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[**Asia: No Law for Nano?**]

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Asia: No Law for Nano?

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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 now in the stage where ICT and use of plastic was in 1960s and biotechnology in 1980s. Already around 2000 consumer products are in the market and ILO predicts that by 2020, 20% of the products will be developed using nanotechnology. 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 majority of the researchers feel that nanoparticles must have some adverse health and environmental effects. Besides, to many organisations, nanotechnology is the next asbestos. However, this is a matter of great concern that there is no specific legal framework to deal with nanotechnology. The mistakes for which the introductions of genetically modified food or nuclear energy could not be 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 other 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 Asia.

1. Introduction

The word 'nano', though literary means 'very small', has apparently turned to be the decisive factor of socio-economic development among countries irrespective of size and economy in recent times. Such a conclusion can be drawn taking into account the race among the countries in nanotechnology research and development (R&D) from the amount of investment in this area. Though after its formal and official kick off in the United States of American (USA) back to 2000 with the enactment of the 21st Century Nanotechnology Research and Development Act,[1] statistics shows that nanotechnology is still a venture of developed countries.[2] Even in such realities, more

[1] The Act basically contains provisions relating to setting up of the national nanotechnology initiative of the USA and relevant administrative provisions.
[2] Shapira, P., & Wang, J. (2010). Follow the money. *Nature, 468*(7324), 627-628. [10.1038/468627a].

than 150 countries have already expressed their intention to join the rally by way of either national framework, statement, roadmap on nanotechnology, or patent application or scientific publication or introducing specific courses in academic institutions at different levels. Almost 2000 consumer products, which are developed using nanomateroials are now in the market,[3] and around 5000 nanomaterials are reported in scientific journals. Manipulating technologies at the atomic or molecular level, scientists have already produced consumer and industrial products which are stronger, cheaper, effective, durable, etc. The International Labour Organisation (ILO) predicts that by 2020, 20% of the products will be developed using nanotechnology.[4]

However, there are serious concerns too as in many scientific researches it was found that some of the nanomaterials may cause adverse effects on human health and the environment. The Reuter report on the death of two Chinese workers from among seven patients of permanent lung damage in a paint factory[5] and re-assurance by the medical team that diagnosised the workers[6] compelled the world community to rethink about safe nanotechnology R & D for everyone involved in the whole process. Furthermore, 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'.[7] Some of the study already warns that unless this issue of harm and risk cannot be properly managed a catastrophic event may occur which will have the whole venture before question mark. Australian Workers' Union expressed their worriedness to use nanoparticle linking nanoparticle with asbestos and advocated for proper regulation.[8]

Some of the Asian countries like Japan, China, South Korea, India, Iran, Taiwan and so on scored tremendous success in nanotechnology R & D and leading the global race of nanotechnology in terms of investment, patent and scientific publication in leading scientific journals. In this back drop, this is high time to assess the adequacy of existing legal and regulatory framework in these Asian countries to handle different aspects of nanotechnology. This paper analyses the

[3] The Project on Emerging Nanotechnologies, developed by the Wilson Center and VirginiaTeach, available at http://www.nanotechproject.org/cpi/ (Last accessed on March 18, 2014). Against this USA based database, European countries are also in the process of developing European register of nanotechnology products. See, for reference, http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/information_concept_nanoregister_npr_e_0.pdf

[4] International Labour Organisation, ILO Introductory Report: Global Trends and Challenges on Occupational Safety and Health, XIX World Congress on Safety and Health at Work: Istanbul Turkey, 11-15 September 2011 at p. 20, available at http://www.ilo.org/wcmsp5/groups/public/@ed_protect/@protrav/@safework/documents/publication/wcms_162662.pdf (Last accessed on March 29, 2014).

[5] 'Deaths, lung damage linked to nanoparticles in China' available at http://www.reuters.com/article/2009/08/19/idUSN19481304 (Last accessed on March 21, 2014).

[6] Song, Y. L., X. Du, X. (2009). Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma. *European Respiratory Journal*, *34*(3), 559-567. doi: 10.1183/09031936.00178308

[7] Resolution of the European Parliament of April 24, 2009 on Regulatory Aspects of Nanotechnology.

