NATIONAL NANOTECHNOLOGY POLICIES IN MALAYSIA, EUROPEAN UNION AND UNITED STATES: A COMPARATIVE ANALYSIS

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Abstract. Nanotechnology development policy embodied crucial strategies that directly influence the output of nanotechnology products and services. At present, Malaysia as a developing nation is still in the early stages of nanotechnology development compared to the European Union (EU) and the United States (US). Both are regarded as the pioneers and leaders in nanotechnology especially according to their research and development (R&D) initiatives, product innovations, and commercialisation policies. This study analyses the nanotechnology development policies adopted in Malaysia in accordance with the EU and the US. The comparison is made based on six aggregated planning strategies for nanotechnology development policy. The comparative analysis reveals the convergences and divergences between the nanotechnology development strategies embodied in Malaysia's nanotechnology policies and the EU as well as the US. The strategies adopted by the EU and the US include the identification of strategic areas, identification of risks, and formulation of legal instruments. Notably, these three strategies are made silent and unperceived in Malaysia's nanotechnology development policies. The analysis provides a useful insight for future directions on strengthening Malaysia's nanotechnology development policies, paving the way to actively taking part in nanotechnology research and development as one of the global leaders.

Keywords: *national nanotechnology policy, nanotechnology strategy, science and technology, Malaysia*

Introduction

The 21st century witnessed an exponential increase of interest in nanotechnology development. Various industries such as engineering, agriculture, food industry, medicine, biotechnology, defence, automotive, cosmetics, and infrastructure have adopted nanotechnology (Ciambelli et al., 2020). The integration of nanotechnology in these industries may resolve the demanding social issue including national innovation, job creation, and generating a continuous chain of wealth (Talebian et al., 2021). The widespread applications mainly stem from the unique, versatile, and novel physicochemical properties of nanosized particles having at least one dimension with a size of 100 nm or less. Moreover, the tiny particles have a large surface area to volume ratio with higher reactivity than their conventional bulk counterparts (Hulla et al., 2015).

Nowadays, nanotechnology is highly recognised as one of the key catalysts for economic growth. By the year 2027, the value of the global nanotechnology market is expected to exceed US$ 126.8 billion (GlobeNewswire Official Portal, 2020). The significant economic growth offered by nanotechnology has spawned governments and private sectors across the world to devise policies to strategise nanotechnology

development. Since 2000, many countries have formulated their own national nanotechnology development policies to stimulate the growth of research and development, innovation, and commercialisation (Ezema et al., 2014). In this regard, the nanotechnology policies and strategies had been used as tools to identify the major gaps in fundamental knowledge of matter and outline the economic applications anticipated for nanotechnology (Roco, 2011, Lederman, 1987). More importantly, by having a comprehensive and systematic policy, it had surely enabled a country to progress rapidly while achieving higher standards of science and technology as well as capitalising on the economic opportunity offers through products and services based on nanotechnology.

The United States (US) began an ambitious R&D effort in nanotechnology with the introduction of the National Nanotechnology Initiative (NNI) in 2000, and federal expenditure has surged from $220 million in 2000 to roughly $750 million in 2003, with a budget proposal of $982 million for 2005. In the case of the European Union (EU), it is estimated that public financing for nanotechnology R&D in Europe has increased from €200 million in 1997 to more than €1 billion now, with roughly two-thirds coming from national and regional programmes. Today, both countries are widely recognised as the global leaders in nanotechnology development with the largest share of the global nanotechnology market (Gao et al., 2016). However, Malaysia is still left behind in terms of gaining direct investment due to its lack a of nanotechnology development policy.

As a guideline, in 2011, the United Nations Institute for Training and Research (UNITAR) (2011) suggested that the design of a national nanotechnology development policy should incorporate aggregate planning or strategies. The policy should incorporate six strategies namely, (i) identification of strategic areas, (i.e., the priority areas for nanotechnology activities), (ii) the allocation of resources (i.e., financial mechanism), (iii) coordination between responsible agencies (domestic and international agencies), (iv) nano assessment (assessment of risks and benefits), (v) legal instruments, and (vi) nanotechnology action plan for implementation of nano programmes. That being said, this study analyses the adoption of these six nanotechnology development strategies in Malaysia, the EU, and the US's nanotechnology development policies. The EU and the US are chosen as both jurisdictions have been serving as a global model for other countries on nanotechnology development (Pisarenko et al., 2020). The analysis is essential to identify the pertaining gap in Malaysia's nanotechnology policy against the EU and US. It offers of the utmost importance recommendations for policy improvement.

