The Readiness of Australian Food Regulation for the use of Nanotechnology in Food and Food Packaging

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Introduction

Food regulations address a multifaceted subject matter. Beyond whole foods, such as fruit, vegetables, meat and milk, there are the ingredients in processed foods, additives, food packaging and other materials in contact with food. Whilst it seems that nanotechnology has not yet altered any whole foods, other aspects of food preparation are already the subject of nanotechnology development, with the so-called 'nanofood' market having been predicted to reach over US$20 billion dollars by 2010.[1] Indeed, nanotechnology is predicted by some to have a major impact on consumers' lives[2] and by others to transform the entire food industry.[3] Others though, have questioned the effects of nanotechnology on foods and human health.[4]

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1 Helmut Kaiser Consultancy, 'Strong increase in nanofood and molecular food markets in 2007 worldwide' (undated) <http://www.hkc22.com/Nanofoodconference.html> (at 6 May 2008).

2 World Health Organisation, International Food Safety Authorities Network (INFOSAN), *INFOSAN Information Note No 01/2008 – Nanotechnology*, 7 February 2008, 1.

3 Tiju Joseph and Mark Morrison, Nanoforum.org, European Nanotechnology Gateway, *Nanoforum Report: Nanotechnology in Agriculture and Food*, May 2006, 2. See also Jennifer Kuzma and Peter VerHage, Woodrow Wilson International Center for Scholars - Project on Emerging Technologies, *Nanotechnology in Agriculture and Food Production*, September 2006 <http://www.nanotechproject.org/74> (at 6 May 2008); Naomi Salmon, 'Size really does matter' 19 June 2008 *The Ecologist* <http://www.theecologist.org/pages/archive_detail.asp?open=y&content_id=1883#36618> (at 4 November 2008); VJ Morris, 'Is nanotechnology going to change the future of food technology?' (2005) *Int Rev Food Sci Technol* 3: 16-18; Vic Morris, International Union of Food Science & Technology (IUFoST), Scientific Information Bulletin, *Nanotechnology and Food*, <http://www.iufost.org/reports_resources/bulletins/documents/IUF.SIB.Nanotechnology.pdf> (as at 4 November 2008).

4 Georgia Miller and Rye Senjen, Friends of the Earth Australia, Europe, and USA, *Out of the Laboratory and on to our Plates. Nanotechnology in Food & Agriculture* (2nd ed, April 2008) <http://nano.foe.org.au> (at 6 May 2008).

The question arises of whether Australian food regulations are ready for nanotechnology use by the food industry. This article considers that issue. The Australian food regulator, Food Standards Australia New Zealand (FSANZ), has moved from considering that '[n]anotechnology has not yet become a regulatory issue'[5] to assuring the public that it will monitor research developments around the world and:

> continue to ensure the safety of food is rigorously assessed through the application of the current provisions of the Code and will make adjustments to the regulatory framework should it become necessary.[6]

What these adjustments may need to be is explored in this paper. It will be seen that in some instances the regulations will apply because the nanomaterial is treated as the same as its conventionally sized counterpart even though its properties may differ. This may result in the nanomaterial avoiding pre-market safety assessment. In other cases though, if the nanomaterial is treated as a new substance, this will result in the material not being limited by current prohibitions applicable to its conventional counterpart. The issue of whether a nanomaterial is new or not is therefore the first important concern in food regulation but, as discussed, cannot be responded to simply by declaring all nanomaterials 'new'. Secondly, important regulatory difficulties arise because many existing regulations are based on mass which may be inappropriate for nanomaterials where mass is not the relevant metric for predicting health effects. A third important general concern is that current safety assessment guidelines do not necessarily assess the properties of importance to nanomaterials or safety data is not available for such assessment.

This paper first briefly introduces the reader to nanotechnology[7] and the potential health risks it raises.[8] It then reviews how nanotechnology is or may be used by the food industry so that challenges that must be

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5 Jim Gruber and Christina Belperlo, 'Nanotechnology – Regulatory Aspects', Food Standards Australia New Zealand, undated <http://www.foostandards.gov.au/_scfiles/AIFST_Nanotech.pdf> (at 6 May 2008).

6 FSANZ, 'Small particles, nanotechnology and food', 2008 <http://www.foostandards.gov.au/newsroom/factsheets/factsheets2008> (at 2, September 2008).

7 For further information on nanotechnology see section on 'Potential Health Risks' below and The Royal Society and Royal Academy of Engineering, *Nanoscience and Nanotechnologies: opportunities and uncertainties*, 2004 <http://ww.nanotec.org.uk.finalreport.htm> (at 6 May 2008), chap 2.

8 For further information on the potential health risks of nanotechnology generally see The Royal Society and Royal Academy of Engineering, *Nanoscience and Nanotechnologies: opportunities and uncertainties*, 2004 <http://www.nanotec.org.uk/finalereport.htm> (at 6 May 2008).

addressed by food regulations can be better understood. The application of current Australian food regulations to nanofoods and their suitability for meeting those challenges is then examined. International responses to the problem are described before conclusions and suggested responses are provided.

Nanotechnology

Nanotechnology involves the manipulation of matter at the atomic or molecular scale, a nanomaterial being material with one or more dimensions of 100 nanometres or less.[9] Their small scale means all nanomaterials have a high surface to volume ratio. That increase in relative surface area has significant consequences. It means an increase in the percentage of atoms at the surface and therefore more sites for bonding or reacting with surrounding materials.[10] Therefore nanomaterials, because of their size and the effect of that size on other properties, can possess different physical, chemical and biological properties compared with their equivalent bulk material, sometimes in unpredictable ways.[11]

This presents 'new opportunities to increase the performance of traditional products, and to develop unique new products'.[12] Titanium dioxide, for example, has long been used in sunscreens and cosmetics for its ultra violet (UV) light blocking properties. It is also widely used as a white pigment in foods (such as confectionary) and food packaging surfaces because of its extreme whiteness and brightness and high refractive index.[13] Nanoscale titanium dioxide has been found to have more surface area for UV absorption and to be transparent. This has made it an attractive additive to food and beverage packaging to prevent UV light reducing the shelf life of food and beverages contained in

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9 Publicly Available Specification on the Vocabulary for Nanoparticles of the British Standards Institution (BSI PAS 71:2005). One nanometre (nm) is one billionth of a metre (10^{-9}). So, for example, a human hair is about 80,000 nm wide and a sheet of paper about 100,000 nm thick.

10 Tracy Hampton, 'Researchers Size Up Nanotechnology Risks' (2005) 294(15) *Journal of the American Medical Association* 1881, 1881.

11 Council of Canadian Academies, *Report in Focus. Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale* (July 2008), p 3.

12 Günter Oberdörster et al, 'Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy' (2005) 2 *Particle and Fibre Toxicology* 8, 10.

