# Nanotechnology through the Lens of Law: Asia and Beyond

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**Abstract**

Nanotechnology, the science of using materials at the atomic or molecule scale, is the next wonder after internet. Its virtually limitless prospects compel the government, research firms and business ventures around the world to invest huge amount for its commercial application. United Nations is convinced nanotechnology can be used to achieve the Millennium Development Goal and it can improve the quality of life 5 billion people of developing countries. More than 2000 consumer products are already in the market and ILO predicts that by 2020, 20% of the products will be nanotech-enabled. However, there are some tensions too regarding the risks and safety issues of nanoparticles and how the legal framework and institutions will react in such situation. To many, due to identical fibrous shape and chemical property, nanomaterial is the next asbestos as it has some serious consequence on environment and human health. Gleaming and spell bound consumer products are conquering the market very fast beating the reactions of regulators. This is a matter of serious concern that there is no specific and comprehensive regulation both in national or international level to handle the possible environment and human health threats, except some voluntary or soft law tools. In this backdrop, this paper aims to focus on ongoing environment and health concerns relating to nanotechnology and the possible legal responses against such concerns within the existing international and national regulatory framework. Such a discussion may portray an overview of the legal and regulatory aspects of nanotechnology to the stakeholders.

**Keywords:** Nanotechnology, Research and Development, Legal and Regulatory aspects, Environmental and health implications of nanotechnology

## INTRODUCTION

Nanotechnology, the science of manipulating materials at the atomic or molecule scale, is the next wonder after internet. At the nanoscale i.e. in between 1-100nm, the scientists are able to manipulate things and can develop things according to their will. From an investigation on the product registers of different countries, including the Project on Emerging Nanotechnologies developed by the Woodrow Wilson International Center for Scholars, it is found that already there are thousands of consumer products available in the market. Thousands of products containing the word 'nano' in the product are already enlisted in the popular e-commerce sites like eBay, Alibaba, etc. Many technological and business forecasts already reiterated and reassured that nanotechnology will drive and control the future. Different countries, business entities, research firms around the world have

taken into account all these forecasts seriously and after evaluating the prospective future of nanotechnology, have already invested huge amount of money. These forecasts further introduced steadfast competition among these research firms, business entities, governments and other stakeholders.

On the contrary, there are serious concerns regarding the adverse human health and environmental effects of nanomaterials too and such concerns are widely reported in leading scientific literature. To many, due to identical fibrous shape and chemical property, nanomaterial is the next asbestos. Based on some symptoms, some of the nanomaterials which are widely used in consumer products are labelled to be dangerous. Many NGOs have been protesting the introduction of nanomaterials before the confirmation of their safety. There are some reasons to be worried in this regard as these nanoparticles are vanishingly small and their long term effect on the human health and environment is yet to be confirmed and conclusively proved. Moreover, there is no nanospecific regulation in the world. Such a situation have created tensions among people of different strata.

Therefore, in an avenue of nanomania and nanophobia, the purpose of this paper is to campaign for the safe and responsible development of nanomaterials with an appeal that nanomaterials and nano-enable products should be developed in a way so that human being and the environment remain free from adverse effects, if any, at all. Even though there is no specific legal framework to regulate and govern nanomaterials, in this paper we shall argue that different provisions that can be found in different international and national legal instruments can be considered to interpret in case there arise any kind of accident or incident leading to human health and environmental effect from the nanomaterials.

## CONCEPTUAL ANALYSIS

We are in a vast see of natural nanoparticles, which are available in air, soil, dust, fume etc. Even though these natural nanoparticles enter the human health through different routes, the respiratory system of the human being and other species can heal and adapt all these nanparticles easily and thus cannot create any adverse effect. Silver, gold or copper nanoparticles were used in 9$^{th}$ Century in Mesopotamia. Anyone who visits British Museum in London displays a Roman cup, called Lycurgus cup of 4$^{th}$ century, which contains gold and silver nanoparticles. Such nanoparticles can be termed as ‘accidental nanoparticle’.

It is found that the word ‘nano’ has attracted business entities of diverse category and the word is frequently used in many kinds of products. The word is usually used to mean anything which is relatively small. However, in the study of nanoscience and nanotechnology, the word has different meaning. In this study, the word ‘nano’ is a prefix used to refer a scale of measurement. It has its origin in Greek, where it is used to denote ‘dwarf’, meaning something which is vanishingly small. The particle is so small that even a very powerful microscope is unable to trace it, instead a special kind of microscope is required.

