

LETTING THE MARKET DECIDE? THE RISE – AND REGULATORY RISKS – OF THE AUSTRALIAN NANOTECHNOLOGY INDUSTRY

PARIS JEFFCOAT*, CARY DI LERNIA** AND ELIZABETH NEW***

In 2022, the European Union moved to ban the use of titanium dioxide as a food additive after it had been on the market for over four decades, due to safety concerns related to the additive's nanoparticulate nature. Marking a significant backflip in the international regulatory approach to consumer products containing nano-objects, the global shifting of regulatory gears following the decision has already begun to filter through to domestic policymaking, with regulator Food Standards Australia New Zealand forced to reconsider their regulatory approach to the additive, which remains largely permissive. In view of the evolving understanding that technologies and objects at the nanoscale present new risks to humans and the environment, it is argued that a more precautionary approach should be considered by Australian regulators to fill the significant gaps in existing regulatory frameworks and safeguard stakeholders.

I INTRODUCTION

The late 20th century saw the rise of several key 'emerging' technologies which promised to revolutionise the material world. As the beneficiaries of neoliberal attitudes and policies promulgated by the governments of developed economies around the world, many of these technologies continue to progress innovation across industries. Nanotechnology, now a USD42.2 billion global industry, is one such technology.¹ With applications continuing to influence consumer product developments – ranging from homewares, medicines, and electronics to personal care and foods – the regulatory permissiveness which once enabled the meteoric rise of nanotechnology now threatens to be its greatest undoing.

* School of Chemistry and Sydney Nano Institute, University of Sydney. Email: paris.jeffcoat@sydney.edu.au.

** Discipline of Business Law, University of Sydney Business School, University of Sydney. Email: cary.dilernia@sydney.edu.au.

*** School of Chemistry and Sydney Nano Institute, University of Sydney. Email: elizabeth.new@sydney.edu.au.

1 ReportLinker, 'Global Nanotechnology Market to Reach \$70.7 Billion by 2026' (Media Release, 23 June 2021) <<https://www.globenewswire.com/news-release/2021/6/23/2251603/0/en/Global-Nanotechnology-Market-to-Reach-70-7-Billion-by-2026.html>> ('Global Nanotechnology Market Media Release').

Growing concern has been raised by the scientific community regarding the lack of investment in nano-safety research – which lags research into applications by decades and several orders of magnitude – and the suitability of current regulatory governance frameworks to manage its iterations and applications.² As such concern trickles down and begins to inform consumer opinion, public sentiment risks swinging swiftly and irreversibly towards an anti-nanotechnology attitude similar to that encountered by biotechnologies in the late 1990s and early 2000s.³ Here, we argue that the economic rationalism feeding the rise (and potential fall) of nanotechnology has created a perfect storm which will put stakeholders at risk if left un- or under-addressed.

While nano-safety research is evolving, it remains a nascent field.⁴ Consequences of this are beginning to emerge. In early 2021, the preeminent food safety authority in the world – the European Food Safety Authority (‘EFSA’) – backflipped on its stance on the pre-supposed safety of a nanoscale food additive (titanium dioxide, E171) that had been on the market for over 60 years (‘EFSA Opinion’).⁵ A harbinger of a regulatory wave poised to destabilise the nanotechnology industry, the European Union (‘EU’) responded to the EFSA Opinion by moving to implement an EU-wide ban on the food additive later the same year.⁶ The EU’s decision to ban the use of titanium dioxide in foods was based on the evolving scientific opinion of the EFSA over a six-year period from 2016 to 2021 (see Figure 1 below). Over this time, consideration toward the toxicological profile of titanium dioxide at the nanoscale played a pivotal role in the evolution of the EFSA’s conclusions on its safety.

-
- 2 Desirée L Plata and Nina Z Janković, ‘Achieving Sustainable Nanomaterial Design through Strategic Cultivation of Big Data’ (2021) 16(6) *Nature Nanotechnology* 612 <<https://doi.org/10.1038/s41565-021-00902-7>>; Aleksandra Zielińska et al, ‘Nanotoxicology and Nanosafety: Safety-by-Design and Testing at a Glance’ (2020) 17(13) *International Journal of Environmental Research and Public Health* 4657:1–23 <<https://doi.org/10.3390%2Fijerph17134657>>.
 - 3 See Rosemary Polya, ‘Genetically Modified Governance Issues’ (Research Paper No 17 2000–01, Science, Technology, Environment and Resources Group, 6 February 2001).
 - 4 Harald F Krug, ‘Nanosafety Research: Are We on the Right Track?’ (2014) 53(46) *Angewandte Chemie International Edition* 12304, 12306–7 <<https://doi.org/10.1002/anie.201403367>>; Nina Jeliaskova et al, ‘Towards FAIR Nanosafety Data’ (2021) 16(6) *Nature Nanotechnology* 644 <<https://doi.org/10.1038/s41565-021-00911-6>>.
 - 5 Maged Younes et al, ‘Safety Assessment of Titanium Dioxide (E171) as a Food Additive’ (2021) 19(5) *European Food Safety Authority Journal* 6585:1–130 <<https://doi.org/10.2903/j.efsa.2021.6585>>; Marie-Hélène Ropers et al, ‘Titanium Dioxide as Food Additive’ in Magdalena Janus (ed), *Application of Titanium Dioxide* (IntechOpen, 2017) 3, 8 <<http://doi.org/10.5772/intechopen.68883>>.
 - 6 *Commission Regulation (EU) 2022/63 of 14 January 2022 Amending Annexes II and III to Regulation (EC) No 1333/2008 as Regards the Food Additive Titanium Dioxide (E 171)* [2022] OJ L 11/1 (‘Commission Regulation (EU) 2022/63’).

Summary of Events Leading to EU Decision

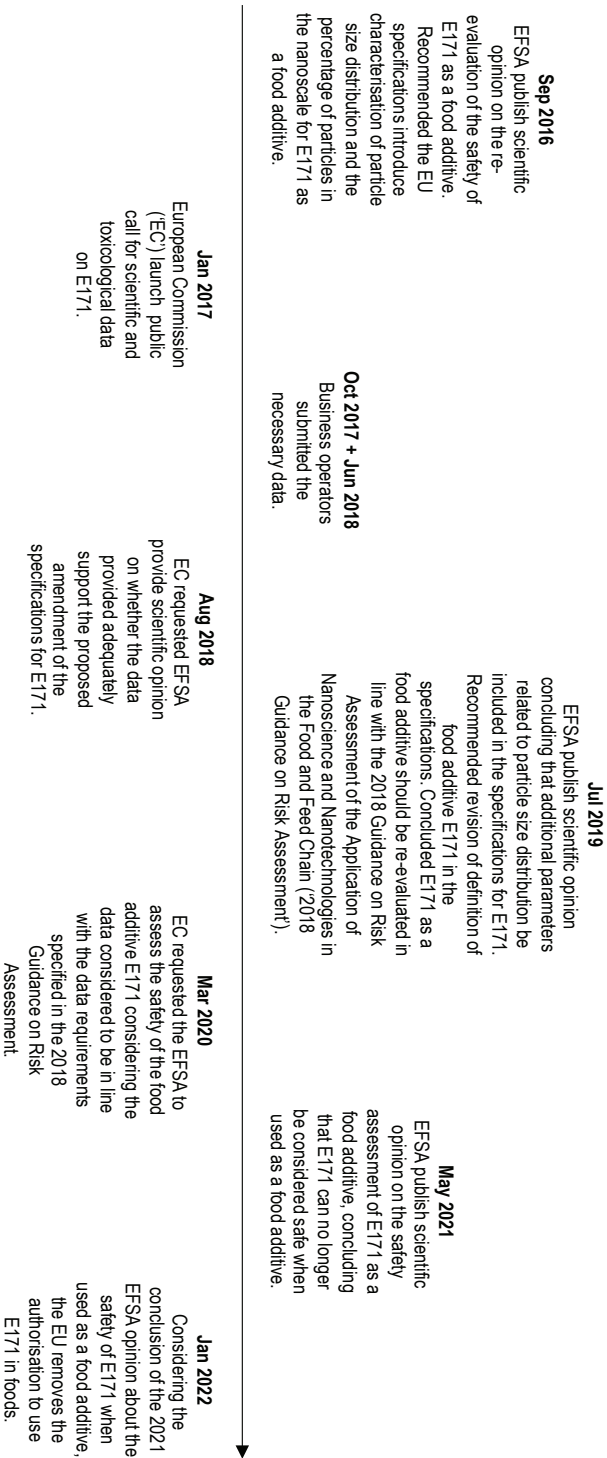


Figure 1: Summary of events, provided by the EU, which led to the ban of the use titanium dioxide (E171) in foods⁷

⁷ Ibid.

Further to the EU ban, debate surrounding the classification of titanium dioxide as a potential carcinogen has garnered significant attention from industry and regulators alike. Based on the emerging evidence of the toxic potential of titanium dioxide when used as a food additive, in 2015 France proposed to have titanium dioxide classified as a Category 1B carcinogen by inhalation.⁸ After public consultation, the final opinion on the proposal from the European Chemicals Agency's ('ECHA') Committee for Risk Assessment was published and adopted in September 2017, which concluded that titanium dioxide should be classified as a Category 2 suspected human carcinogen by inhalation (H351) ('ECHA Opinion').⁹ On the basis of the ECHA Opinion, the European Commission ('EC') formally recognised titanium dioxide as a suspected human carcinogen by inhalation in 2020.¹⁰

Following this, Case T-283/20 (led by chemicals manufacturer, Billions Europe Ltd, and supported by six other companies) and joined Cases T-279/20 and T-288/20 (led by CWS Powder Coatings GmbH, Brillux GmbH & Co KG and Daw SE, and supported by seven other companies) were brought to the EU's General Court in early 2022 disputing the EC's classification.¹¹ The judgment of the case, handed down in November 2022, upheld the main substantive arguments raised by the industry applicants and saw the EC's 2020 classification annulled, reversing the classification and labelling requirements for titanium dioxide. The Court concluded that the EC had made 'manifest errors of assessment' in reaching its 2020 decision, specifically pertaining to the reliability and acceptability of studies, the degree to which a substance has the 'intrinsic property' to cause cancer, and the calculation of lung overload in particles.¹²

While the EC may still appeal the Court's decision, the case and its final ruling highlights the complexities and competing interests at play when attempting to regulate nanotechnology industries. While the reports and opinion of the French Agency for Food, Environmental and Occupational Health & Safety ('ANSES') and ECHA, and the EC classification, clearly demonstrate mounting scientific evidence for the adverse effects of titanium dioxide nanoparticles, the industry-led case brought before the EU Court reinforces the commercial pressures such classifications and associated regulatory change put on the manufacturers, importers, downstream users and suppliers of titanium dioxide. Given its focus on the reliability and acceptability of scientific studies, the case highlights the urgent need to invest in nano-safety

8 The French Agency for Food, Environmental and Occupational Health & Safety submitted a proposal to the European Chemicals Agency registry of classification and labelling to have titanium dioxide classified under the Globally Harmonized System of Classification and Labelling of Chemicals based Classification, Labelling and Packaging Regulations as a Category 1B carcinogen by inhalation (H351): European Chemicals Agency, Committee for Risk Assessment, 'Opinion Proposing Harmonised Classification and Labelling at EU Level of Titanium Dioxide' (Opinion, 14 September 2017) annex I, 5 ('ECHA Opinion').

9 Ibid 109.

10 *Commission Delegated Regulation (EU) 2020/217 Amending, for the Purposes of Its Adaptation to Technical and Scientific Progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures and Correcting that Regulation* [2020] OJ L 44/1.

11 *CWS Powder Coatings GmbH v European Commission* (General Court of the European Union, T-279/20, ECLI:EU:T:2022:725, 23 November 2022) ('CWS Powder Coatings').

12 Ibid [103], [120]–[121], [159]–[160], [179] (The Court).

research and brings to the fore the inherent complexities at play when navigating the interface between scientific and legal reasoning.

International counterparts, including Australian regulators, have begun to respond to the regulatory murmurings occurring in the EU. Australian food regulator Food Standards Australia New Zealand ('FSANZ') issued a call for information and initiated an internal review of the safety of the food additive at the centre of the controversy, which concluded that 'there is no evidence to suggest that dietary exposures to food-grade TiO₂ are of concern for human health'.¹³ Australian regulators, such as FSANZ, have in the past rationalised their regulatory response by unofficially benchmarking with the EU, indicating the influence advanced international policymaking has on the conception of regulatory approaches at the domestic level.¹⁴ The EFSA's shift marks a fork in the road where Australian regulators have chosen to take a different approach.

In Part II of this article, we introduce the burgeoning nano-economy in Australia and detail its incubation by the Australian Government with a view towards economic growth. In Part III, we interrogate the approach of the Australian food regulator, FSANZ, through a case study that exposes the gaps in its regulatory framework. In Part IV, we draw on international approaches before offering our own recommendations for a holistic regulatory approach that addresses the concerns raised in Part III. We postulate that a single, independent, national oversight body might effectively reprioritise nano-safety research and regulatory outcomes for a healthy society, environment, and sustainable nano-economy.

II THE NANO-ECONOMY IN AUSTRALIA

While the scientific advancement of nanotechnology began in the 1960s, the field only truly entered the cultural zeitgeist almost 40 years later at the turn of the century. Touted as a 'key economic driver for the 21st century',¹⁵ the 'Nanotechnology Age' emerged in popular culture with significant hype. In 2003, *Forbes* magazine went so far as to describe it as defining 'an epoch more significant than any preceding age identified by any one material such as stone, bronze, iron or silicon'.¹⁶ With investment in the industry quickly understood by governments to

13 Food Standards Australia New Zealand, *Titanium Dioxide as a Food Additive* (Report, September 2022) 2 <https://www.foodstandards.gov.au/consumer/foodtech/Documents/FSANZ_TiO2_Assessment_report.pdf>.

14 Food Standards Australia New Zealand, Answers to Questions on Notice to Senate Community Affairs Committee, Parliament of Australia, *Supplementary Budget Estimates 2015–16* (Answers to Questions on Notice No SQ15-000778, 21 October 2015) <https://www.aph.gov.au/~media/Committees/clac_ctte/estimates/sup_1516/Health/Answers/SQ15-000778.pdf> ('Answers to Supplementary Budget Estimates Questions SQ15-000778').