Materials and Methods

The study adopted qualitative doctrinal research by analysing the nanotechnology development policies, literature from journals, government reports, and institutional websites. A comparative analysis was done of the nanotechnology development policies in Malaysia, the EU, and the US. For Malaysia, three policies were analysed namely, the National Nanotechnology Initiative of Malaysia (NNIM), NanoMalaysia Program, and National Policy and Strategy on Nanotechnology (NPSN). Similarly, three EU nanotechnology policies, i.e., Towards a European Strategy for Nanotechnology, COM (2004)338, Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009, (COM (2005)243), and Regulatory aspects of nanomaterials, COM (2008) 366,

were analysed. Meanwhile, the analysis for the US is only confined to the only nanotechnology development policy, National Nanotechnology Initiative (NNI). The analysis is to reap the convergence and divergence between nanotechnology strategies adopted by these jurisdictions and to identify the strategies that can be adopted by Malaysia. The recommendations are to improve and vitalise nanotechnology development policy which could further advance Malaysia's nanotechnology activities in the domestic and global market.

Results and Discussion

Nanotechnology in Malaysia

Advanced materials technologies including nanotechnology are one of the five (i.e., artificial intelligence, big data and cloud computing, blockchain, and internet of things) foundational emerging technologies prescribed in the National Fourth Industrial Revolution (4IR) Policy (MOSTI, 2021). In 2001, nanotechnology has been gazetted as a strategic research theme under the Research Focus in Priority Areas (IRPA) program (Hashim et al., 2009). In 2020, the revenue for the nanotechnology product market in Malaysia is worth RM322,307 million and is expected to steadily increase as nanotechnology serves as an integral technology to tackle Covid-19. The compound annual growth rate (CAGR) for the nanotechnology market between 2020-2025 is 10.9 per cent (Nano Malaysia Berhad, 2020).

Even though the market projection indicates nanotechnology application capabilities in Malaysia are improved, the adoption of advanced technology such as nanotechnology in the manufacturing and services industries is still low, at 37 per cent and 20 per cent respectively (Ministry of Economic Affairs, 2019). Hence, it remains relevant to compare nanotechnology development strategies and policies in Malaysia with those in developed countries. It is to identify the limitations and improve the current nanotechnology development framework. Such improvement will significantly extend nanotechnology application to various industries, enhance nanotechnology monetisation, and drive Malaysia as an advanced nation in the field of nanotechnology.

National nanotechnology policies in Malaysia

For the past 20 years, the Ministry of Science, Technology, and Innovation (MOSTI) have formulated three nanotechnology development policies, as listed in *Table 1*, i.e., the National Nanotechnology Initiative of Malaysia (NNIM), NanoMalaysia Program, and National Policy and Strategy on Nanotechnology (NPSN). NanoMalaysia Program and NPSN laid down the ten years of strategies for nanotechnology development. The following analysis offers a comprehensive insight into the adoption of six nanotechnology development strategies in the existing policies

Table 1. *Nanotechnology policies in Malaysia and the relevant strategies.*

Policy	Purpose/objectives	Identification of strategic area	Allocation of resources	Coordination between agencies	Nano assessment (risk and benefits)	Legal instrument	Nanotechnology action plan
National Nanotechnology Initiative of Malaysia (NNIM) 2006 (Hamdan, 2013)	The objectives of NNIM are: -To coordinate and plan the research and development activities; -To prepare a platform for commercialisation and transfer of new technology to generate economic; -To develop educational resources, skilled labour, expertise and infrastructure; -To provide facilities and research support services.	No strategic area identified for nanotechnology development activities.	No provision for the allocation of funds.	Agencies established under NNIM: -National Nanotechnology Centre (previously known as the National Nanotechnology Directorate) -Nano Malaysia Berhad -NanoMalaysia Center	No discussion on benefits and risks assessment.	No legal instrument.	No action plan introduced.
NanoMalaysia Program 2011-2020	The initiatives of NanoMalaysia Program are: -to formulate a strategic action plan, roadmap, and commercialisation framework; -to formulate a national nanotechnology policy; -to provide top-down R&D grant (NanoFund); -to monitor the development of NanoMalaysia Centre (NMC); -to incorporate NanoMalaysia (NanoMy) Berhad.	Prescribed the strategic areas but the area were not gazetted.	No provision for the allocation of funds.	Agencies estabilised under NMP: -Nano Verify Snd Bhd	No discussion of benefits and risks assessment.	No legal instrument	Three action plans have been formulated: -Advanced Materials Industrialisation Programme -National Graphene Action Plan 2020 -iNanovation 2020 (Nano Malaysia Berhad, 2020).
National Policy and Strategy on Nanotechnology (NPSN) 2021-2030 (MOSTI, 2021).	Nanotechnology strategies outline in NPSN: -strengthen nanotechnology ecosystem and	No strategic area identified.	No provision for the allocation of funds.	Agencies established under NPSN: -National Nanotechnology Laboratory Network.	NPSN identified risks and benefits assessment as crucial for nanotechnology activities	No legal instrument.	New action plan has not yet introduced under the NPSN as the policy is still new.

	governance; -prosper nanotechnology R&D; -increase nanotechnology commercialisation and drive the industry; -strengthen nanotechnology standards, safety and regulation.	

