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Nano-sunscreens - a double-edged sword in protecting consumers from harm: viewing Australian regulatory policies through the lenses of the European Union

S M. Solaiman

University of Wollongong, sheikh@uow.edu.au

Jennifer Algie

University of Wollongong, jenni@uow.edu.au

Shahnaz Bakand

University of Wollongong, sbakand@uow.edu.au

Ronald Sluyter

University of Wollongong, rsluyter@uow.edu.au

Vitor Sencadas

University of Wollongong, victors@uow.edu.au

See next page for additional authors

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Keywords

sword, double-edged, -, nano-sunscreens, union, european, lenses, policies, regulatory, australian, viewing, harm:, consumers, protecting

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Authors

S M. Solaiman, Jennifer Algie, Shahnaz Bakand, Ronald Sluyter, Vitor Sencadas, Michael L. F Lerch, Xu-Feng Huang, Konstantin K. Konstantinov, and Philip J. Barker

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Abstract

Nanotechnology has the potential to bring about revolutionary changes in, manufacturing products, including sunscreens. However, a knowledge gap between benefits and detriments of engineered nano-materials used in sunscreens exists, which gives rise to safety concerns. This article is concerned with the protection of consumers without impairing the embellishment of this promising technology. It is widely argued that the harm associated with nano-sunscreens may only occur under certain conditions related mainly to users' skin vulnerability, which can be avoided by informed and careful use of such a product. We thus recognise the need for fostering the growth of nanotech simultaneously with preventing potential harm. We revisit the Australian sunscreens regulatory policies, which embrace a 'wait and see' approach, through the lens of regulatory policies in the European Union (EU) that are influenced by a 'precautionary principle'. We highlight the importance of informing consumers about the sunscreen they are using, and recommend that product labels should disclose the presence of nano-ingredients in line with the EU disclosure requirements. This will allow users to carefully apply the product in order to avoid any potential harm and to protect manufactures from possible costly litigation in future. This can be achieved through a combined collaborative effort of regulators, supply chain entities and end users.

Keywords: Nano-sunscreens, toxicity, regulatory policies, Australia, European Union

Introduction

Nanotechnology, a revolutionary field of study, is believed to be the catalyst of the next technological revolution in the 21st century (Reynolds 2009; Kaddour 2013), and the potential solution to global challenges, such as cancer and renewable energy (Van Tassel and Goldman 2011). Billions of dollars are being spent throughout the world for research and development of this technology and millions of patents are being granted for nanotech-based innovations thus far (Ouellette 2015). Millions of people around the world have been unknowingly using nano-enabled products every day in good faith, for example nano-sunscreens (Krow 2014). Krow (2014) observes that nano-products are everywhere though consumers are unable to identify them, therefore they are unaware of the underlying risks, which generates erosion of public confidence threatening the commercial viability of this technology. Nanomaterials have the potential of ‘both tremendous beneficence and unimaginable destruction’, though the harm is yet to be categorically identified with certainty (Rucinski 2013; Trivedi and Murase 2017). The national and global incidence of cancer as well as many other complex human diseases and conditions continues to increase unfortunately. New causes of such diseases are continually being identified and in some cases linked to products manufactured and/or utilised decades previously (Australian Institute of Health and Welfare 2018). However, the causes sometimes remain undiagnosed. Currently nanotechnology is experiencing a ‘regulatory lag’ in many countries including Australia, so any uptake of nano-technology needs to ensure the benefits clearly out-weigh any potential detrimental impact.

The year 1989 is said to be the beginning of nanotech (nanotech, technology and nanotechnology used synonymously unless otherwise indicated), which creates nanoparticles for various products including sunscreens and medical diagnostics (Ouellette 2016). Over the past years, phenomenal developments have taken place in utilising this technology, including

the use of nanoparticles of chemicals as ultraviolet (UV) radiation filters in sunscreens, where nanomaterials have been recognised as a ‘key enabling technology’ (EC 2018).

