ASSESSING THE IMPACT OF A 'FOR GOVERNMENT' REVIEW ON THE NANOTECHNOLOGY REGULATORY LANDSCAPE

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A number of jurisdictions have now completed reviews of the regulatory issues raised by nanotechnologies. Chronologically, these reviews have moved from treating nanotechnologies as a narrow matter of chemical regulation to a broader perspective that considers both the technology's impact on end-products such as foods and cosmetics as well as the end-of-life issues raised by such products. While the exact nature and focus of these reviews have varied, there is increasing specificity in their analysis and outcomes.

Australia was one of the first jurisdictions to initiate a wide-ranging and independent review of its regulatory frameworks to deal with the potential human and environmental health and safety risks posed by nanotechnologies. It has been five years since the report was handed to the Australian Government.[1] The aim of this article is to critically assess the impact of the regulatory review on the federal government's policy on nanotechnologies. In doing so, this article outlines regulatory developments that have occurred since the report's publication. Particular attention is given to examining the activities that have occurred within the regulatory agencies identified within the report. The broader policy and regulatory landscape for nanotechnologies in Australia is also considered.

This article is both timely and relevant due to current efforts by other jurisdictions to complete their own regulatory reviews. It articulates the impact of one regulatory review on policy developments within Australia, and discusses possible reasons for the domestic responses to that review.

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1 Karinne Ludlow, Diana Bowman and Graeme Hodge, 'A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework' (Final Report, Monash University, September 2007) ('Australian Review').

I INTRODUCTION

Nanotechnologies were always going to be big. Public and private sectors recognised the propensity of nanotechnologies during the very first phase of their emergence, as arguably best demonstrated by their investment in the technology.[2] The research community was similarly captured by the technologies' promise, which is evident due to the growing volume of literature across multiple disciplines and the rapid patenting of inventions.[3] In the midst of this early excitement, two US legal scholars — Fiedler and Reynolds — realised that the technology was going to simultaneously raise important legal, ethical, and social issues that policy-makers and safety regulators, as well as the broader community, would have to grapple with as the technology matured and entered the marketplace.[4] In their own words, the legal challenges nanotechnologies were likely to pose in the coming decades served as 'more of a wakeup call than a road map, and it raises far more questions than it answers'.[5]

The publication of the Royal Society and Royal Academy of Engineering ('RS-RAE') seminal report[6] was arguably the wakeup call to the challenges identified by Fiedler and Reynolds.[7] The territory covered in that report was vast: it spanned technical, industrial and risk management aspects of the technology, as well as human and environmental risk issues, and broader social, ethical and regulatory dimensions.

Importantly the RS-RAE's remit included, among other things, the identification of 'areas where additional regulation needs to be considered'.[8] Their review was not exhaustive as the authors focused on the regulatory frameworks that they considered the most challenging at the time in light of the evolving state of the scientific art. This included regulatory regimes that dealt with industrial chemicals, occupational health and safety, certain consumer products such as cosmetics, and therapeutic goods and product end-of-life. It is within this focus that the RS-RAE noted what they termed 'a regulatory gap'[9] in relation to how the industrial chemical regulatory framework would deal with existing chemicals re-engineered at the nanoscale. The review provided the first in-depth examination

2 Mihail C Roco, Chad A Mirkin and Mark C Hersam, 'Nanotechnology Research Directions for Societal Needs in 2020: Summary of International Study' (2011) 13(3) *Journal of Nanoparticle Research* 897; Philip Shapira and Jan Youtie, 'Introduction to the Symposium Issue: Nanotechnology Innovation and Policy — Current Strategies and Future Trajectories' (2011) 36(6) *The Journal of Technology Transfer* 581.

3 See, eg, Douglas J Sylvester and Diana M Bowman, 'Navigating the Patent Landscapes for Nanotechnology: English Gardens or Tangled Grounds?' in Sarah J Hurst (ed), *Biomedical Nanotechnology: Methods and Protocols* (Humana Press, 2011) 359.

4 Frederick A Fiedler and Glenn H Reynolds, 'Legal Problems of Nanotechnology: An Overview' (1994) 3(2) *Southern California Interdisciplinary Law Journal* 593.

5 Ibid 595.

6 Royal Society and Royal Academy of Engineering, 'Nanoscience and Nanotechnologies: Opportunities and Uncertainties' (Report, July 2004).

7 Fiedler and Reynolds, above n 4.

8 Royal Society and Royal Academy of Engineering, above n 6, vii.

9 Ibid 71.

of the effectiveness of specific UK and EU regulatory regimes when dealing with nanomaterials and nano-based consumer products, and the potential limits thereof.

Faced with these uncertainties and increasing scrutiny over the adequacy of existing regulatory arrangements — in terms of not only the statutory instruments, but also their operation — a number of governments have since initiated reviews of their own regulatory frameworks. Such governments include Australia,[10] the EU,[11] the UK,[12] the US,[13] and New Zealand.[14] Independent analysts and non-government and civil society groups have also undertaken reviews of various kinds. Chronologically, these reviews have evolved from treating nanotechnologies as a matter of chemical regulation to considering the implications of its incorporation into end products.

This paper focuses on the Australian Review,[15] of which we were two of the three authors, and its impact. It first outlines the background and findings of the Australian Review. It then reflects on the evolving policy and regulatory landscape for nanotechnologies in Australia to provide the context within which any policy or regulatory response to the Review has occurred. In Part V, the activities within the individual agencies identified in the Australian Review are considered. For each agency, we analyse legislative and operational changes, attempts to inform or engage the public and whether the potential gaps — or triggers that may fail to fire — identified in the Australian Review have been adequately responded to. Finally, we assess the impact of this one review on policy developments within Australia. Given the number of confounders since the Australian Review — including, for example, changes in the political landscape, the superseding of government strategies, major regulatory reforms initiated for reasons unrelated to nanotechnologies, and the evolving state of the scientific art — the making of definitive statements is impossible. But, putting this overarching caveat to one side, we argue that the explicit responses to the Review by Australian Government agencies such as the Australian Pesticides and Veterinary Medicines Authority ('APVMA') and the National Industrial Chemicals Notification and Assessment Scheme ('NICNAS') provide us with the ability to make more substantial

10 Ludlow, Bowman and Hodge, above n 1.

11 European Commission, 'Accompanying Document to the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee — Regulatory Aspects of Nanomaterials: Summary of Legislation in Relation to Health, Safety and Environment Aspects of Nanomaterials, Regulatory Research Needs and Related Measures' (Commission Staff Working Document No SEC (2008) 2036, 17 June 2008).

12 Health and Safety Executive, 'Review of the Adequacy of Current Regulatory Regimes to Secure Effective Regulation of Nanoparticles Created by Nanotechnology: The Regulations Covered by HSE' (Review, March 2006).

13 Nanotechnology Workgroup, Science Policy Council, 'Nanotechnology White Paper' (White Paper, United States Environmental Protection Agency, February 2007); United States Food and Drug Administration, 'Nanotechnology: A Report of the US Food and Drug Administration Nanotechnology Task Force' (Report, 25 July 2007).

14 Colin Gavaghan and Jennifer Moore, 'A Review of the Adequacy of New Zealand's Regulatory Systems to Manage the Possible Impacts of Manufactured Nanomaterials' (Final Report, University of Otago, January 2011).

15 Ludlow, Bowman and Hodge, above n 1.

conclusions regarding the Review's impact and to explore why that impact has been so significant.

II THE AUSTRALIAN REVIEW: BACKGROUND AND SCOPE

Initiated through the (then) federal Department of Industry, Tourism and Resources ('DITR'), the Australian Review[16] was one of the earlier independent reviews to be commissioned by a national government. The adoption of a 'whole-of-government' approach to nanotechnology appears to have influenced the Review's scope. Rather than adopt a narrow agency-by-agency approach, the Terms of Reference ('ToR') required an analysis of the adequacy of all relevant federal health and safety regulatory frameworks related to nanotechnologies, as well as an examination of the intellectual property ('IP') regimes. Specifically, the objectives set out in the Request for Tender document ('RFT') were:

> to advise the HSE [Health, Safety and Environment] Working Group on the ability of Australia's regulatory systems to handle risks associated with nanotechnology by:
>
> - identifying groups of nanotechnology-based products, materials and applications that are currently available or under development over the next 10 years;
> - assessing Australia's existing regulatory frameworks to determine if, and under what conditions, nanotechnology-based materials, products and applications, and their manufacture, use and handling, are covered by the existing regulatory frameworks; and
> - identifying where nanotechnology-based materials, products and applications may not be covered by any existing regulatory frameworks.
>
> The Consultant will analyse the gaps, if any, in Australia's existing regulatory frameworks to address nanotechnology, but will not make recommendations on addressing these gaps.[17]

For the successful consultants, this amounted to an analysis of 11 regulatory frameworks — including IP — and one state-based environmental regulatory framework. The dynamic nature of legislative frameworks meant that the analysis was undertaken on the law as it stood on 30 March 2007.

The final report was handed to the Australian Government's Health, Safety and Environment ('HSE') Working Group on nanotechnologies in June 2007 for their consideration. The report was

16 Ibid.

17 Department of Industry, Tourism and Resources, *Request for Tender — Requirement: Review of Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks* (2006) 22.

> the result of a regulatory terrain mapping and regulatory analysis exercise rather than a definitive study of the application of particular parts of the relevant regulatory frameworks or a comprehensive analysis of all federal regulatory regimes that could be impacted by nanotechnology.[18]

No official Government response was immediately forthcoming, nor was the report made public for some period.

III KEY FINDINGS OF THE AUSTRALIAN REVIEW

Arguably the key finding of the Australian Review is the one statement that did not appear anywhere in its text: 'there is no need to panic'. However, that is not to say that the regulatory arrangements were perfect and that no further action was required. Rather, the report identified six regulatory triggers that *may fail to fire* when having to deal with nanotechnologies. As noted in the Executive Summary:

> Whilst there is no immediate need for major changes to the regulatory regimes, there are many areas of our regulatory regimes which, potentially, will need amending, and this will be a long term effort across multiple regulators and regulatory agencies as nanoproducts arise and as new knowledge on hazards, exposure and monitoring tools becomes available.[19]

The Review considered each regulatory framework and its appropriateness to regulate nanotechnology in general and the defined nanofamilies in particular. The following five criteria were employed to do this:

1. Trigger and scope;
2. Requirement for regulatory approval;
3. Human safety assessment;
4. Environmental safety assessment; and
5. Post-market monitoring.

Criterion 1 analysed the general scope and triggering of each framework. The authors of the Australian Review found that the frameworks applied equally to conventional products and those containing nanomaterials. However, the authors argued that the implications of application were different. One such example of this difference was found in the failure of a framework to differentiate between conventional and nano-enabled products that had ramifications as to the appropriateness of the regulatory systems for nanotechnologies. This concept of appropriateness or effectiveness was considered in more detail by the employment of criteria 2–5.

A summary of the Review's findings, using the five criteria above as applicable at each life-cycle stage, are presented in Table 1 below.

18 Ludlow, Bowman and Hodge, above n 1, 8.

19 Ibid 4.

Table 1: Summary of Generally Applicable Repercussions of Application of Regulatory Frameworks

	Is regulatory approval required prior to regulated activity?	*Can human safety assessment be required?*	*Can environmental safety assessment be required?*	*Does framework provide for post-market monitoring?*
APVMA	✓	✓	✓	✓
AQIS	✓ (limited)	✓	✓	O
ASCC – HS	O	✓	O	✓
ASCC – DG	O[20]	✓	✓	✓
Customs	✓	O	O	O
DEW/EPA	✓	✓	✓	✓
DOTARS	O	✓	✓	O
FSANZ	✓	✓	O	✓
GTR	✓	✓	✓	✓
NICNAS	✓	✓	✓	✓
TGA	✓	✓	O	✓
IPRs	O	O	O	O

Table Key

✓ (light grey) = positive result; **O** (dark grey) = negative result

The Review concluded that Australia's federal regulatory frameworks were generally well suited to allow adequate management and control of the HSE risks posed by nanomaterials. Acknowledging that these frameworks were not perfect to begin with, this conclusion used the level of HSE protection provided by the regulatory frameworks in relation to conventional products as the baseline. The Australian Review found that due to the generally technology-neutral nature of the regulatory instruments, there was no case where a particular regulatory framework generally did not apply to nanotechnologies as a result of the presence of nanomaterials or the employment of the technology in a process. Moreover, the general repercussions of the regulatory steps required within each framework for nanotechnologies were the same as for conventional products.

That being said, the Australian Review noted that there were six areas of potential concern, which they labelled as 'regulatory triggers', which may fail to fire in relation to nanotechnologies and their applications.

20 In limited circumstances prior approval was required eg Goods Too Dangerous to be Transported ('GTDT') and explosives, where specific prior approval or a separate licence or permit was required prior to undertaking the task.

The most significant potential gap concerned the uncertainty as to whether new nanoforms of conventional products would be considered as 'different' to traditional products. Existing regulation is often on the basis of the naming of particular substances or articles for prohibition (in the case of hazardous pesticides for example) or for permission (in the case of a therapeutic good). It was uncertain whether future nano-enabled forms of conventional products would be considered the same as the named conventional entity. To ensure clarity, it was stated that revisions to the regulatory frameworks would be necessary as an increasing number of conventional products are re-engineered to include nanomaterials over the coming years.

