Regulating Nanotechnology: Timely Stitch for Saving Future

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Abstract

Nanotechnology, the science of using technology at the atomic scale, is the next industrial revolution after internet and is 'the techno *buzzword de jour*'. Its virtually limitless prospects lure the government, research firms and business ventures around the world to invest huge amount for its commercial application and already hundreds of products containing nanomaterials are available in the market. The United Nations also encouraged the application of nanotechnology in ten priority areas for the benefit of 5 billion people of developing countries within its Millennium Development Goal. Conversely, to many people, it is the next asbestos as it has some serious consequence on environment and health and already seven workers in China got lungs infection and two were died. This is a matter of serious concern that there is no effective regulation both in national or international level to handle the possible environment and human health threats. European countries introduced some voluntary reporting systems which were not successful. In this backdrop, the paper, with an appeal in favour of continuous research and development of nanotechnology, aims to focus on some of the regulatory challenges for the regulators around the world with some suggestions to keep the nanotechnology dream alive avoiding nightmares.

Keywords – Nanotechnology, regulation, research and development

Introduction:

Nanotechnology is the next industrial revolution after the internet and is 'the techno *'buzzword de jour*' (Cameron, 2007). The word 'nanotechnology' has turned to be a darling child and everyone has been coining this term with different adjectives e.g. *generic technology* (diversified applications as ICT), *general purpose technology* or *enabling technology* (adding new functions to existing products), and *transformative technology*, which can be compared with steam engine in 18th century and electricity in 20th century in terms of effect.[1] It has virtually limitless potential and will shake up every single sector in near future. Realizing the limitless potential of nanotechnology, country around the world have been investing huge amount of money to be the world leader in nanotechnology.

Besides, though nanotechnology is still in an early phase of development, and is sometimes compared in the literature to information technology in the 1960's and biotechnology in the 1980's, it is no more *terra incognita* i.e. an issue of science fiction or concern of scientists and engineers only rather it has turned to be an inter-disciplinary study. What were in science fictions, many of them are now part of reality.

When group of scientists have been inventing different categories of products ranging from medical devices to sports instruments, transport parts to skin care and cosmetic products using nanoparticles, there are also concerns about unanticipated harms and risks due to which it is also termed as next asbestos. 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.

Science and invention always run faster than law and policy. This is agreed that significant progress in nanotechnology research is already evident, albeit the world community is yet to reach to a consensus about regulating nanotechnology as there is always a risk that too much regulation may hinder the development of the research and application of nanotechnology. However, regulators around the world simply cannot sit idle and wait for any disaster in

terms of human health and environment and are in serious dilemma to make a balance between risk and benefits of nanotechnology.

History of Nanotechnology

Nanoparticles exist on the planet for centuries i.e. smoke particles and viruses and there are many examples of structures in the nature that exist with nanometer dimensions i.e. DNA, proteins, cells, etc. (García et al., 2013) Ideas or techniques of using nano level particles is not a new thing. Use of nanoparticles like silver in its pure form was used in ancient Greece; nanoparticles in ceramics were used in ancient Rome.[2] There are also some researches where scholars have found out some religious roots of nanotechnology (Toumey, 2009); (Hongladarom, 2009).

The history of modern 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'[3] 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 though he admitted that he did not try that yet. In 1974, the Japanese Professor Norio Taniguchi of Tokyo Science University first coined the term 'nanotechnology'. Noble laureate Richard Smally and Eric Drexler played pioneer role to make the idea very popular in the world.

Prospect and perils

Statistics on Investment and Products

This socio-economic promise of nanotechnology has contributed to very rapid growth in public research and development (R & D) investments in this field. In fact, hardly any other technology field has benefited from as much public R & D investment globally in such a short time as nanotechnology, and private sector investment is also picking (Palmberg et al.,

2009). Simultaneously, private companies also have been investing a lot with the intention of making huge amount of money in future.

