

Nanotechnology Safety in Asian Perspective: A Legal Analysis

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Abstract: Nanotechnology has the prospect to vibrate the imagination of human being and has the ability to be used in almost every sector of human need. With its limitless potential, there are concerns too as nanoparticles have been projected as next asbestos. Studies revealed that nanoparticles can enter the human body through the lungs, intestinal tract, and skin and can create serious problems and thus, the researchers and workers who remain the closest due to the nature of their job can be seriously affected. The incident of death and lungs damage of workers of the Chinese paint factory and the confirmation by the physicians compels to consider the issues of nanosafety very seriously. Different organizations at European level and America have been working to frame some Code, Guideline and Policy, etc. in this regard where Asia is still far behind. This paper aims at sharing the legal and regulatory set up of some of the Asian countries in relation to nanotechnology safety. Language being a problem in jotting down the resources on these countries, this paper will consider only the resources available online in English.

Keywords: Nanotechnology, Occupational health and safety, Nanosafety, Risk Assessment, Nanotechnology and Workplace Safety, Nanotechnology in Asia, Research and Development

INTRODUCTION

Nanotechnology, the science of modifying and utilizing objects at the atomic or molecular level, has the potential to solve many of the existing problems of the developing countries of the world. Its limitless potentials lure most of the countries to continuously invest huge amount in the research and development of it. It is a matter of fact that there is no specific legal framework nationally and internationally to regulate nanotechnology. However, the issue of safety is crucial in the development of nanotechnology and if this issue cannot be settled with considerable satisfaction of the consumers and the workers/researchers, there is a possibility that it may create a similar situation like the genetically modified food, nuclear energy, etc.

Nanoparticles can enter the human body through the lungs, the intestinal tract, and skin and can create serious problems, due to which even after continuous assurance from the companies and governments, some people are still considering nanoparticle as the next asbestos. Though this is not yet the right time to decide if the nanotechnology-enabled products are harmful for human health, most of the researches already warned that the researchers and workers can be seriously affected and they are more in a danger zone than the consumers. It has been reported already that seven workers in a Chinese paint factory that was using nanotechnology were suffered from permanent lungs damage and two were died [1]. Interestingly, though the Chinese government denied the fact, the doctors

who treated these workers ruled in favour [2]. The team of the doctors concluded that long-term exposure to some nanoparticles without protective measures may lead to serious damage to lungs and it is impossible to remove nanoparticles that have penetrated the cell.

Asia, the largest and most populous continent of the world, is very lucrative to the multinationals due to available cheaper labour. India and China can be the world's producer of nanoenabled products, Japan, South Korea, Taiwan, Singapore, Iran, Turkey, Hong Kong are known and powerful players in nanotechnology research. Considering all these issues the safety of nanotechnology in Asian countries should be considered and to this end focus should be given on the nanotechnology strategy paper, initiatives taken by the governments, the existing occupational health and safety laws, the performance of the national bodies in this regards, etc. To gather ideas on these issues, this paper is divided into four main parts along with the introduction and conclusion. Part one deals with the some of the standard setting organisations in nanosafety and the challenges faced by these Organisation, the next Part considers the National Nanotechnology Strategies of these Asian countries and the issue of nanosafety considered in those Strategies, after that focus will be given on the occupational health and safety laws of these Asian countries and finally, some suggestions will be shared in this regard.

METHODS

This paper is developed mainly on secondary sources collected from the internet. Asian countries are selected based on the records as compiled in the Iranian National Statistics page on nanotechnology, StatNano

[<http://www.statnano.com>] and the patent information from the United States Patent and Trademark Office (USPTO), which is also included in the StatNano website. Only six countries i.e. China, Japan, South Korea, Iran, Singapore, and Taiwan are considered, though there are other Twenty Nine Asian countries like India, Malaysia, Saudi Arabia, Thailand, Sri Lanka, Vietnam, UAE, Bangladesh, etc. which have already taken discernible initiatives in this regard. Language being a problem in jotting down the resources on these Asian countries, since most of the countries have different languages, this paper considers only the resources available online on these countries in English.

SOME OF THE STANDARD SETTING ORGANISATIONS IN NANOSAFETY AND ASSOCIATED CHALLENGES

This risks and safety issues of nanoparticles are not new phenomena. There are few non-governmental organisations e.g. Greenpeace, Friends of the Earth which have been continuously raising their voice regarding the risks and safety concerns relating to nanoparticles [3] [4]. In this backdrop, international non-governmental organisations and government agencies of different countries have been working relentlessly to set some standard with regard to safety and risk assessment relating to nanotechnology.

