed on 15 March 2015, URL: http://www.oecd.org/sti/nano/oecdworkingpartyonnanotechnologywpnvisionstatement.htm

45. Organisation for Economic Co-operation and Development (2013), *Nanotechnology for Green Innovation*, Working Party on Nanotechnology, DSTI/STP/NANO (2013)3/FINAL.

46. Peterson, Chris (1995), "Nanotechnology: From Concept to Research and Development", [Online: web] Accessed on 25 March 2014, URL: http://www.foresight.org/Hotwired.all.files/index.html.

47. Renn, O and M. C. Roco (2006), "Nanotechnology and the Need for Risk Governance", *Journal of Nanoparticle Research*, 8(2): 153-191.

48. Roco, Mihail C. and William Sims Bainbridge (ed.) (2006), *Nanotechnology: Societal Implications- Individual Perspectives*, Berlin: Springer.

49. Sandler, Ronald (2009), "Nanotechnology: The Social and Ethical Issues", Project on Emerging Nanotechnologies, Woodrow Wilson Centre, [Online: web] Accessed on 30 January 2014, URL: http://www.pewtrusts.org/~/media/legacy/uploadedfiles/phg/content_level_pages/reports/nanofinalpdf.pdf

50. Scholze, Simone (2007), "Nanotechnology and Ethics: The Role of UNESCO in International Context", in Gerhard Banse (ed.), *Assessing Societal Implications of Converging Technological Development*, Berlin: Edition Sigma.

51. Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) (2009), *Risk Assessment of Products of Nanotechnologies* , Brussels: European Commission, [Online: web] Accessed on 21 January 2015, URL:http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf

52. Scrinis, Gyorgy and Kristen Lyons (2007) "The Emerging Nano-Corporate Paradigm: Nanotechnology and the Transformation of Nature, Food and Agri-Food Systems", *International Journal of Sociology of Agriculture and Food,* 15(2): 22-44.

53. Sharma, Kanika and Archana Chugh (2009), "Legal Aspects of Nanobiotechnology Inventions: An Indian Perspective", *SCRIPTed,* 6(2): 433-448.

54. Shew, Ashley (2008), "Nanotech's History: An Interesting, Interdisciplinary, Ideological Split", *Bulletin of Science Technology and Society*, 28(5): 390-399.

55. Strategic Approach to International Chemicals Management (SAICM), *Emerging policy issues: Nanotechnologies and Manufactured Nanomaterials*, Resolution II/4 Part E, May 2009. [Online: web] Accessed on 21 April 2013, URL: http://www.who.int/iomc/saicm/iccm2_resolution_II_4.pdf

56. The Center for International Environmental Law (CIEL) (2009), "Addressing Nanomaterials as an Issue of Global Concern", The Center for International Environmental Law, [Online: web] Accessed on 14 January 2015, URL: http://www.ciel.org/Publications/CIEL_NanoStudy_May09.pdf.

57. The Royal Society and the Royal Academy of Engineering (2004), *Nanoscience and Nanotechnologies: Opportunities and Uncertainties,* London: The Royal Society.

58. UN Millennium Project (2005), Innovation: Applying Knowledge in Development, Task Force on Science, Technology, and Innovation, London: Earthscan.

59. United Nations Educational, Scientific and Cultural Organization (UNESCO) (2006a), *The Ethics and Politics of Nanotechnology*, Brochure, Paris: UNESCO, [Online: web] Accessed on 19 February 2014, URL: http://unesdoc.unesco.org/images/0014/001459/145951e.pdf.

60. United Nations Educational, Scientific and Cultural Organization (UNESCO) (2006b), *COMEST Extraordinary Session 27-28 June Session*, Proceedings, Paris: UNESCO, [Online: web] Accessed on 28 January 2015, URL: http://unesdoc.unesco.org/images/0015/001514/151443e.pdf.

61. United Nations Educational, Scientific and Cultural Organization (UNESCO) (2007), *Nanotechnology and Ethics: Policies and Actions,* World Commission on the Ethics of Scientific Knowledge and Technology (COMSET), Paris: UNESCO, [Online: web] Accessed on 2 February 2015, URL: http://unesdoc.unesco.org/images/0015/001521/152146e.pdf

62. United Nations Institute for Training and Research (UNITAR) (2012), *Strengthening National Capacities to Address Nanotechnology and*

*Manufactured Nanomaterials: Project Information Note on Pilot Projects in 3 Countries*, [Online: web] Accessed on 22 April 2013, URL: http://www.unitar.org/cwm/sites/unitar.org.cwm/files/Concept%20Note_Nano%20Pilots_Final%202_PDF.pdf

63. Visser, Rob (2007), "A Sustainable Development for Nanotechnologies: An OECD Perspective", in Graema Hodge et al. (eds.), *New Global Frontiers in Regulation: The Age of Nanotechnology*, Massachusetts: Edward Elgar Publishing.

64. WHO, *WHO Guidelines on Nanomaterials and Worker's Health*, [Online: web] Accessed on 19 November 2014, URL: http://www.who.int/occupational_health/topics/nanotechnologies/en/

65. Wuger, Daniel and Thomas Cottier (2013), *Genetic Engineering and the World Trade System: World Trade Forum*, Cambridge: Cambridge University Press.