

Nanotechnology and its legal and social implications

Md. Ershadul Karim^a, Abu Bakar Munir^a, Siti Hajar Mohd Yasin^b, Firdaus Muhammad-Sukki^c

^aFaculty of Law, University of Malaya, 50603 Kuala Lumpur, Malaysia

^bFaculty of Law, Universiti Teknologi MARA, 40450 Shah Alam, Selangor, Malaysia

^cFaculty of Engineering, Multimedia University, Persiaran Multimedia, 63100 Cyberjaya, Selangor, Malaysia

Abstract

Nanotechnology is the next industrial revolution after internet and the wave of the future. Countries around the world have been investing huge and thousands of consumer products containing nanomaterial are already in the market. However, industries are apparently more inclined to generate revenue ignoring societal concerns, which may have serious negative impact. This paper aims at reviewing the legal and societal aspects of nanotechnology, and shares an overview of present trend and recent developments around the world. The paper will argue that unless the society is included in the whole process, the ultimate purpose of generating money will be frustrated.

Keywords: nanotechnology research and development; legal aspects of nanotechnology; public perception; public acceptance; societal implications; emerging technology; risk communication

1. Introduction

Nanotechnology, the art and science of using and manipulating technology purposefully and intentionally at the atomic scale, is no more a dream, it's a reality. It is also considered as 'next industrial revolution' and 'wave of the future'. Like the human civilisations were coined as 'Stone Age', 'Bronze Age', 'Iron Age' or 'silicon or advanced material age', the coming decade will be termed as 'Nano age'. After the Industrial Revolution, Manhattan Project (utilization of nuclear energy), deployment of Sputnik (led to space exploration) and Advanced Research Projects Agency Network (ARPANET) (resulted in information explosion), it is the only science that has brought together people of different fields, making it truly inter-disciplinary (Murty, Shakar, Raj, Rath, & Murday, 2013). Some economists predicted that nanotechnology would prove to be magic by 2025 (Glenn & Gordon, 1997).

The word 'nanotechnology' is an omnipresent vogue term and different people have been using different terms with different adjectives to describe it. Nanotechnology is very attractive as a *generic technology* (diversified applications as ICT), enabling technology (adding new functions to existing products), and has disruptive potentiality (can displace existing products or can obliterate a particular type of product in the market) (Shilpa & Bhati, 2012). It is a *transformative technology* and can be compared with steam engine in 18th century and electricity in 20th century in terms of effect (Hassan, 2005). Again, nanotechnology is considered as a *disruptive technology*, as it has the ability to improve a product in ways that the consumers did not expect, may be by way of lowering price (Bower & Christensen, 1995). Nanotechnology is *general purpose technology* like electricity or computers as in its advanced form it will have significant impact on almost all industries and all areas of society. Nanotechnology is *dual-use technology* as it will have both commercial and military applications and will have benefits as risks (CRN 2008). It is also termed as one of the six 'key enabling technologies' included declared by the European Commission

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(European Commission 2012). It is ‘vanishingly small’ and a driver of techno-socio-cultural change (Hunt & Mehta, 2013).

Even though the word ‘technology’ is used, nanotechnology is no more *terra incognita*, an issue of science fiction or concern of scientists and engineers only, rather it has turned to be an inter-disciplinary study, mainly focusing on medicine, chemistry, biology, physics and material science. What were in science fictions, many of them are now part of reality. More than 2000 consumer products containing nanomaterials are already in the market and hundreds are in the pipeline. The International Labour Organisation predicts that by the year 2020, 20% of all products produced in the world will use nanotechnology. Patent offices around the world are flabbergasted with innovation applications. Even though, back to 2006 it was claimed that nanotechnology was in a stage where information technology was in 1960’s and biotechnology was the 1980’s (O. Renn & Roco, 2006), already more than thousands of consumer products which are developed using nanotechnology and nanomaterials are listed in the product inventories of different organisations e.g. in Europe, USA, Japan and also by different organisations.