[8] Available at http://www.brisbanetimes.com.au/technology/technology-news/union-raises-fears-over-nanotechnology-20130226-2f2l5.html (Last accessed on March 21, 2014).

nanotechnology R & D in Asian countries and the adequacy of Asian laws to handle the legal and regulatory challenges in this areas. Part II shares an overview of nanotechnology including terminologies and nomenclature, some statistics as to investment of market prediction. Part III provides a snapshot of initiatives in this area by some of the Asian countries. Part IV attempts to consider the legal and regulatory aspects of nanotechnology and Part V focuses on existing legal and regulatory framework in some of the leading Asian nanotech nation and further assesses the adequacy of such framework to handle nanotech development. Finally, this paper concludes that the public should be involved in the regulatory process before introduction of nanoenabled products, emphasizes on conducting more research to ensure the safety aspects at different level, proposes for making collaborations and developing product inventory and registry of nanoparticles and finally, to assess the existing legal provisions to check their adequacy to convince the consumers in specific and the stakeholders in general.

2. Overview of Nanoscience and Nanotechnology

Nanotechnology, the wave of the future, is the art and science of manipulating things at atomic or molecule scale. Nanoparticles are ubiquitous in the nature and can be found in fire, smoke, viruses, proteins, volcanic erosion, mineral e.g. clay, fog, milk and blood, skin, horns, hair, beaks, insects wing, lotus leaf, Gecko feet, etc. Such natural nanoparticles are naturally not dangerous and can easily be well refined by the defensive mechanism of human body. There are manmade incidental nanoparticles too. Such nanoparticles 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 as are not injurious to human health are not subject matter of modern nanoscience and nanotechnology and as such modern study of nanoscinece and nanotechnology is not concerned about the natural nanoparticles. Rather, 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 suggested that at least back to the 4th Century,[9] people used to know the technique of using nanoparticles in different fields. However, the modern history of nanotechnology started with the ground breaking lecture of the founding genius and Noble laureate Richard Feynman titled 'There's Plenty of Room at the Bottom'[10] 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 manoeuvring things atom by atom. The word 'nanotechnology' was first coined by Japanese professor Norio Taniguchi in 1974.

[9] For an authoritative history of nanotechnology, please visit http://www.nano.gov/timeline

[10] The transcript of the Lecture, which was published in the *Journal of Microelectromechanical Systems*, R. Feynman. "There's Plenty of Room at the Bottom." Vol. 1, No. 1. pp. 60-66, March 1992, is available at http://media.wiley.com/product_data/excerpt/53/07803108/0780310853.pdf (Last accessed on March 31, 2014).

2.1 Terminologies and Nomenclature

At the very outset of the discussion, this should be made clear that the world community is still in the process to reaching to consensus as to 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.

a. Nano

Nano is a unit of measurement like meter, kilometer, centimeter, millimeter, 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", 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 there are 25,400,000 nm in one inch, and a strand of human hair is roughly 75,000 nm across. In a reverse way, if we compare human being with sun, then 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 point to share here that at the nanoscale the particle behave dramatically which bars the regulators to reach to a concrete decision as to regulation of nanomaterials.

b. Nanotechnology

The simple but wholly accurate description of Nanotechnology or, more specifically, that subset of nanotechnology is that "molecular manufacturing" is that it involves manipulating matter on an atom-by-atom or molecule-by-molecule basis to attain desired configurations (Fiedler & Reynolds, 1994). 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.[11]

A close analysis of all these definition will reveal that most of these definitions are derived from the definition suggested by the United State's National Nanotechnology Initiative (NNI).[12] However, pertinent to mention here that NNI has some reservation on attiring something '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.