13 UK, Institute of Food Science and Technology Trust Fund, *Information Sheet – Nanotechnology*, February 2006 <http://www.ifst.org.uploadedfiles/cms/store/ATTACHMENTS/Nanotechnology.pdf> (at 6 May 2008) 6.

transparent or semi-transparent packaging whilst still allowing consumers to see the product inside.[14] DuPont is planning to sell such a plastic packaging additive, called Light Stabilizer 210, in late 2008.[15]

Potential health risks

There are though, some concerns accompanying the use of nanotechnology in food and its packaging. The World Health Organisation (WHO) has noted that '[a]s for all new materials used in food and food processing, the potential health and environmental risks of nanoscale materials need to be assessed before they are introduced into food'.[16] The large surface area and increased reactivity of some nanomaterials may mean different reactions with biological systems such as the human body compared to their larger scale counterparts. But there is a lack of knowledge over the potential effects and impacts of nanomaterials because physicochemical and biological properties of materials at nanosize may differ from their conventional forms.[17] The US National Institute of Environmental Health Sciences has stated that generally the smaller the particles, the more reactive and toxic are their effects.[18] More information is needed on the bioaccumulation and potential toxic effects of ingestion of nanoparticles. As noted by the UK Institute of Food Science and Technology, ingested nanoparticles are more likely than presently used larger particles to penetrate into tissue and cells, influencing accumulation and storage and toxicity risks.[19]

Their relatively large surface area and the effect of that also raise concerns that nanomaterials could be potential catalysts for reactions that would otherwise proceed slowly.[20] Bioavailability may also increase as the particles decrease in size. Little is known about the health effects of

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14 Ahmed ElAmin, 'Nanoscale particles designed to block UV light', *Food production daily.com*, 18 October 2007 <http://foodproductiondaily.com/news/printNewsBis.asp?id=80676> (at 6 May 2008).

15 Ibid.

16 WHO, above n 2, 1.

17 Qasim Chaudhry, 'Project A03063. Assessment of Current and Projected Applications of Nanotechnology for Food Contact Materials in Relation to Consumer Safety and Regulatory Implications', UK Food Standards Agency, undated <http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/contactmaterials/a03prog/a03projlist/a030637> (at 6 May 2008) 7.

18 Emory E Knowles III, 'Nanotechnology. Evolving occupational safety, health and environmental issues' [March 2006] *Professional Safety* 20, 24.

19 UK, Institute of Food Science and Technology Trust Fund, above n 13, 7.

20 UK, Health and Safety Executive (HSE), *Nanotechnology – Horizons Scanning Information Note No HSIN1* 2004, 2.

nanomaterials in the liver or kidney or transfer across the placenta[21] but it is known that certain nanoparticles possess the ability to cross the blood-brain barrier and can serve as carriers for other molecules.[22]

Nanotechnology and Food

Nanofood is food which has been cultivated, produced, processed or packaged using nanotechnology or to which manufactured nanomaterials have been added.[23] In 2006 there were over 400 companies worldwide researching, developing and producing nanofood related products,[24] the general aims of nanotechnology in this arena being largely centred on improving the quality of food. Food industry giants like Kraft, HJ Heinz, Cadbury Schweppes and Unilever are all pursuing nanotechnology food and packaging applications.[25] As noted above, at present no whole foods incorporate manufactured nanomaterials.[26] However, as discussed in this section nanotechnology is being pursued by numerous food companies to create processed food products, particularly food additives and in food packaging. More than 300 nanofood products are available on the worldwide market[27] with at least one of these available on the Australian market.[28]

Foods

Nanomaterials incorporated directly into processed food may provide improved functional properties, such as 'low sodium food products that taste salty due to nanotech-induced interactions with the tongue, and functional food components tailored to the individual consumer's preference.'[29] Nanosized emulsion particles are being developed for use

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21 Knowles, above n 18, 23.

22 WHO, above n 2, 2.

23 Joseph and Morrison, above n 3, 7.

24 Helmut Kaiser Consultancy, above n 1.

25 Miller and Senjen, above n 4, 11. For further, see Andrew Maynard and Evan Michelson, *The Nanotechnology Consumer Products Inventory*, Woodrow Wilson International Center for Scholars - Project on Emerging Nanotechnologies, March 2006 <http://www.nanotechproject.org/reports> (at 6 May 2008).

26 Some whole foods such as milk may naturally contain nanomaterials.

27 Helmut Kaiser Consultancy, above n 1.

28 CSIRO, <http://www.foodscience.csiro.au/foodfacts/foodfacts11-fishoil.htm> (at 6 May 2008).

29 Phillip B Jones, 'A nanotech revolution in agriculture and the food industry' ISB News Report, 1 June 2006 <http://archives.foodsafety.ksu.edu/fsnet/2006/6-2006?fsnet_june_7.htm> (at 6 May 2008). For example, the interactive nature of nanofoods will provide on-demand delivery by the addition of nanocapsules which burst at different microwave frequencies. Chau Chi-Fai, Wu Shiuan-Huei, Yen Gow-Chin, 'The development of regulations for food nanotechnology' (2007) 18 *Trends in Food Science & Technology* 269, 271.

in spreads and ice creams.[30] Emulsions have traditionally been used to improve food texture and it is hoped that use of nanosized particles in emulsions will reduce fat content from 16% to about 1%.[31]

Nanoparticles and nanosize carriers such as nanocapsules are being designed to improve absorption and enhance the availability and dispersion of added nutrients, vitamins and minerals. Already on the overseas market is Canola Active cooking oil fortified with phytosterol nanocapsules claimed to reduce cholesterol.[32] The nanocapsules in that case are expanded micelles (hollow spheres made from fat) and are said to allow the compounds contained in the capsules (in this case phytosterol) to enter the blood stream more easily from the gut and thereby increase their bioavailability.[33] A leading Australian bread manufacturer is including nanocapsules containing tuna fish oil (as a source of Omega 3 fatty acids) in its bread, the nanocapsules being designed to break open when they reach the stomach to avoid the unpleasant taste of fish oil.[34] A number of health drinks and food additives used in some margarines, soft drinks, dairy products, sausages and other processed foods on overseas markets are also claimed to have some nano content.[35] These international developments mean import will be a major point of entry of nanofoods and products into the Australian food chain.

Food packaging

Nanotechnology is also being used to modify food packaging and food contact materials. Nanotechnology developments are improving packaging properties such as durability, flexibility and mechanical and heat resistance of food packaging materials and increasing their barrier properties to provide longer shelf life for the food contained in it. Two new types of food packaging can be identified: active packaging and

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30 European Food Safety Authority, 'EFSA to analyse food safety of nanotechnology' (2007) <http://www.eas.be/NewsItem.aspx?newsid=617> (at 6 May 2008).

31 Joseph and Morrison, above n 3, 11.

32 Jordan Paradise et al, 'Developing Oversight Frameworks for Nanobiotechnology' (2007) 9 *Minnesota Journal of Law, Science & Technology* 187 <http://ssm.com/abstract=1103114 188>.