With all these prospects and predictions, there remain some concerns too as in number of research, it has been proved that some of the nanomaterials can be harmful to human health and environment. Simultaneously, in many reports commission by the government and research bodies of different countries, it has been suggested for conducting more and more research to ensure the safety of nanomaterials so that they do not create any adverse effects on human health and environment. This issue of ensuring safety aspects of nanomaterials is very important because of the fact that the consumers who are at the center of all these predictions and prospects should be made convinced, otherwise the whole purpose of using nanotechnology will be frustrated. Taking into account the experience of genetically modified food in Europe and nuclear energy in many countries like Australia (Bird, Haynes, van den Honert, McAneney, & Poortinga, 2014), it can be said that unless the consumers can be assured about the safety of nanomaterials and the nanoenabled products, the progress of nanotechnology will definitely be hampered.

More than 150 countries, irrespective of size and economy, have been investing and conducting research to avail the benefits offered by nanotechnology. However, it is a matter of serious concern that not many countries are serious to include the society in the whole process, rather their main concern is toward invention of different things. One of the main reasons may be that, in many research, it was claimed that nanomaterials are not harmful to human health. Earlier the regulators in countries like United Kingdom (UK), Australia, Japan, New Zealand claimed that the exiting regulatory framework is sufficient to handle possible risks and threats posed by nanomaterials. However, in Australia, the regulators have been changing their mind set that the nanomaterials are not harmful and now have been treating many substances as ‘new substances’. At the European level also, the European Commission has recently adopted the Cosmetic Regulation and with the regulation, the European Commission changed its stand of 2008, where it claimed that nanomaterials are not harmful.

This paper aims at reviewing the legal and societal aspects of nanotechnology, and shares an overview of recent developments in different parts of the world. It is anticipated that the suggestions which will be shared at the end of the paper will have policy implications and the stakeholders, especially the business community and regulators will highly be benefited.

The paper, with the introduction and conclusion, is organized in the following way. The first part will give an overview of some of the concepts relevant in the study of nanotechnology, then attempts will be taken to share the legal issues associated with nanotechnology. After that, the importance of consideration of social issues in the nanotechnology research and development will be shared. Different practices adopted by different countries to include citizens in the nanotechnology movement will be discussed in this segment and the paper will be wrapped up arguing that unless societal aspects are not considered seriously, the progress in nanotechnology research and development will not be successful.

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2. Conceptual analysis

The word 'Nano' derives from the Greek word 'Nanos' or 'nannos' meaning 'dwarf' or 'very short man'. It is used to refer to a unit of measurement like millimetre, centimetre, metre, kilometre, feet, yard, bite, byte, kilobyte, megabyte, gigabyte, etc. According to the International System of Units (SI) a 'nanometer' (nm) is one billionth of a meter or a millionth of a millimetre. One of the best way to explain the nanoscale is to draw some analogies with things of our everyday use. The relationship of size between a nanometer with a meter is similar to the relationship of a golf ball with the earth, a human being with the sun, one nanometer is about as long as fingernails of human being grow in every second. To share some examples, a sheet of paper is about 100,000 nm thick, there are 25,400,000 nm in one inch and a strand of human hair is roughly 75,000 nm across, a six-foot long human being is two billion nanometer.

Nobel Laureate Richard Smalley defined nanotechnology as the art and science of building stuff that does stuff at the nanometer scale (Linkov & Steevens, 2009). Different organisations, persons and countries define 'nanotechnology' from different perspectives. Two categories of definitions of nanotechnology can be found in literature. *Single-based definition* of nanotechnology, e.g. the definition shared by the United States of America's National Nanotechnology Initiative (NNI) is useful for building consensus and set overall policy definitions, list based definition, developed by the European Patent Office (EPO) is more relevant for the companies (OECD 2010).

A close analysis of these single-based definitions will reveal that most of them are derived from the definition suggested by the USA NNI, is as follows (Mongillo, 2009)-

- a. Research and technology development at the atomic, molecular, or macro-molecular levels, in the length scale of approximately 1 to 100-nm range.
- b. Creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size.
- c. Ability to control or manipulate on the atomic scale.

