ISBN 978-967-11350-2-0

NANOTECHNOLOGY LAW AND POLICY: AN INTRODUCTION

MD. ERSHADUL KARIM

PhD Candidate in Nanotechnology Law and Policy
Faculty of Law
University of Malaya, 50603 Kuala Lumpur, Malaysia
Email: ershad@siswa.um.edu.my; ershadulkarim@gmail.com, Tel: +60 182 182 817

ABSTRACT

Nanotechnology, often referred to as the next industrial revolution after internet, is an interdisciplinary study. It is the science of manipulating technology at atomic scale. One can hardly find any area where the researchers did not attempt to apply it. Based on very optimistic results in many researches around the world, it can easily be inferred that it has virtually limitless potential and it promises epoch making changes in the world. 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. However, to many persons and organisations, nanotechnology is the next asbestos and are reluctant to welcome it with open mind. This is a matter of great concern that the world community is still in search of a consensus on legal and regulatory frameworks to govern it. As of now, there are at least six areas i.e. product safety, privacy and civil liberties, occupational health and safety (OH&S), intellectual property (IP), international law and environmental law, which are directly related with nanotechnology research and application and law must intervene in these areas. While the benefits that can be achieved by using nanomaterials are whole-heartedly welcomed and appreciated, this paper aims at introducing the legal aspects of nanotechnology. The mistakes which hindered the introductions of genetically modified food or nuclear energy should not be repeated and the application of nanotechnology should be encouraged within approved legal framework.

Keywords: Nanotechnology, Law and Policy, Regulation, Policy making, research and development

ISBN 978-967-11350-2-0

INTRODUCTION

Nanotechnology, the next industrial revolution after the internet, has turned to be a darling child and different researchers and bodies have been sharing this term with different adjectives. Nanotechnology is very attractive as a generic technology (diversified applications as ICT), as an 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). Borisenko, V. E., & Ossicini, S. (2004) considered that nanotechnology is a disruptive technology. Nano is general purpose technology as in it advanced form it will have significant impact on almost all industries and all areas of society.

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. What were in science fictions, many of them are now part of reality. However, 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.

However, with all these promises there are many concerns as to the safe application of this technology. Hundreds of papers have already been written on health and environment concerns and safety issues regarding this technology. Apart from the laboratory researches, there are many researches which are conducted on animals and the adverse effect of the technology was noticed and in many of the researches concerns were expressed that the people who are directly in contact of the technology are in real danger. Therefore, the law should intervene to regulate the technology. Earlier the world community witnessed that the genetically modified foods and the nuclear energy were introduced in the world and could not be successful due to many factors. Due to numerous prospects, it is whole heartedly desired that the nanotechnological innovation should be continuous, but within the regulatory framework.

This paper aims at sharing an introductory discussion on nanotechnology and its regulatory aspect and policy initiatives taken around the world. To this end, the paper is divided into four parts, apart from introduction and conclusion. Part One analysises different concepts, Part Two shares some statistics on investment and prospects as to nanotechnology, Part Three deals with the concerns relating to nanotechnology and Part Three will shed focus on the legal developments around the world.

CONCEPTUAL ANALYSIS

NANO

The word 'Nano' derives from the Greek word "Nanos" meaning "dwarf", means one-billionth. A nanometer is one billionth of a meter. 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

ISBN 978-967-11350-2-0

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.

NANOTECHNOLOGY

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 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). 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 (Lövestam et al., 2010). Some international Oraganisations like United Nations (World Health Organisation, Food and Agriculture Organisation, International Standard Organistaion (ISO), International Labour Organisation), 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 emphasized to introduce a comprehensive science-based definition of nanomaterials. Definition is further crucial to assess the label of liability of different people engaged in nanotechnology research and business.