33 Joseph and Morrison, above n 3, 10.

34 CSIRO, above n 28 reporting award given to researchers involved in the work.

35 Miller and Senjen, above n 4, 9 and 55. For a comprehensive summary of the use of nanotechnology in the food industry, see Kuzma and VerHage, above n 3; USDA, *Nanoscale Science and Engineering for Agriculture and Food. A Report of a US Workshop outlining a roadmap for possible nanotech applications in food and agriculture*, September 2003 <http://www.nseafs.cornell.edu/web.roadmap.pdf> (at 6 May 2008); Chau, Wu and Yen, above n 29. See also IUFoST, above n 3.

smart (or intelligent) packaging. Active packaging is packaging that actively works to preserve the food it contains such as 'a plastic film with dispersed clay nanoparticles that prevents oxygen, carbon dioxide, and moisture from reaching food.'[36] For example, Durethan KU2-2601 packaging film developed by Bayer Polymers includes silicate nanoparticles which have a mazelike arrangement in the plastic wrap, making it difficult for unwanted substances such as oxygen which spoils food to travel in. It does this by increasing the distance the gas molecules need to travel. It is claimed the nanoparticles cut the permeability of the film by half compared to conventional film materials.[37] Other types of active packaging possess antimicrobial properties such as silver nanoparticles used in food storage containers to reduce food spoilage. For example, both SharperImage's 'FresherLonger' plastic storage bags and Baby Dream Co Ltd's silvernano baby milk bottles include silver nanoparticles to prevent food spoilage by reducing the growth of bacteria, mould and fungus.[38] Nanocomposite particles have also been incorporated into plastic beer bottles 'to extend the shelf-life to six months by controlling gas flows'[39] and to make the plastic less likely to shatter.[40] Other products, such as SongSing Nano Technology Co Ltd's Nano Plastic Wrap, claim to combine both improved anti-UV properties and a sterilizing and anti-mould function through the addition of nano zinc oxide to the plastic.[41] However, there has been little published research on the risk of exposure from migration of nanoparticles from such packaging and food contact materials into food and drink. For example, as a leading scientific expert has noted that there is currently no published research on the possible effects that foods containing nanosilver may have on the gastrointestinal tract or on the natural gut flora.[42]

Smart packaging incorporates nanosensors to monitor and respond to food condition. For example, it can incorporate nanomaterials that respond to environmental conditions, engage in self-repair, or alert a consumer to the presence of chemical or pathogen contamination. For example, nanoparticle films and other packaging with embedded sensors

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36 Jones, above n 29.

37 Bayer, 'Securely wrapped: Nanoparticles make Durethan films airtight and glossy' undated 15 *Bayer Research* 34, <http://www.research.bayer.com/edition_15/15_polyamides.pdfx> (at 6 May 2008) 35.

38 *Consumer Products Inventory*, above n 25.

39 Gruber and Belperlo, above n 5.

40 'Beer bottle plastics' at *Consumer Products Inventory*, above n 25.

41 'Nano Plastic Wrap' at *Consumer Products Inventory*, above n 25.

42 Chaudhry, above n 17, 9.

will detect food pathogens. These nanosensors trigger a package color change to alert consumers that the food has become contaminated or has begun to spoil. Another type of packaging may incorporate a bio-switch that releases a preservative if the food within begins to spoil.[43]

The ability to detect pathogens, deliberate contamination or spoiling of food is predicted to have enormous commercial value, with the US Department of Agriculture estimating the costs of illness and premature death in the US alone from the top five food borne pathogens to be US $6.9 billion.[44]

In the above cases, the nanomaterials included in the food packaging and food contact materials may migrate into food. Food packaging could be made from a range of materials including plastics and paper, both of which may have nanomaterials incorporated in or on them or used in their manufacture. Other substances, such as processing aids or agricultural and veterinary chemicals may be modified by nanotechnology or incorporate nanomaterials and these may also be added to or left in food.

Australian regulation

Whilst the preparation and sale of food, food packaging and contact materials is regulated by the States, the national food regulator FSANZ develops and maintains a nationally uniform scheme on all these issues. FZANZ is a bi-national agency created under the *Food Standards Australia New Zealand Act 1991 (Cth)* (*FSANZ Act*). It is responsible for developing and maintaining the national *Australia New Zealand Food Standards Code* (*Food Code*). The *Food Code* sets out quality and labelling requirements for food and food packaging prepared and sold in Australia and New Zealand. These requirements are given legal effect in each Australian jurisdiction by adoption by State / Territory legislation.[45] Domestic food regulatory policy is set by the Food Regulation Ministerial Council, including members from two national governments (Australia and New Zealand) and the Australian State and Territory governments.

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43 Jones, above n 29. See further, Ahmed ElAmin, 'Nano ink indicates safety breach in food packaging' Food Navigator. Com.Europe, 14 November 2006 <http://www.foodnavigator.com/news/printNewsBis.asp?id=72022> (at 6 May 2008).

44 Psivida Ltd, *pSivida launches pSiNutria in the Food Industry*, ASX/Media Release (1 December 2005) <http://www.psivida.com/News/download/ASX/ASX%20Release-pSiNutria%20Dec%202005.pdf> (at 6 May 2008).

45 *Food Act 2001* (ACT) s 27; *Food Act 2003* (NSW) s 21; *Food Act 2004* (NT) s 20; *Food Act 2006* (Qld) s 39; *Food Act 2001* (SA) s 21; *Food Act 2003* (Tas) s 21; *Food Act 1984* (Vic) s 16; *Health Act 1911* (WA) Pt VIII and *Health (ANZ Food Standards Code Adoption) Regulations 2001* (WA). With respect to imported food, see *Imported Food Control Act 1992* (Cth) s 8.

The object of the *FSANZ Act* is to 'ensure a high standard of public health protection throughout Australia' by the FSANZ to achieve the following goals:

> (a) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;
>
> (b) an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;
>
> (c) the provision of adequate information relating to food to enable consumers to make informed choices;
>
> (d) the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.[46]

'Food' for the purposes of the *FSANZ Act* is defined inclusively as:

> (a) any substance or thing of a kind used, capable of being used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared); and
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> (b) any substance or thing of a kind used, capable of being used, or represented as being for use, as an ingredient or additive in a substance or thing referred to in paragraph (a); and
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> (c) any substance used in preparing a substance or thing referred to in paragraph (a); and
>
> (d) chewing gum or an ingredient or additive in chewing gum, or any substance used in preparing chewing gum; and
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> (e) any substance or thing declared to be a food under a declaration in force under section 3B.[47]

Given the generality of the scope of the definition of food, the *FSANZ Act* and *Food Code* will generally apply to nanofoods and food related products. For example, fresh milk which can naturally contain nanosized lipids (fats) in colloidal suspension is 'food' in the same way as fresh milk that does not contain such lipids is. Therapeutic goods within the meaning of the *Therapeutic Goods Act 1989 (Cth)* though are not food.[48] Where a food is regulated by the *Food Code*, the relevant Standards in the Code must be complied with.[49] There are no Standards in the Code specifically regulating nanofoods and related products but some regulations will nevertheless be relevant to them. The concern though is

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46 *Food Standards Australia New Zealand Act 1991* (Cth) s 2A.

47 *Food Standards Australia New Zealand Act 1991* (Cth) s 3A(1).

48 *Food Standards Australia New Zealand Act 1991* (Cth) s 3A(2).