15 Diana M Bowman and Graeme A Hodge, 'Nanotechnology and Public Interest Dialogue: Some International Observations' (2007) 27(2) *Bulletin of Science, Technology and Society* 118, 118 <<https://doi.org/10.1177/0270467606298216>> ('Nanotechnology and Public Interest Dialogue').

16 'Get Ready for the Age Of Nanotechnology', *Forbes* (online, 2 October 2003) <<https://www.forbes.com/2003/10/02/1002nanotechnologypinnacor.html?sh=74e78ca81e06>>.

be a strategic economic imperative, national roadmaps and initiatives to foster the industry's growth emerged.¹⁷

The wide-ranging utility and promise of nanotechnology comes from the elemental nature of the technology itself: when starting with the most basic of building blocks at the smallest of scales, anything can be built and everything can be built better. In its simplest sense, nanotechnology describes the manipulation of matter at the nanoscale, where the nanoscale is the size range from approximately 1 nm to 100 nm (with 1 nm measuring a distance approximately a million times smaller than an average grain of sand).¹⁸ Alongside the enabling technologies available at the nanoscale, nano-objects – material objects with one, two or three external dimensions in the nanoscale – have also found great utility. Nano-objects can be categorised as either manufactured (sometimes referred to as ‘engineered’) or naturally occurring. While the International Organisation for Standardisation (‘ISO’) defines a manufactured nano-object as a nano-object ‘intentionally produced to have specific properties or composition’,¹⁹ we employ a broader definition in this article. Taking the *Oxford English Dictionary* definition of manufacture – ‘to produce a substance’ – we include nano-objects that are incidentally present (ie, unintentional by-products of a process) in our definition of a manufactured nano-object.²⁰ In this article, when referring to nano-objects, we refer only to those that are manufactured.

With more of the predicted benefits and applications of nanotechnologies coming into fruition since the dawn of the new millennium – most recently realised with the success of nanotechnology-based vaccines in fighting the COVID-19 pandemic²¹ – a flourishing nano-economy in Australia has developed, placing the nation 5th in the world in terms of nanotechnology institutes,²² and 11th in terms of nanotechnology companies.²³ Australia's reputation as an attractive commercial ecosystem for the emerging nano-economy has developed thanks to high levels of government support provided during the initial nanotechnology boom.²⁴ In

17 Rathjen et al, ‘Nanotechnology: Enabling Technologies for Australian Innovative Industries’ (Working Paper, Prime Minister's Science, Engineering and Innovation Council Working Group, 11 March 2005); Subcommittee on Nanoscale Science, Engineering, and Technology, United States National Science and Technology Council, *National Nanotechnology Initiative Strategic Plan* (Report, October 2021).

18 Marina Theodoris, ‘Mass of a Grain of Sand’, *The Physics Factbook* (Web Page, 2003) <<https://hypertextbook.com/facts/2003/MarinaTheodoris.shtml>>.

19 International Organization for Standardization, ‘Nanotechnologies: Plain Language Explanation of Selected Terms from the ISO/IEC 80004 Series 2017’ (Technical Standards ISO/TR 18401:2017, June 2017) [3.5] <<https://www.iso.org/obp/ui/#iso:std:iso:tr:18401:ed-1:v1:en1/1>>.

20 *Oxford English Dictionary* (2nd ed, 1989) ‘manufacture’ (v², def 1c).

21 Mark Peplow, ‘Nanotechnology Offers Alternative Ways to Fight COVID-19 Pandemic with Antivirals’ (2021) 39 (October) *Nature Biotechnology* 1172 <<https://doi.org/10.1038/s41587-021-01085-1>>; See also Lanying Du et al, ‘Recent Advances in Nanotechnology-based COVID-19 Vaccines and Therapeutic Antibodies’ (2022) 14(4) *Nanoscale* 1054 <<https://doi.org/10.1039/D1NR03831A>>.

22 ‘Nanotechnology Research Laboratories’, *Nanowerk* (Web Page) <https://www.nanowerk.com/nanotechnology/research/research_c.php>.

23 ‘Nanotechnology Companies’, *Nanowerk* (Web Page) <https://www.nanowerk.com/nanotechnology/nanomaterial/commercial_c.php>.

24 Sarah Moore, *Nanotechnology in Australia Market Report* (Report, 15 January 2020) <<https://www.azonano.com/article.aspx?ArticleID=5401>>.

the early 2000s, it was estimated that the Federal Government was investing \$50 million per annum, and that the Victorian State Government alone was investing around \$30 million per annum in nanotechnology and related activities.²⁵ In 2005, an independent working group estimated that the significant private and public investment in nanotechnology had the potential to create multi-trillion dollar industries in the coming decade.²⁶ Recognising the global value of the nanotechnology market, the Victorian State Government just a decade ago described investment in the industry as a ‘significant opportunity for Victoria’.²⁷ An attitude of economic rationalism appears to have informed the Australian Government’s early investment in the industry, with a 2006 Senate report suggesting that to ‘capitalise on the opportunities presented by nanotechnology’, the nation should ‘accelerate industry uptake’.²⁸

From surveys conducted with business and community stakeholders in the early 2000s, it is evident that awareness of nanotechnology among the general population was steadily increasing and that attitudes towards the technology were generally positive.²⁹ Further, in a 2005 report from Nanotechnology Victoria, consultation revealed that industry largely held the government accountable for informing public opinion on nanotechnology, so as not to repeat the economic and reputational fate of biotechnologies.³⁰ DuPont, one of the world’s largest chemicals companies, noted as part of this process:

Nanotechnology is the next biotech in the public’s mind – no doubt about it. Public education is hugely important. It’s the one mistake we made with biotech. We let the science precede the public education, and from then on we were constantly playing catch up. The number one thing we can do is to educate the public.³¹

A 2009 government review shared such sentiment, finding that the ‘social and economic implications of [nanotechnology] are intimately linked to questions of risk communication and risk perception amongst publics’.³² Further, Brian Priestly and Margaret Stebbing, in their 2008 analysis, reported that ‘trust in regulatory

25 Senate Standing Committee on Community Affairs, Parliament of Australia, *Inquiry into Workplace Exposure to Toxic Dust* (Report, 31 May 2006) 85 [7.14] (*‘Inquiry into Workplace Exposure to Toxic Dust’*); Department of Innovation, Industry and Regional Development (Vic), ‘Victorian Nanotechnology Statement: Taking Leadership in Innovations in Technology’ (Statement, February 2008) 5 (*‘Victorian Nanotechnology Statement’*).

26 Rathjen et al (n 17) 12.

27 ‘Victorian Nanotechnology Statement’ (n 25) 4.

28 *Inquiry into Workplace Exposure to Toxic Dust* (n 25) 101 [7.66].

29 Department of Innovation, Industry, Science and Research (Cth), *Australian Community Attitudes Held about Nanotechnology: Trends 2005 to 2011* (Final Report, August 2011) 20–1.

30 Dandolo Partners, *Nanotechnology and the Business Community* (Report, 11 July 2005) 35. Larger companies, particularly those with public shareholders, felt government should provide balanced information to educate the public about both the benefits and risks of nanotechnology, stating ‘[s]everal larger companies believed that the public needed to be actively managed as a stakeholder to ensure it made informed judgments about nanotechnology’: at 5.

31 Ibid.

32 Kate Seear, Alan Petersen and Diana Bowman, *The Social and Economic Impacts of Nanotechnologies: A Literature Review* (Final Report, February 2009) 6, 79.

systems is one factor which can influence community perceptions of risk'.³³ The Australian Government seems to have recognised the supportive and facilitative role it could play in building trust between regulators and the public early on, acknowledging the need for a coordinated national strategy for nanotechnology in the early 1990s.³⁴ Despite this, it was not until 2005 that a National Nanotechnology Strategy Taskforce ('NNST') was formalised and tasked with developing a 'whole of government' strategy.³⁵ Under this strategy, a series of short-lived initiatives were taken up by the government, including the establishment of the Australian Office of Nanotechnology ('AON') and the establishment of a Health, Safety and Environment ('HSE') working group.³⁶ Further to the activities undertaken by the AON between 2007 and 2009, the NNST's recommendation to assess the suitability and capability of existing regulatory frameworks to manage nanotechnology was implemented in 2007 by Karinne Ludlow, Diana Bowman and Graeme Hodge at Monash University.³⁷

As noted above, despite the deep investment that governments have made into nanotechnology, such investment has overwhelmingly been spent on commercial application rather than nano-safety, which we define for the purposes of this article as research approaches, tools, and outcomes related to the health and safety impacts of nanotechnology and nano-objects on humans and the environment. Investment trends which deprioritise nano-safety research are perhaps unsurprising, given government directives to capitalise on the significant economic opportunity nanotechnology promised to bring by 'accelerat[ing] industry uptake'.³⁸ In its first five years of operation, the United States ('US') Government invested 7% of its national nanotechnology research and development budget on nano-safety research, with the 2021 budget investing only 3%.³⁹ As we discuss further in Part IV, in order to reprioritise environmental, health, and safety ('EHS') outcomes, more significant and proportionate investment in EHS research and related activities will be required. Notably, industry representatives have also acknowledged the need for increased investment in this area, with the CEO of DuPont suggesting in 2005

33 Brian Priestly and Margaret Stebbing, 'Risk Perception and Risk Communication: Is Nanotechnology at the Crossroads in Australia?' (Conference Paper, International Conference on Nanoscience and Nanotechnology, 29 February 2008) 238 <<https://doi.org/10.1109/ICONN.2008.4639291>>.

34 Australian Science and Technology Council, *Annual Report 1992–93* (Report, 24 November 1993) 16–17.

35 National Nanotechnology Strategy Taskforce, Parliament of Australia, *Options for a National Nanotechnology Strategy* (Report, June 2006) 3 ('NNST Report').

36 Australian Office of Nanotechnology, *National Nanotechnology Strategy (NNS) Annual Report 2007–08* (Report, 2008) 23 ('NNS Annual Report 07–08'); Australian Office of Nanotechnology, *National Nanotechnology Strategy Annual Report 2008–09* (Report, 2009) 22 ('NNS Annual Report 08–09').

37 NNST Report (n 35) 6; Karinne Ludlow, Diana Bowman and Graeme Hodge, *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework* (Final Report, September 2007) 9.

38 *Inquiry into Workplace Exposure to Toxic Dust* (n 25) 101 [7.66].

39 Mihail C Roco, 'National Nanotechnology Initiative: Past, Present, Future' in William A Goddard III et al (eds), *Handbook of Nanoscience, Engineering, and Technology* (CRC Press, 2007) 3.1, 3.16 <<https://doi.org/10.1201/9781420007848.ch3>>; Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council, *National Nanotechnology Initiative Supplement to the President's 2021 Budget* (Annual Report, October 2020) 9.

that '[g]overnment spending on nanotechnology should be reprioritized so that approximately 10% goes to [studying health and environmental risk]'.⁴⁰

With no active national EHS initiatives or strategies from the Federal Government, current investment in nano-related EHS research is difficult to determine in Australia, with the only available data from 2007 indicating that 3.3% of the Australian Government's support for nanotechnology was targeted toward research on the EHS impacts of nanotechnology.⁴¹ Despite the limited information publicly available, a 2006 Senate report cited the small investment in occupational health and safety outcomes among its concerns in relation to future nanotechnology development.⁴² In the same year, the NNST found that 'there is an immediate need to coordinate the management of, and research into, risks arising from HSE issues, and that there is a need to fund HSE research in Australia'.⁴³ This lack of investment not only reflects a potentially short-sighted prioritisation in political spend, but has tangible public health implications where latent health effects arise from exposure to nano-objects, as the recent EFSA Opinion has found to occur with the popular food additive titanium dioxide.⁴⁴

Given the unique properties and interactions nano-objects exhibit in biological systems, EHS data collected through nano-safety research are crucial to the understanding of nano-risks and form the basis of regulatory risk assessment. Relative to non-nanoscale materials, nano-objects have unique physico-chemical properties, including increased surface area, enhanced chemical reactivity and improved bioavailability.⁴⁵ These properties allow them to accumulate across environmental ecosystems; transfer through food chains; and, following human or animal exposure, enter and interact with biological systems at a cellular level, including entering organs and tissues via the bloodstream and crossing the blood-brain barrier.⁴⁶ Emerging evidence indicates both cellular and systemic effects of nano-objects. Cellular effects

40 Fred Krupp and Chad Holliday, 'Let's Get Nanotech Right', *Wall Street Journal* (online, 14 June 2005) <<https://www.wsj.com/articles/SB11870930078058710>>:

Funding to study health and environmental risk represents only 4% of the proposed federal investment in nanotech and becomes vanishingly small when you factor in private investment. Government spending on nanotechnology should be reprioritized so that approximately 10% goes to this purpose.

41 *NNS Annual Report 07–08* (n 36) 17.

42 *Inquiry into Workplace Exposure to Toxic Dust* (n 25) 88 [7.25].

43 *NNST Report* (n 35) 10, 33.

44 Younes et al (n 5).

45 See Ibrahim Khan, Khalid Saeed and Idrees Khan, 'Nanoparticles: Properties, Applications and Toxicities' (2019) 12(7) *Arabian Journal of Chemistry* 908 <<https://doi.org/10.1016/j.arabjc.2017.05.011>>.

