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Formulation of Regulatory Sandbox for Nanotechnology Innovation

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ABSTRACT

Regulatory sandboxes represent a modern approach to regulatory governance for testing products, services, or programs derived from emerging technologies. Testing enables the identification of risks before releasing innovations to consumers. Innovators are allowed to test their innovation within a controlled environment under the supervision of regulators, without being fully subjected to standard regulations. Currently, there are about 200 regulatory sandboxes worldwide across 92 countries in finance, energy, telecommunications, and health. This widespread adoption suggests that regulatory sandboxes are regarded as a mechanism for promoting innovation and enabling regulators to manage potential risks. While the use of regulatory sandboxes for technological innovation continues to expand, there is currently no equivalent framework tailored specifically to nanotechnology innovations. Nanotechnology is associated with regulatory gaps and scientific uncertainties regarding safety and health risks. This article conceptualises the general framework for designing a regulatory sandbox for nanotechnology innovations. The formulation of this sandbox is based on the conceptual analysis of the essential components and key features adopted by international institutions such as the European Commission (EC) and the Organisation for Economic Co-operation and Development (OECD), as well as those proposed by scholars in designing regulatory sandboxes. The essential components of a regulatory sandbox for nanotechnology innovation identified in this article include the establishment of competent authorities, the evaluation of legal impediments, and the identification of sandbox prerequisites, namely eligibility criteria, the sandbox's scope, duration, monitoring and reporting mechanisms,

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and an exit strategy. Fundamentally, this article contributes to the ongoing discourse on innovation-friendly laws and sustainability for nanotechnology development.

Keywords: Innovation, nanotechnology, regulatory sandbox, sustainable nanotechnology development

INTRODUCTION

In the 21st century, nanotechnology has emerged as the most transformative technology offering innovative solutions across various industries. The ability to manipulate materials and devices at the nanoscale unlocks distinctive physical, chemical, and biological characteristics. This enables innovators to develop products that demonstrate enhanced efficiency, improved design, optimised processes, and superior performance (Kumar et al., 2025; Malik et al., 2023). These advantages are applicable across a broad spectrum of industries, highlighting the transformative potential of nanotechnology innovation.

In 2024, the global nanotechnology market was valued at USD 84.7 billion, and within ten years, the value is projected to increase by USD 26.5 billion (Emergen Research, 2026). The growth, inter alia, is attributable to the rapid pace of nanotechnology innovation in countries such as China, South Korea, and the United States. Likewise, Malaysia's nanotechnology market size is estimated to reach USD 8.5 billion in 2033 (NanoMalaysia, 2024). The characteristics of nanotechnology, supported by a large market size, have stimulated firms to intensify R&D and consequently increase the volume of nanotechnology innovations.

From the innovation law perspective, nanotechnology innovations represent a typical tension of innovation and safety. Despite its significant economic benefits, nanotechnology is considered a controversial technology owing to its scientific novelty (Zabeo et al., 2019). The safety and health risks remain highly uncertain and potentially severe. Scientific studies associate the utilisation of engineered nanomaterials (ENMs) with harmful interactions in biological systems and the environment, raising concerns about toxicity (Borm et al., 2006; Chávez-Hernández et al., 2024; Ma et al., 2024). Such concerns require robust regulatory oversight to safeguard consumers' well-being and the environment from unintended and potentially harmful risks. Consequently, the comprehensive framework will uphold the ethical and sustainable development of nanotechnology.

In certain jurisdictions, such as Malaysia, there is a notable absence of legislation regulating the proliferation of nanotechnology across various industries. For instance, engineered nanomaterials (ENMs) in food products are regulated by the Food Act 1983 [*Act 281*], which contains no express provisions relating to nanotechnology or nanomaterials. As a result, nanofood falls within the regulatory framework enacted before the emergence of nanotechnology in the food processing industry. The physicochemical properties of ENMs differ substantially from those of bulk materials, making nanofood unsuitable for

regulation under legislation designed for conventional bulk-scale materials. As a result, nanofoods are being introduced in the market without adequate regulatory oversight. This regulatory gap allows these products to become available to consumers before there is a comprehensive understanding of their long-term safety for human consumption (Hasmin et al., 2024).

Given the regulatory gaps and uncertainties surrounding safety and health risks, this article argues for the development of a regulatory sandbox for nanotechnology innovations. The growing market size for nanotechnology innovations exemplifies the need for a regulatory sandbox. The market expansion is closely linked to heightened innovation activity driven by the proliferation of novel products derived from ENMs or nanodevices. Originally introduced in the FinTech sector, the regulatory sandbox is now gaining traction among innovators in other industries (Johnson, 2023; Qiu et al., 2025). They allow innovators to test new products in a controlled environment, identify opportunities and risks, and facilitate real-world deployment without being fully subject to standard regulations. At the same time, regulators can use insights from these experiments to refine legal frameworks and grant approvals (Federal Ministry for Economic Affairs and Energy, 2025).

The European Commission (EC) (2023) recognised the regulatory sandbox as a tool for identifying potential regulatory barriers or new laws that affect innovation. A regulatory sandbox for nanotechnology can facilitate the testing and oversight of new products within a controlled environment, thereby addressing the regulatory gaps and ensuring the safety and health of consumers and the environment (Federal Ministry for Economic Affairs and Energy, 2025). The central objective of this article is to conceptualise the design of the regulatory framework for nanotechnology innovation.

Currently, there is no equivalent framework tailored specifically to nanotechnology innovations. A systematic search was conducted in Scopus and Web of Science using the advanced search function for article titles, abstracts, and keywords. The search used the terms “nanotechnology”, “regulatory sandbox”, and “regulatory sandboxes”, and identified three documents. However, these articles do not focus on the formulation of a regulatory sandbox for nanotechnology innovation. The article by Johnson (2023) offers a general framework for characterising regulatory sandboxes across different sectors. In contrast, Safarzadeh and Di Maria (2026) and Maric et al. (2026) focus on the importance of regulatory sandboxes in encouraging nanotechnology innovation.