Nanotechnology is the research and technology development at the atomic, molecular, or macro-molecular levels, in the length scale of approximately 1 to 100-nm range, creating and using structures, devices, and systems that have novel properties and functions because of their small and/or intermediate size and is the ability to control or manipulate on the atomic scale (National Nanotechnology Initiative, 2007).

(Hodge, Bowman, & Ludlow, 2007) studied 18 definitions of nanotechnology shared by different bodies and revealed five crucial characteristics of nanotechnology in the definition. These are-

1. Size: from around 100 nm down to less than 0.1 nm.
2. Range of technologies: imaging, measuring, modelling and manipulating the matter.
3. Multi-disciplinarity: including for instance, physical, chemical and biological, with each being purposefully 'engineered'.
4. Size dependent novel properties and functions.
5. The control and purposeful manipulation of matter at the atomic scale.

## PROSPECTS OF NANOTECHNOLOGY

The prospect of nanotechnology has been explored in all sectors including green engineering (Darvish, 2013); water and waste water treatment (Qu, Alvarez, & Li, 2013); neuroscience , nano-toxicology in engineering and built environment (Lee, Abdul-Rahman, & Wang, 2013); oil and gas (Abdelrahman Ibrahim El-Diasty; M. Salem Ragab, 2013), food industry (Jochen Weiss, 2013), agriculture supply chain (Jianjun Lu, 2013), construction of future cities (Wiek, Guston, van der Leeuw, Selin, & Shapira, 2013), innovation in food firm in Europe (Nardone, Seccia, & Maruotti, 2013), cancer therapy (Zhang, Zeng, & Li), medicine(Himakshi & CP, 2013), Energy (Lund, 2013), diagnostics and therapeutics for gastrointestinal disorder(Laroui, Rakhya, Xiao, Viennois, & Merlin, 2013); AIDS treatment (Banerjee, 2013); Brest cancer (Johnson, Sabnis, McConathy, & Lacko, 2013), architecture and built environment (Niroumand, Zain, & Jamil, 2013), nanoarchitecture (Niroumand & Zain, 2013) and many more.

International Labour Organisation predicted that by 2020 approximately 20% of all goods manufactured around the world will be using nanotechnology (ILO, 2010). Sharing the findings of (Salamanca-Buentello, Persad, Martin, Daar, & Singer, 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. From all these findings, it can safely be said that nanotechnology has limitless potential and can be used in every single area of human need.

## HUMAN HEALTH EFFECTS OF NANOMATERIALS

In many researches, the toxicological effects of nanomaterials towards health and environment were reported (Stern & McNeil, 2008), (Warheit, Sayes, Reed, & Swain, 2008). Nanomaterial can enter human health in at least four ways- dermal exposure, inhalation, ingestion and injection. An analysis of the inventory of Project of Emerging Nanotechnology (PEN), will reveal that out of around 2000 consumer products, 354 products are able to dermal exposure, 173 are able to be ingested and171 can be inhaled (PEN, 2014). But a note is placed in the inventory that even though these products can be exposed, this is not yet confirmed that these products are injurious to health or not.

(Buzea, Pacheco, & Robbie, 2007) summarized the possible adverse health effects associated with inhalation, ingestion, and contact with nanoparticles and emphasized that not all nanoparticles

produce adverse health effects - the toxicity of nanoparticles depends on various factors, including: size, aggregation, composition, crystallinity, surface functionalization, etc. They shared the following diseases which are associated with nanoparticle exposure, shown in Fig. 1.

