The nanotechnology application and workforce health and safety - a study of the Malaysia laws, statutory regulations and guidelines on nanotechnology

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Abstract. In Malaysia perspective, the application of nanotechnology is crucial towards achieving the country’s objective as a developed nation by 2020. This paper aims to examine the current Malaysia laws and statutory regulations of nanotechnology applications, to investigate the occupational diseases and work-related accidents associate to nanotechnology and to examine the risk assessment and management practices executed by the nanotechnology-based manufacturers to facilitate the potential effects of nanomaterials. Nanotechnology is a technology that incorporates nanomaterials, which is extremely small materials in size, equivalent to 1/80,000\textsuperscript{th} of the width of a human hair. Due to their distinctive size, these nanomaterials may contribute to the significant health risks and hazards. The findings conclude that there is no specific law and statutory regulation on nanotechnology application exists in Malaysia. Thus, the none existence of nanotechnology laws means there is no protection of persons at work. Malaysia is currently formulating safety standards relevant to nanotechnology. Recently, the Department of Occupational Safety and Health (DOSH) has published the Guideline on Control and Safe Handling Nano Materials by the end of 2018. It provides information and recommendations on handling nanomaterials in the workplace. According to the DOSH personnel that there is no record of occupational disease and work-related accidents related to nanotechnology per se. In relation to the risk assessment and management activities, most of the respondents from the nanotechnology-based manufacturer indicated that there is no nanotechnology risk assessment and management practices being executed in their workplace. Most of them also concluded that they have no knowledge about the latest guideline published by the DOSH on control and safe handling of nanomaterials in the workplace.

1. Introduction
The emerging of nanotechnology applications would potentially provide significant benefits in various sectors such as manufacturing, food processing, water treatments, disease diagnosis, air pollution, energy storage, drug system, construction, health monitoring, pest control and agricultural...
development. Some of the challenges of nanotechnology application are associated with its impact on workforce safety and health.

Nanotechnology is an industrial revolution of the future. It can be used for multidisciplinary purposes with limitless potential. Presently, there are 2,000 consumer products in the market contain nanoparticles through the nanotechnology revolution. Nevertheless, the global community has expressed their concerns on the legal and regulatory frameworks to govern its impact on product safety, privacy and civil liberties, occupational safety and health, environmental issues, consumer protection, waste management & etc. The main concern is to regulate the application of nanotechnology due to it’s still at an early phase of development. By the year of 2020, the International Labour Organisation (‘ILO’) predicts that 20% of products in the market uses nanotechnology.

In Malaysia, the nanotechnology has been addressed by the National Innovation Council in 2009 as an essential element towards the attainment of a developed nation by 2020. The Ministry of Science, Technology and Innovation (MOSTI) has established the National Nanotechnology Centre (NNC) for the coordination of the research and development, risk management and any other related nanotechnology activities. The nanotechnology program is considered as one of the key economic areas specifically in the production of foods and agriculture activities in ensuring a high level of agricultural productivity, handling pest-resistance and improving food quality. The National Nanotechnology Directorate Working Committee focuses on health related issues including the workforce safety and working environment associated to the nanomaterials. In this arrangement, the industry players as well as its personnel are required to be trained, certified and monitored to deal with safety and health issues comprehensively.

Organizations should emphasize on the potential of adverse impacts of nanotechnology on workforce as they are exposed to the potential hazards with the application of nanotechnology in the workplace. At the beginning stage of the commercialization of nanotechnology, there are many unknown issues about its potential hazard, specific impact and execute the most efficient risk assessment in handling nanomaterials. At present, there is insufficient data pertaining to its toxicology level of assessment and the issues are not addressed by the authorities comprehensively.

1.1 Definition of Nanotechnology
Nanotechnology is a technology that incorporates nanomaterials, which is extremely small materials in size, equivalent to 1/80,000th of the width of a human hair (Wikipedia) [18] (NIOSH) [19]. The European Union (EU) defines nanomaterial as a natural, incidental or manufactured particles in the size dimension range from 1 nm - 100 nm. This definition is used for special provisions related to the risk assessment, ingredient labelling and specific legislation. This definition is generated for the conformity across the legislative areas and technical guidance and support to specifically refer to the nanomaterials (EU, 2011) [1]. Due to their distinctive size, these nanomaterials may contribute to the significant health risks and hazards towards the workforce.

