Nanotechnology in Asia: A Preliminary Assessment of the Existing Legal Framework

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Abstract

Nanotechnology, often referred to as the next industrial revolution after internet, is an interdisciplinary study with limitless potential. It is claimed that nanotechnology is now at the stage where ICT and use of plastic were in 1960s and biotechnology was in 1980s. Already more than 2000 nano-enabled consumer products are in the market and the ILO predicts that by 2020, twenty percent of the products will be developed using nanotechnology. The UNESCO traced top ten applications of nanotechnology within the UN Millennium Development Goals (MDGs), which are: (a) Energy storage, productions and conversion; (b) Agricultural productivity enhancement; (c) Water treatment and remediation; (d) Disease diagnosis and screening; (e) Drug delivery systems; (f) Food processing and storage; (g) Air pollution and remediation; (h) Construction; (i) Health monitoring; and (j) Vector and pest detection and control. With all these promises, concerns are also there, as a majority of the researchers feel that nanoparticles must have some adverse health and environmental effects. Besides, to many organizations, nanotechnology is the next asbestos. However, it is a matter of great concern that there is no specific internationally agreed legal framework to deal with nanotechnology. The mistakes for which the introductions of genetically modified food or nuclear energy could not be completely successful, should not be repeated and the application of nanotechnology should be encouraged within the approved legal framework. Some of the Asian countries like China, Japan, South Korea, Malaysia, Singapore, India, Taiwan and few others have already achieved tremendous success in this area. This paper aims at introducing the legal aspects of nanotechnology and its regulatory developments in some of the Asian countries. The consideration of most of the available literature in this area being mainly from Europe and North America, this paper aims to share the legal development of nanotechnology in the Asian context.

KeyWords: Nanotechnology law and policy, safe handling of nanomaterials, nanotechnology in Asia, legal and regulatory aspects of nanotechnology, responsible and sustainable development of nanotechnology

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I . Introduction

The role of science and technology towards the attainment of basic and fundamental human rights in the present world cannot be ignored in any way. Technologies, if used positively and effectively, can introduce some epoch making changes and can be used as an aid to ensure different aspects of citizens' right to life, health, education, etc. The United Nations Millennium Declaration as adopted in the eighth plenary meeting of the General Assembly on September 8, 2000 stipulated that the benefits of new technologies should be ensured and made available to all. Furthermore, in the World Summit Outcome of 2005 (General Assembly resolution no. 60/1), the vital role of the science and technology for the achievement of internationally agreed development goals was recognized.[1] In this context, the discussion on nanotechnology, which is often referred to as the next industrial revolution, or next wonder after internet and the wave of the future, and its legal and regulatory implications is very timely.

The word 'nano', though literary means 'very small', has apparently turned to be crucial in the socio-economic development of countries irrespective of size and economy in recent times. Such a conclusion can be drawn taking into account the apparent race among the countries in nanotechnology research and development (R&D) from the amount of investment in this area. Though there are hundreds of countries contesting in the race to take the lead, statistics shows that nanotechnology is still a venture of developed countries.[2] Nevertheless, all these countries have already expressed their intention in this regard by way of either national framework, statement, roadmap on nanotechnology, patent application, scientific publication or by introducing specific courses in academic institutions at different levels. Almost 2,000 consumer products, which are developed using nanomaterials or nanoparticles[3] are now available in the market,[4] and hundreds of

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1. U.N. Millennium Declaration para.20, Sept. 8, 2000.
2. Philip Shapira & Wang Jue, *Follow the Money*, 468 Nature 627-28 (2010).
3. In this paper, the words 'nanomaterials' and 'nanoparticles' are used interchangeably and for these two words, both singular and plural forms are used frequently.
4. An Inventory of Nanotechnology-based Consumer Products Introduced on the Market, The Project on Emerging Nanotechnologies, http://www.nanotechproject.org/cpi/ (last visited Aug. 5, 2014). The actual number of products must be more than this number as the database contains the products which are voluntarily listed by the companies only. Against this USA based database, European countries are also in the process of developing European register of nanotechnology products. *See* Umwelt Bundes Amt, Concept for a European Register of Products Containing Nanomaterials (2012), *available at* http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/information_concept_nanoregister_npr_e_0.pdf.

nanomaterials are reported in scientific journals. By manipulating technologies at the atomic or molecular level, scientists have already produced consumer and industrial products which are stronger, cheaper, smarter, effective, durable, etc. The International Labour Organization (ILO) predicts that by 2020, twenty percent of the products will be developed using nanotechnology.[5]

However, there are serious concerns too, as in many scientific research it was found that some of the nanomaterials may cause adverse effects on human health and the environment.[6] The Reuter report on the death of two Chinese workers from among seven patients of permanent lung damage in a paint factory[7] and the re-assurance of the incident by the medical team that diagnosed the workers[8] compelled the world community to rethink about safe nanotechnology R&D for everyone involved in the whole process. The European Parliament also acknowledged that significant new risks are associated with nanomaterials "due to their minute size, such as increased reactivity and mobility, possibly leading to increased toxicity in combination with unrestricted access to the human body, and possibly involving quite different mechanisms of interference with the physiology of human and environmental species."[9] Some of the studies already warned that unless this issue of harm and risk can be properly managed, a cata strophic event may occur, which will put the whole venture before question mark. The Australian workers' union expressed their concern on the use nanoparticles, link-

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5. International Labour Organisation, ILO Introductory Report: Global Trends and Challenges on Occupational Safety and Health 20 (2011), *available at* http://www.ilo.org/wcmsp5/groups/public/@ed_protect/@protrav/@safework/documents/publication/wcms_162662.pdf.
6. *See, e.g.*, Indrani Mahapatra, J. Clark, Peter J. Dobson, Owen Richard & Jamie R. Lead, *Potential Environmental Implications of Nano-enabled Medical Applications*, 15 Envtl. Sci.: Processes & Impacts 123-44 (2013); Antonio Pietroiusti, *Health Implications of Engineered Nanomaterials*, 4 Nanoscale 1231-47 (2012); Vicki L. Colvin, *The Potential Environmental Impact of Engineered Nanomaterials.* 21 Nature Biotechnology 1166 (2003).
7. Tae Ee Lyn, *Deaths, Lung Damage Linked to Nanoparticles in China*, Reuters (Aug. 19, 2003), http://www.reuters.com/article/2009/08/19/idUSN19481304 (last visited Aug. 5, 2014).
8. Yuguo Song, Li Xue & Du Xuqin, *Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma*, 34 Eur. Respiratory J. 559-67 (2009).
9. Resolution of the European Parliament on Regulatory Aspects of Nanotechnology, Eur. Parl. Doc. 2208(INI) (2008).

ing nanoparticle with asbestos and advocated for proper regulation.[10]

Asia is one of the leading continents which have established nanodistricts. A nanodisctrict is a regional concentration of nanotechnology research institutions and firms clustered for research, development and commercialization aiming at sharing the scientific and technical capabilities, tacit knowledge exchange, which cluster large-scale nanotechnology research and commercialization, e.g. USA (San Francisco-San Jose, Boston, Washington, D.C.-Baltimore, Chicago and New York), Europe (Paris, London, Frankfurt, Berlin, Moscow and the Rhine-Ruhr), Asia (Tokyo, Kyoto-Osaka, Seoul, Singapore). Of the two hundred nanotechnology clusters as identified by Kahne et al,[11] concentrating on eighty percent of worldwide nanotechnology publications and ninety-seven percent of worldwide patents, eighty of such clusters are in Europe, fifty each from North America and Asia and twenty from the rest of the world.[12]

Some of the Asian countries like Japan, China, South Korea, Singapore, India, Iran, and Taiwan have already scored tremendous success in nanotechnology R&D, and these countries have been leading the global race of nanotechnology in terms of investment, patent and scientific publications in leading scientific journals. In this back drop, it is high time to assess the existing legal and regulatory framework in these Asian countries to evaluate whether there is any legal net to handle different aspects of nanotechnology and whether these legal frameworks, if any, are sufficient and effective.

Considering the very early stage of nanotechnology for the legal community, this paper sheds focus on the basic and preliminary discussion on nanotechnology law and policy in the Asian context. This paper also analyses the nanotechnology R&D in Asian countries and attempts to preliminarily assess the adequacy of the Asian laws to handle the relevant legal and regulatory challenges. Part II shares an overview of nanoscience and nanotechnology including terminologies and nomenclature, some statistics as to prediction on market and investment and glimpse of position of Asian countries in this area. Part III attempts to consider the legal and regulatory aspects of nanotechnology. Part IV projects an overview

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10. Julian Lee, *Union Raises Fears Over Nanotechnology*, Brisbane Times (Feb. 26, 2013), http://www.brisbanetimes.com.au/technology/technology-news/union-raises-fears-over-nanotechnology-20130226-2f2l5.html (last visited Aug. 5, 2014).
11. Kahane Bernard et al., Knowledge Dynamics and Agglomeration Phenomena, The Case of Nanotechnology (2009).
12. Philip Shapira, *Active Nanostructures, in* Encyclopedia of Nanoscience and Society 454 (David H. Guston ed. 2010).

of existing legal and regulatory framework in some of the leading Asian nanotech nations and further attempts to assess the adequacy of such framework to handle nanotech development in Part V. Part VI highlights some recent developments in nanotechnology regulation with specific focus on nano marking systems of Taiwan, Iran and Thailand. At the end, this paper concludes that the public should be involved in the regulatory process before introduction of nano-enabled products in the market. It also emphasizes on conducting more research to ensure the safety aspects of nanomaterials at different levels of life cycle. It further proposes for making collaborations between diffrent countries and suggests to develop product inventory and registry of nanoparticles. Finally, it adovocates to assess the existing municipal legal provisions to check their adequacy to handle human health and environmental implications of nanomaterials to convince the consumers in specific and the stakeholders in general.

Ⅱ. Overview of Nanoscience and Nanotechnology

Nanotechnology, the wave of the future, is the art and science of manipulating things at the atomic or molecule scale. Nanoparticles are ubiquitous in the nature and can be found in fire, smoke, viruses, proteins, volcanic erosion, minerals; e.g. clay, fog, milk and blood, skin, horns, hair, beaks, insects wing, lotus leaf, gecko feet, etc. Such natural nanoparticles are naturally not seriously dangerous and can easily be well refined by the defensive mechanism of human body. There are also manmade incidental nanoparticles, which are created though cooking smoke, industrial effluents, etc. However, the situation can be changed with the changing of natural nanoparticles into deliberately created engineered nanomaterials. The natural nanomaterials are not the subject matter of modern nanoscience and nanotechnology and therefore, modern study of nanoscinece and nanotechnology is not concerned about the natural nanoparticles. Instead, modern study of nanoscinece and nanotechnology deals with engineered nanomaterials that can be modified intentionally and deliberately in a laboratory setting and different characteristics can be attributed in it.

The use of nanomaterials in developing different products is very old. History suggests that at least back in the 4th Century,[13] people used to know the technique of using nanoparticles in different fields. Modern day cartoonists and science fiction writers have also contributed in introducing some concepts and ideas in this

13. *Nanotechnology Timeline*, Nat'l Nanotechnology Initiative, http://www.nano.gov/timeline (last visited Aug. 5, 2014).

area.[14] However, the modern history of nanotechnology started with the ground breaking lecture of the founding genius and Nobel laureate Richard Feynman, titled 'There's Plenty of Room at the Bottom'[15] at the meeting of the American Physical Society at the California Institute of Technology (CalTech) on December 29, 1959, where he shared the principle of possibility of maneuvering things atom by atom. The word 'nanotechnology' was first coined by Japanese professor, Norio Taniguchi, in 1974, but in the context of ultrafine machining. Kim Eric Drexler is a leading figure in popularizing the concept in the mainstream.