[11] Igor Linkov, Jeffery Steevens (ed.), Nanomaterials: Risks and Benefits, Springer, 2009, p. 196.
[12] 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, National Nanotechnology Initiative, http://www.nano.gov/ (Last accessed on March 31, 2014)

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

In the absence of any authoritative definitions, 18 definitions of nanotechnology given by different people were identified and it was concluded that there are five characteristics which are crucial in the definition. These are-

1. Size: from around 100 nm down to less than 0.1 nm.
2. Range of technologies: imaging, measuring, modelling 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.[13]

Though it is commonly anticipated that the definition of nanomaterials is the prerequisite of any kind of regulation, this issue of definition is not again able to solve all the problems. One of the leading experts in advocating definition of nano, Andrew Maynard 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.[14]

c. Nano Particle

Nanoparticle is considered as a miracle fibre,[15] or magic fibre. 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).

d. Nanomaterial

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. 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 nanofibre); and with three dimensions, it is called nanoparticle.[16]

2.2 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 nanotechnology the scientists can make lighter, stronger, smarter, cheaper, cleaner and more durable consumer and engineered product. Based on 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, Noble. Similarly, a

[13] Hodge, G. A., Bowman, D., & Ludlow, K. (2007). New global frontiers in regulation: The age of nanotechnology: Edward Elgar Publishing.
[14] Maynard, A. D. (2011). Don't define nanomaterials. [10.1038/475031a]. *Nature, 475*(7354), 31-31.
[15] Available at http://www.brisbanetimes.com.au/technology/technology-news/union-raises-fears-over-nanotechnology-20130226-2f2l5.html (Last accessed on February 26, 2013).
[16] NANO - Memory Game Terms and Definitions – Basic Knowledge, European Commission supported project Nanoyou, http://nanoyou.eu/attachments/077_Memory%20game%20-%20terms%20and%20definitions%20final.pdf

lot of people are already making plenty of money out of genetic engineering and gene therapy and the next venture is nanotechnology.[17]

Some experts found similarities between the coming nano revolution with that of the plastic revolution in 1960s from when the 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.[18] Similarly, nano enabled products will be every 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 and better place than it is today.*[19]

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 on how nanotechnology can assist the developing countries in achieving these goals. Sharing the findings of Salamanca-Buentello et al.,[20] 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.

In an article in leading scientific journal, Nature, it was found that in between August 2008 to July 2009, there were more than 91500 publications on nanotechnology.[21] 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 US$ 224 billion.[22] Canada based electronics.ca publications estimated the global market for nanotechnology in 2010 was $15.7 billion and projected that the market will be of $27 billion in 2015.[23] In 2000, the US National Science Foundation (NSF) estimated that the global marketplace for goods and services using nanotechnologies will grow to $1 trillion by 2015, the German Ministry of Education and

[17] Wilson, M., Kannangara, K., Smith, G., Simmons, M., & Raguse, B. (2002). Nanotechnology: basic science and emerging technologies: CRC Press.

[18] John Roach, Nanotech: The Tiny Science Is Big, and Getting Bigger, National Geographic News, 2005, available at http://news.nationalgeographic.com/news/2005/03/0324_050324_nanotech.html, (Last accessed on March 31, 2014)

[19] Wasson, A. (2004). Protecting the Next Small Thing: Nanotechnology and the Reverse Doctrine of Equivalents. *Duke Law & Technology Review, 10*.

[20] Salamanca-Buentello, F., Persad, D. L., Martin, D. K., Daar, A. S., & Singer, P. A. (2005). Nanotechnology and the developing world. *PLoS Medicine, 2*(5), e97.

[21] Shapira, P., & Wang, J. (2010). Follow the money. [10.1038/468627a]. *Nature, 468*(7324), 627-628.

[22] Cassandra D. Engeman, L. B., Benjamin M. Carr, Allison M. Fish, John D. Meyerhofer, Terre A. Satterfield, Patricia A. Holden, Barbara Herr Harthorn. (2012). Governance implications of nanomaterials companies' inconsistent risk perceptions and safety practices. Journal of Nanoparticle Research, 14, 749. doi: 10.1007/s11051-012-0749-0

[23]Available at http://www.electronics.ca/presscenter/articles/1278/1/Global-Nanotechnology-Market-To-Be-Worth-27-Billion-In-2015/Page1.html, (Last accessed on March 31, 2014).

