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Too Enthusiastic to Care for Safety: Present Status and Recent Developments of Nanosafety in ASEAN Countries

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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 potentials, there are many environmental, health and safety related concerns too due to extremely ambivalent effects of nanoparticles. Studies revealed that nanoparticles can enter the human body through the lungs, intestinal tract, and skin. Therefore, the researchers and workers who handle nanoparticles and nanomaterials can theoretically and primarily be affected, whereas on the consumers this will have secondary effects. This paper aims at sharing and evaluating the investment scenario, present status and recent developments in nanotechnology, with specific focus on nanosafety issues in different research projects and national nanotechnology policies, strategies or roadmap in 6 ASEAN countries i.e. Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam. In general, it can safely be inferred that like their western counterparts, though these ASEAN countries have realized the importance of investment and institutional set ups in nanotechnology, and already spent huge amount of money in nanotechnology, the concern of risk and safety is still considered not a serious issue for them. This paper provides a better understanding and highlighting the importance of prioritizing nanosafety issue to the policymakers and the stakeholders of this region.

Keywords: Nanotechnology, occupational health and safety, nanosafety, risk assessment, safe handling of nanoparticle, nanotechnology in Asia

ABBREVIATIONS

ANF	Asia Nano Forum				
ASEAN	Association of South East Asian Nations				
CoE	Center of Excellence				
DOST	Department of Science and Technology				
EDB	Economic Development Board				
EHS	Environmental health and safety				
EU	European Union				
ICON	Industry Consortium on Nanoimprint				
ICON	International Council on Nanotechnology				
IEC	International Electrotechnical Commission				
IOM	Institute of Occupational Medicine				
IRPA	Intensification of Priority Research Areas				
ISO	International Organisation for Standardization				
LIPI	Research Center for Physics of Indonesian Institute of Sciences				
MDGs	UN Millennium Development Goals				
MOSTI	Ministry of Science, Technology and Innovation				
NANOTEC	National Nanotechnology Center				
NICT	Nanosafety Information Center of Thailand				
NIOSH	National Institute for Occupational Safety and Health				
NKEA	National Key Economic Areas				
NND	National Nanotechnology Directorate				
NNI	National Nanotechnology Initiative				
NRDA	Nanotechnology Regulatory Document Archive				
NSTDA	National Science and Technology Development Agency				
NTU	Nanyang Technological University				
NUS	Singapore National University				

OECD	Organisation for Economic Co-operation and Development
R & D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SHTP	Saigon Hi Tech Park
TC	Technical Committees
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNITAR	United Nation Institute for Training and Research
USA	United States of America
USPTO	United States Patent and Trademark Office

1. INTRODUCTION

Nanotechnology, the science of manipulating, modifying and utilizing objects at the atomic level, has the potential to solve many of the existing problems of the developing countries of the world. The wave of the future, nanotechnology is no more *terra incognita*, it is no more an agenda of scientists only, rather it has turned into a multi-disciplinary study. The United Nation (UN) Task Force on Science, Technology and Innovation (part of the process designed to assist UN agencies in achieving the United Nations Millennium Development Goals (MDGs)) addressed the potential of nanotechnology for sustainable development and for the betterment of 5 billion people of the developing countries. It was further discussed on how nanotechnology can assist the developing countries in achieving these goals. Sharing the findings of Salamanca-Buentello et al. (2005), the United Nations Educational, Scientific and Cultural Organization (UNESCO) reiterated the top ten applications of nanotechnology within the UN MDGs, which are (UNESCO 2006): (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, and (j) vector and pest detection and control.

Its limitless potentials lure most of the countries to continuously invest huge amount of money in its research and development (R&D) programme. Starting from mid-1990s (Fairbrother and Fairbrother 2009), the latest data from the Project on Emerging Nanotechnologies developed by the Woodrow Wilson International Center for Scholars shows that more than 1600 consumer products manufactured using nanomaterials are already in the market (PEN 2014). International Labour Organisation (ILO) predicts that by the year 2020, approximately 20% of all goods manufactured around the world will be developed based on nanotechnology (ILO 2010). Besides, the prospect of nanotechnology has been projected in a number of reports by popular market research companies like Lux Research, Scientifica, BCC Research Market and also many government reports.

It is a matter of fact that in the absence of any specific legal framework nationally and internationally to regulate nanotechnology, the issue of risk and safety is crucial in the development of nanotechnology. If this issue cannot be settled with considerable satisfaction of the consumers and the workers/researchers, it may have to embrace a similar situation like the genetically modified food or nuclear energy, etc., which were initiated to introduce with huge expectations but could not be successful in meeting the demand.

Asia, the largest and most populous continent of the world, is very lucrative to the multinationals due to the availability of cheaper labour market. India and China can be the world's producers of nanoenabled products, Japan, South Korea, Taiwan, Singapore, Iran, Turkey, Hong Kong are known and powerful players in nanotechnology research. The Association of South East Asian Nations (ASEAN), the eighth largest economy in the world, is a geo-political and treaty based organization of ten Asian economies i.e. Brunei, Indonesia, Malaysia, Myanmar, Philippines, Singapore, Thailand, Cambodia, Laos, and Vietnam. ASEAN comprises of 4,435,624 km², with 616,632 thousand people (ASEANStat 2013). It has a Gross Domestic Product (GDP) growth of 5.7% in 2012 (ASEANStat 2013). This region is also a very popular tourist destination as every year 85,464 thousand visitors visit this part of the world (ASEANStat 2013). The region is very important in terms of nanotechnology R & D due to some distinctive attributes which is

discussed in details in the later part.¹

The new century began with lots of enthusiasm and inspiration as some of the Asian countries like Japan and China started their nano venture officially since 2001 - in line with their western counterpart - through national nanotechnology policy or strategy. The Republic of Korea, Taiwan, Thailand and Vietnam followed Japan and China immediately. Singapore, Malaysia and Indonesia are the newest entry in the list of Asia Pacific nations (Liu 2009). However, Singapore even started its nanotechnology journey from 1995, which evolved around the National University of Singapore. To add to this discussion, it will be interesting to share here that over the period of time nanotechnology has attracted people from this region and it is turning to be a matter of interest for the people, which is reflected in the Figure 1.