A. Terminologies and Nomenclature

At the very outset of the discussion, it should be made clear that the world community is still in the process of reaching to the consensus as to the meanings of different words used in the study of nanoscience and technology, especially nanoscale, nanoparticle, nanomaterial, nanoobject etc. Therefore, most of the countries have been progressing keeping in front a working definition.[16] Hence, it is significant to grasp the meaning of some of the terms as frequently used in the study of nanoscience and technology.

1. Nano

Nano is a unit of measurement like meter, kilometer, centimeter, millimeter,

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14. 1940s Newspaper comic character Dick Tracey's Watch was used as a communication character. *See* Victoria Sutton, Nanotechnology Law and Policy, Cases and Materials 15 (2011).
15. Richard Feynman, There's Plenty of Room at the Bottom, 1 J. Microelectromechanical Sys. 60 (1992). The transcript of the Lecture, which was published in this Journal of Microelectromechanical Systems is available. See Richard P. Feynman, There's Plenty of Room at the Bottom, available at http://media.wiley.com/product_data/excerpt/53/07803108/0780310853.pdf.
16. E.g., *Policy Statement on Health Canada's Working Definition for Nanomaterial*, Health Canada, http://www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php (last visited Aug. 5, 2014); *Nicnas Working Definition of Industrial Nanomaterial*, National Industrial Chemicals Notification and Assessment Scheme (NICNAS), *available at* http://www.nicnas.gov.au/regulation-and-compliance/nicnas-handbook/handbook-appendixes/guidance-and-requirements-for-notification-of-new-chemicals-that-are-industrial-nanomaterials/nicnas-working-definition-of-industrial-nanomaterial (last visited Aug. 5, 2014).

feet, inches, bite, byte, kilobyte, megabyte, gigabyte, terabyte, etc. The word 'nano', like most of the measurement prefixes, is derived from the Greek word "Nannos" meaning "dwarf/very short man," which means one-billionth. A nanometer (nm) is one billionth of a meter or a millionth of a millimeter. To share some examples, there are 25,400,000 nm in an inch, a sheet of paper is about 100,000 nm thick, and a strand of human hair is roughly 75,000 nm across. In reverse, if we compare a human being with the sun, the sun is billion times bigger than a human being.

The word 'nano' attains huge branding value and business community have been using this term frequently to mean something small and something which work at mini-scale. One of the crucial points to share here that at the nanoscale the particle behave dramatically, compared to their bulk form, which bars the regulators to reach to a concrete decision as to regulation of nanomaterials.

2. Nanotechnology

The simple but wholly accurate description of nanotechnology or, more specifically, the subset of nanotechnology is 'molecular manufacturing' that involves manipulating matter on an atom-by-atom or molecule-by-molecule basis to attain desired configurations.[17] Atom is the smallest unit of any chemical element. Nobel Laureate in Chemistry in 1996, Richard Smalley defined nanotechnology as the art and science of building stuff that does stuff at the nanometer scale.[18]

Already many definitions of the term 'nanotechnology' are available. Two types of definitions for the word are available: (a) single-based definition, which is given by different organizations like the European Commission, having policy implications, and (b) list-based definition, which is developed by the European Patent Office (EPO) and contains the list of applications of nanotechnology; e.g. nanobiotechnology, nanoelectronics, nanomaterials etc. is helpful for the companies involving in this area.[19]A close analysis of all the available single-based definitions will reveal that most of these definitions are derived from the defini-

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17. Frederick A. Fiedler & Reynolds Glenn H., *Legal Problems of Nanotechnology: An Overview*, 3 S. Cal. Interdisc. L.J 593 (1993).
18. G. Adlakha-Hutcheon, R. Khaydarov, R. Korenstein, R. Varma, A. Vaseashta, H. Stamm & M. Abdel-Mottaleb, Nanomaterials: Risks and Benefits 196 (Igor Linkov & Jeffery Steevens eds., 2009).
19. Organisation for Economic Co-operation and Development (OECD), The Impacts of Nanotechnology on Companies: Policy Insights from Case Studies 18-19 (2010).

tion suggested by the United State's National Nanotechnology Initiative (NNI).[20] However, NNI has some reservations on attiring something as 'nanotechnology' and will do so only if it involves all of the following:

a. Research and technology development at the atomic, molecular, or macro-molecular levels, in the length scale of approximately 1 to 100-nm range.

b. Creating and using structures, devices, and systems that have novel properties and functions because of their small and/or intermediate size.

c. Ability to control or manipulate on the atomic scale.

All these three characteristics, i.e. nano scale (1-100-nm), creation and use of structures and devices, ability to control, make present day nanotechnology distinctive from the natural, accidental or environmental nanotechnology. As there is no single authoritative and universally accepted definition of the term, eighteen different definitions of nanotechnology shared by different scholars and bodies between 2001-2005, including Allianz Centre for Technology and Organisation for Economic Co-operation and Development (OECD), Environmental Law Institute, ETC Group, National Nanotechnology initiative, United States Environmental Protection Agency, European Commission, etc. were investigated. It was revealed that there are five characteristics which are crucial in the definition of nanotechnology. These are as follows:

1. Size: from around 100 nm down to less than 0.1 nm.
2. Range of technologies: imaging, measuring, modeling and manipulating the matter.
3. Multi-disciplinarity: including for instance, physical, chemical and biological, with each being purposefully 'engineered'.
4. Size dependent novel properties and functions.
5. The control and purposeful manipulation of matter at the atomic scale.[21]

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20. The National Nanotechnology Initiative (NNI) is the central point of communication, cooperation, and collaboration for twenty-five Federal agencies of USA engaged in nanotechnology research, and brings together the expertise needed to advance in nanotechnology field. For more detail, *see* NATIONAL NANOTECHNOLOGY INITIATIVE, http://www.nano.gov/ (last visited Aug. 5, 2014).

21. Graeme A. Hodge, Diana Bowman & Karinne Ludlow, New Global Frontiers in Regulation: The Age of Nanotechnology 10 (Graeme A. Hodge, Diana Bowman & Karinne Ludlow eds., 2007).

The list of these eighteen definitions did not include some other definitions given by different organizations. Along with the definition of the US NNI, OECD intersected four other definitions given by European Union (7th Framework Programme (2007-2013)), Second Science and Technology Basic Plan of Japan (2001-2005), International Organization for Standardization (ISO) (Working Definition of 2007) and European Patent Office. From these definitions, one may trace out three aspects of nanotechnology: (a) purposeful 'control', 'manipulation' or 'handling' of matter at a very small scale, (b) emphasis on measurement scale, (c) 'novel', or 'new' industrial applications or 'technological innovations'. OECD refrained to point any specific scale, e.g. 1-100nm, or below 100nm, or in between 1-100nm, rather the Organisation was convinced that sometimes the scale may extend 100nm.[22]

Finally, sharing that 'there is no such thing as nanotechnology' and it is just 'labeling' and 'shorthand', it was reiterated that, 'nanotechnology' is not simply one discipline, or family of techniques, but rather a vast range of disciplines including engineering, materials science, biotechnology, medicine, physics, chemistry and information technology.[23]

3. Nanoparticle

Nanoparticle is considered as a miracle fiber,[24] or magic fiber. There are three types of nanoparticles: 'engineered' nanoparticles (also known as 'industrial', or 'manufactured', or 'inorganic' nanoparticle, e.g. gold nanoparticle, silver nanoparticle, etc.), 'incidental' nanoparticles (such as those found in welding fumes, cooking and diesel exhaust), and 'naturally occurring' nanoparticles (salt spray from the ocean, or forest-fire combustion). Of the three dimensions of materials i.e. length, height and width, material with one dimension in the nanometers scale is called nanolayer or nanocoating; with two dimensions, it is called nanowire (or nanofiber); and with three dimensions, it is called nanoparticle.[25]

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22. OECD, *supra* note 19.
23. Graeme A. Hodge, Diana Bowman & Karinne Ludlow, New Global Frontiers in Regulation: The Age of Nanotechnology 10 (Graeme A. Hodge, Diana Bowman & Karinne Ludlow eds., 2007).
24. Lee, *supra* note 10.
25. NANO - Memory Game Terms and Definitions – Basic Knowledge, *available at* http://nanoyou.eu/attachments/077_Memory%20game%20-%20terms%20and%20definitions%20final.pdf.

4. Nanomaterials

Nanomaterials are materials with at least one of its dimensions in the nanometer scale and where at least half of the particles are nanoparticles, i.e. have the features on the scale of 1-100nm. In simple words, the term 'nanomaterials' is used to refer to materials which are developed by using nanoparticles. The European Commission (EC) in its report on *Considerations on a Definition of Nanomaterial for Regulatory Purposes* considered and shared all the definitions given by different international organizations such as OECD, the European Union (EU) Scientific Committee on Emerging and Newly Identified Health Risks, the EU Cosmetic Products Regulation, etc. and definitions which are available in municipal legislation of different countries including Australia, Canada, Denmark, the United Kingdom (UK) and the United States of America (USA). The EC has defined nanomaterials as "materials with internal structures and/or external dimensions within the size range measured in nanometers (nm) where 100 nm is frequently used as a delimiting size between the nanoscale and the micro and macroscopic scales."[26] Though the attempt of the EU has been welcomed, this definition is not free from criticisms. The Brussels based European Chemical Industry Council, Cefic found that the definition is "too broad in scope," which will be difficult to be integrated in the existing legislation in a meaningful way as this will add unnecessary burden for companies, leading to added costs and less efficient use of resources and some decades-old substances, e.g. mineral pigments used in paints and other everyday products will be termed as nanomaterials.[27] This definition will be reviewed in December 2014 by the EC.[28]

Though it is commonly anticipated that the definition of nanomaterials is the prerequisite of any kind of regulation, this issue of definition may not again be able to solve all the problems. One of the leading experts, who advocated towards

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26. Lövestam Goran, Rauscher Hubert, Roebben Gert, Klüttgen Birgit Sokull, Gibson Neil, Putaud Jean-Philippe & Stamm Hermann, Considerations on a Definition of Nanomaterial for Regulatory Purposes 80004-80001 (2010).

27. *See also* Practical Nanomaterials Definition Needed to Push Forward Next Great Innovation Breakthroughs, CEFIC (2011), *available at* http://www.cefic.org/PressReleases/Press%20statement%20nano%20definition.FINAL.pdf.

28. *See* European Comm'n, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Second Regulatory Review on Nanomaterials, COM(2012) 572 (Oct. 3, 2012), available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0572&from=EN.

definition of nano, Andrew Maynard subsequently realized that for nanotechnology, the definition of 'one size fit for all' may not be suitable and therefore, it is better to define nanomaterails case by case.[29] It may be relevant to mention here that while considering the safety aspects of engineered nanomaterials, case by case approach is preferred by the European Commission also.[30]

B. Prospects and Trends of Investment

As predicted and presumed by the scientists of all over the world, there are virtually limitless benefits of nanotechnology and by using and applying technology at the nanoscale, the scientists can make lighter, stronger, smarter, cheaper, cleaner and more durable consumer and engineered products. Based on the market predictions, different countries and organizations have been investing a significant amount of money in this area. One of the main reasons behind this is that wealth is made by the pioneers like people who had the first arrowhead, horses and carts, candles and electric lights, transistors and valves, pharmaceutical medicines and people like Ford, Gates, Nobel. Similarly, a lot of people are already making plenty of money out of genetic engineering and gene therapy; the next venture is nanotechnology.[31]

Some experts found similarities between the coming nanorevolution with that of the plastic revolution in 1960s from when plastic transformed everything in our daily life. Plastic is now used everywhere from kitchen appliances to food containers, from housing construction to automobile, from transport to medical safety and where not.[32] Similarly, nano-enabled products will be very common in coming times. It is further pointed out that *if even a fraction of the predictions about nanotechnology are realized, our society will be a dramatically different*