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.[4] In USA, after launching the world's first national nanotechnology program, the government invested total USD 15.6 billion in between 2001-2012[5] 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).[6]

Based on a broad industry survey and analysis in the Americas, Europe, Asia and Australia, the National Science Foundation of the United Nations estimated that the nanotechnology job market in the United States will require over 2 million nanotechnology-savvy workers by 2014, and about three times as many jobs in supporting activities. Another 5 to 7 million jobs will be created worldwide in this field (Mongillo, 2009). Of them only 20% are expected to be scientists, and the remaining 80% shall be from highly skilled engineers, technicians, business leaders and economists.

The UN Task Force on Science, Technology and Innovation (part of the process designed to assist UN agencies in achieving the United Nations Millennium Development Goals) addresses the potential of nanotechnology for sustainable development considering the benefits of 5 billion people of the developing countries and it was also discussed how nanotechnology can contribute the developing countries in achieving these goals (Singer et al., 2005). UNESCO traced top ten applications of nanotechnology within the UN Millennium Development Goals (MDGs)- (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, (j) Vector and pest detection and control.

Apart from the leading economies, smaller and developing economies are not staying behind. Countries like Thailand and the Philippines, for example, are both devoting a portion of their small science and technology budgets to nanoscience and nanotechnology (Hassan, 2005). (Mahajan, 2006) shared some concern of the US government officials where they expressed that perhaps this is the first time in recent memory, the United States does not have a clear advantage though which is “crucial” for the future economic health of the country; nanotechnology is not dominated by USA and outpaced by Japan, EU, Russia, Korea, China.

Definition of Different Terms:

a. Nano:

The word ‘Nano’ derives from the Greek word "Nanos" meaning "dwarf", means one-billionth. A nanometer is one billionth of a meter. 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 and Reynolds, 1993). To share some examples, a sheet of paper is about 100,000 nanometers thick and there are 25,400,000 nanometers in one inch, a strand of human hair is roughly 75,000 nm across.

At the nanoscale, the characteristics of matter can be significantly changed, particularly under 10–20 nm, because of properties such as the dominance of quantum effects, confinement effects, molecular recognition, and an increase in relative surface area. Downsized material

structures of the same chemical elements change their mechanical, optical, magnetic and electronic properties, as well as chemical reactivity leading to surprising and unpredicted, or unpredictable, effects. In essence, nanodevices exist in a unique realm, where the properties of matter are governed by a complex combination of classic physics and quantum mechanics. At the nanometer scale manufacturing capabilities (including by self assembly, templating, stamping, and fragmentation) are broad and can lead to numerous efficient outcomes.

There are two reasons which cause nanoscale matter to behave differently from materials at other scales. *First*, nanomaterials have a relatively larger surface area when compared to the same mass of material produced in a larger form. This can make materials more chemically reactive (in some cases materials that are inert in their larger form are reactive when produced in their nanoscale form), and affect their strength or electrical properties. *Second*, quantum effects can begin to dominate the behaviour of matter at the nanoscale - particularly at the lower end - affecting the optical, electrical and magnetic behaviour of materials. Materials can be produced that are nanoscale in one dimension (for example, very thin surface coatings), in two dimensions (for example, nanowires and nanotubes) or in all three dimensions (for example, nanoparticles).[7]

One can reach to the nanoscale either from the *top down*, where structures are smaller and even smaller so that it can be reached to a nanometric scale, or from the *bottom up*, whereby nanoscale elements are collected and assembled to make some tiny structures.

b. Nano Technology

Nobel Laureate Richard Smalley defined nanotechnology as the art and science of building stuff that does stuff at the nanometer scale. This is a matter of great concern that the world community is still in search of a regulatory definition of nanotechnology, due to which different organization, person or countries define ‘nanotechnology’ from different

perspective. 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).[8] However, pertinent to mention here that National Nanotechnology Initiative (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-nanoeter 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 (Mongillo, 2009).