No uniform regulatory definition of nanotech exists, which creates regulatory difficulties in itself (Krow 2014). A definition provided by the International Organisation for Standardization (ISO) describes a nano-object as material with one, two or three of its dimensions in size spanning from 1 to 100 nanometres (a nanometre is a billionth of a metre) (Krow 2014). Similarly, as defined by the United States (US) Office of Science and Technology Policy, nanotech is any technology which embraces ‘the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications’ (Ouellette 2015). The technology creates functional structures of materials with at least one of its dimensions measuring between 1 and 100 nanometres (Nel et al. 2006). Consistently, according to the Australian Office of Nanotechnology, nanotech denotes ‘a collective term for a range of technologies, techniques and processes that involve the manipulation of matter at the nanoscale—the sizes range from approximately 1 nanometre to 100 nanometres’ (Capon et al. 2015a). Nanotech thus deals with engineered nanomaterials at the nanoscale size level and their unique physical and chemical characteristics (Makker 2011). Although decades have elapsed with governments and companies spending billions of dollars on nano-technology across the globe, a sustainable strategy to win the trust of scientists and consumers still seems a long way off, and the pace of development is slower than generally expected (Morris 2016). The use of nanotech is fast expanding without having to develop corresponding protective measures. Commentators are divided on the reasons for such an inconsistency in the growth of the technology, as some put the blame on the clumsy patent regulation, whilst others find the roots of obstacles in the science itself (Morris 2016). As a result, the potential harm hidden in engineered nanomaterials is yet to be discovered.

Owing to the uncertainty in the scientific findings on the potential harmful effects of nanoparticles of titanium dioxide (TiO₂) and zinc oxide (ZnO) that are generally used in sunscreens, regulators are yet to be unanimous as to the need for and mechanisms of regulation. Some countries, such as Australia, still rely on suggestions of the ‘majority’ of investigations suggesting no real risk of harm, and thus adopted a soft approach not to impose any nano-specific mandatory disclosure regulation on sunscreens (TGA 2016; TGA 2017); whilst others such as the European Union (EU) have considered the risks differently and therefore have imposed, amongst other conditions, obligatory labelling requirements with a clear mention of ‘nano’ next to the inorganic chemicals used in a given product (EC 2009). Australia seems to be following the US (Krow 2014). Notably, the US regulator, Consumer Product Safety Commission (CPSC), has not received sufficient information that nano-products are safe (Krow 2014), whilst the US Food and Drug Administration (FDA) acknowledges that ‘there is evidence that at least some sunscreen active ingredients may be absorbed through the skin and enter the body’ (FDA 2017). Nonetheless no nano-centric regulation has been put in place to date. Notably, there is demand in the US to impose mandatory labelling requirements of disclosing nanoparticles in order to enable consumers to make informed decisions (Watnick 2014), and the current US cosmetics law and regulations are strongly criticised as having ‘abundant loopholes and weaknesses’, and not being able to ‘adequately protect human health’ (Watnick 2014). The US regulation is not ideal to be followed, and there has been a call for making the ‘cosmetics’ (sunscreens are categorised as cosmetics in the US for regulatory purposes) regulation more consumer protective, and changing the current regulatory approach in the US (Watnick 2014). Therefore, it may no longer be justified to continue to follow the path of the US with respect to sunscreens regulation, which is called for the mutual benefits of consumers and the technology itself.

There is little disagreement that nano-particles of TiO₂ and ZnO can cause serious harm to humans, if they penetrate into the viable skin; however, disagreements exist as to whether those particles have the ability to infiltrate into that layer of skin. While scientists are still divided on this, we have a considerable amount of credible evidence that those particles have the ability to permeate human body barriers and thus cause serious harm as discussed in the following section. In particular, numerous research endeavours, as will be discussed soon, find that such penetration and resultant harm in varying degrees, including cancer, is possible. The health risk is even greater in Australia compared to many other countries including Europe, especially because of the higher magnitude of the UV radiation and extreme exposure condition in the southern hemisphere (Gies et al. 2004; Lemus-Deschamps and Makin 2012). Therefore, appropriate regulatory measures to protect public health need to be taken before risking such detriment at a large scale.

This article views the existing Australian sunscreens regulatory policies in light of their equivalents in the EU, and provides suggestions for a more efficient and protective approach in relation to regulation of nano-sunscreens in order to prevent potential harm to public health. We argue that the current approach in Australia, being ‘wait and see’ – relies upon one side of the existing literature in disregard of the other side; lags clearly behind the EU policies; may result in irreversible consumer harm; and infringes on the people’s right to know. We recommend, based on credible research, that Australia should embrace the EU policies founded on precaution to avoid harm without any prejudice to burgeoning the technology. The current Australian regulatory policies need to be shifted from ‘wait and see’ to a ‘precautionary approach’, before it becomes too late to respond to potential public harm with regard to the concerns discussed below.

