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# ADOPTION OF THE PRECAUTIONARY PRINCIPLE ON THE SAFETY AND HEALTH RISKS OF NANOFOOD IN MALAYSIA

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## ABSTRACT

Food derived from nanotechnology or contains engineered nanomaterials (ENMs) is widely available for consumers in the marketplace. Oral exposure to ENMs has been linked to various potential adverse effects on human safety and health. In Malaysia, nanofood is regulated with a regulatory framework designed for conventional food without considering the unique and novel properties of ENMs. The adequacy of the existing framework for regulating the safety and health risks of nanofood is ambiguous. This study examined the necessity for Malaysia of having such regulatory

framework to govern the safety and health risks of nanofood using the precautionary principle. By adopting the doctrinal analysis, the finding suggests that the existing food safety framework must be amended to incorporate specific provisions on nanotechnology, and that the amendment must be based on the precautionary principle. The new regulatory framework enables the food safety authority to implement the earliest precautionary measure, protecting consumers from serious future harm caused by nanofood. The proposed regulatory framework will strengthen the domestic food safety framework and national food safety policy in meeting the challenge posed by nanofood.

**Keywords**: Food safety, nanotechnology, nanofood, precautionary principle, safety and health risks.

## INTRODUCTION

Nowadays, consumers' dietary composition includes food containing engineered nanomaterials (ENMs), which are food ingredients with sizes ranging from 1 to 100 nanometers. ENM-containing food, also known as nanofood, is widely available to consumers. It is estimated that the market size for nanotechnology to reach 290.93 billion US dollars in 2028, with a steady compound annual growth rate (CAGR) of 18.3 percent (Emergen Research, 2021). It is also predicted that between 2019 to 2023, there will be incremental growth in the global nanofood market, worth 112.48 billion US dollars (Business Wire, 2019). For the domestic market, the market size for nanofood is estimated to reach RM 1.31 billion in 2025 (NanoMalaysia Berhad, 2020). Over the last two decades, the volume of publications and patent registrations on nanotechnology in the food industry increased by 40 percent and 90 percent, respectively (Cerqueira et al., 2017). These statistics strongly indicate that food producers and manufacturers have grown to accept ENMs in food manufacturing and food products. Meanwhile, consumers are being exposed orally to ENMs through food matrices and food packaging.

Despite the growth of the nanofood market, various international, regional, and domestic organizations have raised their concern about the sufficiency of a regulatory framework to regulate the safety and health risks associated with nanofood. Since 2004, the European

Commission (2004) has evaluated the possible regulations for nanotechnology in various industries, including food and agriculture. The existing framework was determined to be ineffective and insufficient in preventing and minimizing potential safety and health risks. A year later, the Organisation for Economic Co-operation and Development (OECD) and Allianz Group (2005) raised concern that regulatory authorities in certain jurisdictions have yet to consider the legal implications of ENMs on human safety and health. In 2008, Friends of Earth Australia, Europe, and the United States contended that the existing law is insufficient to protect consumers from the potential safety and health risks of nanofood as the existing law does not require the disclosure of ENMs. In 2010, the United Nations Food Agriculture Organisation (FAO) and World Health Organisation (WHO) expressed the need for cooperation to develop nanotechnology regulations in the food and agriculture industries to protect consumer safety and well-being (Food Agriculture Organization, 2010). Earlier in 2008, the Federation of Malaysian Consumers Association (FOMCA) cautioned that integrating nanotechnology in various industries poses safety concerns in Malaysia (National Consumer Complaint Centre, 2008). Concerns from these organizations indicate that safety and health risks posed by nanofood need to be adequately addressed.

According to Snir and Ravid (2015), an efficient regulatory framework for nanotechnology products will adequately protect consumers from future catastrophes. Therefore, this study aimed to examine the need for a new regulatory framework to regulate the safety and health risks of nanofoods. Based on a doctrinal analysis, this study discovered that a new regulatory framework must be formulated, and a reform of the existing food safety legislation is needed. The food safety authority needs to immediately respond to scientific evidence from research suggesting the safety and health risks of oral exposure to ENMs. Importantly, the regulatory framework for nanofood must be underpinned by the precautionary principle. The principle enables food regulatory authorities, food manufacturers, and consumers to exercise early precautions to prevent and minimize the safety and health risks associated with oral exposure to ENMs.

This study adopted an in-depth analysis of statutory provisions and literature on the precautionary principle, nanofood safety and health risks, and food safety regulations from research journals, books,

legislation, national food safety policies, and international conventions. This study adopted a descriptive-analytical and comparative-analysis research approach. The former was adopted to describe and analyze the risks of ENMs, the concept of the precautionary principle, and the sufficiency of the existing regulatory framework for nanofood. The latter compared the regulatory framework in the European Union with the provisions on the precautionary principle in the Cartagena Protocol 2007, as well as the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Both approaches enabled this study to recommend a new regulatory framework for nanofood in Malaysia.

## UNCERTAINTY OF RISKS AND INSUFFICIENT RISK ASSESSMENT

Evidence from scientific studies demonstrates that ENMs and conventional materials have distinct psychochemical properties (size, shape, surface area, solubility, aggregates, agglomerates) (Marin-Bustamante et al., 2019; EFSA Scientific Committee, 2021; Tiwari et al., 2021; Bizymis & Tzia, 2022). The tiny particle has a greater surface area to volume ratio, which promotes greater reactivity and allows for novel applications that could be achieved using conventional-size materials (Thangadurai et al., 2020). The unique and novel psychochemical properties of ENMs contribute to the possible toxicity source that is not present in conventional materials (Ali et al., 2021; Yu et al., 2021).