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29. Andrew D. Maynard, *Don't Define Nanomaterials*, 475 NATURE 31, 31 (2011).
30. European Comm'n, Nanomaterials: Commission Proposes Case by Case Approach to Assessment (Oct. 3, 2012), *available at* http://europa.eu/rapid/press-release_MEMO-12-732_en.htm.
31. MICHAEL WILSON, KAMALI KANNANGARA, GEOFF SMITH, MICHELLE SIMMONS & BURKHARD RAGUSE, NANOTECHNOLOGY: BASIC SCIENCE AND EMERGING TECHNOLOGIES 3 (2002).
32. John Roach, *Nanotech: The Tiny Science Is Big, and Getting Bigger,* NATIONAL GEOGRAPHIC (Mar. 24, 2005), *available at* http://news.nationalgeographic.com/news/2005/03/0324_050324_nanotech.html (last visited Aug. 5, 2014).

and better place than it is today.[33]

The United Nations (UN) Task Force on Science, Technology and Innovation (part of the process designed to assist the UN agencies in achieving the United Nations Millennium Development Goals) addressed the potential of nanotechnology for sustainable development and for the betterment of 5 billion people of the developing countries. It was further discussed how nanotechnology can assist the developing countries in achieving these goals. Sharing the findings of Salamanca-Buentello et al.,[34] the United Nations Educational, Scientific and Cultural Organization (UNESCO) reiterated the top ten applications of nanotechnology within the UN Millennium Development Goals (MDGs), which are: (a) energy storage, productions and conversion; (b) agricultural productivity enhancement; (c) water treatment and remediation; (d) disease diagnosis and screening; (e) drug delivery systems; (f) food processing and storage; (g) air pollution and remediation; (h) construction; (i) health monitoring, and (j) vector and pest detection and control.[35]

In an article in a leading scientific journal, Nature, it was found that in between August 2008 to July 2009, there were more than 91,500 publications on nanotechnology.[36] More than $32 billion in products containing nanomaterials were sold globally in 2005. The Lux Research, Inc. reported in 2009 that nanotechnologies were used in goods and products and the value is USD224 billion.[37] Canada based electronics.ca publications estimated that the global market for nanotechnology in 2010 was $15.7 billion and projected that the market will be of $27 billion in 2015.[38] In 2000, the US National Science Foundation (NSF) estimated that the

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33. Andrew Wasson, *Protecting the Next Small Thing: Nanotechnology and the Reverse Doctrine of Equivalents*, Duke L. & Tech. Rev. 10 (2004).
34. Fabio Salamanca-Buentello, Persad Deepa L., Martin Douglas K., Daar Abdallah S., & Singer Peter A., *Nanotechnology and the Developing World*, 2 PLoS Medicine e97 (2005).
35. United Nations Educational, Scientific and Cultural Organization, The Ethics and Politics of Nanotechnology 13 (2006).
36. Shapira & Jue, *supra* note 2.
37. Cassandra D. Engeman, Lynn Baumgartner, Benjamin M. Carr, Allison M. Fish, John D. Meyerhofer, Terre A. Satterfield, Patricia A. Holden & Barbara Herr Harthorn, *Governance Implications of Nanomaterials Companies' Inconsistent Risk Perceptions and Safety Practices*, 14 J. Nanoparticle Res. 749 (2012).
38. Electronics.ca, *Global Nanotechnology Market to be Worth $27 Billion in 2015*, Semiconductor Research News (Sept. 29, 2010), *available at* http://www.electronics.ca/presscenter/articles/1278/1/Global-Nanotechnology-Market-To-Be-Worth-27-Billion-In-2015/Page1.html (last visited Aug. 5, 2014).

global marketplace for goods and services using nanotechnologies will grow to $1 trillion by 2015, the German Ministry of Education and Research is convinced that the amount will be USD3 trillion,[39] whereas the European Commission forecasted that the nanotechnology enabled products will grow a global volume of Euro 200 billion in 2009 to Euro 2 trillion by 2015.[40] European Commission further estimated that the global market of nanomaterials was 11 million tons, value of 20 billion Euro and the direct employment was estimated at 300,000 to 400,000.[41] Mihail Roco, the Chairman of the United State National Science and Technology Council subcommittee on Nanoscale Science, Engineering and Technology and Senior Advisor for Nanotechnology at the National Science Foundation, predicted that the nanotechnology markets and related jobs would be double in every three years.[42]

BCC Research Market forecasting estimated that global market for nanotechnology products at about $15.7 billion in 2010, growing to approximately $26.7 billion by 2015, a compound annual growth rate (CAGR) of 11.1 percent from 2010 through 2015. Different categories of Carbon nanotubes generated an estimated $100 million in revenues in 2009 and the market is projected to grow over the next five years at a compound annual growth rate (CAGR) of 58.9 percent, reaching more than $1 billion by 2014.[43] The world production of carbon nanotubes is expected to increase by $1 billion –$2 billion by 2014.[44]

Another leading market research organization, Cientifica, reported in 2011 that the different governments around the world are currently spending USD 10 billion per year with a growth rate of twenty percent over the next three years. By the end of 2011, the total government funding in this field shall reach to USD 65

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39. Hardy Garupner, *Germany Warns Over Dangers of Nanotechnology*, Deutsche Welle (Oct. 21, 2009), *available at* http://www.dw.de/dw/article/0,,4814083_page_0,00.html (last visited Aug. 5, 2014).
40. Enterprises and Indus., *Nanomaterials*, The European Commission, *available at* http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm (last visited Aug. 5, 2014).
41. *Id.*
42. Mihail C. Roco, *The Long View of Nanotechnology Development: The National Nanotechnology Initiative at 10 years*, 13 J. Nanoparticle Res. 427-45 (2011).
43. *2010 Technology Research Review*, BCC Research, http://www.bccresearch.com/report/2010-nanotechnology-review-nan047b.html (last visited Aug. 5, 2014).
44. Andrea Carter, *Learning from History: Understanding the Carcinogenic Risks of Nanotechnology*, 100 J. Nat'l Cancer Ins. Advance Access 1664-65 (2008).

billion and to USD 100 billion and with the investment of private and corporate funding the figure will reach to USD 250 billion by 2014.[45] In USA, after launching the world's first national nanotechnology program, the government invested a total USD 15.6 billion in between 2001-2012[46] and the president requested to allocate USD 1.766 billion (USD 70 million more which is 4.1% higher than the previous year) for the year 2013 for the National Nanotechnology Initiative (NNI).[47]

In term of products, there are some publicly available product registers containing the list of products developed using nanomaterials in the USA, i.e. Project of Emerging Nanotechnology (PEN),[48] Europe,[49] and Japan.[50]

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45. Global Nanotechnology Funding Report, 2011, Cientifica (2011), *available at* http://cientifica.com/wp-content/uploads/downloads/2011/07/Global-Nanotechnology-Funding-Report-2011.pdf.

46. John F. Sargent Jr., The National Nanotechnology Initiative: Overview, Reauthorization, and Appropriations Issues (2013), *available at* http://www.fas.org/sgp/crs/misc/RL34401.pdf.

47. John F. Sargent Jr., Federal Research and Development Funding: FY 2013 (2013), *available at* http://www.fas.org/sgp/crs/misc/R42410.pdf.

48. An Inventory of Nanotechnology-based Consumer Products Introduced on the Market, The Project on Emerging Nanotechnologies, http://www.nanotechproject.org/cpi/ (last visited Aug. 5, 2014).

49. The European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC) and Bureau européen des unions de consommateurs (BEUC) in 2009 released an inventory of 151 consumer products under different categories like appliances, automotive, cross cutting, electronics and computers, food and drink, products for children, health and fitness, home and garden. The same inventory listed 475 products in 2010.
In 2010, the National Institute for Public Health and Environment of the Ministry of Health, Welfare and Sports of the Netherlands identified 858 consumer products with nanoclaim in the European market. In 2007, there were 143 products. See S.W.P. Wijnhoven, Nanomaterials in Consumer Products: Update of Products on the European Market in 2010 (2010), *available at* http://www.nanogenotox.eu/files/PDF/rivm%20rapport%20nanomaterials%20in%20consumer%20products%2023-02-2011.pdf.

50. A Nanotechnology-claimed Consumer Products Inventory in Japan, developed by the Research Institute of Science for Safety and Sustainability, National Institute of Advanced Industrial Science and Technology has listed 1241 consumer products as of 15.05.2008 under the groups headings of Cosmetics, Clothing, Appliances, Home, Sports, Food, Culture and Miscellaneous. *See* Nanotechnology-claimed Consumer Products Inventory in Japan, *available at* http://www.aist-riss.jp/db/nano/e_index.htm.

C. Human History and Predictions on Nanotechnology

Even with such huge prospects and predictions, the world community, led mainly by the NGOs, is very concerned regarding the introduction of nanotechnology enabled products. It is because that in recent past the world has witnessed some of the ground breaking innovations and incidents, which were initially found to be very lucrative, but subsequently turned to be dangerous. Some of such innovations and incidents are discussed below.

1. Asbestos

In some research a resemblance was portrayed between nanoparticles and asbestos and it was found that there are many similarities between these two.[51] Therefore, it has been argued that nanoparticles may follow the similar consequence of asbestos. History suggests that after the asbestos was projected as magic fiber, it was started to be used in hundreds of different kinds of activities. However, later on, this was found to be deadly. Hundreds of thousands of cases are still pending before different courts around the world and many of the companies were shut down due to worker's injury compensation and continuous litigation.

2. Tobacco

Tobacco was considered as cash crop and initially was depicted as medicine for all illness. The use of tobacco was normal in the USA. It was only in the mid-1960s, when the Surgeon General of the USA, Luther Terry, released his report on smoking and health and claimed that tobacco was the cause of cancer[52] that the world community has started war against tobacco and many countries impose ban on tobacco advertisement, selling of tobacco to children and smoking in pub-

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51. E.g., Günter Oberdörster, Vicki Stone & Ken Donaldson, *Toxicology of Nanoparticles: A Historical Perspective*, 1 NANOTOXICOLOGY 2-25 (2007); Yon Ju-Nam & Jamie R. Lead, *Manufactured Nanoparticles: An Overview of Their Chemistry, Interactions and Potential Environmental Implications*, 400 SCI. TOTAL ENV'T 396-414 (2008).

52. STANHOPE BAYNE-JONES ET AL., SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE, *available at* http://profiles.nlm.nih.gov/ps/access/NNBBMQ.pdf.

lic places.[53] Unless, the predicted risks associated of nanomaterials are properly regulated, it may happen that this will follow the similar fate of tobacco.

3. Nuclear energy

Nuclear energy has been considered as instrumental in production of energy leading to industrial development. The situation has changed recently after the Fukushima Nuclear disaster in 2011 in Japan and now the position is like that the Japanese youth are worried about nuclear energy and are not willing to accept it. It was further found that even after repetitive assurance, seventy-six percent of the respondents in a survey believed that the foods from the Fukushima area are radioactive and they were not willing to accept the assurance of government and scientists.[54]

4. Genetically modified food

Genetically modified (GM) food had to face huge protest in recent times because of many reasons including non-involvement of public in the process of introduction. Due to some negative advertisements, people are not willing to buy GM food. It was in 2002, at the World Summit on Sustainable Development in Johannesburg, even with the unprecedented food crisis in Zambia, the President of Zambia himself refused the proposal of the World Food Programme to accept GM food aid and stated that "simply because my people are hungry, that is no justification to give them poison, to give them food that is intrinsically dangerous to their health."[55]

D. Nanotechnology and Asian Countries: A Snapshot

Some of the Asian countries have been leading the global movement in nanotechnology. Japan can be considered as the home of nanotechnology - the term 'nanotechnology' was first used by Japanese Professor Norio Taniguchi in 1974,

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53. *E.g.*, Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009); Tobacco (Control of Advertisements and Sale) Act (Act No. 10/1993) (amended 2011) (Sing.); Tobacco Hazards Prevention Act (Taiwan).
54. Geoff Brumfiel, *Fukushima: Fallout of Fear*, 493 Nature 290-93 (2013).
55. *Zambia Refuses GM 'Poison'*, BBC News (Sept. 3, 2002), http://news.bbc.co.uk/2/hi/africa/2233839.stm (last visited Aug. 5, 2014).

and Japanese scientist Sumio Iijima discovered carbon nanotube in 1991. Japan is the forerunner from among the Asian countries in this field and has been competing with the USA and European countries. The Japanese people are aware of nanoparticles since 1970s, with the winning of Noble Prize in physics by EaskiReona.[56] China is another Asian country which is placed in a number of research as one of the future global leaders in nanotechnology. Though there are some questions as to the quality of publication comparing to the USA and Europe, the dominance of China in terms of funding in this area is also well documented.[57] South Korea have been using unlimited amount of nanomaterials in its electronic products, India is considered as a lucrative place for production, and Singapore, during 2004-2006, obtained almost three times the average share of all nanotechnology patents.[58] The following Tables share the competence of Asian countries in this area in terms of scientific publications and patent in the United States Patent Office (USPTO).