Nano-sunscreens and the validity of health and safety concerns

As mentioned earlier, nanotechnology is concerned with the size of materials and it is generally described as being the manipulation of material on an atomic scale to create incredibly small, novel, and functional structures (Reese 2013). It creates completely new materials or improves the usefulness of existing products by increasing their function, cost-effectiveness, and/or both (Reese 2013). The usefulness of nanotechnology is widely recognised, however, its potential harm is yet to be scientifically proven with certainty in relation to sunscreens. Numerous research findings, as shown shortly below, suggest its probable harmful effects on consumers, which generates concerns amongst consumers and researchers alike, and in some jurisdictions regulators too. There is little dispute that nanoparticles of TiO₂ and ZnO can cause serious harm to humans if these can somehow manage to penetrate into the viable human skin; however, a disagreement exists as to whether those particles have the ability to permeate that layer of human skin. Many researchers have found that nanoparticles of TiO₂ and ZnO have the potential to reach the bloodstream through the skin by which they can travel anywhere in the body and can potentially cause severe detriments as will be discussed shortly below. Hence, safety concerns continue to exist alongside the advancement, acceptance and commercialisation of nano-products, necessitating implementation of different forms of hard and soft regulations aimed at safeguarding humans and the environment, and harvesting economic benefits of nanotech across developed nations (Bowman and Bennett 2013). This safety concern creates a ‘double-edged sword’ to the use of nanotech in sunscreens. Both sides (benefits and concerns) are as follows.

Benefits of using nanoparticles in sunscreens

To protect human skin against the harmful effects of solar UV radiation, the two chemicals, TiO₂ and ZnO, in bulk or conventional size, have been used in sunscreens for decades. These inorganic UV filters are more preferable than organic UV filters in terms of their shielding

efficacy, lower toxicity and chemical stability under exposure conditions of both high temperatures and UV radiation (Popov et al. 2005). When used in conventional size, they do not function by absorbing UV light, but by reflecting and scattering all incident light (including the UV component) and hence appear white, like a conventional surface coating, when topically applied. They are also termed ‘physical UV blockers’ because of this visible physical barrier, but which, from a cosmetic standpoint, is often perceived as unsightly (Cole et al. 2012).

At nano-size, the particles are too small to scatter and reflect UV efficiently, they are not physical blockers but function by absorbing UV light (Popov et al. 2005), and moreover, the UV absorption spectra of both TiO₂ and ZnO have broad maxima in the UV-B region. This property renders them excellent absorbers of UV-B radiation and good substitutes for organic UV-B absorbers such as oxybenzone and others, which are of much recent concern because of their effects upon both human health and the environment (Downs et al. 2015).

Another resulting benefit therefore, albeit purely cosmetic, of employing the nano-sized versions of these materials is that, when optimally dispersed, sunscreen formulations containing them appear clear after topical application, avoiding the obvious appearance issue of conventional sunscreens mentioned above. Thus, nano-sunscreen formulations are commonly referred to as ‘smarter’ sunscreens: designed to be transparent on human skin yet retaining the capacity to combat incident UV.

Ironically, the efficient absorption of UV radiation by ZnO and TiO₂ nanoparticles also results in the photocatalytic properties of the materials and is partially responsible for the concerns and corresponding need for regulation, now outlined below.

Potential harm of nanoparticles used in sunscreens

Numerous studies suggest that chemicals such as TiO₂ and ZnO are harmless when employed at conventional size, however, mounting evidence continues to indicate that this is not the case for nanoparticles of the same materials as the following discussion notes. Underpinning this evidence is the fact that many chemical and physical properties of these materials change when their size is reduced to the nano-scale. Many of the property changes are unavoidable and induced by the dramatic increase in surface area to mass ratio when moving down the nano size range. Chemical reactivity, photochemical reactivity and solubility increase, for example, as a function of surface area (Oberdorster et al. 2005), while shape, surface area, surface charge, crystallinity, hydrophobicity and hydrophilicity strongly affect the biophysicochemical interactions at the interface between nanoparticles and biomolecules (Nel et al. 2009).