As illustrated in *Table 1*, the nanotechnology policies in Malaysia are silent on the identification of strategic or priority areas for nanotechnology development. The NNIM and NPSM do not have a specific stipulation on the identification of strategic areas for nanotechnology development. The NPSM only states that it is crucial to identify strategic and priority areas to drive and support R&D activities and the commercialisation of nanotechnology products and services. Meanwhile, the NanoMalaysia Program has listed seven high-impact strategic areas in nanotechnology R&D namely, nano delivery systems, nano detectors, nanomaterials, nanostructured materials, nano lab-on-chip, health, safety, and social environment of nanotechnology. However, the strategic areas were not gazetted as national nanotechnology strategic areas (MOSTI, 2021). The absence of strategic areas for nanotechnology R&D has caused a delay in achieving national nanotechnology goals, as there is no specific direction for R&D (MOSTI, 2021).

Besides, all the policies do not specify the allocation of resources, i.e., financing mechanisms, or funds. It is also silent on the total amount of funds allocated under each policy in carrying out nanotechnology activities. For instance, the NPSN only stipulates the need to establish specific funds to finance nanotechnology R&D and commercialisation projects. However, the government has allocated a seizable sum of money for nanotechnology activities since the launch of NNIM. The allocation can be classified into two categories: (i) specific funds for nanotechnology, and (ii) funds for science, technology, and commercialisation activities. First, it is for specific funds for nanotechnology. According to MOSTI, from 2008 until 2015, RM165 million has been allocated for nanotechnology R&D and commercialisation (MOSTI, 2021). In 2011, RM2.5 million was allocated to five nanotechnology Centers for Excellence (CEO) and RM 7 million was spent under NMP 2011-2020 for R&D grants (MOSTI, 2021). Second, funds for science, technology, and commercialisation activities, which shall include nanotechnology activities. In 2021, RM220 million were allocated for R&D, commercialisation, and innovation under the Strategic Technology Drive Fund (PEMACU) Program. The aim is to make Malaysia a high-tech nation. The availability of funding mechanisms from the government has assisted researchers in ushering new innovations into the marketplace.

Malaysia's nanotechnology strategy also involves comprehensive coordination between agencies. MOSTI has decided to establish specific agencies that are responsible for nanotechnology development in Malaysia. As stipulated in *Table 1*, four nanotechnology agencies, i.e, the National Nanotechnology Centre (previously known as the National Nanotechnology Directorate), Nano Malaysia Berhad, NanoMalaysia Center, NanoVerify Sdn Bhd, and one laboratory network (National Nanotechnology Laboratory Network) have been established under three separate nanotechnology development policies. Overall, these agencies were established to coordinate shape, integrate, promote, manoeuver, and commercialise nanotechnology activities and industry in a more progressive and dynamic way. The combined efforts resulted in various advances in the field of nanotechnology and have been successfully implemented. For instance, National Graphene Action Plan 2020 with 50 active projects, creating over 2,000 high-value employment opportunities including company revenue contributions of up to RM3 billion in the first five (5) years of commercialization (Life News Agency, 2021).

Nanotechnology is also known as a double edge sword where it offers benefits and risks. The strategy for nanotechnology must not only focus on the exploitation of

benefits but the potential risks should be monitored and regulated. The benefits and risks must be carefully assessed before placing nanotechnology products on the market. It is to protect consumers against scientifically uncertain risks and promote responsible nanotechnology development (MOSTI, 2021). The NPSN has adopted the assessment of benefits and risks as part of the strategy. Safety data for nanotechnology-based products in the local market must be collected. MOSTI has introduced a three-year project known as Benchmarks for Material-Based Safety Risks Nano 2020-2023 (MOSTI, 2021). On the contrary, the assessment of risk is not part of the strategy in the NNIM and NanoMalaysia Program.

Furthermore, Malaysia does not have specific legislation for nanotechnology. The strategies embodied in the policies exclude the enactment of legal instruments. The existing legislation enacted for conventional materials and without nano-specific provisions is used to regulate all nanotechnology development activities applicable to nanomaterials. The activities and potential risks of nanotechnology are regulated using a 'soft law' approach (Zainal Abidin et al., 2020). The NPSN highlights the need for a comprehensive nanotechnology legal framework to regulate the risks and promote responsible nanotechnology development. The strategy to develop a competitive and resilient nanotechnology development also involves the formulation of several nanotechnology action plans such as the National Graphene Action Plan 2020, National Nanotechnology Ecosystem, and Advanced Materials Industrialisation Programme, which have activated several nanotechnology projects connecting the industry and research community (Nano Malaysia Berhad, 2020). These action plans are essential for the rapid exploration of nanotechnology applications and economic benefits.

Nanotechnology in the European Union

In the EU, Nanotechnology activities started since the mid to late 1990s (Kozhukharov and Machkova, 2013) Between 1997 and 1999 the EU shared 32% of the global publication on nanoscience (European Commission, 2004a). Currently, the EU is still one of the leading nations in nanotechnology R&D, commercialisation, and innovations. Nanotechnology is also regarded as one of the key enabling technology for the European economy (European Commission, 2022a). The European Commission (EC), the European Parliament, and the European member states are committed to the progress of nanotechnology in various industries namely, chemicals, consumer products, health, energy, environment, food processing, and agriculture (Commission of the European Union Community, 2008).