3. Legal implications of nanotechnology

Nanotechnology is no more an issue for the scientists only, rather it is a multi-disciplinary study. Due to its multi-disciplinary nature, when legal issues are concerned, it is to be considered whether the existing laws are sufficient to handle different aspects of nanotechnology including processing and manufacturing of nanomaterials, research and development activities and commercialisation activities etc. Furthermore, there is a need to examine which set of laws are relevant in the study of nanotechnology.

The study of nanoscience and nanotechnology is primarily considered as branch of chemistry or chemical and therefore, this is obvious that the laws on chemical should be considered primarily in the discussion of nanotechnology. According to the European Commission, legislation relevant for health, safety and environment aspects of nanomaterials can be grouped under chemicals, worker protection, products and environmental protection, simultaneously applicable (EC 2008).

Though in most of the cases, there can be found laws on chemical, toxic substances in most of the countries, there is no nano specific legislation so far in any country of the world. Only two countries have enacted laws in this regard and these countries are the United States of America i.e. the 21st Century Nanotechnology Research and Development Act 2003 and Republic of South Korea i.e. the Nanotechnology Development Promotion Act 2008 (Act No. 8852). A cursory view of these two laws will reveal that the provisions of these laws do not contain any substantive provisions rather these laws contain provisions relating to administrative set up toward nanotechnology program under the authorities of the respective

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governments. These laws will be considered in detail in subsequent chapters.

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.¹ 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 (ABC News 2013).

Law has great role to play in promoting the benefits and controlling the risks of nanotechnology. So, which sets or branches of laws are relevant in the discussion of nanotechnology? Bowman and Hodge claimed that there are at least 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 (Bowman & Hodge, 2007). The authors 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 concluded 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 concluded that the existing regulatory provisions will frame the immediate structure of regulations. 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. Of the four countries i.e. UK, USA, Japan and Australia, 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 (Bowman & Hodge, 2007). However, the UK newspaper, the Independent reported on January 26, 2013 that the leading scientists of UK are in favour of regulating nanoparticles (Independent 2013).

4. Societal implications of nanotechnology

There are a good number of reasons, why the society should be included in the entire process of nanotechnology life cycle i.e. from laboratory to market in the form of consumer or industrial goods, to waste disposal. All the three players should consider the societal aspect of nanotechnology. These players are: (a) government as regulator and policy maker; (b) business community, as producer and developer of the products, and (c) consumers/society as tax payer and ultimate decision maker and buyer of consumer goods developed using nanotechnology.

The government works as policy maker and it runs of the money given to it by the consumers and the business community in the form of tax. The citizens decide the government in power by way of popular vote. Therefore, the government should consider the

¹ Bill Summery & Status, 112th Congress (2011-2012), retrieved from <http://thomas.loc.gov/cgi-bin/bdquery/z?d112:s.01662>:

well-being of the citizens and should also provide sufficient scope for the business community so that they can do business, make profits after paying government tax, etc. and employment opportunities. Nanotechnology requires huge amount of investment and the business communities normally invest money to make profit. After investing huge amount of money if it is found that the society is not going to welcome the products developed by them, the whole amount of investment will go to astray.

The relationship between these three actors can be described in the following way-