European Union in its report on *Considerations on a Definition of Nanomaterial for Regulatory Purposes* considered and shared all the definitions given by different international Organisations like Organisation for Economic Co-operation and Development (OECD), EU Scientific Committee on Emerging and Newly Identified Health Risks, European Union Cosmetic Products Regulation, etc. and definitions which are available in municipal legislation of different countries including Australia, Canada, Denmark, the United Kingdom, USA and 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. Some international Oraganisations like United Nations (World Health Organisation, Food and Agriculture Organisation, International Standard Organistaion (ISO), International Labour Organisation (ILO), European Union (EU), Organisation of Economic Cooperation and Development (OECD) are in the process of developing nanotechnology framework.

From regulatory point of view, definition is immensely important as unless one thing cannot be defined properly, legal sanctions and attributes cannot be attached to it. The issue of definition deserves further attention because of the unanticipated environmental and health hazards which may occur from nanomaterials. The European Parliament also emphasized to introduce a comprehensive science-based definition of nanomaterials.[9] Definition is further crucial to assess the label of liability of different people engaged in nanotechnology research and business.

c. Nano Particle/Nanomaterial

Nanoparticle is considered as miracle fibre.[10] There are three types of nanoparticles: 'engineered' nanoparticles (such as buckyballs and gold nanoshells), '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). Only 'engineered' nanoparticles constitute an entirely new class of particles and, to date, buckyballs are the only engineered nanoparticles that have been seriously studied, whereas 'incidental' nanoparticles (often referred to as 'ultrafine particulate matter') such as auto exhaust have clearly been more extensively studied. The handful of studies on the toxicity of fullerenes so far suggest that they are indeed hazardous – but also that they can be engineered to be less so, in particular by conjugating other chemicals to the surface of buckyballs, thus changing their chemical properties.[11]

To nanoparticles are of three types (i) unintentionally produced particles (e.g., diesel engines and welding processes) or originate from natural sources (volcanoes and forest fire); (ii) particles produced in bulk in traditional industries such as the chemical industry or the

polymer industry (e.g., carbon black and titanium dioxide); (iii) particles that are deliberately engineered to have specific properties and characteristics only existing in the nano-range and utilized for a specific function (e.g., carbon nanotubes, fullerenes and quantum dots).

Nanoparticle can take different shapes- cylindrical, discoidal, spherical, tabular, ellisodial, equant or irregular.

Health and environmental concerns of nanotechnology:

Technology, be it 'low' technologies like slash-and-burn agriculture, or "high" technologies like nuclear weapons do cause some environmental harm, but new technologies are often cleaner and safer than their older counterparts and offer ways of remedying environmental harms which were previously thought of as impossible. (Reynolds, 2001)

The social implication of nanotechnology was first prognosticated by Eric Drexler in his 1986 book on *Engine of Creation: The Coming Era of Nanotechnology*. Drexler was seriously concerned about the abuse of nanotechnology. Nanotechnological devices for military use also raise the issue that they do the work of chemical and biological weapons, but—at least arguably—do not fall within treaties regulating chemical and biological weapons (Reynolds, 2001). Challenges are there about nanobotes leading to 'gray goo' situation and use of nuclear weapon by the military weapons. Some of these will have no significant impact on the nonhuman environment, but nanotechnology-based agents for crop destruction, forest-cover removal, and area-denial applications are likely to pose familiar environmental problems in a new fashion. (Reynolds, 2001) shared that the civilian nanotechnology will be less harmful than the military nanotechnology and the 'open source' software is less harmful that the 'closed source' software.

Though there are limited number of research regarding the health and environmental implications of nanotechnology, every single research so far done around the world have

placed a warning on the health and environmental issues associated with nano materials. European Parliament realized 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'. [12] The Parliament further realized to evaluate the community legislation regarding waste, workers, chemicals, etc.