NANOPARTICLE

Nanoparticle, a microscopic particle or powder with at least one dimention of less than 100 nm, is considered as miracle fibre. 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

ISBN 978-967-11350-2-0

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

NANOTECHNOLOGY AND SOME STATISTICS

In an article in Nature, (Shapira & Wang, 2010) found that in between August 2008 to July 2009, there were more than 91,500 publications on nanotechnology. More than $ 32 billion in products containing nanomaterials were sold globally in 2005. (Cassandra D. Engeman, 2012) shared that the Lux Research, Inc. reported in 2009 that nanotechnologies were used in goods and products and the value is US$ 224 billion. 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. In 2000, the US National Science Foundation (NSF) estimated that the global marketplace for goods and services using nanotechnologies will grow to $1 trillion by 2015 (Mongillo, 2009), whereas the German Ministry of Education and Research is convinced that the amount will be US$ 3 trillion.

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. The world production of carbon nanotubes is expected to increase by $1 billion – $2 billion by 2014 (Carter, 2008).

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

Some experts claimed that 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.

HOW NANOPARTICLES CAN AFFECT US?

This is now accepted that all kinds of technology has some adverse environment affects. Even though every single report on nanotechnology expresses concerns regarding health and environmental impacts of nanotechnology, till date, all the experiments with the nanotechnology and its adverse effects are mainly laboratory based and the long term effects of the nanoparticles are not yet tested. One single accident may significantly shake the confidence of the consumers. For example, the Japanese were not against the use of nuclear energy, but the recent Fukushima Nuclear Power Plant Disaster due to the Tsunami makes the people afraid of the nuclear power.

ISBN 978-967-11350-2-0

This is the main concern with nanotechnology. This is not yet confirmed how the nanoparticles will react in the environment, how the biodiversity will be affected or benefited with the release of nanoparticles are not sufficiently tested. 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.

This is a matter of fact that in Germany, the Federal Environment Agency advised the consumers against using products containing nanomaterials. Australian Workers' Union expressed their worriedness to use nanoparticle linking nanoparticle with asbestos and advocated for proper regulation. 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).

NANOTECHNOLOGY AND LEGAL FRAMEWORK IN THE WORLD

There is no comprehensive legislation in any country in the world. Countries have been working to reach to a legal solution to deal with nanotechnology. There are already sectoral legislation on occupational health, environment, product labeling or cosmetic legislation, product liability, healthcare or chemical, etc. in most of the countries and the countries are reluctant to enact laws as, *inter alia*, in the absence of comprehensive laws, these legislation may assist the countries.

However, one of the main reasons behind non-legislation is that there is a significant knowledge gap between the health and environmental effect of nanotechnology. Since all the tests are till laboratory based, people are not sure about the adverse effects of nanotechnology. There was an incident occurred in China in a paint factory where seven workers while dealing with nanoparticles in where the seven workers were affected by the nanoparticles though this is not sure whether the nanoparticles were responsible for the injury.

In this context, hence let us consider the legal framework relating to nanotechnology around the world in a brief manner. In 2003, the USA enacted the 21st Century Nanotechnology Research and Development Act of 2003 to establish a National Nanotechnology Program (NNP), for funding for nanotechnology research and development (R&D) over 4 years, starting in Fiscal Year 2005 and provided authorizations under section 6 of the Act for a subset of the National Nanotechnology Initiative (NNI), one of the President's highest multi-agency R&D priorities, namely the National Science Foundation (NSF), Department of Energy (DOE), National Aeronautics and Space Administration (NASA), National Institute of Standards and Technology (NIST), and Environmental Protection Agency (EPA). NNI is now a collaborative, multi-agency, cross-cut program among 26 Federal entities with a range of research, industry, trade, educational and regulatory roles and responsibilities. This Act contains basically administrative provisions and there is nothing with nanotechnology and its adverse effects. However, the Toxic Substances Control Act; the Occupational Safety and Health Act; the Food, Drug and Cosmetic Act; and the other major environmental laws (Clean Air Act, Clean Water Act, and Resource Conservation and Recovery Act) provide some legal basis for reviewing and regulating nanomaterials.

The Toxic Substances Control Act (TSCA), 1976 allows the Environmental Protection Agency of USA to regulate new commercial chemicals before they enter the market, to regulate existing chemicals (1976) when they pose an unreasonable risk to health or to the environment, and to regulate their distribution and use.