Some of such organisations which are working in this area include United Nations International Standard Organisation [ISO/TR 12885:2008] and Organisation for Economic Co-operation and Development (OECD), U.S. Environmental Protection Agency (EPA), National Institute for Occupational Safety and Health (NIOSH), American National Standards Institute (ANSI), British Standards Institution (BSI),

Association of Powder Process Industry and Engineering (APPIE), Deutsches Institut für Normung (DIN), European Economic Community (EEC), and International Organization for Standardization (ISO), International Electrotechnical Commission (IEC). There is also a nanosafety cluster [9] and nanoreg [10] at the European level.

World Health Organisation is in the process of adopting a guideline on Nanomaterials and worker's health by 2014. European Commission has started the process of amendment of workers protection legislation and hopefully it will be completed by 2013 and will finalise the assessment of review of occupational health and safety legislation by 2014.

There is hardly any acceptable standard method due to which monitoring of nanomaterials in the workplace is technically challenging [5]. Different organisations have been working with the standard method, standard setting, risk assessment, hazard exposure, etc.

STRATEGIES ON NANOTECHNOLOGY IN ASIAN COUNTRIES AND THE ISSUE OF SAFETY

All these Asian countries have already adopted some strategies relating to nanotechnology and most of these strategies include safety related provisions. For example, the government of Thailand adopted the National Nanosafety and Ethics Strategic Plan (2012-2016) in 2012 and the Ministry of Science and Technology was held responsible for the implementation of this.

Korea is one of top five countries in the world in nanotechnology field and the government of Korea has

already taken three agendas for the National Nanotechnology Initiative in the years 2001, 2005 and 2011. South Korea established a Nano Substance Safety Policy Committee in March 2007 where the Korean Agency for Technology and Standards, National Institute of Toxicological Research and National Institute of Environmental Research are members. There is a Nano Safety Policy Council to measure, inter alia, exposure of nanomaterials among workers, consumers and the environment, hazard assessment, risk assessment and broader environment impacts.

Ministry of Economy and Planning of the Kingdom of Saudi Arabia introduced the Strategic Priorities for Nanotechnology Program [2008-2012] and realized the health related concerns of nanotechnology and priorities the initiative to develop health and safety related guideline and in this regard, it has advocated to take active role in the standard setting meetings of any of the two globally renowned international standard setting bodies i.e. American Society for Testing and Materials International (ASTM International) and International Organization for Standardization (ISO).

Singapore has completed the NanoSafety Survey, which was jointly commissioned by the Ministry of Manpower and Singapore Economic Development Board and administered by NanoConsulting [9]. Taiwan has been considering the nanosafety issue in the Phase II (2009-2014) of the National Program on Nanotechnology.

Iran Nanotechnology Initiative Council (INIC) was established in 2003 and in 2010 the country has published the 2nd National Nanotechnology Standard titled Nanotechnology – Health and Safety in Nano

Occupational Settings – Code of Practices on the basis of standards published by the ISO, ASTM and NIOSH, USA.

In Japan, a number of ministries including Ministry of Economy, Trade and Industry, Ministry of the Environment, Ministry of Health, Labour and Welfare, Ministry of Agriculture, Forestry and Fisheries, Ministry of Education, Culture, Sports, Science and Technology have been working in the safety of nanomaterials. The Japanese Ministry of Economy, Trade and Industry (METI) established the “Committee on Safety Management for Nanomaterials”. A new notification on precautionary measures for prevention of exposure of nanomaterials replacing the earlier one was issued in 2013.

OCCUPATION HEALTH AND SAFETY LAWS IN ASIAN COUNTRIES

None of these Asian countries can be considered as purely civil or common law countries rather they are having mixed legal system and in the absence of codified laws, the relevant government strategies can be found in policies, etc. However, from the point of view of interpretation of statutes, these policies do not have equal status like the codified laws since the policies are like guidelines and the codified laws act as the primary legislation in these countries. The provisions of policies though are very important, can hardly be implemented.

In this segment, we will be focusing on the occupational health and safety related laws in these Asian countries. This will be premature to assess the adequacy of these laws, when no specific legislation in this area can be found in all over the world at this point of time and only in USA, there is a

Nanotechnology Safety Bill 2010, which was introduced and referred to the Senate Committee [11]. Article 8 of the Taiwanese Labour Standard Act 2000, generally provides that an employer shall take precautions for the safety and benefit of his / her hired workers against occupational hazards, create a proper working conditions and provide welfare facilities. All safety, sanitation and welfare matters related thereto shall be governed by the regulations of applicable statutes. Other safety related provisions are shared in the law in the context of female workers, i.e. working in the night shifts. Responsibility to monitor such activities is given to Central Competent Authority. The Environment Protection Administration of Taiwan maintains a Nanotechnology EHS Database, which provides up-to-date information about global and municipal research development in environmental health and safety issue [12].