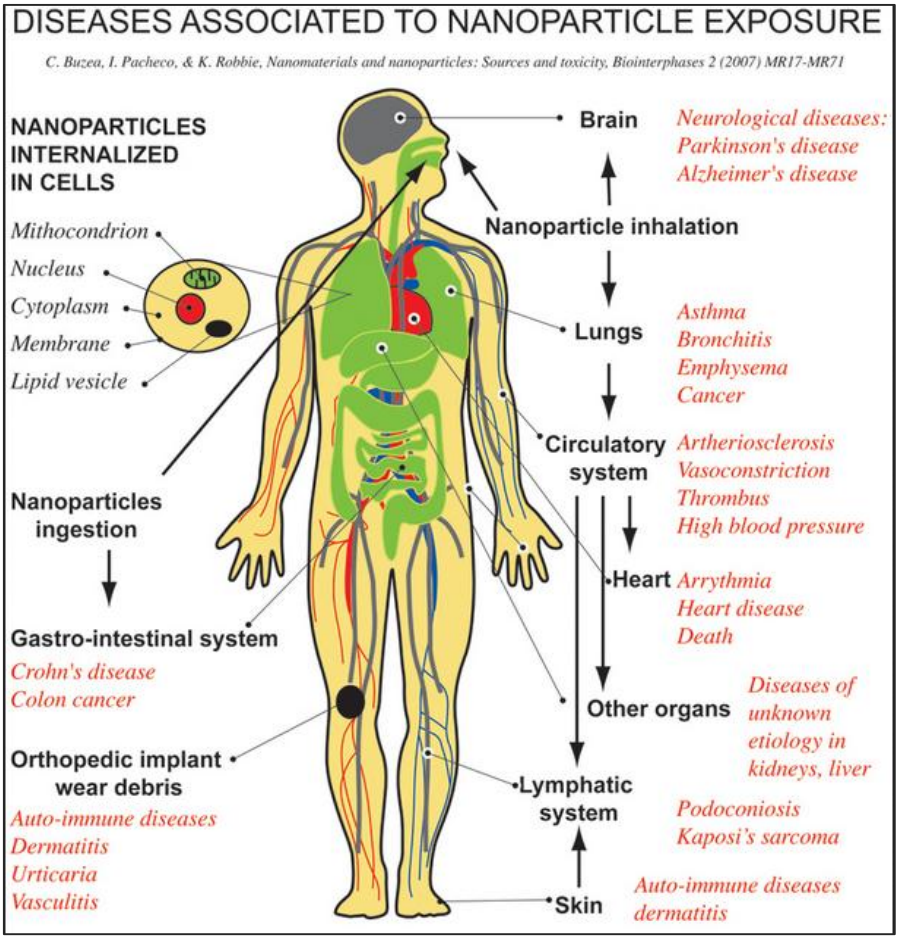


Fig. 1: Diseases Associated to Nanoparticle Exposure adapted from (Buzea, Pacheco, & Robbie, 2007)

Nevertheless, there are opposite findings from the industries too. (Becker, 2013) opined that in the absence of nano-specific regulation, the views of nanotechnology industries, who are the primary agent to ensure that the consumers are adequately protected, are very important. With that aim he interviewed 17 industrial individuals of USA and found that the industries do not consider nanotechnology as novel or risky and they feel that uncertainty over risk should not delay the further development of nanotechnology. This sounds to be very inspiring but the regulators should not reply on such understanding. If that would be the case, there would not need any law relating to consumer protection, etc.

**NANO REGULATION AND LIFE CYCLE OF NANOMATERIALS**

One of the best ways to understand the legal aspects of nanotechnology is the life cycle analysis of nanomaterials i.e. from the laboratory stage to ultimate exposure in the nature. It will be seen that in every stages of nanomaterails, there are some legal provisions starting from labour law, occupational

health and safety law, environmental law, consumer protection law, sale of goods, carriage of goods, product liability laws and many more.

## NANOTECHNOLOGY AND INTERNATIONAL LAW

At the very outset of the discussion, this should be made clear that the discussion on the legal aspects of nanotechnology can be discussed under the broad area of chemical legislation. It is further understood that not all the chemicals are injurious to human health and environment, rather most of the chemicals are refined and processed for the benefits of mankind. Similarly, not all nanomaterials are injurious to human health.

This is for sure that so far there is no specific international law dealing with nanomaterials. Even with hundreds of consumer products in the market, a survey of movement of global community under the umbrella of United Nations Organization (UN) will reveal that the organization is still preferring the 'wait and see' approach. European Union is by far the most active international organization that has been working relentlessly to regulate nanomaterials.