This article advances a general framework applicable to nanotechnology innovation, without focusing on any product category. The proposed sandbox aims to address several key objectives: reduce regulatory gaps, foster nanotechnology innovation, safeguard consumer protection, and promote ethical and sustainable nanotechnology development. This article is divided into three parts. The first part presents the research methodology. The second part offers an overview of nanotechnology innovations. The discussion in

this section aims to understand the fundamental nature and dynamics of innovation in nanotechnology, thereby informing the design of the sandbox. The third part is the characteristics of a regulatory sandbox, including the design of the regulatory sandbox, the structure of the regulatory authority responsible for the sandbox, and the sandbox's design. The final part is the conclusion.

METHODOLOGY

In formulating the regulatory sandbox for nanotechnology innovation, this article adopts a qualitative doctrinal research approach by analysing relevant literature from reports, research journals, and books available in online databases and on institutional websites. A content analysis method was used to critically examine the design of regulatory sandboxes. The analysis was primarily guided by the Organisation for Economic Co-operation and Development (OECD) Regulatory Sandbox Toolkit, which provides comprehensive guidance for regulators on establishing and managing regulatory sandboxes. In addition, the study examined the European Union's regulatory sandbox for artificial intelligence, as the framework is expressly enacted into legislation, namely the EU Artificial Intelligence Act. The analysis was further supplemented by academic literature proposing frameworks and key elements for establishing regulatory sandboxes. This method focused on identifying the key components and features required for designing a regulatory sandbox. Even though reference is made to existing frameworks such as AI and FinTech, the relevant features are critically adapted and refined to reflect the distinctive nature of nanotechnology innovation.

NATURE OF NANOTECHNOLOGY INNOVATION

Nanotechnology has existed since at least the fourth century. The modern era of nanotechnology began in the 1980s and has continued to evolve to date (Pisano & Durlo, 2025). The term nanotechnology refers to the size scale of objects or materials, expressed in nanometres (nm) or the nanoscale. The nanoscale length range is approximately 1 nm to 100 nm (International Organization for Standardization, 2015). The nanometre is about 100,000 times smaller than the diameter of a human hair or 1,000 times smaller than a red blood cell (Science Policy Council, 2007). Hence, it is impossible to see nano-sized particles using the naked eye or with a conventional microscope.

The core components of nanotechnology innovation rested in the development and application of nanomaterials and nanodevices, as illustrated in Figure 1. The Organisation for Economic Co-operation and Development (2024) defines nanomaterials as chemicals that are either in the form of nano-objects or nano-structured. A nano-object is defined as a material confined in one, two, or three dimensions at the nanoscale, and nano-structured means having an internal or surface structure at the nanoscale. Conventional bulk-sized materials can be engineered into a nanoscale and referred to as engineered

nanomaterials (ENMs). The tiny size offers novel ways to manipulate, control, and formulate materials, structures, devices, and systems that differ greatly from their bulk counterparts. Such a distinction is mainly attributable to novel physicochemical properties, including enhanced reactivity, quantum effects, increased surface area, and electrical conductivity (Asha & Narain, 2020). Examples of ENMs include nanoparticles, nanofibers, and nanoplatelets such as carbon nanotubes, graphene, quantum dots, gold nanoparticles, and metal oxides, which are widely used in various industries.

Other than nanomaterials, the utilisation of nanotechnology also consists of nanodevices. These refer to nanoscale technologies that integrate mechanical, electronic, magnetic, and biological systems. Nanodevices may include nanosensors, nanoelectromechanical systems (NEMS), chip technologies, and implantable biomedical devices, which are commonly used in energy harvesting, medicine, the semiconductor industry (electronic devices across various sectors), environmental control, and countless other applications (Bhattacharjee & Maiti, 2021). As of January 2026, the Nanotechnology Products Database classified nanotechnology products into 15 categories. These categories encompass diverse sectors, including electronics, medicine, construction, cosmetics, textiles, automotive, environmental, renewable energy, food, home appliances, petroleum, agriculture, printing, sports and fitness, and others.

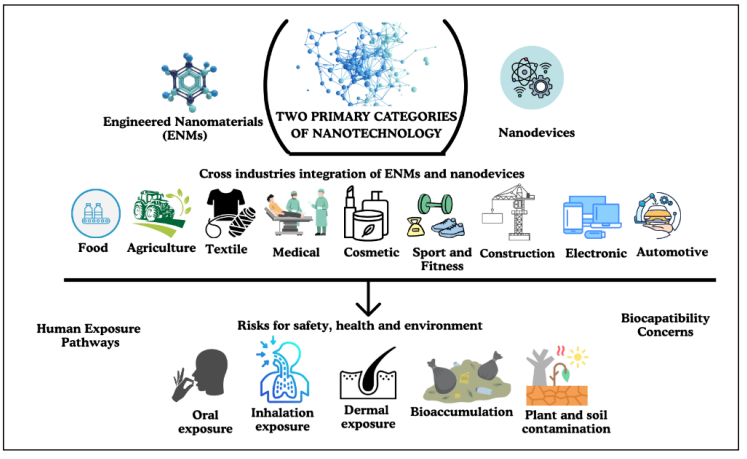

Figure 1. The applications of nanotechnology and potential risks to safety, health, and the environment

As shown in Figure 1, the applications of ENMs in certain product categories, such as foods, cosmetics, personal care, medicines, and textiles, allow these materials to come into intimate contact with the human body via oral, dermal, or inhalation exposure routes. Exposure of the human body to ENMs is associated with various safety and health concerns, as demonstrated by laboratory studies. The tiny particle has a greater surface area-to-volume ratio, and a larger surface area leads to higher chemical reactivity, thereby

increasing its ability to penetrate human tissue (Pathak et al., 2025; Xie et al., 2024). Likewise, nanomaterials are more adhesive to human tissue surfaces than larger particles. They cannot be easily removed from the lungs, gastrointestinal tract or other organs compared with conventional bulk counterparts, resulting in potential accumulation within the body (Fiordaliso et al., 2022; Oberdörster et al., 2005).