Table 1 summarises the usage of commonly found nanomaterials in food matrices and food packaging, such as silver, titanium dioxide, zinc, and silica nanoparticles, together with the potential safety and health risks. Experiments using silver nanoparticles have demonstrated the possible toxicity to various organs, including the intestinal glands, gastrointestinal tissue, liver, kidneys, and spleen abnormalities. Oral administration of titanium dioxide nanoparticles can worsen tumour formation (colon cancer) and may have adverse effects on the liver and intestines, causing bowel disease. Meanwhile, zinc nanoparticles can cause corrosive injury to blood vessels. Oral exposure to silica nanomaterials is potentially harmful as it may lead to inflammatory effects and genetic damage.

**Table 1**

*Overview of the name of ENMs, Usage, and Potential Safety and Health Risks from in vitro, in vivo and in silico Experiments*

| Name of ENMs | Usage | Potential Safety and Health Risks from *in vitro*, *in vivo* and *in silico* Experiments |
|---|---|---|
| Silver nanoparticle | ▪ found in dietary supplements, antimicrobial, anti-odour, and food additives. | ▪ Damage of the intestinal glands and microvilli (tiny hair membranes in the body) (De Moura et al., 2012) consequently reducing the absorptive capacity of the intestinal tract, leading to a decrease in body weight (Shahare & Yashpal, 2013). |
| | ▪ Food packaging. | ▪ Liver inflammation, induces organ toxicity, and inflammatory responses (Carbone et al., 2016).<br>▪ Increase in sperm abnormalities and reduced sperm parameters, damage to intestinal glands, changes in gastrointestinal tissue (Gaillet & Rouanet, 2015), and potentially harmful effects to the liver, kidney, and spleen (Baki et al., 2014). |
| Titanium Dioxide Nanoparticle | ▪ Found in food products where at least 36% of the TiO2 present in food is in the nanoscale.<br>▪ Available in sweet foods such as chewing gum, chocolate, candy, coffee creamer, sauces products, and food supplements. | ▪ Accumulated titanium dioxide nanoparticles in human tissue may have adverse effects on the liver, cause inflammatory bowel disease (Rompelberg et al., 2016; Heringa et al., 2018), impair the intestine, increase gene expression, changes in tissue and cell structure (Smolkova et al., 2015), and worsen the pre-existing intestinal disease, i.e., enhance tumour formation (Koeneman et al., 2009; Hagen & Drew, 2016). |

(continued)

| Name of ENMs | Usage | Potential Safety and Health Risks from *in vitro*, *in vivo* and *in silico* Experiments |
|---|---|---|
| Zinc Nanoparticle | ▪ Found in nutritional supplements such as multivitamins (Wang et al., 2014). | ▪ Oral exposure to zinc nanoparticles may cause corrosive injury in human small blood vessels in the abdomen without evidence of toxicity (Liu et al., 2006).<br>▪ Mice that were treated with N-ZnO suffered from lethargy, vomiting, diarrhoea and death after the first week of treatment because of intestinal obstruction (Wang et al., 2008).<br>▪ Induce toxicological effects on different organs such as lung, liver, and kidney (Esmaeillou et al., 2013). |
| Silica nanoparticles | ▪ Found in food additives used as an anti-caking agent or anti-clumping agent (powdered mixes, and whiteners). | ▪ High concentrations of silica lead to potential toxicity such as interfering with glutathione biosynthesis (Contado et al., 2016), inflammatory effects, oxidative stress, and possible genetic damage (Di Cristo et al., 2016; Dussert et al., 2020). |

*Source*: Author's Interpretation

Besides, unlike conventional foods, the insufficient risk assessment for nanofood has contributed to the lack of data on the extent of adverse effects from oral exposure to ENMs to the gastrointestinal track (Mirabile et al., 2014; Zhang et al., 2019). The Ministry of Health Malaysia issued the Guideline on the Application of Risk Management for Food Safety in 2004. The Guideline describes the risk management framework and provides examples of risk management activities for any food-related organization, industry, or individual. It has a general application to all types of microbiological and chemicals found in food products, regardless of particle size (Ministry of Health, 2004). The Guideline makes no mention of nanotechnology, ENMs, or other nanoparticle-related terms. The unique psychochemical

properties of ENMs, as well as the difficulties in characterizing them, also challenge the existing risk assessment methodology designed for conventional food (Xiarchos et al., 2020). There is a possibility that the risk assessment design for conventional food is insufficient to assess the safety status of nanofood. Reliable risk assessment for nanotechnology has yet to be realized, and doubts concerning safety status persist (Sharifi, 2012).

The scientific evidence of safety and health risks, as well as the inadequacy of risk assessment, provides a solid basis for regulating nanofood. The utilization of ENMs should be treated with caution, and ENMs in the food industry should receive more regulatory attention than conventional materials. Because ENMs have novel and unique psychochemical properties that differ from conventional materials, a specific regulatory framework for nanofood is required. The regulatory framework should consider the peril of scientific evidence from experimental studies and offer precautionary measures to prevent and minimize future damage.