49 Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, Standard 1.1.1 cl 3.

that such Standards will not apply to nanofoods and other nano products as appropriately as they should. For example, the *Food Code* sets out estimated safe and adequate daily dietary intake (ESADDI) and recommended daily intake (RDI) levels for vitamins and minerals, such as some metal oxides. These are expressed by weight. The adult RDI for zinc oxide is, for example, 12 mg zinc. Deficiencies in current scientific knowledge of nanomaterial uptake and utilisation in the human body may mean this requirement, set on the basis of weight, is not appropriate where the zinc oxide is in nanoform and is therefore responded to differently by the human body.

Safety Assessment

Generally no prior regulatory approval is required for the lawful sale of food, food packaging materials and articles in contact with food sold or prepared for sale in or imported into Australia unless it is specifically required by the *Food Code*. Therefore no safety assessment of such items is required before sale. Indeed, FSANZ may not be aware that nanomaterials were included in the food or other item.

However, new substances such as food additives added to food and also novel foods require pre-market approval. Such approval involves a safety assessment discussed further below and if approved, an amendment to the *Food Code*. Changes to the Code are considered a regulatory measure. FSANZ must therefore produce a regulatory impact statement (RIS) before any such change.[50] The aim of the RIS is to 'identify and assess any social, economic and/or environmental impacts of an application or proposal to vary the Code'.[51] FSANZ is required to consider the impact of all options on all sectors of the community[52] and whether the benefits of the application outweigh the costs.

The *FSANZ Act* provides that any person or FSANZ itself may apply for either the development or variation of a food regulatory measure before a specific regulation is included / amended in the Code or a code of practice. Information to support the application must be included with

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50 Food Standards Australia New Zealand, *Annual Report 2004–2005,* 2005, 26–7. The relevant practice is set out in the Council of Australian Governments, *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*, April 1995 as amended by COAG June 2004 <http://www.coag.gov.au/meetings/250604/coagpg 04.pdf> (at 6 May 2008).

51 Food Standards Australia New Zealand, 'Format for applying to amend the Australia New Zealand Food Standards Code food produced using gene technology' (2005).

52 Food Standards Australia New Zealand, *Initial assessment report. Application A580 food derived from amylase-modified corn line 3272*, 31 May 2006.

the application.[53] What that information should include is determined by the FSANZ's objectives in developing such measures. The first and most important of these objectives is 'the protection of public health and safety'.[54] Standards may relate to the composition of food including the maximum amounts of contaminants or residues that may be present in food and the maximum or minimum amounts of additives that may be present. Standards may also relate to methods used to determine food composition and the production and handling of food.[55] Handling includes packaging and transportation and disposal of food.[56]

FSANZ's approach must in all cases ensure that Standards are 'based on risk analysis using the best available scientific evidence'.[57] However, where FSANZ considers that scientific evidence to be insufficient FSANZ may provisionally adopt sanitary or phytosanitary measures. Such measures expressly include those applied 'to protect human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs' and 'the packaging and labelling requirements directly related to food safety'.[58] However, FSANZ must then, within a reasonable time, take all reasonable steps to obtain the information necessary for a more objective risk analysis and a review of such measures.[59]

Where a safety assessment is required, it is performed in accordance with FSANZ's safety assessment guidelines.[60] It must be established that there is a reasonable certainty that no harm to humans will result from the intended use of the food. The guidelines are such that information that a nanomaterial is present would probably have to be disclosed to FSANZ. For instance, in relation to food additives, whilst the nanoform of a chemical may not be distinguished by its chemical name and Chemical Abstract Service (CAS) registry number (for example, carbon nanotubes currently have the same chemical name as conventional graphite) in the application document, the guidelines expressly require information on the

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53 *Food Standards Australia New Zealand Act 1991* (Cth) s 12(2)(b) and *Food Standards Australia New Zealand Regulations 1994* (Cth) r 7.

54 *Food Standards Australia New Zealand Act 1991* (Cth) s 10(1)(a).

55 Ibid s 9.

56 Ibid s 9(3).

57 Ibid s 10(2).

58 Ibid s 10(5).

59 Ibid s 10(4).

60 Ibid ss 22 and 23. See Food Standards Australia New Zealand, *Food Standards Australia New Zealand Application Handbook*, 1 October 2007.

manufacturing process of the additive.[61] This may indicate that the additive is a nanomaterial.

However, even if the FSANZ is made aware that a nanomaterial is present, current risk assessment methodologies may not be adequate for determining potential risks of food and food contact materials containing nanomaterials to human health. For example, it is not known whether current toxicology testing techniques are suitable for nanomaterials. It is not clear that current testing methods and techniques for measuring nanomaterials are adequate for detecting nanomaterials in food and food contact materials.[62] There is also no safety assessment of the environmental consequences of the ultimate disposal of foods and associated products under the food regulations.

Safe for human consumption

In addition to imposing a requirement that the provisions of the *Food Code* be complied with, State / Territory legislation imposes a general obligation that food be safe for human consumption. For example, under the Victorian legislation a person who handles food intended for sale in a manner that will or is likely to render the food unsafe is guilty of an offence.[63] Packaging or labelling material or equipment must also not be sold if its use for its intended purposes would render or is likely to render food unsafe.[64] Food is unsafe if it is likely to cause physical harm to a consumer who uses it as reasonably intended.[65] The requirement of likelihood means that on the basis of scientific knowledge at this time, a successful prosecution regarding nanofoods would be difficult.

It is also an offence to sell unsuitable food or handle food intended for sale in a manner that renders or is likely to render it unsuitable.[66] Food is unsuitable if, inter alia, it 'contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food'.[67] Prima facie it could be argued that nanomaterials meet this description. However, the definition of unsuitable food goes on to provide that if the agent is permitted by the *Food*

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61 Food Standards Australia New Zealand, *Food Standards Australia New Zealand Application Handbook*, 1 October 2007, s 3.3 cl 5.

62 FDA, *Nanotechnology. A Report of the US Food and Drug Administration Nanotechnology Task Force*, 25 July 2007, pp 17-18.

63 *Food Act 1984* (Vic) ss 8(1), 8A(1) and 11. See also definition of 'handling' and unsafe food' in ss 4(1) and 4D respectively.

64 Ibid s 15.

65 Ibid s 4D(1).

66 Ibid s 12.

67 Ibid s 4E(1)(d).

Code, its presence does not make food unsuitable.[68] Given the uncertainty as to whether and when nanofood is permitted under the Code discussed below, prosecution under this provision regarding nanofoods also seems difficult.

Even if these offences may be relevant in the case of some nanofoods, the Victorian legislation provides for a defence of due diligence that will cause further problems for successful prosecution for harms caused by nanofoods.[69] Section 17E(1) provides that it is a defence if it is proved that the person took all reasonable precautions and exercised all due diligence to prevent the commission of the offence.[70]

It is a question of fact whether the defence is made out. However, because it must be shown that 'all' reasonable precautions were taken rather than simply 'reasonable precautions' the statutory defence probably requires a higher standard than the common law. Nevertheless it has been suggested in relation to the predecessor of the current section which had included the same phrase that the courts would imply a 'commercial reality' qualification into the Victorian section so that the court would take into account only feasible steps consistent with commercial reality and a proper consideration for the mischief at which the statute was aimed.[71] Manufacturers of nanofoods may be able to rely on this defence where the current lack of scientific data on the health risks of nanomaterials probably means that there is no foreseeable injury requiring precautions to be taken and where the *Food Code* discussed below is complied with.