Scientific studies using in vitro, in vivo, and in silico experiments demonstrated diverse toxicology effects of ENMs on human safety and health, such as reducing the capacity of the intestinal tract (Carbone et al., 2016), damaging the intestinal glands (Shahare et al., 2013), harmful effects to liver and kidney (Baki et al., 2014), membrane damage (Cid-Samamed et al., 2023), oxidative stress (Zhang et al., 2021), respiratory inflammation (Halappanavar et al., 2021), immune dysregulation (Tang et al., 2021), and metabolic disturbances (Wojciechowska et al., 2023). Collectively, these studies provide important scientific evidence of the potential toxicity of ENMs and their possible adverse effects on human health and safety.

The utilisation of nanodevices does not involve direct contact with internal organs or tissues, as it does not cross human biological barriers. The potential adverse impacts are predominantly linked to environmental risks arising from the use of non-biocompatible devices. ENMs may enter the environment either through direct or indirect pathways. Direct release of ENMs into the environment can occur through agricultural activities, such as incorporating ENMs into agricultural products such as fertilisers and pesticides (Servin et al., 2015). On the contrary, indirect releases arise throughout the life cycle of ENMs, including manufacturing, consumer use, and end-of-life disposal, resulting in their discharge into air, water, and soil (Giese et al., 2018). These release pathways make the accumulation of ENMs in soil and groundwater effectively unavoidable, leading to soil and water contamination (Kokilavani et al., 2023). Therefore, the introduction of ENMs into products must be rigorously monitored to mitigate the potential risks to safety, health, and the environment.

Based on the above analysis, the design for the nanotechnology regulatory sandbox must take into consideration the nature and specific modes of nanotechnology utilisation. This includes whether the innovation involves the utilisation of ENMs or nanodevices. Furthermore, it is essential to evaluate the potential impacts of these technologies on human safety, health, and the environment. The design of the regulatory sandbox should be tailored to address these unique characteristics of nanotechnology.

General Description of Regulatory Sandboxes

A regulatory sandbox is a legal framework that allows innovators to test and experiment with innovative products, services, programs, or businesses with actual consumers under the supervision of regulatory authorities for limited periods (Madiega & Van De Pol, 2022).

It operates like a real laboratory for testing new products and brings together stakeholders to ensure responsible, ethical technological innovation by protecting consumers from unintended risks and losses. The regulatory sandbox has been established as a responsive regulatory framework to address the potential risks posed by fast-moving technological innovations (Allen, 2019; Attrey et al., 2020; Ringe & Ruof, 2020). A landmark adoption of a regulatory sandbox was to nurture FinTech innovations. The United Kingdom's Financial Conduct Authority (FCA) is the world's pioneer for the regulatory sandbox, launched in 2016. This initiative allows FinTech companies to test new solutions with real consumers under controlled conditions. The success of the FCA regulatory sandbox has been replicated in nearly 60 jurisdictions worldwide (Fahy, 2022; Jeník & Duff, 2020). Later, lessons from regulatory sandboxes for FinTech have been applied in other industries, such as AI (Artificial Intelligence Act, 2024), energy sectors (Aydın & Yardımcı, 2024), blockchain, and the Internet of Things (IoT) (Durham, 2023).

According to Parenti (2020), the regulatory sandbox benefited not only innovators but also regulators and consumers. The innovator-driven regulatory sandbox allows them to test their innovations in a controlled environment, i.e., under the watchful eyes of the regulators, to help mitigate the unintended consequences and reduce legal risks. Likewise, the worldwide presence of regulatory sandboxes has positively promoted technological innovation (Gumbo & Chude-Okonkwo, 2025), influenced venture investment in innovation (Goo & Heo, 2020), and reduced time to market (Alaassar et al., 2020). Meanwhile, a regulator-driven regulatory sandbox helps regulatory authorities assess whether the current regulatory framework is effective in regulating innovation arising from emerging technologies.

The sandbox is seen as pivotal to modern regulatory governance, especially for new technologies. The formulation of a regulatory sandbox for nanotechnology innovation reflects the adoption of anticipatory governance (Morgan, 2023). In an era of rapid technological advancement, anticipatory governance serves as an important decision-making approach that prepares society for future challenges and risks. It does so by actively exploring, experimenting with, and continuously learning about emerging technological developments (Guston, 2014). A regulatory sandbox reflects anticipatory governance by encouraging innovators, policymakers, regulators, and other stakeholders to reflect on their roles and responsibilities in shaping nanotechnology development.

The OECD also emphasises the importance of incorporating a robust consumer protection mechanism in a regulatory sandbox (Organisation for Economic Co-operation and Development, 2025). From consumers' perspective, the sandbox enables them to access the latest innovations in a supervised environment, without being exposed to the typical uncertainties associated with unregulated technological experimentation. The mechanisms include a requirement that the measure under test have a beneficial effect on consumers and the disclosure of potential risks (Poncibò & Zoboli, 2020). The potential

risks can be properly monitored, preventing further harm to consumers. Furthermore, the transparency of sandboxes is also high. The participating firms are required to disclose comprehensive information regarding product performance, limitations, and potential risks. Such transparency enhances consumer trust and addresses information asymmetry, a persistent challenge in markets driven by emerging technologies.