In October, 2009, the Scientists of Institute for Health and Consumer Protection (IHCP) of the Joint Research Centre (JRC) of the European Commission performed basic risk assessments for four types of nanomaterials: fullerenes**,** carbon nanotubes**,** nano-silver and metal-oxides and in its 426 pages report concluded that health risks are likely to arise from chronic occupational inhalation of nanoparticles and the consumer may be affected by the spray applications of the nanomaterials.[13]

Toxic wastes in contaminated aquifers may be neutralized by specially designed nanorobots that selectively capture undesirable molecules and then either sequester them for removal or (where the danger is chemical, not nuclear) break them down into harmless substances. While nanodevices cannot, for example, render radioactive materials nonradioactive, they could capture molecules of radioactive waste and concentrate them into a form that would be easily removed. (Reynolds, 2001)

Application and use of Nanomaterials should carefully be used so that additional problems which were occurred previously, are not occurred like destructive action on the atmospheric ozone layer by extensive application of chlorinated and fluorinated hydrocarbons or asbestos fiber-based materials. (Andreev et al., 2009)

In order to assess the health effect of nanotechnology, this is important to consider how human may be exposed to engineered nanoparticles. Workers are obviously exposed to nanomaterials. Few companies like Japanese Mitsubishi opened the first fullerene plant in May, 2003. In USA, the material safety data sheets (MSDS) contains the list the naomaterials with bulk materials and workers handling such substances do not take any safety precautions beyond those adopted for bulk solids of identical composition. Therefore, workers are in contact with nanoparticles. Furthermore, consumers come in contact with nanomaterials through personal care products i.e. cosmetics, sunscreen, etc. Back to 2011, the physician-led American organization Nanodermatology Society in its first position statement claimed that the use of sunscreen containing nanomaterials were safe to use.

Consumers are in great dilemmas. Even in some recent studies, it has been claimed that nano-sized cosmetic or sunscreen ingredients pose no potential risk to human health (Nohynek et al., 2008). In Australian researches these were found that sunscreen use reduce melanoma risk by 50% and one kind of skin cancer i.e. squamous cell carcinoma by 39% (Green et al., 2011). Again, on the other hand, nanoparticles are used in sunscreen which are of specific concern that it can penetrate through the skin and may cause another problem.

Nanoparticles can enter the human body through the lungs, the intestinal tract, and skin (Khaled Radad, 2012), and are likely to be a health issue, although the extent of effects on health are inconclusive. Nanoparticles can be modified to cross the brain blood barrier for medical applications, but this suggests other synthetic nanoparticles may unintentionally cross this barrier. According to (Albrecht et al., 2006), people working within emerging nano-industries are some of the first coming into contact with the new materials, therefore, this is a challenge to ensure the safety of these people.

Given the limited number of research findings, though the challenge is tough, is not impossible. Previous studies have shown that inhaled mineral dusts such as quartz and

asbestos fibers can lead to lung damage and cancer. (Carter, 2008, Kai, 2012) (M. Ellenbecker, 2011) (Song et al., 2009). Some of the news are already reported. In 2009, Reuter reported that seven young Chinese women suffered permanent lung damage and two of them died after working for months without proper protection in a paint factory using nanoparticles. These cases arouse concern that long term exposure to nanoparticles without protective measures may be related to serious damage to human lungs[14] (Gilbert, 2009). Interestingly, though the Chinese government denied the fact, the doctors who treated these workers ruled in favour. The team of the doctors who dealt with these patients concluded that long-term exposure to some nanoparticles without protective measures may lead to serious damage to lungs and it is impossible to remove nanoparticles that have penetrated the cell(Song et al., 2009).

A research group at the National Institute of Health Sciences in Japan reported in the Journal of Toxicological Sciences in February that carbon nanotubes injected into mice led to actual tumors. Their mice had a mutation that made them more sensitive to asbestos, predisposing them to form tumors. The study found that the carbon nanotubes caused scarring as well as tumors in 88% of the mice, compared with 79% of the mice treated with asbestos. (Carter, 2008)

Chiu-Wing Lam of NASA's Johnson Space Center conducted a study and found that carbon nanotubes, when directly injected into the lungs of mice, could damage lung tissue (Mongillo, 2009). Malaysia has done significant development in terms of carbon nanotubes and therefore, this issue should be considered seriously.