46 Evan P Stater et al, 'The Ancillary Effects of Nanoparticles and Their Implications for Nanomedicine' (2021) 16 (November) *Nature Nanotechnology* 1180 <<https://doi.org/10.1038/s41565-021-01017-9>>; Nell Hirt and Mathilde Body-Malapel, 'Immunotoxicity and Intestinal Effects of Nano- and Microplastics: A Review of the Literature' (2020) 17 *Particle and Fibre Toxicology* 57:1–22 <<https://doi.org/10.1186/s12989-020-00387-7>>.

include cytotoxicity,⁴⁷ impact on cell membrane composition,⁴⁸ autophagy,⁴⁹ DNA strand breaks and chromosomal damage,⁵⁰ and redox dysregulation.⁵¹ Systemic effects include vascular dysfunction,⁵² procoagulant and anticoagulant effects on blood,⁵³ immunotoxicity,⁵⁴ inflammation,⁵⁵ neurotoxicity,⁵⁶ cardiotoxicity,⁵⁷ carcinogenicity,⁵⁸ genotoxicity,⁵⁹ and disturbance of the gut microbiota and critical intestinal functions.⁶⁰ Despite this understanding, nano-safety research remains a relatively nascent field, with many variables and uncertainties remaining which hinder the ability of scientists

-
- 47 Esther Belade et al, 'The Role of p53 in Lung Macrophages following Exposure to a Panel of Manufactured Nanomaterials' (2015) 89(9) *Archives of Toxicology* 1543 <<https://doi.org/10.1007/s00204-014-1324-5>>; Sandra Vranic et al, 'Impact of Serum as a Dispersion Agent for In Vitro and In Vivo Toxicological Assessments of TiO₂ Nanoparticles' (2017) 91(1) *Archives of Toxicology* 353 <<https://doi.org/10.1007/s00204-016-1673-3>>.
 - 48 Pégah Jalili et al, 'Chronic Effects of Two Rutile TiO₂ Nanomaterials in Human Intestinal and Hepatic Cell Lines' (2022) 19 *Particle and Fibre Toxicology* 37:1–22 <<https://doi.org/10.1186/s12989-022-00470-1>>.
 - 49 Ali Kermanizadeh et al, 'Nanomaterial-Induced Cell Death in Pulmonary and Hepatic Cells Following Exposure to Three Different Metallic Materials: The Role of Autophagy and Apoptosis' (2017) 11(2) *Nanotoxicology* 184 <<https://doi.org/10.1080/17435390.2017.1279359>>.
 - 50 Younes et al (n 5) 1.
 - 51 Elizabeth C Bowdridge et al, 'Nano-Titanium Dioxide Inhalation Exposure during Gestation Drives Redox Dysregulation and Vascular Dysfunction across Generations' (2022) 19 *Particle and Fibre Toxicology* 18:1–17 <<https://doi.org/10.1186/s12989-022-00457-y>>.
 - 52 Ibid.
 - 53 Stater et al (n 46) 1182.
 - 54 See Younes et al (n 5).
 - 55 Hana Barosova et al, 'An In Vitro Lung System to Assess the Proinflammatory Hazard of Carbon Nanotube Aerosols' (2020) 21(15) *International Journal of Molecular Sciences* 5335 <<https://doi.org/10.3390/ijms21155335>>; Ali Kermanizadeh et al, 'Assessment of Nanomaterial-induced Hepatotoxicity Using a 3D Human Primary Multi-cellular Microtissue Exposed Repeatedly over 21 Days: The Suitability of the In Vitro System as an In Vivo Surrogate' (2019) 16(1) *Particle and Fibre Toxicology* 42:1–14 <<https://doi.org/10.1186/s12989-019-0326-0>>.
 - 56 Younes et al (n 5).
 - 57 Niels Hadrup et al, 'Acute Phase Response as a Biological Mechanism-of-Action of (Nano)particle-induced Cardiovascular Disease' (2020) 16(21) *Small* 1907476:1–12 <<https://doi.org/10.1002/smll.201907476>>; H Kan, D Pan and V Castranova, 'Engineered Nanoparticle Exposure and Cardiovascular Effects: The Role of a Neuronal-regulated Pathway' (2018) 30(9–10) *Inhalation Toxicology* 335 <<https://doi.org/10.1080/08958378.2018.1535634>>; Eelco Kuijpers et al, 'Cardiovascular Effects among Workers Exposed to Multiwalled Carbon Nanotubes' (2018) 75(5) *Occupational and Environmental Medicine* 351 <<https://doi.org/10.1136/oemed-2017-104796>>.
 - 58 D Lison, S van den Brule and G Van Maele-Fabry, 'Cobalt and Its Compounds: Update on Genotoxic and Carcinogenic Activities' (2018) 48(7) *Critical Reviews in Toxicology* 522 <<https://doi.org/10.1080/10408444.2018.1491023>>; Atsushi Sobajima et al, 'Organ Accumulation and Carcinogenicity of Highly Dispersed Multi-walled Carbon Nanotubes Administered Intravenously in Transgenic rasH2 Mice' (2019) 14 *International Journal of Nanomedicine* 6465 <<https://doi.org/10.2147/IJN.S208129>>.
 - 59 Michael J Burgum et al, 'Few-Layer Graphene Induces Both Primary and Secondary Genotoxicity in Epithelial Barrier Models In Vitro' (2021) 19(1) *Journal of Nanobiotechnology* 24:1–15 <<https://doi.org/10.1186/s12951-021-00769-9>>; Samantha V Llewellyn et al, 'In Vitro Three-Dimensional Liver Models for Nanomaterial DNA Damage Assessment' (2021) 17(15) *Small* 2006055:1–19 <<https://doi.org/10.1002/smll.202006055>>; Adriana Vieira et al, 'Investigation of the Genotoxicity of Digested Titanium Dioxide Nanomaterials in Human Intestinal Cells' (2022) 161 *Food and Chemical Toxicology* 112841:1–12 <<https://doi.org/10.1016/j.fct.2022.112841>>.
 - 60 Stater et al (n 46) 1183.

to predict and make definitive conclusions of safety for the nano-objects that entire societies are exposed to.⁶¹

Humans are repeatedly and cumulatively exposed to nano-objects on a daily basis through the normal processes of modern life – many homes, offices, cars, laptops, clothes, medicines, and even foods are known to contain manufactured nano-objects that humans are exposed to for various time periods (resulting in either short-term/acute or long-term/chronic exposure) by various routes (resulting in either oral, dermal or inhalation exposure).⁶² For example, both acute and chronic exposure to titanium dioxide (food additive E171) can occur via oral and dermal pathways through food and food packaging, with one report finding that 51% of chewing gums, 10% of jellies/gummies and 10% of lollipops contain the food additive.⁶³ Considering this, adult dietary exposure to titanium dioxide (E171) – which, despite containing nano-objects with limited safety data, has been on the market for 60 years – is estimated to be approximately 1 mg/kg per day.⁶⁴ The exposure estimation *increases* to approximately 2 mg/kg per day for children due to dietary habits.⁶⁵

It is important to recognise that human and environmental exposure to nano-objects is increasing at an unprecedented rate while nano-safety research emerges and risk governance protocols are being established. This puts stakeholders at potential risk of physical, economic, legal and reputational ramifications should the nano-safety research conclude definitively that exposure to nano-objects leads to serious harm, or if the free market shifts toward anti-nanotechnology sentiment independently of any such conclusions. The 2021 EFSA Opinion on titanium dioxide as a food additive, and the subsequent EU ban on the substance, provides something of a wake-up call for governments that have to date implemented a largely criticised ‘wait and see’ regulatory approach to the matter.⁶⁶

61 Andrew J Chetwynd, Korin E Wheeler and Iseult Lynch, ‘Best Practice in Reporting Corona Studies: Minimum Information about Nanomaterial Biocorona Experiments (MINBE)’ (2019) 28 *Nano Today* 100758:1–12 <<https://doi.org/10.1016/j.nantod.2019.06.004>>.

62 Ibid.

63 Ropers et al (n 5) 4–5, citing EFSA Panel on Food Additives and Nutrient Sources Added to Food, ‘Re-evaluation of Titanium Dioxide (E 171) as a Food Additive’ (2016) 14(9) *European Food Safety Authority Journal* 4545:1–83 <<https://doi.org/10.2903/j.efsa.2016.4545>>.

64 Roger Drew and Tarah Hagen, *Potential Health Risks Associated with Nanotechnologies in Existing Food Additives* (Report, May 2016) 6.

65 Ibid.

66 Robert Falkner and Nico Jaspers, ‘Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap’ (2012) 12(1) *Global Environmental Politics* 30, 35 <https://doi.org/10.1162/GLEP_a_00096>; Christopher Bosso, ‘Settling into the Midstream? Lessons for Governance from the Decade of Nanotechnology’ (2016) 18(6) *Journal of Nanoparticle Research* 163:1–15, 2, 6, 8 <<https://doi.org/10.1007/s11051-016-3451-9>>; Koen Beumer, ‘Travelling Risks: How Did Nanotechnology Become a Risk in India and South Africa?’ (2018) 21(11) *Journal of Risk Research* 1362 <<https://doi.org/10.1080/13669877.2017.1304978>>.

III AUSTRALIA'S REGULATORY APPROACH TO NANOTECHNOLOGY

Given Australia's strong nano-economy – a result of neoliberal attitudes and policies introduced in the early 2000s – the response of Australian regulators as they try to manage what might develop into a crisis of confidence in nanotechnology is keenly awaited by stakeholders: a shift in regulatory approach toward the technology will have significant social and economic implications. Further, Australian regulators have a demonstrated history of following the regulatory lead of international counterparts, and of operating in a legal environment which, at the very least, considers the precautionary principle among other concerns to address issues of scientific uncertainty.⁶⁷ In particular, the potential introduction of more cautionary risk management strategies following the EFSA Opinion and EU ban on titanium dioxide as a food additive by the nation's food regulator, FSANZ, is of widespread interest. To assess and predict such regulatory responses, we first consider the Australian regulatory complex as it relates to nanotechnology as a whole.

In Australia, based on end-product use, five key federal agencies share the responsibility of regulating the introduction and use of products or substances at the nanoscale or containing nano-objects (see Figure 2 below). By and large, these regulators use existing regulatory nets, initially developed without consideration toward nanotechnology, to capture and address any issues as they arise.⁶⁸

In 2006, the Australian Government commissioned independent analysis into the capability of the nation's regulatory infrastructure to assess and manage nanotechnology. Despite concluding that there were no immediate concerns relating to the suitability of Australia's regulatory frameworks to manage nanotechnologies, the review highlighted areas of concern.⁶⁹ While sounding cautionary notes, in view of the scientific evidence then available, the authors recommended iterative changes to regulatory frameworks to catch nanotechnology concerns as they evolved.⁷⁰ Five years after the initial review, its impact was assessed by two of the report's original authors, who found that all of the regulatory schemes responsible for end products had responded to the regulatory gaps identified in some form, adopting incremental changes to their legislative instruments or frameworks.⁷¹

67 Polya (n 3) ii, 2.

68 The Australian Industrial Chemicals Introduction Scheme introduced new legislation in 2019 – the *Industrial Chemicals Act 2019* (Cth) – which included categorisation guidance specific for chemicals at the nanoscale: 'Categorisation of Chemicals at the Nanoscale', *Department of Health and Aged Care (Cth)* (Web Page, 19 September 2022) <<https://www.industrialchemicals.gov.au/help-and-guides/extra-resources-help-you-categorise-your-introduction/categorisation-chemicals-nanoscale>>.

69 Ludlow, Bowman and Hodge (n 37).

70 Ibid.

71 Diana M Bowman and Karinne Ludlow, 'Assessing the Impact of a "For Government" Review on the Nanotechnology Regulatory Landscape' (2012) 38(3) *Monash University Law Review* 168, 209.

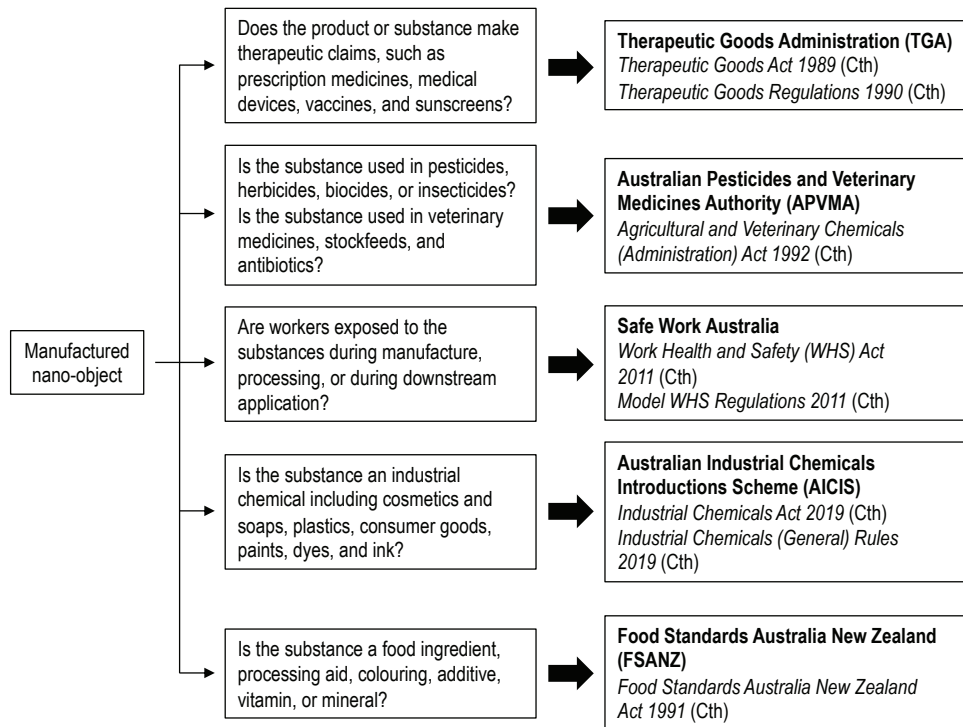


Figure 2: Five key federal agencies share the responsibility of regulating the introduction and use of nano-objects in Australia

Almost 20 years on from the original review of Australia's regulatory landscape, and in light of new evidence and an evolved understanding of nano-safety research, we revisit the analysis and consider how Australia's current regulatory framework manages nanotechnology risks. With significant international regulatory development occurring in the nano-food space, we further consider the regulatory response and regulatory framework employed by FSANZ with concern as to how both industry and consumer interests alike are being managed.

A Introduction to FSANZ

In Australia, substances used as food additives and in food packaging (both those that are domestically manufactured and those that are imported) fall under the jurisdiction of the *Food Standards Australia New Zealand Act 1991 (Cth)* ('*FSANZ Act*'), enacted by Federal Department of Health Portfolio agency, FSANZ. FSANZ primarily acts as an independent standard-developing body, with standards collated in the Australia New Zealand Food Standards Code ('*Code*').⁷² With only approved

⁷² Food Standards Australia New Zealand, 'Australia New Zealand Food Standards Code' (Code) ('*Food Standards Code*').

substances listed in the Code allowed onto the Australian market, the processes by which FSANZ interprets and amends the Code warrant critical review. Since 2007, FSANZ has received significant scrutiny from the public, media and both the state and federal governments – a large portion of which questions the agency’s ability to manage the risks associated with nanotechnology as it finds its way across the food market.