As explained in the previous subtopics, nanomaterials research in various industries is highly associated with scientific uncertainties. There are major gaps in knowledge regarding the potential safety and health risks associated with ENMs (Heidmann & Milde, 2013). Currently, the safety and risks associated with ENMs across various industries are only assessed through in vitro, in vivo, and in silico studies conducted in laboratories. There are concerns that these laboratory studies are not validated, are contradictory or inconsistent, or are not reproducible. Furthermore, the use of animal data from in vivo studies is debatable because test results often cannot be transferred to humans due to potential biological differences between animals and humans (Jahnel, 2015). Therefore, the regulatory sandbox for nanotechnology offers a practical way to identify or measure safety and health risks associated with ENMs beyond lab-based studies. Additionally, the data generated can be used to collaterally produce information relevant to the authorisation process for products that require post-market approval.

Furthermore, there is a lack of systematic, mandatory reporting to identify ENM-related accidents. Although there are accident cases involving ENMs, it was often difficult to find detailed information, leading to uncertainties on the actual number of accident cases, the nature or physicochemical properties of ENMs that contribute to the accidents, and the nature of safety and risks (Organisation for Economic Co-operation and Development, 2022). This gap hampers effective risk governance of ENMs due to the refusal to enact legislation to govern potential safety and health risks. For instance, in Malaysia, nanotechnology risks are managed through soft law, with no specific legislation or amendments addressing nanomaterials, as safety concerns have only been observed in laboratory settings. The country relies on international and local guidance documents. Although the United States enacted the 21st Century Nanotechnology Research and Development Act of 2003, the aim is to coordinate nanotechnology programs and R&D under the National Nanotechnology Initiative (NNI).

On the other hand, the European Union has incorporated specific provisions on nanotechnology, nanomaterials, and nanoparticles in regulations for cosmetics and foods. These provisions aim to regulate nanotechnology activities and protect consumers against the potential risks (Angelopoulou et al., 2022). The incorporation of nanotechnology-specific provisions is supported by the European Commission's adoption of the precautionary principle in regulating nanotechnology activities (Heselhaus, 2010). The precautionary principle is a legal principle that allows regulators to take the earliest possible measures when there is a reasonable indication of risks to the environment, safety, and health, and

in which lack of scientific certainty is not a reason for inaction (Todt & Luján, 2014). For the European Union, the regulatory sandbox for nanotechnology innovation aligns with the precautionary principle that has been expressly adopted in regulating nanotechnology activities across member countries.

The article argues that regulatory sandboxes are justified for nanotechnology innovation because of scientific and legal uncertainties. These sandboxes can help address those challenges. With the systematically recorded and reported data from the sandbox, innovators could identify the potential safety and health risks associated with their innovations. The data collected from the sandbox could overcome the limitations of in vivo, in vitro, and in silico studies and strengthen consumer protection by providing evidence on how the innovations perform under a controlled environment.

Additionally, cooperation in the mutual exchange of expertise between innovators and regulators in the sandbox enables assessment of the adequacy of the regulatory framework, ensuring that existing rules become more resilient and that unregulated activities enter a regulated perimeter. The regulatory sandbox for nanotechnology innovation also serves as a mechanism aligned with the precautionary principle for governing the scientific uncertainties associated with nanotechnology products. The sandbox will accelerate nanotechnology innovation, increase nanotechnology investment, and promote responsible nanotechnology development. The following discussion is on the design of a regulatory sandbox for nanotechnology innovations.

The Design of a Regulatory Sandbox for Nanotechnology Innovation

According to Jeník and Duff (2020), regulatory sandboxes vary in design, as no two sandboxes are the same. The most important consideration in designing a regulatory sandbox is that it should serve its purpose and be customised to the nature of the technological products. The discussion in this section outlines the elements to consider when implementing a sandbox, including the organisational and governance of the sandbox and the operational prerequisites.

Organisational and Governance of Regulatory Sandbox for Nanotechnology Innovation

The design of a regulatory sandbox begins with establishing competent authorities to supervise and govern the sandbox. These authorities play a central role in ensuring effective oversight throughout the sandbox's operation and management, facilitating coordinated governance and compliance with applicable regulatory requirements. The European Union Artificial Intelligence Act (AI Act) may serve as a useful reference in developing the framework for the competent authorities responsible for the nanotechnology innovations sandbox.

Article 70 designates national competent authorities (NCAs) for the AI regulatory sandbox. The NCA for the AI sandbox shall consist of at least a notifying authority and a market surveillance authority that exercises its power independently. Article 3(19) states that the notifying authority is responsible for establishing and carrying out the necessary procedures for the assessment, designation, and notification of conformity assessment bodies, as well as for their monitoring. Additionally, Article 70(3) contains express provisions mandating that the NCA be equipped with adequate technical, financial, and human resources, as well as comprehensive infrastructure, to effectively fulfil its responsibilities.

This article suggests that the framework for competent authorities overseeing the nanotechnology innovation sandbox should also consist of (i) the notifying authority and (ii) the market surveillance authority. The illustration in this subtopic depicts the nanotechnology ecosystem in Malaysia, as shown in Figure 2. The notifying authority should comprise national agencies responsible for coordinating, developing, and governing the regulatory sandbox and nanotechnology. For instance, in Malaysia, the National Technology and Innovation Sandbox (NTIS) and the National Nanotechnology Centre (NNC), under the Ministry of Science, Technology, and Innovation (MOSTI), must be among the notifying authorities. The NTIS is responsible for creating a sandbox for innovators across sectors, including capacity building, funding facilitation, regulatory pathway facilitation, and commercialisation facilities (National Technology & Innovation Sandbox, n.d.). The NNC focuses on coordinating research, technology development activities, and standards and regulatory issues related to nanotechnology in Malaysia (National Nanotechnology Centre, n.d.).

