Nanotechnology in the Food and Cosmetics Sectors: A Study of Policy and Regulatory Frameworks in the United Kingdom

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Abstract

The new technology has presented the platforms to revolutionise many sectors of human endeavours, such as enhancing agricultural productivity, pharmaceutical production, and most especially food processing, food preservation, storage, and labeling, as well as the production of cosmetics and personal care products. However, the toxicity or associated risks without the level of certainties said to be attributed to the application of nanotechnology or engineered nanomaterials in food and cosmetics products have raised necessary worries about the potential adverse effects of nano-enabled products on human consumers and the environment, more so when it has been pointed out that there are hundreds of consumer goods in circulation in the United Kingdom (UK), with nanomaterials as components or produced with nanotechnology efficiency.

Researchers have also established that some nanomaterials are injurious to health, with an uncertain level of toxicity. Incredibly, some regulators do not see the precautionary model as fit for regulating the nano-products under the usual guise that it would hamper the development of the novel technology. They, therefore, rely on incremental legislation of existing regulations, which in most cases are alleged to be lagging to govern the new substances in food and cosmetics, are they even fit for purpose? The adequacy of the UK's voluntary scheme or relevant industries' self-regulatory approach to regulating nanotechnology is rather questionable. Suffice it to say that the fragmented approach to regulating the novel substances and technology in food, its packaging, and cosmetic products with attendant uncertainty in their toxicity analyses are critical to humans and the environment, and that calls for law reform. A case for heavy regulation of the sectors cannot be more critical.

Background

The word 'nano' which prefixes the term 'nanotechnology' comes from the Greek word 'nanos' which means 'a dwarf'. Therefore, 'nanotechnology' may simply mean a technology to process small things. In the same vein, nanotechnology has been defined as operations on the 10-9 meter, a simple explanation of this is to view a strand of hair as 10,000nanometer and imagine how small 1nanometer would look like. Precisely, a nanometre (nm) is one billionth of a meter. Nanomaterials have been defined loosely as 'a material which is developed by using nanoparticles'. A Japanese scientist, Norio Taniguchi was the person who coined the word 'nanotechnology' in 1974 and defined it thus; "nanotechnology mainly consists of the processing of separation, consolidation, and deformation of materials by one atom or one molecule". Generally, defining nanotechnology is dependent upon the exploitation and application of materials within the nanometre scale.

Challenges – the manufacture and use of chemicals or materials of extremely small sizes are challenging. The very said nano-size, materials have different properties compared to the same material in massive size.
Secondly, there are palpable uncertainties or doubts about the risks the widespread exploitation of nanotechnology may bring to human consumers and the waste generated from the use of nanoparticles in the environment.
The third concern is the absence of a precise definition of nanomaterial/nanoparticle in existing sectoral laws for the regulation, evaluation of substances, and risk assessment of nanotechnology-enabled ingredients for manufacturing food and personal care products.
Fourthly, the UK regulation style for ensuring the safe use of nanomaterial substances by manufacturers and importers as well as downstream users has been one of a voluntary report system.

The objective of the study

This dissertation gives a critical analysis of the application of nanotechnologies/nanomaterials in food and personal cosmetic products with the concomitant benefits of the novel technology as well as the potential risks they might have on human consumers and the environment. The dissertation studies the policy and legal frameworks which regulate the exploitation and application of nanotechnology in food and cosmetics products, with special concern for the effects of the life cycle of nanotechnology-enabled food and cosmetics on human consumers and the environment. The adequacy of the substantive law and how effective and complementary is the procedural aspect of the law towards ensuring the safety of humans and the environment.

Research Method

The study is based on the theoretical framework and doctrinal legal research, as such, authoritative texts such as legislation, case law, and doctrinal works of literature would be highly considered during the research. This study also made use of environmental law method (ELM) - centered research findings. The environmental law method is based on inquiries on how to achieve the objective of environmental sustainability. Also, theoretically, the study explored some regulatory models including the precautionary principle of ELM regulating emerging problems in the field of environmental law and human safety practices. The precautionary method is preventative in approach.

Findings

Challenges in the Legal Definition-The classification as a nanomaterial in a regulatory context has been challenging for regulators of nanotechnology in many jurisdictions, due to the following: 1. The relative novelty - a regulatory statute must clearly define what must be regulated for compliance and enforcement purposes.
2. To identify nanomaterials in products, and to know that nanotechnology-specific provisions apply, the size of particles involved is used across the board as a criterion.
3. The assessment of nanomaterials for legal and regulatory purposes should be predicated on definite methods of measurements and the same should be fit for the protection of human consumers and their environments.
4. The challenge of having a communicative definition of nanomaterials and one that is capable of easing enforceability for that matter.