Figure 1: Search of the term nanotechnology in top ten regions between 2004-2012. Adapted from Rogers et al. (2013).

This figure clearly shows the interest of Asia with nanotechnology and three of the countries from this Figure 1, i.e. Singapore, Malaysia and Philippines will be considered in this paper.

¹ Pertinent to mention here that this paper has no connection with the ASEAN as an organization and the word ASEAN in the title of the paper was selected to share an idea of the content of the paper with the readers only.

All these issues inspire to examine the government policy or regulations set up to handle the risks and safety of nanotechnology in these countries. To this end focus should be given on various aspects including the nanotechnology strategy paper, initiatives taken by the governments, the existing occupational health and safety laws, the performance of the national bodies e.g. health administration, food and drug authority, department of labour, department of standard and so on in this regards, etc. To gather ideas on these issues, this paper is divided into four main segments alongside with the introduction and conclusion. Initially, the findings related to risk and safety published in leading academic journals is presented, followed by some models of risk assessment and management suggested by different organization or researchers in this regard is discussed. Then, focus will be given on developments of some of the standard setting in organizations related to nanosafety in different countries around the world. After that, an evaluation of the investment scenario, nanotechnology framework, national nanotechnology strategies, policies and roadmaps of these 6 ASEAN countries, highlighting the issue of nanosafety considered in their strategies or policy papers will be made. Subsequently, focus will be given on some developments in this region triggered by Asia Nano Forum (ANF). Finally, based on the developments of other parts of the world, some suggestions will be shared at the end of the paper.

2. RISK AND SAFETY CONCERNS WITH NANOTECHNOLOGY

The risk and safety concerns of nanotechnology are almost contemporary with the emergence of it. However, this is a matter of fact that in order to share different kinds of risk and safety associated with nanotechnology, the phrase 'nanosafety' is used which is not defined by any authority, rather it is used as the title of some projects and then gained the popularity e.g. EU NanoSafety Cluster. This phrase is commonly used by many people to refer to different issues relating to safety of nanomaterials and nanotechnology. The concept of 'safety' is used to mean all kinds of risks and safety issues relating to nanoparticles, noting that the evolving definition of nanosafety globally in scientific research communities and under law is an emerging issue in itself.

Organisation for Economic Co-operation and Development (OECD) identified seven types of risks associated with nanotechnology, i.e. (a) business risks, due to marketing of products; (b) intellectual property protection risks; (c) political risks due to economic development of countries; (d) privacy risks due to unlimited sensors; (e) environmental risks due to nanoparticle release; (f) safety risks of workers and consumers; (g) futuristic risks e.g. human enhancement and self replicator (Lauterwasser 2005). A plain look at the publications on nanotechnology allows us to conclude that the benefits, risks and safety concerns of nanotechnology are parallel. One of the main reasons behind this concern is that the nanoparticle in between 1-100 nm scale reacts dramatically which is not evident in its bulk form. In a number of researches, both in vivo and in vitro, it has been confirmed that nanoparticles can enter the human body through the lungs, the intestinal tract, and skin (Hoet et al. 2004; Khaled Radad 2012; Yah et al. 2012; Poland et al. 2008) and even to unborn baby from pregnant worker mother (Takeda et al. 2009). Even after continuous assurance from the companies and governments (Becker 2013), some people are still considering nanoparticle as the next asbestos (UNESCO 2006; Carter 2008; Matsuda and Hunt 2009; Grimshaw et al. 2011). Though this is not yet the right time to conclude if the nanotechnology-enabled products are harmful to human health, most of the research already warned the researchers and workers about this risk due to their close propensity with nanoparticles or nanomaterials (Albrecht et al. 2006). In fact, it is suggested that they are more in a danger zone than the consumers (Albrecht et al. 2006). It has already been reported that seven workers in a Chinese paint factory that was using nanotechnology were suffered from permanent lung damage where two of them died (Lyn 2009). Interestingly, although the Chinese government denied the fact, the doctors who treated these workers ruled in favour (Song et al. 2009). The team of 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 cells. Besides, studies revealed that carbon nanotubes, when directly injected into the lungs of mice, could damage lung tissue (Mongillo 2009), cause scarring (Carter 2008), etc.

Even with such predictions and findings, the companies dealing with nanomaterials are reluctant

to consider this issue seriously (Becker 2013). Helland et al. (2007) emphasized on voluntary risk assessment initiatives adopted by different companies and surveyed 40 companies in Germany and Switzerland. They found that around 65% of the companies did not perform any risk assessment of their nanomaterials and for 32.5% of them, although they did carry out some risk assessment, it was not practice regularly i.e. sometimes the companies conducted risk assessment and sometimes they did not.

The database of the Project on Emerging Nanotechnologies developed by the Woodrow Wilson International Center for Scholars has also listed the products according to potential exposure pathways into the human body. It is claimed that the product can be exposed to human bodies by four ways- dermal, ingestion, inhalation, and oral. Though it was further claimed that the products are not tested to verify if there is any actual risk for human exposure or toxicity, the listing of these products and categorization are sufficient to be warned. Of the total 1600 plus consumer products, 422 products can enter the human body- 218 products can enter the human body through dermal, 96 products by way of injection, 42 products by way of inhalation, and 66 products can enter orally. It is a matter of concern that a good number of products from this 422 products are manufactured in Japan, Korea and China. From the regulatory point of view, listing of these four ways as the possible route to human exposure gives clue to draw conclusions that the laws governing nanorisk and safety should consider these in the black letters of law.

Simultaneously, the concern of existing occupation health and safety and regulatory adequacy have been shared in a number of previous research (Munir and Mohd Yasin 2007, 2008; K Savolainen et al. 2010; Schulte and Salamanca-Buentello 2007). The importance of consideration of occupational health and safety in the development of sustainable and responsible nanotechnology was considered by Iavicoli et al. (2009). However, this is a matter of great concern that this issue is still overlooked even though the concern has been expressed in a number of commissioned research conducted by individuals, organizations and government authorities.

Rogers et al. (2013) shared the statistics of Google on what people search regarding nanotechnology on May 24, 2012, and the data is presented in Figure 2.