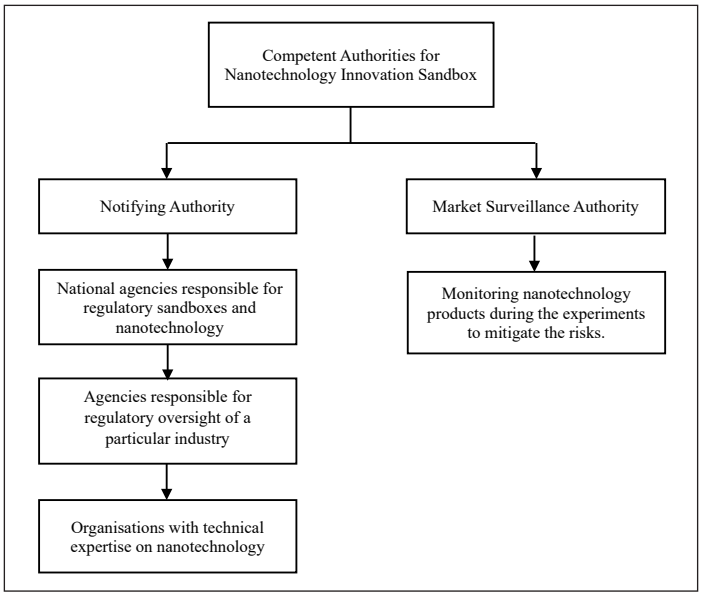

Figure 2. Competent authority for the nanotechnology sandbox

The notifying authority should also consist of the regulatory body and the designated standard organisation. The identification of the relevant regulatory body should follow the sectoral approach, i.e., the regulatory authority with jurisdiction over a particular industry serves as the lead regulator for legal and safety compliance. For instance, if the nanotechnology innovation is a nanofood that utilises new chemical compounds at the nanoscale, the Food Safety and Quality Division (FSQD) would assume the role of the regulatory authority. In this capacity, the FSQD is responsible for overseeing compliance with the food safety standards and legislative requirements.

Standard organisations provide essential technical expertise for nanotechnology across all industries. These bodies provide a horizontal layer of support for characterisation, measurement, and safety, which shall include the National Institute of Occupational Safety and Health (NIOSH), the Department of Chemistry Malaysia, SIRIM QAS International, the National Metrology Institute of Malaysia (NMIM), and NanoVerify. The market surveillance authority is responsible for conducting appropriate checks on product characteristics, including physical and laboratory checks based on adequate samples, prioritising its resources and actions to ensure effective market surveillance, including the possible risks.

Additionally, the competent authorities must be accorded the necessary power to act effectively, independently, impartially and without bias. This is to safeguard the experiment's principles of objectivity. According to the Organisation for Economic Co-operation and Development (2025), the competent authorities should be empowered in three different ways, namely, a binding decision for the grant of approval, simple discretion giving room to the authority to decide within its scope and intended discretion that should generally be exercised in the manner specified.

The Operational Requirements of Regulatory Sandboxes

The planning and designing process is pivotal for the success of regulatory sandboxes. According to Chen and Taeihagh (2026), the design of regulatory sandboxes shall start with a decision flow process for introducing a sandbox and identifying operational prerequisites consisting of (i) eligibility criteria, (ii) scope, (iii) duration of testing, (iv) monitoring and reporting, (v) exit rules, and (vi) a transition plan, as shown in Figure 3.

The initial stage in designing a regulatory sandbox involves establishing a decision flow process. This process begins by assessing the appropriate basis for experimentation, including an evaluation of applicable legal requirements and any prohibitions on testing the proposed innovation. If a prohibition exists, the regulator shall exercise their power to grant legal derogations or issue participants a no-enforcement letter exempting them from a specified set of regulations for a certain period. This is to ensure that the existing regulation never constitutes a significant barrier to tested innovation (Buocz et al., 2023).

The power to grant legal derogation and issue a no-enforcement letter is also connected with the enactment of experimental legislation for the sandbox.