This paper aims to examine the current Malaysia laws and statutory regulations of nanotechnology applications, to investigate the occupational diseasess and work-related accidents associate to nanotechnology and to examine the risk assessment and management practices executed by the nanotechnology-based manufacturers to facilitate the potential effects of nanomaterials.

1.2 Assessment of Human Health Risks
The Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) (2010 and 2012) [2] [3] jointly coordinate the collaboration and information exchange internationally amongst the academia, industries and authorities to look into the data gaps of nanomaterials and food matrices, it’s possible consequences in the human body and determine the best methods of handling the nanomaterials. The focus is looking into its interactions and behaviours and gathering the relevant data for risk assessment. There are many products offer on the market such as
food additives or pesticides that are critical need to conduct a risk assessment for the safety evaluation of nanoparticulate materials (JECFA, 2007) [4].

It is difficult to assess the engineered nanomaterials used in the consumer product due to insufficient data. The mandatory labelling enforced by the authorities provide information for the consumers, but this enforcement could contribute to the avoidance of the use of nanotechnologies in consumer products that are beneficial for human needs (Gruère, 2011) [5]. Till now, apart from the European Union (EU), there is no country has a regulated framework for mandatory labelling of nanomaterials in food (EU, 2011) [1]. It would result in technical barriers trading of foods with nanomaterials. However, the current interest of the global communities is to address the technological solutions in the packaging to reduce food losses and facilitate traceability (FAO/WHO, 2012) [3].

The potential hazards of the use of nanomaterials in the wastewater treatment for the quality improvement and safety of water in the agriculture, aquaculture and human consumption may lead to the issue of food safety in their disposal at the end of the life cycle (FAO/WHO, 2010) [16]. In addition, the research projects on the development of “nanovaccines” to target animals of small size in aquaculture (e.g. fish larvae, shrimp) is in the early conceptual stage and thus, there is no information available on its potential risks or hazards (FAO/WHO, 2012) [3].

The determination of risk of an engineered nanomaterial is based on chemical composition, physicochemical properties, interactions with tissues and potential exposure levels. The European Food Safety Authority (EFSA) [23] is uncertain about the identification, characterization and detection of engineered nanomaterial due to the lack of suitable and validated test methods. For these reasons, EFSA recommends conducting more research to address uncertainties and limitations of the application of nanomaterials. In general, the EFSA supports the use of conventional risk assessment and acknowledge the limitation of data related to nanofood applications.

In addressing the future use of nanomaterials for industrial purposes, it has recently raised concerns regarding their disposal at the end of their life cycle. These materials may not be degradable and interact with compounds in the environment. This potential hazard has raised a concern especially in the developing countries in considering which waste containing nanomaterials may be exported (FAO/WHO, 2012) [3].

A study conducted by Horie & Fujita (2011) [14] concluded that, the vitro and in vivo tests without the characterization of the nanomaterial does not contribute to a rational outcome. The chemical compositions are likely to have different effects and therefore, the risk evaluation requires the characterization of each substance. In addition, studies related to the occupational health on nanoparticle toxicology in the lung are scarce. Morris (2011) [15] reported that, less research has been published on nanomaterial toxicity. He added, at present there is a little information on the effect of antimicrobial nanomaterials such as nanosilver on normal microbial populations in the mouth and gut. There is a requirement for considerable further research to be conducted on nanomaterial toxicity (Tran & Chaudhry, 2010) [6].

The critical parameters of nanomaterials safety assessment are biopersistence and digestibility. Studies conducted by Krug & Wick (2011) [7] identified three transport principles associated to “nanotoxicology”. The first principle requires a thorough understanding of what form of nanomaterials enters into cells to elicit a toxic response. The second principle addresses the smaller particle surfaces with active molecules focus on the proportion of atoms or molecules exposed and reacted with biological structures. It has concluded that, it increases exponentially with a decreased diameter if the same amount is administered. And finally, the third principle is on the material states. The change in dimensions does not produce the same effects, but it depends on the properties of the material and its composition, including impurities.