Research is convinced that the amount will be US$ 3 trillion,[24] 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.[25] European Commission further estimated that the global market of nanomaterials is 11 million tonnes, value of 20 billion Euro and the direct employment is estimated at 300,000 to 400,000. [26]

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% 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 5 years at a compound annual growth rate (CAGR) of 58.9%, reaching more than $1 billion by 2014.[27] The world production of carbon nanotubes is expected to increase by $1 billion –$2 billion by 2014.[28]

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 20% over the next three years. By the end of 2011 the total government funding in this field shall reach to USD 65 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.[29] In USA, after launching the world's first national nanotechnology program, the government invested total USD 15.6 billion in between 2001-2012[30] 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).[31]

2.3 Human History and Predictions on Nanotechnology

a. Asbestos

In some researches a resemblance was portrayed between nanoparticles and asbestos and it was found that there are many similarities between these two. Therefore, it has been argued that nanoparticle 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

[24] Germany warns over dangers of nanotechnology, available at http://www.dw.de/dw/article/0,,4814083_page_0,00.html (Last accessed on March 31, 2014).
[25] European Commission, REACH and nanomaterials, http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm (Last accessed on March 31, 2014).
[26] Ibid.
[27] BCC Research, http://www.bccresearch.com/report/2010-nanotechnology-review-nan047b.html (Last accessed on March 31, 2014).
[28] Learning from History: Understanding the Carcinogenic Risks of Nanotechnology. JNCI Journal of the National Cancer Institute Advance Access, 100(23), 1664-1665. doi: DOI: 10.1093/jnci/djn431
[29] Cientifica, Global Nanotechnology Funding Report, 2011, at p. available at http://cientifica.com/wp-content/uploads/downloads/2011/07/Global-Nanotechnology-Funding-Report-2011.pdf (Last accessed on March 31, 2014).
[30] John F. Sargent Jr., The National Nanotechnology Initiative: Overview, Reauthorization, and Appropriations Issues, May 22, 2012, available at http://www.fas.org/sgp/crs/misc/RL34401.pdf, (Last accessed on March 31, 2014).
[31] John F. Sargent Jr., Federal Research and Development Funding: FY 2013, October 1, 2012, p. 1, available at http://www.fas.org/sgp/crs/misc/R42410.pdf, (Last accessed on March 31, 2014).

activities. However, later on, this was found to be deadly and many of the companies were shut down due to worker's injury compensation and continuous litigation.

b. Tobacco

Tobacco was similarly considered as cash crop and initially was depicted as medicine of all illness. Use of tobacco had been normal in the USA. It was only in mid-1960s, when the Chief Surgeon of USA wrote an article that tobacco causes cancer and from then on the world community has started war against tobacco and in many countries there are embargo on tobacco advertisement, selling of tobacco to children and smoking in public place. Unless, the predicted risks associated of nanomaterials are properly regulated, it may happen that this will follow the similar fate of tobacco.

c. 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 youths are worried about it and are not willing to accept it. It was further found that even after repetitive assurance 76% of the respondents in a survey believed that the food from Fukushima area radioactive and are not willing to accept the assurance of government and scientists.[32]

d. 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. 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."[33]

3. Nanotechnology and Asian Countries: A Snapshot

Some of the Asian countries have been leading the global movement in nanotechnology. Japan is the forerunner from among the Asian countries in this field. Though there are some question as to the quality of publication comparing to the USA and Europe, the dominance of China in terms of funding in this area is well documented. South Korea have been using unlimited amount of nanomaterials in its electronic products, India is considered as lucrative place for production, and Singapore topped in the patent list. The following Tables share the competence of Asian countries

[32] Brumfiel, G. (2013). Fukushima: Fallout of fear. *Nature*, *493*, 290-293.
[33] Zambia refuses GM 'poison', BBC News, available at http://news.bbc.co.uk/2/hi/africa/2233839.stm (Last accessed on March 22, 2014)

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 Web of Science for the countries with more than 500 articles until July 2012

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
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

[**Source:** Iran Nanotechnology Initiative Council, 2014]

Table 1 shows the top 15 countries in terms of publications in Web of Science. It was found that from 2010 to 2012, more than 50% of the top 15 countries were from Asia, with the top spots were dominated by Asian countries (3 in 2010, 4 in 2011 and 8 in 2012). This 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 nanotechnology area. From 2005 till 2013, there is an increase in the numbers of patent applications by the Asian countries – from 6377 in 2005 to 21, 379 in 2013, an increase of 235%. These Tables, therefore, projects the trends as how serious the Asian countries, irrespective of economy and size, are keen to take lead in this field.