Both UNESCO (2006) and Royal Society of UK (2004) were concerned about a different type of risk and challenge regarding the enjoyment of benefits and risks of nanotechnology as the can predict that the products with nanotechnology application will be produced in one area and may be used in another place and finally may be disposed of in another place. Thus

it may not harm the people who will consume or use the benefits of nanotechnology application instead will people in a state of danger where the production will be made and the waste will be disposed.

It is a matter of fact that the way companies and the governments are interested in commercial application of nanotechnology, are not equally interested on research on health and environmental concerns arising out of nanotechnology, if any. It has been revealed that China is investing only 3% for safety studies and USA is spending 6% of the federal nanotechnology funding, in 2006, out of $ 1.5 billion of USD, 2.5% were allocated for the health and safety risks of nanoscale materials.[15]

However, the year 2013 started with a good news in this regard. In a very recent research it has been revealed that the concern of carbon nanotube as asbestos can be completely alleviated if their effective length is decreased as a result of chemical functionalization, such as with tri (ethylene glycol) (TEG). But not all chemical treatments alleviate the toxicity risks associated with the material. Only those reactions that are able to render carbon nanotubes short and stably suspended in biological fluids without aggregation are able to result in safe, risk-free material(Ali-Boucetta et al., 2013).

Regulating Nanotechnology:

Legislations and regulation have great role to play in the development of nanotechnology. Earlier, based on the available exciting data and research findings, the Commission of the European Communities, in its communication to the European Parliament, the Council and the European Economic and Social Committee Regulatory Aspects of Nanomaterials, after evaluating community legislation relating to chemical, worker protection, product and environment concluded that the current regulatory set up in principle covered the potential health, safety and environmental risks in relation to nanomaterials.[16]

However, the situation has been changing. Nanotechnology should not be treated as a blank cheque to the scientists. (Scheufele et al., 2007) shared a Switzerland study where it was found that the scientists similarly perceived lower risks associated with nanotechnology as they perceived with nuclear energy, food biotechnology etc. This is an irony of fate that after few years of utilization and commercialization of nuclear energy and food biotechnology the world community has witnessed some serious disasters around the world.

Calls for tighter regulation of nanotechnology have occurred alongside a growing debate related to the human health and safety risks of nanotechnology (Rollins, 2009). Being a nanotechnology researcher, since it would be tough to assess engineered nanoparticles, (Colvin, 2003) was against formulation of any risk assessment tool or guideline in the absence of clear data. However, (Hoet et al., 2004) were against this contention and suggested for risk assessment of every particle based on size, shape, surface area, chemical composition and biopersistence since these are crucial and may create substantially different health effects. They further imposed a duty on the part of the producers of nanomaterials to provide relevant toxicity test result for any new materials as per the international guidelines of risk assessment and in this regard the regulatory authorities and the legislators should support fundamental research to construct scientifically valid, lo-cost, fast-throughput toxicity test.

While discussing on the benefits of engineered nanoparticles in medicine in terms of drug delivery, cancer therapy, neuroprotection, tissue engineering, tissue imaging (Khaled Radad, 2012) also considered the potential hazards of engineered nanoparticles and took strong stand in favour of regulatory health risk assessment of engineered nanoparticles mandatory. For doing so, they suggested to consider the exposure assessment by collecting data and knowledge about potential exposure of engineered nanoparticles and hazard identification

through assessing the physicochemical characteristics of these nanoparticles, in vitro assays, in vivo assays and human epidemiological studies.

There is significant debate about who is responsible for the regulation of nanotechnology. Some regulatory agencies currently cover some nanotechnology products and processes (to varying degrees) – by "bolting on" nanotechnology to existing regulations – there are clear gaps in these regimes (Bowman and Hodge, 2006). (Davies, 2008) has proposed a regulatory road map describing steps to deal with these shortcomings.

Renowned NGO ETC-group is against distinct regulatory set up and in favour of a similar approach like the EU Chemical Regulation, REACH which will make liable the producers for the risk and safety of their products, for regulating nanoparticles. (Aasgeir Helland, 2006)

This is already accepted and realized that the nanotechnology should be regulated though there are some differences of opinion as to the nature of regulation e.g. to what extent research, application and commercialization of nanotechnology should be regulated, how nanotechnology should be regulated etc.