## PRECAUTIONARY PRINCIPLE

The precautionary principle is a legal principle that allows and encourages regulators to take the earliest possible precautionary measures when there is a reasonable indication of a threat or harm toward the environment, safety, and health (Sandin, 1999). It offers excellent significance for the sustainability of scientific activities whilst protecting the environment, safety, and health from the risks posed by such activities. The idea is not to wait for actual injury and to act in time, although the nature and extent of harm are not fully apparent (Trouwborst, 2006). In certain situations, waiting for complete certainty is of no avail if the government acts too late and the risks have materialized.

Notable historical examples of emerging technology products that were initially deemed to be safe include dichlorodiphenyltrichloroethane (DDT) and asbestos. After a lengthy period of use, the harmful effects of such products on humans and the environment were discovered. For instance, DDT was discovered and used in the 1940s as effective insect control in the agricultural industry. It was only in 1972, that DDT was prohibited after being used for more than 30 years owing

to adverse effects on safety and health (United States Environmental Protection, 2023). Meanwhile, the detrimental effects of asbestos on health were only discovered after it was commercialized due to the long latency period of asbestos. The law to govern asbestos was unduly lagged, even after death cases were reported (Sandoval, 2009). The regulatory authorities failed to impose early precautionary measures due to refusal and failure to acknowledge the initial evidence of risks and instead waited for actual injury or full scientific certainty. There is concern that the safety and health risks of ENMs used in the food and agriculture industry will be the new asbestos, latent side effects, and delay in regulation due to uncertainty of risks (Johnson, 2016). An effective regulatory framework to prevent the potential safety and health risks from oral exposure to ENMs is much needed. It is to prevent the tragic history of DDT and asbestos from repeating.

The precautionary principle does not have a standardized formulation. Several formulations of the precautionary principle have been advanced in the international, regional, and national regulatory framework to manage and regulate major global issues that threaten the environment, safety, and health, such as genetically modified organisms (GMOs), climate change, and nuclear energy (Boyer-Kassem, 2017). According to Trouwburst (2006), the absence of standardized formulation does not render the precautionary principle of ineffective legal principle in regulating risks. Three core elements must guide the application; 'threat of harm,' 'lack of scientific certainty,' and 'precautionary measures.' The imposition of a precautionary measure is only valid in the presence of threats of harm and scientific uncertainty. Besides, the existence of a threat of harm and the lack of scientific uncertainty must be proven based on scientific evidence rather than merely logic or assumption (von Schomberg, 2006).

The effectiveness of the precautionary principle in regulating various environmental, safety, and health issues has been proven. The precautionary principle has progressively influenced international, regional, and national legal systems on risk management (Trouwborst, 2006). It is argued that this principle has attained the status of a legal obligation known as *opinio juris* (Pedersen, 2014), to the extent it has crystallised and emerged as customary international law (Cameron & Abouchar, 1991). To date, more than 90 international instruments have recognized and incorporated the precautionary principle into their operation, with applications ranging from environmental to public health protection (Širinskienė, 2009).

The discussions and debates on managing the potential safety and health risks of nanotechnology often involve the precautionary principle. According to the OECD and Allianz Group (2005), the precautionary principle is an excellent approach to regulating the potential risks of nanotechnology. Sodano and colleagues (2016), as well as Hansson (2020), suggested a strong regulatory will for nanotechnology based on the precautionary principle is required. A study by Saldívar-Tanaka and Hansen (2021) demonstrated that 70 percent of the experts on nanotechnology governance in Europe strongly believe that the precautionary principle is the most appropriate way to manage nanomaterials. These suggestions can be incorporated into the domestic food safety framework to regulate the safety and health risks of nanofood.

**Precautionary Principle in Malaysia's Food Safety Framework**

In Malaysia, the National Food Safety Policy and the 2010-2020 Food Safety Action Plan are two main national policies that address food safety issues (National Food Safety and Nutrition Council, 2010). Noticeably, the precautionary principle is absent from these policies. Likewise, the primary legislation regulating food safety issues, namely the Food Act 1983 and Food Regulations 1985, do not explicitly embody the precautionary principle. It is an indication that the precautionary principle is not regarded as the heart of the food safety framework in protecting consumers from food safety issues.

In the absence of the precautionary principle, food safety measures can only be implemented when it is scientifically certain that the substance contained in the food products is harmful for consumption. For instance, the removal of chilies (Ministry of Health, 2018a) and iceberg lettuce (Ministry of Health, 2018b) contaminated with fipronil and listeria monocytogenes from the market. The harmful effects of both microbial on human safety have been scientifically proven based on the injuries recorded. On the contrary, the threat of harm from nanofood is not fully apparent and is only illustrated through scientific studies. This study contended that the existing legislation on food safety is insufficient to deal with nanofood safety and health risks that are not fully apparent.