Furthermore, the number of published risk assessments of products contains nanomaterials or contain particles is limited and due to that, it is difficult to conclude the number of substances for nanomaterials. The risk assessment with defined chemicals is generally conducted, but it does not address the particle size. The low knowledge of the nanomaterial toxicity is insufficient to categorize particles into low-toxicity or high-toxicity groups. Due to these reasons, it is crucial to carry out the
nanomaterial risk assessment on a case-by-case basis according to its size, shape, chemical composition, surface area and surface charge in assessing the toxicity level of nanomaterials (Park et al., 2010)[8]. There are a lot of nanomaterial products on the market in the form of textiles, cosmetics and sprays rather than in food. Thus, it requires more risk assessment for inhalation and dermal exposure rather than for ingestion exposure.

The relationship between a specific dose and response-metrics was examined by Rushton et al. (2010) [17]. The generation of hazard scale is based on the highest reactivity (or effect) per unit surface area to evaluate different types of dose. The toxicokinetics, that is known as 'TK' provides a description the level of chemical enter the body and its consequences in the form of what occurs to excrete and metabolize once it is in the body. Nevertheless, due to the uncertainty of the risk assessment data, it limits the knowledge on the application of nanotechnologies and its impact on human health.

2. Methodology
The Malaysia Acts and Statutory Regulations were examined thoroughly to assess the sections and clauses associated with the nanotechnology. Some of the legal documents examined are the Occupational Safety and Health Act 1994 (Act 514), Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000, Occupational Safety and Health (Notifications of Accident), Dangerous Occurrence, Occupational Poisoning and Occupational Disease) Regulations 2004, Factories and Machinery Act 1967 (Act 139) (Revised – 1974), Petroleum (Safety Measures) Act 1984, Factories and Machinery (Special Scheme of Inspection) (Risk-Based Inspection) Regulations 2014, Food Act 1983 (Act 281), Regulations Under Occupational Safety and Health Act 1994 (Act 514), and other relevant laws and non-statutory regulations and Code of Practice on Prevention Eradication of Drug, Alcohol and Substance Abuse in the Workplace, 2005, Guideline on Control and Safe Handling Nanomaterials 2018, Guidelines on Storage of Hazardous Chemicals: A Guide for Safe Warehousing of Packaged Hazardous Chemicals, 2005 and Guidelines on the Control of Chemicals Hazardous to Health, 2001 (DOSH Legislations)[21]

Phone interviewing was conducted with the Department of Occupational Safety and Health personnel located in the Northern Region and its head office in Putrajaya. The respondents hold a position as the Enforcement Officers, three of them, the Director of DOSH in Putrajaya and the balance are the Medical Officer and Assistant Medical Officers of DOSH, Pulau Pinang and Kedah. The other respondents are the Safety Managers and Human Resource Managers from the identified manufacturers or companies dealing with the term of “nano” in the Northern Region. Five respondents are from the chemical based manufacturing, three are from the Nanotechnology Machinery, Appliances and Parts and the balance of two respondents are from the manufacturers of plastic packaging. They were interviewed to get feedback on nanotechnology occupational disease and work-related accidents. They were also asked about their current practices in managing the nanotechnology risks and assessments.

The interviewing by telephone is considered as the primary method used in qualitative research. It has become increasingly common. The phone interviewing mode has gained popularity as evidenced through the relevant literatures. This method of data collection is concluded that able to produce comparable results to face-to-face interviewing (Holt, 2010) [9], Miller, 1995 [10], Opdenakker (2006) [11], Sturges and Hanrahan (2004) [12] and Vogl (2013) [13].