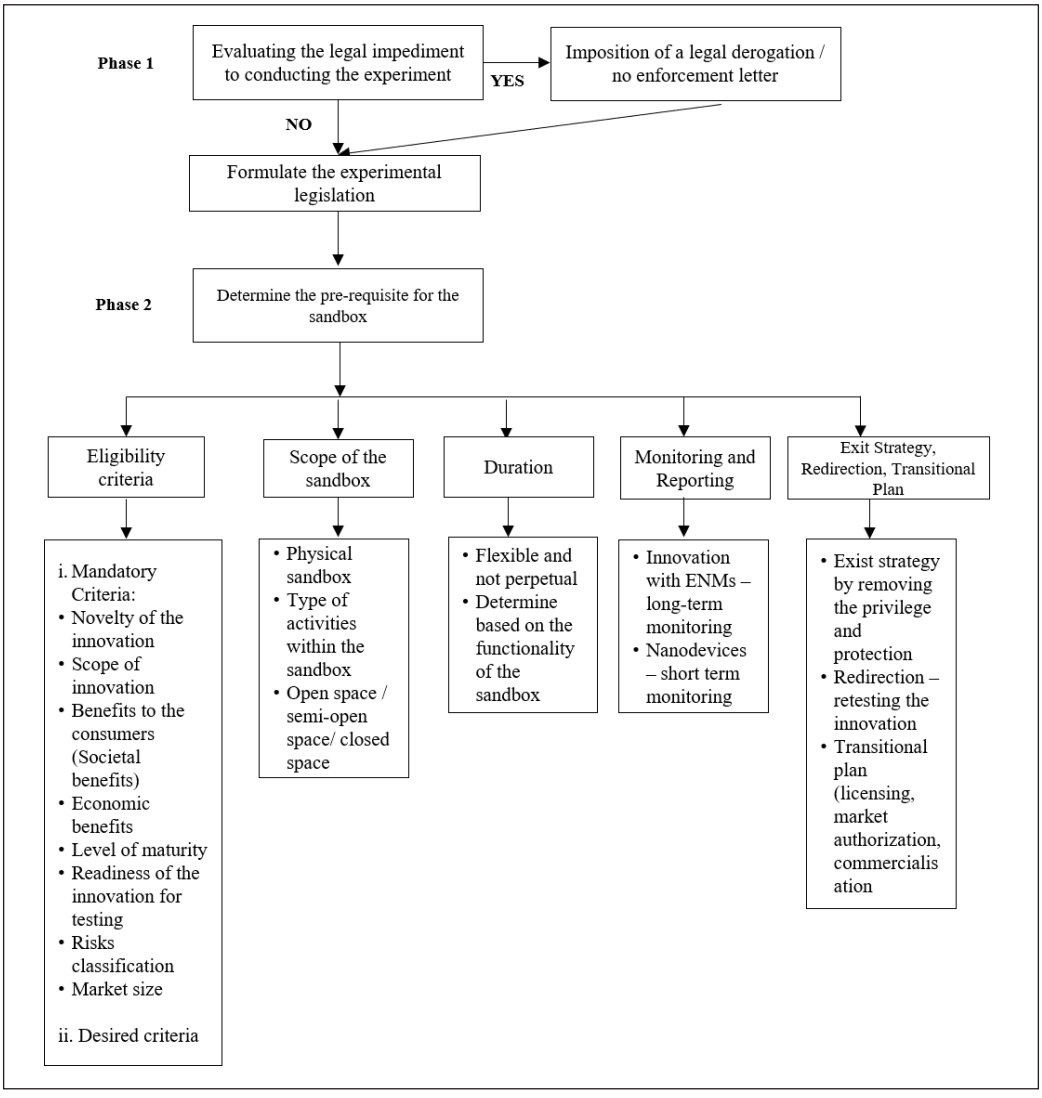

Figure 3. The regulatory sandbox framework for nanotechnology innovation

The experimental legislation shall contain express authorisation and conditions for the participant to deviate from the legal requirements. Thereby offering innovators the freedom to experiment with their innovations without incurring legal liabilities. The experimental legislation must safeguard not only the innovator's interests but also the public interest, particularly that of consumers. Accordingly, it shall contain clauses to protect a group of citizens or a territory which is subject to the experiment (Eichengreen, 2023).

To compensate for the derogations, the regulatory authorities should impose compensatory obligations and conditions on innovators for any adverse effects arising during the experimental period (Raudla et al., 2025). Innovators must bear responsibility for compensating for any injury or loss affecting safety, health, and the environment that arises during the experimental period. The compensation also operates as a risk-balancing mechanism to promote innovation and discourage negligent practices throughout the testing phase.

As previously discussed, in certain jurisdictions, nano-specific legislation is not part of the regulatory framework. The absence of nano-specific legislation removes formal regulatory impediments to establishing a nanotechnology sandbox, thereby allowing experimental activities to proceed within a legally unencumbered environment. However, other legislation must also be examined, as nanotechnology activities continue to fall under the regulatory framework enacted before the proliferation of such technology. The regulatory authority must carefully analyse whether legal derogation and experimental legislation are appropriate. The regulatory requirements for clinical trials and pre-market approval, such as substance or dossier authorisation, must be strictly observed and shall not be bypassed to protect public health and safety.

For example, nanotechnology innovation in medicine and medical devices may not be appropriate for experimentation within a regulatory sandbox. These innovations are subject to strict clinical trials and stringent compliance with regulatory requirements, protocols and ethical standards. Establishing a regulatory sandbox for nanotechnology-based medicines and medical devices would therefore necessitate targeted derogations from existing pharmaceutical and medical device laws. Allowing the innovation to enter the market prior to approval will expose the public to unassessed risks. For instance, the use of ENMs as new food additives must comply with the Codex General Standard for Food Additives (GSFA, Codex STAN 192-1995) (Liang, 2022) and obtain authorisation in accordance with the conditions specified, including prior written approval of the director, as stipulated under the Food Act 1983. Under such circumstances, granting legal derogation may contravene medical ethics principles and public health protection. Therefore, the primary distinction between a regulatory sandbox and a clinical trial is that a clinical trial is subject to strict regulatory requirements, whereas a regulatory sandbox may allow legal derogations that relax certain legal requirements.

Experimental legislation may also introduce new regulatory mandates that are currently absent from the existing regulatory frameworks. The introduction of new regulatory requirements is to embed essential protections for consumers participating in the experiments. For instance, in the context of food nanotechnology, international food labelling standards do not mandate disclosure of the presence of ENMs, resulting in some countries, such as the United States and Malaysia, adopting voluntary nano-labelling. The sandbox could insert a clause mandating the innovators to label their innovations as part

of the experimental legislation. Consumers must be informed about the presence of ENMs to enable them to make an informed decision on using the products and participating in the experiment.

The next stage is defining the operational prerequisites for the regulatory sandboxes. First, the eligibility criteria for the participant. It is the responsibility of the regulatory authority, i.e., the notifying authority, to determine the eligibility criteria for the nanotechnology regulatory sandbox. A wealth of literature has discussed the eligibility criteria for a regulatory sandbox. Seferi (2025) highlights three primary criteria to consider: the degree of innovativeness, public and societal benefit, and level of maturity. Meanwhile, the UK's FCA imposed five criteria: the scope of innovation, the novelty of the innovation, consumer benefits, the readiness of the innovation for testing, and the need for support to test the innovation in the sandbox (Financial Conduct Authority, 2026). The other eligibility requirements would be firm-specific criteria, benefits to the economy and society, and risk classification (Nabil, 2024).

This article is of the view that the other factor that should be considered in deciding the eligibility criteria for the regulatory sandbox for nanotechnology innovation is the market size of nanotechnology products. In countries with small markets and limited nanotechnology innovation, the eligibility criteria should be sufficiently flexible to avoid deterring potential participants from engaging in experimental activities. For instance, in Malaysia, the utilisation of nanotechnology across various industries remains relatively nascent compared with global nanotech hubs. As of January 2026, the Nanotechnology Products Database only listed 163 nanotechnology products from Malaysia across various industries (Nanotechnology Products Database, n.d.-b). Hence, the eligibility criteria should ensure equal access for both large corporations and small- to medium-sized enterprises, fostering inclusive innovation ecosystems. Such an approach is essential to accelerate nanotechnology development, expand market availability of nanotech products, and enhance regulatory learning through diverse participation.