According to the EC, nanotechnology is one of the fastest-growing markets in the EU. In 2015, the European nanotechnology market has generated revenue of $2,536 million. It is expected that in 2022 European nanotechnology market will reach $9,078 million with a CAGR of 20% (Sahu, 2016). A huge volume of nanotechnology products such as nanofood, coating, anti-bacterial clothing, cosmetics, and medicine are present on the European market (European Union Food Safety Authority, 2022). The following section discusses the nanotechnology development strategies adopted by the EU nanotechnology policies.

Nanotechnology policies in the European Union

The EC is the executive branch of the EU that is responsible to instigate and implement the EU's policies as well as drawing up proposals for new European

legislation (European Commission, 2022b). The EC issues varieties of communications in the form of policy evaluation brief outline on future policies or arrangements concerning details of current policy (European Union Monitor, 2022). The EC communication is not binding and has no legal effects, but it embodied EC opinions, views, and suggestions on nanotechnology development in the EU. As listed in *Table 2*, the EC has formulated three communications on nanotechnology development, i.e., Towards a European Strategy for Nanotechnology, COM (2004)338, Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009, (COM (2005)243), and Regulatory aspects of nanomaterials, COM (2008) 366 def. Other than communications, the EC also issued two recommendations on nanotechnology, i.e., the European Commission Code of conduct for responsible nanosciences and nanotechnologies research, COM (2008)424 final and Recommendation on the definition of a nanomaterial (2011/696/EU). This study only analyses the nanotechnology development strategy adopted in three EC communications on nanotechnology. The EC communication Towards a European Strategy for Nanotechnology 2004 identified the strategic areas for nanotechnology development for the EU. It consists of seven strategic areas namely, medical applications, information technologies, information technologies, energy production and storage, material science, instrumentation, manufacturing, and food, water, and environment. Meanwhile, the EC communication on Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009 reaffirmed the seven strategic areas identified in the first EC communication on nanotechnology. The strategic areas enable the EU to define the direction for nanotechnology development and establish realistic goals and objectives.

Noticeably, as summarised in *Table 2*, all the EC communications for nanotechnology do not have a specific provision on budget allocation for nanotechnology R&D, commercialisation, and innovation. The first communication compares the funding strategies of the EU with other countries such as the US and Japan. The EC believes that the EU can remain competitive at the global level even with a disparate range of rapidly evolving programmes and funding sources among the 25 member states. The EC communications are silent on budget allocation as it is provided under separate programs such as Community's Framework Programmes, Seventh Research Framework Program (FP7), and Horizon Europe 2020. The EU had invested a large amount of funding to support and boost nanotechnology activities in the region and the amount continuously increase. Under the Community's Framework Program, EUR 1.4 billion has been invested to support nanotechnology research in 2003-2006 and EUR 2.5 billion in 2007-2008 under the (FP7) (European Commission, 2009). The Europe Horizon 2020 (2014-2020) had allocated approximately EUR 2 billion for projects on nanomaterials and nanotechnology (European Union Observatory for Nanomaterials, 2022a). However, private funding still lagged and reliance on the government is still high (European Commission, 2009). Next, the EC nanotechnology policies also focus on coordination between agencies, as seen in *Table 3*.

Table 2. *Nanotechnology policies in the European Union and the relevant strategies.*

Year communication/recommendation/resolution	Purpose/objectives	Identification of strategic area	Allocation of resources	Coordination between agencies	Nano assessment (risk and benefits)	Legal instrument	Nanotechnology action plan
Towards a European Strategy for Nanotechnology COM (2004)338 (European Commission, 2004a)	To propose actions as part of an integrated approach to maintain and strengthen European R&D in nanosciences and nanotechnologies.	7 strategic area: -Mediccal applications -Information technologies -Energy production and storage -Material science -Manufacturing -Instrumentation -Food, water and environmental	No provision for the allocation of funds	Coordination research institutes and stakeholders	Discussed the importance of regulation to protect safety health and environment from the potential risks.	Discussed the importance of regulation to protect safety, health and environment from the potential risks.	Proposed for the formulation of action plans.
Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009 (COM (2005) 243) (European Commission, 2005)	-To take concrete steps forward to implement an intergated and responsible approach on nanotechnology at teh EU level. -To be able to meet the challenges and to ensure Europe's competitiveness in this sector we need to join forces across disciplines, sectors and national borders.	The 2005-2009 action plan reffirmed seven strategic areas in EC COM 2004.	No provision for the allocation of funds.	Focus on effective coordination for R&D programs between agencies at the national and regional levels.	Training and education on identification and assessment of risks.	Emphasized the necessity to examine and propose an adaptation to EU reguation in managing the potential risks.	COM (2005)505 is itself a nanotechnology action plan proposed by the EC.
Regulatory aspects of nanomaterials, COM (2008) 366 def. (European Commission, 2008)	-To review the EU regulations on nanoscience and technologies in relevant sectors.	The previously identified strategic areas are used by the EC as a guideline in reviewing the sufficiency of the EU regulations in regulating nanotechnology activities in Europe.	No provision for the allocation of funds.	Coordination between agencies is privotal in providing information for the implementation of regulation.	Analyse the suitabilty of the existing EU legislation in regulating the potential risks.	The current EU legislation may have to be modified in the light of new information becoming available.	No new action plan introduced

