



Risks of nanotechnology in the food industry: A review of current regulation

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Nanotechnology is a new emerging science and it has enormous opportunities for innovation and development in the food and health food sectors. At the same time, the technology has raised new challenges regarding ensuring consumer safety and communicating the risks and benefits without risking the pace of the new technological developments. The lack of risk research and management in place for the vast range of applications of nanoparticles in the food and food health sectors makes legislation challenging. The long-term effect of nanoparticle use may be positive, but there may also be a negative impact on health. From the food safety and health protection standpoints, the objective of this paper is to give a preliminary discussion on the potential applications, risks, food safety and current regulatory situation of nanotechnology in relation to foods and health protection. It provides the industry, legislators and government with some points for attention, rather than a roadmap.

Keywords: food safety, nanoparticles, nanotechnology, regulations

1. Introduction

Over the past few decades, a number of new science disciplines and technologies have been revolutionized, such as biotechnology, information technology, cognitive sciences and, recently, nanotechnology, which is a broad interdisciplinary area of research and development that involves the manufacture, processing and application of materials at the nanoscale. Nanotechnology is a form of molecular engineering and has been heralded as the new technological revolution.¹ It is a scale of technology, not a type, and it has applications in every economic sector. It represents the scaling-down of technology to a new scale generally agreed to be between 1 and 100 nanometres (nm). Its applications are expected to bring a range of benefits

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¹ Wood, S., Jones, R. & Geldart, A. *The Social and Economic Challenges of Nanotechnology*. Swindon: Economic and Social Research Council (2003).

to the food sector, including new tastes, textures and sensations, less use of fat, enhanced absorption of nutrients, improved packaging, traceability, and security of food products.²

Studies show that nanoparticles can easily penetrate DNA and the cells of the lungs, skin and digestive system, thereby causing harm to living organisms.³ One example of a commonly used but potentially harmful nanoparticle can be found in the beverage industry. Beverage companies have been using plastic bottles made with nanocomposites that minimize the leakage of carbon dioxide out of the bottle. This increases the shelf life of carbonated beverages without using heavy glass bottles or more expensive aluminium cans.⁴ Think of the number of people who are thereby presumably unknowingly being exposed to untested nanocomposites!⁴ Nanotechnologies cover many aspects, such as disease treatment, food security, new materials for pathogen detection, packaging materials and delivery systems. As with most new and evolving technologies, potential benefits are emphasized, while little is known about the safety of the application of nanotechnologies in the agrofood sector.⁵

There are many food substances or ingredients that have natural nanostructures and are present at the micro- or nanometre size. Food proteins, which are globular particles between tens and hundreds of nanometres in diameter, are true nanoparticles. In general, physicochemical properties including particle size and size distribution, agglomeration state, shape, crystal structure, chemical composition, surface area, surface chemistry, surface charge, and porosity may all be important for understanding the toxic effects of nanomaterials.³ This emerging technology opens up a whole universe of new possibilities for the food industry, but the entry of manufactured nanoparticles into the food chain may result in an accumulation of toxic contaminants in foods and adversely affect human health.⁶

The main route of entry of micro- or nanosized particles into the gut is through consumption of food and drink. A healthy digestive system allows absorption of substances such as nutrients from the gut only after digestion of foodstuffs. The gut wall is thus designed to ensure the passage of dietary nutrients but prevent larger or foreign materials from passing. The very small size of nano food ingredients and additives may give them a greater ability to cross the gut wall.⁷ Nanoparticles of 50 and 70 nm can enter cells and lungs, respectively, while those of 30 nm can

² Chaudhry, Q., Scotter, M., Blackburn, J., Ross, B., Boxall, A., Castle, L., Aitken, R. & Watkins, R. Applications and implications of nanotechnologies for the food sector. *Food Additives and Contaminants A* **25** (2008) 241–258.

³ Oberdörster, G., Oberdörster, E. & Oberdörster, J. Nanotoxicology: An emerging discipline evolving from studies of ultrafine particles. *Environmental Health Perspectives* **113** (2005) 823–839.

⁴ Soliman, A., The need for stronger nanotechnology regulation. Food Safety News (16 October 2012). Retrieved from <http://www.foodsafetynews.com/2012/10/why-we-should-have-more-regulations-on-nanotechnology/#.VTW6niGqqko>

⁵ Bouwmeester, H., Dekkers, S., Noordam, M.Y., Hagens, W.I., Bulder, A.S., De Heer, C. & Sips, A.J. Review of health safety aspects of nanotechnologies in food production. *Regulatory Toxicology and Pharmacology* **53** (2009) 52–62.

⁶ Chau, C., Wu, S. & Yen, G. The development of regulations for food nanotechnology. *Trends in Food Science and Technology* **18** (2007) 269–280.

