Regulating the Nano Frontier: Global Legal and Policy Perspectives on Emerging Nanotechnologies

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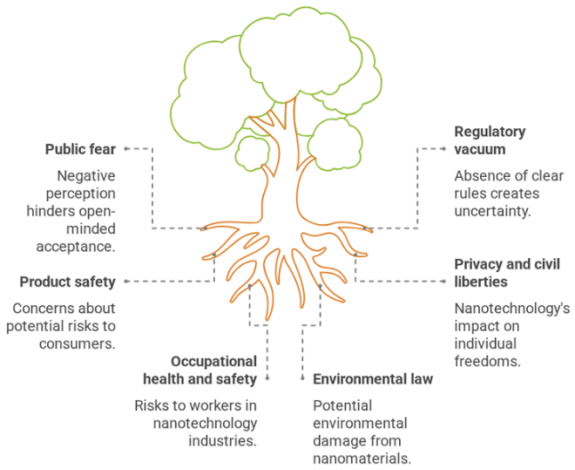
Abstract- ***The nanotechnology, which is expected to be the next industrial revolution after the internet, is a field of interdisciplinary research. It's the science of literally being an atomic engineer with technology. You'd be hard-pressed to find a field in which that theory wasn't tested. From extremely positive news from many researches around the world, it is safe to say that it has almost unlimited potential and it is ready to provide earth shaking changes to the world. UNESCO identified ten priority applications from nanotechnology concerning 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 system., (f) Food processing and storage., (g) Air pollution and remediation., (h) Construction., (i) Health monitoring., and (j) Vector and pest detection and control. But for a lot of individuals and groups, nanotechnology is the new asbestos, and they are not willing to embrace it with open mind. This is a matter of concern as the world community is yet to arrive at a consensus on legal and regulatory structures to regulate it. As of now 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, has a direct bearing upon the field of nanotechnology research and it is here that law is expected to step in. Although all the advantages of exploiting nanomaterials are highly desirable and are more than welcomed, this paper is designed to introduce to readers the legal issues involved in nanotechnology. Mistakes which have stunted the introductions of GM-food or nuclear energy must be avoided and the use of nano-technology could be stimulated as long as they operate within the framework of national law.***

Indexed Terms- Law; Policy making, research and development; Regulation; Nanotechnology

Graphical Abstract:



I. INTRODUCTION

Nanotechnology, the internet's baby brother as the next industrial revolution has become Baby Dear and people have been coupling this term with different adjectives. The concept of nanotechnology is highly appealing both as generic technology (ICT-type applications), as an enabler technology (by adding new feature to established product), and represents the disruptive potential (that is, can replace existing products in the marketplace or can eliminate a particular kind of product from the marketplace) (Shilpa & Bhati, 2012). It is a revolutionary technology and can be compared with steam engine in the 18th century and electricity in 20th century in terms of impact (Hassan, 2005). Nanotechnology as a Disruptive Technology Borisenko, V. E., & Ossicini, S. (2004) reflected on the fact that nanotechnology

was a disruptive technology. Nano is GPST, as in its most-developed form (see below), it will be of general relevance for almost all branches and fields of sectors of industry and industry itself.

Nanotechnology is not terra incognita, not a matter of science fiction or a concern for the scientists and engineers only but has become an inter-discipline subject. In science fictions and futurist projects many of them are part of our daily lives. But nanotechnology is in a stage of early development, and in some ways is described in the literature as being similar to information technology in the 1960‟s and biotechnology in the 1980‟s.

However, along with these promises there are a number of worries about the safety of this technology. Already, hundreds of papers have been written about public-health and environmental concerns and safety issues related to the technology. In addition to that lab research, several researches are conducted on the animals, where the opposing effect of the technology was observed and in many of the researches alert was issued that the people who are close to the technology have a real danger. So, the law must step in to oversee the technology. We have already seen when the world community had seen how the genetically modified produces and the nuclear power itself was introduced to the world and could not be successful in many ways. Because of the various prospects, the nano technology is whole heartedly wished as the continuous one but under the guidance of regulatory.

The purpose of this paper is to provide a general overview of nanotechnology and some issues related to regulatory and policy approaches emerged internationally that deserve attention. For this purpose, the paper is organized in four sections other than introduction and conclusion. Literature review deals with the very basics of Nano, Nanotechnology, Nanoparticles and related statistics whereas the next section discussed about its affect, followed by global regulation and recent progress.