***Table 3**. European Union Agencies responsible for Nanotechnology and Nanoscience.*

Agency/Institution	Purpose	Works related to nanotechnology
The European Commission Joint Research Centre (JCR)	JCR provides independent scienific evidence and advice to support the EU policies (Joint Research Centre, 2022a)	-The JCR provides sciencetific and technical advice concerning nanomaterials to other commission services. -JCR seientists are contributing to the reduction of uncertainties about the potential impact of nanomaterials on health and the environment (Joint Research Centre, 2022b).
Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)	SCENIHR provides opinions on emerging or newly-identified health and environmental risks and on broad, complex, or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health. The potential area of activity includes emerging technology such as nanotechnology (European Commission, 2022c).	SCENIHR adopted the following opinions: -Opinion on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies (SCENIHR, 2005). -Opinion on the Appropriateness of the Risk Assessment Methodology in Accordance with the Technical Guidance Documents for New and Existing Substances for Assessing the Risks of Nanomaterials (SCENIHR, 2007).
Scientific Committee on Consumer Products (SCCP)	SCCP is responsible provide the Commission with unambiguous scientific advice on the safety of consumer products (non-food products intended for the consumer). (European Commission, 2022d)	SCCP approved a Preliminary Opinion on Safety of Nanomaterials in Cosmetic Products. (Scientific Committee on Consumer Products, 2007)
European Food Safety Authority (EFSA)	EFSA's work is undertaken in response to requests for scientific advice from the European Commission, the European Parliament, and the EU Member States. (European Food Safety Authority, 2022)	Two guidance documents on the assessment of nanomaterials in the food and feed chain: - Guidance on risk assessment of nanomaterials in the food and feed chain: animal and human health. - Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles.
European Chemical Agency (ECHA)	ECHA is responsible to implement the EU's chemicals legislation to protect health and the environment. (European Chemical Agency, 2022a)	ECHA is directly involved with nanotechnology activities under Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Regulation (EC) No 1272/2008 - classification, labelling and packaging of substances and mixtures (CLP). (European Chemical Agency, 2022b)
European Union Observatory for Nanomaterials (EUON)	EUON provides information about existing nanomaterials on the EU market. (European Union Observatory for Nanomaterials, 2022b)	All EUON works related with nanotechnology.

The EC communications, Towards a European Strategy for Nanotechnology and Nanotechnology and Nanoscience Action Plan for Europe 2005-2009 focus on the coordination between the EU's agencies, research institutes, and stakeholders to increase the effectiveness of nanotechnology R&D programs (*Table 3*). Meanwhile, the Regulatory Aspects of Nanomaterials, COM (2008) 366 emphasises the importance of coordination between European Union agencies in providing state-of-the-art information for the implementation of nanotechnology regulation. *Table 3* listed six agencies in the EU addressing nanotechnology and nanoscience. Five of these agencies, i.e., the European Commission Joint Research Centre (JCR), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Scientific Committee on Consumer Products (SCCP), European Food Safety Authority (EFSA), and European Chemical Agency (ECHA). These agencies are not specifically designed for nanotechnology activities, but the responsibility includes addressing issues and activities related to nanotechnology, as summarised in *Table 3*. Only the EU Observatory for Nanomaterials (EUON) is designed to monitor the availability of nanomaterials in Europe, including the safety issues, and engages in dialogue with the relevant authorities. *Table 4* lists the legislation related to nanotechnology passed by the US Congress, its purpose, and the provision related to nanotechnology from 2000 until 2015.

Table 4. *Legislation related to nanotechnology passed by the United State Congress, purpose and provision related to nanotechnology.*

Legislation/purpose	Provision on nanotechnology
21st Century Nanotechnology Research and Development Act of 2003. (To require the President to implement a National Nanotechnology Program and incorporate all nanotechnology programs under the National Nanotechnology Initiative (NNI) into laws).	All provisions are related to the research and development of nanotechnology.
Agriculture Risk Protection Act of 2000 (To strengthen the safety net for agricultural producers)	Section 221 (c) (1) The funds to conduct research to improve the scientific basis of using land management practices to increase soil carbon sequestration, including research on the use of new technologies to increase carbon cycle effectiveness, such as biotechnology and nanotechnology.
Consolidated Appropriations Act of 2001 (Making consolidated appropriations for the fiscal year ending 30 September 2001)	Section 314 Department of Defense Appropriations Act, 2001 (Public Law 106–259) under the heading ‘‘Research, Development, Test and Evaluation, Navy’’, up to $3,000,000 shall be made available to the Marine Corps to pursue research in Nanotechnology for Consequence Management.
National Science Foundation Authorization Act of 2002 (To authorise appropriations for fiscal years 2003, 2004, 2005, 2006, and 2007 for the National Science Foundation, and other purposes)	Section 5 (a) (2) (A) $4,155,690,000 shall be made available to carryout research and related activities, of which $704,000,000 shall be for information technology research described in paragraph (1) of section 8 and $301,000,000 shall be for nanoscale science and engineering described in paragraph (2) of section 8.
Bob Stump National Defense Authorization Act of 2003 (To authorise appropriations for military activities of the Department of Defense, and for defense activities of the Department of Energy)	Section 246 Defense nanotechnology research and development program to ensure the USs global superiority innanotechnology necessary for meeting national security requirements.
Consolidated and Further Continuing Appropriations Act of 2015 (To consolidated appropriations for the fiscal year ending 30 September 2015)	Section 34 (c)(1)(B) Predominant focus on a manufacturing process, novel material, enabling technology, supply chain integration methodology, or another relevant aspect of advanced manufacturing, such as nanotechnology applications.