Figure 2: Googling Nano on May 24, 2012. Adapted from Rogers et al. (2013).

This figure reflects that Google users were not accustomed to with the findings of researchers on nanorisk or they did not have much interest on safety issues relating to nanomaterial or nanoparticles, or in another way it can be interpreted that comparatively a small number of the stakeholders search for information on nanosafety and risk. To add to this finding, Tanthapanichakoon et al. (2013a) analyzed and compared journal statistics of selected ASEAN countries including Japan, Singapore, Thailand, Malaysia, Vietnam and Indonesia from Science Direct between 2001 and January 2013 and classified the published papers in different heading but the issue of risk and safety was not considered. Almost similar findings are shared by Tanthapanichakoon et al. (2013b), when they considered the publications of Science Direct between 2006 and March 2012. It was revealed that Singapore has experts in a wide range of the nanotechnology field and applications i.e. carbon materials, biosensors, bioelectronics and pharmaceuticals, Malaysia has interest on alloys and compounds along with carbon materials, and separation technology, Thailand put focus on molecular modeling, carbon materials and, biosensor and finally classified 612 papers in different categories - but again, failed to classified the safety and risk issues. These reiterate the importance of re-visiting the issue of risk and safety in ASEAN context.

3. NANOTECHNOLOGY DEVELOPMENT AND RISK AND SAFETY INITIATIVES IN ASEAN COUNTRIES.

This paper is developed mainly on secondary sources collected from the websites of government bodies or nanotechnology authorities of the six ASEAN countries. These countries are selected based on the records as compiled in the Iranian National Statistics page on nanotechnology, StatNano (INIC, 2014) and the patent information from the United States Patent and Trademark Office (USPTO), which is also included in the StatNano website. Only 6 ASEAN countries i.e. Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam are considered and for the obvious reasons of non-availability of a considerable amount of information. This paper does not consider nanotechnology development in the context of Brunei, Myanmar, Cambodia and Laos PDR.

Nanotechnology Regulatory Document Archive (NRDA) developed by the Arizona State University was consulted and no documents for these countries could be found except one single document on Thailand (ASU 2014). Azonano (2014) developed a list of suppliers from countries around the world and the latest data shows that from the ASEAN region, Singapore is the leading country with 24 suppliers, Malaysia and Thailand have 5 suppliers each, 3 suppliers are listed from Vietnam and 1 from Indonesia. There is no supplier from five other member states of ASEAN i.e. Brunei, Cambodia, Myanmar, Philippines and Laos PDR. Whereas the database of Project on Emerging Nanotechnologies developed by the Woodrow Wilson International Center for Scholars indicated 4 products from Thailand, 24 products from Singapore, 1 from the Philippines and 4 from Malaysia (Pen 2014). All these findings guide us to confine our focus only on these six countries.

The latest Human Development Index based on three basic dimensions of human development i.e. long and healthy life, knowledge and descent standard of leaving released by the UNDP, Singapore with 0.895 points [18th in world ranking] and Malaysia with 0.769 points [64 in world ranking] are listed as high human development country, Thailand with 0.69 points [ranked 103] and Philippines with 0.654 points [ranked 114] are listed as medium human development country, Indonesia with 0.629 points [position 121] and Viet Nam with 0.617 points [position 127] were listed as low human development country (UNDP 2013). Simultaneously, based on the research publications of 165,020 original articles in ISI indexed journals between 1991 to 2010, Nguyen and Pham (2011) classified Singapore in group one, Thailand and Malaysia in group two, Viet Nam, Indonesia and the Philippines in group three with medium number of publications and the rest four countries of ASEAN i.e. Cambodia, Laos, Myanmar and Brunei in group four with lowest number of publications. Interestingly, this categorisation also reflects that these 6 countries primarily give due attention to scientific development.

It has been shared initially that these 6 ASEAN countries have taken many initiatives towards achieving a leading position in nanotechnology R&D and have already adopted some strategies relating to nanotechnology and most of these strategies include safety related provisions. The summary of the findings in this section is presented in Table 1. In this segment the risk and safety issue and research relating to nanotechnology in these 6 countries, with references to the respective strategy papers will be the issue of consideration.

Countries	ISI Publication related to Nano [From 2000-Feb, 2014] (INIC 2014)	R&D expenditure	Patent per 100 nano- articles in USPTO [2009- 2013] (INIC 2014)	Policies related to Nano	
Singapore	14290	SGD 20 million per annum (SNG Gek Khim 2008)	45.44	-	
Malaysia	4407	MYR 3640 million (MNA 2012)	5.87	National Nanotechnology Statement	
Thailand	3202	Annual budget of USD 11 million (Songsivilai 2013)	8.12	The National Nanotechnology Policy Framework (2012-2021), The Nanosafety and Ethics Strategic Plan (2012 – 2016),	
Philippines	141	PHP 2.5 billion (Villafania 2009)	-	Ten Years Nanotechnology Roadmap 2009.	
Indonesia	346	USD 100,000 (in 2005)	12.18	-	
		IDR 265 billion (in 2010) (Ariffahmi 2009)			
Vietnam	1000	VND 5 billion	5.03	National Strategy of	
		(Khoi and Minh 2009)		Science and Technology Development	

Table 1: Summary of the initiatives by selected ASEAN countries towards achieving a leading position in nanotechnology R&D.

3.1 Singapore

Singapore is very prospective for nanotechnology investment and its competence in nanotechnology R&D has been projected in a number of research (Hassan et al. 2012; Nguyen and Pham 2011). The country does not have any national strategy on nanotechnology, albeit it has already been acclaimed by the OECD that it is specialised on nanotechnology related patenting activity. In fact, during 2004 - 2006 period, the country obtained nearly three times the average share of all nanotechnology patents (OECD 2009). By initiating such endeavours, the country has established a new trend to achieve global leadership even without broad national nanotechnology policy (Matsuura 2006).

The country is the member of OECD Working Party on Manufactured Nanomaterials, ANF, ISO TC 229, IEC/TC on Nanotechnology. There is a working group for ISO/TC 229 and IEC/TC 113 on Nanotechnology under the Chemical Standards Committee of the National Standardization Program.