II. LITERATURE SURVEY

2.1 NANO

The term „Nano‟ comes from the Greek word Nanos (dwarf) and its literal definition, one billionth. A nanometer is one billionth of a meter. Just to give you an idea about size, a piece of paper is around 100,000 nanometers thick, there are 25,400,000 nanometers in one inch, and the width of a human hair is about 75,000 nm.

At the nanoscale there can be substantial changes in matter properties, typically under 10– 20 nm due to such trends as the dominance of quantum effects, confinements, molecular recognition, and enlarged relative surface area. Chemical material properties, i.e. mechanical, optical, magnetic, electronic, and chemical reactivity, of the structures made from such elements change, as they are reduced in size, resulting in unexpected or unpredictable effects. Put differently, nanodevices reside in an interesting regime, where the promises of classical physics and quantum mechanics conspire. Manufacture at the nanometer scale is wide open (including self assembly, templating, stamping and fragmentation) and can yieldmany efficient solutions.

2.2 NANOTECHNOLOGY

In the words of Nobel Laureate Richard Smalley, nanotechnology refers to the art and science of building material and devices at the scale of the nanometer (Linkov & Steevens, 2009). Various organization, an individual or countries define „nanotechnology‟ in differentway. Closer scrutiny to all of these definition will tell us that most of these definitions are developed from the definition proposed by the National Nanotechnology Initiative (NNI) of United States. However it is worth mentioning here that the NNI (National Nanotechnology Initiative) has held reservations on dressing anything „nanotechnology‟, and will do so only if it satisfies all of the following:

a. R&D at atomic, molecular, and macro-molecular scale with the length scale ranging between about 1-100 nano meters.

b. Fabrication and utilization of structures, machines and systems possessing unique characteristics and properties due to their small size and/or intermediate scale.

c. Capability to alter the atomic scale (molecular control or manipulation (Mongillo, 2009).

United Nations Industrial Development Organization in its report on the Considerations on a Definition of Nanomaterial for Regulatory Purposes referred by and provided all definitions suggested by from different international organization, such as Organization for EOR (OECD), EU, EU Cosmetic products Regulation, etc., and in municipal law of different countries, including Australia, Canada, Denmark, UK, USA and defined nanomaterials as a material having an internal or surface structure in the typical nanoscale (1-100 nm) size range encompassing at least one dimension or feature before or after any processing (e.g., milling, surface treatment, mixing or other forms of 1 processing) or average-sized anatomic entities (e.g., polymers, dendrimers, mesh, etc.), even if these polymer and mesh size are greater than 100nm (Lövestam et al., 2010). Few 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 also working on nanotechnology framework.

From the regulatory perspective, definition is very crucial as unless you can't define something, you cannot attach legal sanctions and attributes to it. The definitional question warrants some discussion in this context, as unforeseen risks to the environment, health and safety could be posed by nanomaterials. The European Parliament recommended to establish a sound and full science based definition of nanomaterials. Definition is also vital for determining liability of various individuals involved in the nanotech research and business.

2.3 NANOPARTICLE

'Nanoparticle' a particle or powder with at least one dimension smaller than 100 nm is also described as magical fibre. There are three different types of nanoparticles: „engineered" nanoparticles (e.g.: buckyballs, gold nanoshells • size specific properties), „incidental" nanoparticles (e.g.: found in welding fumes, cooking fumes, diesel exhaust • the size of the particles is the only property important to health) and „naturally occurring" nanoparticles (salt spray from the ocean, forest-fire combustion etc). The only truly „engineered"-class of particles are nanoparticles, and buckyballs are the only meaningful examined-engineered-class nanoparticles to date, while „incidental"-engineered-class nanoparticles (i.e., ultrafine particulate matter, e.g., from auto exhaust) certainly have been investigated in a much wider-ranging way. So far, the few studies on the toxicity of fullerenes indicate yes but also point at techniques for engineering buckyballs to be less so, in particular by attaching other chemicals to the surface, which alters their chemical behavior. Nanoparticle element can be of cylindrical, discoidal, spherical, tabular, ellisodial, equant or irregular shape.

2.4 NANOTECHNOLOGY AND A FEW STATISTICS

(Shapira & Wang, 2010) in an Nature article reported that during August 2008 to July 2009, there were over 91,500 publications on nanotechnology. In 2005, worldwide sales of these products, which incorporated nanomaterials, were more than $32 billion. (Cassandra D. Engeman, 2012) reveals to us that in 2009 the Lux Research, Inc. disclosed that there was US$ 224 billion market for nanotechnologies in goods and productsimesteps (Embedded Image Processing System)Chien Nguyen timesteps (Embedded Image Processing SystemWith vast potential and emerging very rapidly, nanoscale semiconductor devices have been a key area of research interest and hotly pursued by the semiconductor industry, from the early exploration of III-V semiconductor through high-speed and profound concentration on silicon technology, many advanced devices have been proposed into market for volume production which will be benefited to the end user. Canada based electronics. nasapub the global nanotechnology

market in 2010 is estimated at around $15.7 billion, and is expected to increase to about $27 billion by 2015. The NSF (2000) of the US has estimated that the world market for nanotechnologically produced goods and services will reach 1 trillion US dollars by 2015 (Mongillo, 2009) while the German Ministry of Education and Research is in expectation of 3 trillion US dollars.