The authors also noted that many regulatory triggers exist on the basis of a threshold weight or volume. For many nanomaterials, such a threshold may not be meaningful because: current production levels are low; the current state of the scientific art does not support the appropriateness of these threshold levels; and there are in any case real difficulties in accurately measuring the presence of nanoscale materials at this time.

Third, the Australian Review noted that in some instances, appropriate regulation requires particular knowledge of either the presence of nanomaterials and/or risks posed by the presence of the nanomaterials. For the authors of the Australian Review, public awareness and scientific knowledge in 2007 was such that these triggers were unlikely to be met.

The authors also found that Australia's regulatory regimes rely on risk assessment protocols as a means to ensure human or environmental safety of products or applications. In their view, if such protocols were not appropriate to determine the potential risks of nanomaterials, then the current regulatory arrangements may not be adequate to protect human or environmental health.

Fifth, the Australian Review considered that the specific exemptions relevant to research and development uses of conventional materials may be problematic in relation to nanotechnologies, especially in relation to potentially hazardous nanomaterials and their products.

The final regulatory trigger found to be potentially problematic was the referencing within the Australian regulatory documents to a number of international documents. Unless these documents themselves adequately address human and environmental health and safety concerns raised by nanotechnologies, these triggers may also fail to fire.

While the Australian Government did not directly respond to the findings of the Review, the Australian Office of Nanotechnology ('AON'), as it was then known, made the following statement:

> Australian Government agencies accept the findings of the [Australian Review] that:
>
> …

- whilst there is no immediate need for major changes to the regulatory regimes, there are areas that potentially will need amending.

Australian Government agencies also accept that:

- each of the regulatory agencies should now consider in detail the potential regulatory gaps identified in this report;
- this will require a long-term effort across multiple regulators and regulatory agencies as nanomaterials and products using nanotechnology are developed and as new knowledge on hazards, exposure and monitoring tools becomes available …[21]

The following sections of this article analyse the changing landscape and extent to which action has been taken following the findings of the Australian Review.

IV A FIVE-YEAR REFLECTION: THE EVOLVING POLICY AND REGULATORY LANDSCAPE FOR NANOTECHNOLOGIES IN AUSTRALIA

The Australian policy and regulatory landscape for nanotechnologies has continually evolved since 2007. This is not surprising given the changing political landscape, the evolution of the state of the scientific art, and the increasing focus on regulatory and governance issues surrounding nanotechnology within the international arena.

Arguably the most significant whole-of-government change impacting on the federal government policy landscape was the implementation of the National Enabling Technologies Strategy ('NETS') in 2009.[22] Housed within the Department of Innovation, Industry, Science and Research ('DIISR'), the four-year, $A38.2 million strategy[23] superseded the National Nanotechnology Strategy (2007–2009). As articulated by the Australian Government, NETS:

> provides a framework to support the responsible development of enabling technologies. Its aim is to improve the management and regulation of biotechnology and nanotechnology in order to maximise community confidence and community benefits from the use of new technology.[24]

The focus on 'enabling technologies', rather than specific technologies, provides NETS with much needed scope to continuously adapt to new or emergent technologies and materials.

21 Australian Office of Nanotechnology, *National Nanotechnology Strategy (NNS) Annual Report 2007–08* (2009) 24.

22 Department of Innovation, Industry, Science and Research, *National Enabling Technologies Strategy* (2009).

23 Ibid.

24 Ibid 3.

NETS is underpinned by six themes and objectives, two of which — *balancing risk and reward* and *planning for the future* — incorporate policy and regulatory objectives. Pursuant to the *planning for the future* theme, 'the strategy will assist government … to prepare for the advent of new technologies by undertaking foresighting activities and supporting the development of policy and regulatory frameworks'.[25] The HSE Working Group continues to coordinate Australia's regulatory response to nanotechnologies. One of the core areas of work of this group is facilitating general communication with the community on these matters.

It is not within the scope of this article to articulate the objective of the activities initiated by NETS or the HSE Working Group. However, it is fair to say that there is much activity going on at the different government levels and within the different sectors of the Australian community. Moreover, the aim of this article is to highlight key regulatory and policy developments that have occurred within each of the agencies that we reviewed in the 2007 report. This article does not, and cannot, in this form provide the level of analysis and detail as that presented in the Australian Review.

V INDIVIDUAL AGENCIES

A *Australian Pesticides and Veterinary Medicines Authority (APVMA)*

APVMA is Australia's regulatory authority for the evaluation, registration, and review of agricultural and veterinary chemicals and the control of those chemicals up to the point of retail sale. After that, responsibility reverts to individual states and territories. APVMA therefore regulates the import, manufacture, and supply of these chemicals up to retail sale.

At the time of the Review, specific examples of existing nanotechnology products and potential future products or applications were identified as being manufactured or imported into Australia currently or in the near future, which would be expected to fall within the ambit of APVMA responsibility. A 2009 APVMA Position Paper stated that although APVMA had not identified any registered products containing nanomaterials by that date, it did have a 'very small number of applications for registration of agvet chemicals or chemical products' that did.[26] As of 2012, one veterinary chemical (an anaesthetic) with nanotechnology involvement is registered and therefore compliant with the scheme's requirements.[27]

25 Ibid 4.

26 Australian Pesticides and Veterinary Medicines Authority, 'The APVMA and Nanotechnology' (Position Paper, October 2009) 2 <http://www.apvma.gov.au/supply/docs/nanotechnology.pdf>.

27 Australian Pesticides and Veterinary Medicines Authority, 'Chapter 3: Performance Management Report' in *APVMA Annual Report 2009–10* (2009) <http://www.apvma.gov.au/about/corporate/annual_reports/2009-10/chapter_03/strategy-1.php>.

Unrelated to nanotechnology reform, there has been considerable change to the APVMA regulatory scheme since the Australian Review. As a consequence of the Australian Government's *Better Regulation Reform Agenda*, there have been two rounds of legislative reform to APVMA since 2007 — the first in 2010 and the second in 2011–12.[28] These reforms are aimed at reducing regulatory burden in line with that Agenda, rather than responding to nanotechnology issues.

In 2010, five main amendments were made to the central code containing the operational provisions for the regulation of agricultural and veterinary chemicals, known as the Agvet Code.[29] These amendments related to labelling procedures and are directly relevant to nanotechnologies. In particular, when approving labels prior to use, APVMA need now only assess whether product labels have adequate instructions for the safe and effective handling and use of a product — these are called 'Relevant Label Particulars' ('RLP').[30] It is also now a specific offence to include misleading or deceptive information about a RLP or the use, safety, environmental impact or efficacy of the chemical product on a product label.[31] In the context of nanotechnologies, whilst the RLPs do not expressly require the form of material to be included on the label, this clearly could be required by APVMA if it was relevant to the safety, use or disposal of the product or if it was made an additional condition of label approval.

In furtherance of the *Better Regulation Reform Agenda* in 2011, the Australian Government introduced further reform measures to APVMA's governance framework and operational activities.[32] Amongst other things, these measures are intended to introduce a single, national scheme to regulate the control of use of agvet chemicals (that the states and territories are currently responsible for) and also bring in a mandatory scheme of continuation of approval and registration (the 'continuation scheme'). The aim of the continuation scheme is to 'consider the on-going suitability of the entire inventory of agvet chemicals in the Australian marketplace.'[33] This means that all existing registrations and approvals will be reviewed. In part, this process will 'identify whether there are any grounds for believing the active constituent or product no longer satisfy the APVMA's statutory criteria'.[34] Therefore, a previously registered or approved product now

28 See Department of Finance and Deregulation, *Better Regulation* (13 March 2012) <http://www.finance.gov.au/deregulation/index.html>.

29 The *Agricultural and Veterinary Chemicals Code Amendment Act 2010* (Cth) contains five amendments to the Schedule (that is, the Agvet Code itself) to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth).

30 See further Australian Pesticides and Veterinary Medicines Authority, *Draft Labelling Standard for Agricultural and Veterinary Products* (2011). Previously APVMA also assessed marketing and registrant information included on the label.

31 *Agricultural and Veterinary Chemicals Code Regulations 1995* (Cth) reg 18F(1).

32 Australian Pesticides and Veterinary Medicines Authority, *Overview of APVMA Operations and Future Direction: A Tool for Business Reform* (January 2012) 3. See also Exposure Draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011 (Cth).

33 Australian Pesticides and Veterinary Medicines Authority, *Overview of APVMA Operations and Future Direction*, above n 32, 12.

34 Ibid.

made using nanoparticles could be assessed.[35] APVMA already has power to reconsider a product's approval or registration without these amendments, but reconsideration is not currently mandatory.

1 *'Nano-Specific' Action since the Australian Review*

APVMA released a position paper and strategy document in October 2009 responding to the Australian Review.[36] It has also updated its webpage, and therefore information on nanotechnology in this regulatory arena is easily available to the public, as discussed below. APVMA is also participating in the process of delivering a coordinated national approach to nanotechnology through its membership of the Nanotechnology Inter-departmental Committee, the Nanotechnology HSE Working Group and the Nanotechnology Communications and Public Awareness Network.

The 2009 Position Paper describes APVMA's strategy as being to progressively assess and address the potential gaps identified by the Australian Review by:

- Reviewing the existing regulatory framework against the potential gaps identified in the [Australian Review], for its suitability in regulating for nanomaterials in agvet chemicals and chemical products;
- Amending operational procedures to accommodate nanomaterials;
- Publishing a 'Call for Information — Nanomaterials in Agricultural or Veterinary Chemicals, or Agricultural or Veterinary Chemical Products' on the APVMA website and in the APVMA Gazette;[37]
- Providing APVMA staff with appropriate training in the science of nanomaterials and in any changes to operational processes;
- Continuing to be involved in national and international forums on the regulation of nanomaterials; and
- Publishing information on nanotechnology and providing the community and industry with information on any change to the regulatory process.[38]

In 2009, APVMA consulted with stakeholders and the public as to whether a question specifically regarding nanotechnology should be included in its updated application forms. The website says in relation to this option that

> [t]he question on nanotechnology is primarily for information and falls within the general information required by the APVMA in regards

35 For older products, the cost of compliance may mean it is not worthwhile for a commercial entity to pursue continuance, given the small Australian market. This means some older products may become unavailable as their registrations lapse.

36 Australian Pesticides and Veterinary Medicines Authority, 'The APVMA and Nanotechnology', above n 26.

37 The call for information was made in 'Nanomaterials in Agricultural or Veterinary Chemicals or Products in Australia' in Commonwealth, *APVMA Gazette*, No 9, 2 September 2008, 15, 17.

38 Australian Pesticides and Veterinary Medicines Authority, 'The APVMA and Nanotechnology', above n 26, 3.

> a product's formulation and also reflects the developing regulatory framework under the National Nanotechnology Strategy.[39]

The data required from applicants includes the chemical's physical properties, and this is expanded in the guide to expressly require 'particle size distribution for active constituents having poor aqueous solubility'. However, there is no express reference to nanoparticles.

APVMA's 2011–2012 Operational Plan states that in achieving its target of developing a strategic approach to regulating emerging technologies, it intends to progress the development of chemistry data requirements for nanoproducts and develop a nanotechnology expert advisory panel.[40] In 2011, APVMA established the Regulation of Nanotechnology Product Registration Committee and Nanotechnology Strategic Management Committee.[41]

At the public and stakeholder level, APVMA's webpage now includes a tab on its home page taking visitors to a specific 'Nanotechnology and Agvet Chemicals' page.[42] This page includes a link to the Australian Review as well as to a Nanotechnology and Agvet chemicals fact sheet, a question and answer page on nanotechnology, and the Position Paper described above. The fact sheet essentially sets out the strategies described above.[43] It also notes that an independent review of the scheme has been completed, and that the review concluded that the scheme 'is capable of effectively and reliably addressing nanomaterials'.[44] There is no reference in this document to any potential gaps or concerns. However, the webpage itself gives the date of the Australian Review, and notes that the Review identified 'four potential gaps in relation to health, safety and environment considerations' and says that 'these are under active review by the APVMA'.[45]

2 *Gaps Filled?*

Potential Gap 1 — whether existing substances reformulated at the nanoscale would be considered as new substances

APVMA concluded that existing substances reformulated at the nanoscale would be treated as new substances. It now says on its webpage that '[a]ny change to the

39 Australian Pesticides and Veterinary Medicines Authority, *Changes to Application Forms* <http://www.apvma.gov.au/consultation/public/closed/2009/morag_changes/new_app_forms_intro.php>.

40 Australian Pesticides and Veterinary Medicines Authority, *Operational Plan 2011–2012* (2011) 21 <http://www.apvma.gov.au/about/corporate/docs/operational_plan_2011-12.pdf>.

41 Australian Pesticides and Veterinary Medicines Authority, *Factsheet: Nanotechnology and Agvet Chemicals* (August 2010) 2 <http://www.apvma.gov.au/publications/fact_sheets/docs/nanotechnology.pdf>.

42 Australian Pesticides and Veterinary Medicines Authority, *Nanotechnology and Agvet Chemicals* <http://www.apvma.gov.au/supply/nanotechnology/index.php>.