Both foods created using nanotechnologies and foods containing nano-objects are well documented to have spread across global food markets due to their ability to meet consumer demands in developed economies – extending shelf lives and enhancing packaging, taste, texture and aesthetics⁷³ – and to ensure food security in developing economies.⁷⁴ Such vast benefits and promise have allowed governments around the world to maintain a degree of regulatory permissiveness toward nanotechnology applications as they make their way into the food sector. Despite being subject to intense regulatory debate, the laissez-faire policies and regulatory frameworks responsible for managing the issue have ultimately progressed little over the past 10 years.⁷⁵ Overwhelmingly, existing regulatory frameworks and risk management strategies, rather than new, tailor-made legislative treatments are applied to substances at the nanoscale, leaving little room for the unique properties and biological interactions of nano-objects to be taken into consideration – a scenario that can lead to such objects being un- or under-regulated.

In the following sections, we consider FSANZ’s regulatory tools and assess the suitability of their current application to nano-objects given recent developments in nano-safety research. Further, we compare these applications to those in evidence at an international regulatory level, in terms of both supranational cooperative frameworks, and overseas jurisdictions.

B Primary Policy Approaches to Nanotechnology: An International Lens

When considering Australia’s approach to nanotechnology policy development, we consider this primarily within a transatlantic context due to the history Australian regulators have of following the lead of international counterparts.⁷⁶ While both the EU and the US have engaged in integrative risk management strategies that incrementally adjust existing legislative frameworks to manage the rise of nanotechnology and its applications, divergence in policy processes and stringency have been observed between the two regulatory powerhouses.⁷⁷ Ronit Justo-Hanani and Tamar Dayan argue that such ‘transatlantic divergence’ is

73 SM Alfadul and AA Elneshty, ‘Use of Nanotechnology in Food Processing, Packaging and Safety Review’ (2010) 10(6) *African Journal of Food, Agriculture, Nutrition and Development* 2719, 2726 <<https://doi.org/10.4314/ajfand.v10i6.58068>>.

74 Mansi Mishra et al, ‘Prospects, Challenges and Need for Regulation of Nanotechnology with Special Reference to India’ (2019) 171 *Ecotoxicology and Environmental Safety* 677 <<https://doi.org/10.1016/j.ecoenv.2018.12.085>>.

75 Falkner and Jaspers (n 66) 54; Bosso (n 66).

76 Answers to Supplementary Budget Estimates Questions SQ15-000778 (n 14).

77 Ronit Justo-Hanani and Tamar Dayan, ‘Explaining Transatlantic Policy Divergence: The Role of Domestic Politics and Policy Styles in Nanotechnology Risk Regulation’ (2016) 16(1) *Global Environmental Politics* 79 <http://dx.doi.org/10.1162/GLEP_a_00337>.

enabled not simply by ‘differing public attitudes, economic interests, and advocacy pressure groups’,⁷⁸ but by the ‘policy preferences of influential policymakers and parties’ at a domestic level.⁷⁹

The EU’s more proactive policy approach has allowed cautionary risk management strategies related to nanotechnology, such as product bans and labelling mandates, to be embedded into the legislative framework in an iterative process. One of the most recent examples of this is a suite of annexes introduced in 2020 through the EU’s *Registration, Evaluation, Authorisation and Restriction of Chemicals* (‘REACH’) regulation.⁸⁰ Supporting the 2020 amendments are the EU’s definitions of ‘nanomaterial’ (2011/696/EU)⁸¹ and ‘engineered nanomaterial’ (2015/2283/EU),⁸² which provide the most substantial work to date done to incorporate regulatory definitions of nano-related terms into primary policy, and thereby corporate activity.

These amended requirements reflect a cautionary risk management approach, legislating for manufacturers and importers to hold adequate data to allow for sufficient EHS assessment and subsequent risk management. To be compliant with the updated laws, manufacturers and importers must assess new substances and reassess existing substances, then (re)register the nanoforms with *REACH* according to the new requirements. This re-registration is an important aspect of data collection and stewardship, allowing information on the types and scale of nanoforms on the market to be managed by regulators.

The EU is known to exert unilateral influence across a number of areas of global regulatory policy – a phenomenon known as the ‘Brussels Effect’.⁸³ While the EU has established itself as *the* global regulator of the chemicals industry, consistently implementing stringent and precautionary regulation that responds directly to elevated public concern toward the adverse effects of unsafe chemicals, when it comes to the regulation of nanotechnologies and nano-objects, leading jurisdictions such as the US are yet to follow its lead.⁸⁴ While the EU introduced its first regulatory definition of a nanomaterial in 2009,⁸⁵ Australia and New Zealand only introduced regulatory definitions in 2019 and 2017 respectively.⁸⁶ While the US and Canada are yet to introduce regulatory definitions, Canada introduced a working definition

78 Ibid 79.

79 Ibid 92.

80 *Commission Regulation (EU) 2020/878 of 18 June 2020 Amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)* [2020] OJ L 203/28.

81 *Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial* [2011] OJ L 275/38, 3 [2].

82 *Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods* [2015] OJ L 327/1, art 3(f).

83 Anu Bradford, ‘The Brussels Effect’ (2012) 107(1) *Northwestern University Law Review* 1.

84 Ibid 15.

85 *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products* [2009] OJ L 342/59 (‘EU Regulation No 1223/2009’).

86 See *Industrial Chemicals Act 2019* (Cth); Environmental Protection Authority (NZ), ‘Cosmetic Products Group Standard 2017’ (Standard No HSR002552, December 2017) (‘Cosmetic Products Group Standard’).

in 2011, which represents an effort toward international harmonisation.⁸⁷ The EU first legislated labelling requirements for cosmetics containing nanomaterials in 2009,⁸⁸ later following suit for foods in 2011 and biocides in 2012.⁸⁹ Despite these early regulatory efforts, only one other jurisdiction has followed suit in this area: New Zealand introduced labelling requirements for cosmetics containing nanomaterials in 2017.⁹⁰ Attempts toward the global harmonisation of introduction to market pathways are yet to crystallise, with only Australia's industrial chemicals regulator and New Zealand's Environmental Protection Authority following the EU's lead and legislating nano-specific introduction requirements at this stage.⁹¹

C Regulatory Gaps in the Domestic Approach to Nanotechnology Management

When considering the policymaking and risk management strategies introduced in Australia by FSANZ, we argue that, in general, the cautionary, adaptive changes observed in the EU over the past decade have not translated into regulatory trends observed at a domestic level. No major legislative reform in relation to nanotechnology has occurred, with existing legislative structures designed for more general chemicals management still relied upon to manage the technology and its novel applications. In particular, the precautionary principle – in either name or theory – has not been employed by FSANZ to manage the uncertainties that nanotechnology brings to the food sector, in spite of its previous use in similar circumstances by the Australian Government in the early 2000s in response to biotechnologies, with positive results.⁹² Below we identify significant governance gaps in FSANZ's regulatory framework in relation to nanotechnology, that may present physical, legal, reputational and economic risks to stakeholders should they be left unaddressed (see Figure 3 below).

87 Health Canada, 'Policy Statement on Health Canada's Working Definition for Nanomaterial' (Policy Statement, Government of Canada, 26 May 2011) <<https://www.canada.ca/en/health-canada/services/science-research/reports-publications/nanomaterial/policy-statement-health-canada-working-definition.html>>.

88 *EU Regulation No 1223/2009* (n 85).

89 *Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, Amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and Repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004* [2011] OJ L 304/18 ('EU Regulation No 1169/2011'); *Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 Concerning the Making Available on the Market and Use of Biocidal Products* [2012] OJ L 167/1 ('EU Regulation No 528/2012').

90 'Cosmetic Products Group Standard' (n 86).

91 *Industrial Chemicals (General) Rules 2019* (Cth); *ibid.*

92 *Polya* (n 3) ii, 2.

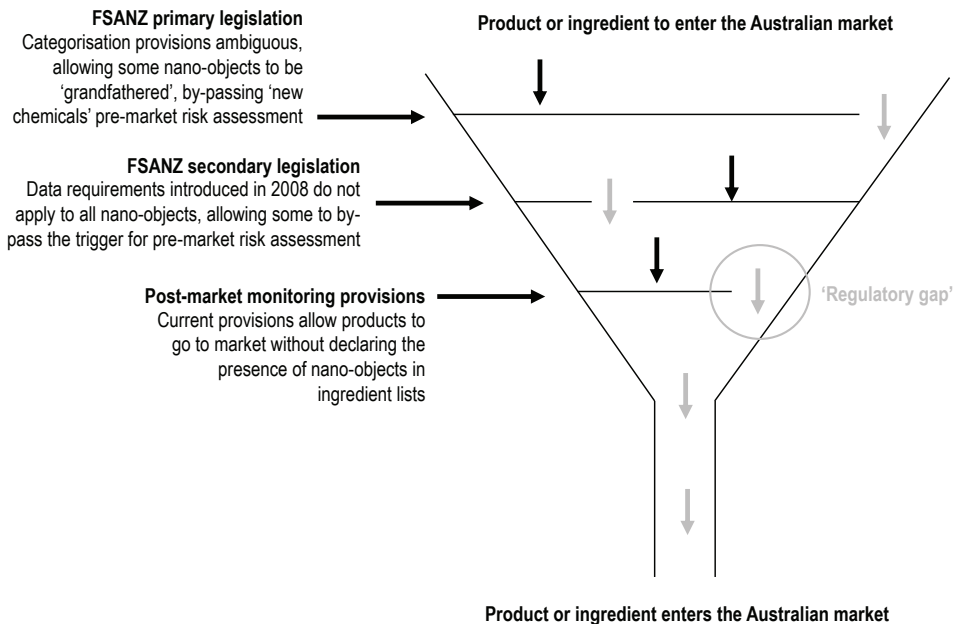


Figure 3: Gaps can occur within a regulatory framework that ‘funnels’ products to market

The *FSANZ Act* does not contain any specific provision for nanotechnology and does not include any regulatory definitions for nano-related terms.⁹³ Further, no standards in the Code specifically cater toward foods produced using nanotechnologies or containing nano-objects.⁹⁴ Despite not fostering an adaptive regulatory capacity similar to that seen in the EU where recent regulatory amendments have provided for nanotechnology, FSANZ has claimed that its existing regulatory approach is sufficient to address the uncertainty and risks nanotechnology poses. In 2011 Senate estimate hearings, FSANZ founded such claims on the effectiveness of its regulatory framework to capture and assess products before they go to market:

[FSANZ undertakes] a comprehensive risk assessment of products regardless of whether they contain nanomaterials or use ingredients derived through nanotechnology. Therefore, products on the market in Australia have been assessed by the relevant regulator as not presenting health risks.⁹⁵

Despite this justification being made 12 years ago, no significant adjustments to the FSANZ regulatory framework have been made to address developing scientific understandings of the EHS impacts of nano-objects. Considering this,

93 *Food Standards Australia New Zealand Act 1991* (Cth) (*‘FSANZ Act’*).

94 *‘Food Standards Code’* (n 72).

95 Department of Health and Ageing, Answers to Questions on Notice to Senate Community Affairs Committee, Parliament of Australia, *Budget Estimates 2011–12* (Answers to Questions on Notice No E11-003, 20, 31 May 2011) <https://www.aph.gov.au/~media/Committees/clac_ctte/estimates/bud_1112/DoHA/003.pdf>.

our analysis finds FSANZ's outdated approach wanting in the face of growing scientific consensus concerning the EHS impacts of particular nano-objects, further representing a divergence from the adaptive policymaking observed in the EU. More specifically, our analysis highlights regulatory gaps in the *FSANZ Act*, which in effect negate any claims that all products on the market have been assessed and therefore do not present health risks.

Regulatory gaps in the *FSANZ Act* can be observed in the Act's categorisation provisions, which directly affect regulatory treatment. These regulatory gaps allow a mechanism for producers and manufacturers to put substances at the nanoscale onto the Australian market without new risk assessments that would consider their novel properties and biological effects. When categorising substances seeking market approval, the *FSANZ Act* provides pathways for 'novel foods' which require pre-market risk assessment to establish their safety before they are added to the food supply.⁹⁶ While in some cases there is little to no ambiguity in the categorisation of a nano-object as 'novel', ambiguity remains for some nano-objects which may have been manufactured or incidentally produced from a bulk (non-nanoscale) substance.

For example, the bulk substance titanium dioxide (E171) is an approved food additive which has been used on the market for over 60 years and is thus not considered 'novel'. Bulk titanium dioxide is known to contain up to 50% of constituent particles at the nanoscale.⁹⁷ However, there is no unanimous guidance in Australia as to whether such nano-objects, unique in their physical and chemical properties, should be categorised as 'novel', and thus whether their regulatory treatment should differ from that provided to their non-nanoscale bulk counterpart. This ambiguity remains despite a New South Wales ('NSW') Inquiry into nanotechnology finding that the most frequent concern expressed about the current regulatory frameworks for nanotechnology in Australia (including FSANZ) was that 'nano versions of existing chemicals are not automatically assessed as new chemicals'.⁹⁸ The Inquiry subsequently recommended that 'nano-versions of existing chemicals [be] assessed as new chemicals',⁹⁹ providing the following reasoning:

[T]he position that nano versions of existing chemicals should be assessed as new chemicals is supported by a number of Inquiry participants. The basic underlying argument is hard to rebuff: chemicals are assessed and regulated accordingly in order to address their inherent characteristics and risks – *if a nano version of a chemical has different characteristics and presents different risks then it should be assessed and regulated according to its specific risks*.¹⁰⁰

96 'Food Standards Code' (n 73) standard 1.5.1.

97 Robert Reed et al, *Detecting Engineered Nanomaterials in Processed Foods from Australia* (Final Report, 18 August 2015).

98 Legislative Council Standing Committee on State Development, Parliament of New South Wales, *Nanotechnology in New South Wales* (Report No 33, 29 October 2008) 30 [3.61] ('*Nanotechnology in NSW*').

99 Ibid xxi, 48 [3.164].

100 Ibid 58 [3.210] (emphasis added).

Despite the NSW Inquiry's recommendation, such categorisation guidelines have not been introduced into Australian legislation.¹⁰¹ Workarounds to implementing this policy change have been in review by FSANZ for over a decade – Proposal P1024,¹⁰² which has been in review since 2012, contains a proposal to allow some 'low risk' novel foods (including nanoscale materials) to be either introduced without pre-market assessment or introduced following industry self-assessment based on their solubility properties and related effects.¹⁰³ More recently, the EFSA released guidance which offers technical advice on how to establish the presence of incidentally produced nanomaterials in food and feed products based on solubility (among other factors),¹⁰⁴ which may come to inform the approach taken domestically by FSANZ.