Based on the above discussion, this article suggests the following eligibility criteria as mandatory, namely the novelty of the innovation, scope of innovation, benefits to the consumers (societal benefits), economic benefits (commercial value of the innovation), level of maturity, readiness of the innovation for testing, risks classification (including life-cycle risk assessment), and market size. The notifying authority may impose other eligibility criteria it deems appropriate, based on the nature of the nanotechnology innovation.

The second operational prerequisite is the scope of a regulatory sandbox. According to Chen and Taeihagh (2026), the scope should be delineated across three factors, namely the (i) parameter or scale of experiments, (ii) boundaries placed on its physical and virtual spaces, and (iii) types of activities allowed within a sandbox. The parameters and scales of experiments are fundamentally influenced by the characteristics and nature of

nanotechnology innovations. ENMs are widely used across diverse industries, including the manufacturing of consumer products such as fertilisers, foods, cosmetics, personal care products, textiles, medicines, sports equipment, and electronic products.

The sandbox for nanotechnology innovation should be designed as a physical rather than a virtual one, given the tangible nature of nanotechnology products. Unlike digital innovation, which can be experimented with online to assess performance and risks, nanotechnology innovation involves products containing ENMs or nanosized devices. Consumers ingest, apply, or physically operate these products in daily life. The assessment of safety and health risks associated with ENMs must be based on robust empirical data (Justo-Hanani, 2025), post-market monitoring (Mitra et al., 2024), and direct supervision. Therefore, online or virtual testing environments are inappropriate for evaluating safety and health risks, environmental impacts, and performance.

Given the nature of risks and benefits of nanotechnology, the activities conducted within the regulatory sandbox should extend beyond mere product development and improvement. The physical experiments must also assess the potential adverse effects of ENM use on human health and safety. The geographical scope pertains to the regulatory sandbox's spaces. Molitorisová and Purnhagen (2025) conceptualise the spaces of sandboxes into three categories: open, semi-open, and closed. These spaces will determine the extent of control that regulators and innovators have over the sandbox's object.

A closed regulatory sandbox is highly rigid, as the object cannot leave the sandbox during testing or be accessed from the outside. Only participants, innovators, and regulators are allowed in the sandbox, without interference from third parties. The rigidity will lower risks, as there is a high level of traceability, which serves as a risk-mitigation measure for human safety and health. On the contrary, an open regulatory sandbox entails a higher level of risk due to its openness. It allows the public to enter the experimental space, which is not separated from other facilities of ordinary commercial activity. The open space also reduces traceability because the product under test is neither labelled nor documented. A semi-open regulatory sandbox is not open to the public; only selected participants are allowed to engage with the labelled and recorded objects. The objects are also allowed to leave the sandbox but remain under regulatory oversight.

This article asserts that the sandbox for nanotechnology innovation should be designed to reflect the distinct characteristics of various nanotechnology innovations. As previously discussed, the integration of nanotechnology into innovation activities involves ENMs or nanodevices. The closed regulatory sandbox is appropriate for innovation that utilises novel ENMs with uncertainties regarding potential safety and health risks, in which experiments are conducted under regulatory supervision with predefined parameters, monitoring protocols, and containment measures. On the other hand, open or semi-open sandboxes are

appropriate for innovation that utilises nanodevices, as they do not involve direct exposure to human safety and health risks. When the sandbox for nanotechnology innovation operates in a closed environment, its geographical boundaries must be clearly defined and confined to domestic territory to enable continuous, close-range oversight by both innovators and regulatory authorities. In contrast, open and semi-open regulatory sandboxes may extend beyond national boundaries, allowing experimental nanotechnology products to circulate within international markets and across jurisdictions, considering the global nature of nanotechnology trade. Hence, it is also necessary for the notifying authorities to evaluate the potential interaction between the regulatory sandbox and international trade laws. It is also important to note that closed, open, and semi-open sandboxes should all be physical in nature, given the tangible nature of nanotechnology innovations, as explained in the previous paragraph.

The third operational prerequisite is the duration of the regulatory sandbox. According to Seferi (2025), the duration of the experimentation phase is typically pre-defined and may range from 3 to 36 months. Meanwhile, Novelli et al. (2026) argued that the sandbox duration must remain flexible within a reasonable timeframe. The sandbox may end early if the experiment achieves its objectives. Likewise, Ranchordás (2021) suggested that no specific duration be set for the regulatory sandbox, as it needs to be operated in line with the specificities of the innovations. Chen and Taeihagh (2026) contended that the duration of the regulatory sandbox depends on its functionality. They classified the regulatory sandbox's functionality as exploratory, confirmatory, and on demand. The exploratory regulatory sandbox aims to explore and test innovations. Therefore, the duration of the regulatory sandbox should be longer than that of a confirmatory regulatory sandbox, which is primarily intended to validate and substantiate previously explored technological applications and can be completed within a shorter time frame. Meanwhile, the on-demand regulatory sandbox can be long- or short-term, as it is used when the intention is to make the innovation available to the public upon exiting the sandbox.

Scholars have suggested different approaches to determine the appropriate duration of a regulatory sandbox. The general rule is that the regulatory sandbox shall not be perpetual. Instead, it must be within a reasonable timeframe given the objectives of the experiments. This article argues that the duration of the sandbox for nanotechnology innovation should be based on functionality, as suggested by Chen and Taeihagh (2026). Given this dynamic landscape, exploratory, confirmatory, and on-demand regulatory sandboxes are all appropriate for nanotechnology. For instance, if an innovation utilises ENMs commonly used across industries and regarded as safe, a confirmatory regulatory sandbox with a shorter time frame is more appropriate. If an innovation utilises ENMs with unknown toxicity, it should be placed in an exploratory sandbox with a longer experimental duration. Regulatory authorities must assess the nature of these innovations and the objectives of innovators, particularly regarding their intent to commercialise the technology.