(Bowman and Hodge, 2006) identified 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 and extensively considered three of them i.e. occupational health and safety, product safety and environmental law within the regulatory frameworks in Australia, Japan, the United Kingdom and the United States and conclude that there was no nano specific regulation and legislation in these countries though all these countries have legislation on Occupational Health and Safety, Industrial Chemicals, Therapeutic Goods & Medical Products, Cosmetics, Food, Pesticides & Veterinary Medicines / Agricultural Chemicals Environment and these countries deal with nano scale chemicals with the existing legal framework of the country. In this given

situation, they went on examining whether the existing regulatory framework will be sufficient to handle the possible threats and challenges posed by nanotechnology application and conclude that the existing regulatory provisions will frame the immediate structure of regulations. (Bowman and Hodge, 2006) revealed that one of the most important factors in having no specific legislation on nanotechnology in these countries is because nano scale chemicals are not treated as 'new chemical' and can be considered under the existing legal framework. They further found that of the four countries they studied the laws of UK are the most advanced to handle nanotechnology challenges and they proposed for short term to medium regulatory set up instead of making any comprehensive legal or regulatory set up. However, the UK newspaper, the Independent reported on January, 26, 2013 that the leading scientist of UK are in favour of regulating nanoparticles.[17] The findings of this article will be good to consider in details as the article assessed the existing regulatory framework of civil law countries where codified laws play crucial role and common law countries where the judges by way of precedent play crucial role. Therefore, this will be a great opportunity to test the findings of the article in the context of Malaysia.

When (Bowman and Hodge, 2006) were claiming in the abovementioned way and (Paradise, 2012) also repeated that USA's FDA Regulations are not sufficient to deal with nanotechnology, a report by the U.S. Food and Drug Administration (FDA), for example, essentially recommended that existing regulatory structures were already comprehensive for nanotechnology drugs and biological products subject to premarket authorization.[18]

UK Health and Safety Executive (HSE) issued an information sheet on Risk management of carbon nanotubes in March 2009, where it has been stated that the occupational use of nanomaterials is regulated under the Control of Substances Hazardous to Health Regulations (COSHH) 2002 (as amended). The information sheet further stated that the principles of risk assessment as mentioned in the Control of Substances Hazardous to Health Regulations

(COSHH) 2002 shall be applicable and companies should take precautionary approaches.[19] This information sheet will be very useful to check the existing practice with regard to carbon nanotube in Malaysia.

In recent times, the scholars around the world are divided into main platforms on whether new legislation on Nanotechnology is required or amendment in the existing sectoral laws like environmental law, occupational health law, food and agriculture law will be suffice. Scholars who are in favour of regulating nanotechnology through existing regulation concludes that no comprehensive legislation is required, it will be enough to regulate moderately some sector of nanotechnology like invisibility, micro-locomotion and self-replication applications (Pinson, 2004). They find momentum in favour of their argument as some of the regulatory actions are already taken under the existing regulations. For example, in 2008 the Environmental Protection Agency (EPA) fined the US Company Aten Technology US$ 208,000 for failing to register nanosilver as a pesticide. Reynolds has continued to engage in the debate over nano-regulation, articulating the advantages and disadvantages of several theoretical models for regulating nanotechnology and advocated for self-regulation and co-regulation (Reynolds, 2003). However, this may not be true as in a wakeup call Fiedler and Reynolds suggested that some of the problems posed by nanotechnology may be sui generis, which may be addressable only through the creation of entirely new rules (Fiedler and Reynolds, 1993) since the existing regulatory framework will not be adequate to human and environment safety.[20] Therefore, one of the best approaches to settle down the debate may be a cooperative government industry initiative in which there can be open dialogue and input from many different technological and administrative bodies with some expertise in managing technology (Wejnert, 2004).

The ‘Nano Risk Framework’ jointly launched by the Environmental Defense Fund and DuPont in 2007 is a useful tool for the industries dealing with nanotechnologies to follow.