If we consider the human health and more specifically occupational health and safety, there are at least three Conventions developed under the preview of the International Labour Organization which can be used to include the nanotechnology industry. These are - Conventions on Safety in the use of Chemicals at Work, 1990, on the Promotional Framework for Occupational Safety and Health, 2006 and Protocol of 2002, and on Occupational Safety and Health and the Working Environment, 1981. Furthermore, ILO has issued some recommendations e.g. Recommendation on the Prevention of Industrial Accidents, 1929, Recommendation on Occupational Safety and Health and the Working, 1981, Recommendation on Safety in the use of Chemicals at Work, 1990, Recommendation on the Prevention of Major Industrial Accidents, 1993, Recommendation on the promotional framework for occupational safety and health, 2006.

If we consider the environmental implications of nanomaterials, there are a good number of international instruments that can be used to include nanomaterials. The list of such international instruments include the Declaration of the United Nations Conference on the Human Environment, 1972, (Stockholm Declaration), Rio Declaration on Environment and Development, 1992, the Convention on Biological Diversity, 1992, Cartagena Protocol on the Protection of Biosafety, 2000, Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, 1998, (the "Aarhus Convention"), Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, 1998.

Apart from these hard law provisions, there can be found some voluntary agreement like Strategic Approach for International Chemical Management (SAICM). SAICM is a voluntary agreement of the international community envisaged to serve as a global framework in which to discuss methods of cooperation and specific actions that can be taken in relation to achieving safe, responsible, and sustainable management of chemicals. Since 2009, nanotechnologies and manufactured nanomaterials are addressed as an emerging policy issue. At the Third International Conference on Chemical Management (ICCM3) held in September 2012 in Nairobi, Kenya, specific activities related to nanomaterials were added to SAICM Global Plan of Action, as well as a resolution recommending,

among other measures, the development of international technical and regulatory guidance and training materials for the sound management of manufactured nanomaterials

## NANOTECHNOLOGY AND MUNICIPAL LAW

Taking into account the life cycle of the nanomaterials, this is obvious that in any jurisdiction one can easily find out municipal legal provisions relating to occupational health and safety, environment, consumer, product liability, strict liability, chemical legislation etc. based on the findings published in the recent scientific literature this is important to assess whether the existing municipal legal and regulatory framework is sufficient or not. Some of the countries in the world have completed such assessment and concluded that for the time being the legal and regulatory framework is sufficient to handle different aspects of nanomaterials.

Apart from these general municipal law provisions, some of the countries like United State of America (USA) or South Korea has enacted statutory laws on nanotechnology. The laws which were enacted by these countries provide for some administrative set up only. In case of USA, some of the small cities like City of Berkley, Cambridge have started the process to regulate nanotechnology. Such an initiative is actually a tip in the iceberg (Bowman & Hodge, 2008).

In Brazil, the Congress very recently rejected a bill relating to labeling in food and drug containing nanotechnology on the ground that there is yet no evidence against the nanotechnology and that this will not be right to make the consumers panic, instead the government allocated more USD 186 in nanotechnology initiative. Even though the bill was not passed this time, this is a clear “warning” to the producers and manufacturers who are using nanotechnology and taking the advantages over other companies who are not using so. In 2005, there was another similar attempt when a more ambitious bill, with provisions for a national policy on nanotechnology, including labelling, risk assessment and other decisions, was evaluated by the industry, science, and finance committees from Congress's Chamber of Deputies, which found the field to be at too early a stage for legislation. Such legislation would definitely bring benefits to the industries. A look on this law will reveal that this is more or less an amendment law, which proposed to amend provisions of the Law on Establishment of Basic Standards on Foods, 1969 and Labelling related Law of 1976. The newly proposed bill, suggested to include article 22a in the 1969 law, and amendment of article 57 of the 1976 law. In general, this bill is something like the USA Nanosafety Bill which was also similarly rejected. The Brazilian Senate may soon come up with totally a new bill relating to labeling of all nanotech products, including export and import and the bill is now pending in the Chamber of Deputies.