43 Ibid.

44 Ibid.

45 Australian Pesticides and Veterinary Medicines Authority, *Nanotechnology and Agvet Chemicals*, above n 42.

composition or form of a registered chemical or chemical product creates a new chemical or chemical product requiring new assessment'.[46]

Potential Gap 2 — the existing regulatory framework provides for exemptions to the licensing conditions including experimental use (R&D)

Exemptions such as the 'experimental use' exemption continue to exist. However, APVMA has taken steps to gather information as to whether the gap is of practical concern. In 2008, APVMA's call for information included this type of use. The call was addressed to all persons variously involved with agvet chemicals in 2008, which did not necessarily have to be registered, approved, or licensed. However, the provision of information to APVMA required persons to first be aware of the call, and secondly to respond to APVMA.

Potential Gap 3 — whether the existing regulatory framework assesses substances on the basis of both physico-chemical properties and the effect of product

The Strategy devised by APVMA included that it examine whether changes were needed to its assessment procedures, risk management framework, or legislation.[47] The legislation has not been changed in this regard, but it is not known if the procedures or risk management framework have been changed.

Potential Gap 4 — whether the current risk assessment protocols based on conventional methods are suitable for nanomaterials

Publically available information says that APVMA is currently developing, in concert with other Australian agencies, a comprehensive risk assessment framework for all aspects of nanotechnology.[48]

B *Australian Quarantine and Inspection Service (AQIS)*

AQIS is Australia's primary federal quarantine authority, having jurisdiction in relation to the quarantine of imported goods pursuant to the *Quarantine Act 1908* (Cth). As noted by the Australian Review, AQIS administers legislation under which nanotechnology-based products may fall. This includes, for example, the *Quarantine Act*, the *Imported Food Control Act 1992* (Cth) ('*IFC Act*'), the *Export Control Act 1982* (Cth) ('*EC Act*'), and a number of supplementary regulations. Products and processes will fall within the remit of AQIS by virtue of being

46 Ibid.

47 Australian Pesticides and Veterinary Medicines Authority, *Operational Plan 2011–2012*, above n 40.

48 Australian Pesticides and Veterinary Medicines Authority, *Results of Public Consultation: Draft of APVMA Operating Principles in relation to Spray Drift Risk* (15 July 2008) 2 <http://www.apvma.gov.au/use_safely/docs/spraydrift_submissions.pdf>.

defined as a 'good',[49] a 'food' imported into Australia,[50] or a 'prescribed good' subject to export inspection regime.[51] While numerous nanotechnology-based products no doubt fall under this regime, regulatory oversight is not triggered by the presence of nanomaterials, but rather by virtue of the 'good' or the 'food' with which it is associated.

Unlike its sister agency at the Customs Service, AQIS does not have a seat on the HSE Working Group. The agency has, at least publically, retained the policy and regulatory status quo observed in relation to nanotechnologies in the Australian Review. This is not a surprise given the evolving state of the scientific art and the fact that no analogous agencies in the international arena have made any such changes to their policy and/or regulatory regimes.

1 *Gaps Filled?*

Potential Gap 1 — focus on items that are of 'quarantine interest' which are generally defined by reference to particular classes of goods

Publically available information suggests that the status quo has been retained in relation to nanotechnologies, and that approach continues. This approach does not discriminate between classes of goods that do and do not contain nanomaterials.

C *Department of Sustainability, Environment, Water, Population and Communities (formerly the Department of Environment (DEW))*

At the time of the Australian Review, responsibility for protecting the environment was shared between the federal DEW and state environmental agencies. The DEW has since been superseded and, as of September 2010, environmental matters at the federal level are dealt with by the Department of Sustainability, Environment, Water, Population and Communities ('DSEWPAC'). Responsibility for protecting the environment is still shared between the different levels of government, with each state and territory having their own environment agency.

Examples of existing nanotechnology products and potential future products or applications were identified by the authors of the Australian Review as including, for example, fuel and fuel additives and hazardous materials. These products fell within the ambit of the Department's regulatory scope by virtue of being a defined class of product (such as a 'fuel'), and not due to the presence of nanomaterials within such products.

Unrelated to nanotechnology reform, there has been considerable change to the federal environmental regulator and scheme since the Australian Review. This

49 *Quarantine Act 1908* (Cth).

50 *Imported Food Control Act 1992* (Cth).

51 *Export Control Act 1982* (Cth).

has seen the Department morph in name and the matters that it is responsible for as part of an overall reform package.[52] As noted in their Annual Report, the 'department's mission has broadened from: protecting and enhancing Australia's environment, heritable and culture to: Advancing a sustainable Australia: our environment, water, heritage and communities'.[53] The DSEWPAC is now responsible for administering, among other instruments, the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ('*EPBC Act*'), the *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth) ('*EPBC Regulations*'), the *Fuel Quality Standards Act 2000* (Cth) and the *Hazardous Waste (Regulation of Exports and Imports) Act 1989* (Cth).

1 *'Nano-Specific' Action since the Australian Review*

The federal environmental regulator has had limited engagement on nanotechnologies since the publication of the Australian Review. However, while not expressly included within the terms of reference of the 2008 Independent Review of the *EPBC Act*,[54] the impact of nanomaterials in the environment was raised in at least one of the written submissions.[55] In the final report, it was noted that the 'impacts it may have on the environment remain largely unknown', and that:

> Processes associated with the manufacture, use or disposal of nanomaterials could be considered as actions that may have a significant impact on matters protected under the Act. It is important that the Act be able to assess the risk posed by these materials on matters protected under the Act.[56]

In its response to the Review of the *EPBC Act*, the Australian Government did not expressly respond to the proposed challenges that nanotechnologies may bring with it. However, it did acknowledge the continuing role of the *EPBC Act* in regulating emerging technologies and the potential risks associated with them, and the need to ensure identification of individuals associated with the manufacturing or distribution of such technologies.[57]

The 2009–10 NETS Annual Report indicates that following on from the Australian Review, DEW staff undertook an in-house desktop review on the

52 Department of Sustainability, Environment, Water, Population and Communities, *Annual Report 2010–2011* (2011).

53 Ibid 13.

54 Department of the Environment, Water, Heritage and the Arts, 'Independent Review of the *Environment Protection and Biodiversity Conservation Act 1999*' (Discussion Paper, September 2008).

55 See also Jeremy Tager, Submission No 132 to Department of the Environment, Water, Heritage and the Arts, *Independent Review of the Environment Protection and Biodiversity Conservation Act 1999*, 21 December 2008 <http://www.environment.gov.au/epbc/review/submissions/pubs/132-j-tager.pdf>.

56 Allan Hawke, 'The Australian Environment Act: Report of the Independent Review of the *Environment Protection and Biodiversity Conservation Act 1999*' (Final Report, Department of the Environment, Water, Heritage and the Arts, October 2009) 148.

57 Department of Sustainability, Environment, Water, Population and Communities, *Australian Government Response to the Report of the Independent Review of the Environment Protection and Biodiversity Conservation Act 1999* (2011).

fate of manufactured nanomaterials in the environment. While this report is not publically available, funding was obtained by the Department — from NETS — for an independent ecotoxicology study on nanomaterials.[58] This report is available on the Department's website.[59] This appears to be the Department's main method of informing the Australian public about the potential impact of nanotechnologies in the environment.

2 *Gaps Filled?*

Potential Gap 1 — regulatory framework triggered in many circumstances 'after the fact'

Much of Australia's environmental legislation deals with addressing risks once they have emerged within the environment — eg hazardous waste, air pollution, litter. While there are a number of pre-market approval processes (eg fuel quality standards, controlled waste), these frameworks do not differentiate between defined classes of goods that do or do not contain nanomaterials. The overall reform package to Australian environmental legislation has not addressed this issue. As such, the status quo observed in 2007 in relation to the regulatory frameworks administered by the DSEWPC remains.

Potential Gap 2 — whether the current risk assessment protocols based on conventional methods are suitable for nanomaterials

It appears that as part of its involvement in the HSE Working Group, the DSEWPC is an active participant in ensuring that protocols used by the various agencies are adequate for assessing potential risks. It is still unknown how appropriate the current risk assessment protocols used by the DSEWPC are for assessing the potential risks of, for example, nanomaterial 'waste' in the environment.

D *Therapeutic Goods Administration (TGA)*

The TGA is responsible for the regulation of therapeutic goods in Australia, including duties of assessing and registering such goods. In undertaking a risk assessment, the Administration focuses on evaluating risks to human health. The functions of the regulator are exercised through three main processes: auditing and assessment of the quality of therapeutic goods in terms of their manufacture, pre-market assessment of therapeutic goods, and post-market monitoring.

At the time of the Australian Review, specific examples of existing or potential products that were likely to fall under the regulatory scope of TGA included items

58 Department of Innovation, Industry, Science and Research, *National Enabling Technologies Strategy (NETS): Annual Report 2009–10* (2010) 21. See also Australian Office of Nanotechnology, *National Nanotechnology Strategy (NNS) Annual Report 2007–08*, above n 21.

59 G E Batley and M J McLaughlin, 'Fate of Manufactured Nanomaterials in the Australian Environment' (CSIRO Niche Manufacturing Flagship Report, CSIRO, March 2010) <http://www.environment.gov.au/settlements/biotechnology/publications/pubs/manufactured-nanomaterials.pdf>.

such as sunscreen products, medical implants with nano-coatings, and dendrimer based drugs. According to the TGA:

> Therapeutic products containing nanomaterials in the form of metal oxides, liposomes, polymer protein conjugates, polymeric substances and suspensions have been registered in Australia and/or marketed overseas in the United States or the European Union.[60]

Since 2007, there has been considerable debate over the future of the TGA as Australia's regulator of therapeutic goods. As part of the Labor Government's national health reform package, an agreement was reached in 2011 to establish a trans-Tasman regulatory scheme for therapeutic goods. The Australian New Zealand Therapeutic Products Agency ('ANZTPA') will increasingly absorb the functions of the TGA and their New Zealand equivalent (MediSafe) throughout 2011–16, at which time it is anticipated that the joint scheme will become fully operational.[61] While these reforms are unrelated to nanotechnology-based products that fall within this regulatory framework, and the details of the joint scheme are still unclear, the reform will be relevant to the regulation of therapeutic goods enabled by nanotechnologies in the coming years.

In addition to the proposed establishment of the ANZTPA, a number of other reforms and reviews have affected the TGA. These include, for example, reviews of transparency arrangements within the TGA,[62] and of regulatory requirements relating to advertisement of therapeutic products.[63] In conjunction with a number of other reviews and initiatives these culminated in the release of the *TGA Reforms: A Blueprint for TGA's Future* report.[64] While the blueprint does not expressly touch upon the topic of nanotechnologies, it is inevitable that the proposed reforms will impact on the regulation of nanotechnology by the TGA or, in due course, the ANZTPA.

1 *'Nano-Specific' Action since the Australian Review*

As with APVMA, the TGA has responded publically to many of the issues raised by the Australian Review. The way in which the Administration regulates nano-based therapeutic goods, including sunscreens, is clearly articulated on their

60 Therapeutic Goods Administration, *Nanotechnology and Therapeutic Products* (9 July 2008) <http://www.tga.gov.au/industry/nanotechnology-qa.htm>.

61 Catherine King, 'Opening Address' (Speech delivered at the Consumers' Health Forum, Parliament House, Canberra, 29 August 2011) <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/BF04B327C3F1EED2CA2578FB00137E13/$File/cksp290811.pdf>.

62 Panel to Review the Transparency of the Therapeutic Goods Administration, 'Review to Improve the Transparency of the Therapeutic Goods Administration' (Final Report, June 2011) <http://www.tga.gov.au/pdf/consult/review-tga-transparency-1101-final-report.pdf>.

63 Therapeutic Goods Administration, 'Advertising Therapeutic Goods in Australia' (Consultation Paper, June 2010).

64 Australian Government, *TGA Reforms: A Blueprint for TGA's Future* (December 2011) <http://www.tga.gov.au/pdf/tga-reforms-blueprint.pdf>.

website 'Nanotechnology and therapeutic products'.[65] The site contains a number of key questions and answers that the public are likely to have in relation to nanomedicines — including the benefits associated with using nanomaterials in therapeutic goods and a discussion about the potential risks — with a link to the topic of nanomaterials in sunscreens. It is on this page that the public can access the TGA's review of the scientific literature on nanomaterials in sunscreens.[66]

The TGA has played a central role in the coordinated national approach to nanotechnologies through its membership of the HSE Working Group. As highlighted in the AON 2008–09[67] and NETS 2009–10 annual reports,[68] the TGA has undertaken a range of activities in response to the Australian Review, including:

- reviewed the capacity of existing regulatory arrangements for therapeutic products to adequately manage issues arising from the use of materials derived from nanotechnologies;
- built the scientific capacity of the TGA, and other government regulators, to assess nanotechnology based applications;
- supported the coordinated whole of government response to nanotechnology issues; and
- organised a 2 ½ day regulators training workshop led by the TGA.[69]

Information regarding the TGA's in-house review of its regulatory regime following the Australian Review is not publically available at the time of writing.[70] However, the TGA's website contains the following statement: 'To date, the existing regulatory framework of the TGA has proved more than adequate to identify, assess and manage the risks associated with therapeutic products that incorporate nanotechnologies.'[71] There is no reference to any potential gaps or concerns identified by the Australian Review, nor does the webpage make reference to the independent review.