Nevertheless, the Food Regulations 1985 had indirectly adopted the precautionary principle on labeling for genetically modified

food products, as required by the Biosafety Act 2007 *(Act 678)*. The official reception of the precautionary principle into the Malaysian legal system was made through the Biosafety Act 2007 after ratifying the Cartagena Protocol in 2003. It is the first legislation that expressly embeds a precautionary statement (Kamilan et al., 2011). Section 35 stipulates that *the lack of scientific certainty about the adverse effects of the release and use of genetically modified organisms shall not forbid the regulatory authority from imposing precautionary measures to prevent and minimize the potential adverse effects*. Meanwhile, the precautionary measures prescribed by the Biosafety Act 2007 include identifying and labelling under Section 61. Products containing or derived from GMOs must be identified and labelled, according to Regulation 7 of the Food Regulation 1985. Until today, the Biosafety Act 2007 remains the only legislation that expressly incorporates the precautionary principle into the statutory provisions.

However, the precautionary principle in the Biosafety Act 2007 and the labelling measure in the Food Regulations 1985 are only applicable to GM foods. It could not be extended to nanofood because ENMs in food products and food packaging are not living organisms. ENMs are composed of chemical substances or materials intentionally manufactured and used at nano sizes, such as titanium dioxide, silica dioxide, iron oxide, silver nanoparticles, and nanoscale polymer (Bandala & Berli, 2019). Therefore, a new regulatory framework that embodies the precautionary principle must be formulated for nanofood. It is important to determine whether the adoption of the precautionary principle to regulate nanofood risks violates the practices of international food regulatory bodies. The domestic food safety framework is also connected with regulations and practices of the United Nations Food Agriculture Organization (FAO) and Codex Alimentarius Commission (CAC). Next, this study examined the position of the precautionary principle in regulating food safety risk by the FAO and CAC.

## Precautionary Principle under the International Food Regulatory Bodies

The FAO has explicitly recognized the precautionary principle as one of the major trends in the agricultural and fisheries industry. The Vancouver Statement on the Globalization and Industrialisation of Agriculture expressly highlighted the importance of the precautionary

principle to remedy agro-environmental degradation (Institute for Agriculture & Trade Policy, 1998). It encourages farmers to choose non-destructive mechanisms to provide more food to avoid future damage to the environment. Furthermore, the FAO Code of Conduct for Responsible Fisheries (CCF) widely implemented the precautionary principle to protect and preserve living aquatic species from extinction. The inadequacy of scientific information on the adverse effects on the aquatic environment shall not be used as a reason by the regulatory authority for postponing or failing to take conservation or management measures (Food Agriculture Organization, 1995).

The application of the precautionary principle by the FAO in the agriculture and fisheries industry focuses on food security to guarantee the availability, accessibility, and stability of global food supplies. The interpretation of food security by the FAO also includes food safety, which requires e sufficient and safe food access (Food Agriculture Organization, 2006). Moreover, the application is not directed to a specific technology or substance. If nanotechnology and ENMs cause agro-environmental degradation, precautionary measures can be adopted to avoid food supply disruption. Hence, the precautionary principle adopted by the FAO is also applicable to food safety issues, including those generated by nanotechnology.

CAC's primary mandate is to protect consumers' health by issuing Codex texts that prescribe the global food safety standard. The precautionary principle has never been expressly embedded in 224 standards, 79 guidelines, and 54 codes of practice. On the other hand, the CAC Procedural Manual and Codex Working Principle for Risk Analysis have adopted the precautionary principle for risk analysis on food safety issues. Paragraph IV(10) of the Procedural Manual recognized the existence of insufficient or incomplete scientific evidence in assessing food safety risks to human safety and health. Paragraph IV(11) further stipulates that the degree of uncertainty and variability in scientific information should be explicitly considered in the risk analysis. The scope of risk analysis in the Procedural Manual is intended for the overall Codex Alimentarius framework on food safety issues arising from different technologies utilized in the food processing industry (Codex Alimentarius Commission, 2007). It shall address food safety issues posed by various emerging technologies such as nanotechnology.

Therefore, the adoption of the precautionary principle in the domestic food safety regulatory framework to regulate the risks of nanofood is not in conflict with FAO and CAC practices. Both organizations have applied the precautionary principle to food safety issues that have emerged as a result of the use of emerging technologies. As the amendment to the food safety regulatory framework requires a new formulation of the precautionary principle for nanofood, this study referred to the formulation of the precautionary principle in international instruments on food safety, namely the Cartagena Protocol on Biosafety 2000 and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

**Precautionary Principle under the International Instruments**

This study analyzed the precautionary principle in the Cartagena Protocol as it is the instrument that treats the precautionary principle as a general application in protecting the environment, safety, and health. Furthermore, GMOs and nanotechnology are regarded as emerging technologies and there is a resemblance between the risks of nanofood and the risks of GM food, both of which are still surrounded by scientific uncertainties. Meanwhile, the SPS Agreement adopted the precautionary principle for food safety.

The Cartagena Protocol is the most recent international instrument with the precautionary principle to regulate the potential environmental, safety, and health risks of GMOs. The precautionary principle is adopted as the legal principle for GMOs due to the scientific uncertainty surrounding the commercialization of GMO products. Knowledge about the probability of safety and effects of GMOs is still lacking, and the predictive ability of science on the risk assessments for GMO release is also limited (Zilberman, et al., 2018). The precautionary principle is reiterated twice in the Protocol in Article 10(6) and Article 11(8). Article 10(6) states that:

> *Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, about the import of the living modified organism […].*

Meanwhile, Article 11(8) stipulates that:

> *Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, about the import of that living modified organism intended for direct use as food or feed, or for processing, to avoid or minimize such potential adverse effects.*

By Article 10(6) and Article 11(8), the precautionary principle in the Cartagena Protocol regulates GMO activities in two categories. First is the transboundary movement for GMOs intended to be introduced into the environment, such as seeds for cultivation and breeding animals. Second is the safety procedure for handling GMOs that are intended for direct use as food, feed, or processing, such as corn, cotton, and soy. Hence, the precautionary principle in the Cartagena Protocol is adopted as a food safety measure to prevent and minimize the potential adverse effects of oral exposure to GMOs in food products. In preventing and minimizing the potential adverse effects of GM foods, Article 16 requires the Party to the Protocol to take appropriate measures in the safe handling, storage, transport, and use of GMOs.