It has been estimated that 750 researchers in the National University of Singapore and 90 faculty members in Nanyang Technological University (NTU) are actively involved in nanotechnology research. The industry in the country has been growing at a rate of about 8% to 21%, and the number of companies dealing with nanomaterials increased by three times in the last three years (IEC, 2014). With the current number of 41, the country spends SGD 20 million per annum for R&D and human resource development in Nanotech (SNG Gek Khim 2008). Singapore Economic Development Board (EDB Singapore) estimated that there are 50 companies and 1000 researchers, scientists and engineers are currently working in Nanotech industries. The Nanoscience & Nanotechnology Initiative of Singapore National University (NUSNNI), established in January 2002, have been investigating the environmental and health implication of gold nanoparticle using in vitro model, but there has not been any research yet on human health and safety aspect (NUS 2014). There are consortiums and partnership platforms like Industry Consortium on Nanoimprint (ICON) and Nanotechnology in Manufacturing Initiative (NiMI)

and some Centers of Excellence like the Singapore Graphene Research Center at NUS and Energy Research Institute at NTU. The Workplace Safety and Health Institute drafted a Research Agenda for Singapore for 2011-2016, where under the category of new technologies, the study of risk management and safety issues relating to nanotechnology was placed under research theme 2, i.e. research on workplace safety and health risks and solutions. However, this is still a matter of fact that the experts of Singapore are still in favour of concentrating on the benefits and needs than the safety issues compared to the experts of Europe and Australia (Gupta et al. 2013).

Singapore has completed the NanoSafety Survey, which was jointly commissioned by the Ministry of Manpower and EDB Singapore and administered by NanoConsulting (NanoConsulting 2010). It was found that the country uses a very small amount of nanomaterials, i.e. not even one kilogram, and the organisations which were studied are keen to know more details about nano-specific safety measures. Only 26% of the respondents claimed to have the availability of the state-of-the-art nanosafety measures and out of the rest of the respondents, 5% did not consider the issue of nanosafety as an immediate issue of concern, 16% did not have enough knowledge on this issue and 53% were in search of effective nanosafety measures which can be implemented in their company.

3.2 Malaysia

Malaysia proclaimed its national vision, i.e. *Vision 2020* in 1990 with the goal of attaining the status of a developed nation by the year 2020. To that end, Malaysia aspired to be one of the top 10n nanotech nations and took the initiative in 2001 with a mission for sustainable national development of science, technology, industry and economy (Hashim et al 2008). The Intensification of Priority Research Areas (IRPA) programme of the Eighth Malaysia Plan,² which is administered by the Ministry of Science, Technology and Innovation (MOSTI), identified nanotechnology as one of the 14 research priority areas. Up to 2005, Malaysia spent

 $^{^{2}}$ Malaysia Plan is an economic plan developed by the Government of Malaysia. It span s for a duration of five years. For example, the Eight Malaysia Plan covered the economic development between 2001 and 2005.

more than MYR 140 million IRPA grants on different projects on nanotechnology (TheSunDaily 2005).³ The government allocated MYR 1 Billion under the Eighth Malaysia Plan and MYR 2.5 Billion under the Ninth Malaysia Plan (MNA 2012) and intended to increase the amount significantly in the Tenth Malaysia Plan.

With the hope and aspiration to be high-incoming country by the year 2020, the government has identified 12 National Key Economic Areas (NKEA). Under these 12 NKEAs, till date 159 Entry Point Projects (EPP) were identified, and the "EPP 20: Enabling Industries through nanotechnology" is placed under electrical and electronics industry (E&E), which is very significant sector in terms of export. This sector contributed 41% of Malaysia's total exports in 2009. It is estimated that this EPP 20 will add gross national income of MYR 1,247.9 million and will create new job opportunity for 798 people.

The government of Malaysia has established a National Nanotechnology Directorate (NND) and launched the National Nanotechnology Statement (MNA 2012). Besides, significant advancement in the field of nanotechnology in Malaysia can also be noticed. Around 15 universities established well-equipped nano science centers. The government has established a National Nanotechnology Directorate and National Nanotechnology Initiative (NNI), Malaysia with the vision of "nanotechnology for sustainable national development of science, technology, industry and economy". The government has also incorporated nanotechnology as a national priority in the Ninth Malaysia Plan by the Cabinet and proposed the establishment of the National Nanotechnology Centre by the MOSTI (Bernama 2011). Moreover, the government has published the National Nanotechnology Statement in July 2010 where the Fourth theme in the statement is to 'uphold regulations and acts' relating to nanotechnology.

Hashim et al. (2008) studied the nanotechnology development status in Malaysia from industrial strategy and practices perspective and successfully identified some of the strengths, weaknesses,

³ Deputy Prime Minister Datuk Seri Najib Abdul Razak (as he was then) during inauguration of the Malaysia Nanotechnology Forum 2005 and the Annual Fundamental Science Seminar at the IbnuSina Institute, University Teknologi Malaysia (UTM).

opportunities and threats of nanotechnology in Malaysia. But this is understood that being scientists, though they shared the prospects of nanotechnology in health and medicine, they failed to consider the risk and safety issues relating to nanotechnology. Even though the infrastructure and facilities for nanotechnology are not adequate, seven factors i.e. external forces, human resource, technical issues, internal issues, technology partnership, knowledge and culture influenced the country towards nanotechnology drive (Elley Nadia 2009).

The Department of Occupational Safety and Health of the Ministry of Human Resources of Malaysia developed a manual of recommended practices in 2000 to assess the health risks arising from the use of hazardous chemicals in the workplace (DOSH 2000) and suggested 10 steps to follow. However, it should be realised that the manual was prepared at a time when the issue of nanotechnology was not in a much developed stage.