Novel foods

Nanofoods may be considered to be new or 'novel' foods that should go through a safety assessment prior to sale or import and FSANZ refers to this standard in its fact sheet on nanofoods regulation.[72] *Standard 1.5.1 – Novel Foods* is intended to ensure that novel foods undergo a mandatory pre-market safety assessment by FSANZ by making it a criminal offence

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68 Ibid s 4E(2)(b)-(d).

69 Cf defence in other States: *Food Act 2001* (ACT) s 30; *Food Act 2003* (NSW) s 26; *Food Act 2004* (NT) s 24; *Food Act 2006* (Qld) s 44; *Food Act 2001* (SA) s 26; *Food Act 2003* (Tas) s 26.

70 *Food Act 1984* (Vic) s 17E(1).

71 Maurice W Gerkens, Randell J Gerkens and Audrey Cleeve, *Food Legislation – Victoria* (looseleaf) (1990 - Law Book Company Ltd), 634 [16.390]. See also *Carrick DC v Taunton Vale Meat Traders* (1994) 158 JP 347 with respect to *Food Safety Act 1990 (UK) s* 21(1) where it was held that the express requirement that the defendant 'took all reasonable precautions' did not mean all precautions.

72 FSANZ, above n 6.

to sell a novel food unless it is listed in the Standard[73] and there is compliance with any specified conditions of use.[74] This reflects the public's insistence

> on pre-market review of health-sensitive products, such as food ingredients ... that involve substances having no prior history of exposure to human beings and no widely accepted and scientifically established demonstration of safety.[75]

The safety assessment is performed in accordance with the FSANZ's safety assessment guidelines discussed above and it must be established that there is a reasonable certainty that no harm will result from the intended use of the food.[76] The determination of novelty is made by FSANZ with the advice of the Advisory Committee on Novel Foods (ACNF).

A 'novel food' is defined as a non-traditional food and the food requires an assessment of the public health and safety considerations having regard to –

(a) the potential for adverse effects in humans; or

(b) the composition or structure of the food; or

(c) the process by which the food has been prepared; or

(d) the source from which it is derived; or

(e) patterns and levels of consumption of the food; or

(f) any other relevant matters.[77]

This definition of novel food specifically refers to the process by which a food was prepared, but to be a novel food a food or food ingredient must be a non-traditional food. A 'non-traditional food' is:

> (a) a food which does not have a history of human consumption in Australia and New Zealand; or
>
> (b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or

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73 Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, Standard 1.5.2 cl 2. In particular such foods are listed in column 1 of Table to cl 2.

74 Such conditions would be specified in Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, column 2 of Table to cl 2.

75 Michael R Taylor, Woodrow Wilson International Center for Scholars – Project on Emerging Nanotechnologies, *Regulating the Products of Nanotechnology: Does FDA Have the Tools it Needs?* 2006, 22.

76 Food Standards Australia New Zealand, *Final Assessment Report Proposal P291 Review of Novel Food Standard*, 3 October 2007, 34.

77 Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, Standard 1.5.1 cl 1.

(c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.[78]

The Guidance Tool prepared by FSANZ to assist the ACNF and manufacturers in interpreting the Novel Foods Standard expressly requires consideration of whether the food or ingredient is produced by a process not previously applied to food and whether the structure or composition of the final food or ingredient is altered because of the process of preparation in interpreting the term 'history of human consumption'.[79]

The non-traditional food must also raise safety concerns to be a novel food.[80] Assessment of this issue is separate from the safety assessment referred to above which is undertaken once it is determined that a food is a novel food. Once again, whether the structure of the substance is completely new is a relevant matter. However, the issue arises at both steps of the determination of whether a food is a novel food as to whether food manufacturers would consider nanoforms of previously used ingredients or foods to be altered or new and therefore compliance with the Standard as being necessary. Nanoform is not expressly referred to in the Guidance Tool or the Novel Foods Standard as being an issue relevant to the determination of novelty. Enforcement of the Code is the responsibility of the State and Territory Governments and therefore interpretation of the Standard and whether a food is novel is ultimately a decision of the States and their courts. Whether jurisdictions would even be aware of the use of nanotechnology in food is an important issue to be addressed. Further, unless and until a food or food ingredient is recorded in the Standard as a novel food, successful prosecutions for offences under the Standard (such as placing a novel food on the market without legal authority) are difficult.[81]

Nevertheless, it is possible that the differences in 'composition and structure' of nanofoods could mean such foods are treated as novel. However, the involvement of nanotechnology in the process of

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78 Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, Standard 1.5.1 cl 1.

79 Food Standards Australia New Zealand, *Final Assessment Report Proposal P291 Review of Novel Food Standard*, 3 October 2007, 54, Questions 4.12 and 4.13.

80 See Part 2 of the *Guidance Tool for Determining whether a Food is Novel or Not*, Attachment 4 of Food Standards Australia New Zealand, *Final Assessment Report Proposal P291 Review of Novel Food Standard*, 3 October 2007.

81 Food Standards Australia New Zealand, *Final Assessment Report Proposal P291 Review of Novel Food Standard*, 3 October 2007, Attachment 9 Summary of Submissions, 86.

production alone will not trigger the Standard. The use of nanotechnology will need to significantly alter the properties of the final product.[82]

The EU Novel Foods Regulation which is under revision has recently had nanotechnology aspects added to the proposal for revision.[83] In the review of the Australian Novel Foods Standard only one submission supported the introduction of specific standards for different technologies.[84]

Food additives

The intentional incorporation of nanomaterials into food or food packaging or contact materials from where it intentionally migrates into food, where these materials have a technological function in the food, will be regulated as food additives.[85] For example, where active or smart packaging results in a nanomaterial being released to migrate into the food, this would be regulated as an additive. A 'food additive' is:

> Any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5. It or its by-products may remain in the food. Food additives are distinguishable from processing aids and vitamins and minerals added to food for nutritional purposes.[86]

Only expressly permitted food additives may be added to food.[87] The regulations regarding approval of additives apply regardless of whether the additive is or incorporates nanomaterials, and all permitted additives undergo a safety assessment prior to approval. However, whilst permitted additives must comply with specified identity and purity requirements, and specified maximum levels of use and can only be used in the listed foods set out in the Code,[88] these specifications do not refer to particle size. Therefore substances meeting the specifications are

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82 See Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, amended Editorial Note to cl 1 in Standard 1.5.1 which now expressly refers to foods produced by a process not previously applied to food. See also UK, Food Standards Agency, *Draft Report of FSA Regulatory Review*, March 2006, [20].

83 EAS, 'Nanotechnology use in food applications: a scientific and regulatory challenge' <http://www.eas.be/NewsItem.aspx?newsid=127> (at 6 May 2008).

84 Food Standards Australia New Zealand, above n 81, 78.

85 Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, Standard 1.3.1.