Table 2: Asian Countries and Nanotechnology Patent in USPTO

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
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

[**Source:** Iran Nanotechnology Initiative Council, 2014]

Simultaneously, 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.[34] Thailand has been offering 200% tax exemption for nanotechnology business.[35]

4. 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 (around 5000), not all are dangerous. Nanomaterials, being nanoscale chemical, 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 nanomaterials which are used in ubiquitous scale in consumer products and are seriously predicted to be injurious. For such nanomaterials, law should immediately intervene. Pertinent to mention here that the long before the official inauguration of nanotechnology in USA through the National Nanotechnology

[34] Article 4, the Regulations on Tax Reduction or Exemption Concerning Foreign Investment 2010 [South Korea].
[35] Maclurcan, D. (2012). *Nanotechnology and Global Equality*. CRC Press, at p. 310

Initiative in 2000, the legal and regulatory issues relating to nanotechnology were considered in 1989[36] and 1993.[37]

In support of such intervention, some experience can be shared. For example, NGOs like Friends of the Earth, Green Peace warned that nanomaterials have some adverse human health effects and may cause danger to environment. Organization like Australian teachers refused to give sunscreen to school students, while the German government warns the consumers to take precautions before using toothpaste. 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.'[38]

From the inventory of Project of Emerging Nanotechnology (PEN),[39] it is revealed that out of around 2000 consumer products, 354 products are able to dermal expose, 173 are able to be ingested, 171 can be inhaled. However, even though these products can be exposed to human health, their adverse health effects are not tested and therefore, this 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 advocate in favour of nanotechnology R & D, we also like to believe that there is no adverse human health and environmental effects of nanomaterials like all these reports. However, the issue is how the consumers will react unless the regulators assure them. Therefore, this is crucial to know the legal and regulatory aspects of handling and governing nanomaterials. In order to know the legal and regulatory aspects of nanomaterials, the best way to know it is from the life cycle of nanomaterails itself, which is discussed in a way of potential exposure route of nanomaterials below-

[36] David Forrest. (1989). Regulating Nanotechnology Development, Foresight Institute, available at http://www.foresight.org/nano/Forrest1989.html (Last accessed on March 16, 2014).

[37] Fiedler, F. A., & Reynolds, G. H. (1993). Legal problems of nanotechnology: an overview. *S. cal. interdisc. LJ*, *3*, 593.

[38] http://www.hsph.harvard.edu/nano/research/a-high-throughput-nanogenotoxicity-assay/ (Last accessed on March 16, 2014).

[39] The Project on Emerging Nanotechnologies, developed by the Wilson Center and VirginiaTeach, available at http://www.nanotechproject.org/cpi/ (Last Accessed on March 31, 2014).