In the South Korea, there are a number of municipal legislation which have relevance to deal with nanotechnology. These laws include Industrial Safety Health Act, Quality Management & Safety Control of Industrial Products Act, Pharmaceutical Act, Cosmetic Act, Food Hygiene Act, Medical Device Act, Hazardous Chemical Control Act, Environmental Health Act, Pesticide Control Act, Lab Safety Act, Maritime Safety Act. Furthermore, South Korea has already developed national standards relating to nanoparticle e.g. Measurement of nanoparticle diameter –Transmission Electron Microscopy [KSD 2716], Guidance to safety of nanomaterial handling workplace and laboratory [KSA 6202] and another standard on Exposure assessment of manufactured nanomaterials is under development. The country has also taken five year inter-ministerial national plan for the years 2012-2016.

Nanosafety research has started in China from 2001 and already the country has adopted a good number of national standards on nanosafety and few other standards are in the process of finalization.

Iran has established the Iran Nanosafety Network (INSN) to, inter alia, draft national priorities, program and strategic plan and the Iran Nanostandardization Committee has already adopted six national standards [14]. Nanotechnologies-Health and safety in nanooccupational settings-Code of Practices (ISIRI 12325), Nanotechnologies-Safe packaging and transport of nanomaterials-Code of practices (ISIRI 13736) are of particular interest in this regard.

WHAT ARE TO BE DONE?

Already there are existing legislation on chemical and pesticide, worker's safety, occupational health, environment etc. in most of the countries. Nevertheless, the main problem faced by the regulators is the definition of 'nano' scale. If consensus can be reached on the definition of nanomaterial at the international level, it will solve many problems for the regulators. It will decide whether the existing municipal law is sufficient or new legislation is required.

The regulators have to make a balance between the ongoing research activities and the risk and safety issues. For the research organisations and companies, it is suggested that in the absence of any guidelines recommended by the international bodies or the national regulators, the best way so far is to take precautionary approaches i.e. all sorts of possible precautions should be taken. Simultaneously, there are some manuals suggested by different organisations. The companies and research organisations may

consider these manuals until there is any further significant development. Recently in 2013, the Health and Safety Executive, UK's national independent watchdog body for work-related health, safety and illness released a Guideline to comply with the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH). Oregon State University's Dr. Stacey Harper has been maintaining a protected wiki site 'goodnanoguide' which contains resources on occupational health and safety and risk management and assessment. This site specially includes an OHS Reference Manual, which can be considered too [15].

There are many researches going on every day and the findings of such researches are not always published as in many cases the output of these researches may not have desirable results. Even in such cases, all kinds of positive and negative findings must be reported to and indexed in database readily accessible by everyone [6].

The regulator should conduct research on the companies working with nanoparticles. In September 2011, a group of researchers from University of California, Santa Barbara studied 78 companies working with nanoparticles and found that 87% of the companies have a basic program to deal with environmental health and safety (EHS) issues, 50% companies have nano-specific EHS programs and 13% do not have any such programs. Though 60% of the companies were monitoring work areas for nanoparticles, it was revealed that these companies were doing something which would make the situation worse [7]. A similar survey was conducted in Singapore [9].

Some of the NGOs have been playing pivotal role in the discussion of nanotechnology development. The

trade unions and employers association have the scope to play substantive role in terms of nanosafety.

CONCLUSION

Asian countries are still moving forward with an eye open on the implementation of Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) in European level and what is going to happen in USA and North American countries. Apart from this, in the absence of regional bodies at the continent level like the European Union, African Union this is suggested that the issue of nanosafety should be discussed in Asian regional bodies i.e. in ASEAN or SAARC, which will give Asian countries a stronger voice in international level.

There is no alternative to conduct more research on safety aspects of nanotechnology. More budgets should be allocated for research focusing the health implications of nanotechnology. This is a matter of great concern that USA spent 6% of the federal nanotechnology funding in safety research and china spent 3% only [8]. All these Asian countries are still in the primary stage of research and development and such issues of occupational health is not seriously considered. This is a good sign that the Korean government increased its budget to 7% in the third agenda in 2011 until 2015 for the protection of environment, safety and health, etc.

There must have synergies between companies, research organisations, regulators and policymakers of countries around the world regarding the safe use of nanomaterials for the benefit of all at a large.

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