This framework is information-driven and in the absence of information it will not assume the presence of any risk instead it will suggest to use 'reasonable worst case assumption'. The framework suggests for six different steps to assess the safety of nanoparticles i.e. (1) development of a general description of nanomaterials and their intended used, (2) development of three sets of profile i.e. properties profile (to identify physical and chemical properties), hazard profile (to check potential safety, health and environmental hazard) and exposure profile (to identify the scope of human and environmental exposure of nanomaterials), (3) evaluation of risks in all these three properties profile, hazard profile and exposure profile, (4) assessment of risk and adoption of course of action through engineering controls, protective equipment, risk communication and product or process modifications, (5) decide in an appropriate review team, document the decision with rationale and information and act, and finally (6) review the action in changing circumstances with the availability of new information, technology change, etc.[21]

The next issue of consideration is that if nanotechnology is to be regulated should it be done through binding laws or through some policy documents or issues should be left for self regulations. Though self regulation should be an ideal stand in dealing with emerging technology like nanotechnology in UK this approach was not successful. There are already some The Department for Environment, Food and Rural Affairs (DEFRA) of the United Kingdom introduced a Voluntary Reporting Scheme (VRS) for engineered nanoscale materials at any stage of a product's life-cycle in between September 2006 to September 2008 to develop appropriate controls in respect of any risks to the environment and human health from free engineered nanoscale materials from anyone involved in their manufacture or use and anyone involved in nanoscience research or managing wastes consisting of engineered nanoscale materials. It is a matter of fact that even after repeated assurance about the end result of the Voluntary Reporting Scheme, DEFRA received only twelve completed

submissions and one more after conducting the telephone survey done as a consequence of very low submissions (Fiedler and Welpe, 2010).

Some of the countries, on the other hand, have enacted laws relating to nanotechnology, e.g. the U.S 21st Century Nanotechnology Research and Development Act, 2003 etc. Being concerned with the potential health and safety risks of products containing nanotechnology materials, in October, 2011, the US Senator for Arkansas introduced a bill to amend the Federal Food, Drug, and Cosmetic Act to establish a nanotechnology regulatory science program titled the Nanotechnology Regulatory Science Act, 2011. Under the proposed bill, it is proposed to appropriate US$ 15 million, 16 million and 17 million for the fiscal year 2013, 2014 and 2015 respectively. The Bill is now pending before the Committee on Health, Education, Labor and Pensions of the Senate.[22] Other countries like Ireland, Germany are in the process of enacting laws regulating nanotechnology, whereas countries like Australia and New Zealand identified that the existing regulatory framework is not adequate. Though the Australian Cancer Council did not find any evidence in favour of any unacceptable safety risks in sunscreens containing nanoparticles, the Australian Education Union resolved to use sunscreen without nanoparticles only.[23] In 2012, in USA, the NGO, Friends of the Earth sued the FDA for failing to regulate nanoparticles.

In February 2012, the final decree of the French Ministry for Ecology, Sustainable Development, Transportation and Housing introduced the first mandatory reporting scheme for nanomaterials in Europe. The decree, which shall be in operation from January 2013, was adopted to have a better understanding of nanomaterials and their use, to enable better traceability, to have a better knowledge of the market and volume of nanomaterials involved and to collect available information on toxicology and ecotoxicology of nanomaterials. Under the decree, the importers, producers, distributors of nanomaterials, as well as “professional users” and research laboratories located in France that manufacture, import, distribute

nanomaterials in quantities of ≥ 100g must submit an annual declaration on 1st May of every year containing the quantity and use information to the Minister of the Environment. The decree entails the French National Agency for Food Safety, Environment and Labour (ANSES) for management of data thus collected.[24] Whereas, in another European country i.e. in Germany, the Federal Environment Agency advised the consumers against using products containing nanomaterials.[25]

Though Japan is one of the most advanced countries in the field of nanotechnology and robotics in the world, the word 'nanotechnology' was first used by Japanese Norio Taniguchi in 1974 and Sumio Iijima discovered carbon nanotube (CNT) legal issues associated with it is not discussed enough (Kai, 2012). The main reason is that the people cannot concretely understand and foresee the dangers and results which nanotechnology can bring about to human body or human life.