BCC Research Market forecasting The global market for nanotechnology products was worth nearly$15.7 billion in 2010 and about $26.7 billion in 2015, a compound annual growth rate (CAGR) of 11.1% for 2010-2015. Various categories of Carbon Nanotubes made the world $100 million in 2009, in 2014 the market is expected to be $1 billion, according to market analysts Cientifica. The world's production of carbon nanotubes should only be in strengthened by an estimated $1-2 billion by 2014 (Carter, 2008).

According to the leading organization, market research organisation Cientifica's report, the various governments around the world are currently investing at a combined rate of USD 10 billion annually and that the market would grow by 20% in the next three years. The total government spend on this area by end of 2011will be USD 65 billion and it will be USD 100 billion and USD 250 billion with the help of private and corporate investments by2014. Upon establishing the world‟s first national nanotechnology program, USA government had a total expenditure of USD 15.6 billion throughout the period 2001 – 2012 and the President submitted on 13 February 2012 to the Congress a budget of USD 1.766 billion (USD 70 million more which is 4.1% higher than the previous year) for the year of 2013 specifically for the National Nanotechnology Initiative (NNI).

Entire body of plastic being transformed is then compared with the coming nano revolution to that of the plastic revolution back in 1960s i.e. from the period where plastic started changing everything in the daily life of human's this is how it all began. There's hardly any place where you haven't used plastic right from the kitchen appliances, food containers, housing construction, automobile, transport, medical safety and you name it.

III. HOW DO NANOPARTICLES MAY AFFECT US?

This is now understood that technology of any kind has its impact in the environment as well. But like every other document on nanotechnology, It raises concerns about the health and environmental effects of nanotechnology and while all of the experiments done about the effects of nanotechnology are lab based experiments and no long term effects of nanoparticles have been tested. It may take just one accident to compound significantly the confidence of the consuming public. "So if you consider the Japanese were not antinuclear. I mean they were not, they did not oppose having nuclear power plants, yet the most recent We need people to reframe what it means to be an American If you apprecate for discussions on racial identity dressing with less than intentionality or shopping when you're not rich, come hang out with me on the blog, Instagram and youtube.

Tsunami runs the Nuclear Power Plant Disaster Diesels Nuclear Power Plant Daiichi Fly to Japan Apocalypse The Tsunami Attacks Japan: Disaster of Nuclear Power Plant Japan Bites the Bullet. This is the biggest worry with nanotech. It is still not known how the nanoparticles will behave in the environment, it has not been sufficiently tested how biodiversity will be intervened with or said benefited by the release of nanoparticles. If nanoparticles are able to enter the human body through the lungs, the intestinal tract and the skin (Khaled Radad, 2012) and are potentially a health concern, the effects on health are not clear.

It's a fact: in Germany, Federal Environment Agency has issued alerts against consuming products that contain nanomaterials. The Australian Workers‟ Union voiced their concern about the use of nanoparticle linking nanoparticle with asbestos and called for appropriate regulation. Study author Chiu-Wing Lam of NASA‟s Johnson Space Center reported on a test that involved pumping carbon nanotubes directly into mice lungs, causing them to become inflamed and grow less lung tissue (Mongillo, 2009).

IV. NANOTECHNOLOGY AND THE GLOBAL REGULATORY CONTEXT

There isn't a single country in the world with an all-encompassing piece of legislation. Nations have been struggling toward a legal definition of nanotechnology. Most of the countries already have sectoral laws on Occupational Health, Environment, Product Labelling or Cosmetic laws, Product Liability, Healthcare laws or Chemical laws etc in place and it may be difficult for the countries to adopt the law as it would, inter alia, in the absence of comprehensive law may help the countries.

Nevertheless absence of legislation can be largely explained by a lack of knowledge of health and environmental impact of nanotechnology. All the tests are till laboratory base and people are uncertain about side effects of nanotechnology. There was an episode happened in China, 7 workers in a paint factory over in China were exposed to nanoparticles in the 7 workers due to nanoparticles although it is not sure whether the nanoparticles was responsible for causing the injury.