The next operational requisite is monitoring and reporting. The purpose is to determine whether the nanotechnology products continue to meet relevant standards, especially in terms of safety and health. The activities conducted within the regulatory sandbox must be subjected to formal ongoing monitoring. This article suggests that the frequency and detail of monitoring should depend on the complexity of the products, their life cycles, and the potential risks they pose. High-risk products will require more detailed and frequent monitoring, while lower-risk products could benefit from lighter monitoring. The information obtained from monitoring activities must be reported, shared among participants in the regulatory sandbox, and evaluated (Organisation for Economic Co-operation and Development, 2025).

This article suggests that nanotechnology-based products, such as foods and feeds, cosmetics, personal care items, and fertilisers, should undergo long-term monitoring due to their high-risk profile stemming from direct consumer exposure to ENMs. This contention is based on various laboratory studies demonstrating potential adverse effects of ENMs on human health and safety. Data obtained from the regulatory sandbox provides critical empirical evidence that may validate or challenge laboratory study findings, thereby strengthening the scientific basis for risk assessment of nanotechnology products.

On the other hand, nanotechnology products such as devices, semiconductors, and fabrics with no added ENMs are suitable for short-term monitoring, as there is no direct exposure of ENMs to human safety and health. Conversely, nanotechnology products without added ENMs, such as devices, semiconductors, and fabrics, are appropriate for short-term monitoring, as they do not involve direct exposure to ENMs that could potentially compromise human health and safety. Most importantly, the risk classification should consider the unique characteristics of each ENM category, including physicochemical properties such as size distribution, surface properties, solubility, persistence, routes of exposure, and exposure duration.

The last operational requisite is the exit strategy. There are two ways for the participant to exit the regulatory sandbox. First, the regulatory authority may revoke the sandbox when the participant fails to comply with the sandbox conditions or unacceptable risks arise. There must be a matrix outlining acceptable and unacceptable risks that can serve as a guideline for determining when the regulatory sandbox should be terminated. It is the responsibility of the regulatory authority and the participant to formulate the exit strategy from the experiment (Ringe & Ruof, 2020). For the regulatory authority, the exit strategy shall include issuing at least one month's written notice of its intention to terminate the sandbox and removing privileges or protections granted to participants under legal derogation.

For the participant, when unacceptable risks arise, the exit strategy must specify the participant’s responsibility to provide compensation or redress mechanisms to any consumers who have suffered financial losses or safety and health issues arising from

the tested nanotechnology innovation (Bank Negara Malaysia, 2024). The participant must also clearly outline the procedure for recalling the nanotechnology products from consumers' possession. The exit strategy may also involve redirection, in which the participant will restart the experiment in an improved environment to reassess the risks (Stazi & Jovine, 2025). The second way to exit the sandbox is after the successful completion of the experiment within the stipulated timeframe. When the experiment is successfully completed, the participant may proceed with a transitional plan, which may include licensing, market authorisation, or commercialisation.

As previously analysed, the function of the regulatory sandbox for nanotechnology innovation, inter alia, includes a systematic reporting scheme on the utilisation of ENMs and nanodevices, particularly regarding potential safety and health risks. In certain jurisdictions, it is a requirement that a formal exit report be prepared by the competent authority upon completion of the regulatory sandbox experiment (Stazi & Jovine, 2025). Therefore, this study contended that the regulatory authority and the participant should prepare a formal exit report summarising the experimental outcomes, the compliance trajectory, the regulatory implications, concerns regarding safety, health, and the environment, and lessons learned from the experiment. Such reports play a critical role in ensuring transparency and accountability in the regulatory sandbox framework. The monitoring and final reports should be made publicly available to uphold transparency in the regulatory sandbox for industries and consumers. However, such disclosure should be subject to certain limitations, particularly where the innovation is protected under intellectual property rights or confidential data. It must balance the need for transparency with the innovator's proprietary interests.

CONCLUSION

Nanotechnology is a highly versatile and transformative technology that has stimulated innovation across various industries. However, there are two major concerns regarding the adoption of nanotechnology for innovation across various industries: the risks to safety, health, and the environment remain uncertain, and there is a lack of nanotechnology-specific legislation to govern these risks. There is a need to formulate a framework to protect consumers and the environment against the risks posed by nanotechnology innovation. A regulatory sandbox is an appropriate legal framework for regulating risks by testing innovation in a controlled environment. While this framework has been adopted by other technologies, there is a lack of academic exploration of the regulatory sandbox for nanotechnology.

Figure 3 illustrates the basic framework for a nanotechnology innovation sandbox that could be adopted in governing the innovation and risks associated with nanotechnology. The formulation of the sandbox for nanotechnology innovation must commence with

establishing a competent authority comprising the notifying authority and the market surveillance authority. The design of the sandbox must take into consideration the current legal position governing the specific nanotechnology innovation and the nature of nanotechnology itself, whether ENMs or nanodevices. While testing, the innovator must systematically monitor, assess, and report the impacts of their innovation on safety, health, and the environment before fully releasing the products to market. The sandbox will be terminated if risks are identified and persist. Hence, the sandbox serves as a precautionary measure in the absence of specific nanotechnology legislation while promoting sustainable nanotechnology development. This article also highlights the need for further research into the relationship between the regulatory framework for nanotechnology innovation and international trade law, particularly the World Trade Organisation (WTO) instruments. Further research is also essential to develop a risk-based monitoring framework tailored for each category of nanotechnology innovations across various industries.

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