(Cassandra D. Engeman, 2012) in a very recent article shared the result of an international survey on nanomaterials companies in 14 countries where though the participant companies were also concerned about the high level of risks and uncertainties with regard to the engineered nanomaterials, were not careful enough to take counter measures. Lack of regulatory oversight and lack of information about the particular risk were the main reasons behind such practices.

Finally, (Hansen and Baun, 2012) with an austere tone questioned the initiative taken by the European Commission in December, 2011. The European Commission asked the Scientific Committee on Engineering and Newly Identified Health Risks (SCENIHR) to provide scientific opinion on safety, health and environmental effects of nanosilver and its role in antimicrobial resistance. (Hansen and Baun, 2012) opined that all these issues have already been discussed in 18 review articles, which covered the same ground, identified some common data gaps and research needs and thus the Commission should avoid the 'paralysis

by analysis' situation and should not wait for regulating nanomaterials as already twenty years elapsed from the publication of first article on effects of nanotechnology with concerns. Some of the governments are still asking for further information, may be because nanomaterials are used by all big companies like pharmaceuticals, medical equipment, oil, arms etc. All these companies are big donors to run the state machineries and that may prevent the government to take strict steps in favour of regulation. If the Commission does so, it will definitely be a ground breaking event as in terms of commercialization Europe has already overtaken East Asian countries and holding second position after USA.

Legal and Regulatory Interventions and Policy Implications:

After all these discussion on in favour of and against regulating nanotechnology for the benefits of mankind, this is obvious that it is high time that the international community should reach to a consensus on the definition of nanoscale which will enable the regulators of the countries around the world to regulate the products which are developed using nanotechnology. The precise definition of the nanoscale will allow the countries to assess whether the existing laws relating to chemical, product liability, occupational health, environment are sufficient or not. On the basis of such assessment, the countries will be able to go for further reform in the existing regulatory framework.

The governments, regulators and companies around the world should take initiative to make people aware of nanotechnology enabled products and should allow them to choice. Since this is a new technology to many countries in the world the regulators of the developed countries where most of the companies are registered and functioning. The regulators there should be more cautious before exporting such products in another country.

The United Nations and other international organization should also come forward to assess the perception or opinion of the people who will be the ultimate stakeholders of this

technology. Back to 1996, the United Nations Office of the Outer Space conducted a survey on the legal issues relating to aerospace objects. Similar initiative relating to nanotechnology shall highly be welcomed. If such initiative will be taken under the supervision of the United Nations all the countries will feel obliged to share information and it is presumed that the countries irrespective of size, economy will be properly represented.

This is again a matter of great concern that though the companies are interested to spent huge amount of money in developing commercial products using nanotechnology, they are reluctant to spent money for the research on human health and environmental concerns of nanotechnology. It has been revealed that China is investing only 3% for safety studies and USA is spending 6% of the federal nanotechnology funding, in 2006, out of $ 1.5 billion of USD, 2.5% were allocated for the health and safety risks of nanoscale materials (Rico et al., 2011). Therefore, the companies and government should increase the amount in conducting more research pertaining to health and environmental concerns relating to nanotechnology. At least the companies should realize that the people should be convinced about the safety of the nano-enabled products otherwise all the hard work, investment will go in vain.

Finally, before being assured about any kind of danger the companies and the research organization working on nanotechnology should observe the ‘precautionary principle’ always as the guiding rule to avoid any kind of injuries.

Conclusion:

There should not have any doubt or debate that the magic technology, nanotechnology and research should be continuous within the approved regulatory framework as it has huge potential which should be used for the betterment of mankind. Simultaneously, the scientist should not be offered a blank cheque to do researches according to their own will with this technology and therefore their activities must be regulated. It may give a comfort feeling that

so far no accident or damage has been evident, but this is equally true that the effect of the technology is dormant and not visible and therefore a precautionary approach shall be the best approach.

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