The present absence of regulatory definitions which distinguish between incidentally produced and manufactured nano-objects in the *FSANZ Act* allows for inconsistency in the application of the 'novel foods' definition, and thus ambiguity in the regulatory treatment encountered by many nano-objects, allowing them to effectively slip through the regulatory net.¹⁰⁵ The implication of this is that the strict regulatory treatment afforded to 'novel foods', including pre-market risk assessment, may not always apply for some nano-objects, allowing them to go to market without a new assessment that takes into consideration their novel risk profiles. This issue is not unique to nano-objects – referred to as 'grandfathering', this treatment of legacy chemicals is a well-documented practice within the chemicals management field.¹⁰⁶

Formally, a 'grandfather clause' is defined as 'an exemption from, or relaxation of, regulatory requirements, allowing actors to continue an activity following an institutional change that either legally prohibits or regulates the activity for others'.¹⁰⁷ Analysis of the US Environmental Protection Agency's ('EPA') *Toxic Substances Control Act of 1976* ('TSCA')¹⁰⁸ provides one of the most well-documented instances of 'grandfathering' in chemicals management – 62,000 industrial chemicals which were already in commercial use when the *TSCA* was enacted were 'grandfathered' into the scheme without further consideration toward

101 New South Wales Government, 'NSW Government Response to the Legislative Council Standing Committee on State Development Inquiry into Nanotechnology in NSW' (Response, 29 April 2009).

102 Food Standards Australia New Zealand, *Administrative Assessment Report: Proposal P1024* (Report, 17 December 2012).

103 Food Standards Australia New Zealand, 'Assessment of Risks and Safety Data Requirements for New Foods: Proposal P1024' (Supporting Document No 2, 4 December 2015) 2.

104 More et al, 'Guidance on Technical Requirements for Regulated Food and Feed Product Applications to Establish the Presence of Small Particles Including Nanoparticles' (2021) 19(8) *European Food Standards Authority Journal* 6769:1–48 <<https://doi.org/10.2903/j.efsa.2021.6769>>.

105 'Food Standards Code' (n 72) standard 1.5.1.

106 Melissa Lee Phillips, 'Obstructing Authority: Does the EPA Have the Power to Ensure Commercial Chemicals Are Safe?' (2006) 114(12) *Environmental Health Perspectives* 706 <<https://doi.org/10.1289/ehp.114-a706>>; Harvey Black, 'GAO Sounds Off on Chemical Regulation' (2005) 113(12) *Environmental Health Perspectives* 828 <<https://doi.org/10.1289/ehp.113-a828>>; Maria Damon et al, 'Grandfathering: Environmental Uses and Impacts' (2019) 13(1) *Review of Environmental Economics and Policy* 23 <<https://doi.org/10.1093/reep/rey017>>.

107 Damon et al (n 106) 25.

108 15 USC §§ 2601–97 (2022).

their EHS impacts. Notwithstanding the incremental amendments introduced by the US EPA to collect information on some of these existing chemicals, at large, these chemicals remain on the market today, in effect unregulated and assumed to be safe, despite their EHS risk profiles not being fully known or understood.¹⁰⁹ International counterparts have faced similar, though smaller scale, issues. In Australia, the Australian Industrial Chemicals Introduction Scheme ('AICIS') (formerly the National Industrial Chemicals Notification and Assessment Scheme) 'grandfathered' 38,000 industrial chemicals into their scheme, and in Canada, 23,000 substances were 'grandfathered' into the New Substances Notification Program.¹¹⁰

Where legacy chemicals are in use and a 'grandfathering' policy treatment is in place, existing chemicals are assumed to be safe. Such an assumption has been widely criticised as an oversight that puts consumers at unnecessary risk, particularly where EHS research has developed over time to reveal serious health impacts of what, at one point or another, have been considered 'safe' legacy chemicals, for example, asbestos.¹¹¹ Indeed, inherent problems have been identified with 'a history of use' being made equivalent to 'a history of *safe* use' in a regulatory setting – particularly in cases where the commercialisation of novel products or technologies has rapidly outpaced research into their EHS implications.¹¹² FSANZ, who continue to employ the practice, have used the 'history of safe use' justification multiple times regarding titanium dioxide, which has been used as a food additive on the Australian market of over 60 years:

[T]here are some manufactured foods, including food additives, with a history of safe use that contain nanoscale particles, for example silica dioxide (used to avoid caking of powdered food) and food grade titanium dioxide (used to enhance the whiteness of some foods, eg, chewing gum). Therefore FSANZ would not agree that a recall 'of all products containing nanomaterials' would be a logical or practical course of action.¹¹³

-
- 109 Environmental Protection Agency (US), 'Health and Safety Data Reporting: Addition of 20 High-Priority Substances and 30 Organohalogen Flame Retardants' (Final Rule, 29 July 2021) <<https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0474-0001>>.
- 110 Department of Health and Aged Care (Cth), 'Options for Reforming the National Industrial Chemicals Notification and Assessment Scheme' (Regulation Impact Statement, November 2014) 93; Government of Canada, *Follow-Up Report to the House of Commons Standing Committee on Environment and Sustainable Development on the Canadian Environmental Protection Act, 1999* (Report, 29 June 2018) 7.
- 111 Phillips (n 106) 708; Ariana M Chiapella et al, 'Toxic Chemical Governance Failure in the United States: Key Lessons and Paths Forward' (2019) 69(8) *BioScience* 615 <<https://doi.org/10.1093/biosci/biz065>>; Norah MacKendrick, *Better Safe than Sorry: How Consumers Navigate Exposure to Everyday Toxics* (University of California Press, 2018) <<https://doi.org/10.1525/california/9780520296688.001.0001>>.
- 112 A Constable et al, 'History of Safe Use as Applied to the Safety Assessment of Novel Foods and Foods Derived from Genetically Modified Organisms' (2007) 45(12) *Food and Chemical Toxicology* 2513 <<https://doi.org/10.1016/j.fct.2007.05.028>>; Karl-Heinz Engel et al, 'The Role of the Concept of "History of Safe Use" in the Safety Assessment of Novel Foods and Novel Food Ingredients' (2011) 55(6) *Molecular Nutrition and Food Research* 957 <<https://doi.org/10.1002/mnfr.201100206>>.
- 113 'Media Coverage about Nanotechnology in Food and Food Additives', *Food Standards Australia New Zealand* (Web Page, May 2021) <<https://www.foodstandards.gov.au/consumer/foodtech/nanotech/Pages/Sydney-Morning-Herald-nanotechnology-response.aspx>> ('Nanotechnology Media Coverage'). See, eg, Answers to Supplementary Budget Estimates Questions SQ15-000778 (n 14); Food Safety Australia and New Zealand, Answers to Questions on Notice to Senate Community Affairs Committee,

FSANZ employing the ‘history of safe use’ justification in relation to titanium dioxide six years ago in the statement above sits in stark contrast to the current and emerging scientific evidence which indicates that nano-objects have cellular and systemic effects including immunotoxicity, inflammation and potential genotoxicity.¹¹⁴ Further, such remarks can be considered outdated in light of the recent developments in the EU concerning the same food additive, where it is no longer considered safe for use as a food additive.¹¹⁵

These developments illustrate the flaws inherent in ‘grandfathering’: over time, as science progresses, new EHS impacts can come to light for substances which may already be in wide commercial circulation. This demonstrates how important an adaptable, cautionary regulatory framework which can ‘assess, adjust, and foster adaptive regulatory capacities’ in light of novel challenges is to ensure adequate protection is provided for consumers where safety information about substances and technologies changes over time.¹¹⁶ Given that the *FSANZ Act* does not contain any specific provisions or standards for nanotechnology, does not include any regulatory definitions for nano-related terms, and allows for ambiguity around the categorisation of nano-objects as ‘novel’, we argue that neither the primary legislation guiding FSANZ’s work, nor the Agency’s regulatory approach (discussed further below), is cautionary or adaptive and cannot, in its current form, be employed to sufficiently prioritise the EHS outcomes of nanotechnology and protect consumers from the potential risks associated with the technology.

D Secondary Policy Approaches to Nanotechnology at a Domestic Level

Despite evidence that nano-objects are present in foods available on the Australian market,¹¹⁷ FSANZ has defended its choice not to implement more cautionary risk assessment or management strategies for nanotechnology, based on an understanding that the substances which would warrant such regulatory attention are not available on the Australian market. FSANZ have maintained that they have ‘not received an application to amend the [Australia New Zealand] Food Standards Code in relation to a new or novel nanotechnology’.¹¹⁸ To assess the validity of such an assumption, we consider the process by which the Code, FSANZ’s secondary legislative instrument, is amended. Such analysis illustrates a second mechanism through which substances at the nanoscale can enter the

Parliament of Australia, *Budget Estimates 2014–15* (Answers to Questions on Notice No SQ14-000577, 2/3 June 2014) <https://www.aph.gov.au/~media/Committees/clac_ctte/estimates/bud_1415/DoH/answers/SQ14-000577.pdf>; Food Safety Australia and New Zealand, Answers to Questions on Notice to Senate Community Affairs Committee, Parliament of Australia, *Budget Estimates 2017–18* (Answers to Questions on Notice No SQ17-000731, 29–30 May 2017) <https://www.aph.gov.au/~media/Committees/clac_ctte/estimates/bud_1718/Health/Answers/SQ17000731.pdf>.

114 Younes et al (n 5) 4, 5, 30, 45.

115 Ibid 5, 75.

116 Justo-Hanani and Dayan (n 77) 93.

117 Reed et al (n 97).

118 ‘Nanotechnology and Food’, *Food Standards Australia New Zealand* (Web Page, September 2022) <<https://www.foodstandards.gov.au/consumer/foodtech/nanotech/Pages/default.aspx>> (‘Nanotechnology Media Coverage’).

Australian market without undergoing new risk assessment (see Figure 3 above) – an oversight posing social and corporate risks which could otherwise be mitigated by more adaptive and cautionary policy approaches.

For a food product to be made available on the Australian market, it must only contain ingredients listed as approved substances in one of the standards in the Code. To introduce new ingredients into the Australian market, an application to introduce a new standard, which constitutes an application to vary the Code, must be made. When applying to vary the Code, available data on the new ingredient must be submitted to FSANZ, which will form the basis of its risk assessment. The *FSANZ Act* provides that FSANZ may make guidelines specifying the data requirements for such applications.¹¹⁹ The Act also provides that applicants comply with the Authority's guideline requirements,¹²⁰ and allows an application that does not meet the guideline requirements to be rejected.¹²¹ The regulatory instrument implemented by FSANZ to meet this provision is the *Application Handbook* ('*Handbook*'). The *Handbook* contains the information requirements for applications under each Standard of the Code, all of which have different requirements.¹²² As such, regulatory decision making is made on a case-by-case basis considering the weight of evidence presented.¹²³

To provide context for FSANZ's regulatory approach, it is important to understand how it has developed over time. Acknowledging that the nanotechnology boom had created a need for regulators to begin capturing the information required to 'identify and discriminate between particulate substances', in December 2008 FSANZ introduced an amendment to the *Handbook* which saw new data requirements pertaining to size and shape come into effect.¹²⁴ Under these requirements, information including particle size, size distribution, morphology and any size-dependent properties were required to be disclosed if they were known.¹²⁵ These amendments applied to food additives, processing aids, novel foods, nutritive substances and contaminants.

Since its introduction, these amendments have been regarded by FSANZ as a sufficient regulatory trigger for the pre-market risk assessment of nano-objects. In 2014 Senate Estimates, FSANZ stated that the new requirements 'provide appropriate information for FSANZ to conduct a robust risk assessment

119 *FSANZ Act* (n 93) s 23.

120 *Ibid* s 22(2).

121 *Ibid* s 26(2)(a).

122 Food Standards Australia New Zealand, *Application Handbook* (Handbook, 1 July 2019).

123 Food Safety Australia and New Zealand, Answers to Questions on Notice to Senate Community Affairs Committee, Parliament of Australia, *Budget Estimates 2017–18* (Answers to Questions on Notice No SQ17-000754, 29–30 May 2017) <https://www.aph.gov.au/~media/Committees/clac_ctte/estimates/bud_1718/Health/Answers/SQ17000754.pdf>.

124 Australian Government, 'Amendments to Food Standards Australia New Zealand Application Guidelines, Amendment No 2' (Explanatory Statement, December 2008) 2 ('Explanatory Statement of 2008 Amendments to FSANZ Application Guidelines'). Schedule Amendments included items [1.2], [2.2], [3.2], [5.2]; items [1.1], [2.1], [3.1], [5.1]; and item [4.1].

125 'Nanotechnology and Food' (n 118).

on food substances that may be manufactured using novel nanotechnologies',¹²⁶ and described the amendment as a 'conservative risk management approach ... considered sufficient to assess the safety of new or novel nanoscale materials'.¹²⁷ Standardised characterisation of the physicochemical properties of nano-objects remains a crucial, yet challenging, element of risk assessment, with international effort continuing to advance the area so as to provide the most accurate risk characterisation and prediction of nano-objects possible.¹²⁸ FSANZ have acknowledged that the collection of size and shape data of particulates is critical for risk assessment, stating that '[t]he precise identification of particulate substances may be a critical future element in assigning substance specific permissions in the Code and in ensuring the feasibility of compliance and enforcement monitoring or testing'.¹²⁹

However, while the amendments may carry out this purpose for 'novel foods', the amendments were not retrospective, and so do not pertain to foods already on the market. This allows 'grandfathered' substances, which may be nanoscale and/or novel, to be exempt from (re)submitting size and shape data, and thus to be exempt from (re)assessment for risk based on this new data. As such, the 2008 FSANZ *Handbook* amendments are not in and of themselves sufficient to allow for appropriate information collection, and thus robust risk assessment, of nano-objects in foods. They, in fact, provide a second mechanism for substances at the nanoscale to enter the Australian market without pre-market risk assessment. We thus conclude that FSANZ's secondary legislative tool, the *Handbook*, is not sufficiently cautionary or adaptive to protect consumers from the potential risks associated with nano-objects.

E Post-market Monitoring Provisions within the Regulatory Approach

As we have previously argued, the driving of nano-enabled or nanoscale products straight to market without proportionate investment in nanotechnology-focused risk assessment frameworks has left regulators on the back foot when it comes to managing the potential risks associated with the technology's applications.