⁷ Chaudhry, Q., Watkins, R. & Castle, L. Nanotechnologies in the food arena: New opportunities, new questions, new concerns. In: *Nanotechnologies in Food* (RSC Nanoscience & Nanotechnology No 14) (eds Q. Chaudhry, L. Castle & R. Watkins), pp. 1–17. London: Royal Society of Chemistry (2010).

even pass through the blood and brain barrier.⁶ They can translate from the respiratory system to the blood circulatory system, distribute themselves throughout the body, and further be taken up into the liver, spleen, bone marrow, heart, brain and other organs.^{6,8} A recent Institute of Food Science & Technology (IFST) report has recommended that nanoparticles be treated as new, potentially harmful materials, until testing proves their safety.²

2. Regulations for the safety of nanotechnology in food

There are many nanotechnology initiatives, commissions and centres that have been launched by governments, academia and private organizations in the United States, Europe, Japan and some other regions and countries around the globe to ensure rapid development and deployment of nanotechnology, promote economic growth, maintain global competitiveness and improve innovative capability.⁹ Some countries have existing laws such as the Toxic Substances Control Act (USA); Food, Drug, and Cosmetic Acts (the Philippines and the USA); and Occupational Safety and Health Acts (USA, Malaysia, Kenya, India and doubtless others). Major environmental laws may at least provide some legal basis for regulating nanotechnology. In the United States, nanofoods and most food packaging are regulated by the United States Food and Drug Administration (US FDA)¹⁰ while the European Union (EU) regulations for food and food packaging have recommended that for the introduction of new nanotechnology, specific safety standards and testing procedures are required.¹¹ In Australia, nano food additives and ingredients are regulated by Food Standards Australia, and in New Zealand by the Food Standards Code.¹² In India, food safety regulations have been introduced but are not adequate for monitoring the safety of nanoparticles.¹³

In the United Kingdom (UK), the Health and Safety Executive (HSE) has participated in the negotiation, agreement and enforcement of regulations for manufactured nanoparticles. It has been suggested that regulations dealing with harmful chemicals, fire risk and explosion risk of materials, such as the Approved Code of Practice (ACOP) under the Control of Substances Hazardous to Health Regulations (COSHH), guidance on COSHH risk assessments, ACOP for the Dangerous Substances and Explosive Atmosphere Regulations (DSEAR), and guidance on precautions against the explosion risk of combustible dusts, might be applied for regulating the

⁸ Kreyling, W. G., Semmler, M., Erbe, F., Mayer, P., Takenaka, S., Schulz, H. et al. Translocation of ultrafine insoluble iridium particles from lung epithelium to extra pulmonary organs is size dependent but very low. *Journal of Toxicology and Environmental Health* **65** (2002) 1513–1530.

⁹ Chen, H., Weiss, J. & Shahidi, F. Nanotechnology in nutraceuticals and functional foods. *Food Technology* **3** (2006) 30–36.

¹⁰ Badgley, C., Moghtader, J., Quintero, E., Zakem, E., Chappel, L. M., Aviles-Vazquez, K., Salon, A. & Perfecto, I. Organic agriculture and the global food supply. *Renewable Agriculture and Food Systems* **22** (2007) 86–108.

¹¹ Halliday, J. EU Parliament votes for tougher additives regulation. (2007). Retrieved from Foodnavigator.com.

¹² Bowman, D. & Hodge, G. Nanotechnology: Mapping the wild regulatory frontier. *Futures* **38** (2006) 1060–1073.

¹³ Wesley, S.J. Raja, P., Raj, A.S. & Tiroutchelvar, D. Review on nanotechnology applications in food packaging and safety. *International Journal of Engineering Research* **3** (2014) 645–651.

use of nanomaterials.⁶ In Hong Kong, the Centre for Food Safety has referred to the World Health Organization's (WHO) requirement for risk assessment of nanoscale materials for assessing nanoparticles before they can be used in food.¹⁴ The US FDA regulates on a product by product basis and many products are currently regulated.¹⁵ With the recommendation of WHO and the United Nations Food and Agriculture Organization (FAO), the *Codex Alimentarius* has been updated regarding the use of nanotechnology in food and agriculture.¹⁶

Existing laws are inadequate to assess risks posed by nano-based foods and packaging because:

- (1) toxicity risks remain very poorly understood;
- (2) nanoparticles are not assessed as new chemicals, according to many regulations;
- (3) current exposure and safety methods are not suitable for nanomaterials;
- (4) many safety assessments use confidential industry studies.²

Uncertainty exists over the regulation of nano-based products and is linked in part due to a lack of necessary safety data needed to inform regulatory bodies.¹⁷ FAO and WHO are engaged in organizing expert consultations for identifying the applications of nanotechnology to the food sector in the future, as well as exploring areas for research and international guidance.

3. Conclusions

Presently, there are no proper regulations for using nanotechnology in the food and health food sectors. Only a few government agencies or organizations from different countries have established standards and regulations to define and regulate the use of nanotechnology in the food sectors. The existing regulation of nanotechnology in several representative countries and regions such as the United States, the United Kingdom, the European Union and China are focused on monitoring the safety of nanoparticles. There are numerous food products, forthcoming and already in the market, containing nanomaterials, hence it is essential to construct a standardized policy framework for this emerging technology to protect society across the globe, not least since the food trade is truly international.

¹⁴ Chow, S. Nanotechnology and food safety. Centre for Food Safety: Food Safety Focus, 54th issue (2011). Retrieved from http://www.cfs.gov.hk/english/multimedia/multimedia_pub/multimedia_pub_fsf_54_02.html

¹⁵ Weiss, J., Takhistov, P. & McClements, D.J. Functional materials in food nanotechnology. *Journal of Food Science* **71** (2006) 107–116.

¹⁶ The Codex Alimentarius Commission, established by FAO and WHO in 1963, develops harmonized international food standards, guidelines and codes of practice to protect the health of consumers and ensure fair practices in the food trade (<http://www.codexalimentarius.org>).

¹⁷ Sandoval, B. Perspectives on FDA's regulation of nanotechnology: Emerging challenges and potential solutions. *Comprehensive Reviews in Food Science and Food Safety* **8** (2009) 375–393.