Toxicology - Inherent cytotoxicity of TiO₂ nanoparticles increases due primarily to increased oxidative stress and cell membrane disruption (Vevers and Jha 2008). A recent study on a range of engineered nanoparticles (including ZnO) showed dose dependent increases in DNA damage and cytotoxicity (via Comet assay) while also reporting the genotoxicity of these nanoparticles on two cell lines (Watson et al. 2014). Pulmonary toxicity increases when these particles are reduced to nano-size (Tran et al. 2005; Nel et al. 2006; Van Tassel and Goldman 2011) and thus, inhalation of TiO₂ may cause lung tumours via mechanisms similar to that for mesothelioma, the condition caused by asbestos (Fransman et al. 2017; Nel et al, 2009). Intravenous injection of nanoparticles of TiO₂ has the potential to contribute to pathological lesions to different internal organs (Trivedi and Murase 2017). Consistently several studies over recent years demonstrate that the unique physicochemical properties of nanoparticles actually generate negative health effects that may create unintended risks in people (Nel et al. 2009).

Furthermore, the potential harmful effects of nano-sunscreens are conceded by not only researchers and commentators, but also by leading government regulatory bodies. For example, the European Chemicals Agency (ECHA) on 9 June 2017 concluded that ‘the available scientific evidence meets the criteria in the CLP [Classification, Labeling and Packaging] Regulation to classify titanium dioxide as a substance suspected of causing cancer through the inhalation route.’ Similarly, the American Chemical Society (ACS) announced on 3 May 2017, based on scientific findings in human and animal studies, that ‘nanoparticles can travel from the lungs into the bloodstream and reach susceptible areas of the cardiovascular system where they could possibly increase the likelihood of a heart attack or stroke’ (Miller et al. 2017). Consistently, an Australian government authority, The Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education, also recognises that nanoparticles have potentially greater toxicity than other materials (DIISRTE 2013).

An exhaustive review of toxicological effects is beyond the scope of this research but the studies reported are illustrative of potential harmful effects of components of nano-sunscreens. However, for sunscreens, this harm is probably contingent upon penetration of these nano-chemicals across the skin barrier, and into viable human cells. Now the question is whether such penetration is possible and this is discussed shortly.

Phototoxicology - Another major concern for nanoparticles of TiO₂ and ZnO is their potential, when exposed to UV radiation, to generate a class of free radicals known as reactive oxygen species (ROS) well known to be responsible for a diverse range of largely negative medical outcomes (Rogers and Moorthy 2018). The ROS generation can damage the DNA of skin cells when photoactive nanoparticles penetrate into the upper layer of human skin (Trivedi and Murase 2017). These claims conform to the early research conducted during the 1990s that

TiO₂ in nano-size can create free radicals which have the potential to cause serious harm (see also: Cole et al. 2012; Cardillo et al. 2016; Trivedi and Murase 2017; Bogusz et al. 2018).

It is beyond doubt that highly photoactive grades of TiO₂ and ZnO are present in commercial sunscreen formulations. Two independent studies, in different Hemispheres, published a few months apart unequivocally confirm this. The study of Rampaul et al. (2007) examined sunscreens purchased over-the-counter (OTC) in Europe while the study of Barker and Branch (2008) studied OTC sunscreens purchased in Australia. Both studies isolated the nanoparticles from several sunscreens and conducted X-ray diffraction analyses to characterise the crystal phases. Both studies characterised relative photocatalytic activity of each inorganic material isolated – one study by observing methylene blue discolouration (Rampaul et al. 2007), the other by electron paramagnetic resonance (EPR) spectroscopy using the ‘DMPO spin trapping’ technique (Barker and Branch 2008). Both studies showed that a single culpable TiO₂ crystal phase led to extreme photocatalytic activity, which on the one hand was shown to effectively kill three viable cell lines: MDCK-1, PtK2 and human HaCaT cells (Rampaul et al. 2007), and on the other, to destroy highly durable surface coatings used in roofing, walling and cars (Barker and Branch 2008). The culpable material in both cases had a unique crystal phase with 80% anatase and 20% rutile, while both studies showed that TiO₂ based nano-sunscreens employing the rutile crystal phase of TiO₂ were protective (not damaging) towards the effect of UV upon the cell lines studied (Rampaul et al. 2007) and did not damage surface coatings (Barker and Branch 2008). A nano-ZnO containing sunscreen was also found to be photoactive (Barker and Branch 2008). A third independent study, undertaken in Italy (Tiano et al. 2010) subsequently not only characterised several commercial nano-mineral concentrates available to sunscreen formulators, but also found just one culpable material (again with a 80:20 Anatase : Rutile crystal phase) after undertaking a range of *in vitro* methods for characterising ROS

activity : DPPH assay; Deoxyribose assay; Comet assay; a cell viability assay on cultured human skin fibroblasts and an intracellular ROS assay on the same cell line. Not only did this study re-affirm the findings of the previous two, but also named the culpable mineral concentrate and advised strongly against the use of anatase-based materials in sunscreens.