3. Findings and Discussion
Malaysia is in the process of constructing legal instruments, appropriate parameters and monitoring mechanisms of nanotechnology development and commercialization. It is noted that, none of the current legislations specify the terms of nanotechnology or nanoparticles in the clauses or sections. The imported foods or domestically produced foods are governed under the Food Act 1983 in Malaysia. This is to ensure that foods must be safe for human consumption. Nevertheless, there is no
specific clauses or sections stated in the Food Act 1983 (Act 281) addresses the term of “nanotechnology” or “nanomaterials” per se. In the PART III Offences and Evidence states food containing “substances injurious to health”. The Section 13(1) stated therein: “Any person who prepares or sells any food that has in or upon it any substance which is poisonous, harmful or otherwise injurious to health commits an offence and shall be liable, on conviction, to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding ten years or to both. The Section 13(2); In determining whether any food is injurious to health for the purpose of subsection (1), regard shall be had not only to the probable effect of that food on the health of a person consuming it but also to the probable cumulative effect of the food of substantially the same composition on the health of a person consuming the food in ordinary quantities. And, referring to the False labelling, etc, under the Section 16 specifies that, any person who prepares, packages, labels or sells any food in a manner that is false, misleading or deceptive as regards its character, nature, value, substance, quality, composition, merit or safety, strength, purity, weight, origin, age or proportion or in contravention of any regulation made under this Act commits an offence and is liable on conviction to imprisonment for a term not exceeding three years or to fine or to both. As mentioned above, there is a term of “substance” applied in the section, but it is associated to the “poisonous and harmful” effects. Section 13 is not referring to any particles or sizes of foods, or incorporates nanomaterials or extremely small materials or size related particles. In accordance to the Clause of Power, Section 34 (1) is to prescribe the size, dimensions and other specifications of packages of food. Again, the term of “nanotechnology” or “nanomaterials”, “nanoparticles” are not mentioned under these sections or sub sections.

The Occupational Safety and Health Act 1994 (OSHA 1994) referring to Section 18 (1) (2), Section 21 (1) (c), Section 21 (2), Section 22 (3), Section 22 (4) (b), Section 28 (a) (d), Part IX Prohibition Against Use of Plant Or Substance, Section 40, Section 41, Section 48 (6), Part XIV Regulations; Section 66 (2)(a)(i)(ii), (c) (d) (e) and the Third Schedule, Schedule 3 [Paragraph 28 (1)(d)] – Occupations Involving Special Risk to Health specified “substance” and do not specifically prescribed the nanomaterials or nanotechnology substances.

The findings conclude that there are no specific laws and statutory regulations addresses nanotechnology application particularly. In addition, there is no clause or section specifically mentioning nanotechnology or nanomaterials or nanoparticles specified in the Malaysia Acts and Statutory Regulations. Most of the sections and clauses mentioned the general term of “hazardous substances”. Thus, the none existence of nanotechnology laws means there is no protection of persons at work. Latest updates by the Department of Occupational Safety and Health (DOSH), they have published the Guideline on Control and Safe Handling Nanomaterials 2018 (DOSH0 [20]. The regulations coverage is specifically on the process and method of nanotechnology, safety and health concerned, nanomaterial risk assessment (NaRa) and control measures on 12th. December 2018. It provides information and recommendations on handling nanomaterials in the workplace and specifies its potential hazards according to the process and method of nanotechnology.