The activities documented above have been supplemented by internal consultations with entities such as the FDA. The TGA has maintained a watching

65 Therapeutic Goods Administration, *Nanotechnology and Therapeutic Products*, above n 60. Interestingly, while the TGA's nanotechnology website was last reviewed in 2011, the contents of it were last updated in 2008.

66 Therapeutic Goods Administration, *A Review of the Scientific Literature on the Safety of Nanoparticulate Titanium Dioxide or Zinc Oxide in Sunscreens* (July 2009) <http://www.tga.gov.au/pdf/review-sunscreens-060220.pdf>.

67 Australian Office of Nanotechnology, *National Nanotechnology Strategy Annual Report 2008–09* (2009).

68 Department of Innovation, Science and Research, *National Enabling Technologies Strategy (NETS): Annual Report 2009–10*, above n 58.

69 Australian Office of Nanotechnology, *National Nanotechnology Strategy Annual Report 2008–09*, above n 67, 26–7.

70 January 2013.

71 Therapeutic Goods Administration, *Nanotechnology and Therapeutic Products*, above n 60.

brief on the relevant scientific literature.[72] This is best illustrated by a reference to the updated review on safety issues associated with the use of nanomaterials in sunscreens (as noted above). As stated by the TGA in that report, the objective of the work was to examine '[t]he potential for titanium dioxide (TiO2) and zinc oxide (ZnO) nanoparticles in sunscreens to cause adverse effects'.[73]

The literature review examined 40 published articles. Having examined the articles in relation to toxicity/photo-toxicity and dermal penetration, the TGA drew the following conclusions:

> Currently, there is no in vivo evidence to indicate possible toxicity of nanoparticulate TiO2 or ZnO in people using sunscreens. To date, the current weight of evidence indicates the particles remain on the surface of the skin and in the outer dead layer (stratum corneum) of the skin.[74]

The Administration has acknowledged the need for continual vigilance in this area, and has committed to 'assess the literature and provide annual updates to this review'.[75] No such updates were identified on the TGA's website. It is noted here that a number of commentators, including leading academics, members of the scientific community and NGOs, have expressed considerable concern within both the academic literature and the media over the TGA's conclusions regarding the safety of nanotechnology, particularly the use of nanomaterials in sunscreens.[76] However, it was not the objective of the Australian Review or of this article to make a judgment on regulators' assessments of safety risks, but instead to review the adequacy of the coverage of regulatory frameworks under which those assessments occur.

2 *Gaps Filled?*

Potential Gap 1 — 'excluded or exempted goods' not required to be entered onto the ARTG prior to their supply in Australia

This potential gap, which applies to products such as sunscreens and antiperspirants, including those that may contain metal oxide nanoparticles such as titanium dioxide, zinc oxide and/or silver, continues under current regulatory

72 Therapeutic Goods Administration, *A Review of the Scientific Literature on the Safety of Nanoparticulate Titanium Dioxide or Zinc Oxide in Sunscreens*, above n 66.

73 Ibid 1 (emphasis altered).

74 Ibid 32.

75 Ibid 2.

76 See, eg, Friends of the Earth Australia, 'Nanomaterials, Sunscreens and Cosmetics: Small Ingredients, Big Risks' (Report, Friends of the Earth, May 2006); Thomas Faunce et al, 'Sunscreen Safety: The Precautionary Principle, The Australian Therapeutic Goods Administration and Nanoparticles in Sunscreens' (2008) 2 *Nanoethics* 231; Thomas Alured Faunce, 'Exploring the Safety of Nanoparticles in Australian Sunscreens' (2010) 1(1) *International Journal of Nanoscience and Nanotechnology* 87; Brian Gulson et al, 'Small Amounts of Zinc from Zinc Oxide Particles in Sunscreens Applied Outdoors are Absorbed Through Human Skin' (2010) 118 *Toxicological Sciences* 140. See generally Scientific Committee on Consumer Products, 'Opinion on Safety of Nanomaterials in Cosmetic Products' (SCCP/1147/07, European Commission, 18 December 2007); Gerhard J Nohynek et al, 'Grey Goo on the Skin? Nanotechnology, Cosmetic and Sunscreen Safety' (2007) 37 *Critical Reviews in Toxicology* 251.

arrangements. This is not surprising given that the TGA has concluded that, '[t]here is currently no evidence to suggest that therapeutic products which incorporate nanotechnologies pose greater safety risks than conventional products.'[77] As such, the Administration's focus has been on reviewing developments within the scientific literature, and collaborating with overseas counterparts such as the FDA.

Potential Gap 2 — TGA is not required to assess the efficacy of 'listed goods' prior to their supply in Australia

This potential gap is again most relevant to products such as sunscreens and antiperspirants, both of which potentially may contain nanomaterials. Other commentators have also noted this potential gap.[78] However, this potential gap applies to all 'listed goods', and not only those containing nanomaterials. Given the Administration's current position on potential risks associated with nanomaterials in therapeutic products, it appears likely that the status quo will remain. This assumes that evidence will not appear in the scientific literature suggesting additional steps — or checks and balances — are needed for such products to safeguard human health and safety.

E *Safe Work Australia (SWA) (previously Australian Safety and Compensation Council (ASCC))*

At the time of the Australian Review, each state and territory was responsible for the regulation and enforcement of workplace occupational health and safety ('OH&S') in their respective jurisdictions. Following but unrelated to the Australian Review, Australian OH&S arrangements were harmonised[79] through the implementation of uniform laws and complemented by a policy on a nationally consistent approach to compliance and enforcement.[80] Safe Work Australia ('SWA') has also replaced the ASCC as the government statutory agency responsible for workplace OH&S policy.[81] SWA prepares the model OH&S policy, legislation, codes of practice, and other material and monitors its adoption by the states although the states and territories remain responsible for regulation and enforcement. A five-year transition period will allow the regulatory scheme in the Australian Review and the new scheme to be used concurrently, during which time either scheme may be used.[82] However, from 1 January 2017, all workplace

77 Therapeutic Goods Administration, *Nanotechnology and Therapeutic Products*, above n 60.

78 Faunce et al, above n 76.

79 Council of Australian Governments, *Inter-Governmental Agreement for Regulatory and Operational Reform in Occupational Health and Safety* (3 July 2008) <http://www.coag.gov.au/sites/default/files/OHS_IGA.pdf>.

80 The *Work Health and Safety Act 2011* (Cth) and the *Work Health and Safety (Transitional and Consequential Provisions) Act 2011* (Cth) commenced from 1 Jan 2012.

81 Safe Work Australia, *Safe Work Australia Fact Sheet* (18 November 2011) <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/swa-fact-sheet>.

82 The transitional arrangements have not been reviewed here.

chemicals must be classified and relevant information provided according to the new regulatory framework (discussed below).

The model regulations[83] incorporate the United Nations developed *Global Harmonized System of Classification and Labelling of Chemicals* ('*GHS*').[84] The *GHS* creates an internationally uniform method to classify chemicals and provide information to users about possible chemical hazards and is updated by the UN about every two years.[85] However, pursuant to the definition of the *GHS* in the model regulations,[86] the 2009 version is the incorporated version.[87] No version of the *GHS* has express reference to nanotechnologies. A further important development since the Australian Review is the combining of the regulation of hazardous substances ('HS'), dangerous goods ('DG') and explosives.[88] These are all now referred to as Hazardous Chemicals ('HC'). In 2007, these three groups were regulated and reviewed separately.

Specific examples of existing nanotechnology products and potential future products or applications were identified in 2007 as being (or in the future being) manufactured or imported into Australia, which were expected to fall within the ambit of the HC (as it now known) regime. Given that other regulators, such as APVMA, are now reporting actual instances of products falling under their schemes, this number must have increased or been realised.

1 *'Nano-Specific' Action since the Australian Review*

SWA has been active in responding to the challenges of nanotechnology. It is a member of the HSE Working Group, has its own Nanotechnology Work Health & Safety Advisory Group to promote 'a coordinated national approach to the management of nanotechnology work health & safety issues', and a Nanotechnology Work Health & Safety Measurement Reference Group which is 'developing nanomaterial exposure and emissions measurement capability'.[89] SWA also presents at conferences and workshops on nanotechnology and has produced the following documents to assist workplaces using nanomaterials:

- August 2010: Engineered Nanomaterials: Investigating substitution and modification options to reduce potential hazards

83 *Work Health and Safety Regulations 2011* (Cth) are made under *Work Health and Safety Act 2011* (Cth) s 276.

84 *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, UN Doc ST/SG/AC.10/30/Rev.3 (2009). The UN has since released a 2011 4th version.

85 The group responsible for keeping the *GHS* up to date is a subcommittee of a committee of the UN ECOSOC (United Nations Economic and Social Council). The committee is the UNCETDG/GHS and its sub-committee is UNSCEGHS (Sub-committee of Experts on the *GHS*).

86 *Work Health and Safety Regulations 2011* (Cth) reg 5.

87 SWA must periodically consider whether to update the model regulations to align with newer versions of the *GHS* 'based on an assessment of the costs and benefits'. Safe Work Australia, 'Guidance on the Classification of Hazardous Chemicals under the WHS Regulations' (26 April 2012) 8.

88 Not all provisions apply to explosives. See *Work Health and Safety Regulations 2011* (Cth) reg 328(5) regarding which provisions apply to explosives.

89 Howard Morris, 'Nanotechnology Work Health & Safety' (Speech delivered at the Hazmat Conference, Sydney Showgrounds, 11 May 2011).

- November 2009: Engineered Nanomaterials: A review of the toxicology and health hazards
- November 2009: Engineered Nanomaterials: Evidence on the effectiveness of workplace controls to prevent exposure
- June 2010: Developing Workplace Detection and Measurement Techniques for Carbon Nanotubes
- June 2010: An evaluation of MSDS and labels associated with the use of engineered nanomaterials
- August 2010: Engineered Nanomaterials: Feasibility of establishing exposure standards and using control banding in Australia
- 2011: two reports relating to nanoparticle emissions from laser printers in office environments.[90] The first report measured the characteristics and behaviour of nanoparticles and assessed them against national and international air quality guidelines and exposure standards. The second report reviewed the health risks associated with the levels of emissions measured in the original study and concluded that it was low, although this did not exclude the possibility of health effects for highly sensitive people.

(a) Duty regarding Workers' Health

All persons conducting a business or undertaking, including employers, self-employed, principal contractors, persons with management or control of a workplace, designers, manufacturers, importers and suppliers of plant, substances, or structures that are used for work have health and safety duties to their workers. They must 'manage risks' by eliminating health and safety risks so far as is reasonably practicable, and if it is not reasonably practicable to do so, minimise those risks so far as is reasonably practicable.

In regards to nanomaterials, SWA acknowledges that knowledge of hazards is occasionally limited and in such circumstances it advises entities using nanotechnology to adopt a precautionary approach to control exposure to engineered nanomaterials. They are advised to 'use the best practicable means of preventing or minimising workplace exposures to engineered nanomaterials'.[91] In 2012, SWA released a publication that provides guidance for the safe handling and use of carbon nanotubes in the workplace.[92] SWA has also produced a *Code of*

90 Safe Work Australia, 'Nanoparticles from Printer Emissions in Workplace Environments' (Report, 16 December 2011) <http://safeworkaustralia.gov.au/AboutSafeWorkAustralia/WhatWeDo/Publications/Documents/635/Nanoparticles_from_printer_emissions.pdf>; see also Roger Drew, *Brief Review on Health Effects of Laser Printer Emissions Measured as Particles* (Report, Safe Work Australia, 16 December 2011) <http://www.safeworkaustralia.gov.au/sites/SWA/AboutSafeWorkAustralia/WhatWeDo/Publications/Documents/636/Brief%20Review%20Laser%20Printer%20Emissions.pdf>.

91 Morris, above n 89.

92 Safe Work Australia, 'Safe Handling of Carbon Nanotubes in the Workplace' (Media Release, 5 March 2012) <http://www.safeworkaustralia.gov.au/sites/SWA/media-events/media-releases/Documents/2012%20Media%20Releases/MR05032012CarbonNanotubes.pdf>.