## INTERNATIONAL MOVEMENT TOWARDS NANO REGULATION

This is a matter of hope that some of the international organizations have started the process of regulating nanomaterials. International organizations have been debating and monitoring the issue of nanotechnologies for several years. Five international organizations have been quite active in this respect: the Food and Agriculture Organization, the International Labour Organization, the Organization for Economic Cooperation and Development, the United Nations Educational, Scientific and Cultural Organization, and the World Health Organization. Nevertheless, due to their different mandates, the actions of these international organizations have been rather fragmented. In particular, they have been unable to agree on whether a universal regulatory framework is necessary in order to better address the uncertain risks that may derive from nanotechnologies. Furthermore,

they have not yet clearly identified the principles of international environmental law (e.g., sustainable development, precautionary principle) that should govern any action in the field of nanotechnologies. Despite this fragmentation, there are international efforts to foster coordination between international organizations, with the establishment of two important fora: the Inter-organization Programme for the Sound Management of Chemicals and the Inter-governmental Forum on Chemical Safety (Mbengue & Charles, 2013).

World Health Organization is in the process of adopting a guideline on Nanomaterials and workers' health by 2014. In 2010, in the Declaration on Environment and Health, adopted in Parma, Italy between 10 to 12 March 2010, the Ministers of Health and Environment and Representatives in the European Region of the WHO listed health implications of nanotechnology and nanoparticles as the key health and environmental challenge in article 3 (e) of the Declaration.

Besides, some of the international non-governmental organizations, like Organisation for Economic Co-operation and Development (*OECD*), International Standard Organisation (ISO) have also been working to make some guidelines and standards that the member states can follow. So far, OECD has formed two working party i.e. Working Party on Nanotechnology (WPN) and Working Party on Manufactured Nanomaterials (WPMN), which is a subsidiary to the Chemical Committee.

The Working Party on Nanotechnology (WPN) was established in March 2007 under the Committee on Scientific and Technological Policy (CSTP) to advise on emerging policy-relevant issues in science, technology and innovation related to the *responsible development and use of nanotechnology*. On the other hand, the OECD Chemicals Committee Working Party on Manufactured Nanomaterials (WPMN) (established in 2006) is working on international co-operation in health-related and environmental safety-related aspects of manufactured nanomaterials.

The WPNM has undertaken a number of projects on Development of a Database on Human Health and Environmental Safety Research; Research Strategies on Manufactured Nanomaterials; Safety Testing of a Representative Set of Manufactured Nanomaterials; Manufactured Nanomaterials and Test Guidelines; Co-operation on Voluntary Schemes and Regulatory Programmes; Co-operation on Risk Assessment; The role of Alternative Methods in Nanotoxicology; and Exposure Measurement and Exposure Mitigation.

International Standard Organization has established one Technical Committee on Nanotechnologies (ISO/TC 229 Nanotechnologies) and International Electrotechnical Commission Technical Committee on Nanotechnology Standardization for Electrical and Electronic Products and System (IEC/TC 113).

## SOME RECENT DEVELOPMENTS

One of the important issues in relation to regulation of nanomaterial is that the regulatory agencies should have the knowledge about the amount, type of raw nanomaterials that are manufactured or imported. To this end, some of the countries introduced voluntary reporting schemes and invited the companies to report on these issues. The Department for Environment, Food and Rural Affairs (DEFRA), UK introduced voluntary reporting schemes in 2006, the Australian Department of Health and Ageing conducted a similar reporting in 2006, German Federal Institute for Occupational Health and Safety and the Association of the Chemical Industry initiated a scheme between 2005 and 2006,

Ireland did that in 2006 and Denmark in 2007. But these initiatives were not successful except the two years long one conducted by the United States Environmental Protection Agency (EPA).

Recently, France has introduced mandatory reporting system and other European countries like Belgium, Norway, Sweden, Italy and Denmark are inspired by France's initiative and in the process of adopting similar initiative.

On the other hand, some of the Asian countries like Iran, Thailand and Taiwan introduced "nano labelling system", which can be termed as inception initiative towards nanotechnology regulation. The Iranian regulators declared to offer some incentives for the companies that will use nano label in their products. The Taiwanese scheme has been declared to be very successful both in terms of business and public confidence.

## CONCLUSION

Nanotechnology has limitless potential. It can be used to make things or consumer products according to the demand of the consumers. It has the prospect to make things which are durable, stronger, cheaper, lighter, effective and efficient. The research and development of nanotechnology should be continuous within the set legal framework. Earlier the world community observed the negative impacts of the genetically modified foods and nuclear energy. The regulators should come forward to select the appropriate legal framework to govern nanotechnology and should not wait for occurrence of any incident which will truly shake the confidence of the consumers.

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