Perhaps with these studies in mind, the European Commission Scientific Committee on Consumer Safety (SCCS) updated their position on the use of TiO₂ in sunscreens (SCCS 2014) stating clearly “Nano materials used in cosmetic products should ideally be non-photocatalytic” and realising not only that significant photocatalytic activity could lead to localised effects upon exposed skin, but also that photoactive nanoparticles trapped in hair follicles or sweat glands could provide a longer term threat (NB These threats *do not* depend upon dermal penetration). As a result, new guidelines for the formulation of sunscreens with nano-TiO₂ were published in 2015 (SCCS and Choudhry 2015). Three of the six critical recommendations were use of TiO₂ nanomaterials that: (i) are composed of mainly the rutile form, or the rutile form with not more than 5% anatase; (ii) are photostable in the final formulation; and (iii) do not have photocatalytic activity and (iii) do not have photocatalytic activity (although, the SCCS considers up to 10% photocatalytic activity compared to corresponding non-coated or non-doped reference as acceptable).

It is interesting to note that these three SCCS recommendations remind us of the potential harm and aim to prevent the harmful effects of currently available nano-sunscreens which contain potentially culpable nanomaterials. Thus, implementation of these recommendations would effectively lead to use of safe nano-materials in sunscreen products for consumers across the board. Nano-ingredient disclosure and regulation thus remain critical until these recommendations are fully implemented in a given jurisdiction. Notably, Australia seems still

quite a way off to adoption of such recommendations - let alone implementation, which reinforces the significance of this article.

Penetrability of nanoparticles used in sunscreens

Scientific research demonstrates that nanoparticles such as TiO₂ and ZnO can *enter* the human body via ingestion, inhalation, injection, and *skin absorption* (Oberdorster et al. 2005). Once absorbed, they can travel via the blood stream and access to distance organs such as the brain (Van Tassel and Goldman 2011; Miller et al. 2017). Very small size distribution of nanoparticles enables them to cross biological barriers more effectively. Arguably, nanoparticles applied to skin would conceivably enter the circulation via the lymphatic system too (Oberdorster et al. 2013; Smulders et al. 2015; Bakand and Hayes 2016). Several recent studies conducted on an animal skin model confirm that localised ROS production released from absorbed nanoparticles can alter DNA (Watson et al. 2014).

Many sunscreens are formulated to remain on the skin surface and function, as mentioned above, by absorbing UV radiation and preventing it from reaching the skin surface. However, many cosmetic sunscreen and moisturizer products use excipients that increase skin permeability to deliver active ingredients such as vitamins (Tran and Salmon 2011; Reese 2013). In addition, the intercellular space between the cells composing the stratum corneum measures about 100 nm³ and following topical application of sunscreens it can potentially be expanded (Newman et al. 2009). This may raise the concern of whether nanoparticles used as sunscreen ingredients have the potential to penetrate the stratum corneum. Research findings on skin penetration of nanoparticles are inconsistent and the ability of dermal penetration of TiO₂ and ZnO nanoparticles is still under debate. While some *in vitro* and *in vivo* studies have demonstrated no penetration for specific types of commercial nanoparticle (Zvyagin et al. 2008), others have demonstrated that these nanoparticles have a potential to minimally

penetrate the stratum corneum and underlying layers of skin (Tan et al. 1996; Lademann et al. 1999; Wu et al. 2009).

Certain nanoparticles have the potential to *invade* the surface of the skin (Silpa et al. 2012), and because of their size they are likely to interact with more sensitive cells (Silpa et al. 2012). An EU report revealed that some nanomaterials have the capability to *penetrate* viable living cells (SCENIHR 2006). Recent studies find that because of their small size distribution, large surface area and greater biological activity, nanomaterials can be more easily *absorbed* and distributed in the human body compared to their bulk equivalents, and thereby are capable of intruding into some of the natural defence systems of the human body (Krow 2014). It has been further argued that nano-enabled materials can more easily *permeate* human cells and they possess a higher level of interaction with biological tissues, which gives them a greater potential for toxicity (Van Tassel and Goldman 2011).