Practice on Managing Risks of Hazardous Chemicals in the Workplace which,[93] in discussing managing the general risk of dust explosions, gives nanomaterials as an example of a dust that poses a significant risk and notes that special precautions may be necessary.[94]

(b) Responsibilities relating to HC

A HC is defined as 'a substance, mixture or article that satisfies the criteria for a hazard class in the *GHS*'.[95] Whilst the trigger definition has therefore changed compared to the previous frameworks, it will still trigger regardless of whether nanomaterials are used or not. Like its predecessor, the new framework applies to 'the use, handling and storage of hazardous chemicals at a workplace and the generation of hazardous substances at a workplace'.[96] However, like the previous framework, chemicals intentionally used by a consumer such as pharmaceuticals, food additives, cosmetics, pesticide residues in food, and chemicals intentionally administered to an animal are not regulated under the GHS or model regulatory framework.[97] These risks would be managed by the Australian regulator for that particular end use product — such as the TGA, FSANZ or APVMA. These chemicals would be regulated by SWA where workers are exposed to them whilst being manufactured in the workplace or whilst being handled. HC are also not regulated by the new framework where they are being transported, where that transport is regulated under another relevant state law.[98]

As under the previous framework, where the regulations are triggered, manufacturers and importers of all articles, mixtures, or substances have a duty to determine whether it is a HC and if so, correctly classify it.[99] As under the previous regime, if it is a HC, adequate information on the chemical must be given to downstream users.[100] This is done by Safety Data Sheets ('SDSs')[101] (previously called Material Safety Data Sheets ('MSDS')) and labelling. Unlike its predecessor, the new regime provides specifically for SDSs to be prepared for research chemicals. However, it is not clear whether the definition of 'research chemical'[102] or the terms 'waste product' or 'sample for analysis' (which are both

93 Safe Work Australia, *Managing Risks of Hazardous Chemicals in the Workplace: Code of Practice* (July 2012).

94 Ibid 24.

95 *Work Health and Safety Regulations 2011* (Cth) reg 5(1). Some *GHS* hazard classes and categories are not covered by the *WHS Regulations*. Refer to the definition of 'hazardous chemical' in the *WHS Regulations* for more information. The tables in sch 6 of the *WHS Regulations* replace some tables of the *GHS*. This relates to cut-off concentrations for some hazard categories.

96 Ibid reg 328(1)(a).

97 Ibid reg 328(6).

98 Ibid reg 328(3).

99 Ibid reg 329.

100 Ibid regs 330, 335.

101 SDSs must comply with cl 1 of sch 7 unless reg 331 (regarding research chemical etc) applies: *Work Health and Safety Regulations 2011* (Cth) reg 330.

102 *Work Health and Safety Regulations 2011* (Cth) reg 5:

> Research chemical means a substance or mixture that:
>
> (a) is manufactured in a laboratory for genuine research; and
>
> (b) is not for use or supply for a purpose other than genuine research or analysis.

undefined) includes reaction intermediates, which were not covered under the previous regime.[103]

Classification of chemicals[104] determines the information that must be included on labels and SDSs to comply with the model regulations. If a HC classification changes or new and relevant information comes to light, the label and SDS must be reviewed and revised. SDSs are also to be reviewed by manufacturers and importers every five years in order to ensure they are kept up to date in light of new information. This is particularly relevant in nanotechnology where the state of scientific knowledge is continually changing.

Chemicals may be categorised by translating the classification under the previous scheme into the *GHS* scheme[105] or from 'first principles'. The latter applies the *GHS* criteria to available raw test data for the chemical. The *GHS* does not mandate particular risk assessment procedures or risk management decisions.[106] However, tests to determine risk must follow internationally scientifically recognised principles and in the case of tests for physical hazards, specific test methods are required.[107]

Many nanomaterials are not yet classified as HC because limited information still exists about their hazard properties.[108] Therefore, it will not be mandatory to prepare SDSs or to label the chemical. Given this problem, SWA has publicly supported 'the need to provide information for people handling nanomaterials when it is suspected they might be hazardous'.[109] SWA recommends a precautionary approach to labelling and SDSs for nanomaterials. It also recommends that if the health hazards are not fully characterised, the SDS / label of the nanomaterial should state:

- *Contains engineered/manufactured nanomaterials. Caution: Hazards unknown; or*
- *Contains engineered/manufactured nanomaterials. Caution: Hazards not fully characterised.*[110]

103 *National Code of Practice for the Control of Workplace Hazardous Substances* (1 January 1994) *[NOHSC: 2007 (1994)]* s 8.9 <http://www.safeworkaustralia.gov.au/sites/SWA/AboutSafeWorkAustralia/WhatWeDo/Publications/Documents/259/NationalCodeOfPractice_ControlOfWorkplaceHazardousSubstances_NOHSC2007-1994_PDF.pdf>.

104 *Work Health and Safety Regulations 2011* (Cth) reg 329(a). Classification is to be done as provided in pt 1 of sch 9 of the Regulations.

105 Safe Work Australia, 'Guidance on the Classification of Hazardous Chemicals under the *WHS Regulations*' (26 April 2012) 6 <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/guidance-classification-whs-regulations>.

106 *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, UN Doc ST/SG/AC.10/30/Rev.3 (2009) para 1.1.2.6.

107 Ibid para 1.1.2.5.

108 Safe Work Australia, 'Guidance on the Classification of Hazardous Chemicals under the *WHS Regulations*', above n 105, 8.

109 Morris, above n 89.

110 Safe Work Australia, 'Guidance on the Classification of Hazardous Chemicals under the *WHS Regulations*', above n 105, 8 (emphasis in original).

SWA also advises that this information should be updated as new hazard information becomes available. Similarly, in the *National Code of Practice for Workplace Labelling*, a precautionary approach to handling nanomaterials is supported and it is recommended that labels be provided for engineered or manufactured nanomaterials unless ample evidence indicates that they are not hazardous.

(c) Safety Data Sheets

The content requirements for SDSs are established in model regulations.[111] The requirements continue to be broad, and do not expressly refer to nanotechnology. However, the guidance document now includes a specific section on 'Products Containing Nanomaterials' that recommends a precautionary approach be taken in the handling of nanomaterials. As with the labelling approach noted above, the specific advice is that '[f]or engineered or manufactured nanomaterials or chemicals containing engineered or manufactured nanomaterials, an SDS should be provided unless there is evidence that the nanomaterials are not hazardous'.[112] It advises additional but non-mandatory information should be included for nanomaterials, including

> particle size (average and range); size distribution; shape and aspect ratio; crystallinity; dustiness; surface area; degree of aggregation or agglomeration, and dispersibility; … biodurability or biopersistence; surface coating or chemistry (if different to rest of particle).[113]

The SWA guidance documents do not have force of law, but instead serve as practical guides to achieve the standards of health, safety, and welfare required under the workplace OH&S legislation. In most cases, following a relevant approved code of practice achieves compliance with the health and safety duties. Courts may also regard codes of practice as evidence of what is known about a hazard, risk, or control, and may rely on them in determining what is reasonably practicable in the circumstances to which a code relates. However, codes do not cover all hazards or risks that may arise. The statutory health and safety duties require duty holders to consider *all* risks associated with work, not only those for which regulations and codes of practice exist.

In conclusion, the new framework still relies on self-regulation, as was the case with the previous framework which also permitted additional information such as particle size to be included in SDSs. However, nanomaterials are now specifically addressed in the guidance documents. This raises awareness, and makes it more difficult for regulated parties to claim ignorance in cases of prosecution or other legal proceedings. The SWA website also has a specific webpage called

111 *Work Health and Safety Regulations 2011* (Cth) sch 7.

112 Safe Work Australia, *Preparation of Safety Data Sheets for Hazardous Chemicals: Code of Practice* (23 December 2011) 5 (footnotes omitted) <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/safety-data-sheets-hazardous-chemicals-cop>.

113 Ibid 21.

'Nanotechnology and Work Health and Safety'.[114] This page refers to SWA having a Nanotechnology Work Health and Safety Program, pursuant to which SWA provides policy direction, conducts research and provides guidance on the potential work safety and health implications from nanotechnology applications. It also states that the Nanotechnology Work Health & Safety Program supports the NETS. Under a tab relating to 'Nanotechnology Work Health and Safety Regulatory Issues', there is a link to the Australian Review.[115]

2 *Gaps Filled?*

(a) Hazardous Substances

Potential Gap 1 — determination of whether something is a hazardous substance will be made in reference to certain classes of hazardous substances, whether or not they are, or contain, nanomaterials

Although the terminology of the new regulatory framework differs to that reviewed in 2007, classification of substances as a HC (or HS as it was then) is still done using a system that does not expressly address nanotechnologies. However, there are now specific references to nanomaterials in the guidance documents, and recommendations on labelling and SDS state that there may need to be specific note that nanomaterials are involved. SWA is also working to develop and gather information to allow classification of nanomaterials to occur.

Potential Gap 2 — whether the current human risk assessment protocols based on conventional methods are suitable for nanomaterials

The HSE Working Group, of which SWA is a member, is working to address possible gaps in risk assessment protocols.

Potential Gap 3 — the existing regulatory framework provides for exemptions to the regulatory requirements including experimental use (R&D)

The new regulatory scheme makes some changes to the previous exemptions, although as discussed above, there are still some uncertainties.

Potential Gap 4 — regulatory limits based on quantity thresholds for some hazardous substances may be inappropriate

The HSE Working Group, of which SWA is a member, is working to address possible gaps in data on nanomaterials.

114 Work Safe Australia, *Nanotechnology and Work Health and Safety* <http://www.safeworkaustralia.gov.au/sites/swa/whs-information/nanotechnology/pages/nanotechnology>.

115 Work Safe Australia, *Nanotechnology Work Health and Safety Regulatory Issues* <http://www.safeworkaustralia.gov.au/sites/swa/whs-information/nanotechnology/pages/nanoregulatoryissues>.

(b) Dangerous Goods

Potential Gap 1 — regulated persons must determine classification as DG

See Potential Gap 1 regarding HS above.

Potential Gap 2 — in some cases, determination of whether something is a DG will be made in reference to certain classes of DGs, whether or not they are, or contain, nanomaterials

See Potential Gap 1 regarding HS above.

Potential Gap 3 — whether the current human and environmental risk assessment protocols based on conventional methods are suitable for nanomaterials

See Potential Gap 2 regarding HS above.

F *Australian Customs Service (Customs)*

Customs is Australia's primary border protection agency, with the movement of goods and people across Australia's borders governed by a number of pieces of legislation such as the *Customs Act 1901* (Cth). As noted by the Australian Review, Customs will play an important role in safeguarding Australians with respect to nanotechnologies by virtue of its power to control goods[116] entering Australia, including those containing nanomaterials. This includes, for example, toys for children, sporting goods, and clothing that incorporate nanomaterials of one kind or another. Therefore, it is not surprising that Customs is one of the agencies represented on the HSE Working Group.

By virtue of being a 'good' imported into Australia, goods fall under the regulatory remit of the Service and not as a consequence of nanomaterials being incorporated into the good. A number of products containing nanomaterials may also fall under the scope of the *Customs (Prohibited Imports) Regulations 1956* (Cth) ('*C(PI) Regulations*'). However, as with the *Customs Act*, the trigger for the application of this legislative instrument will not be whether the goods contain nanomaterials, but whether the goods are listed in the Schedules of the *C(PI) Regulations.*

The Australian Review found that while Customs has the ability to prohibit or restrict the importation of certain goods, Customs is not required to undertake a case-by-case safety or hazard assessment of goods imported into Australia. Accordingly, it is likely that many goods containing nanomaterials will enter the country without Customs having knowledge of the presence of nanomaterials in the goods. Moreover, Customs does not have a post-market monitoring power in relation to goods imported into the country. This situation has not changed

116 As defined in *Customs Act 1901* (Cth) s 4.

generally, or in relation to nanotechnologies more specifically, since the Australian Review.

While Customs is represented on the HSE Working Group, it would appear that its role on the Working Group is primarily to enable the Group to maintain a 'watching brief on the work of other regulators',[117] as opposed to playing an active role in policy development. A similar watching brief appears to have been maintained in relation to the international landscape. However, Customs has publically maintained the status quo in relation to its policy stance on nanotechnologies.

1 *Gaps Filled?*

Potential Gap 1 — prohibition of imports of certain goods into Australia and export of goods out of Australia is based on defined classes

Goods may be prohibited for import into or export from Australia on the basis of a defined class of good (eg product type). This approach does not differentiate between products of the same type that do and do not contain nanomaterials. This approach has not been changed since the Australian Review.

G *Department of Infrastructure and Transport (DOIT) (previously called Department of Transport and Regional Services (DOTARS))*

The Australian government department now called DOIT remains responsible for transport safety, including the transport of dangerous goods and for representing Australia on the UN Committee of Experts on the Transport of Dangerous Goods. The legislation considered in the Australian Review has been replaced, but the framework continues to be underpinned by the *Australian Code for the Transport of Dangerous Goods by Road and Rail* ('*ADG Code*').[118] The *ADG Code* continues to have no specific provisions for nanotechnology.[119] The new

117 Department of Innovation, Science and Research, *National Enabling Technologies Strategy (NETS): Annual Report 2009–10*, above n 58, 15.

118 National Transport Commission, *Australian Code for the Transport of Dangerous Goods by Road and Rail* (7th ed, 2011). The *Model Act on the Transport of Dangerous Goods by Road or Rail Act 2007* (Cth) and the *Model Subordinate Law on the Transport of Dangerous Goods by Road or Rail 2007* (Cth) have replaced the *Road Transport Reform (Dangerous Goods) Regulations 1997* (Cth) and the *Rail (Dangerous Goods) Rules 2007* (Cth). The model Act and Subordinate Law can be found in the *National Transport Commission (Model Legislation — Transport of Dangerous Goods by Road or Rail) Regulations 2007* (Cth) sch 1.