Life Cycle Assessment of Nanomaterials

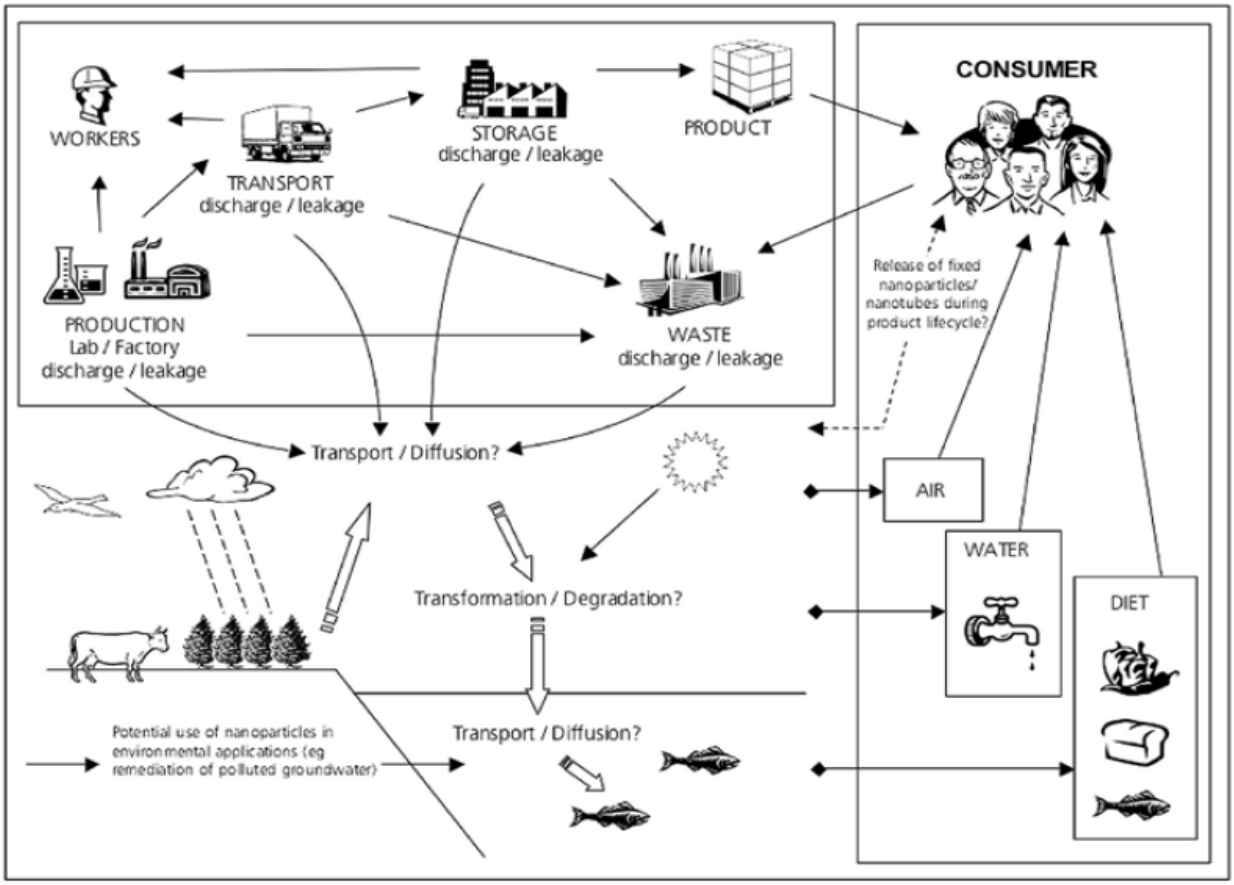

Figure 1: Life cycle of nanomaterials.

From the Figure 1 on life cycle of nanomaterials, this 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, food packaging and labelling, medical devices, intellectual property, insurance etc. that may be relevant in the discussion of different aspects of nanotechnology. This is obvious that specific mention of the term with 'nano' cannot be found as this is still premature, but there should have provisions that can be interpreted. 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.[40] 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 the food,[41] which may be

[40] Preamble, the Occupational Health and Safety Act 1994 (Act 514) [Malaysia]

[41] Many kinds of nanomaterials or ingredients at the nanoscale can be used in food and the food packaging industry. For an overview, please read, Institute of Medicine (US) Food Forum. Nanotechnology in Food Products: Workshop

found injurious to human health can be considered through the provisions of this law. Same is the case with other areas of laws.

5. 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, Viet Nam 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, etc. 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, in the form of codified law/statute, precedent/judge made law, secondary/subordinate legislation, etc. Furthermore, there are also some guidelines, standards, etc. Simultaneously, most of these countries are member of international organizations like the United Nations, the Organisation for Economic Co-operation and Development (OECD), the International Standards Organisation (ISO), the Association of South East Asian Nations (ASEAN), Asia Pacific Economic Cooperation (APEC) etc. and all of the countries are members to many international and regional human rights treaties and other treaties and agreements in most of the abovementioned areas. Many of these Asian countries i.e. Japan, China, Singapore, India etc. have collaboration programs with universities and research organizations in Europe and America, where it is presumed that legal provisions, standards, guidelines 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.