-
- 126 Food Safety Australia and New Zealand, Answers to Questions on Notice to Senate Community Affairs Committee, Parliament of Australia, *Supplementary Budget Estimates 2014–15* (Answers to Questions on Notice No SQ14-001305, 22 October 2014) <https://www.afp.gov.au/~media/Committees/clac_ctte/estimates/sup_1415/DoH/answers/SQ14-001305.pdf>.
 - 127 Food Safety Australia and New Zealand, Answers to Questions on Notice to Senate Community Affairs Committee, Parliament of Australia, *Supplementary Budget Estimates 2014–15* (Answers to Questions on Notice No SQ14-001329, 22 October 2014) <https://www.afp.gov.au/~media/Committees/clac_ctte/estimates/sup_1415/DoH/answers/SQ14-001329.pdf>.
 - 128 European Food Safety Authority Scientific Committee, 'Guidance on Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain: Part 1' (2018) 16(7) *European Food Safety Authority Journal* e05327:1–95 <<https://doi.org/10.2903/j.efsa.2018.5327>>; Ozge Kose et al, 'Impact of the Physicochemical Features of TiO₂ Nanoparticles on Their In Vitro Toxicity' (2020) 33(9) *Chemical Research in Toxicology* 2324 <<https://doi.org/10.1021/acs.chemrestox.0c00106>>; Alejandro Déciga-Alcaraz et al, 'Toxicity of Engineered Nanomaterials with Different Physicochemical Properties and the Role of Protein Corona on Cellular Uptake and Intrinsic ROS Production' (2020) 442 *Toxicology* 152545:1–16 <<https://doi.org/10.1016/j.tox.2020.152545>>.
 - 129 'Explanatory Statement of 2008 Amendments to FSANZ Application Guidelines' (n 124) 2.

For Australian regulators to successfully manage what might develop into a crisis of confidence in nanotechnology, they must be enabled and emboldened to employ a holistic regulatory approach which considers both pre- and post-marketing risk management strategies. While previous sections have discussed where flaws in the current pre-market strategies exist, this section examines the opportunities that post-market strategies present for a more balanced and cautionary approach.

Post-market monitoring efforts such as audits and surveys allow governments and regulators to continuously monitor and evaluate the safety (and often efficacy) of products on the market, and efficiently recognise and manage any emergent risks in a timely manner. Such efforts are enabled by cautionary risk management strategies which may include the introduction of product labelling and the implementation of a national product registry. Such strategies are particularly valuable in cases where there are high levels of uncertainty as they provide for high levels of transparency and flexible and pre-emptive emergency management, both of which work to build and maintain the public's trust in the regulatory system, which Hodge, Bowman, and Maynard describe as paramount to enabling socially responsive decision-making.¹³⁰

The application of cautionary risk management strategies such as product labelling to nano-enabled products has been controversial. While the primary objective behind the employment of such regulatory tools is to provide consumers with access to information to enable informed decision-making,¹³¹ there remains concern that labelling (in particular, labelling without suitable consumer awareness and education campaigns) could be misinterpreted as a safety statement or warning, which would be unnecessarily damaging for the nano-brand.¹³² When considering nano-specific labelling for consumer products, there are options to introduce labelling that is 'positive', which indicates the presence of nano-objects, and that which is 'negative', which indicates the absence of nano-objects.¹³³ Such labelling can either be adopted voluntarily or mandated. To assist both industry and legislators with the introduction of nano-specific labelling, the ISO published technical guidance on voluntary labelling for consumer products containing manufactured nano-objects under 'Nanotechnologies: Guidance on Voluntary Labelling for Consumer Products Containing Manufactured Nano-objects'.¹³⁴ This guidance applies only to intentionally produced nano-objects, rather than those that are naturally occurring or incidentally present, and specifies that the presence of

130 Graeme A Hodge, Diana M Bowman and Andrew D Maynard (eds), *International Handbook on Regulating Nanotechnologies* (Edward Elgar, 2010) 583 <<https://doi.org/10.4337/9781849808125>>.

131 Karin Aschberger et al, *Considerations on Information Needs for Nanomaterials in Consumer Products* (Policy Report, April 2014) 27; Frans Møller Christensen, *Comparative Analysis of Nano-Registries in EU/EEA Member States* (Report, 15 December 2017).

132 Joel D'Silva and Diana Megan Bowman, 'To Label or Not to Label? It's More than a Nano-sized Question' (2010) 1(4) *European Journal of Risk Regulation* 420, 422 <<https://doi.org/10.1017/S1867299X00000891>>.

133 Ibid.

134 International Organization for Standardization, 'Nanotechnologies: Guidance on Voluntary Labelling for Consumer Products Containing Manufactured Nano-objects' (Technical Standards, ISO/TS 13830:2013, December 2013) ('Guidance on Voluntary Labelling').

manufactured nano-objects in consumer products should preferably be disclosed as part of the ingredient list on a label with the inclusion of the term ‘nano’ or ‘nanoscale’. The guidance also provides the option to place the phrase ‘contains manufactured nano-objects’ on the label.¹³⁵

Despite being recommended in the Dakar Statement on Manufactured Nanomaterials,¹³⁶ at an international level, the first jurisdiction to legislate the labelling of nano-enabled consumer products is the EU. The first legal instrument stipulating labelling requirements was introduced in the EU through *Regulation No 1223/2009 – Cosmetic Products*.¹³⁷ Through this Directive, cosmetic products containing intentionally manufactured nanomaterials have had to be labelled since July 2013. Further, a directive pertaining specifically toward foods entered into force in 2014. This Directive, *EU Regulation No 1169/2011 – Food Information to Consumers*, stipulates that all ingredients present in the form of intentionally manufactured nanomaterials must be clearly indicated in the list of ingredients, and that ‘[t]he names of such ingredients shall be followed by the word “nano” in brackets’.¹³⁸ Only the EU’s 2012 *Regulation No 528/2012 – Biocidal Products* regulates for the labelling of nanomaterials that may be naturally occurring or incidentally present, as well as those which are intentionally produced.¹³⁹

In contrast to the cautionary approach taken by policymakers in the EU, the US Food and Drug Administration has recommended against the introduction of labelling requirements for nano-objects,¹⁴⁰ and in Australia, there are no laws which mandate an explicit declaration of the presence of nano-objects at an ingredient level in foods and other consumer products. FSANZ has not used its powers under section 16 of the *FSANZ Act* to introduce labelling laws that would see the presence of nano-objects declared in the ingredient lists of foods on the Australian market. This is despite receiving express recommendations to do so from community stakeholders,¹⁴¹ a 2011 Council of Australian Governments report,¹⁴² and a 2008 NSW Standing Committee report into nanotechnology in NSW:

The Committee supports the view that consumers should be advised of the presence of nanomaterials in food products, particularly until more knowledge is gained on the risks that may be associated with them. The Committee recommends that an amendment should be sought to the national *Food Standard Code* to require labels to identify the presence of materials at the nanoscale.¹⁴³

135 Ibid.

136 ‘Producers to provide appropriate information about the content of manufactured nanomaterials in order to inform consumers about potential risks through product labeling and, as appropriate, websites and databases.’: World Health Organization, Intergovernmental Forum on Chemical Safety, *Forum VI Final Report*, 6th sess, IFCS/FORUM-VI/07w (15–19 September 2008) 10.

137 *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products* [2009] OJ L 342/59.

138 *EU Regulation No 1169/2011* (n 89) art 18(3).

139 *EU Regulation No 528/2012* (n 89).

140 United States Food and Drug Administration (US), *Nanotechnology Task Force Report* (Report, 25 July 2007) 35.

141 Georgia Miller and Rye Senjen, *Out of the Laboratory and on to Our Plates: Nanotechnology in Food and Agriculture* (Report, April 2008).

142 Neal Blewett et al, *Labelling Logic: Review of Food Labelling Law and Policy* (Report, 27 January 2011).

143 *Nanotechnology in NSW* (n 98) xv, 74 [3.296].

The 2008 NSW Standing Committee report applied not only to FSANZ, but to the other key federal regulators, with similar disclosure recommendations from the committee directed toward the Therapeutic Goods Administration ('TGA'), which regulates prescription medicines, medical devices, and cosmeceuticals: 'The Committee believes that there is a strong case for labelling requirements for sunscreens and cosmetics to indicate the presence of materials at the nanoscale.'¹⁴⁴

This recommendation has not been taken up, with the TGA later specifying that while all active ingredients (including those at the nanoscale) within the scope of their authority are required to be declared on ingredient labels, declaration of particle size (or use of the explicit phrase 'nano') is not required. The TGA has justified its decision to not explicitly declare particle size information on labels due to concern that such disclosure would falsely indicate to the public that such objects are unsafe, stating on their website as late as April 2023 that '[t]here is no evidence suggesting that nanoparticles in sunscreen are unsafe'.¹⁴⁵ Such a statement reinforces the need for investment in nano-safety research and highlights the central role it plays in the development of cautionary risk management strategies and policies.

Within the current regulatory landscape in Australia, where no nano-specific labelling provisions are enforced across a range of consumer products (from sunscreens to foods), consumers wishing to make an informed decision regarding nano-objects in the products they are purchasing must interpret an ingredients list, which often only contains chemical names. They must then do their own research on each ingredient individually to see if any are a product of nanotechnology or contain a percentage of particles at the nanoscale. To reach any meaningful conclusion from this process, the consumer relies on

- (a) such information being available (the physicochemical characterisation having been done on that particular ingredient, which may not always be the case) and
- (b) such information, if available at all, being freely available online for the general public to access.

This process currently places a large burden on consumers, should they wish to make informed purchasing choices regarding nano-objects in their products.

Labelling that discloses the presence of nano-objects on the market is not only important to enable a consumer's 'right to know', but also serves a crucial regulatory purpose in that it provides a mechanism for industry to engage in more efficient and effective post-market monitoring activities such as audits or surveys, as they are forced to have a more complete understanding of what ingredients are in their products. When such information is able to be reported back to regulators, this in turn allows regulators to better assess the number of products on the market with certain ingredients, which provides crucial information on the scale of an issue should concerns be raised. To date, FSANZ has not surveyed Australian food importers

¹⁴⁴ Ibid xv, 77 [3.311].

¹⁴⁵ Therapeutic Goods Administration, 'About Sunscreens', *Department of Health and Aged Care (Cth)* (Web Page, 28 July 2021) <<https://www.tga.gov.au/community-qa/sunscreens-information-consumers>>.

and manufacturers to determine if they import or produce any foods containing nanomaterials, leaving the scale of the issue in Australia largely unknown.¹⁴⁶

The 2008 NSW Standing Committee report acknowledged how vital such an awareness is within a regulatory context, stating that ‘the lack of industry and economic information on nanotechnology is an important issue for New South Wales, as it is for Australia and the international community’.¹⁴⁷ As we have demonstrated, activities such as labelling play an integral part in the more cautionary regulatory approaches emerging in the EU that allow regulators to be adaptive and flexible as they respond to novel risk management challenges. Such an approach gives insight into how Australian regulators could integrate more cautionary policies into their frameworks to increase transparency and ease the significant burden currently on consumers.

F The Risks Posed by an Insufficient Regulatory Framework

The EU’s recent, decisive action to ban titanium dioxide as a food additive provides what we argue is a ‘wake-up call’ for governments which have prioritised the commercial development of the nanotechnology industry without proportionate attention to nano-safety. The regulatory gaps present in both FSANZ’s primary and secondary legislation – which see both pre- and post-market strategies lagging behind the developments made by international counterparts – is particularly concerning given the emerging scientific evidence, which contradicts the conclusions of safety FSANZ have drawn from commissioned toxicological reports,¹⁴⁸ and suggests immunotoxicity, inflammation and potential genotoxicity to be some of the emerging effects on human health following exposure to nano-objects.¹⁴⁹ Such mounting evidence raises serious concerns regarding the regulatory approach towards nano-objects in Australia and makes it difficult to justify FSANZ’s assumptions that no novel nano-objects are in foods in Australia. This in turn makes it difficult to justify its decision not to implement more cautionary risk assessment or management strategies related to nanotechnology. Such shortcomings increase the likelihood of consumers being exposed to potentially harmful nano-objects without their knowledge, and thus increase the legal, economic and reputational risks posed to the industry stakeholders ultimately responsible for putting the products to market.

146 Food Safety Australia and New Zealand, Answers to Questions on Notice to Senate Community Affairs Committee, Parliament of Australia, *Additional Estimates 2013–14* (Answers to Questions on Notice No SQ14-000080, 26 February 2014) <https://www.afp.gov.au/~media/Committees/clac_ctte/estimates/add_1314/Health/Answers/SQ14-000080.pdf>.

147 *Nanotechnology in NSW* (n 98) 77 [3.313].

148 Roger Drew and Tarah Hagen, *Nanotechnologies in Food Packaging: An Exploratory Appraisal of Safety and Regulation* (Report, May 2016); Food Safety Australia and New Zealand, Answers to Questions on Notice to Senate Community Affairs Committee, Parliament of Australia, *Supplementary Budget Estimates 2016–17* (Answers to Questions on Notice No SQ16-000561, 19 October 2016) <https://www.afp.gov.au/~media/Committees/clac_ctte/estimates/sup_1617/Health/Answers/SQ16-000561.pdf>.

149 Younes et al (n 5).

Should serious harm to human health and the environment eventuate, how much damage will be sustained by the USD42.2 billion global nanotechnology industry?¹⁵⁰ What impact would these outcomes and continued un- and under-regulation have on the technology and its prospects? From a reputational perspective, the rise and fall (at least in terms of public perception) of biotechnologies in the late 1990s and early 2000s provides an analogous case where premature governance structures that did not properly take EHS outcomes into consideration, and the failure of governments to engage and educate the public early on, ultimately presented an impediment to the growth of the industry. In the words of one commentator, this saw the emerging technology go from ‘wow’, to ‘yuck’, to ‘nearly bankrupt’.¹⁵¹

The laissez-faire approach to emerging technologies and its consequences from a legal perspective should also be noted. While no product liability cases regarding damage from nano-objects appear to have been launched, insurance companies have begun to prepare and respond to the uncertainties and risks posed by the nanotechnology industry.¹⁵² A 2015 cursory analysis by Mark Raffman and Andrew Kim¹⁵³ did not foresee a “‘mass torts’ explosion” in relation to nanotechnology and product liability cases occurring.¹⁵⁴ However, this conclusion was based on the premise that nanotechnologies on the market did not ‘appear to be particularly worrisome’¹⁵⁵ – an assumption that emerging scientific consensus is debasing given recent advances in nano-safety research. Should latent health risks manifest after exposure to nano-objects, and causation then be sufficiently established,¹⁵⁶ nanotechnology companies may face claims raised under ‘traditional tort law, consumer law, fraud, contract [or] medical negligence’¹⁵⁷ for damages and deceptive trade practices, depending on the product or service delivering the particular nano-object causing damage.¹⁵⁸ Further, it is unlikely that time in court and media attention in such a negative context would have any positive implications for the nanotechnology industry as a whole and its perception in the eyes of the general public. The 2022 case(s) brought by industry to the EU’s General Court regarding

150 ‘Global Nanotechnology Market Media Release’ (n 1).