86 Ibid.

87 Ibid.

88 Ibid, Standard 1.3.4.

permitted for use, whether or not they are in nanoform. The listing of the larger scale counterpart of the nanomaterial may therefore mean that if a currently permitted additive is produced in a nanoform, it is unlikely to require a separate listing and therefore will not need to be assessed prior to introduction to the market. Further, FSANZ would not even have to be notified of the change in form. More specific regulations may therefore be required for the regulations to appropriately respond to nanofoods used as additives.[89]

A further difficulty is that the maximum level of use for some additives, namely some colours, is set by weight. This is likely not to be an appropriate trigger if that additive is in a nanoform and therefore less material can be included to produce the same or changed outcomes. The European Parliament has said that 'the permitted limits for an additive in nanoparticle form should not be the same as when it is in traditional form'.[90] Australian regulation may also need updating to deal with this issue.

Food contaminants

Nanomaterials *unintentionally* included in food or that migrate into food from food packaging or contact materials will not be regulated as food additives but could be regulated as contaminants.[91] Maximum limits (ML) for some contaminants and natural toxicants have been set in the *Food Code* and these apply regardless of whether the contaminant is a nanomaterial or not. However, the trigger levels may need to be reviewed if nanoforms of the specifically referenced contaminants begin being used and the nanoform of the contaminant means the weight threshold is inappropriate. Conversely to the issue for nanoforms of additives, this means that if a nanoform of a substance is treated as a 'new' substance as compared to its conventional counterpart, any listing of the conventional counterpart as prohibited or only permitted at specified levels would be irrelevant to the nanoform. Whilst for those nanomaterial contaminants not listed the manufacturer / importer must still comply with the general obligation to ensure the food is safe imposed under State / Territory legislation, prosecutions would encounter the

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89 See further FAO/WHO Sixty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report Series 940, WHO, Geneva, 2007.

90 Jess Halliday, 'EU Parliament votes for tougher additives regulation' Food Navigator.com, 12 July 2007 <http://www.foodnavigator.com/news/ng.asp?n=78139-additives-regulation-enzymes-flavourings> (at 6 May 2008).

91 Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, Standard 1.4.1.

important difficulties discussed above. They must also comply with *Standard 1.4.3 – Articles and Materials in Contact with Food* discussed below.

Food contact materials

Permission for articles and materials to be in contact with food is given by Standard 1.4.3. Such contact is forbidden if 'likely to cause bodily harm'.[92] Deficiencies in current knowledge regarding the effects of nanomaterials mean this provision is unlikely to prevent the use of nanomaterials at this time because it could not be shown to be 'likely' to harm. For example, it is unknown whether reducing the size of additives in food packaging, such as titanium dioxide, affects the migration of the nano-additive from the film to the food.[93]

An Australian Standard developed by Standards Australia, *AS 2070-1999 Australian Standard. Plastics materials for food contact use*, gives guidance as to what can be used in food contact materials by specifying the 'materials and procedures for use' in producing 'plastics materials, coating and printing of plastics items for food contact and subsequent use'.[94] This includes 'packages, domestic containers, wrapping materials, utensils or any other plastics items intended for food contact application'. Pursuant to the *Plastics Standard*, plastics materials used in the manufacture of plastics items for food contact use must comply with either the referenced US regulations (US, Code of Federal Regulations 21CFR Parts 170 to 199 and amendments) or EC Directives 89/107/EEC and 90/128/EEC and amendments.[95] The *Plastics Standard* therefore 'applies' regardless of whether nanomaterials are used or not but it is unclear whether plastics with nanoparticles in it are being retested or whether the previous classification of plastics with the larger scale equivalents is still being relied on. It should also be noted that the referenced international instruments have been the subject of review by others in the context of suitability for nanotechnology.[96] In all cases,

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92 Ibid, Standard 1.4.3 cl 2.

93 UK, Institute of Food Science and Technology Trust Fund, above n 13, 7.

94 Standards Australia, *AS 2070-1999 Australian Standard. Plastics materials for food contact use* cl 1.

95 Ibid, cl 4.

96 Qasim Chaudhry et al, (2006), *Final Report: A scoping study to identify gaps in environmental regulation for the products and applications of nanotechnologies*, London, Defra; UK Food Standards Agency, *Draft report of FSA Regulatory Review. A review of potential implications of nanotechnologies for regulations and risk assessment in relation to food*, UK Food Standards Agency, 2006, <http://www.food.gov.uk/multimedia/pdfs/nanotech.pdf> (at 6 May 2008); Taylor,

some gaps in the regulatory schemes or knowledge base on which they are based have been identified.

Classification difficulties

Difficulties may also arise in classifying the nanomaterials concerned for the purposes of food regulation. For example, as discussed above, different requirements apply depending upon whether a substance is classified as an additive or a contaminant; even nanomaterials intentionally added to food or packaging should not all be classified as additives. If, for example, silver nanoparticles were incorporated into food packaging to provide anti-fungal properties, the function of those particles must be determined. For a food additive to be allowed to be added to food, it must perform one of the approved technological functions in Schedule 5 of Standard 1.3.1. Silver nanoparticles could be viewed as acting as a preservative, an approved function and, subject to approval, could be an allowed food additive. However, if the nanoparticles are instead regarded as acting as a catalyst they cannot be an approved additive. Some catalysts are approved for use in food but this is on the basis that they are processing aids. Silver is not currently an approved catalyst.[97]

If an additive to food or packaging is not an 'approved' additive, then whilst its addition to food is illegal, a legally specified, quantitative migration limit needs to be crossed before an offence is committed.[98] These levels may need review to take into account the use of nanomaterials if the migration levels of such particles and levels at which they can cause harm are different to their larger scale counterparts.

Dietary supplements

Dietary supplements incorporating nanomaterials, such as nanoscale calcium, magnesium and silver, are being developed for incorporation in food.[99] *Standard 1.3.2 – Vitamins and Minerals* regulates the addition of vitamins and minerals to food. Regulation is on the basis of weight, recommended daily intake (RDI) and estimated safe and adequate daily dietary intake (ESADDI). Whilst the regulations apply to nanoforms of vitamins and minerals, whether the regulation is triggered and the

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above n 75; FDA, *Nanotechnology. A Report of the US Food and Drug Administration Nanotechnology Task Force*, 25 July 2007.

97 Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, Standard 1.3.3 cl 5.

98 UK, Institute of Food Science and Technology Trust Fund, above n 13, 8.

99 *Consumer Products Inventory*, above n 25.

thresholds are appropriate depends on the ability to accurately measure levels of nanoforms of materials and scientific knowledge of the effects of these things being in nanoform. Similarly, the maximum residue limits (MRL) set for the presence of agricultural and veterinary chemicals in food[100] and which apply equally to nanoforms of such chemicals are also dependent on these same issues. Neither Standard considers how the substance / chemical was manufactured.