Source: Ridge (2018)

Furthermore, the EC and the European Parliament (EP) acknowledged the existence of potential risks associated with the exploitation of nanotechnology and nanomaterials. *Table 2* demonstrates that all the EC communications for nanomaterials contain a discussion and analysis of the risks and benefits of nanomaterials on the safety, health, and environment. The European Commission (2004b) communication on Towards a European Strategy for Nanotechnology expressly discusses the urgent need to address the risks of nanomaterials to the health, safety, and environment. The risk assessment also must be integrated into every step of the life cycle of nanotechnology-based products before market release. Furthermore, EC Communications on Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009 emphasized that all nanotechnology activities must comply with a high level of protection either for public safety, health, and the environment. Thus, the responsible nanotechnology development approach has become the core of the EU policy for nanotechnology.

The EU also has introduced specific legal instruments to regulate nanotechnology activities. The existence of potential risks forced the EC to review the sufficiency of the existing EU legislation to regulate the potential risks of nanotechnology. The EC had issued two communications on nanotechnology regulation namely, Regulatory Aspects of Nanomaterials 2008 and Second Regulatory Review on Nanomaterials 2012. Both communications inter alia concluded that the existing EU legislation is sufficient to regulate nanotechnology activities in Europe. However, an amendment is necessary as new information on nanotechnology is available. In 2009, the European Parliament passed the first resolution for an amendment to incorporate specific provisions on nanotechnology, nanomaterials, and nanoparticles were made to Regulation (EC) No 1223/2009 on cosmetic products. The amendment involves legislation in different sectors, namely, food, feed, agricultural, medical, pharmaceutical, chemical, and cosmetic (Hansen and Baun, 2012). The EU is the only region in the world that has amended its legislation to include specific provisions regulating the use of nanotechnology and nanomaterials (Rodríguez, 2018).

Lastly, Europe's nanotechnology development strategies also involve formulating action plans. As illustrated in *Table 2*, the EC issued a four years nanotechnology action plan, i.e., Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009. The aim is to take concrete steps forward to implement an integrated and responsible approach to nanotechnology and nanoscience development across the identified strategic areas across Europe. The action plan highlights seven essential needs: increasing investment and coordination of R&D, world-class R&D infrastructure, interdisciplinary human resources, industrial innovation, integrating the social dimension in R&D, addressing the potential risks to health, safety, and environment, and international cooperation. The EC also published two implementation reports, (i) Nanosciences and nanotechnologies: An action plan for Europe 2005-2009 First Implementation Report 2005-2007, COM (2007)505 final, and (ii) Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009 Second Implementation Report 2007-2009, COM (2009)607 final. The implementation report is essential as it identified progress achieved and addresses societal and safety concerns to ensure the safe and sustainable development of nanotechnology.

Nanotechnology in the United States

As a global leader, the US shares the largest market size for nanotechnology owing to the large applications of nanomaterials in various industries such as electrical,

electronics, pharmaceuticals, and chemical products (Zhang, 2019). In 2021, the nanotechnology market in the US is valued at US$13.2 billion and is expected to continue growing (Report Linker, 2022). The growth is among others contributed by the spread of Covid-19 as the use of lipid nanoparticles that are a vital component of the Moderna mRNA Covid-19 vaccines and Moderna is based in the US (Chung et al., 2020). Unlike Malaysia and the EU, the US only has one nanotechnology development policy, National Nanotechnology Initiatives (NNI).

Nanotechnology policies in the United States

The NNI is the world's earliest and the biggest national research programme in nanotechnology. It was launched in 2000 by former President Bill Clinton. It is tasked to coordinate works and research on nanomaterials across the US and to ensure that nanotechnology leads to a revolution in technology and industry to benefit society (National Nanotechnology Initiative, 2022). It is important to note that, all NNI activities have been incorporated under federal legislation known as the 21st Century Nanotechnology Research and Development Act 2003 and become the priority of the federal government. The following is the analysis of the strategies adopted by NNI in advancing nanotechnology activities in the US. First, the identification of strategic areas, the NNI acknowledges that the applications of nanoscience and nanotechnology are prevalent across the R&D landscape. Nanomedicine, nanoelectronics, food industry, agriculture, water treatment, transportation, and energy generation and storage are the strategic areas for nanotechnology R&D in the US (National Nanotechnology Initiative, 2022). According to StatNano, the top five industries in the US that apply nanotechnology are electronics, medicine, transportation, environment, and textile (StatNano, 2022).