119 The *ADG Code*, which was in its 6th edition at the time of the 2007 Review, has now been published in its 7th edition ('*ADG7*') and was revised in 2011. This newer version of the Code adopts the structure, format, definitions and concepts of the United Nations Recommendations on the Transport of Dangerous Goods Model Regulations but retains some Australian specific provisions. Department of Infrastructure and Transport, *The Australian Dangerous Goods Code 7th Edition* (22 August 2012) <http://www.infrastructure.gov.au/transport/australia/dangerous/dg_code_7e.aspx>. See also NTC Australia, *Summary of Key Changes to Australian Dangerous Goods Code 7th Edition* (September 2008) <http://www.ntc.gov.au/filemedia/bulletins/SummaryofKeyChangestoADG7_Sep08.pdf>.

regulatory framework also continues to include exemptions for the transport of small quantities.

An independent statutory authority, the National Transport Commission ('NTC'), has the ongoing responsibility to develop, monitor, and maintain uniform or nationally consistent regulatory and operational reforms relating to road, rail, and intermodal transport and now reports to the Standing Council on Transport and Infrastructure ('SCOTI') (NTC previously reported to the Australian Transport Council ('ATC')) which comprises the Australian transport ministers. SCOTI has not explicitly addressed the issue of nanotechnology.

The Australian Review anticipated that this regulatory framework would be relevant to at least some nanofamilies. Given some regulators are reporting nanoproducts falling under their frameworks, it is likely some are also being transported. Whether they are dangerous goods is unclear.

Like Customs, DOIT is a member of the HSE Working Group, but does not appear to have played an active role in policy development. Although there have been changes to the regulatory framework, there have been no changes in relation to nanotechnology. Finally, none of the DOIT, NTC or SCOTI websites have any specific links to information regarding nanomaterials or the Australian Review.

1 *Gaps Filled?*

Potential Gap 1 — regulated person must determine classification as DG

Transport and packaging requirements and also safety equipment requirements continue to be dependent on the good's classification as a dangerous good. Responsibility for classification is left to the regulated person. They must classify the good either because the particular good is already listed in the ADG Code, or by determining whether it satisfies the criteria in the ADG Code. As with the previous regulatory framework, the criteria link to the UN dangerous goods classes, which in turn refer back to the *GHS* discussed in relation to the SWA above. As noted in regards to the SWA, the *GHS* does not expressly deal with nanomaterials. However, unlike the HC regime administered by SWA no advice is given to regulated persons with respect to nanoproducts.

Potential Gap 2 — for some classes of dangerous goods, whether or not a good is a dangerous good is decided irrespective of whether nanomaterials are present

This approach does not differentiate between products of the same type that do and do not contain nanomaterials. This approach has not been changed since the Australian Review.

Potential Gap 3 — international documents incorporated into regulatory framework may or may not be appropriate for nanomaterials

Reference continues to be made to international documents which do not in turn have express provision for nanoproducts.

H *Food Standards Australia New Zealand (FSANZ)*

FSANZ is the Australian national food regulator, and is responsible for food, food packaging, labelling, and processing. Whilst there are specific requirements regarding certain foods sold in Australia (and New Zealand), including restrictions or prohibitions on the addition of substances to foods (including food additives, processing aids and nutritive substances) and on the sale of certain foods (such as genetically modified foods), many foods and food products are not specifically regulated. State legislation always imposes a generally applicable obligation that food generally must be fit for human consumption.

The Australian Review identified existing examples and potential future products and applications in the Food Processing and Production nano-family that are particularly relevant to this regulator.[120] Nevertheless, from publicly available data provided by FSANZ, the organisation has still not received any applications to approve nanoparticles in foods although it has noted that

> we have undertaken a detailed assessment of the pharmacokinetics of nanoparticles as a potential cause of novel toxicities. This information will serve to underpin the risk assessment of novel nano-particulates in food in the event that we receive an Application.[121]

1 *'Nano-Specific' Action since the Australian Review*

In 2011, FSANZ published a paper on its regulatory approach to nanotechnology in an international journal.[122] In that paper, FSANZ states that it

> has assessed the capacity of the food regulatory framework in Australia and New Zealand to manage any human health risks posed by nanotechnologies under the existing legislation, the Australia New Zealand Food Standards Code, and risk assessment framework.[123]

The responses taken by FSANZ to that assessment have been operational or administrative in nature. As noted above, some foods are specifically regulated,

120 Ludlow, Bowman and Hodge, above n 1.

121 FSANZ, *Emerging Public Health and Safety Issues* (18 January 2013) <http://www.foodstandards.gov.au/scienceandeducation/publications/annualreport/annualreport20092010/regulatorystandards10/emergingpublichealth4929.cfm>.

122 Nick Fletcher and Andrew Bartholomaeus, 'Regulation of Nanotechnologies in Food in Australia and New Zealand' (2011) 1(2) *International Food Risk Analysis Journal* 33 <http://www.intechopen.com/source/pdfs/26273/InTech-Regulation_of_nanotechnologies_in_food_in_australia_and_new_zealand.pdf>.

123 Ibid 33.

and require prior assessment and approval before first sale in Australia. In 2008, the FSANZ *Application Handbook* was amended to specifically address nanotechnology in these types of foods.[124] Following amendment, application forms for foods requiring preapproval such as new substances added to food and novel foods, expressly require information on inter alia, particle size, size distribution and morphology as well as any size-dependent properties. It is interesting to note here that the paper's authors point out that by requiring information on all particle sizes, the regulatory framework is not tied to any particular definition or understanding of the term 'nano'.

In relation to food that has already been approved for sale in Australia but which could now incorporate nanoscale particles, the paper admits the 'regulatory pathway' is less certain. The paper's authors point out that the general requirements of state and territory legislation requiring food to be safe for human consumption apply and that 'FSANZ also has the capacity to establish relevant restrictions in the Code should it become aware of a risk posed by a nanoscale material of an existing substance approved under existing Standards'.[125] There have been no relevant changes to the Code.

With respect to food packaging,[126] the paper repeats that the general requirement that food be safe for human consumption applies. However, there is no response to the deficiency raised by the Australian Review that the Standard itself only forbids contact if it is 'likely to cause bodily harm' and that lack of knowledge regarding nanotechnology means this is unlikely to apply. The paper does note though that

> FSANZ is currently reviewing regulatory requirements for food packaging materials in Australia and New Zealand to determine whether there is a need for change to current requirements, including a consideration of the application of nanotechnologies in this area.[127]

The paper also notes that modifications to current risk assessment methodologies may be necessary to deal appropriately with nanoscale materials.[128] However, further research including pharmacokinetic studies and monitoring of nanotechnology developments are needed.

FSANZ is now considering amending its approach to novel foods, a group into which some (although not all) nanofoods may fall. In the words of FSANZ in relation to these foods generally (rather than with respect to nanofoods):

> some of these foods and substances are not adequately captured by the current prohibitions in the Code for … novel foods and are therefore entering the market without an appropriate level of pre-market assessment.

124 FSANZ *Application Handbook — Amendment No 2 — 2008*.

125 Fletcher and Bartholomaeus, above n 122, 35.

126 Standard 1.4.3 — more specifically articles and materials in contact with food.

127 Fletcher and Bartholomaeus, above n 122, 35.

128 Ibid 36.

> In addition, a number of foods and substances captured by these definitions do not warrant pre-market assessment.[129]

As noted in the Australian Review, it is unclear whether food or packaging incorporating nanomaterials or substances or food produced using nanotechnology are novel foods, and therefore need to go through a safety assessment prior to sale or import. The applicability of this standard to 'nano-foods' is still not clear. The Consultation Paper — on whether a new approach to novel foods is generally required and what that approach should be —has only recently been released to the public, yet does not expressly refer to nanotechnology issues.

There is extensive information on the FSANZ webpage regarding nanotechnology. Amongst other references on the webpage, there is a link to a fact sheet on 'Nanotechnology and Food'.[130] This sheet has a link to the DIISR and Tertiary Education website, in particular to the Department's webpage on nanotechnology.

In its international journal article on FSANZ's regulatory approach to nanotechnology, it says

> FSANZ has sought to inform the public debate through the development of fact sheets, web videos, presentations at international conferences outlining the FSANZ regulatory strategy on nanotechnologies, informed media comment and participation in public discussions.[131]

FSANZ is also a member of the HSE Working Group.

2 *Gaps Filled?*

Potential Gap 1 — whether existing substances reformulated at the nanoscale would be considered as new 'foods' or 'food contact materials'

It seems reformulated substances would not be considered new. However, if the substance then had a different technological function, it would be and would need to be specifically approved.

Potential Gap 2 — maximum limits based on weight may be inappropriate for nanomaterial forms

As for all foods, FSANZ relies on the regulated persons to decide whether the use or presence of nanomaterials makes a food likely to harm or unsafe or unfit for human consumption. However, FSANZ is actively involved with international bodies and the HSE Working Group to develop further scientific data on human safety issues that can inform its future approach to these issues.

129 FSANZ, 'Proposed Future Regulation of Nutritive Substances and Novel Foods in the *Australia New Zealand Food Standards Code*' (Consultation Paper, 26 March 2012) 7.

130 FSANZ, *Nanotechnology and Food* (December 2011) <http://www.foodstandards.gov.au/consumerinformation/nanotechnologyandfoo4542.cfm>.

131 Fletcher and Bartholomaeus, above n 122, 38.

Potential Gap 3 — labelling provisions may not be appropriate for foods and food contact materials containing nanomaterials for protection of human health and safety

Unlike SWA, FSANZ has not made any recommendations for labelling where a food or food packaging contains nanomaterials.

Potential Gap 4 — international documents incorporated into regulatory framework may or may not be appropriate for nanomaterials

FSANZ is actively involved with international bodies such as the UN FAO, which is in turn looking at this issue.

I *Gene Technology Regulator (GTR)*

The GTR regulates the undertaking of gene technology and dealings with genetically modified organisms ('GMOs') in Australia. At the time of the Australian Review, it was recognised as possible that nanotechnology could be used in this arena,[132] but no nano-family fell clearly within this sphere. Since the review, an application for approval to undertake research on a project involving a combination of nanotechnology and gene technology has been assessed by the GTR.

1 *'Nano-Specific' Action since the Australian Review*

There have been no legislative changes relevant to nanotechnologies since the Australian Review. However, administrative processes have been adjusted to explicitly address the possible involvement of nanomaterials in gene technology or GMOs. For example, forms have been updated to seek information about the involvement of nanotechnology. In particular, the application forms for both DNIR (for dealings that do not involve the intentional release of a GMO into the environment) and DIR (for dealings that do involve the intentional release of a GMO into the environment) licences, require specific information about whether the proposed dealings involve nanotechnology or inclusion or production of nanoparticles.[133]

In September 2011, The University of Queensland notified the GTR that its Institutional Biosafety Committee ('IBC') had approved a NLRD (Notifiable

132 See, eg, Ludlow, Bowman and Hodge, above n 1, 73.

133 Office of the Gene Technology Regulator, *Application for Licence for Dealings with a GMO Involving Intentional Release of the GMO into the Environment (DIR)* (April 2009) 14 <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirform-1/$FILE/dirform5.pdf>; Office of the Gene Technology Regulator, *Application for Licence for Dealings with a GMO Not Involving Intentional Release of the GMO into the Environment (DNIR)* (August 2011) 15 <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dnir-form2011-htm>.

Low Risk Dealing) involving both gene- and nanotechnology.[134] The project is called 'Micro-nano projection patches (Nanopatch) for targeted vaccine and drug delivery to the skin'. Whilst the IBC must record its assessment decision and provide that to the GTR if requested, that information is not available to the public. Based on media reports, it seems that a skin patch will use nano-sized projections to introduce DNA vaccines to the skin without the use of a syringe.[135] The form reporting the approval of the project to the GTR would not have made the involvement of nanotechnology apparent to the GTR as that information is not expressly asked for in that form.

While the GTR's website does not provide information regarding nanotechnology, some of the forms used by the GTR now include a statement on the issue. The DNIR and DIR licence application forms include the statement:

> The Australian Government has committed to taking a proactive approach in monitoring developments in nanotechnology so as to ensure the regulatory frameworks charged with protecting public health, safety and the environment keep pace with these changes.

The GTR is also a member of the HSE Working Group.

2 *Gaps Filled?*

Potential Gaps 1 and 2 — risk assessment protocols focus on gene technology risks and are based on conventional materials

It is not known whether the risk assessment protocols used by the GTR are suitable for nanomaterials. Given that this regulatory scheme regulates gene technology and the risks it poses (not nanotechnologies), the limited changes that have been made to the GTR's administrative processes appear appropriate and perhaps more than expected. Those uses of gene technology undertaken other than under the context-based licence approval process where application forms expressly refer to nanotechnology, would be undertaken in laboratories. Laboratories must comply with other regulatory schemes which can more properly regulate for nanotechnology concerns, such as OH&S regulations discussed above (see SWA) and, where a product is developed for use, by the end product regulators, such as APVMA.

J *NICNAS*

The National Industrial Chemicals Notification and Assessment Scheme ('NICNAS') is Australia's regulator of industrial chemicals. Pursuant to the

134 *NLRD-4681*: Office of the Gene Technology Regulator, *List of NLRDs as Notified to the Gene Technology Regulator* (July 2012) <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/appslisting-1/$FILE/nlrdrecjul12.pdf>.

135 ABC Radio Australia, 'Nanopatch — No Pain Vaccination Gets a Boost', 28 February 2012 (Desley Blanch) <http://www.radioaustralia.net.au/international/radio/onairhighlights/nanopatch-nopain-vaccination-gets-a-boost>.