ISBN 978-967-11350-2-0

In UK, the Health and Safety at Work etc. Act (1974) sets out the responsibilities for health and safety that employers have towards employees and members of the public, and employees have to themselves and to each other.

There are few government agencies in charge of nanomaterials in Australia and the list include National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Therapeutics Goods Administration (TGA), Australian Pesticides and Veterinary Medicines Authority (APVMA), Food Standards Australia New Zealand (FSANZ), and Australian Competition and Consumer Commission (ACCC). Even with all these agencies, it can safely be said that the Australia's present regulatory set up does not completely regulate nanomaterials, researcher found that though there is no immediate need for major changes to the regulatory regimes, there are many areas of Australian regulatory regimes which, potentially, will need amending, and this will be a long term effort across multiple regulators and regulatory agencies as nanoproducts arise and as new knowledge on hazards, exposure and monitoring tools becomes available.

Colin Gavaghan and Jennifer Moore reviewed the adequacy of New Zealand's regulatory systems across workplace and food safety, environmental protection and for consumer products, to manage the possible impacts of manufactured nanomaterials and concluded that none of the areas of the New Zealand regulatory system require wholesale changes in order to be applicable to nanomaterials and the regulatory mechanisms applicable to conventional products will, in broad terms, apply to nanomaterials. Nonetheless, they identified a number of possible regulatory gaps or weaknesses that are more specific to products containing mNMs and appear to occur at different levels: respectively, at the level of legislation, at the level of regulatory policy, and at the level of compliance and enforcement.

NANOTECHNOLOGY REGULATION AND RECENT DEVELOPMENTS

There some significant developments to regulate nanotechnology around the world. 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 $\geq$ 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. Belgium and Denmark are in the process of following the instances of France.

CONCLUSION

Human beings should be in the center of all development projects. The future of this planet is greatly dependent on how we will use the resources of it. Nanotechnology has virtually limitless potential with some challenges and if these challenges can be managed and handled smartly, nanotechnology will truly be a blessing for the coming world. Simultaneously, it should be remembered that manufactured nanomaterials are referred as the top emerging workplace risk by the European Union's Agency for Health and Safety at Work and have repeatedly rated as a top, global technology risk in annual World Economic Forum reviews since 2006. Therefore a concerted effort from all of us, be we corporate managers, shareholders, stakeholders, regulators,

ISBN 978-967-11350-2-0

policy makers, analysts is the demand of the time since we all have common but differentiated responsibility to this end and in this regard the regulators should take the lead based on the results and findings of existing research and consider to enact or codify a comprehensive law.

REFERENCES

Carter, A. (2008). Learning from History: Understanding the Carcinogenic Risks of Nanotechnology. *JNCI Journal of the National Cancer Institute Advance Access, 100* (23), 1664-1665.

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.

Hassan, M. H. A. (2005). Small Things and Big Changes in the Developing World. *Science 309*(5731), 65-66.

Khaled Radad, M. A.-S., Rudolf Moldzio, Wolf-Dieter Rausch, . (2012). Recent advances in benefits and hazards of engineered nanoparticles. *Environmental Toxicology and Pharmacology, 34*(3), 661-672.

Linkov, I., & Steevens, J. (2009). *Nanomaterials: risks and benefits*: Springer.

Lövestam, G., Rauscher, H., Roebben, G., Klüttgen, B. S., Gibson, N., Putaud, J.-P., & Stamm, H. (2010). Considerations on a definition of nanomaterial for regulatory purposes. *Joint Research Centre (JRC) Reference Reports*, 80004-80001.

Mongillo, J. F. (2009). *Nanotechnology 101*. New Delhi: Pentagon Press.

Shapira, P., & Wang, J. (2010). Follow the money. *Nature, 468*(7324), 627-628.

Shilpa, S. B., & Bhati, M. (2012). China and India: The Two New Players in the Nanotechnology Race. *Scientometrics, 93*(1), 59-87.