Second, is the allocation of resources under the NNI. After the announcement of the NNI, $220 million has been allocated and the amount is increased to $750 million in 2003, and $982 million in 2005 (European Commission, 2004b). In 2021, the President's Budget requests over $1.7 billion for the NNI. Cumulatively, totaling over $31 billion has been allocated for nanotechnology R&D since the inception of the NNI (Nanoscale Science, Engineering, and Technology Subcommittee, 2020). The continuous growth of budget allocation indicates the importance of investment for the advancement of R&D and translation of nanotechnology knowledge into technological breakthroughs that benefit the American people. Third is the coordination between responsible agencies. The objective of the NNI is inter alia to enhance interagency coordination of nanotechnology R&D by strengthening a shared infrastructure, resources, and expertise (National Nanotechnology Initiative, 2022). The NNI itself operates within the National Science and Technology Council (NSTC) and is supported by a formal organisational structure including an inter-agency coordinating committee known as NanoScience and Technology Council (NSTC) and a subcommittee, the Nanoscale Science, Engineering and Technology (NSET) Committee. The NSTC is represented by 20 federal departments and agencies (Marchant et al., 2010). There are also eight-leading centres for nanotechnology research namely, the University of Santa Barbara, Cornell University, the University of California at Los Angeles, Stanford University, IBM Research Laboratories, Northwestern University, Harvard University, and the Massachusetts Institute of Technology (Arnall, 2020). There is a comprehensive network and linkages between agencies, supporting the nanotechnology R&D, innovation, and commercialisation in the US.

Fourth is the existence of legal instruments under the NNI. As mentioned previously, the Senate and House of representatives of the US have enacted the 21st Century Nanotechnology Research and Development Act 2003. The Act was enacted to authorize the appropriations for nanoscience, nanoengineering, and nanotechnology research under the NNI. It also prescribes the requirements for the implementation of the National Nanotechnology Program consisting of various activities. Besides that, the development of nanotechnology's regulatory framework has begun in 1999. Until 2018, 185 bills related to nanotechnology have been introduced to the US Congress, but only six have been passed into law (Ridge, 2018). Noticeably, five of the legislation listed are not exclusively intended for nanotechnology and it only has one provision on nanotechnology, which is on find appropriation for nanotechnology R&D (*Table 4*).

Fifth is the assessment of benefits and risks. Other than exploring the benefits of nanotechnology, the NNI is also concerned about managing the potential risks. The NNI has five strategic goals and the last goal is the responsible development of nanotechnology (National Nanotechnology Initiative, 2022). The responsible development of nanotechnology demands an integrated risk management approach to access and manage the potential risks to the environment, health, and safety (Forloni, 2012). The NNI published the NNI Environment, Health, and Safety Research Strategy 2011 to guide the Federal agencies in reporting the scientific information on risk management on the use of nanotechnology to avoid unforeseen risks (National Science and Technology Council Committee on Nanotechnology, 2011). Lastly, the NNI is silent on the formulation of an action plan for nanotechnology. This study believes that an action plan is not essential with the enactment of the comprehensive 21st Century Nanotechnology Research and Development Act 2003 to regulate and monitors all the activities related to nanotechnology.

The global market size for nanotechnology continues expanding and many countries including Malaysia, the EU, and the US are competing to seize the global nanotechnology market. The value of the nanotechnology market in these three countries is constantly increasing. The growth is among others contributed by the existence of a national nanotechnology policy and strategy. There are two grounds of convergence between nanotechnology development policies and strategies adopted in these countries, (i) coordination with the relevant agencies and (ii) the assessment of the benefits and risks of nanotechnology. This study has also identified four grounds of divergence, (i) duration of the policy, (ii) the identification of strategic areas and the formulation of an action plan, (iii) allocation of resources, and (iv) existence of legal instruments related to nanotechnology. This study believes that the grounds of divergence could provide future perspectives on nanotechnology policy in Malaysia. It could be adopted into the existing policy or future policy as a means for Malaysia to lead the global nanotechnology market. The first divergence is the duration of the policy. The US is the earliest country that formulates the nanotechnology policy and strategy in 2000 and followed by the EU in 2004. Malaysia was a bit left behind as the first policy was formulated in 2006. Besides, the nanotechnology policy in Malaysia and the EU is formulated for a certain period of time as stipulated in *Table 1* and *Table 3*. In Malaysia, each policy is valid for ten years. Meanwhile, the EU adopted a short-term policy which is four years. In the US, the NNI remains the main and only nanotechnology policy and strategy, applicable until today. According to Roco (2005), the establishment of broad and long-term policy could accelerate the techno-economical of nanotechnology development. Such policy can be consistently updated to ensure the

availability and synergism of investigative tools, knowledge creation and production means supporting nanotechnology activities. This study contended the duration of the policy is immaterial. The utmost condition is the strategy embedded in the policy must be constantly updated as the landscape of nanotechnology development and activity is fast changing. The strategy must be aligned with the state-of-the-art of nanotechnology and the demand from the nanotechnology market.