Industrial Chemicals (Notification and Assessment) Act 1989 (Cth) ('*ICNA Act*'), NICNAS is required to 'provide for a national system of notification and assessment of industrial chemicals and providing information, and making recommendations about, the chemicals to Commonwealth, state and territory bodies with responsibilities for the regulation of industrial chemicals.'[136] NICNAS is required to undertake assessments of industrial chemicals within Australia in order to protect human and environmental health and safety; its focus is on chemical entities and not products. Regulation of industrial chemicals beyond the point of sale remains the responsibility of state and territory governments, in partnership with those regulators concerning OH&S, environment, public health, and transport.

At the time of the Australian Review, specific examples of existing and future industrial chemicals that would fall under the regulatory scope of NICNAS included items such as carbon nanotubes, buckyballs, paints and coatings containing nanomaterials and cosmetic products, such as foundations and moisturisers that contain nanomaterials. NICNAS's own research on the use of nanomaterials in 2008 — a second voluntary call for information — indicated that the largest use of nanomaterials in Australia at that time was in surface coatings.[137] While recognising the limitations of the voluntary call, the regulator made the following observations:

> All six of the reported nanomaterials that were used in commercial applications or research are nanomaterials that have a bulk conventional form. The largest use by volume of nanomaterial was acrylic latex used in surface coatings in the range 1,000–10,000 tonnes. Zinc oxide followed next in volume of up to 5 tonnes/year in surface coatings and a similar volume in exterior timber coatings. All other reported nanomaterials were used in volumes of less than 1 tonne/year.[138]

While the market reality may be somewhat different to the findings garnished by NICNAS through the voluntary call, they would appear to provide the regulator with at least some sense of what is happening in the Australian market and identify particular nanomaterials that may be of 'interest' to NICNAS.[139]

1 *'Nano-Specific' Action since the Australian Review*

The response of NICNAS to the Australian Review is arguably impressive, with the regulator having undertaken a number of activities, engagements and reviews since the Australian Review. The most significant activity to date is the introduction of a new administrative process for the notification and assessment of industrial nanomaterials that are considered new chemicals. Including a working

136 *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth) s 3.

137 NICNAS, *NICNAS Information Sheet: Summary of 2008 Call for Information on the Use of Nanomaterials* (November 2010) <http://www.nicnas.gov.au/Publications/Information_Sheets/General_Information_Sheets/NIS_Results_Call_for_Information_2008_Nov_2010_PDF.pdf>.

138 Ibid 2.

139 Ibid.

definition of an 'industrial nanomaterial' for the purposes of the process, this process came into effect on 1 January 2011.[140] Pursuant to the process, substances require a NICNAS permit or certificate if introduction is to continue after that date. This is discussed in more detail below in relation to the potential gaps.

Looking across the Scheme, NICNAS has undertaken a range of public activities since the Australian Review. The Scheme provides an up-to-date website for nanotechnologies, which contains numerous resources for the interested public.[141] Information on nanomaterials can be found on this site, and generally includes:

- Determining the volumes, types and data holdings of nanomaterials that are being used within Australia as industrial chemicals via a voluntary call for information directed to industry and researchers;
- Keeping abreast of, and influencing, international developments in nanomaterials by active participation in the OECD Working Party on Manufactured Nanomaterials;
- Creation of a NICNAS Nanotechnology Advisory Group to advise on strategic directions NICNAS might take in addressing the potential impacts of nanomaterials as industrial chemicals …[142]

Additional activities, reported by the AON[143] and NETS[144] include:

- building technical expertise in-house, including knowledge related to risk assessment and modelling
- commissioning technical consultancies of the HSE literature
- engaging with the public about the regulation of nanomaterials through a public consultation process
- publication of numerous publications dealing with nanotechnologies and
- contributing / supporting capacity building workshops, which has most recently included one in partnership with the APVMA on nanotechnology regulation (held in November 2011).

NICNAS is also contributing to the coordinated national approach to nanotechnology through its membership of the HSE Working Group.

140 NICNAS, *Guidance on New Chemical Requirements for Notification of Industrial Nanomaterials* (2010) <http://www.nicnas.gov.au/current_issues/Nanotechnology/Guidance%20on%20New%20Chemical%20Requirements%20for%20Notification%20of%20Industrial%20Nanomaterials.pdf>.

141 See NICNAS, *Nanomaterials* (12 December 2012) <http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp>.

142 NICNAS, *Nanotechnology — Your Online Guide — Nanotechnology Advisory Group* (14 December 2012) <http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Nanotechnology_Advisory_Group.asp>.

143 Australian Office of Nanotechnology, *National Nanotechnology Strategy (NNS) Annual Report 2007–08*, above n 21.

144 Department of Innovation, Science and Research, *National Enabling Technologies Strategy (NETS): Annual Report 2009–10*, above n 58.

NICNAS's Online Guide to nanotechnologies and the public consultation discussion document[145] make explicit reference to the Australian Review and contain links to the report. A number of the activities listed above highlight how the regulator is progressively assessing and addressing the potential gaps identified by the Review. Of particular relevance are the following activities undertaken by the regulator:

- a secondary voluntary call for information on nanomaterials
- continuing to be involved in, and building linkages with, national and international agencies and bodies looking at the regulation of nanomaterials
- development of a Regulatory Reform of Industrial Nanomaterials strategy, underpinned by a public consultation process, which involved a discussion paper, questionnaire, business impact survey, presentations at several specialised forums and public workshops in Melbourne and Sydney (2009–2010)
- adoption of a new administrative process for the notification and assessment of 'new' chemicals that fall within the definition of an industrial nanomaterial, which took effect from 1 January 2011, and
- adoption of a working definition of an 'industrial nanomaterial' for the purposes of this new administrative process.[146]

The 2009–10 stakeholder consultation process directly addressed many of the triggers raised by the Australian Review. As noted in the Discussion document:

> Many industrial nanomaterials however are nano-forms of existing chemicals, (that is chemicals on the national inventory), that can legally be introduced and used without notification to NICNAS but have not been assessed for their novel nano-scale properties. Consequently these chemicals are not required to undergo a pre-market assessment and there is uncertainty in some cases about the health and environmental impacts. A consequence of current existing chemical obligations and exemption categories is that the extent of use of industrial nanomaterials in Australia is uncertain. NICNAS proposes to use legislative and administrative changes detailed via options in this Paper to address this issue. *These options address the 'gaps' identified by the [Australian Review] that are relevant to the industrial chemicals regulatory framework*.[147]

145 NICNAS, 'Proposal for Regulatory Reform of Industrial Nanomaterials' (Public Discussion Paper, November 2009) <http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Stakeholder_Consultation_2009_10/Nanotechnology_Discussion_Paper_2009/NICNAS_Nano_Public_Discussion_Paper_2009_PDF.pdf>.

146 Ibid; NICNAS, *Guidance on New Chemical Requirements for Notification of Industrial Nanomaterials*, above n 140.

147 NICNAS, 'Proposal for Regulatory Reform of Industrial Nanomaterials', above n 145, 5–6 (emphasis added).

As noted above, the public consultation preceded the adoption of new administrative processes for 'new' chemicals that fell within the regulator's definition of an industrial nanomaterial.

2 *Gaps Filled?*

Potential Gap 1 — 'new' versus 'existing' substances when reformulated at the nanoscale

Chemicals that appear on the Australian Inventory of Chemical Substances ('AICS') that are reformulated on the nanoscale are still considered to be 'existing' substances for the purposes of triggering regulatory oversight. As such, an importer or producer of a chemical substance that is already on the AICS — such as titanium dioxide, which is reformulated at the nanoscale — will not be required to notify NICNAS of the importation/production of the chemical substance.[148] That being said, NICNAS continues to have the power to assess existing chemicals under the Prior Existing Chemicals Assessment Regime.

The introduction of the new administrative process for 'new' industrial chemicals that fall within the definition of an 'industrial nanomaterial' does not address this potential gap per se. Rather, the administrative process is focused on only those chemicals that are not already listed on the AICS. For these 'new' nano-forms of industrial chemicals, changes to the administrative process have been summarised by NICNAS as follows:

- exclusion of the introduction of nanomaterials through exemption categories where human or environmental exposure can reasonably be anticipated, thereby converting the current post-market compliance approach for exemptions to a pre-market assessment approach, and
- exclusion of self-assessments by industry, thereby ensuring that NICNAS undertakes pre-market assessment of all new nanomaterials.

Introducers reporting use under exemption categories, and those applying for certificates or permits will be required to declare that their chemicals are not nanomaterials. More specific information (such as particle size, shape and other specific information on properties) may be required under specified conditions. In addition, NICNAS may stipulate permit conditions for conventional chemicals where it can be reasonably assumed that a nano-form may be introduced in the future.[149]

148 NICNAS, *NICNAS Information Sheet — Adjustments to NICNAS New Chemicals Processes for Industrial Nanomaterials* (December 2010) <http://www.nicnas.gov.au/Current_Issues/Nanotechnology/FAQs_Nano_Adjustments_for_New_Chemicals_Processes_Dec_2010.pdf>.

149 Ibid 2.

Potential Gap 2 — triggers on the basis of weight or volume

The status quo has been retained in relation to the 100 kilogram threshold per person per calendar year for a new chemical for triggering the regulatory oversight.

The new administrative process does, however, include reference to mass thresholds for new nano-forms of industrial chemicals in relation to the exemption categories. Pursuant to these new procedures:

> From 01 January 2011, nano-forms of new chemicals will not be permitted under exemption categories where human and/or environmental exposure can reasonably be anticipated, these being:
>
> - Low volume cosmetic and non-cosmetic exemptions (S21(4))
> - Low concentration (<1%) non-hazardous cosmetic exemption (S21(6c)).
>
> Introducers who advise NICNAS of introductions under these exemption categories will be required to declare that their chemicals are not nanomaterials, according to the NICNAS working definition above.
>
> The following exemption categories will remain available for nanoforms of new chemicals:
>
> - Transhipment exemptions — current conditions of introduction remain unchanged (S21(6b))
> - R&D exemptions S21(6a) — with some amendments to the annual reporting requirements. All nanomaterials introduced in volumes over *100g/year* will be identified as nanomaterials and their full chemical name provided.[150]

Potential Gap 3 — whether the current risk assessment protocols based on conventional methods are suitable for nanomaterials

NICNAS has examined the appropriateness of current risk assessment protocols for nanomaterials through several avenues. This includes a review of the scientific literature on six nanomaterials,[151] as well as engaging with the ISO and the OECD in relation to guidance for additional data requirements for nanomaterials.[152]

As part of the recently introduced administrative processes for new nanomaterials, NICNAS has the authority to require additional data on the new nano-scale industrial chemical. As the regulator notes:

150 NICNAS, 'Adjustments to NICNAS New Chemicals Processes for Industrial Nanomaterials' in Commonwealth, *Chemical Gazette*, No C 10, 5 October 2010, 14, 14–15 (emphasis added).

151 Brian G Priestly, 'Review of 2007–09 Literature on Toxicological and Health-Effects relating to Six Nanomaterials' (Scientific Review Report, NICNAS, 30 October 2009).

152 NICNAS, *Guidance on New Chemical Requirements for Notification of Industrial Nanomaterials*, above n 140.

As a minimum requirement particle size information (primary particle size and number-weighted size distribution) will be required in the following cases:

- where the chemical is an industrial nanomaterial
- where it can be anticipated or there is uncertainty that the chemical could be a nanomaterial and exposure to human health or the environment is expected based on use scenarios

AND

- the chemical is introduced as a solid/powder or as a dispersion and is insoluble (eg water insolubility < 1 mg/L); and/or known to be biopersistent.[153]

NICNAS also has the authority to require additional data under the notification category under certain circumstances.[154]

Combined with the ability to request additional information relating to the physico-chemical characteristics of the nanomaterial, these activities should assist the regulator with determining whether or not the current risk assessment protocols are appropriate for those materials which they are required to assess.

K *Intellectual Property Rights (IPRs) and IP Australia*

Despite the ToR focusing the review of Australia's regulatory frameworks on potential human and environmental risks associated with nanotechnologies, the authors of the Australian Review were required to consider the application of certain Australian intellectual property laws to the technology. The authors found that the two key legislative instruments — the *Copyright Act 1968* (Cth) and the *Trade Marks Act 1995* (Cth) — while triggered by the technology, are not directly relevant to the ability of Australia's regulatory systems to handle potential human and environmental risks associated with the technology.

While IPRs are and shall remain important in relation to nanotechnologies, agencies such as IP Australia (or their equivalents, such as the US Patent and Trademark Office), do not wield risk management or regulatory powers.[155] One can assume it is for these reasons that IP Australia is not a standing member of the HSE Working Group.

While several of their counterparts, such as the US Patent and Trademark Office, have implemented a class definition for nanotechnology patents,[156] IP Australia

153 Ibid 3.

154 Ibid.

155 Gregory N Mandel, 'Regulating Nanotechnology through Intellectual Property Rights', in Graeme A Hodge, Diana M Bowman, and Andrew D Maynard (eds), *International Handbook on Regulating Nanotechnologies* (Edward Elgar, 2010) 388.