Food hygiene

Pursuant to Chapter 3 of the *Food Code* States and Territories are to require food businesses to implement food safety programs based on the Hazard Analysis and Critical Control Point (HACCP) System adopted by the joint WHO/FAO Codex Alimentarius Commission. The meanings of 'hazard' and 'contaminant', both of which are to be avoided using the food safety programs, apply to nanomaterials and products incorporating nanomaterials in the same way as they apply to conventional materials. Industrial end-users of construction materials, electrical appliances and other implements and containers incorporating nanomaterials and used in food premises would also be regulated by virtue of this part of the Code because the Standard provides that food businesses can only use equipment, fixtures or fittings that comply with the Standard.[101] The suitability of these provisions for nanotechnology though, once again depends upon it being appropriate that nanoforms of materials are treated as equivalent to their larger scale counterparts. Inter alia, food contact surfaces of fixtures, fittings and equipment are required to be 'made of material that will not contaminate food'.[102] 'Contaminant' means 'any biological or chemical agent, foreign matter, or other substances that may compromise food safety or suitability'.[103] Food is not safe if 'it would be likely to cause physical harm to a person who might later consume it'[104] and is not suitable if, inter alia, it 'contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food'.[105]

If a nanomaterial is considered different to its larger scale counterpart and is able to migrate into food that comes into contact with it, then its presence may make such food not suitable or even unsafe and therefore contaminated meaning the nanomaterial should not be used. Further,

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[100] Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, Standard 1.4.2.

[101] Ibid, Standard 3.2.3 cl 2(3).

[102] Ibid, Standard 3.2.3 cl 12(3)(c).

[103] Ibid, Standard 3.1.1 cl 1.

[104] Ibid, Standard 3.1.1 cl 2(1).

[105] Ibid, Standard 3.1.1 cl 2(5).

industrial end users using nanomaterials in such articles in the transport, display or packaging of food would fail to comply with the requirements under Standard 3.2.2 to ensure that food does not become unsafe or not suitable through, for example, how it is displayed or transported or the use of packaging material. Whether this is the case though, depends on it being known that the presence of the nanomaterial makes the food unsafe or unsuitable and is subject to the same difficulties as discussed above in relation to prosecutions under State legislation.

Labelling and consumer choice

It is possible some consumers may have concerns with nanofoods particularly regarding the safety of such foods and products. A 2007 survey found that about 73% of Australian consumers supported the use of nanotechnology in smart packaging and 54% in boosting nutrients and vitamins in foods. Nevertheless the survey also found that specific knowledge of what nanotechnology is and the nanotechnology process is low.[106] Others, such as Friends of the Earth Australia, Europe and United States have called for a moratorium on the further commercial release of food products, food packaging and food contact materials that contain manufactured nanomaterials until nanotechnology-specific safety laws are established and the public is involved in decision making.[107]
The UK Royal Society and the UK Institute of Food Science and Technology have both recommended that nanomaterials be stated on food labels for consumer information.[108] Although the primary objective of the Australian food regulatory scheme is the protection of public health, some non-scientific issues such as consumer information are also addressed. The *FSANZ Act* requires the provision of adequate information relating to food, to enable consumers to make informed choices and to prevent misleading or deceptive conduct.[109]

Nevertheless, it is unlikely that the food regulatory scheme would respond to concerns of consumers who do not want to eat nanofoods because the generally applicable labelling provisions of the *Food Code*[110]

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[106] Aust, Department of Industry, Tourism and Resources, *Australian Community Attitudes Held About Nanotechnology – Trends 2005 to 2007*, Market Attitude Research Services Pty Ltd, 12 June 2007, 3-4.

[107] Miller and Senjen, above n 4, 3.

[108] The Royal Society and Royal Academy of Engineering, *Nanoscience and Nanotechnologies: opportunities and uncertainties*, 2004 <http://www.nanotec.org.uk/finalreport.htm> (at 6 May 2008) section 8.3.3 [26] rec 11; UK Institute of Food Science and Technology Trust Fund, above n 13, 16 and 18.

[109] *Food Standards Australia New Zealand Act 1991* (Cth) s 10(1).

[110] Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code* Pt 1.2.

do not require labelling simply so consumers would have the choice to avoid a technology they are opposed to. FSANZ is to 'ensure that consumers have access to sufficient information to enable informed and healthy food choices'.[111] This does not include choices on the basis of ethical beliefs or personal views regarding possible safety risks. Only if there is a difference in the nutrition or function of nanofood is this provision likely to be applicable. For example, the *Food Regulation Ministerial Council Policy Guidelines* specifically regarding the *Novel Foods Standard* provide that FSANZ is to 'ensure consumers are not misled by novel foods ... which appear similar to existing foods but *may differ in terms of nutrition or function*' (emphasis added).[112] If nanofood does not differ in this regard, there would be no misleading for the purposes of this Guideline.

The labelling provisions of the *Food Code* may also not alert consumers of the presence of nanomaterials even where there are deficiencies in scientific knowledge concerning the nutritional value of foods or the technological function of substances in food due to the presence of nanomaterials. The *Food Code* requires that, subject to exceptions irrelevant to this paper, every ingredient and food additive in the food be declared on the food package.[113] Ingredients generally should be declared using their common name or a name that describes their true nature. Additives should be declared by the specific name or number provided in the Schedule to Standard 1.2.4. Once again uncertainty as to whether the name (for example, titanium oxide as listed in the Schedule) would include that additive in a nanoform, means there is a possible gap here if this regulation is relied on as a means to alert consumers to the presence of nanomaterials for the purposes of protecting their health and safety. Whilst manufacturers could voluntarily include such information, this is unlikely because of the tendency in the commercial sector 'to keep product development under wraps'.[114]

Other labelling issues also arise. For example, as noted by the Northern Ireland Food Advisory Committee 'if nanolabs or nanosensors indicate shelf stability certain labelling practices may not be necessary.'[115] Label

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[111] Ministerial Council Policy Guidelines, endorsed 12 December 2003, High Order Principles, 2nd dot point.

[112] Ibid, Specific Principles, 3rd dot point.

[113] Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, Standard 1.2.4 cls 3 and 8(1).

[114] Kuzma and VerHage, above n 3, 17.

[115] Report from the Chair of the Northern Ireland Food Advisory Committee INFO 06/09/04, 21 September 2006 to the UK Food Standards Agency, section 2 'Nanotechnology'.

requirements, such as use by or best before dates may become unnecessary if nanotechnology developments render them redundant. Other label components such as lists of ingredients may also no longer be needed. 'Advances in labelling technology, are also expected to offer new ways to store, display and interrogate information on packaging. For example, these types of advances might allow individuals to access more information on the source, history and storage of specific foods their nutritional characteristics and their suitability to the genetic makeup and lifestyle of individual consumers'.[116]

Post-Market Monitoring

The power referred to above for FSANZ to begin the process of development or variation of a Standard is not limited to the initial introduction of a food to the market. It can be used at anytime and therefore provides FSANZ with power to respond to new information about nanomaterials or products incorporating nanomaterials. However, because any Standard amendment is so resource intensive, it is likely only to occur if evidence of new public health and safety considerations arises.[117] FSANZ is expressly given responsibility, together with the States and Territories, for monitoring and conducting research and surveys in relation to any of the matters that may be included in a Standard. As noted above, FSANZ also has the obligation to take all reasonable steps to obtain the information necessary for objective risk analysis and a review of any sanitary or phytosanitary measures that it introduces. It is unknown what research is being done as part of its 'watching brief' referred to in the Introduction above.