Table 1: Top 15 Countries in Nanotechnology Local Share [total number of scientific articles/total number of nanotechnology articles] in the Web of Science for the countries with more than 500 articles until July 2012[59]

Rank	Country	2010	Rank	Country	2011	Rank	Country	2012
1	Singapore	17.7	1	Singapore	19.47	1	Singapore	20.08
2	China	14.77	2	China	15.75	2	Iran	16.28
3	South Korea	13.22	3	South Korea	14.45	3	China	16
4	Ukraine	12.22	4	Iran	14.36	4	South Korea	14.53
5	Iran	12.02	5	Ukraine	13.32	5	India	13.57

56. To gather an idea on the contribution of Japanese scientists in the field of nanotechnology, *see* Matsuda Masami, Geoffrey Hunt & Obayashi Masayuki, Nanotechnology: Risk, Ethics and Law 59 (Geoffrey Hunt & Michael Mehta eds., 2013).
57. Ronald N. Kostoff, Ryan B. Barth & Clifford GY Lau, *Quality vs. Quantity of Publications in Nanotechnology Field From the People's Republic of China*, 53 Chinese Science Bulletin 1272-80 (2008).
58. *Nanotechnology Patents*, *in* OECD Science, Technology and Industry Scoreboard 2009, *available at* http://dx.doi.org/10.1787/sti_scoreboard-2009-27-en.
59. Iran Nanotechnology Initiative Council, 2014

Rank	Country	2010	Rank	Country	2011	Rank	Country	2012
6	Taiwan	11.17	6	India	12.61	6	Saudi Arabia	13.42
7	India	10.68	7	Romania	12.35	7	Taiwan	11.78
8	Russia	10.16	8	Taiwan	11.99	8	Malaysia	11.59
9	Romania	9.78	9	Saudi Arabia	11.17	9	Ukraine	11.15
10	Japan	8.74	10	Russia	10.35	10	Russia	11.01
11	Saudi Arabia	8.65	11	Malaysia	10.24	11	Romania	10.85
12	Malaysia	8.65	12	Japan	9.22	12	Egypt	9.73
13	Germany	7.31	13	Germany	7.79	13	Japan	9.07
14	Egypt	7.01	14	Egypt	7.67	14	Germany	7.85
15	France	6.89	15	France	7.38	15	France	7.73

Table 1 shows the top fifteen countries in terms of publications on nanotechnology comparing to the total number of publications in the Web of Science. It was found that from 2010 to 2012, more than fifty percent of the top fifteen countries were from Asia, with the top spots dominated by Asian countries (eight in 2010, nine in 2011 and nine in 2012). It is an important indication as to how serious the Asian countries are in this area.

Table 2 indicates a list of Asian countries which have applied for patents in the nanotechnology area. From 2005 to 2013, there is an increase in the numbers of patent applications by Asian countries – from 6,377 in 2005 to 21,379 in 2013, an increase of 235 percent. These Tables, therefore, reflect the eagerness of the Asian countries, irrespective of economy and size, to take lead in this field.

Table 2: Asian Countries and Nanotechnology Patent in USPTO[60]

Global Ranking	Countries	2004	2005	2006	2007	2013
2	Japan	908	799	1,068	1,185	3,182
3	South Korea	130	112	208	249	943
5	Taiwan	108	139	216	234	649
7	China	11	28	46	36	420

60. Iran Nanotechnology Initiative Council, 2014

Global Ranking	Countries	2004	2005	2006	2007	2013
12	Singapore	9	17	25	51	129
20	India	13	10	15	15	53
23	Saudi Arabia	0	0	1	0	31
27	Malaysia	7	1	3	0	15
30	Iran	0	0	0	0	12
35	Turkey	0	0	0	0	6
39	Thailand	0	0	2	0	4
46	UAE	0	0	0	0	2
50	Vietnam	0	0	0	0	1
	World	**6,822**	**6,377**	**8,387**	**8,708**	**21,379**

Besides, some of the Asian countries like South Korea declared different nanotechnology related products and machineries as 'high technology' capable of tax reduction or exemption when there will be foreign investment.[61] Thailand has been offering 200 percent tax exemption for nanotechnology business.[62] Malaysia and Singapore have been inviting investment projects referring to this as 'high technology area'. In this paper, we will be focusing on the legal framework of some of the countries listed in these above two Tables.

Ⅲ. Legal and Regulatory Aspects of Nanotechnology

After all these discussion, questions may be raised as to what is the role of law or regulation in the discussion of nanotechnology. Before such discussion, this should be made clear that of all the nanomaterials reported in scientific journals, not all are dangerous. Nanomaterials, being nanoscale chemical, presumed to have more or less similar features of chemicals, and the way all chemicals are not harmful and there are many lifesaving and commonly used chemicals that we use in our daily life, nanomaterials are not exceptional. But there are some nanoparticles, i.e. silver nanoparticle, titanium dioxide, carbon nanotube, zinc

61. [Regulations on Tax Reduction or Exemption Concerning Foreign Investment 2010], art. 4 (S. Kor).
62. Donald Maclurcan, Nanotechnology and Global Equality 310 (2011).

nanoparticle etc., which are used in ubiquitous scale in consumer products are seriously predicted to be injurious. For such nanoparticles and nanomaterials, law should intervene immediately. Pertinent to mention here that long before the official inauguration of the nanotechnology program in the USA through the National Nanotechnology Initiative in 2000, the legal and regulatory issues relating to nanotechnology were considered in 1989[63] and 1993.[64]

NGOs like Friends of the Earth warned that nanomaterials have some adverse human health effects and may cause danger to environment.[65] Organizations like Australian teachers refused to give sunscreen to school students,[66] while the Federal Environment Agency (UBA) of the German government warns consumers to take precautions before using toothpaste.[67] Canada has banned the use of nanotechnology in organic food production.[68] There are some valid reasons to be worried about engineered nanomaterials when the School of Public Health of the Harvard University, the best university in the world confirms that "there is mounting evidence that engineered nanoparticle (ENPs) exposure can lead to DNA damage that ultimately contributes to cytotoxicity and mutations that drive cancer."[69]

It is obvious that the long term effects of the engineered nanomaterials on the environment are yet to be confirmed. However, it has been predicted that nanomaterials can enter the human body in a number of ways - dermal, ingestion,

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63. David Forrest, *Regulating Nanotechnology Development*, Foresight Institute, Mar. 23, 1989, *available at* http://www.foresight.org/nano/Forrest1989.html.
64. Fredrick Fiedler & Glen Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. Cal. Interdisc. L.J. 593 (1994).
65. *See New Report: "Tiny Ingredients, Rig Risks: Nanomaterials Rapidly Entering Food and Farming"*, Friends of the Earth, *available at* http://www.foe.org/projects/food-and-technology/nanotechnology (last visited Aug. 5, 2014).
66. Friends of the Earth Australia, Fukushima Nuclear Disaster: The Fallout in Australia 16 (2011), *available at* http://www.foe.org.au/sites/default/files/CR112-web-4MB.pdf.
67. Hardy Garupner, *supra* note 39.
68. *Nanotechnology*, Canadian Biotechnology Action Network, http://www.cban.ca/Resources/Topics/Nanotechnology (last visited Aug. 5, 2014).
69. *A High Throughput Nanogenotoxicity Assay*, Center for Nanotechnology and Nanotoxicology, http://www.hsph.harvard.edu/nano/research/a-high-throughput-nanogenotoxicity-assay/.

inhalation and injection. From the inventory of Project of Emerging Nanotechnology (PEN),[70] it is revealed that out of around 2,000 consumer products, 354 products are prone to dermal exposure, 173 are prone to ingestion, and 171 can be inhaled. Even though these products can be exposed to human health, their adverse health effects are not tested and therefore, it is not yet confirmed that these products are injurious to health or not.

Against such concerns, different governments and organizations have released research reports to assure the consumers. As confident and serious advocates in favor of nanotechnology R&D, we also like to believe that there are no adverse human health and environmental effects of nanomaterials as reported in all these reports, but many scientific publications in leading journals bar us to remain confident. In such circumstance, it is a matter of concern to evaluate how the consumers will react, and thus the regulators should come forward to assure them. Therefore, it is crucial to know the legal and regulatory aspects of handling and governing nanomaterials.

It was identified that there are six regulatory frontiers for nanotechnology i.e. product safety, privacy and civil liberties, occupational health and safety (OH&S), intellectual property (IP), international law and environmental law.[71] Besides, it was felt that two areas of laws, i.e. (a) health and safety regulations, and (b) patent and other intellectual property protection laws, will have initial applications and laws on product liability and toxic tort liability, privacy law and international regulation will have to consider nanotechnology in the long run. Therefore, the existing legal arrangements for health and safety regulations for nanotechnology are the most important demand.[72]

In order to know the legal and regulatory aspects of nanomaterials completely, one of the best ways is to know the life cycle of nanomaterails itself, which is discussed in a way of potential exposure route of nanomaterials below.

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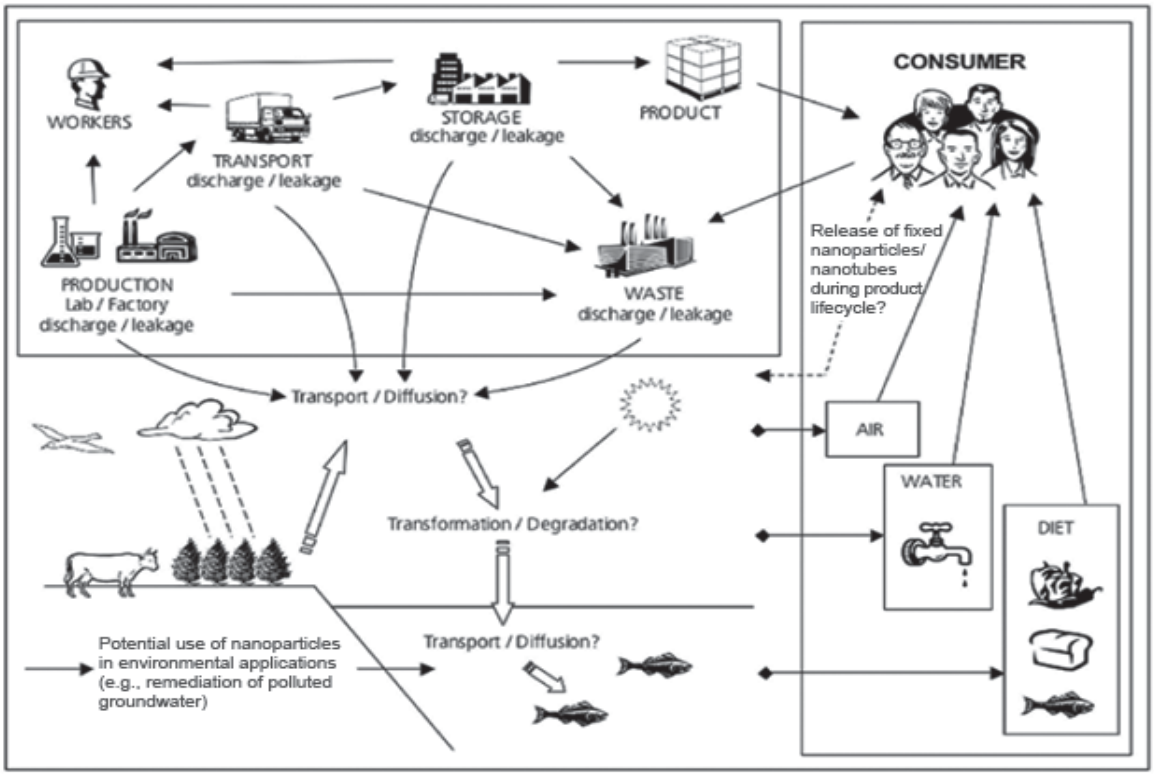
70. An Inventory of Nanotechnology-based Consumer Products Introduced on the Market, The Project on Emerging Nanotechnologies, http://www.nanotechproject.org/cpi/ (last visited Aug. 5, 2014).
71. Diana M. Bowman & Graeme A. Hodge, *A Small Matter of Regulation: An International Review of Nanotechnology Regulation*, 8 Colum. SciTech. L. Rev. 12 (2007).
72. Gary E. Marchant, *Law, in* Encyclopedia of Nanoscience and Society 395 (David H. Guston ed. 2010).