5.1 Asian Constitutions and Nanotechnology

This will be very extremely optimistic to check the constitutions of the Asian countries whether there are provisions relating to nanotechnology, though provisions relating to technology, etc. can be found. However, this is obvious that there are many 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 a

Right to life

Even if there is no direct provision on health and environment, the 'right to life'[42] is perhaps the one single provision which can be found in most of the human rights treaties and all the constitutions of the countries around the world. The courts of laws also in the process of extending this right almost every day with attaching newer attributes in the law.

Summary. Washington (DC): National Academies Press (US); 2009. 2, Application of Nanotechnology to Food Products. Available from: http://www.ncbi.nlm.nih.gov/books/NBK32727/ (Last accessed on March 31, 2014).

[42] For example, Article 13, the Constitution of Japan 1947; Article 21, the Constitution of India 1949.

Right to health

Health is an important human right and hardly there will be anyone who will argue that sound health is the prerequisite to enjoy all other human rights.[43] Most of the countries have incorporated the provision on right to health[44] and the governments are usually committed to ensure sound health for all living within the territorial limit of the country.

Right to pollution free environment

The right to sound environment is also embodied in the constitutions.[45] In many cases, the courts of law also give decisions to ensure pollution free environment. The courts are also approving sustainable development.[46]

5.2 Municipal Legislation

Based on the life cycle of nanomaterials, it is clear that all the 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 labelling, 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 system, there are courts of laws to interpret the provisions of these laws.

5.3 Membership within the International Organizations

This is a fact that there are no organizations in Asia like the European Union, African Unity or Organizations of American States (OAS). But ten economies of the south east Asia are members of the ASEAN. However, the Asian countries are members of some regional and international organization like the UN and its specialized agencies like Food and Agriculture Organization (FAO), World Health Organization (WHO), ILO, OECD, Asia Pacific Economic Cooperation (APEC), ISO, etc. All these organizations have been working to develop frameworks and guidelines relating to nanotechnology. Besides, there are some already existing directives which are adopted by the ASEAN can be used in this regard and all these ten member economies that are members of ASEAN have to follow these directives. For example, the ASEAN Cosmetic Detective was entered into force on 2011, and being a member of the organizations the ten countries are

[43] Karim, M. E. (2010). Health as Human Rights under National and International Legal Framework: Bangladesh Perspective. *Journal of East Asia and International Law, 3*(2).
[44] For example, Article 25, the Constitution of Japan 1947, Article 21, the Constitution of the People's Republic of China 1982.
[45] For example, Article 26, the Constitution of the People's Republic of China 1982
[46] Vellore Citizens Welfare Forum v Union of India, AIR 1996 SC 2715; M.C Mehta v Kamal Nath, (1997) 1 SCC 388; [India];

usually committed to follow the guidelines, etc. Another similar directive is the recently adopted ASEAN Medical Device Directive.

In ASEAN, there are guidelines like ASEAN Guidelines on Good Industrial Relations Practices, the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme, signed at Phnom Penh, Cambodia in September 2, 2003 and entreated into force on the same date. The Agreement on the ASEAN Harmonised 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 signed and entered into force on 10 April 2009. All these ASEAN legal instruments have binding effects as they are the reflection of the member states expressed through consent. Similarly APEC has adopted 'Product Safety Framework'. If this can be followed, then many concerns relating to nanomaterials can be overcome.

However, the main legal question which will arise in this regard is the legal implications of these guidelines or regulations. Another possible future concern will be obligations and responsibilities of the countries which are members of more than one organization and those organizations have different guidelines on similar fields.