The SPS Agreement is the World Trade Organisation (WTO) agreement that implicitly adopted the precautionary principle. The Agreement lays down the basic rules of food safety and plant health standards to protect consumers against food hazards and prevent food safety measures from being unjustified trade barriers (World Trade Organisation, 1998). The implicit adoption of the precautionary principle has resulted in a debate on whether Article 5.7 represents the precautionary principle. Article 5.7 states that:

> *In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures based on available pertinent information, including that from the relevant international organizations as well as from sanitary*

> *or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measures accordingly […]*

*The European Communities – Measure Concerning Meat and Meat Products (Hormones) WT/DS26/2* is the landmark case that argued the significance of the precautionary principle in the SPS Agreement. The WTO Appellate Board held that the precautionary principle has indeed found its reflection in Article 5.7. Likewise, in the case of European *Communities – Measures Affecting the Approval and Marketing of Biotech Products,* the WTO Panel ruled that Article 5.7 is the expression of the precautionary principle, and the principle has become a fully-fledged and general principle of international law. The findings from both cases signify that the precautionary principle is indirectly reflected in Article 5.7. When scientific evidence is insufficient, the SPS measure is equivalent to a precautionary measure to prevent or minimize potential risks to humans, animals, or plant life.

Suppose the adoption of the precautionary measure for nanofood is based on the SPS Agreement, two conditions laid down in Article 5.7 must be strictly observed. First, the safety measure adopted must have been applied by the relevant international organization or other members. It is pertinent to note that the FAO and CAC have not yet consolidated or implemented any measures to prevent or minimize the potential safety and health risks of nanofood. In 2013, the FAO published a technical paper on nanotechnologies in the food and agricultural industry. The technical paper discussed the importance of nanofood labelling as a precautionary measure (Food Agriculture Organization, 2013). Nonetheless, it is merely an expert discussion that has never been translated into a formal policy. Likewise, the CAC has yet to issue any specific standards or guidelines on nanofood.

Second, a precautionary measure adopted under the SPS Agreement should not entail incursion into international trade. In certain instances, the imposition of SPS measures such as product labelling, packaging, or standards is non-tariff barrier. It occurs when the SPS measure hampers the importation or exportation of products and is

costly. Therefore, the Party to the SPS Agreement must cautiously evaluate the available scientific evidence to justify trade restrictions based on precautionary measures. Thus, the precautionary principle in the Cartagena Protocol is more concise and less complicated than in the SPS Agreement.

Despite being adopted in international instruments, it is also essential to highlight the criticisms received by the precautionary principle. First is the vagueness of the precautionary principle. It occurs due to the absence of a harmonizing formulation of the precautionary principle adopted by international instruments, national legislation, or scholars (Ahteensuu, 2007). The lack of uniformity may lead to inconsistent, improper considerations and arbitrary decisions, which could end with a precautionary measure that could be a catastrophe (Marchant, 2003). Second is the possibility of the wrong presumption of risks as the decision is made based on scientific uncertainty and imperfect knowledge in assessing the magnitude of the harm (Sunstein, 2003). Lastly, the precautionary principle is employed as a disguised form of protectionism. Marchant (2003) also contended that the precautionary principle intends to harm the future generation by denying the benefits of technology and only focusing on the probable risks rather than the benefits. Regardless of the criticisms, the following discussion highlights the arguments to save the precautionary principle from criticism.

## REGULATORY FRAMEWORK FOR NANOFOOD IN THE EUROPEAN UNION

The European Union is the prominent champion of the precautionary principle. The precautionary principle is not only stamped on the European framework for environmental protection as required by the Treaty on the Functioning of the European Union (TFEU) and the Treaty on the European Union (TEU). In February 2000, the European Commission extended the application of the precautionary principle across any area for containment of risks, including food safety and consumer protection. Regulation (EC) No 178/2002 on general principle on food law, which is the primary legislation on food safety in the European Union, expressly embedded the precautionary principle under Article 7(1). The provisions in Regulation (EC) No

178/2002 on the general principle of food law are also applicable to all substances intentionally incorporated into the food during its manufacture, preparation, or treatment, as stipulated in Article 2. Hence, the precautionary principle in Regulation (EC) No 178/2002 shall also apply to ENMs in food products. The precautionary principle elevates the level of protection for consumers on food safety issues. It allows the food safety authorities to implement the precautionary measure even if the risks are not fully certain or apparent.