Figure 1: Potential Exposure Route and Life Cycle Assessment of Nanomaterials[73]



From the Figure 1 on possible exposure routes of nanoparticles, we can develop an idea of cradle-to-grave life cycle of nanomaterials and how these nanomaterials can come in contact with human health and environment. If we analyze this figure from a legal point of view, it can be inferred that many areas of laws, e.g. laws relating to occupational health, factory, chemical substance, hazardous substance, consumer, waste, environment (land, air, and water), food and agriculture, fisheries, biodiversity, cosmetic, product liability, food packaging and labeling, medical devices, intellectual property, insurance etc., may be relevant in the discussion of legal aspects of nanotechnology. Moreover, provisions relating to these fields may be available both in the Constitution and in municipal laws. Such a life cycle assessment will allow to understand the presence of nanomateri-

73. The Royal Society & the Royal Academy of Engineering, Nanoscience and Nanotechnologies 37 (2004), *available at* https://royalsociety.org/~/media/Royal_Society_Content/policy/publications/2004/9693.

als in different stages, i.e. manufacturing, processing, distribution and disposal of a product.

It is obvious that specific mention of the term 'nano' cannot be found in the existing legal provisions as it is still premature, but there should have some indirect provisions that can be interpreted in this regard. For example, the laws relating to occupational health are enacted, inter alia, to secure the safety, health and welfare of persons at work, for protecting others against risks to safety or health in connection with the activities of persons at work.[74] Such provisions are very broad and can be interpreted to include that the risk and safety issues relating to nanomaterials can be regulated under this law. Similarly, the Malaysian Food Act, 1983 (Act 281) was enacted to protect the public against health hazards in the preparation, sale and use of food. Therefore, any kind of nanomaterial with an intention to use in food,[75] which may be found injurious to human health, can be considered under the provisions of this law. Same is the case with other areas of laws.

There are some similarities between biotechnology and nanotechnology.[76] In a number of research, it has been revealed that the experience of biotechnology regulation can be of use to regulate nanotechnology. Most of these Asian countries have already enacted laws or are in the process of enacting laws on biotechnology.[77] Therefore, for the aspired Asian countries that want to take lead in the nanotechnology area, the same experience in terms of biotechnology regulation should be re-visited.

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74. Occupational Health and Safety Act (Act No. 514/1994) pmbl (Malay.).
75. Many kinds of nanomaterials or ingredients at the nanoscale can be used in food and the food packaging industry. For an overview, *see* Institute of Medicine (US) Food Forum, Application of Nanotechnology to Food Products (2009), *available at* http://www.ncbi.nlm.nih.gov/books/NBK32727/.
76. For an understanding on similarities and dissimilarities between nanotechnology and biotechnology, please *see* Douglas J. Sylvester, Kenneth W. Abbott, & Gary E. Marchant, *Not again! Public Perception, Regulation, and Nanotechnology*, 3 Reg. & Governance 165-85 (2009).
77. *E.g.*, Saengmyung gonghakyuksungbeob [Biotechnology Support Act], Act No. 8852, Feb. 29, 2008 (S. Kor.); Biotech and New Pharmaceutical Development Act, July 4, 2007 (Taiwan); The Biotechnology Regulatory Authority of India (2013) (the Bill was lapsed later on).

Ⅳ. Nanotechnology and Legal and Regulatory Setup in Asian Countries

Asian countries have diversified legal systems, e.g. the legal systems of China, Indonesia, Japan, South Korea, Taiwan, Vietnam are predominantly influenced by civil law legal system; India, Singapore, Malaysia mostly adopted English common law legal system; Islamic law legal system is followed in Saudi Arabia; Shia Islamic Law legal system is followed in Iran, a mixture of civil law and common law can be seen in the Philippines. Even though there are some different features of these legal systems, all the countries have written Constitutions, most of the countries have legal provisions relating to the abovementioned areas touching the life cycle of nanomaterials, in the form of codified law/statute, precedent/judge made law, secondary/subordinate legislation, etc. In order to implement the provisions of these laws, there are some regulatory bodies also and furthermore, there are also some guidelines, standards, etc. usually developed by such regulatory bodies. Simultaneously, most of these countries are members of different international organizations like the United Nations, the OECD, ISO, the Association of South East Asian Nations (ASEAN), Asia Pacific Economic Cooperation (APEC), etc. and are also members to many international and regional human rights treaties and other treaties and agreements relating to most of the abovementioned areas. As a member of any of these organizations, these Asian countries are obliged to adhere to different initiatives taken by these organizations to regulate nanotechnology. Many of these Asian countries, i.e. Japan, China, Singapore, India etc., have collaboration programs with universities and research organizations in Europe and USA, where, it is presumed that the legal provisions, standards, guidelines on nanomaterials are strictly followed. Therefore, based on the life cycle of nanomaterials, we will consider here some of the legal provisions of some Asian countries in this segment.

A. Constitutional Provisions in Asia and Nanotechnology

In any country with a written Constitution, the Constitution is the supreme law of that country[78] and fountain of all rights bestowed to the citizens. Though pro-

78. *See, e.g.*, XIANFA [CONSTITUTION] pmbl (1982) (amended 2004) (China); NIHONKOKU KENPO [KENPO] [CONSTITUTION], art. 98 (Japan); Malaysian Federal Constitution art. 4, Aug. 27, 1957.

visions relating to technology, etc. may be found in a Constitution, it will be extremely optimistic to check the Constitutions of the Asian countries whether there are provisions relating to nanotechnology. However, it is obvious that there are many provisions, e.g. provisions relating to right to life, right to health, right to environment, sustainable development, etc., which can be interpreted to discuss different aspects of nanotechnology. In many cases, these rights are judicially enforceable and in many cases these rights are embodied in the Constitution as fundamental in the governance of the country and used during the law making.[79] Some of these Constitutional principles relevant in the discussion on nanotechnology are discussed below-

1. Right to Life

In modern time, one of the prime responsibilities of the state and government is to ensure 'right to life' for the citizens. Even though in some cases it may happen that there is no direct provision on health and environment, the 'right to life'[80] perhaps is the single right which can be found in most of the human rights treaties and Constitutions of most of the countries around the world. The courts of laws are also in continuous process of extending this right frequently by attaching newer attributes.[81] Such interpretations by the municipal courts of laws are very important as in most of the cases, in the Constitutional provisions on right to life, a criminal law aspect is attached. For example, Article 32 of the Thailand Constitution provides the following:

> "A person shall enjoy the right and liberty in his or her life

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79. *E.g.*, INDIA CONST. art. 37.

80. *E.g.*, NIHONKOKU KENPO [KENPO] [CONSTITUTION], art. 13 (Japan); INDIA CONST. art. 21.

81. For example, in some Indian judgments, *e.g.*, K. Chandu v. State of Tamil Nadu, A.I.R. 1986 S.C. 204 (India); Oliga Tellis v. Bombai Municipal Corporation, A.I.R. 1986 S.C. 180 (India); Board of Trustees v. Dilip Raghvendra Nadkarni, A.I.R.1983 S.C. 109 (India) (declaring that right to life under article 21 of the Indian Constitution includes livelihood). *But see* Delhi Development Horticulture Employees' Union v. Delhi Administration Delhi, (1993) 4 L.R.C, 18 (India) (holding that the right to life under the article 21 of Indian Constitution could not be interpreted to incorporate the right to livelihood and the right to work as India lacked the economic capacity and development to honour such guarantees). *See also* Krishnan v. State of Andhra Pradesh, (1993) 4 L.R.C. 234 (India) (holding that the right to education was implicit in the right to life and personal liberty under article 21 of the Indian Constitution 1950).

> and person. A torture, brutal act, or punishment by a cruel or inhumane means shall not be permitted; provided, however, that punishment in execution of a judgment of the Court or as provided by law shall not be deemed the punishment by a cruel or inhumane means under this paragraph."

Article 21 of the Indian Constitution of 1949 has incorporated a simplified version of the above provision and states that "No person shall be deprived of his life or personal liberty except according to procedure established by law." The Singapore Constitution of 1965 also contains similar words while embodying the right to life.[82] It may be argued that such criminal law aspects are attached in this constitutional right to life due to the influence of the international human rights instruments, e.g. the Universal Declaration of Human Rights of 1948,[83] the European Convention on Human Rights of 1950.[84]

On the other hand, the approach of the Japanese Constitution is more favorable in terms of overall protection of right to life as it is not confined within the boundary of criminal law and it is provided that unless the right to life, liberty, and the pursuit of happiness does not interfere with public welfare, this right shall be the supreme consideration in legislation and in other government affairs.[85] The framers of the South Korean Constitution took a different approach and gave the right a superior status by incorporating this in the Preamble to the Constitution, as it is stated that the Constitution was adopted "to elevate the quality of life for all citizens …"

Finally, it can be argued that this Constitutional right to life as enshrined in the Asian Constitutions can be interpreted to protect the citizen from any kind of adverse human health effects, if any, of nanoparticles. However, the competence of the lawyers and judges in the court of laws to take account of all these will be a serious concern in recent future.

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82. Constitution of the Republic of Singapore art. 9(1), Aug. 9, 1965.
83. Universal Declaration of Human Rights art. 3, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948).
84. Convention for the Protection of Human Rights and Fundamental Freedoms art. 2, Nov. 4, 1950, 213 U.N.T.S. 221.
85. NIHONKOKU KENPO [KENPO] [CONSTITUTION], art. 13 (Japan): "All of the people shall be respected as individuals. Their right to life, liberty, and the pursuit of happiness shall, to the extent that it does not interfere with the public welfare, be the supreme consideration in legislation and in other governmental affairs."

2. Right to Health

Health is an important human right and hardly there can be anyone who will argue that sound health is the prerequisite to enjoy all other human rights.[86] Most of the countries have incorporated the provision on right to health[87] either in the national constitution or in municipal laws of the lands and the governments are usually committed to ensure sound health for all living human being within the territorial limit of the country. As it has been claimed repeatedly that nanomaterials have some adverse human health effects and already hundreds of products containing nanomaterials are in the market, this 'right to health' can be interpreted to protect the citizens. However, one of the main concerns in this regard is that this 'right to health' is not judicially enforceable in developing economies and the ultimate health effects of nanoparticles may not be traced out immediately, rather it may take a long time and thus, it will be tough to prove the case.

3. Right to pollution free environment

The right to sound environment is also embodied in the national constitutions.[88] In many cases, the courts of law also pronounce decisions to ensure pollution free environment, and have been approving sustainable development.[89] Like the right to health, this right to environment also is not always judicially enforceable. Furthermore, there are scopes of lack of co-ordination among different bodies responsible to maintain different environmental components. Nevertheless, if there is any genuine intention to regulate the environmental implications of nanotechnology, the governments can easily do so by giving effect to the constitutional provision of pollution free environment.