As it is just released, the circulation should be made known to the nanotechnology based manufacturers, suppliers of nanotechnology machines and equipment as well as its customers and workers. As the interviews took place earlier before the guideline was announced where the respondents claimed that they did not know about any regulation formulated by the DOSH and there is no specific nanotechnology risk management procedures and policies implemented in the workplace specifically for handling nanomaterial hazards and risks. The distribution of the information needs to be shared immediately through an excessive distribution channel as to ensure that nanotechnology potential hazards and risks assessment is applied and implemented in the workplace without further delay. This is also to ensure the nanomaterials are handled properly and rest assure a high compliance level amongst the industries and the necessary precautionary measures are taken to safeguard the workforce safety and health.
It is concluded by the DOSH personnel that there is no record or category of occupational disease and work-related accidents related to nanotechnology per se. Based on DOSH statistical data [22], as at September 2018, a total of 3058 cases of occupational disease and poisoning has been reported to the Occupational Health Division as compared with 6020 cases reported in the year of 2017; A total of 1775 cases reported as the occupational noise-related hearing disorders (HD), followed by Occupational Muscular-Skeletal Disorders (OMSD) with a total of 85 cases, Occupational Lung Diseases (OLD) recorded 55 cases, Occupational Poisoning with 47 cases, Occupational Skin Diseases (OSD), 22 cases, Disease cause by Biological Agent, 13 cases, Other Types of Occupational Diseases indicated 2 cases only, both the Occupational Cancer and Psychosocial Problem recorded no case at all and finally the Non Occupational Diseases recorded 1058 of the cases. According to the DOSH Medical Officers and Assistant Medical Officer, they have no specific data on nanotechnology occupational disease and poisoning case.

In relation to the risk assessment and management practices, most of the respondents from the nanotechnology-based manufacturer indicated that there are no nanotechnology risk assessment and management practices specifically being executed in their workplace but only for general risk and hazard assessment. Most of them also concluded that they have no knowledge about the latest guideline published by the DOSH on control and safe handling of nanomaterials in the workplace. The outcome of this project is an increase understanding of the potential effects of nanomaterials and to legally regulate the nanotechnology applications as to safeguard the workforce from the nanotechnology occupational diseases and work-related accidents. This multi-level study also has highlighted the level of respondents understanding towards the nanotechnology risks and hazards, and level of uncertainties of approach utilised in their workplaces. Most respondents concluded that there are no nanotechnology or nanomaterial risk assessments implemented either as part of their obligation to assess and manage risks for nanotechnology effects on the workforce health and safety. The respondents confirmed that, there is an assessment of chemical substances related health risk case, but unable to substantiate that, they are related to nanotechnology. Thus, it is critical to educate and provide training programs on nanotechnology that not only deal with scientific and technical aspects, but also social sciences, to ensure that the ethical implications and legal aspects of nanotechnologies are also addressed. The legal documents should be drafted as to increase the protection of the workforce health and safety aspects. It is also critical for the public sector, especially DOSH to allocate more resources and efforts to be devoted towards the nanotechnology education programs. Various mechanisms should be identified, including the use of training programs and extension services to conduct research on nano-applications and their use to generate more evidence to substantiate the potential effects of nanotechnology.

4. Conclusions
As a conclusion based on the risks and assessments specified in the DOSH Guideline for Control and Safe Handling of Nanomaterials and a thorough examination of other reviews and reports specified by FAO, WHO, ILO and EU, there are five crucial actions should be considered and practiced by organizations, decision makers in the business or even societal levels to deal with potential hazards of nanotechnology. These include: (1) anticipate, identify, and track potentially hazardous nanomaterials in the workplace; (2) assess workers’ exposures to nanomaterials; (3) assess and communicate hazards and risks to workers; (4) manages occupational safety and health risks; and (5) foster the safe development of nanotechnology and realization of its societal and commercial benefits. All these criteria are necessary to responsibly manage the nanotechnology in the workplace. Furthermore, the Department of Occupational Safety and Health has recently introduced Guidelines for Control and Safe Handling of Nanomaterials by the end of 2018. It provides the specific information and recommendations for the workers and employers on basic understandings of potential hazards associated with nanotechnology, safety and health concerned, nanomaterials risk assessments and highlight the measure to control exposure nanomaterials in the workplace. This guideline could help the workers and employers take the safest precaution measures in handling the nanotechnology
and implement the nanotechnology risk assessments properly and systematically. An orchestrated effort from all, be it corporate, managers, shareholders, stakeholders, regulators, policy makers, suppliers, consumers and customers should initiate more laboratory based studies to conclude the actual effect of nanomaterials or nanoparticles to conclusively confirm its possible risks. The legislation should be in place to regulate the application of nanotechnology, nanomaterials or nanoparticles in the workplace to ensure that workers are legally protected.

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