156 See, eg, the definition used by the USPTO for Class 977: United States Patent and Trademark Office <http://www.uspto.gov/web/patents/classification/uspc977/defs977.htm>.

has refrained from creating such a distinction. Whether such a move will be forthcoming remains to be seen. However, the recently completed survey of the international nanotechnology patent landscape — with a particular focus on nanotechnology patenting in Australia — commissioned by DIISR, may provide IP Australia with some of the qualitative data needed to make such decisions.[157]

VI DISCUSSION AND CONCLUSIONS

While the Australian Review was focused on the Australian context, the method we developed and employed in undertaking the analysis has broader scope. For Brown,

> the [Australian Review] is exemplary in providing a thorough review of the way nanomaterials are covered by existing regulations. This is a very useful starting point, as it is implausible that good governance could be established without understanding the difficulties that nanotechnology presents for each country's existing regulations. Most other countries have yet to attempt such a report.[158]

Following on from this critique, Gavaghan and Moore — who were commissioned to assess the adequacy of New Zealand's federal regulatory framework for nanotechnologies in 2010 — noted the following: 'Our approach has closely followed that adopted in the report conducted by staff at Monash University in 2007, regarding Australia's regulatory frameworks'.[159]

To determine the impact of the Australian Review on Australian regulatory policy, it is important to step back and reexamine the purpose of the review, as well as the broader objectives associated with the commissioning of such an independent report. In 2006, NNST recommended that there be an assessment of 'whether [Australia's] current regulatory framework is appropriate in light of nanotechnology … priorities'.[160] Under the RFT instructions, the consultants were to 'analyze the gaps, if any, in Australia's existing regulatory framework to address nanotechnology, but will not make recommendations on addressing these gaps'.[161] No assessment of the significance of any identified gaps was therefore made.[162] On a superficial level then, the delivery of the report in June 2007 fulfilled its purpose because the report identified the relevant gaps. However, the true purpose and what this five-year assessment seeks to assess is the impact of the Review's findings.

157 E White, *Nanotechnology IP Landscaping Analysis* (Thomas Reuters IP Consulting, 2011).

158 Simon Brown, 'The New Deficit Model' (2009) 4 *Nature Nanotechnology* 609, 611.

159 Gavaghan and Moore, above n 14, 6.

160 National Nanotechnology Strategy Taskforce, *Options for a National Nanotechnology Strategy — Report to Minister Industry, Tourism and Resources* (2006).

161 Department of Industry Tourism and Resources, *Request for Tender — Requirement: Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework* (August 2006).

162 Ludlow, Bowman and Hodge, above n 1, 8.

The Australian Review has arguably had a significant impact on Australian regulatory and policy discourse on nanotechnologies. All of the regulatory schemes responsible for end products — agricultural chemicals, veterinary medicines, food / food packaging, therapeutic goods — have responded to the gaps identified by the authors of the Australian Review in one manner or another. The regulator responsible for workplace safety has also responded. The approach adopted by these regulatory agencies may generally be considered as incremental, with none of the agencies having adopted wholesale changes to their instruments or regimes. This can be contrasted to the recent reforms in the EU, in which several legislative instruments, as part of broader reform programs, were passed with nano-specific articles within their text.[163]

Those regulators primarily responsible for regulating intended 'activities' rather than end products — gene technology, road and rail transport, the environment and imports/exports — have responded to a lesser degree. There are good explanations for this — the central one being that fewer, if any, gaps were identified in these regulatory schemes.

Similarly, if the regulatory schemes are grouped according to the type of prior regulatory approval required before the end product or activity can be sold, used, or done (Criteria 2 in the Australian Review), those regimes involving traditional approval or registration processes (such as those followed by APVMA, NICNAS, GTR and TGA) are more likely to have fully responded than those requiring proponents to first satisfy themselves as to the safety of the intended activity before undertaking it (such as DOTARS as it was then). This may be because the gaps identified for the second group were not significant. But it could also be because the proponent, being a member of the public rather than part of the regulatory agency, is being left with the responsibility to ensure proper steps are taken.

It is also important to note that some regulatory agencies — such as DOIT — may be limited by legislation/regulation in terms of the actions and activities that it can undertake; for instance, DOIT does not have the necessary power to call on the public for information.

In the case of several of the regulatory agencies, and in particular the APVMA and SWA, the response to nanotechnologies has coincided with extensive changes to their respective regulatory schemes.

Why was the impact of the Australian Review so great? We would argue that the major contributing factor here is due to the involvement of the regulatory agencies and individuals within these agencies on the HSE Working Group at the time that the Review was commissioned. These individuals, and the Working Group itself, appear to have been committed to the process of the Review, as well as to acting on the key findings arising from it. The Working Group continues to

163 See, eg, Qasim Chaudhry, Anna Gergely and Diana M Bowman, 'Regulatory Frameworks for Food' in Qingrong Huang (ed), *Nanotechnology in the Food, Beverage and Nutraceutical Industries* (Woodhead Publishing, 2012) 85; Diana M Bowman, Geert van Calster and Steffi Friedrichs, 'Nanomaterials and the Regulation of Cosmetics' (2010) 5(2) *Nature Nanotechnology* 92.

be comprised of high level experts, drawn from their respective agencies/bodies, many of whom are champions of not only nanotechnologies per se, but the broader context in which the technology falls. As such, it would appear that the Group has an inherent interest and commitment to ensuring the safe and responsible introduction of nanotechnologies into the Australian market.

However, there are a number of confounders that we believe may have contributed to the evolving nanotechnology landscape in Australia and the way in which the report was received. This includes, for example, the public release of the document. Organisations such as Friends of the Earth Nanotechnology Project and the Australian Council of Trade Unions were able to utilise the findings of the Review in order to support their own campaigns, and engender support for action within their own constituencies.[164] While the policy impact that these organisations have had may have been less than what they had hoped,[165] they have been successful in attracting the attention of the media and pushing the debate along.

Unlike several of the other reviews that have taken place in jurisdictions such as the US and the EU, the Australian Review was independent. While the authors consulted the relevant regulators to ensure that they had a thorough understanding of how the instruments operated in practice, and accuracy in their analysis of the frameworks, the authors undertook their analysis and drew their conclusions independent of any agenda. While some may argue that the government took a gamble in out-sourcing the review for this very reason, the feedback that we received on this point was positive; to many, it added veracity and credibility to the Review.

The timing of the Australian Review, we would argue, has also been influential in shaping the subsequent responses to its findings. The Australian Government was one of the first governments to conduct such a review in any form. However, since its release, a number of high profile inquiries and reports have been released,[166] and there have been a number of incremental policy and more substantive regulatory changes in some jurisdictions.[167] In sharp contrast to the incremental approach adopted in Australia, the European Union has pushed through a number of more wholesale legislative changes. As part of broader reform and recast measures,

164 See, eg, Friends of the Earth Australia, 'Nano-Ingredients in Sunscreen: The Need for Regulation' (Report, July 2012); Friends of the Earth Australia, Submission to the Review of the National Innovation System, April 2008; Friends of the Earth Australia, Submission to NSW Parliamentary Inquiry into Nanotechnology, March 2008; ACTU, 'Nanotech Poses Possible Health and Safety Risk to Workers and Needs Regulation' (Media Release, 14 April 2009); ACTU, Submission to NICNAS Regulatory Consultation on Proposal for Regulatory Reform on Industrial Nanomaterials, February 2010.

165 Georgia Miller and Gyorgy Scrinis, 'The Role of NGOs in Governing Nanotechnologies: Challenging the "Benefits versus Risks" Framing of Nanotech Innovation' in Graeme A Hodge, Diana M Bowman and Andrew D Maynard (eds), *International Handbook on Regulating Nanotechnologies* (Edward Elgar, 2010) 409.

166 Including, for example, Science and Technology Committee, *Nanotechnologies and Food*, House of Lords Paper Nos 22-I and 22-II, Session 2000–2010 (2010); Royal Commission on Environmental Pollution, *Novel Materials in the Environment: The Case of Nanotechnology*, Twenty-seventh Report, Cm 7468 (2008).

167 See generally Graeme A Hodge, Diana M Bowman and Andrew D Maynard (eds), *International Handbook on Regulating Nanotechnologies* (Edward Elgar, 2010).

the European Parliament and Council have adopted a number of nano-specific provisions in new Cosmetic Regulation and the Food Information to Consumers Regulation.[168] Against this backdrop the European Commission has adopted its own definition of a nanomaterial[169] for the purposes of funding, research and policy. These actions have signalled its intent to be at the forefront of regulatory developments.

Such an approach highlights increasing divergence with not only Australia, but also other countries such as the US.[170] In a similar vein to Australia, the US has focused its attention on utilising existing regulatory tools to more effectively regulate nanotechnologies including, for example, the creation of guidance material for industry by agencies such as the FDA,[171] and the employment of the Special New Use Rule ('SNUR') by the Environmental Protection Agency for carbon nanotubes and buckyballs.[172]

Against these jurisdiction specific activities, we have also seen a number of major transnational programs and activities implemented in order to address some of the challenges posed by nanotechnologies.[173] A comprehensive understanding of the regulatory landscape for nanotechnologies, and the potential strengths and weaknesses thereof, as this momentum has built, has enabled the Australian governments and actors within it to respond from a more considered position than many others.

Similarly, the fact that the Review did not call for wholesale changes to regulatory approaches, but rather identified triggers that may fail to fire appears to be important. As noted above, the Review was received during a time when other jurisdictions were beginning to examine or tweak existing arrangements, including the development of guidance material and employment of existing tools

168 Bowman, van Calster and Friedrichs, above n 163; Jean-Phillipe Monfort, Sebastien Louvion and Leticia Lizardo, *New EU Food Labeling Regulation Published* (November 2011) Mayer Brown <http://www.mayerbrown.com/files/Publication/a8878b90-17fa-4495-a3b1-6aeafafdc212/Presentation/PublicationAttachment/28487465-8029-4295-81ee-6c44471d5300/11870.pdf >.

169 *Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial* [2011] OJ L 275/38.

170 John P Holdren, Cass R Sunstein and Islam A Siddiqui, *Memorandum for the Heads of Executive Departments and Agencies: Policy Principles for the US Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials* (9 June 2011) <http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf>.

171 US Food and Drug Administration, *Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, including Food Ingredients that are Color Additives* (2012).

172 Environmental Protection Agency, *Significant New Use Rules on Certain Chemical Substances 40 CFR Part 721*, 74(120) Fed Reg 29 982 <http://www.epa.gov/fedrgstr/EPA-TOX/2009/June/Day-24/t14780.pdf>; Markus Widmer and Christoph Meili, 'Approaching the Nanoregulation Problem in Chemicals Legislation in the EU and US' in Graeme A Hodge, Diana M Bowman and Andrew D Maynard (eds), *International Handbook on Regulating Nanotechnologies* (Edward Elgar, 2010) 238.

173 These have included, for example, the establishment of ISO/TC229 Nanotechnologies and the OECD Working Party on Nanotechnology and the Working Party on Manufactured Nanomaterials.

such as 'special new use rules' for certain types of nanoparticles.[174] Potential gaps were identified and the authors suggested that a watching brief, as well as more in-depth analysis, was required so as to enable decision makers to address potential gaps in a measured and systematic way. The authors did not suggest that wholesale changes (which were at odds with the world-at-large) were required at that time. Such an approach, we would argue, is likely to be more appealing to those wielding the decision-making powers.

Finally, the Australian Review was received during a time in which the Australian Government acknowledged the need to minimise potential harms associated with the technology to human and environmental health.[175] Under this stated objective, there appears to have been a broad push by DIISR, primarily through the HSE Working Group, to ensure that regulatory frameworks and policies are robust enough to cope with forthcoming products/processes. This overarching focus by the Department appears to have helped pave the way for regulators to undertake their own internal activities, consult and work with their international counterparts through forums such as the OECD, consult with the public and make initial incremental, non-legislative, changes as they have seen fit.

The commercialisation of products containing nanomaterials and nano-objects is still in its infancy. There is still much to be learned from the scientific, social, ethical and legal perspectives. Whether we, as authors of the Australian Review, 'got it right' at the time is one of those unknowns; so too the impact of the Australian Government's response to our findings. What this article highlights is that since the delivery of the Australian Review in 2007, the Australian Government has been proactive in addressing some of the issues and challenges by nanotechnologies within the Australian regulatory landscape.

But this is just the beginning. While we acknowledge that the Government and regulators are unlikely to push for wholesale regulatory changes, we would argue that this is not a time to become complacent. Rather, there appears to be an opportunity for those regulators involved in traditional approval or registration regimes to work with their Australian and international counterparts to develop a sophisticated triage system built on sound scientific principles that addresses the issue of 'novelty' and/or 'uniqueness.' Such a triage system would not have to deal with the contentious issue associated with the debate around particle size, but would focus instead on the very characteristics of the particles that give rise to concern. Such a system, we believe, could be introduced without formal legislative changes, and be designed to evolve with the state of the scientific art.

174 See, eg, Federal Register, Environmental Protection Agency, 40 CFR Parts 9 and 721 [EPA–HQ–OPPT–2008–0252; FRL–8835–5] RIN 2070–AB27 Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules, *Federal Register*, Vol 75, No 180, 56880-56889 (2010).

175 Department of Innovation, Industry, Science and Research, *National Enabling Technologies Strategy*, above n 22.