Few highly well-equipped nanoscience/nanotechnology research centers were already established in different universities e.g. the Ibnu Sina Institute for Fundamental Science Studies (IIS), Universiti Teknologi Malaysia, Institute of Microengineering and Nanotechnology (IMEN), Universiti Kebangsaan Malaysia, Advanced Materials Research Centre (AMREC) of SIRIM Bhd and the Combinatorial Technology and Catalysis Research Centre (COMBICAT), Universiti Malaya. Though the government has established a number of Centers of Excellence in the country the latest report from the Academy of Sciences of Malaysia reveals that none of the Center of Excellence (CoE) considers the issue of nontoxicity and environmental toxicity and there is no guideline on safe handling of nanomaterials (Akademi Sains Malaysia 2013).

Pertinent to mention here that the Standards Malaysia, the national department of standards, formed a TC on Nanotechnology and there is also a Working Group on the Health, Safety and Environmental Aspects of Nanotechnologies (WG3) under its Industry Standards Committee (ISC B). The country has participated in the ISO/TC 229 on Nanotechnology and IEC/TC 113, Nanotechnologies Standardization for Electrical and Electronics Products and System (Standards Malaysia 2009).

3.3 Thailand

Thailand can be seen as the ASEAN leader in terms of nanosafety programs since it has taken a number of initiatives and to this end, has already taken strategy, framed different guidelines, established Nanosafety Information Center etc. The government nanotechnology initiative was formally triggered with the visit of former President Thaksin Shinawatra at the National Science and Technology Development Agency (NSTDA) in Thailand Science Part in December 2002 with his order to the authority of the NSTDA to investigate the prospect of establishing a national nanotech center (Tanthapanichakoon et al. 2009).

In 2007, Thailand took a National Strategic Plan for nanotechnology with an allocation of THB 300 million with an intention to earn 1% of countries GDP i.e. US\$ 3 billion by 2013. Even with huge investment in nanotechnology R & D, initially shortage of researchers and scientist were identified as problems (Sandhu 2008). As of 2010, there were seven associate centers with about 400 researchers, with aims, *inter alia*, to raise health and environmental stands of international levels and to take lead in ASEAN in nano-based education and R&D.

The cabinet on 11 September 2012 approved the National Nanotechnology Policy Framework (2012-2021) for 10 years with the objectives of enhancing the competitiveness, quality of life and sustainable development and promoting Thailand as a leader in nano-education and nano-researches among ASEAN countries. The Ministry of Science and Technology and relevant agencies will be implementing this policy framework (MOST 2012).

In the Policy Framework, the country identified four clusters i.e. health and medicine, food and agriculture, manufacturing industry and energy and environment. There are also eight targeted industries from these four clusters i.e. food and agriculture, electronics, automotive, textile, chemicals/petrochemicals, health and medicine, SMEs/Community and energy and environment. The Policy Framework further identified seven products where the country can claim its competence i.e. nanosensors, nanoelectronics, drug delivery system, nanocosmeceuticals,

nanocatalysts and Nanofiltration Materials, Nano Coating Materials and Functional Nanostruture. The Policy Framework realised that the issue of management e.g. improvements of quality, standard, safety and ethical system for quality of life and wellness is important to improve the enabling factors at the fundamental level.

The country specified five strategic intents to achieve the three main goals, and the first strategic intent is the utilisation of nanotechnology for the improvement of quality of life, health, medicine and public health. In order to ensure this intent, the country set a goal, *inter alia*, to develop a management system and guidelines for nanosafety and nanotechnology applications. Hence, the strategy was stipulated to provide knowledge and mechanism for nanotechnology in safety, monitoring, ethics and standards. In this regard, (a) efficient mechanisms for the management and dissemination of knowledge on safety and ethics will be provided, (b) the activities of the national committee on nanotechnology safety and ethics will be supported, and (c) the quality control, standards and safety of nanoenabled products will be improved.

The country has established a National Nanotechnology Center (NANOTEC) within the NSTDA, which has boosted up the nanotechnology R&D in the country (Charinpanitkul et al. 2008; Tanthapanichakoon 2008). Furthermore, in the Thailand Science Park, there is the NANOTEC Central Laboratory and within this Laboratory, a Nano Safety and Risk Assessment Laboratory was established. Moreover, the Center has been arranging different programs to make citizens aware of nanotechnology and its application with the assistance of the Public Awareness and Training Section of NANOTEC and Teacher Training of Nanotechnology Network (TTN). With such programs the, organisers inform students about different safety aspects of nanotechnology. The NANOTEC, in collaboration with the United Nation Institute for Training and Research (UNITAR), has initiated a pilot project on nanosafety in the country.

The country has further adopted the Nanosafety and Ethics Strategic Plan (2012-2016) (NSTDA 2012), focusing on three strategies i.e. (a) knowledge creation and management relating to nanosafety and nanoethics, (b) development and improvements of supervision and enforcement

mechanisms and (c) promotion of public participation. Before finalising the plan, the National Nanotechnology Center (NANOTEC) arranged a public hearing session, which is very positive and significant in this region as citizens were included within the process (Dalton-Brown 2012). The Nanosafety and Ethics Strategic Plan (2012-2016) is summarized in Figure 3.



Figure 3. Thailand's Nanosafety and Ethics Strategic Plan (2012-2016) (NSTDA 2012).

The country has already established the Nanosafety Information Center of Thailand (NICT) and further prepared three Nanosaftey Guidelines i.e. for (i) factory workers, (ii) university researchers, (ii) for general public (Tanasugarn 2012). Apart from these guidelines, there are at least three laws which can be interpreted to consider nanosafety issues, i.e. the Hazardous Substance Act of BE 2535 of AD 1992, the Enhancement and Conservation of National Environmental Quality Act of BE 2535 of AD 1992 and the Labour Protection Act of BE 2541 of AD 1998.

Besides, it has been reported that the country has been working to introduce a voluntary Nano Mark, i.e. NanoQ, a label to inform the customer about the possible existence of nanoparticle and the mark will initially be introduced in paint, textile and household products. This is undoubtedly a significant breakthrough in the context of Asia as this will serve multi-purposes for the consumers, manufactures and the regulators. A paint formulation production company named Supreme Products Co. Ltd. was given the first Nano Q Label Certificate on 27 September 2012 for two years and the company will have to renew the certificate after two years. The National Nanotechnology Association will be collecting samples of products from the market to monitor the production of the product. The Nano Q label is illustrated in Figure 4.



Figure 4: The Nano Q label (NSTDA 2011).