Against that backdrop therefore let us briefly glimpse at the legal framework regarding nanotechnology in different countries of the world. In 2003, the USA enacted the 21st Century Nanotechnology Research and Development Act of 2003 establishing that a National Nanotechnology Program (NNP) is necessary, to provide funding for nanotechnology research and development (R&D) over 4 years, beginning in Fiscal Year 2005 and include authorizations under section 6 of the Act for NNI agency funding, one of the President's highest multi-agency R&D priorities consisting of 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 currently a coordinated, multi-agency, cross-cut program involving 26 Federal entities (with a variety of research, industry, trade, education and regulatory functions) working on different aspects of nanotechnology R&D. There is really no other apart from this nanotechnology and negative side related. There are really only administrative provisions, about it. But the Toxic Substances Control Act; the Occupational Safety and Health Act; the Food, Drug and Cosmetic Act; and the other main environmental statutes (Clean Air Act, Clean Water Act, and Resource Conservation and Recovery Act) at least generate a glimmer of legal authority to review and regulate nanomaterials.

Toxic Substances Control Act (TSCA) 1976 -The Environmental Protection Agency (EPA) has authority over new commercial chemicals before market and existing chemicals (1976) when they present an unreasonable risk to health or the environment, and their form, use and distribution are regulated.

UK The Health and Safety at Work etc. Act (1974) details what is expected by employers for health and safety to their employees and to members of the public, and employees to themselves and to each other.

Only few of the regulators are responsible for nanomaterials in Australia and are NICNAS, TGA, APVMA, FSANZ, and ACCC. But with these organisations, the regulatory regime could be said safe only, in present context of Australia’s regulatory regime because there is no immediate reason to overhaul the regulatory regimes, although there are few areas of Australia’s existing regulatory regimes which potentiality would need amendments and that is going to be happened for a long period involving many of regulators and regulatory bodies as and when nanoproducts comes to market and new understanding on hazards, exposure and monitoring tools emerges.

Colin Gavaghan and Jennifer Moore examined New Zealand‟s regulatory systems for workplace safety, food safety, environmental protection and for consumer products, as their ability to deal with possible impacts of the manufacture of new materials applications such as nanomaterials, and they came to the conclusion that none of the areas of New Zealand‟s regulatory system looked at required fundamental changes to accommodate the dimensions of nanomaterials and that the regulatory arrangements now in place for traditional products will to all intents and purposes apply to nanomaterials. However, they highlighted several potential gaps or weaknesses that

generally focus on products with mNMs, which seem to be at different levels: in the case of laws, in the case of regulative policies, and in terms of compliance and enforcement).

V. NANOTECHNOLOGY REGULATION AND RECENT PROGRESS

Then I mentioned some major organizations to regulate nanotechnology globally. In February 2012 a decree from the French Ministry for Ecology, Sustainable Development, Transportation and Housing established the first mandatory reporting system for nanomaterials in Europe. The decree, which will enter into force in January 2013 purpose to have a better understanding of nanomaterials and its using, for best traceability of the product, the market and volume of the nanomaterials and to gather the available information on toxicology and ecotoxicology of nanomaterials. According to the Decree, corporations which: • import, produce or distribute nanomaterials (as such or as ingredients) using amounts exceeding 100g or more of nanomaterials, "professional users" or research laboratories located within France that produce, import, distribute nanomaterials in an amount of over 100g, shall declare on the 1st of May of each year to the Minister of the Environment the Statement and, the use of quantities and application of the nanomaterials. The decree refers to the French National Agency for Food Safety, Environment and Labour (ANSES) for supervision of such data. Belgium and Denmark are in the process of emulating the examples of France.

CONCLUSION

Humans should be at the heart of all development schemes. The future of this planet will be determined to a very large extent how we use it. The potential of nanotechnology is almost infinite, with a few hiccups, and if these hiccups can be handled and managed well, then nanotechnology is going to be indeed a blessing for the future world. At the same time, it should also be borne in mind that manufactured nanomaterials are identified as the number one emerging workplace risk by the European Union‟s Agency for Health and Safety at Work and have consistently been identified in annual World Economic Forum surveys as a leading global technology risk since 2006. So it is the need of an effort, a common effort made by all of us be it managers of the corporate, shareholders, stakeholders, regulators, policy makers, analyst etc., since all are shouldering common but varied responsibility to this need, and here the role of the regulators is pivotal who should lead the movement based on what we have discovered so far and should contemplate to come out with a law or codify the same covering all the aspects.

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