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86. Md. Ershadul Karim, *Health as Human Rights under National and International Legal Framework: Bangladesh Perspective*, 3 JE ASIA & INT'L L. 337 (2010).
87. *E.g.*, NIHONKOKU KENPO [KENPO] [CONSTITUTION], art. 25 (Japan); XIANFA [CONSTITUTION], art. 21 (1982) (amended 2004) (China); MINGUO XIANFA [CONSTITUTION], arts. 157, 169 (1947) (Taiwan).
88. *E.g.*, XIANFA [CONSTITUTION], art. 26 (1982) (amended 2004) (China); 1948 DAEHAN MINKUK HUNBEOB [HUNBEOB] [CONSTITUTION], arts. 35(1),(2) (July 17, 1948) (S. Kor.).
89. Vellore Citizens Welfare Forum v. Union of India, A.I.R. 1996 S.C. 2715 (India); M.C Mehta v. Kamal Nath, (1997) 1 S.C.C. 388 (India).

4. Right to Food and Water

Right to food[90] along with right to clean drinking water are two most important rights required for the human being for its survival in the world. Nanotechnology has great prospect to ensure clean water, energy and food security.[91] Nanoparticles are used in foods and therefore, existing provision on food in the national constitutions can be considered. However, it should be noted that in the constitutions of developing countries the provisions relating to food are encapsulated within the fundamental principle of state policy, meaning these are not judicially enforceable.[92] Simultaneously, in the case of *People's Union for Civil Liberties v. Union of India and Others, 2001* (Writ Petition (Civil) No. 196 of 2001), in relation to starvation deaths in the state of Rajasthan, the Indian Supreme Court recognized citizens' right to food.

B. Municipal Legislation

The constitution as the supreme law of the land contains some broad provisions and to give effect to those provisions, the countries enact required numbers of municipal laws. In this segment we will specifically shed focus on the relevant municipal legislation in some of these Asian countries in general and South Korean Law on Nanotechnology in particular. Due to the fact that South Korea is one of the two countries in the world[93] which has enacted such law, the law will be

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90. For a general discussion on constitutional right to food, *see* LIDIJA KNUTH & MARGRET VIDAR, CONSTITUTIONAL AND LEGAL PROTECTION OF THE RIGHT TO FOOD AROUND THE WORLD (2001), *available at* http://www.fao.org/docrep/016/ap554e/ap554e.pdf.

91. *See, e.g.*, UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION, THE ETHICS AND POLITICS OF NANOTECHNOLOGY (2006).

92. For example, Article 47 of the Indian Constitution, 1949, provides that the State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purpose of intoxicating drinks and of drugs which are injurious to health.

93. To the best of knowledge of the authors and such a decision was taken after a thorough literature search available in English. The other country is the USA, which has enacted the 21st Century Nanotechnology Research and Development Act, 15 U.S.C. 7501 (2003).

presented in a more detailed form, with the hope that this will enable other Asian countries to consider the enactment of similar legal provisions.

1. General Discussions

Based on the life cycle of nanomaterials, it can be anticipated that all the Asian countries have more or less legal provisions relating to occupational health, factory, chemical substance, hazardous substance, consumer, waste, environment (land, air, and water), food and agriculture, fisheries, biodiversity, biotechnology, cosmetic, food packaging and labeling, medical devices, intellectual property, insurance etc. Apart from specific laws in these areas, there are further secondary (also known as 'delegated' or 'subordinate' or 'subsidiary') legislation. There are many policies and guidelines too and in the Asian countries where there are English common law legal systems, the courts of laws interpret the provisions of these laws. These countries have also established some administrative bodies to implement the provisions of these laws.

2. South Korean Law on Nanotechnology

The Republic of South Korea is the only country in Asia which has enacted specific law to deal with nanotechnology titled the Nanotechnology Development Promotion Act 2008 (Act No. 8852) in order to make systematic nationwide effort to promote nanoscale research and industrial applications.[94] The Act went into effect on February 29, 2008, with the promulgation of the Enforcement Decree of the Nanotechnology Development Promotion Act 2008 (Act No. 20740).[95]

It may be relevant to share that earlier the country passed another law in 2002 with the similar title, i.e. Nanotechnology Promotion Act of 2002. As a legal foundation for the strategic development of nanotechnology, this Act of 2002, while providing a pivotal impetus, was passed at the 234th Plenary Session of the Korean National Assembly on November 12, 2002 and was enacted as Law No. 6812 on December 26, 2002. Subsequently, the law went into effect on June 27, 2003, through the promulgation of the Nanotechnology Promotion Enforcement

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94. The authors would like to thank the unanimous reviewer for sharing the information regarding the current South Korean Law no. 117113 (5th Revision of law, 2013). However, after a rigorous search, they failed to locate an English version of the law.

95. For English Texts of the laws, *see* Ministry of Government Legislation, http://www.moleg.go.kr/english/korLawEng?pstSeq=52226 (last visited Aug. 5, 2014).

Decree (Executive Order 18011).[96]

Article 1 of the 2008 Act, dealing with the purpose of enactment, states that the purpose of the Act is to contribute to the innovation of scientific technology and the development of the national economy by pursuing systematic support and development of nanotechnology by laying down the foundation for research of nanotechnology. According to Article 2, 'nanotechnology' means the scientific technology which - (a) creates materials, elements or systems (hereinafter referred to as 'materials, etc.') that displays new or improved physical, chemical and biological features, by handling and analyzing materials in the category of nanometer size and by controlling it; (b) processes materials, etc. minutely in the scale of nanometer size. The Korean legislature, in this definition, did not consider the issue of specific scale, e.g. between 1-100 nm or up to 100nm, etc., rather they only generally include the words 'nanometer size'. This has two implications from a regulatory point of view, it is right that no specific scale is shared, but at the same time it is good for the stakeholders that at least there is something which can be considered as legal framework.

Article 3 deals with some responsibilities of the government, i.e. formulation of basic policies and taking measures on nurturing and developing nanotechnology with the cooperation of the national and public research institutions; expansion of financial resources for the investment in nanotechnology R&D.

Article 4 provides for formulation of comprehensive development plan for nanotechnology promotion of nanotechnology R&D containing information relating to development targets of nanotechnology and basic direction of policies; promotion and execution of nanotechnology R&D; expansion of investment, facilitation of cooperation among industries, academic and research circles and interdisciplinary research; strengthening of research infrastructure, facilities and information; facilitation of international cooperation for nanotechnology; dissemination of nanotechnology research results and technology transfer, and other important matters concerning nanotechnology development.

Article 5 imposes obligations on the central administrative agencies to formulate annual implementation plan based on the comprehensive development plan. Article 6 provides for the initiatives to be taken for the promotion of R&D. Article 7 deals with the establishment of nanotechnology research council. Article 8 stipulates the types of actions to be taken by the government for supporting the technology development in the private sector. Article 9 empowers the Minister

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96. So Young Kim, *National Nanotechnology Development Plan (South Korea), in* Encyclopedia of Nanoscience and Society 556-557 (David H. Guston ed. 2010).

of Education, Science and Technology for efficient execution of supporting measures in Article 8. Articles 10 provides for development of specialized human resources development. Article 11 deals with expansion of research facilities. Article 12 provides for putting the R&D results into practical use. Article 13 refers to establish specialized research institute in nanotechnology. Article 14 focuses on building of technology information system. Article 15 focuses on establishment of standard measurement system. Article 16 deals with the development of nanotechnology research complex. Article 17 on fostering of cooperation with nonprofit organizations. Article 18 on reduction and exemption of taxes.

Interestingly, Article 19 provides that the government shall conduct impact assessment of nanotechnology before adopting any policy. Article 17 of the Enforcement Decree of the Nanotechnology Development Program Act 2008, the assessment shall include: (1) effects of the advancement and industrialization of nanotechnology to the increase of benefits in the lives of people and development of related industries; (2) effects of the advancement and industrialization of nanotechnology to the overall society and the nation; and (3) negative effects which may be incurred by nanotechnology, and their preventive measures. Even though this provision contains such assessment, it will be interesting to study how the government completes such assessment when there are differences of opinion among scholars and different organizations as to methods of assessment.

It is apparent that this law basically contains provisions relating to the setting up of the nanotechnology program in the country like many other programs, alongside with how the issue shall be administered in the country. This can be understood that being a civil law country, what South Korea did through all these provisions of the law, other countries, mainly the common law countries did the same thing through some roadmap, statement, or strategy. However, one thing is common in both the initiatives, i.e. there is as such no substantive legal provision relating to safety, liability, evidence, etc. relating to nanotechnology in these initiatives. It can be concluded that like the USA, this South Korean law on nanotechnology provides for legal and regulatory foundation for government administrative support towards nanotechnology research and development.

C. Membership within the International Organizations

It is a fact that there are no organizations in Asia like the European Union, African Unity or Organizations of American States (OAS). Nevertheless, the Asian countries are members of some regional and international organizations like the United Nations and its specialized agencies like Food and Agriculture Organiza-

tion (FAO), World Health Organization (WHO), ILO, OECD, Asia Pacific Economic Cooperation (APEC), ISO, etc. All these organizations have been working to develop different frameworks and guidelines relating to nanotechnology.

Ten economies of South East Asia are members of the ASEAN, a regional economic community in South East Asia. The ASEAN countries have already adopted some directives, e.g. on cosmetic[97] and medical devices,[98] which can be used in this regard and all the members of ASEAN have to follow the provisions of these directives after incorporating the provisions in their municipal law. Some of the ASEAN countries have already adopted national legislation by way of statutory law or in the form of guidelines by giving effect to the ASEAN Directives.[99] Furthermore, there are also guidelines like ASEAN Guidelines on Good Industrial Relations Practices, the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme, which was signed at Phnom Penh, Cambodia on September 2, 2003 and was entreated into force on the same date. The Agreement on the ASEAN Harmonized Electrical and Electronic Equipment (EEE) Regulatory Regime, signed at Kuala Lumpur in December 9, 2005; and the ASEAN Sectoral Mutual Recognition Arrangement for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products, 2009 was signed and entered into force on April 10, 2009. All these ASEAN legal instruments have, to some extent, binding effects as they are the reflection of the member states expressed through signature in international forum.

Concurrently, many of the Asian countries and nanotech leaders are members of APEC, a leading forum to promote trade and economic cooperation. APEC has taken many significant initiatives including the APEC Privacy Framework, which was adopted to promote and enforce information privacy and to maintain the continuity of information flows among APEC economies and with their trading partners.[100] APEC has established a Product Safety Incidents Information Sharing System to build capacity among developing APEC economies on safety incident information management, develop a product safety incident information sharing

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97. Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme, Sept. 2, 2003.

98. ASEAN Medical Device Directive (AMDD), 2014.

99. For example, the Health Sciences Authority (HSA) of Singapore has implemented the ASEAN Cosmetic Directive (ACD) since January 1, 2008.

100. Asia-Pacific Economic Cooperation, *Preamble to The* APEC Privacy Framework 2005 (2005), available at http://www.apec.org/Groups/Committee-on-Trade-and-Investment/~/media/Files/Groups/ECSG/05_ecsg_privacyframewk.ashx.

web portal and guideline document on product safety incident information sharing. This initiative can play a crucial role and is anticipated that if it is successful, many concerns relating to nanomaterials can be overcome. Such an initiative can be compared to the similar initiative of developing a product register at the European level.

Some of the Asian countries are members to the working groups of the OECD, i.e. Working Party on Manufactured Nanomaterials (WPMN) and OECD Working Party on Nanotechnology (WPN).[101] These working parties have been working towards regulation of nanomaterials. Out of thirteen nanomaterials, three Asian countries, i.e. China, Japan and South Korea, have been sponsoring the testing of five manufactured nanomaterials: iron nanoparticles [China], fullerenes (C60), single-walled carbon nanotubes (SWCNTs), multi-walled carbon nanotubes (MWCNTs) [Japan], and silver nanoparticles [South Korea].