The nanoparticles' unique physicochemical properties such as small size distribution, chemical composition, surface characteristics and high reactivity can harm the living tissues (Nel et al. 2009), and once entered into cells, these nanoparticles interrupt the cell signalling that may result in structural impairment and DNA damage (Dunford et al. 1997; Hidaka et al. 1997; Wong-Ekkabut et al. 2008), though reactivity alone may not be responsible for DNA damage. For example, as mentioned earlier, it has been shown that a range of engineered nanoparticles such as ZnO are able to cause DNA damage and cytotoxicity (Watson et al, 2014). Furthermore, the scavenger cells which usually remove foreign substances, phagocytes, may cease to function and become damaged when overloaded with nano-materials (Lundborg et al. 2001; Barlow et al. 2008; Nel et al. 2009; Bakand et al. 2012). This will reduce the natural immunity of the body by allowing foreign particles to enter into with impunity (Lundborg et al. 2001; Barlow et al. 2008).

The studies cited above are just a few of many which reveal that nanoparticles of TiO₂ and ZnO can permeate the human body and thereby can cause serious harm. However, some researchers have indicated that nanoscale TiO₂ does not normally invade the human body through healthy skin, it can do so through sunburned, wrinkled, cut, or otherwise scuffed skin (Krow 2014). Consistently, other research reveals that nanoscale chemicals used in sunscreens up to 7000 nm can be absorbed through the skin which is traumatised in any way, such as sunburn, shaving cuts, blemishes, and eczema (Oberdorster et al. 2005). However, *in vitro* experiments involving the repetitive application of cosmetics containing nanoparticles to animal skin reveal that these particles can be absorbed through intact skin as well (Rouse and Yang 2007). It is noteworthy that many sunscreens and other cosmetics containing nanoparticles are not particularly formulated for use on damaged skin (Van Tassel and Goldman 2011; Van Tassel 2013), and are generally used regardless of skin condition, which increases the probability of harm. In addition, it is also important to consider the possibility of oral absorption of nanoparticles in sunscreens applied for lips and inhalational absorption of aerosolized sunscreens and powder makeup containing TiO₂- and ZnO-based sunscreens (Newman et al. 2009).

Findings viewed differently in Australia and the EU

Having regard to studies and reports cited above, it can be concluded that nanoparticles of TiO₂ and ZnO carry significant potential health risks. Despite such substantial scientific revelations and acknowledgment of these particles' ability to perpetrate sometimes irremediable harm, the concern is viewed differently by regulators in Australia compared with those in the EU.

The Therapeutic Goods Administrator (TGA), the Australian principal authority responsible for the regulation of such sunscreens, has in 2017 upheld their previous inference that these chemicals in nano-form do not enter the living cells, therefore cannot cause harm, so there is no need to impose regulatory restrictions on manufacturers, importers and/or consumers (TGA

2016; TGA 2017). This argument seems inherently biased towards one side of the research and ignores the findings on reactivity, penetrability and solubility of nanoparticles at hand as presented above. Notably, the TGA previously formed an identical view, which was criticised by many stakeholders, and commentators including prominent academics, scientists and non-government organisations (NGOs), who expressed substantial concerns over such conclusions of the TGA, with particular reference to nano-sunscreens (Nohynek et al. 2007; Faunce et al. 2008; Faunce 2010; Gulson et al. 2010). Nonetheless, the TGA remains attached to the ‘wait and see’ policy, which is even more surprising considering the increased levels of UV-A and UV-B experienced in Australia.

In drawing such a critical conclusion, the TGA refers to the majority of research (TGA 2016; TGA 2017), as opposed to the whole body of scientific investigations available. It should be noted that the TGA findings do not rule out the possibility of skin penetration of TiO₂ and ZnO, rather it is confident in the findings of the majority of selected research they considered, apparently adopting a quantitative method of evaluation of the available literature. However, much of the TGA reviewed references employ uncharacterised materials, non-culpable materials, or conduct studies in the absence of UV-light. The ‘majority principle’ implies that the TGA itself has found studies showing potential harm but did not pay sufficient heed to them perhaps as those are ‘minority’ in number and call for regulation.

The EU has taken a different, and arguably a more realistic, stance compared to Australia. Given the foregoing potential harmful consequences, the EU regulation requires, amongst other things, disclosure of nanoparticles in the product labels, whereas Australia does not yet recognise the need for such a requirement. As mentioned above, the EU also provides rational formulation guidelines for sunscreen producers seeking to employ nanomaterials in their products (SCCS and Choudhry 2015).