151 Kristen Kulinowski, ‘Nanotechnology: From “Wow” to “Yuck”?’ (2004) 24(1) *Bulletin of Science, Technology and Society* 13, 17 <<https://doi.org/10.1177/0270467604263112>>.

152 Mark Popovsky, ‘Nanotechnology and Environmental Insurance’ (2011) 36(1) *Columbia Journal of Environmental Law* 125; Hodge, Bowman and Maynard (n 130).

153 Mark Raffman and Andrew Kim, ‘Could Nanotechnology Face Mass Torts?’, *Industry Week* (online, 7 April 2015) <<https://www.industryweek.com/technology-and-iiot/emerging-technologies/article/21964922/could-nanotechnology-face-mass-torts>>.

154 Thomas A Hemphill, ‘Regulating Nanomaterials: A Case for Hybrid Governance’ (2016) 36(4) *Bulletin of Science, Technology and Society* 219, 222 <<https://doi.org/10.1177/0270467617719820>>, citing *ibid*.

155 Raffman and Kim (n 153).

156 Katharine A Van Tassel and Rose H Goldman, ‘The Growing Consumer Exposure to Nanotechnology in Everyday Products: Regulating Innovative Technologies in Light of Lessons from the Past’ (2011) 44(2) *Connecticut Law Review* 481.

157 Shane McNamee, ‘The Regulatory and Liability Implications of Nanoscale Drug Delivery in the Human Body’ (2014) 11(1) *Nanotechnology Law and Business* 48, 63.

158 Lynn L Bergeson, ‘Emerging Nanomaterial Governance Systems: The State of Play’ (2011) 10(1) *Molecular Imaging* 17, 18 <<https://doi.org/10.2310/7290.2010.00052>>; Edward R Gladly Jr, Gregorio M Garcia and Blair H Moses, ‘Nanotechnology Liability: Do We Steer or Just Go Along for the Ride?’ (2012) 52(3) *Jurimetrics* 313.

the classification of titanium dioxide as a potential carcinogen are a prime example of the lengths industry groups are willing to go to maintain their commerciality in the face of mounting scientific evidence.¹⁵⁹

Further to claims for damages made by a consumer against a nanotechnology company (or manufacturer of nano-objects), damages claims can also, of course, be made by a company against a regulator that acts against its interests (ie, where a precautionary approach demands a product recall, ban or suspension of a certain manufacturers licence). Domestically, there is precedent for civil litigation and class action tort litigation against the Commonwealth to recover compensation for the losses incurred as a result of regulatory action. In 2011, an eight-year long class action was settled between therapeutics manufacturer Pan Pharmaceuticals and the Federal Government, with \$67.5 million in compensation awarded to a group of 162 creditors, distributors and retailers, all of whom suffered loss and damage when the company was forced into liquidation following the TGA's 2003 decision to suspend the manufacturer's licence and recall 1,600 products after reports emerged of adverse reactions and hospitalisations from one of its products.¹⁶⁰ The 2011 settlement followed a \$55 million pay-out awarded to the Pan Pharmaceuticals founder a few years earlier, where the civil litigation case claimed the TGA had 'breached its duty of care and engaged in misfeasance in public office', bringing the total settlement amount for the case to \$122.5 million.¹⁶¹ While both settlements were made without admissions of wrongdoing by the Government, the landmark decisions have been criticised as reinforcing a perception that the TGA, as a federal regulator, 'owe[s] a higher duty of care to pharmaceutical companies and their stakeholders than to the consumers of therapeutic products or the Australian public at large'.¹⁶²

The legal risks posed to, and by, the nanotechnology industry and its many stakeholders reinforces the need for protective and proportionate measures to minimise harm. For the nanotechnology industry, such measures may include contractual protection, warranties, indemnification agreements, complaint tracking, labelling or disclosure strategies.¹⁶³ For regulators, such measures may include the implementation of the precautionary principle in risk management, risk assessment, and risk communication strategies.¹⁶⁴ In the following Part, we discuss how such strategies could manifest domestically in a holistic regulatory approach

159 *CWS Powder Coatings* (n 11).

160 Esme Shirlow and Thomas Faunce, 'Recent Legal Developments and the Authority of the Australian Therapeutic Goods Administration' (2009) 16(5) *Journal of Law and Medicine* 764; Louise Hall, 'Pan Debacle Yields Further \$67.5m Payout', *The Sydney Morning Herald* (online, 26 March 2011) <<https://www.smh.com.au/business/pan-debacle-yields-further-67-5m-payout-20110325-1c9vo.html>>; Bronwyn Herbert, 'Govt Settles Pan Lawsuit for \$67.5m', *ABC News* (online, 25 March 2011) <https://www.abc.net.au/news/2011-03-25/govt-settles-pan-lawsuit-for-675m/2643904?utm_campaign=abc_news_web&utm_content=link&utm_medium=content_shared&utm_source=abc_news_web>.

161 Shirlow and Faunce (n 160) 765.

162 Ibid 767.

163 Bergeson (n 158) 18; Van Tassel and Goldman (n 156).

164 Shirlow and Faunce (n 160) 767.

that more effectively manages the perfect storm posed by an emerging technology and a regulatory system that was not designed to tame it.

IV RECOMMENDATIONS FOR A PURPOSE-BUILT REGULATORY APPROACH FOR THE AUSTRALIAN NANO-ECONOMY

In the wake of the meteoric (and largely unchecked) rise of nanotechnology over the past 30 years, there is justified concern regarding the lack of investment in nano-safety research (Part I) and the suitability of current regulatory risk governance frameworks, particularly at a domestic level, to manage the technology's iterations, applications and potential risks (Part II). Further, we have outlined the various litigation risks that this current status quo poses to stakeholders, particularly those in the nanotechnology industry who may be deemed ultimately responsible for the public's exposure to nano-objects through consumer products including foods (Part III).

Acknowledging this complex interplay of forces, we seek to find a way forward. With applications continuing to influence consumer product developments – ranging from homewares and electronics to personal care and foods – and the industry contributing to the Gross Domestic Product of developed economies around the world, nanotechnology looks set to remain an important (and perhaps ever-increasing) part of modern life. It is thus crucial for regulatory solutions for the responsible governance of the technology to continue to evolve (as the technology itself does) in a way that mitigates or minimises risk (real or perceived) and maintains the general interests of all stakeholders.

Equipped with an understanding that modern governments regulate through more than just rules and legislation, we present a number of basic requirements which, based on our analysis, we believe should be made available within Australia's regulatory framework for nanotechnology if the industry is to mitigate risk and realise its full potential.¹⁶⁵ Consistent with Arie Freiberg's approach to regulation,¹⁶⁶ we seek to move beyond a binary understanding which distinguishes between 'regulation' and 'deregulation' with a process of 'regulatory reconfiguration' which balances traditional 'command and control' mechanisms with other 'softer touch' tools.¹⁶⁷

165 Christopher C Hood, *Tools of Government* (Macmillan Press, 1983) 8, 9.

166 Arie Freiberg, 'Re-stocking the Regulatory Tool-Kit' (Working Paper No 15, Jerusalem Forum on Regulation & Governance, June 2010) 1.

167 Ibid 4.

‘Command and control’ mechanisms have been referred to in the regulatory models of Baldwin, Cave and Lodge,¹⁶⁸ Gunningham and Grabosky,¹⁶⁹ Stewart,¹⁷⁰ and Morgan and Yeung,¹⁷¹ and in general, refer to the direct regulation of an industry or activity (permission, prohibition, standard setting and enforcement) as opposed to the implementation of financial incentives (taxes and subsidies) to incentivise compliance.¹⁷² The dominant regulatory approach observed in industrialised nations over the past few decades, ‘command and control’ mechanisms have been noted as being remedial and reactionary in nature, rather than being preventative,¹⁷³ which makes the approach not necessarily well suited for application to the regulation of nanotechnology where more adaptive, iterative and cautionary regulatory measures are needed to manage the risk, uncertainty and other novel challenges of the technology.

Despite this, ‘command and control’ policies have begun to be employed in European states to manage the risks associated with nano-objects, particularly regarding titanium dioxide as a food additive. In April 2019, the French Government signed a decree stopping sales of foodstuffs containing titanium dioxide as a food additive for one year, which entered into effect on 1 January 2020 and was eventually extended for another year (to 31 December 2022).¹⁷⁴ The French suspension was eventually superseded by an EU-wide ban on the use of titanium dioxide as a food additive, which was approved by European Commission State members in October 2021. Pursuant to *Commission Regulation (EU) 2022/63*, enacted in February 2022, titanium dioxide (E171) was removed from Annexes II and III of *REACH Regulation (EC) No 1333/2008*, meaning it is no longer allowed for use in commerce as a food additive.¹⁷⁵

In the past, FSANZ has dismissed suggestions to implement a recall of products containing nanomaterials due to their ‘history of safe use’;¹⁷⁶ however, in light of

168 Robert Baldwin, Martin Cave and Martin Lodge, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press, 2nd ed, 2012) 107 <<https://doi.org/10.1093/acprof:osobl/9780199576081.001.0001>>.

169 Neil Gunningham and Peter N Grabosky, *Smart Regulation: Designing Environmental Policy* (Clarendon Press, 1998) 38–50.

170 Richard Stewart, ‘Regulations and the Crisis of Legalisation in the United States’ in Terence Daintith (ed), *Law as an Instrument of Economic Policy: Comparative and Critical Approaches* (Walter de Gruyter, 1988) 114, 124.

171 Bronwen Morgan and Karen Yeung, *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press, 2007) ch 3 <<https://doi.org/10.1017/CBO9780511801112>>.

172 Organisation for Economic Co-operation and Development, ‘Command-and-Control Policy’, *OECD Glossary of Statistical Terms* (Glossary, 2 November 2001) <<https://stats.oecd.org/glossary/detail.asp?ID=383>>.

173 Michael Böcher, ‘A Theoretical Framework for Explaining the Choice of Instruments in Environmental Policy’ (2012) 16 *Forest Policy and Economics* 14 <<https://doi.org/10.1016/j.forpol.2011.03.012>>.

174 *Arrêté n° 0310 du 21 Décembre 2020 Portant Suspension de la Mise sur le Marché des Denrées Contenant L’additif E 171 (Dioxyde de Titane – TiO2)* [Order of 21 December 2020 Suspending the Marketing of Foodstuffs Containing the Additive E 171 (Titanium Dioxide – TiO2)] (France) JO, 23 December 2020.

175 *Commission Regulation (EU) 2022/63* (n 6).

176 ‘Nanotechnology Media Coverage’ (n 113).

the 2021 EFSA Opinion on E171,¹⁷⁷ and the 2022 EU ban,¹⁷⁸ domestic regulators have faced timely decisions about whether or not to follow the lead of the more proactive and cautionary EU. While currently a cornerstone to the modern regulatory complex, ‘command and control’ measures such as product or ingredient bans cannot be the whole picture. Our analysis of the EU’s adaptive and cautionary approach to nanotechnology demonstrates a unique modelling of Frieberg’s thesis that regulation involves more than just rules and legislation: ‘softer touch’ tools, such as labelling, have been successfully implemented, contributing to an environment more conducive, receptive and adaptable to the implementation of cautionary policies.¹⁷⁹ This modelling provides insight into how Australian regulators can begin to implement such principles into their own policy frameworks.

A Post-market Activities Proposed for Domestic Implementation

Regulatory mechanisms which combine hard and soft law approaches should be utilised in Australia to meet the unique demands of the nanotechnology industry and adequately address consumer demands for greater levels of disclosure, monitoring, transparency and traceability. We argue that in the Australian context, labelling requirements and public education campaigns for nano-objects in consumer products are a suitable first step. They should be made available to manage the potential risks posed by nanotechnology and initiate a transition toward more cautionary ‘command and control’ policies should these be deemed necessary in future, based on the scientific evidence emerging around nanotoxicology.

Joel D’Silva and Diana Bowman argue that ‘government paralysis in relation to the labelling question is not a sensible long-term approach to effectively regulate nanotechnologies’.¹⁸⁰ In agreement with this sentiment, and in line with ISO Standard 13830:2013,¹⁸¹ we recommend labelling that is ‘positive’ in that it indicates the presence of nano-objects through inclusion of the term ‘nano’ or ‘nanoscale’ as part of the ingredient list on the label. To avoid what D’Silva and Bowman refer to as a ‘market driven approach’¹⁸² which sees ‘significant divergence in labelling practices between industry players and product sectors’,¹⁸³ we make our recommendation applicable to all consumer products, including foods, in an effort to harmonise labelling practices and maintain consumer confidence.

As previously mentioned, there remains concern that labelling without suitable consumer awareness and education campaigns could be misinterpreted as a safety

177 Younes et al (n 5).

178 *Commission Regulation (EU) 2022/63* (n 6).

179 Sophie Boutillier, Sophie Fourmentin and Blandine Laperche, ‘Food Additives and the Future of Health: An Analysis of the Ongoing Controversy on Titanium Dioxide’ (2020) 122 *Futures* 102598:1–14 <<https://doi.org/10.1016/j.futures.2020.102598>> (‘Food Additives and the Future of Health’); Sophie Boutillier, Sophie Fourmentin and Blandine Laperche, ‘History of Titanium Dioxide Regulation as a Food Additive: A Review’ (2021) 20(2) *Environmental Chemistry Letters* 1017 <<https://doi.org/10.1007/s10311-021-01360-2>>.

180 D’Silva and Bowman (n 132) 427.

181 ‘Guidance on Voluntary Labelling’ (n 134).