Some of the Asian countries are members to the ISO Technical Committee on Nanotechnology (ISO/TC 229 on Nanotechnologies)[102] and International Electrotechnical Commission Technical Committee on Nanotechnology Standardization for Electrical and Electronic Products and System (IEC/TC 113). Under the ISO/TC 229, four Working Groups were established and two Asian nanotech giants convened two groups: Japan convened Working Group 2 on Measurement and Characterization and China convened Working Group 4 on Materials Specification. Pertinent to mention here that some of the member countries have already adopted national standards on nanotechnology which are in line with the ISO standards on nanotechnology. For example, Malaysia so far has adopted three Malaysian Standards relating to carbon nanotube, i.e. test methods for measurement of electrical properties of carbon nanotubes (IEC 62624:2009, IDT) [MS IEC 62624:2011], Nanotechnologies - Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy (ISO/TS 10867:2010, IDT) [MS ISO/TS 10867:2012], Nanotechnologies - Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry (ISO/TS 11251:2010, IDT) [MS ISO/TS 11251:2012]. All these standards are adopted at the municipal level to give effect to the provisions of the corresponding ISO and IEC standards.

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101. From among the Asian countries Japan and South Korea are members and China, Singapore and Thailand are observers in the WPMN.

102. Asian countries like China, India, Indonesia, Iran, Japan, South Korea, Malaysia and Singapore are participating countries and Hong Kong, Mongolia, Sri Lanka and Thailand are observing countries in this ISO/TC 229 on Nanotechnologies.

Similarly, the Standardization Administration of China has already published and implemented seven national standards, which are voluntary in nature: (a) GB/T 19619-2004 on Terminology for nanomaterials, (b) GB/T 13221-2004 on nanometer powder-determination of particle size distributions-small angle X-ray scattering method, (c) GB/T 19578-2004 on determination of the specific surface area of solids by gas adsorption using the BET method, (d) GB/T 19588-2004 on nano-nickel powder, (e) GB/T 19589-2004 on nano-zinc powder, (f) GB/T 19590-2004 on nano-calcium carbonate, (g) GB/T 19591-2004 on nano-titanium dioxide.[103]

Important to reiterate here that the ISO standards are voluntary in nature[104] and perhaps for this reason all these Malaysian standards explicitly mention that "compliance with a Malaysian Standard does not of itself confer immunity from legal obligations."[105] Furthermore, there are few arguments against the role of the ISO as the organization is a member-dues-paying NGO and it is believed that this Organization has been representing the interest of its members which are national standard bodies.[106] Though participation in ISO is open for any country, effective participation is a challenge for many countries.[107] There is no voice of the consumers in the organization and therefore, the interest and need of the consumers

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103. In between 2004-2009, China adopted more than twenty standards on nanomaterials or nanoparticles. *See* Darryl Stuart Jarvis & Richmond Noah, *Regulation and Governance of Nanotechnology in China: Regulatory Challenges and Effectiveness*, 2 Eur, J.L. & Tech. (2011). For a list of nine new technical published standards, *see* Tsung-Tsan Su, A List of Nine New Technical Published Standards of China, *available at* http://www.asia-anf.org/admin/upload/files/general/News172_16.pdf.

104. So far ISO has published a total of 42 standards relating to ISO/TC 229. For a list of standards, *see Standards Catalogue,* International Organization for Standardization, http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=381983&published=on&includesc=true (last visited Aug. 5, 2014).

105. *See, e.g.*, Draft Malaysian Standards, *Foreword to* Fresh Dokong – Specification (2014), available at http://www.sirim.my/srmc/documents/Aug-Sept-2014/11A012R0_PC.pdf.

106. For a discussion on how decisions are taken and made in ISO, *see* John Miles, International Handbook on Regulating Nanotechnologies 88 (Graeme A., Hodge, Diana M. Bowman & Andrew D. Maynard eds., 2010).

107. Stephanie Howard & Kathy Jo Wetter, Nanotechnology and Global Sustainability 95 (Donald Maclurcan & Natalia Radywyl eds., 2011).

may not get priority.

Apart from such tensions, the main legal question which will arise in relation to the different guidelines, standards and regulations is the legal implications of these guidelines or regulations. Another possible future concern will be the obligations and responsibilities of the countries which are members of more than one organization and those organizations have different guidelines on similar fields.

V. Legal and Regulatory Framework: An Appraisal

At this stage of our discussion, it can be argued that at least there are some legal provisions in different Asian countries which are apparently appropriate to handle the legal issues relating to nanotechnology. These provisions can be found in different sections of different categories of municipal laws. Nonetheless, one of the most important concerns will be the competence of different bodies to implement the provisions of such laws. The provisions of these laws provide for the roles, responsibilities and functions of different legal and regulatory bodies which may not be in a position to assess the real danger. For example, to handle the labor related issues, there are labor courts. Now, if we consider the China incident reported by Reuters,[108] where it was confirmed by the physicians that the incident was caused because of nanomaterials, the courts are presumed to bind to hold the company liable initially. This decision of the physicians was not ultimately accepted by many.[109] Therefore, there remains a scope of miscarriage of justice, if the courts rely on the decisions of the physicians. Thus, it is suggested to frame out some guidelines on different aspects of nanomaterials. Though based on the type of legal system, i.e. civil law legal system or common law legal system, these guidelines may have different implications; this will serve the initial purposes.

Many of the Asian counties are developing countries and the governments have to compromise the public health, etc. with that of the development. Industrialization being a problem, these Asian countries have to consider some of the legal rules in a flexible way. The countries cannot be too strict to implement the legal provisions relating to occupational health and safety. The dilemma for most of these countries is that nanotechnology in these regions is mainly developed by Small and Medium Enterprises (SMEs).

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108. Lyn, supra note 7.

109. Nature Publishing Group, *Recommended Reading*, 4 NATURE NANOTECHNOLOGY 533 (2009).

Besides, in many of these Asian countries, the implementation of law is a crucial challenge. For example, even in the case of Japan being a developed country, the implementation of tort law, e.g. product liability, is very tough. The tort liabilities in the country are dealt with by the Civil Code,[110] a statute greatly influenced by French and German law, for more than 115 years. The government has introduced many administrative compensation schemes for different kinds of tort liabilities including environmental pollution, medical products, vaccinations, blood donation accidents, and asbestos. However, these systems did not work properly.[111]

In those Asian countries, which are predominantly common law countries, the burden of proof that a person is affected by nanomaterials, if at all, will lie on the part of that person. For example, section 101 of the Malaysian Evidence Act 1950 provides that "Whoever desires any court to give judgment as to any legal right or liability dependent on the existence of facts which he asserts must prove that those facts exist." Whereas, section 102 of the same law provides that "The burden of proof in a suit or proceeding lies on that person who would fail if no evidence at all were given on either side."[112] These legal provisions were reconfirmed in the case of *MGI Securities SdnBhd v Teong Tech Leng&Ors* [2000] 1 MLJ 354, where Rekhraj J of the Kuala Lumpur High Court held that "ss. 101 and 102 of the Evidence Act 1950, requires 'whosoever desire any court to give judgment as to any legal right or liability dependent on the existence of facts, which he exerts, must prove those facts do exist ⋯ ;"

Other important concerns are the assessment of exposure of nanomaterials, risk assessment and risk management of nanomaterials. Some of the leading Asian countries like South Korea have been following the exemplar model, e.g. the Registration, Evaluation, Authorisation and Restriction of Chemicals, 2007 (REACH) of Europe. South Korea introduced REACH through the Act on Registration and Evaluation of Chemicals of Korea (K-REACH). Other Asian countries should come forward to adopt similar approaches. Alternatively, for the assessment of exposure of nanomaterials, risk assessment and risk management of nanomaterials, collaboration among the countries will play a crucial role since all these may demand huge amounts of investment.

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110. MINPO [MINPO] [Civ. C.] 1896, arts. 709-724, pt. III (Japan).

111. Eri Osaka, *Reevaluating the Role of the Tort Liability System in Japan*, 26 ARIZ. J. INT'L & COMP. L. 393 (2009).

112. Similar provisions can be found in section 101 of the Indian Evidence Act, 1872, and sections 103, 104 of the Singapore Evidence Act, 1893.

Ⅵ. Recent Developments in Asia

It is obvious that when there is no significant development in terms of adaptation of separate law on nanotechnology in Europe and in the USA, this will be premature to expect so in Asia. Some steps towards the regulation of nanomaterials have been taken in France by way of mandatory reporting to register nanomaterials.[113] Other European Countries like Denmark and Belgium are in the process of following France. A thorough literature review revealed no such instance in Asia to date, except one survey which was conducted in Singapore, jointly by the Ministry of Manpower and Singapore Economic Development Board and administered by NanoConsulting Ltd.

However, there are some guidelines, basically relating to safe handling of nanomaterials and nanoparticles.[114] Japan has recently completed the risk assessment of three nanomaterials- titanium dioxide (TiO_2), fullerene and carbon nanotube.[115] Relating to titanium dioxide, it was found that "majority of work sites where TiO_2 nanomaterials are handled, the health risks to the worker are considered to be small on the whole, but for materials which are aerosolized easily and for work in which the materials are easily aerosolized, it can be said that it is necessary to appropriately reduce exposure using enclosures, local exhaust

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113. Decree no. 2012-232 of 17 February 2012 on the annual declaration on substances at nanoscale in application of article R. 523-4 of the Environment Code. *See* Safe Nano, Questions and Answers on the French Declaration of Nanoparticulate Substance, *available at* http://www.safenano.org/Portals/3/SN_Content/Documents/French%20decree%20FAQs%20-%20SAFENANO%20English%20Translation.pdf.

114. For example, Nanomuljil jaejochigeup gunroja anjeonboguneh guanhan gisuljichim [Technical Guidance on the Safety and Health of Workers Involved in Manufacture and Handling of Nanomaterial], 2009 (S. Kor.); Nanojaepoom anjeonguanlieh guanhanjichim [Guidance on Safety Management of Nano-based Products], Korean Agency for Technology and Science Public Notice No.2011-0108, May 12, 2011 (S. Kor.); Guidelines for Preventing the Environmental Impact of Manufactured Nanomaterials (2009) (Japan), *available at* https://www.env.go.jp/chemi/nanomaterial/eibs-conf/guideline_0903_enab.pdf.

115. *Risk Assessment Documents and a Document of Protocols for Manufactured Nanomaterials*, Research Institute of Science for Safety and Sustainability, *available at* http://www.aist-riss.jp/main/modules/product/nano_rad.html?ml_lang=en (last visited Aug. 5, 2014).

ventilations, etc. as well as personal protection equipment." Such statement can be interpreted in a way that this cannot be said conclusively that TiO_2 is not injurious to health, rather it is obvious that there is still the need to take necessary precautions. It is obvious that the reports of such risk assessment do not have any legal implications, but have important persuasive value and are important initiatives to uphold the trust and confidence of consumers to use products containing these nanoparticles.

In Malaysia, the court has taken note of the Material Safety Data Sheet (MSDS) as evidence in different cases. Chemical organization specifies MSDS to give an indication of possible adverse effects of the chemical in the human health and environment. It will be interesting to share here that such MSDS have evidentiary value in the courts of law. For example, the Kuala Lumpur High Court in the case of *Ing Hua Fu Marine Line Sdn Bhd v Vitachem (M) Sdn Bhd & Anor* [2013] 9 MLJ 825, recognized the MSDS in relation to a chemical explosion in Port Klang by the vessel Ing Hua Fu resulting in damage of the vessel and the cargo. The court found that "in order to comprehend the nature and characteristics of the chemicals it is necessary to study the MSDS for each chemical. The safety data sheet which draws reference from United Nations, 2011, Globally Harmonized System of Classification and Labelling of Chemicals, is a means of communication of information about a substance or mixture for use in the workplace for the purposes of establishing a chemical control regulatory framework. It is a source of information on the hazards a substance poses and provides guidance on safety precautions." The court further held that the MSDS is issued by a manufacturer of a product and provides an important source of information for the transportation sector and emergency responses. To add to this, in an earlier case of *Tropical Network Sdn Bhd v Geo-Chem Inspection (M) Sdn Bhd* (FIMA Bulking Services Bhd, third party), [2011] 8 MLJ 359, the High Court (Johor Bahru), in a different context referred to MSDS.