The second divergence is the identification of strategic areas and the formulation of an action plan. The EU and the US specifically identified several strategic areas for nanotechnology R&D, innovation, and commercialisation. Meanwhile, all Malaysian nanotechnology policies are silent on the identification of strategic areas. Identification of strategic areas is crucial to avoid generic investment in fundamental research because of the diverging views on the distribution of nanotechnology benefits (Chowdhury et al., 2011). Besides, for a country that is already behind the developed countries in nanotechnology R&D by 5-10 years, it is important to choose the application areas for nanomaterials to compete in the global nanotechnology market (Sundararajan and Rao, 2009). The third divergence is the allocation of resources. The amount of funds appropriated by MOSTI for nanotechnology R&D, commercialisation, and innovations are still low compared to the EU and the US. The financing mechanism is one of the integral elements in STI activities. Common funds allocation for research and development, experimental funds, and commercialisation grants are examples of financial mechanisms that may accelerate the monetisation of science and technology products (Magro et al., 2014). The higher mobility of capital including a legislative mandate for budget allocation, infrastructure, and knowledge in the US not only promotes the agglomeration of nanotechnology research activity but also enables them to dominate the global nanotechnology market. However, this study believes that the appropriation of funds by the Malaysian government for nanotechnology R&D, commercialisation, and innovation corresponds with Malaysia's nanotechnology market size, which is smaller than the EU and the US.

The final divergence is the existence of legal instruments related to nanotechnology. In Malaysia, the adoption of three nanotechnology policies over the past 17 years has not resulted in the enactment of a legal instrument to regulate nanotechnology activities. The EU has incorporated specific nanotechnology provisions in the existing legislation to regulate nanotechnology activities and risks. Meanwhile, the US has translated the NNI into specific federal legislation that comprehensively laid down the requirement for the national nanotechnology programs, regular review of programs, advisory panel, and appropriation of budget. Furthermore, as illustrated in *Table 4*, legislation for agriculture, national science foundation, and defenses consist of a specific provision on budget appropriation for nanotechnology R&D. A legal instrument for STI such as nanotechnology goes one step beyond the policy itself by stipulating obligations, rights, rewards, and penalties for achieving the goals (Lemarchand, 2020).

The way forward

As a way forward, this study provides three recommendations to close the gap of Malaysia's nanotechnology policy and strategy. First, the policy must identify the strategic areas as practiced by the EU and the US. The identification is essential to prevent government funds from being allocated or invested in unprofitable nanotechnology activities. This study suggests that in choosing the appropriate strategic area, the government should evaluate the talent and strength of local nanotechnology

experts or scientists and the availability of research infrastructures. Hence, the government can fully utilise the existing resources and maximise the profit. The government should also assess the market demand for nanotechnology products and services. The strategic areas should focus on products and services that can monetise the nanotechnology R&D and expand the nanotechnology market, locally and globally. Currently, pharmaceutical and plastic products are the main two sectors that dominate the Malaysian nanotechnology market, with RM249.46 million and RM234.72 million respectively (Nano Malaysia Berhad, 2020).

The second recommendation is the enactment of a specific legal instrument, i.e., legislation for nanotechnology. The legislation serves as a binding instrument that prescribes the types and requirements of national nanotechnology programs, funding allocation, agencies' responsibilities, and coordination between agencies. Reference can be made to the 21st Century Nanotechnology Research and Development Act 2003. This study also believes that the enactment of legislation will reinforce the commitment of the government, relevant agencies, research institutes, and relevant stakeholders in nanotechnology R&D, as it is a legal obligation. Besides, nanotechnology legislation is also crucial to regulate the potential risks associated with the manipulation of nanomaterials and to promote responsible nanotechnology development, as practiced in the EU. Finally, private institutions should be encouraged to fund nanotechnology activities. It is to supplement funding resources from the government. A dual funding structure can accelerate nanotechnology R&D, innovation, and commercialization.

Conclusion

Strategies in nanotechnology development policies charted by experts are fundamental for economic and social well-being. Malaysia is a developing nation that is actively involved in nanotechnology activities and still has a tall ladder to climb to be with the EU and the US. The Malaysian government has taken various initiatives to advance nanotechnology development and increase the market size including formulating nanotechnology development policies, following the pursuit of developed countries. However, this study found the convergences and divergences between the strategies adopted by Malaysia with the EU and the US. The convergences cover strategies for coordination with the relevant agencies and the assessment of the benefits and risks of nanotechnology. Meanwhile, the divergences are in the identification of strategic areas, identification of risks, and formulation of legal instruments. These three strategies are not part of Malaysia's nanotechnology development policies, unlike the EU and US policies. This study suggested that the government should identify the strategic areas for nanotechnology R&D, and enact nano-specific legislation to further strengthen the nanotechnology development strategy in Malaysia.

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Conflict of interest

The authors confirm that there is no conflict of interest involved with any parties in this research.

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