International scene

At present there are no internationally relevant regulations specifically for nanotechnology in food although various jurisdictions have begun reviewing their laws with respect to nanotechnology. For example, the WHO/FAO Codex Alimentarius Standards do not deal with this issue and no official definition of the technology has yet been established.

As noted by the WHO, most jurisdictions that have undertaken regulatory reviews for nanotechnology in food have concluded that 'while consumers are likely to benefit from this technology, new data and new measurement approaches may be needed to ensure that the safety of

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[116] WHO, above n 2, 2.

[117] Food Standards Australia New Zealand, *Final Assessment Report Proposal P291 Review of Novel Food Standard*, 3 October 2007, 15.

products using nanotechnology are properly assessed.'[118] A review by the UK Food Standards Agency to 'identify potential gaps in regulation or risk assessment relating to the use of nanotechnologies and the potential deliberate or adventitious presence of manufactured nanomaterials in food'[119] did not identify 'any major gaps in regulations'.[120] However, it concluded that 'there is uncertainty in some areas whether applications of nanotechnologies would be picked up consistently'.[121] The UK Advisory Committees on Toxicity, on Carcinogenicity and on Mutagenicity of Chemicals in Food, Consumer Products and the Environment concluded that 'the existing model for risk assessment is applicable to nanomaterials although there are major gaps in information for hazard identification'.[122]

The European Parliament's Committee on the Environment, Public Health and Food Safety has also recognised that certain existing EU food safety standards may be inadequate for nanofoods.[123] The EU has asked the European Food Safety Authority (EFSA) to provide an initial scientific opinion on potential risks arising from the use of nanotechnology in food.[124]

The US has also undertaken a review of its food regulations.[125] The Review recognises that the lack of awareness of the presence of nanoscale materials by the US food regulator, the Food and Drug Administration (FDA), is not appropriate. Recommendations have been made to improve the sharing of this knowledge with the FDA and its' incorporation in the safety evaluation process.

A review of Australian food regulations was completed in 2007 for the National Nanotechnology Strategy Taskforce within the now Australian Department of Innovation, Industry, Science and Research.[126] That

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118 WHO, above n 2, 2.

119 UK, Food Standards Agency, *Draft Report of FSA Regulatory Review*, March 2006, [1].

120 Ibid [5].

121 Ibid [5].

122 Ibid [6].

123 Halliday, above n 90.

124 EFSA, above n 30.

125 US FDA, 'Nanotechnology. A Report of the US Food and Drug Administration Nanotechnology Task Force', 25 July 2007 <http://www.fda.gov/nanotechnology/taskforce/report2007.html> (at 6 May 2008).

126 Karinne Ludlow, Diana Bowman and Graeme Hodge, *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework. Final Report*, September 2007,

Department is also leading an inter-departmental committee to coordinate a national approach to nanotechnology.[127]

Conclusions

The Australian food regulatory scheme makes no mention of nanotechnology, and was created in the absence of any consideration thereof. However, it may nevertheless be applied to nanofoods and related products. It may be though, that the small size of nanomaterials means it can slip through some regulatory gaps. Possibly the most important gap is the lack of a decision on whether existing substances reformulated at the nanoscale are different to their pre-existing large scale counterparts for the purposes of the *Food Code*. This is important for at least two reasons. First, many regulations revolve around lists of named substances. A clear understanding of whether a nanoform is the same as its larger scale counterpart is essential for these lists to effectively operate. The use of both permitted and prohibited substance lists and the existence of natural nanofoods means though that the response should not be a simple declaration that nanofoods are or are not 'new'. Secondly, if manufacturers consider that the use of nanoforms of previously used substances is simply the use of the same ingredient or substance, new toxicological information for the product may not be developed.[128] Related to that, whilst FSANZ has assessment protocols for the evaluation of risks to human health, current risk assessment methodologies may not be adequate for determining potential risks of food and food contact materials containing nanomaterials to human health. The outcome of these two deficiencies in the generation and application of scientific risk assessment could mean proper steps are not taken to find out if nanofoods are actually a safety risk.

A second gap in the food regulatory scheme is the maximum limits for some 'food' on the basis of its weight, including additives, contaminants, natural toxicants and dietary supplements. Some of these may be inappropriate for nanoforms of these foods. Thirdly, where international documents are referenced in Australian regulations these need to be reviewed to see if they take into account the potential safety implications of nanomaterials or products containing nanomaterials. Finally, it is also unclear whether current methods and techniques for measuring

<http://www.innovation.gov.au/Section/Innovation/Documents/MonashReport.pdf> (at 10 November 2008).

127 FSANZ, above n 6.

128 UK, Institute of Food Science and Technology Trust Fund, above n 13, 9.

nanomaterials are adequate for detecting nanomaterials in food and food contact materials.

Whether the above gaps are of concern is not yet clear because the safety of such materials is not sufficiently understood. FSANZ's approach of monitoring the situation is therefore an important first step to addressing the problem. Depending upon consumers' attitude to risk and if a precautionary approach is to be taken the known gaps in the regulations should be responded to by FSANZ. The lengthy process required to amend Food Standards means that work should commence sooner rather than later on this. In particular, a decision should be made on whether and which nanoscale substances are different to their pre-existing large scale counterparts. Caution in addressing this issue is particularly needed because some foods may naturally contain nanomaterials. For example, the boiling of starch to make custard relies on the melting of nanosized 3-D crystalline structures and the recrystallisation of nanostructures formed by starch polysaccharides.[129] Unless safety concerns arise, such nanomaterials should not now be regulated any differently to past regulation because of concerns over new uses of nanotechnology. Maximum limits for relevant 'foods' should also be reassessed and there should be a review of international documents referred to in Australian regulations. The adequacy of current measuring methods and techniques should also be investigated.

A final more general step in preparing Australian food regulations for nanotechnology is to reflect on what the Australian public expects from its end product regulatory schemes and to compare current regulations with international best practice. Risk assessments under the food regulations are concerned only with human health and safety and FSANZ is not required to consider broader environmental risks associated with nanomaterials from food or food contact materials that will inevitably enter waterways and landfill. This is not a great concern if environmental protection regulations satisfactorily deal with the issue but whether that is the case needs to be investigated. Other interfaces between regulatory schemes seem satisfactory although there is potential for confusion as to which is the relevant scheme in some cases. For example, an increasing number of products which contain nanomaterials will sit on the FSANZ-Therapeutic Goods Administration regulatory interface.[130] If a product is a therapeutic good, it will be regulated under the therapeutic goods regulatory scheme; if it is a food, it is regulated under the food

[129] UK, Institute of Food Science and Technology Trust Fund, above n 13, 4.

[130] For general information on this, see Food Standards Australia New Zealand, *Final Assessment Report Proposal P291 Review of Novel Food Standard*, 3 October 2007, 12.

regulations discussed above. Furthermore, there is the issue of how much consumers wish to know about nanotechnology in their food and whether the food regulatory scheme should accommodate that choice. If members of the public do not want to participate, the current labelling provisions are unlikely to require labelling such that consumers could chose to avoid nanotechnology used in connection with their food. This means manufacturers will be truly able to keep the use of this new technology 'under wraps'.