Taiwan has developed an Environmental Health and Safety Database, i.e. Taiwan National Nanotechnology EHS Database.[116] From August 2011, the Policy initiative was taken to confirm that the nano-food should have safety test reports of food products that contain nanomaterials as additives and precludes the use of some toxic nanomaterials. Furthermore, the medical-device manufacturers need to provide safety evaluation report, cosmetics containing nanomaterials need to

116. Taiwan National Nanotechnology EHS Database, http://ehs.epa.gov.tw/Home/EN_F_Home_Index (last visited Aug. 5, 2014).

be registered, obtain permission and be evaluated before import or manufacturing in order to ensure safety of the consumers.

Very recently, the country has amended Articles 11 and 13 of the Taiwan Occupational Safety and Health Act, as amended in 2013, pertaining to labeling, MSDS and management of toxic substances to protect the workers from potential hazards due to the exposure of chemical substances like nanomaterials.

On November 22, 2013, the Taiwan government amended the Taiwan Toxic Chemical Substance Control Act to empower the registry of chemical substances and strengthened the management of toxic chemical substances having the possibility to affect human health. Additional resolution was adopted to empower the Environmental Protection Administration of the country to consider nanomaterials below 1 kg which are in existence within one year of the establishment of the registry of management of chemical substances.

A. Nano-marking Systems

At least three Asian countries, i.e. Iran, Taiwan and Thailand, have introduced a nano-marking system, which can be considered as identical to a product labeling system. It is interesting to share here that all these three nano-marking systems in these three countries though were introduced for identical purposes to, inter alia, maintain standard, uphold consumer confidence, there are some distinctive features in these three systems.

Taiwan has started the Nano-Mark scheme, i.e. nanoMark Product Certification System, a voluntary program for the manufacturer, to enhance the overall competitiveness of the companies back to 2003. The Industrial Development Bureau (IDB) of the Ministry of Economic Affairs (MOEA) authorized Industrial Technology Research Institute (ITRI) to develop the Nano-product Certification System for the implementation of nano-product certification specification. The ITRI ultimately developed the world's first certification system relating to nanotechnology. For the last ten years (2004-2014), already thirty-eight manufacturers and 1,488 products achieved nanoMark certificate. It has been revealed that with the increase of consumers' trust and confidence and improvement of corporate image, the nanoMark certification increased the selling price of the products by twenty percent. The certificate is valid for three years and the application for renewal of the certificate should be submitted within two to six months before the expiry date of the certificate. The countries has established at least thirteen registered laboratories for the certification purposes and for different industries, e.g. food, textile, footwear and recreation, paint, plastic, sensor devices and ceramic,

etc.[117] Under the certification, the primary focus is on nano size and functionality of a product. However, it is obvious that in order to be more successful, other relevant issues, i.e. health and environmental implications of such nano-enabled products already approved by the nanoMark Product Certification System need to be settled by other quality certification systems.

Iran Nanotechnology Initiative Council (INIC) was established in 2003 and in 2010 the country has published the 2nd National Nanotechnology Standard titled **Nanotechnology – Health and Safety in Nano Occupational Settings – Code of Practices on the basis of standards published by the ISO, ASTM International and National Institute of Occupational Safety and Health (NIOSH), USA. The country has initiated the process of adopting 'Nano-Mark', a certification scheme to be unveiled by the head of the standardization committee of Iran Nanotechnology Initiative Council (INIC). It is intended that the 'Nano-Mark' certificate will validate the product's dimensions of engineered nanomaterials which are less than 100 nm according to the ISO/TC 229 and the mark will specify health, safety and environmental information in the future for the consumers and regulators. It is an innovative initiative in a sense that the scheme is so far voluntary in nature, but in order to encourage the start-ups, SMEs and large industrial plants actively involved in nanotechnology, it has been declared that such commercial organizations with this Nano-Mark will get priority to avail various incentives, facilities, and supports from the INIC. The latest data shows that a total of 294 applications were filed and ninety-eight products got the approval from the INIC.**[118]

Thailand is very keen to take the lead in this area of nanotechnology and in this regard the country has already taken a good number of initiatives comparing to other developing economies of Asia. The country has introduced the 'nano marks', for reliable assessment of nanosafety. The mark is known as 'Nano Q', which contains potential safety tag in products which contain nanoparticles. This mark will be issued and such products will be certified by the Nanotechnology Association of Thailand. It is anticipated that such 'Nano Q' mark will increase public trust, protect both consumers and business entities and facilitate trade.[119]

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117. For details of nanoMark system in Taiwan, *see* NanoMark, http://www.nanomark.org.tw/Eng/ (last visited Aug. 5, 2014).

118. Ali Beitollahi, Nano Mark in Iran, *available at* http://irannano.org/filereader.php?p1=main_cb0df69b4d3e9327f05075052c9ea583.pdf&p2=news&p3=3&p4=1.

119. *See also* Sirirurg Songsivilai, National Nanotechnology Center (NANOTEC) Thailand (2011), http://nanotech.apctt.org/countryreports/Thailand%20Country%20Report.pdf.

B. Asia Nano Forum

Asia Nano Forum (ANF) is an important organization of fifteen economies from the Asia Pacific region with its headquarters in Singapore. All the leading nanotech nations of Asia, e.g. China, Japan, South Korea, Singapore are members of ANF. The forum creates a necessary and effective space for communication between governments and industries from different countries, and promotes discussion on ways to raise government, public and private sector awareness on nanotechnology.[120] The Organization is actively involved in ISO/TC 229 on Nanotechnologies Standards. The forum has also established few working groups e.g. Standardization and Risk Management Group, Education Group, Infrastructure and Resource Group, Nano Safety Group, Water and Energy Group. Even after all these initiatives taken by the forum, it can be inferred safely that the main and primary focus of the organization is the technical and commercial aspects of nanotechnology, and the focus on legal issues relating to nanotechnology is not still a priority. This Organization can work as a leading forum and bridge the stakeholders by initiating programs on legal aspects of nanotechnology.

C. Bangi Recommendations on Nanotechnology

Stakeholders including scientists and engineers, academics and professionals and policy makers mostly from developing countries like Bangladesh, Bulgaria, Cambodia, Egypt, India, Indonesia, Iraq, Kenya, Malawi, Malaysia, Mauritius, Morocco, Myanmar, Nepal, Pakistan, Sudan, Tunisia, Uganda and Vietnam gathered in National University of Malaysia, Bangi on November 24-27, 2012. The participants in the meeting expressed concerns on the health and environmental risks and ethical, legal and societal implications of nanotechnology and recommended to establish regulatory bodies to ensure the safe use and applications of nano-enabled products. The establishment of such bodies will also assist to avoid many possible health and environmental hazards as well as such bodies can prescribe some safety and precautionary measures for the people who stay close to nanomaterials in the development of nanoscience and nanotechnology in private and public sectors. It was recommended that the regulations should also be defined and followed strictly. It is obvious that from the legal point of view, such a recommendation does not have any implication, but since this was adopted

120. Donald Maclurcan, Nanotechnology and Global Equality 310 (2011).

recently in an Asian country and stakeholders of different strata participated, this resolution is shared here with a hope that this may guide the future path in regulating nanotechnology in Asia.

D. Asian Citizens and Nanotechnology

In 2000, the Select Committee on Science and Technology of the House of Lords of the UK pointed out the necessity to include citizens and demanded that the public should be consulted regarding science and technology policies.[121] The assessment of public perception by way of public consultation is simultaneously very popular now-a-days. For example, at the European level, the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) recently asked for public opinion. Even though the questionnaire, which was developed, is technical in nature, the EU citizens were made free to express their opinion till September 13, 2013. The United Nations Economic Commission for Europe (UNECE) adopted the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, 1998. This Convention is an important instrument in Europe and as of January 2014 most of the European countries become members to the Convention and protocol. Besides, many international instruments contain provisions relating to involvement of citizens in matters which may have different and indirect effect on them.

What happened in genetically modified (GM) food is that the public were not included in the whole process and as a result there was technical success but it failed commercially. Keeping all these instances in mind, fortunately, Japan has started the responsible development of nanotechnology and initiated the attempts to engage the public in the whole process through the Third Science & Technology Basic Plan (2006-2010). The National Institute of Advanced Industrial Science and Technology of Japan conducted open forum and symposium in between August 2004 and March 2005. Besides, the country has undertaken a number of research, e.g. risk assessment, environment, health, ethical and societal issues for public acceptance of nanotechnology. Thailand has also started some initiatives to include citizens in different activities relating to nanotechnology.

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121. Chapter 5: Engaging the Public, PARLIAMENT UK, http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3807.htm (last visited Aug. 5, 2014).

Ⅶ. Conclusion

Nanotechnology is often referred to as a 'double-edged sword' and all actions should be taken carefully so that to solve one problem, another is not created. Asia, the cradle of the ancient human civilization, has gained significant importance especially after the US President Barack Obama's one of the central foreign policy initiatives, the 'Pivot to Asia'. The 21st century is projected as the Asian century and Asian countries are very promising and prospective in terms of nanotechnology R&D. Convinced by the promises, some of the Asian countries that are even small in terms of the size of the economy have also invested huge amounts of money in this area. But, when the regulation and governance of nanotechnology is an issue, these Asian countries have taken the 'wait and see' approach, comparing to their European and American counter parts, and no Asian country is planning specific regulatory actions for nanotechnologies, but are looking at legislation developed in Europe and USA as a benchmark for the development of their own.[122]

Many European countries (UK, Sweden, Denmark), Oceania countries (Australia and New Zealand), and Canada and USA have completed the assessment on whether the existing legal and regulatory framework are adequate enough to meet different aspects of nanotechnology, which the Asian countries have not considered yet. It is high time that the Asian countries consider the importance of assessing the adequacy of the legal and regulatory framework relating to nanomaterials to assure the consumers, business communities and other stakeholders.

Such an assessment from the government bodies will assist the citizens and consumers to remain informed about the safety features of nanomaterials. One important reason behind advocating for such assessment is that the citizens are in a dilemma in between the reports and findings of business entities and the scientific communities. Business communities have been trying to convince the consumers that there is no serious side effect of nanomaterials, whereas the scientific communities have already shared many findings that there are some adverse human health effects of nanomaterials. Taking into account the general perception that the consumers mostly rely on the reports of the scientific community rather than the business community, the regulators of the respective Asian countries should come forward to make things clear to the people.

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122. Mantovani E. et al., Developments in Nanotechnologies Regulation and Standards 2011 (2011), *available at* http://www.steptoe.com/assets/htmldocuments/DevelopmentsInNanotechnologiesRegulationandStandards_20111.pdf.

The Asian governments should consider to include and to engage stakeholders, especially the consumers in the whole process of nanotechnology R & D. Different awareness programs and promotional activities can be carried out in this regard. In a recent study in Japan, it is found that the citizens are not willing to welcome nuclear energy after the Fukushima nuclear plant disaster. Similar things must not be happened in case of nanomaterials. One single accident may shake the confidence of the consumers and may leave them reluctant to accept products developed through nanomaterials. The business entities normally invest money for making profits and therefore, they must not take any undue risk with regard to the nano-enabled products and they should push forward the regulators to provide them necessary guidance as to safe development of nanotechnology. The regulators should be concerned and alert so that the Asian countries are not used as a 'dumping ground' for nanomaterials developed by western countries and imported by Asian countries and also risks and hazardous wastes arising out of nanomaterials are not 'outsourced' in this region.

In this paper, we have attempted to share an overview of legal and regulatory aspects of nanotechnology and attempted to connect some of the legal provisions in some of the Asian countries. This attempt is not conclusive and exhaustive, rather an introduction; it is anticipated that such a discussion will enable the Asian countries to look before they leap with the nanotechnology programs at the national and regional level.

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