5.4 Legal and Regulatory Framework: An Appraisal

Now, this is clear that at least there are some legal provisions in different Asian countries which are apparently sufficient to handle the legal issues relating to nanotechnology. These provisions can be found in different sections in different categories of law. However, the most important concern will be the implementation of such provisions. These laws provide for different legal and regulatory bodies which may not be in a position to assess the real danger. For example, to handle with labor related issues, there are labor courts. Now, if we consider the China incident reported by Reuter, where it was confirmed by the physicians that the incident was caused because of nanomaterials, the courts are initially bound to hold the company liable. The decision which was given by the physicians are not proved conclusively. Therefore, there remain scope of miscarriage of justice. Therefore, this is suggested to frame some guidelines on different aspects of nanomaterials. Though based on the type of legal system, these guidelines will 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 legal provisions relating to occupational health and safety. The dilemma for most of these countries is that nanotechnology in these region is mainly developed by the Small and Medium Enterprises (SMEs). Besides, in many of this Asian countries, the implementation of law is a crucial challenges. For example, even in 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,[47] a statute greatly influenced by French and German law, for more than 115 years. The government has introduced many administrative compensation scheme for

[47] Articles 709-724, Part III, the Civil Code.

different kind of tort liabilities including environmental pollution, medical products, vaccinations, blood donation accidents, and asbestos. However, these system did not work properly.[48]

Other important concerns are the assessment of exposure of nanomaterials, risk assessment and risk management of nanomaterials. In these cases, collaboration among the countries will play crucial role since all these may demand huge amount of investment.

5.5 Recent Developments in Asia

This is obvious that when there is no significant development in terms of adaptation of separate law on nanotechnology in Europe and the USA, this will be premature to expect so in Asia. Pertinent to mention here that some steps towards the regulation of nanomaterials has been taken in France by way of mandatory reporting to register nanomaterials and Denmark and Belgium are in the process of following France.

However, there are some guidelines, basically relating to safe handling of nanomaterials and nanoparticles. Japan has completed the risk assessment of three nanomaterials- titanium dioxide (TiO_2), fullerene and carbon nanotube. 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 ventilations, etc. as well as personal protection equipment.' Such statement can be interpreted in a way that this cannot be said conclusively that TiO2 is not injurious to health, rather it is obvious that there still the need to take necessary precautions.

In Malaysia, the court has taken note of 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. This 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.

Asian countries like Iran, Taiwan and Thailand have introduced voluntary Nano Mark system. Iran as a result of introducing nano marking system also declared some incentives for the

[48] Osaka, E. (2009). Reevaluating the Role of the Tort Liability System in Japan. *Ariz. J. Int'l & Comp. L.*, *26*, 393.

companies that will be willing to use the nano marking in their goods. In Taiwan, it was found that the nanoMark has been very successful to enhance the overall enterprise competitiveness, increased 'corporation image', gained customer affirmative and promoted 'market sales'. It was further found that with the nanoMark certification, companies can even increase 20% of their selling price. For the last ten years (2004-2014), 1488 products of 38 companies received the nanoMark certification and the countries has established at least 13 registered laboratories for the certification purposes and for different industries, e.g. food, textile, footware and recreation, paint, plastic, sensor devices and ceramic, etc.[49]

5.6 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 and demanded that the public to be consulted regarding science and technology policies.[50] 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, Authorization 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. 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 was commercially failed. 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-March 2005. Besides, the country has undertaken a number of researches e.g. risk assessment, environment, health, ethical and societal issues for public acceptance of nanotechnology.

The citizens are in a dilemma in between the reports and findings of business entity and the scientific communities. Business communities are try to convince the consumers that there is no serious side effects of nanomaterials, whereas the scientific communities shared a number of findings that there are some adverse effects of nanotechnology. Taking into account the experience of Australia, where the consumers replied that they mostly rely on the reports of the scientific community rather than the business community, the regulators of the respective countries should come forward to make things clear to the people.

6. Conclusion

Nanotechnology is often referred to as '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 USA President Barack Obama's one of the central foreign policy initiatives, the "Pivot to Asia". 21st century is 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 amount of money in this area. Many European countries (UK, Sweden,

[49] For details on nanoMark system in Taiwan, please visit http://www.nanomark.org.tw/Eng/

[50] http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3807.htm, (Last accessed on January 11, 2014).

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

One of the important consideration should be to include and 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. The business entities normally invest money for making profits and therefore, they must not take any undue risk with regard to the nanoenabled products and push forward the regulators to provide them necessary guidance as to safe development of nanotechnology. Finally, the regulators should be concerned and be alert so that these Asian countries are not used as a 'dumping ground' for nanomaterials developed by western countries and imported by Asian countries.