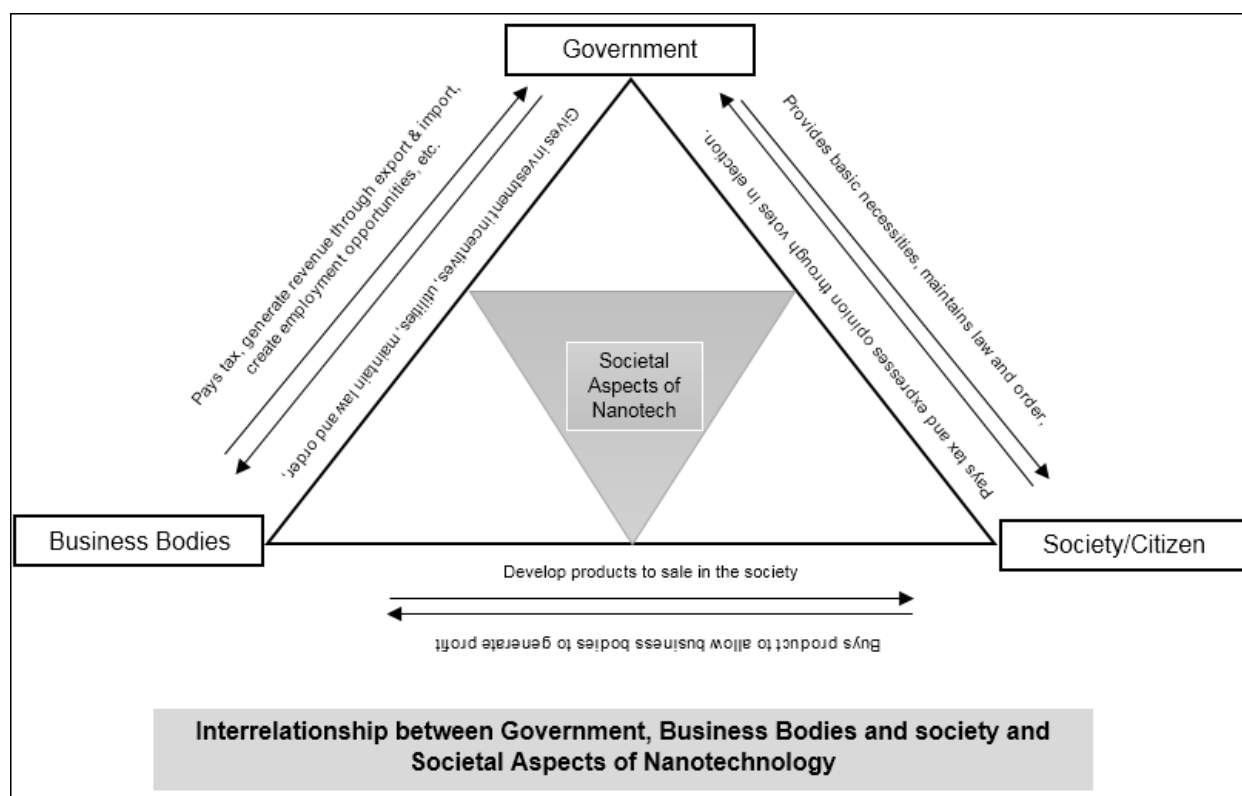


Figure 1. Interrelationship between government, business bodies and society and societal aspects of nanotechnology.

Under the societal implications of nanotechnology, answer to the following questions are tried to be found out. These questions are- How nanotechnology research and applications are introduced into society; how transparent decisions are; how sensitive and responsive policies are to the needs and perceptions of the full range of stakeholders; and how social issues are addressed will determine public trust and the future of innovation driven by nanotechnology.²

Roco (2003) proposed several guidelines to evaluate societal implications in relation of nanotechnology research and development, inter alia, using of a balanced approach between envisioned social benefits and unexpected consequence, societal applications of nanotechnology apply in many areas, e.g. technological, economic, environmental, health, and educational, ethical, moral and philosophical, understanding of public acceptance of risks, taking experience from the first industrial revolution, etc.

5. Inclusion of Public in the policy decision making

² <http://www.nano.gov/you/ethical-legal-issues>

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Inclusion of public to have a say in making any decision affecting them is very normal now-a-days. Already thousands of consumer products containing nanomaterials are available in the market. When it is anticipated that most of the products are developed for consumer goods, there are some products which were found to be injurious to human health. Apart from these products, many surveillance tools are also developed using nanotechnology. The citizens should have clear idea about these products and tools, so that they do not react negatively on the issue of invasion of privacy. The present modern day governments are welfare governments and should remain accountable to the citizens as they are the taxpayers and government must go back to them for mandate to govern the country through general election.