In 2012, the European Commission published a communication to the European Parliament with three critical recommendations: (i) the statutory definition of nanomaterials must be integrated into the relevant legislation, (ii) the method for detection and characterization of nanomaterials in finished products must be established, and (iii) nanomaterials in the various industry should be subjected to risk assessment and risk management (European Commission, 2012). Based on the recommendations, the European Parliament amended the existing legislation to incorporate provisions on nanotechnology, including legislation for the food and agricultural industry. The amendment involves the incorporation of provisions related to the (i) statutory definition of ENMs, (ii) labelling of nanotechnology products, and (iii) risk assessment for ENMs, in Regulation (EU) 2015/2283 on novel Foods and Regulation (EU) 1169/2011 on food information to consumers, Regulation (EC) 1333/2008 on food additive, Regulation (EU) No 609/2013 on special food, and Regulation (EC) No 10/2011 on plastic food contact materials.

In 2011, the European Commission issued a recommendation on the definition of nanomaterial (2011/696/EU) as guidelines for determining whether a material is regarded as nanomaterial for legislative or policy purposes. The definition sets a parameter or technical specification that clarifies the statutory requirements for nanotechnology activities and products, such as ENM labelling and risk assessment. Later, the statutory definition of ENMs for food law is embedded in Article 3(2)(viii) of Regulation (EU) 2015/2283. It is to harmonize the definition of nanomaterials across the food and agriculture industry. Preamble 10 stipulates that for consistency and coherence purposes, the definition of ENMs in Regulation (EU) 2015/2283 applies to all legislation in the area of food law. The European Parliament also has mandated nanofood labelling as a precautionary measure. Article 18(3) of Regulation (EU) 1169/2011

stipulates that if the characteristic of materials or ingredients in a food product fits the definition of ENMs in Regulation (EU) 2015/2283, a nano label must be affixed to the product.

It is important to note that the regulations and directives passed by the European Parliament and Council of the European Union are known as the legislative act or legislative instrument, which is a binding law upon all the members of the European Union (European Union, n.d.). Hence, the incorporation of the precautionary principle in Regulation (EU) 2015/2283 and the adoption of the precautionary measure on nanofood in Regulation (EU) 1169/2011 binds all European Union members. Consequently, members have to incorporate the requirements to regulate the risks of nanofood using the precautionary principle in their domestic legislation. However, the scope of this study does not extend to analyzing how each European Union member implemented such requirements into their national legislation.

Despite the hard law, the European Union also adopted the soft law approach to regulate the risks of nanofood. European Food Safety Authority (EFSA) published two non-binding guidance documents on nanofood risk assessment, *Guidance on the Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain 2011* and *Guidance on Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain: Part 1, Human and Animal Health 2018*. These guidance documents serve as a soft law for assessing and regulating nanomaterials' potential safety and health risks in the food and agriculture industry. It proposed an appropriate approach for assessing the potential risks of applying nanotechnology in the food and agriculture industry (European Food Safety Authority, 2018).

The European Union regulates the risks of nanofood through a combination of hard law and soft law approaches. The incorporation of nano-specific provisions by the European Parliament into the existing legislation signifies that a specific regulatory framework is needed to regulate the risks of nanotechnology. The existing legislation designed before nanotechnology development or without considering nanomaterials' unique and novel properties is insufficient. Labelling and risk assessment are two precautionary measures that may help prevent and minimize nanotechnology risks (Ismail et al., 2019).

## REGULATORY FRAMEWORK FOR NANOTECHNOLOGY AND NANOFOOD IN MALAYSIA

The Malaysian government has officially recognized nanotechnology as one of the key enabling technologies to vitalize national economic development (Hamdan, 2013). The Ministry of Science, Technology, and Innovation (MOSTI) has formulated two national policies on nanotechnology, which are the National Nanotechnology Initiative (NNTI) and the NanoMalaysia Programme 2011-2020 (NMP). Both policies aim to intensify nanotechnology development and commercialization toward creating a thriving innovation-driven national economy. However, the NNTI and NMP are silent on the strategic intents or strategies to prevent and minimize the potential safety and health risks of nanotechnology.

MOSTI also tabled a proposal for the nanotechnology regulatory framework that comprises two legislations, the Nanotechnology Industries Development and Nanotechnology Safety Act. The proposal also expressed the need to establish the National Nanotechnology Regulatory and Safety Committee to monitor the activities and products related to nanotechnology, particularly on the potential adverse effects (National Nanotechnology Directorate, 2013). The proposed framework will stimulate responsible nanotechnology development, i.e., balancing the effort to maximize nanotechnology development and minimize the safety and health risks. Nevertheless, the proposed legislation has yet to be implemented, rendering the absence of specific legislation regulating the potential risks of nanotechnology in Malaysia.

National Food Safety Policy and Food Safety Action Plan 2010-2020 are also silent on nanotechnology, but both policies have general applications to all food products, either produced using conventional or emerging technologies. The food safety aspects enumerated under both policies also apply to nanofood. Nevertheless, a specific strategy to manage any potential safety and health risks of nanotechnology or ENMs is still absent. According to the FSQD, the Department has started collecting information on the perspective of nanotechnology in the food industry by consumers and the industry (Nur Hidayah Othman, personal communication, November 4, 2020). Additionally, the Food Act 1985 and Food Regulations 1985 do not have a specific provision on nanotechnology. The food labelling requirements in the Food

Regulations do not contain any provisions requiring the disclosure of the size or scale of materials (either nanosize or conventional size) or specific safety measures to prevent or minimize the risks of nanofood. Besides, the risk assessment for nanofood is based on the assessment procedure designed for conventional food. The MOH's Guideline on Risk Management for Food Safety never specifies the risk assessment methodology for food with ENMs or requires the risk assessor to consider the unique physical characteristics of ENMs.