182 D’Silva and Bowman (n 132) 427.

183 *Ibid.*

statement or warning, which would be unnecessarily damaging for the nano-brand. As such, our recommendation for labelling is tied closely to a recommendation for coordinated public education and engagement activities which can allow for increased awareness among the general public about nanotechnology, its benefits, risks, surrounding social and ethical issues, and the risk management frameworks in place to regulate the technology. Our initial analysis of historic public engagement and awareness activities implemented both domestically and at an international level reveal commonalities that are readily applicable in a modern-day Australian context. In the US, public workshops, forums and education programs such as museum exhibitions have been utilised as part of the National Nanotechnology Initiative's ('NNI') commitment to educating the public on the current state of nanotechnology development.¹⁸⁴ In Germany, the 'nanoTruck' campaign – a mobile exhibition of nanotechnology products, lectures and panel discussions – ran from 2004 to 2006, engaging 78,000 visitors in its first 10 months alone.¹⁸⁵ Further, Bowman and Hodge reveal grant schemes, scoping studies, surveys, public consultation and debates as other activities which can be undertaken by governments to engage the public in nanotechnology decision-making.¹⁸⁶

Domestically, under the NNS and the AON, a \$1.3 million Public Awareness and Engagement Program ran from 2007 to 2009 aiming to 'raise awareness and develop knowledge of the opportunities and potential of nanotechnology and to encourage an informed debate based on balanced and factual information'.¹⁸⁷ Under this scheme, activities such as surveys, public forums, websites, educational materials, factsheets, and community engagement and outreach events were carried out.¹⁸⁸ In adopting a modern approach to consumer education and awareness, we recommend resuscitating some of the AON's former activity, and combining this with approaches that have proven successful overseas, to bring the campaign to life in a new decade in ways that can have a wider reach and longer-term impact.

As an initial recommendation, we suggest an Australian 'nanoTruck' campaign, similar to that seen in Germany, which could offer public workshops, educational materials and consultation opportunities.¹⁸⁹ As part of our recommendation, we also suggest coupling this 'on the ground' approach with strategic social media education campaigns, which can vastly increase reach. Under the NNS, audience sizes for public engagement activities ranged from 12–100 participants,¹⁹⁰ while with targeted online advertising, audience sizes ranging from thousands to millions of viewers can easily be reached, depending on the budget and engagement rates. Finally, in making our recommendations, we emphasise that any awareness activities undertaken by government should involve, and allow active participation in the decision-making process by, a wide range of stakeholders, including the

184 Bowman and Hodge, 'Nanotechnology and Public Interest Dialogue' (n 15) 122.

185 Ibid 124.

186 Ibid.

187 *NNS Annual Report 07–08* (n 36) 37; *NNS Annual Report 08–09* (n 36) 20.

188 Ibid.

189 Bowman and Hodge, 'Nanotechnology and Public Interest Dialogue' (n 15) 124.

190 *NNS Annual Report 07–08* (n 36) 38.

public service sector, industry, academia, the media, non-government organisations, schools and universities, and the general public.

Our recommendations to engage and empower a wide group of stakeholders through labelling and education activities serve to manage and mitigate the risks posed by nanotechnology applications and safeguard Australia's nano-economy, ensuring commensurate, cautionary measures are in place to protect consumers and industry interests alike. As the Australian Government has formerly acknowledged, risk communication and risk perception among consumers are innately tied to the social and economic implications of nanotechnology.¹⁹¹ In allowing for a proactive, rather than reactive, regulatory approach, our recommended measures aim to create and maintain public trust in the governance of this powerful ever-emerging new-world technology, which Ragnar Löfstedt suggests will prevent the need to fight the retrospective 'fires' that can so easily damage public trust and 'derail' new technological applications.¹⁹²

B Proposal to Reinstate a Domestic Oversight Body for Nanotechnology

We suggest that an autonomous, regulatory science body concerned solely with nanotechnology, its applications and EHS outcomes – similar in structure and authority to ANSES,¹⁹³ and the European Union Observatory for Nanomaterials¹⁹⁴ – would be useful to implement in Australia to address the currently unmet risk management needs of the nanotechnology industry. Given the cost-recovery financial models of Australia's current regulators, the introduction of an autonomous, entirely government-funded body to the regulatory landscape would allow for a transition away from regulatory structures that see decision-making bodies entwined with the very industry stakeholders they are seeking to regulate.¹⁹⁵ France and the EU have led what has been described as the 'transition from a period when expertise was embedded in the structures of administrative and political power, to a new era, that of regulatory agencies affirming competence, transparency and independence as the key words of expertise'.¹⁹⁶ If strategically designed, the establishment of such a body to oversee Australia's nanotechnology regulatory framework could allow for the amalgamation of expertise from civil society ('lay-members', linked to experience), professional scientists (academics), and government – an effective 'democratization of expertise' where 'nobody has a monopoly of resources'.¹⁹⁷

191 Sear, Petersen and Bowman (n 32) 6.

192 Ragnar E Löfstedt, *Risk Management in Post-trust Societies* (Palgrave Macmillan, 2005) 12.

193 'Our Identity', ANSES (Web Page, 12 April 2022) <<https://www.anses.fr/en/content/our-identity>>.

194 European Chemicals Agency, 'About Us', *European Union Observatory for Nanomaterials* (Web Page, 2022) <<https://euon.echa.europa.eu/about-us>>.

195 'Charging for Regulatory Activities (Cost Recovery)', *Department of Finance (Cth)* (Web Page, 16 June 2022) <<https://www.finance.gov.au/government/managing-commonwealth-resources/managing-money-property/managing-money/australian-government-charging-framework/charging-regulatory-activities-cost-recovery>>.

196 Boutillier, Fourmentin and Laperche, 'Food Additives and the Future of Health' (n 179) 5.

197 Ibid.

An autonomous, regulatory science body which includes a range of stakeholders in the setting of the nation's regulatory agenda toward nanotechnology could reprioritise EHS outcomes, and specifically influence the investment directed towards nano-safety research. Indeed, as we have noted above, there is precedent for the Australian Government to establish a new body to manage the uncertainties of a new technology. In 2000, the *Gene Technology Act 2000* (Cth) established the Office of the Gene Technology Regulator,¹⁹⁸ and the Australian Office of Nanotechnology operated for two years from 2007 to 2009, advising government on policy, coordinating an EHS working group and overseeing public awareness campaigns. We therefore recommend that to suitably manage the risks posed by nanotechnology at a domestic level, the Australian Government should (re)establish an autonomous, regulatory science body – similar in scope to the Australian Office of Nanotechnology – which advises across the five currently siloed federal regulatory agencies.

Such an approach would see streamlined monitoring and policy development across federal regulators, and would allow for simplified national harmonisation (which would translate to simpler international translation). It would also reduce the duplication of effort that currently sees the five siloed regulators all independently monitoring the suitability of their legislative frameworks and keeping abreast of the emerging nano-safety research and international best practice in how to apply nano-specific risk assessment tools to substances and products within their scope. Under such arrangements, if more cautionary policy adaptations were implemented, such as the introduction of labelling directives mandating disclosure of nano-objects in the ingredients list of products, then such directives would be applicable to all regulatory jurisdictions (TGA, AICIS, FSANZ, etc) within a defined, domestic scope. This would lead to domestic harmonisation, which would reduce trade barriers and make the process of implementing future amendments more streamlined, which in turn allows the framework to be more adaptive and responsive to risk, uncertainty and other novel challenges. This strategy ensures that there is a coordinated, national approach to nanotechnology regulation and that a consistent level of regulatory scrutiny is applied across industries. Further, it provides a streamlined, harmonised risk mitigation and minimisation process for risk managers to follow, which in turn could potentially fast-track entry to market processes for the nanotechnology industry in a way that does not compromise on EHS outcomes.

C A Proposed Holistic Regulatory Approach in Australia

Finally, it is imperative to recognise that the challenges nanotechnology poses to regulatory risk assessment and risk management are not unique to one regulator alone and, as such, regulatory guidance needs to extend across regulatory spheres to have a meaningful impact. While fixing the flaws in the system of one regulator (ie, FSANZ) is perhaps achievable in some cases, it will not address the challenges

¹⁹⁸ *Gene Technology Act 2000* (Cth) pt 3.

that the entire regulatory complex faces, and will never be able to *eliminate* risk entirely due to the many uncertainties that remain (and that perhaps may be ever-present). Despite this, we argue that avenues to *reduce* risk in the system at large are possible and should be seriously considered (or in some cases, reconsidered) by legislators holding responsibility regarding health and environmental safety outcomes. We suggest that any such (continually evolving) regulatory solution should be holistic in the sense that it should be applicable to the legislation and regulation of nanotechnology applications and nano-objects regardless of their end use – ie, it should be applicable across industries (from the food sector to pharmaceuticals and electronics).

An autonomous, regulatory science body developing and delivering a holistic, cautionary and adaptive regulatory approach to nanotechnology will increase Australia's capability to build up and modernise the concepts and models used to 'understand, assess, characterise, communicate, and (in a wide sense) manage/govern risk'.¹⁹⁹ The body should have capacity via appropriate funding to put such theory into practice, using risk assessment and management to study and treat the risk of specific activities, such as the provision of nanoscale food additives on the Australian market. Such a strategy, with an EHS focus designed to be robust in the face of uncertainty, would provide the opportunity to recognise indicators of serious health or environmental concerns *before* they manifest in the general population and would allow for flexible and pre-emptive emergency management.

We argue that our recommendations provide for a national nanotechnology strategy that will suitably steward the Australian nano-economy through the 21st century. These recommendations ensure that:

- EHS outcomes (through nano-safety research) are prioritised;
- consumer demands for greater levels of disclosure and transparency are addressed;
- a platform for international standardisation/harmonisation and nano-safety data generation and (re)use is provided;
- regulators are enabled by a more independent model of financing; and
- mechanisms are in place which ensure that all nano-enabled or nanoscale objects (across industries) are subject to thorough and tailored pre-market risk assessment.

These recommendations address the growing concern regarding the lack of investment in nano-safety research discussed throughout the article, as well as the challenges facing associated risk management. Further, they address the regulatory gaps which we have demonstrated exist in both FSANZ's primary and secondary legislation, and reduce the various economic, reputational and litigation risks faced by industry stakeholders in light of high degrees of uncertainty. However, to enable the implementation of these recommendations, a significant increase

199 Terje Aven, 'Risk Assessment and Risk Management: Review of Recent Advances on Their Foundation' (2016) 253(1) *European Journal of Operational Research* 1, 1 <<https://doi.org/10.1016/j.ejor.2015.12.023>>.

in the government funding made available to nano-safety research and policy implementation is required.

D Funding Structures Required for a Holistic Regulatory Approach

We have noted above that the Australian Government has invested only 4% of its nanotechnology spend on EHS-related research and applications. While industry representatives have suggested this spending be increased by 10%,²⁰⁰ we suggest that an increase to at least 20% is required to more proportionately reprioritise EHS research and associated outcomes, given the historical failure to do so. As Neena Mitter and Karen Hussey have noted:

[I]f governments want their investments in science and technology to deliver economic, social and environmental benefits, then it is time regulators are provided with sufficient resources to enable them to generate the robust, agile and connected regulatory frameworks that new scientific frontiers demand.²⁰¹

Further to this recommendation, in an attempt to increase and maintain transparency and build public trust, we suggest that such budgetary breakdowns be made public in an annual report, similar to how the NNI reports their annual spending across nanotechnology applications, EHS research and other areas.

Our recommendation to increase government investment in nano-safety research allows for the priority funding of regulatory activities related to nanotechnologies, including the establishment and maintenance of an autonomous, regulatory science body for nanotechnology and the ability of that body to resource the introduction of labelling requirements, education and awareness campaigns, and grants schemes. While not traditionally considered within a regulatory approach, Bowman and Hodge suggest that government grants can stimulate and encourage activities, including research and development activities, particularly when paired with tax concessions.²⁰² Further, they argue that grants provide governments the opportunity to reprioritise EHS research within the nanotechnology industry, in that grant recipients are bound to a range of conditional ancillary requirements, which could specify EHS outcomes and/or risk management strategies.²⁰³ With appropriate investment, such a strategy could begin to reshape the priorities of the nanotechnology research and development landscape domestically.

V CONCLUSION

The aim of this article has been to analyse the nano-economy in Australia and assess the suitability of existing regulatory frameworks to manage the risks

200 Krupp and Holliday (n 40).

201 Neena Mitter and Karen Hussey, 'Moving Policy and Regulation Forward for Nanotechnology Applications in Agriculture' (2019) 14(6) *Nature Nanotechnology* 508, 509 <<https://doi.org/10.1038/s41565-019-0464-4>>.

202 Diana M Bowman and Graeme A Hodge, 'A Big Regulatory Tool-Box for a Small Technology' (2008) 2(2) *NanoEthics* 193, 201 <<https://doi.org/10.1007/s11569-008-0038-7>>.

203 Ibid 201.

associated with nanotechnology and its applications. In our analysis, we build upon the comprehensive analyses of the then regulatory landscape by Ludlow, Bowman, and Hodge in the early 2000s, contributing a contemporary perspective that considers the recent, decisive action taken by the EU against certain nano-objects which have been declared ‘unsafe’ after being in commerce for decades.²⁰⁴

In Part II, we demonstrated that the Australian Government initially viewed the nanotechnology industry through a lens of economic rationalism and that the industry was relying on the government to play a supportive and facilitative role to manage the risk perceptions of the public so as to not repeat the fate of biotechnologies. In Part III, we analysed the regulatory framework and regulatory response of food regulator, FSANZ, exposing regulatory gaps which put stakeholders at risk and missed opportunities to implement more cautionary regulatory approaches in line with the regulatory trends observed in the EU. In Part IV, seeking a path forward, we presented recommendations for a more holistic regulatory approach that addresses the concerns raised in Part III, allowing Australia to better align with its international regulatory counterparts. These recommendations centred around the (re)establishment of a dedicated and autonomous oversight body for nanotechnology, through which EHS research can be reprioritised (and appropriately funded), and a more cautionary regulatory strategy can play out given the ever-developing knowledge concerning nano-safety.

This work reveals that while several regulatory gaps for nanotechnology remain within the Australian regulatory landscape, opportunities to overcome these challenges are within the scope of government to implement. As the field of nano-safety research continues to develop, the suitability of current regulatory schemes will continue to be put to the test. It is thus imperative for the Australian Government to act now and re-evaluate its national approach to nanotechnology – an agenda that has not seen the light of day in over 10 years. Such action is crucial to maintain the nano-economy, realise the benefits of nanotechnology applications, and maintain the safety of consumers and the environment as applications continue to permeate their existence.

204 Ludlow, Bowman and Hodge (n 37).