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.³ 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. The United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, was adopted on 25 June 1998 in Aarhus, Denmark at the Fourth Ministerial Conference as part of the "Environment for Europe" process, and was entered into force on 30 October 2001. This Convention incorporates a number of rights of the public (individuals and their associations) with regard to the environment, including access to environmental information, public participation in environmental decision making and right to review procedures to challenge public decisions violating environmental law in general. This Convention is an important instrument in Europe and as of January 2014 most of the European countries become member to the Convention and protocol. Besides, many international instruments contain provisions relating to involvement of citizens in matters which may have different and indirect effect on them.

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

6. Perception of nanotechnology and recent developments

Consideration of public perception and societal implications of nanotechnology is crucial to avoid any kind of disastrous impact on trust and acceptance of nanotechnology (Siegrist, Wiek, Helland, & Kastenholz, 2007). Leading figure in USA in Nanotechnology research and policy, Mihail C Roco, while sharing different generations of nanotechnology, envisioned for a global strategy guided by broad societal goals of mutual interest (Roco, 2004).

Assessment of perception and understanding of nanotechnology of experts, researchers, public, citizens, students etc. in relation to nanotechnology, its risk and benefit, etc. have been documented in a number of researches (Ortwin Renn, 2004), (Handy & Shaw, 2007),

³ Science and technology, House of Lords. Retrieved from <http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3807.htm>

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(Siegrist, Keller, Kastenzholz, Frey, & Wiek, 2007), (Burri & Bellucci, 2008), (Hosseini & Rezaei, 2011), (Rahimpour et al., 2012), (Soleimanpour, Hosseini, & Mirdamadi, 2013). (Gupta, Fischer, George, & Frewer, 2013) conducted a comparative study to assess expert views on societal responses to different applications of nanotechnology in different countries with different economic and regulatory environments. However, (Chen, Lin, & Cheng, 2013) revealed that the public attitudes toward nanotechnology applications is found to be determined by their perceived benefits and risks of applying nanotechnology.

Simultaneously, similar researches were conducted in different countries around the world, for example, *inter alia*, Iran (Farshchi, Sadrnezhaad, Nejad, Mahmoodi, & Ibrahim Ghavam Abadi, 2011), Australia (Russell, 2013), Taiwan (Chen et al., 2013). Some of the countries like Japan have made this practice a continuous one and have been assessing the perception of citizens almost every year. In UK, recent study revealed a significant increase of knowledge about nanotechnology from 29% in 2004 to 48% in 2011 (Scienceview 2013).

A number of methodological instruments have been used so far all over the world to assess the perception of the people regarding nanotechnology, including simple survey, face-to-face survey, telephone survey, online studies, pre-post survey based experiments, expert opinion etc. (Frewer et al., 2011), (Zhou, 2013) (Besley, 2010; Currall, 2009).

In a number of researches, similarities between nanotechnology and biotechnology were tried to find out and it was revealed that there are some similarities between nanotechnology and biotechnology. Malaysia has successfully addressed legal and regulatory aspects of biotechnology and has included citizens in a number of ways. It was realized that a major factor in the emergence of controversies surrounding biotechnology has been the neglect of the needs, interests, and concerns of the primary stakeholders-the commoners (Amin, 2013).

Neighbouring countries like Thailand has realized the prospect of nanotechnology and has already taken a number of good initiative to involve the citizens there and has adopted many promotional activities. With regard to labelling, countries like Thailand, Iran and Taiwan have also introduced the voluntary nano-marking system, which can be termed as something similar to 'quality control sign/mark'. The regulators will put such marking on any product only after being satisfied about the safety aspects of the nanomaterials used in the product. Such initiative will definitely assist to increase the trust and confidence of nanoenabled products in the market.

7. Suggestions

There is no doubt that nanotechnology offers huge prospects and it can be used for the betterment of humankind and many of the crucial issues like safe drinking water, energy, food, medicine can be solved with the assistance of nanotechnology. However, the citizens should be involved in the whole process towards the sustainable and responsible development of nanotechnology. To this end, the policy makers can do the following things-

7.1. Assessment of public perception, understanding and knowledge of nanotechnology

The policy makers should take initiatives to assess the perception, knowledge and understanding of the citizens. Already the findings of a good number of research targeting different class of people and using different methodology are available in popular literature. Most of these research were conducted in developed countries with some exception in Asian countries. Some of the countries like Japan has been conducting such research through national institute of advanced science and technology.