The Food and Drug Administration of the country has released a 61 page booklet on nanosafety in national language with pictures and illustrations for officials, entrepreneurs and academics (FDA 2011), and Ministry of Industry formulated a Guideline on Safety in Working with Nanotechnology (Tanasugarn 2012). These are undoubtedly great efforts to make citizens aware of nanotechnology and its associated safety issues in the national language as they are the ultimate stakeholders of nanotechnology.

3.4 The Philippines

Of all the 6 countries considered in this paper, the Philippines is the newest member to join the revaluation powered by nanotechnology. It has started its formal move in this regard since 2009

through the adoption of the 10 years Nanotechnology Roadmap. However, it has been reported that in 2003, at least 6 working groups were working on nanotechnology (Maclurcan 2011). The Department of Science and Technology (DOST) with its concerned agency i.e. the Philippine Council for Advance Science and Technology Research and Development adopted the roadmap with a proposed budget of PHP 2.5 billion and it has attached significant priority on nanotechnology R&D and formed a multi-disciplinary group.

Being the newest member, the country could spell out emphatically the importance of safety issues relating to nanoparticles or nanomaterials. Five areas for the application of nanotechnology i.e. ICT and semiconductors, energy, agriculture and food, medicine and environment were specified and health and environmental risk were identified with score (1=High and 5=Low). For example, while sharing the prospect of nanocatalysts for combustion, smart delivery systems in agriculture and food, nanodiagnostics (in vitro, ex vivo), nanoimaging (in-vivo), Nanoprobes (in vivo), it has been identified that the health and environmental risk in these categories are high (score 1). For environmental remediation and treatment, the risk is almost high (score 2), and for food packaging, nanosensors, plant and animal breeding, environmental sensors, green materials (including forest products), the risk is in between high and low (score 3). Moreover, the nanotechnology roadmap spells out the importance of health and environmental risk and puts emphasis on public education, public engagement, needs of public, establishment of a nanotechnology clearing house and parallel research on the health and environmental risks of nanotechnology products, life-cycle assessments, and societal impacts. Furthermore, as per the roadmap, the country formed one study group on Health and Environmental Risk (Dayrit 2010). This is obvious that the country is still in its initial stage and even in such stages its realisation as to risk and safety identification and forming of the working group are really praiseworthy.

3.5 Indonesia:

The fourth largest country in the world - Indonesia - was a country in transition when its ASEAN neighbours triggered the nanotech race. In the absence of any government policy or government funding, the nanotechnology venture started in Indonesia through universities and research center, e.g. with the University of Indonesia in 2001 (Wahyuni et al. 2011) and later on with the establishment of Indonesian Nanotechnology Profession Society (Masyarakat Nanoteknologi Indonesia), the Indonesian Nanotechnology Profession Society 2005 by the Research Center for Physics of Indonesian Institute of Sciences (LIPI) and State Ministry of Research, Science and Technology of Indonesia. The Mochter Riady Center for Nanotechnology and Bioengineering which was privately established in 2004 has a great contribution in the development of nanotechnology and the government adopted the nanotechnology development roadmap in 2006 (Rochman and Brama 2009). In 2005, the government allocated USD 100,000 for nanotech R & D and a good number of researches have already been undertaken and obviously the issue of risk and safety with nanotechnology were not a priority and were not considered in any of these projects. Simultaneously, very recently in 2010, the government allocated IDR 265 billion (USD 28 million approx.) for nanotech R&D. A significant increase in government funding is evident from different statistics. The country undertook a detailed plan and adopted a number of projects for nanotechnology R&D, however, it can safely be said from reading in the chapter by Rochman and Brama (2009) that the issue of risk and safety is not at all a concern for the country.

3.6 Vietnam

Professor Nguyen Van Hieu as the President of Vietnamese Physical Society in 1987 while channeling his dream to the participants of the third Conference on Solid State Physics to develop Nanoscience, nanomaterials and nanotechnology (Hong 2011), shared an overview of prospects of nanotechnology R&D in Vietnam. However, it is found that the process nanotechnology R&D started in the country from 1992 and the country joined Asia Nano Forum

in 2002 (Maclurcan 2011). The nanotechnology journey in Vietnam started officially in December 2003, when the Prime Minister signed the National Strategy of Science and Technology Development for the country until 2020, where nanotechnology was targeted as one of the high priority fields, with the allocation of VND 5 billion (USD 0.35 million) (Khoi and Minh 2009).

The absence of the country in biotechnology industry triggered the National Assembly of Vietnam to concentrate on nanotechnology (Maclurcan 2011). From 2004, the government of Vietnam planned to establish a total of 17 National Key Laboratories in different parts of the country with VND 3-4 million for each. It was claimed that some of these laboratories have started operations and some of these laboratories have been focusing on Nanotech R&D. The government has also established two high tech parks i.e. the Saigon Hi Tech Park (SHTP) and Hoa Lac Hi Tech Park (Nguyen and Van 2010).

The International Journal of Nanotechnology published a Special Issue on Nanotechnology in Vietnam [2011, Vol. 8 No. 3/4/5] and a total twenty papers were included in the Special Issue. An analysis of the keywords and abstracts of all these papers compel to draw a conclusion that the issue of risk and safety is not a prior concern, at least at this stage, for the country.

In the database of Asia Nano Forum, there listed a total of 14 Government projects and Khoi and Minh (2009) shared a total of 9 large scale government research projects on nanotechnology in between 1999-2010. It is a matter of fact that none of the projects focuses on nanosafety and risk issues, which gives a clue that comparing to the investment in nanotechnology research, the country opted to concentrate on basic research till date. However, it is very significant to share that the government has given serious attention on nano education from 2003-2004. Khoi and Minh (2009) claimed that the objectives of these courses are to ensure the multidisciplinary characteristics of the programs from theoretical and practical aspects and listed the names of at least 17 courses offered by different institutions. However, looking at the names of the courses it can be inferred that the focus is only on technical aspects of the course.

4. NANOSAFETY AND ASEAN COUNTRIES: AN EVALUATION AND OPTIONS FOR IMPROVEMENTS

From the discussion made above, this is obvious that these 6 ASEAN countries have rightly realized the importance of investment in nanotechnology R&D.