Malaysia's regulatory framework for food safety is still lagging behind nanotechnology development. The food safety and food labelling laws treat nanofood and conventional food identically, contrary to current scientific evidence. In comparison to the European Union, the regulatory framework for nanofood is a hybrid of hard and soft laws, aimed at preventing possible negative effects. In Malaysia, it is not only the hard law on nanofood is missing, but the food safety authorities have never issued specific soft laws for nanotechnology in the food and agriculture industry to regulate the safety and health risks of ENMs.

## FINDINGS AND RECOMMENDATIONS

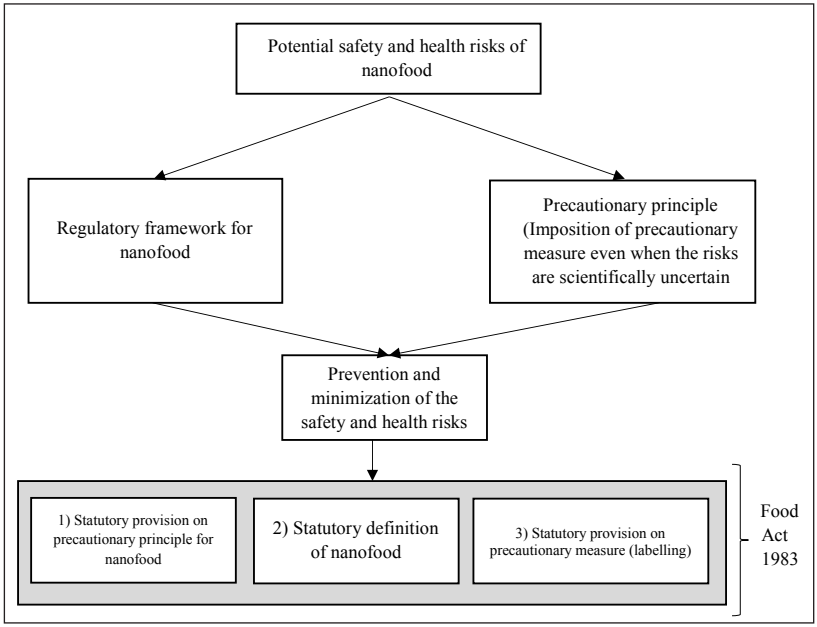
According to Sodano (2018), the major issue with regulating nanofoods is a lack of scientific information on the potential adverse effects of nanofoods. The evidence of the adverse effects is currently illustrated through scientific studies rather than through reported injuries. Hence, nanotechnology is not regarded as an immediate threat to safety and health, resulting in regulatory delays. On the contrary, this study contended that the regulatory framework for nanofood is essential and this is high time to regulate the safety and risks of nanofood. This contention is made based on three grounds. First is due to the growth of the global nanofood market, which would increase the volume of nanofood on the market and, subsequently, consumers' exposure to ENMs. The second is to avoid the history of DDT and asbestos being repeated. Third jurisdictions such as the European Union have taken necessary regulatory measures to regulate the safety and health risks of nanofood. The MOH and FSQD should be more proactive in protecting consumers from the potential risks of nanofood. A similar regulatory approach adopted by the European Union should be considered, i.e., amending the existing food safety legislation to

incorporate provisions on nanofood, and uncertain or insufficient information on risks should not be used as an excuse for inaction.

This study believes that the precautionary principle should be the foundation for the regulatory framework for nanofood. It is based on the suggestions and contentions forwarded by international organizations and scholars, as previously discussed. The results from scientific studies on the safety and health risks of ENMs provide credible scientific evidence to support the amendment. Besides that, the precautionary principle is being adopted by FAO and CAC to deal with food safety issues.

**Figure 1**

*Regulatory Framework for Nanofood in the Food Act 1983*




The adoption of the precautionary principle in nanotechnology regulation will also promote responsible and sustainable nanotechnology development, balancing the commercial value and risks aspects (McManus & Eijmberts, 2017). Figure 1 illustrates the new nanofood regulatory framework which consists of three main provisions.

First is the statutory provision adopting the precautionary principle. It is an express mandate to food manufacturers and food safety authorities to exercise precaution when dealing with nanofood. The provision can be incorporated into food safety or nanotechnology safety legislation. It is recommended that the formulation of the precautionary principle be put into the Food Act 1983 rather than the newly proposed legislation by MOSTI, the Nanotechnology Safety Act. The amendment to the Food Act 1983 is more convenient and less time-consuming as the legislation is already enforced. It allows prompt and timely protection granted to the consumers. On the other hand, it is still uncertain when the Nanotechnology Safety Act will be tabled in the parliament.