7.2. Activities leading to awareness of citizens

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It is very crucial to take different activities through online, offline, print and electronic media to make people aware of nanotechnology. It can be done by way of information, informative campaign, audio clip, arrangement of rally, etc. The citizens should be made aware so that they can take their own decision for or against nanotechnology. Awareness programs run exclusively by the government or the industry alone may be successful as there remain scopes to take wrong message by the community, rather a program run and co-ordinated by government-industry will be helpful.

7.3. *Development of promotional materials*

The policy makers can develop promotional materials to this end. Different products, which were manufactured or developed using nanomaterials can be distributed among citizens. Informational booklets, and pamphlets containing relevant information in plain language can be disseminated in local languages.

7.4. *Establishment of center for societal implication of nanotechnology*

In a number of developed countries, many universities have realized the importance of societal aspects of nanotechnology and established center for societal implication of nanotechnology, e.g. Center for Nanotechnology in Society at Arizona State University, Center for Nanotechnology in Society at Arizona State University at the University of California, Santa Barbara, USA. All the countries should at least allocate a small amount of their annual budget of nanotechnology research and development in establishing such a center. The main responsibility of such a center will be to run different programs to make people aware of nanotechnology.

7.5. *Nanoproduct registry*

Already many countries have developed registry of products containing nanomaterials. The development of this product registry is an ongoing process and is regularly updated. Such a product registry will be very helpful for the citizens as they will be able to know and understand different kinds of nanoproducts available in the market. In some countries, the policy makers even allow the citizens to take photographs of products they bought from the market, claiming to contain 'nanomaterials' and to share with the policy makers, so that they can include them in the registry if the product is truly of that nature.

Such a registry is again very important due to the fact that the word 'nano' has a huge commercial value and even though a product does not contain nanomaterial, the manufacturer, producer or distributor like to add the word 'nano' in the name of the product, a glaring example is 'Tata Nano', an Indian economical car introduced targeting consumers who are unable to buy expensive and luxury cars. A rampant search in the popular e-commerce sites has revealed that there are thousands of products already in the market containing the word 'nano', either in the name of the product or in the description. One may expect two consequences from such use of the word 'nano' in the product: (a) the regulators may find it somehow impossible to monitor such hundreds of thousands of products, and (b) consumers may develop an understanding that nanomaterials are not harmful as already there are thousands of products in the market.

7.6. *Introduction of academic courses*

For any country having the vision to take lead in the nanotechnology area, it must have to introduce course materials on nanotechnology according to the standard of academic level and students, who will be future leaders of the country should be encouraged to study the course.

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8. Conclusion

Consideration of effects of technology on society is not a new issue, rather it has been observed and recorded for thousands of years (Kostakos, O'Neill, Little, & Sillence, 2005). Business community should realize that in order to market the products they will be developing using nanomaterials, they need to go to the consumers and therefore, the consumers should be properly convinced with reliable information. Already, some of the NGOs have been campaigning in favour of 'no information no market'.

The role of science and technology towards the attainment of basic and fundamental human rights in the present world cannot be ignored in anyway. Technologies, if can be used positively and effectively, can introduce some epoch making changes and can be used as aid to ensure different aspects of citizen's right to life, health, education, etc. The United Nations Millennium Declaration as adopted in the 8th plenary meeting of the General Assembly on September 8, 2000 stipulates that the benefits of new technologies should be ensured and made available to all. Furthermore, in the World Summit Outcome of 2005 (General Assembly resolution no. 60/1), the vital role of the science and technology for the achievement of internationally agreed development goals was recognized.⁴ But, unless the society can be included in the process, the whole purpose may turn to be a nightmare.

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⁴ Clause III, Development of poverty eradication, para 20, United Nations Millennium Declaration.

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