1. Absence of specific guidelines:

None of these ASEAN countries can be considered as purely civil or common law countries - rather they are having a mixed legal system. In the absence of codified laws, the relevant government strategies can be found in policies, guidelines, or recommendations 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. From the discussion made above, it is clear that except Thailand, the other five countries are not considering seriously the issue of safety, at least it is not documented, though there are some isolated initiatives e.g. company survey conducted by Singapore, jotting down of nanosafety in the 10 year Nanotechnology Roadmap of the Philippines, etc. This is obvious that such initiatives are not sufficient at all comparing to the total amount of investment in nanotechnology in these countries. Therefore, this is suggested that these countries should at least adopt some guidelines from among the list shared above towards safe handling of nanoparticles and nanomaterials.

2. Assessment of Adequacy of Existing Legal Framework

It is accepted that these countries have many laws in force at the national level on environment, health, labour, chemical, hazardous substance etc. and this is a high time to check if the existing laws are sufficient enough to handle the nano risks. Most of the countries in Europe, USA, Australia and New Zealand have already completed such assessment (Frater et al. 2006; Executive 2006; Ludlow 2007; Gavaghan and Moore 2011; Moore 2012). Now these ASEAN countries should take similar endeavor and such attempt of the regulators will give comfort to the

stakeholders to use the nanoenabled products and will allow them to decide whether they will welcome nanotechnology at the national level or not.

After the assessment, if it is found that these countries do not need an immediate new law -they can opt to adopt some guideline, policy, standard or code. Again, the rule of interpretation may come into the scene that these are not judicially enforceable and not judicially binding (Schwartz et al. 1999). In 1974, the government of Malaysia issued one Guideline i.e. "Guidelines for the Regulation of Acquisition of Assets, Mergers and Take-Overs" which prohibited the acquisition of the property value over MYR 5 million by any foreigner without the prior approval of the Foreign Investment Committee's (FIC). In the case of Thong Foo Ching & Ors v Shigenori Ono [1998] 4 CLJ 674, the Court of Appeal examined the legality of the guideline. The court found that the Guidelines imposed moral obligations on the aggrieved. Non-compliance of these Guidelines "can be used as a means of refusing to exercise a discretion, a purely administrative act..." The non-compliance or avoidance of the Guidelines did not render any agreement to be invalid or unenforceable.⁴ These guidelines and policies do not have a strict legal effect as the FIC is a government department and not a statutory authority, meaning that any guideline issued by any statutory authority will have legal effect (Ngan 2008). The Guidelines are not a substitute of domestic law and regulations, passed either by the parliament or the government agencies in a way of subordinate legislation, nor they have the overriding effect. However, adopting such guidelines will at least manifest the positive intention of the relevant authority. On the same Guideline, Balia Yusof J in the case of Brett Andrew Macnamara v Kam Lee Kuan, [2008] 2 MLJ 450, held that, "the guidelines and policies issued by the Foreign Investment Committee are meant for the general wellbeing of the Malaysian citizen. It protects the general public interest and safeguard the public welfare. A breach of these guidelines will be injurious to the public welfare." Taking into account this interpretation, the government can adopt some guidelines on safe handling of nanomaterials and nanoparticles and this will be the starting towards governing nanotechnology.

Needless to share again that nanotechnology offers unlimited benefits in almost every sector of

⁴ Zaifa Otomobil Sdn Bhd v Sarju Khetshi Popat and Anor, [2009] MLJU 662

human need. For that reason the best of it should be utilized for the betterment of mankind. The regulators have to make a balance between the ongoing research activities and the risk and safety issues. Moreover, this is agreed that even though in a number of instances though the environment, health and safety concerns associated with nanotechnology are shared, the actual risk is yet to be confirmed. Taking into account the regulatory developments with other emerging technology, e.g. biotechnology, information and communication technology, etc., this is important to take some long term initiatives or programs, some of which are shared below.

3. Sectoral guidelines on nanosafety

The most important of all is to realise the importance of health and safety aspects of handling nanoparticles and once realised, the provisions should be included in the national strategy or roadmap, etc. Next, the national focal point like NND in Malaysia, NANOTEC in Thailand should develop a database of companies, research organisations working with nanoparticles along with the particle they have been working. This is because different database developed by different organisation like Azonano, PEN, ANF give different data on companies, etc. Therefore, when the national focal point will provide data that will be more authentic. Then the risk and safety aspects of nanoparticles used by different organisations at the national level can be assessed on the basis of findings of different research. The regulator should conduct research on the companies working with nanoparticles. In September 2011, a group of researchers from the 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 nanospecific EHS programs and 13% do not have any such programs (Engeman et al. 2012). 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 (Engeman et al. 2012). A similar survey was conducted in Singapore, which was jointly commissioned by the Ministry of Manpower and Singapore Economic Development Board and administered by NanoConsulting (NanoConsulting 2010). Now the other five countries can follow this. Furthermore, such database will allow the national focal points to monitor the activities of the organisations. This monitoring is not to control the organisations rather this is for the overall benefits of the stakeholders.

4. Introduction of Reporting System

After that, the reporting system can be introduced where the companies and organisations dealing with nanoparticles will report to the national focal point as to the type and amount of nanoparticle they have been using. Initially, such reporting system can be voluntary. Even though, such voluntary system was not successful in a number of instances i.e. in UK, but that will be more desirable in the context of these 6 ASEAN countries. However, some incentive can be offered such as companies which report voluntarily will get some benefits from the government. Once the voluntary reporting becomes successful, then mandatory reporting can be considered. Such practice is already implemented in France, Belgium and Denmark.