This study suggests that the formulation of the precautionary principle in the Cartagena Protocol be adopted for nanofood. The precautionary principle in the Cartagena Protocol adequately protects the safety and health risks caused by food products derived from GMOs, a product of emerging technology. On the other hand, the adoption of the precautionary principle in the SPS Agreement is more complex as two conditions set out in Article 5.7 must be fulfilled. However, the formulation of the precautionary principle in the Cartagena Protocol must be adopted with modification. It is to suit the nature and risks of nanomaterials in the food and agriculture industry. The following is the suggested formulation of the precautionary principle for nanofood: *"Where there is a lack of scientific certainty due to insufficient relevant scientific information and knowledge on the extent of the potential safety and health risks from oral exposure of ENMs, shall not prevent the regulatory authority from deciding as appropriate concerning the direct use of ENMs in food, or for processing, or food package to avoid or minimize potential adverse effects."*

Second is the provision for a statutory definition of nanofood. Based on the European Union's experience, the framework to regulate nanofood safety and health risks must embed the statutory definition of nanomaterials for the food and agriculture industry. The statutory definition ensures the precautionary principle can be adopted with legal certainty as it sets the parameter to whether the food is classified as nanofood or otherwise. It is suggested that the statutory definition of nanomaterials must be a scientific definition that considers the characteristics of nanomaterials that are commonly used in the food and agriculture industry. Besides, approaches adopted by the EFSA

Scientific Committee in formulating the statutory definition of nanomaterials for the European Union food law may be referred to, and the definition of ENMs in the Regulation (EU) 2015/2283 on novel food may be implemented. The statutory definition is incorporated into the Food Act 1983 and applicable to the area of food law.

Third is the provision that imposed precautionary measures to prevent or minimize the safety and health risks of nanofood. The precautionary measures will maintain the check and balance between the development and potential detrimental effects of nanotechnology. Maynard (2015) suggested that free-market safety testing is to be adopted as a precautionary measure. Manufacturers must disclose safety evidence before the commercial release of food containing nanomaterials. According to Tager (2015), pre-market safety testing is critically important for public health and enriches nanomaterials' safety data. The standard imposed must be reasonable, taking into consideration the absence of risk assessment for nanofood. The unrealistic and unreasonable standards of risk assessment for nanomaterials will kill nanotechnology innovation. The MOH may issue a guidance document on risk assessment for nanotechnology applications in the food and agricultural industry, specifying the appropriate risk assessment approach for nanomaterials. It is to supplement the existing risk assessment guidance designed for conventional food.

A more stringent precautionary measure, in the form of the moratorium for nanotechnology products, was suggested by Blackwelder, the former president of the Friend of Earth, and Douglas Parr, Greenpeace's chief scientist (Blackwelder, 2007). They contended that nanotechnology products should not be allowed into the market until some appropriate regulatory regime exists. It ensures that nanotechnology development does not spiral out of control and protects society from the worst possibilities. On the contrary, this study believes that a moratorium will impair the government's aspiration of using nanotechnology as a catalyst for national economic development. It will adversely affect the market value for nanotechnology consumer products that are free of harmful nanomaterials or have a negative exposure to safety and health, such as nanodevice and nanofiltration. Most importantly, the moratorium will also freeze the research and innovation activities related to nanotechnology and deprive society of the benefits of

nanotechnology. It is also important to highlight that adopting the precautionary principle is not a strategy to halt nanotechnology activities or products completely. Instead, it is to enable cautious acts when engaging with ENMs.

Another viable measure is food labelling as prescribed by the Cartagena Protocol and the Biosafety Act 2007 for GM foods. This study believes that the labelling measure is the appropriate precautionary measure for nanofood. Nano labels communicate the presence of ENMs in food products and enhance the information transparency and traceability of ENMs in the food industry. The traceability of nanofoods in the market is crucial when the current food safety framework treats ENMs and conventional materials as similar materials (Bowman & Ludlow, 2017). If an injury related to oral exposure to ENMs occurs or is reported, nanofood can be effectively withdrawn or removed from the market.

Meanwhile, transparency allows consumers to make an informed choice between conventional food or nanofood. According to Zulkupri and others (2022), consumers should be given the right to make informed decisions about nanofood consumption, especially when it exposes them to health issues. Legislative reform to enhance consumers' informed decisions about nanofood is supported by theories on consumer protection such as the Theory of Planned Behaviour, Consumerism Theory, and Postmodernism Theory.

Most importantly, labelling will not distort nanotechnology innovations, unlike moratorium. Labelling of nanotechnology products promotes responsible nanotechnology development. It helps tackle the complex issues of potential safety and health risks associated with nanotechnology and at the same time allows the R&D on nanotechnology to continue (Thangadurai et al., 2020). Food manufacturers may continue to explore novel applications of ENMs in food processing and food packaging industries. They only have to comply with labelling requirements to inform consumers about the presence of ENMs. If the current safety and health concerns are proven to be incorrect, the mandatory labelling measure can be retained as one of the information on food ingredients required by consumers in the future. Therefore, this study contended that a regulation enacted in the face of scientific uncertainty may end up being an efficient law that protects the interests of consumers.

## CONCLUSION

Consumers have been served with nanofoods and exposed to ENMs that are potentially harmful to their safety and health. The potential risks should not be left unattended. Instead, the risks must be assessed and regulated as early prevention to avoid future catastrophes. Therefore, there is a need to formulate a regulatory framework to regulate the safety and health risks of nanofoods. The framework must be based on the precautionary principle. The idea is to develop a robust food safety framework that confers the earliest possible protection without waiting for the potential risks to become fully apparent. It will also systematically tackle the challenge of nanotoxicity posed by nanofood. The proposed regulatory framework will also reinforce the national nanotechnology and food safety policy in facing the challenges posed by nanotechnology in the food and agriculture industry.

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