Nanomaterials in Food and Cosmetics - Nanomaterials are introduced into specific foods to produce a certain desired effect or gains in the food industry. For instance, nutrient fortification of foods is one of the possibilities enabled by nanotechnology techniques such as nanosuspensions, nanoemulsions, nanoliposomes, and cyclodextrin carriers. Food nanotechnology is being applied in many facets of consumer products in the UK, it is used for food additives, packaging/labeling, and food preservation.

Voluntary model -Generally, the permissive regulations approach has been defined as a predisposition to approve a technology on the market even if it falls short of certain standards of efficiency, which may concern safety. Some argued that permissive regulations allow proactive measures, which aid research and development and foster a framework that engenders coordination and cooperation among the regulating government units in setting appropriate governing rules in the relevant industry; consequently, it promotes research and development and controls the risks.

Prophylactic regulations are commonly preventative unlike the permissive regulations model, the regulations would stipulate mandatory procedures for reporting and review of emerging technologies for their introductions to the public.

The precautionary principle in public decision-making is about situations where after an assessment of the existing scientific information, there exist reasonable grounds concerning potential harmful effects on the environment or human health, but scientific uncertainty continues. In that situation, interim risk management measures may be applied, without waiting for the certainty and seriousness of those harmful effects to grow completely into a visible risky situation.
For instance, the EU recently withdrew particular antibiotics in feeds from the market while invoking the precautionary principle. A subsequent and very revealing European Court of Justice ruling, concerning the case of this antibiotic in the case of Alpharma v Council [2oo2] ECR II-3495, in this contested case, the court justified the ban of the antibiotics in the feeds while relying on the safe application of the precautionary principle.
It is worth mentioning that the principle was clearly approved by the United Nations' 1992 Rio Declaration on environment and development and has become particularly adopted and included in the European Union treaty, hence its readiness to be applied in the regulatory model administering the safe consumption of food and cosmetics in the UK's regulation of nanomaterials.

Some drawbacks – 1. There is no universal or basic measure or an established version of the precautionary principles and therefore appears disjointed as a direction for a regulatory process.
For instance, the application of the precautionary principle was termed capricious and arbitrary in the Prohibition of Kellogg's Corn Flakes in the Netherlands and Norway because of the likelihood of risks associated with some vitamins applied to fortify the cereal and the way cranberry fruit drinks was banned in Denmark because of the likelihood, however remote, that the vitamin C in the juice could pose risk to someone oddly sensitive to vitamin C. However, the precautionary principle tends to rationalize the adoption of measures that stimulate the generation of more safety data on consumer goods, when the precautionary principle is invoked, the aim is "to correct an imbalance between our perception of the costs of regulatory action and our understanding and consideration of the costs of regulatory inaction"
A proactive organization had applied the precautionary principle as justification for regulating nanomaterials' use. Soil Association is a United Kingdom charitable organization on environmental issues, it sets standards for organic food and farming that exceed statutory organic standards.
UK REACH The focal point of the REACH regulation, in general, is that the manufacturers and importers of chemical substances are obliged to ensure that the substances that are in circulation or on the market would not constitute harm or have an adverse effect on human health or the environment. In consonance, UK REACH requires concerned companies/registrants to submit data on the core physical and chemical properties, the hazards, behaviours, and risks of their substances including the substance in nanoform by the provisions of Annexes VI to XI of the Reach regulation and perform risk assessments for each registered substance. The obligation to register substances under Article 6(1) is restricted to those that are manufactured or imported over one tonne per year by a manufacturer or an importer. For any chemical substance, whether new or non-pre-registered existing substances the registration procedure must be passed before the substances go into the consuming market.

Conclusion

There is no single type of nanomaterial, whether it was engineered or not, hence the recognition of case-by-case assessment of nanomaterials/nanoparticles in food and cosmetics by the regulators. Arguably, research and developments in nanotechnology are more particular about engineered nanomaterials, which are intended for multiple commercial exploitations. Certainly, there are thousands of consumer products such as food and food packaging, sunscreens, cosmetics, and some other human personal products manufactured using engineered nanomaterials. This has enhanced manufacturers' stability and great profitability, even though there is consensus in science that very little is known about nanomaterials' reaction to and/or how they pose harm/hazard to human health and the environment. Several inquiries conclusively dovetail into a caveat that there are possibilities of harm to human consumers as a result of the ingestion or consumption of nanotechnology-enabled products. The United Kingdom's trajectory of regulating nanotechnology has passed through many phases, including the pilot stage of the self-regulation process of reporting nanomaterials ingredients by importers/manufacturers, then to the enhanced recommendations of the Royal Society and Royal Academy of Engineering. The United Kingdom like the European Union was stuck to the incremental approach, trusting the available regulatory frameworks in the various sectors of the country crossing the emerging technology. This study has already shown by merits that the voluntary scheme is not fit for purpose. It is without equivocation that it is posited that a central repository with a mandatory data gathering scheme on nanomaterials that are made ingredients of food and cosmetics in the UK will bring about accountability, confidence, and credibility.

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