There are already existing legislation on chemical and pesticide, worker's safety, occupational health, environment, product liability, food, water etc. in most of the countries, including these 6 ASEAN countries, but there is no specific and comprehensive regulation on nanotechnology so far. One of the main problems faced by the regulators is to define the 'nano' scale and this definition is crucial in regulating nanotechnology. If consensus can be reached on the definition of nanomaterial at the international level, it will solve many problems for the regulators. It will ease the job of the regulators to decide whether the existing municipal law is sufficient or new legislation is required. However, the leading vocal in defining 'nano' scale, Andrew Maynard who was advocating for defining 'nano' has changed his mind and feels that 'the definition of one size for all' will not be working in case of nanotechnology (Maynard 2011). Pertaining to mention here that some of these 6 countries have realised the importance of defining 'nanoscale' and moving closely with ISO/TC 229 (where Singapore and Malaysia are participating countries and Thailand is an observer) and IEC/TC113 (where Malaysia is the participating member and Indonesia and Singapore are the observer countries).

For the research organisations, companies, and different universities in these 6 ASEAN countries, 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, which can also be considered - taking into account the socio-

economic - 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', fostered by the International Council on Nanotechnology (ICON) which contains resources on occupational health and safety and risk management and assessment (GoodNanoGuide 2014). This site specially includes an OHS Reference Manual, which can be considered too (GoodNanoGuide 2014).

5. Database Development on Research Findings

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 (Hankin et al. 2011). The platform of the ANF can be used in this regard.

6. More Research on Nanaosafety:

There is no alternative to conduct more research on safety aspects of nanotechnology and hence more budgets should be allocated for research focusing on the safety and health implications of nanotechnology. This is a matter of great concern that even the major economy like USA spent 6% of the federal nanotechnology funding in safety research and China spent only 3% (Qiu 2012). The allocation of the total budget for the nanotechnology R&D and environment, health and safety budget in the USA for the last 6 years (2007-2012) is shared in Table 2.

Table 2: Allocation of Budget in EHS Research in Nanotechnology in USA (Sargent 2013)

Year	2007	2008	2009	2010	2011	2012
Total [in USD Million]	1424.1	1554.4	1701.5	1912.8	1847.3	1857.3
EHS [in USD Million]	48.3	67.9	74.5	90.2	88	109.9
Percentage [%]	3%	4%	4%	5%	5%	6%

Based on the information in Table 2, it can be revealed that in EHS research consumed a very small amount i.e. between 3 and 6% of the annual budget for the 2007-2012 period.

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. In South Korea in the construction industry, a special amount of budget has to allocate for safety research. Nanotechnology industry should consider to adopt such practice as well. Besides, when the spending of research budget is an issue, more focus should be given on the assessment process to avoid uncertainties as to nanomaterials (Grieger et al. 2009). Such efforts will help to avoid unnecessary fear and tension as to safety concerns of nanoparticles based on perceived risks.

Very recently on December 20, 2013, the US National Institute for Occupational Safety and Health (NIOSH) published a document to be used as roadmap to advance basic understanding of the toxiocology and workplace exposure to implement appropriate risk management practices during discovery, development, and commercialisation of engineered nanomaterials (NIOSH 2013). Furthermore, in the USA, a number of initiatives were taken to introduce new law or to insert amending provisions in the existing laws (Sargent 2013). Interestingly, there is an association of legal community called the ASEAN Law Association, an organisation of legal professionals i.e. judicial officers, faculty members, legal practitioners and government attorneys, established in 1979, that can be a good forum to discuss the legal issue related to risk and safety of nanotechnology based on the existing findings of different research published in

world's leading scientific journals.

6. CONCLUSION

This paper attempts to share the development of nanotechnology in the 6 ASEAN countries i.e. Singapore, Malaysia, Thailand, Indonesia, Philippine and Viet Nam. Some of these countries like Singapore and Malaysia have achieved remarkable developments in technological aspects of nanotechnology. However, these countries are not exceptional considering their western counterpart where the developed economies like USA, European Union and Australia are slow in action to address the human health risks arising out of nano ingredients available in hundreds of products (Miller and Scrinis 2011). All huge investments will be meaningless unless EHS issues and public perception cannot be handled as these are few of the main challenges as noted towards the smooth development of nanotechnology by the OECD (Palmberg et al. 2009).

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

There are some distinctive features of nanotechnology R&D and safety research in these 6 ASEAN countries. Of these 6 countries, even without a national strategy, Singapore is leading in terms of research publications and patents. Thailand is very keen to take a lead in ASEAN region and in the process of introducing a nano mark system for the paint, textile and household products. This is undoubtedly a ground breaking system as this will provide safety related information to the consumer. The wonderful part of this nano mark is that such mark will be issued to and will have to be renewed by any company every two years and the regulators will be collecting samples from the market regularly. Besides, the country has already adopted nanosafety related strategies, guidelines and set up a Nanosafety Information Center. Vietnamese

policy makers are also very active to realise the benefits of nanotechnology as they missed the opportunity to utilise biotechnology. The Indonesia nanotechnology activities are evolved around different universities. The Philippines, the newest member to join the race, is more successful to include nanosafety related provisions in the national strategy more systematically.

Undoubtedly, the progress, growth and development of nanotechnology in these Asian countries rely mostly on how the countries are preparing themselves and in this course the public engagement in vital. The people should be made aware and the public should be involved in the development of nanotechnology in this region. The findings shared by Rogers et al. (2013) makes it clear that Asia should take a leading role in policy making as it has gathered a huge interest from the people and if the people can be included in the process, they will welcome the safe development of nanotechnology.

Allocation of more budget and country specific research as to risk, safety etc. are solicited. However, until such research can be completed, it is suggested that the countries should consider some good practices shared in this paper. This is good that except Singapore, all the countries considered in this paper have adopted some general policy or strategy on nanotechnology. However, having the nanotechnology policy or strategy at the national level is not enough – rather, a tool or measure should be included to evaluate the adequacy of the policy to meet the demand of the time (Soltani et al. 2011), and to make technology analysis to set future priorities (Schaper-Rinkel, 2013), which must include the safety issues.

ACKNOWLEDGEMENT

The authors would like to thank University of Malaya for funding this research under the Bright Spark programme. The authors are also indebted to Professor Ilise L Feitshans JD and ScM, Visiting Scientist at Institute for Work and Health University of Lausanne, Switzerland for her comments and inputs in the draft of the manuscript and Dr. Michael Riediker, Director of SAFENANO, Institute of Occupational Medicine (IOM), Singapore for his support at the initial stages of writing the paper on definition of nanosafety.

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