The need for regulation

In the age of freedom of information, it may sound unrealistic as well as unacceptable to conceal critical information which is of interest, and has the potential to affect, stakeholders. A recent study shows that members of the Australian public are inclined to know about the presence of nanoparticles in consumer products including sunscreens (DIISRTE 2013). Australian people do support labelling of nanoparticles, and view that the government has the responsibility to ensure this disclosure through regulation (DIISRTE 2013) and they want ‘more regulation, not less’ (DIISRTE 2013). In relation to labelling, they also strongly support that it is the right of consumers and citizens to know about the nano-contents (DIISRTE 2013). This finding is reinforced by a recent empirical study conducted on four different ‘stakeholder groups’ (including general public, academics, business and government officials who are involved in this technology) of five consumer nano-products including sunscreens and foods in Australia, which finds that most of them, regardless of their categories, support proper labelling of products containing engineered nano-particles (Capon et al. 2015a). This public preference is consistent with the previous studies (Throne-Holst and Rip 2011; IPSOS 2013; Brown and Kuzma 2013).

The claim of labelling transcends individual choice, as nondisclosure goes against the consumer’s right to know of the ingredients as Australian people are also entitled to know about ingredients of a product under consumer law (Parts 3-5 of the Australian Consumer Law, ACL, contained in Schedule 2 of the *Competition and Consumer Act 2010* (Cth)). This claim can be further premised on two grounds. First, the labelling requirements set forth in Australian Competition & Consumer Commission (ACCC) Product Safety guide provides as follows:

Product *ingredient information* should be available to consumers at the point of sale.

The listing of product ingredients is required *on the container or on the product itself*, if not packed in a container.

Where the container or the product is of a size, shape or nature that prevents ingredient labelling by any of the above methods, the mandatory information standard requires the *display of information to allow consumers to be informed*.

The labelling of ingredients on cosmetics ... usually appears on the packaging or outer casing of the product for *consumer knowledge* [Italics added] (ACCC 2014).

The above articulation of labelling requirements clearly recognise consumers' right to know about the product, and it is reasonably arguable that the phrase 'consumer knowledge' does refer to knowledge of the truth, as opposed to any misleading or deceptive information as alluded to earlier.

Second, Australian Consumer Law (ACL) entitles consumers to seek compensation or damages for personal injury or other loss caused by a safety defect in products supplied by a manufacturer (Part 3-5 of ACL). Although, generally manufacturers or importers are liable, retailers can also be held liable if they fail to identify the manufacturer or importer. This impliedly recognises consumers' right to know, and as a matter of general principle of law, remedies are available only when a right is infringed.

In addition, such a denial of consumers' right to know contradicts the current worldwide dominating principle of 'caveat venditor' (let the seller beware). Permitting nondisclosure of nanoparticles implicitly adopts the *doctrine caveat emptor* (let the buyer beware) which is old and outdated, and therefore has been replaced with the *doctrine of caveat venditor* even for conventional consumer products (Solaiman 2013). Consistently, the product disclosure requirement has been commonplace around the world triggered by the emergence of consumerism, a stronger sense of manufacturers' accountability, and product transparency. Nano-labelling is particularly significant in that consumers are eager to know and they have

the right to know about it, nonetheless they remain unaware as they are unable to discover the harm themselves by applying ordinary skills because of the sophistication of technology.

Further, Van Tassel states in the present context that hiding nanoparticles from product ingredients is misrepresentation and misleading, and it adversely affects consumers on several accounts. Several convincing arguments in favour of nano-ingredients disclosure were made, some of them are as follows. *Firstly*, if the ingredients are honestly disclosed, consumers can remain vigilant about their impacts and take self-protection measures where needed to avoid a serious harm. Misrepresentation disarms a consumer's self-protection mechanism (Van Tassel 2013). *Secondly*, consumers who are prone to adverse health effects of industrial nanoparticles would remain in darkness about the true cause of these effects and unduly blame the safe products. This may tempt them to avoid those products in the future, and this unnecessary avoidance of safe sunscreen products may invite further harm in a sense that the product avoided actually could have saved them from serious health consequences. It can also unfairly affect the manufacturers or importers of those safe sunscreen products. So the practice of hiding or omission is unfair, deceptive and misleading (Van Tassel 2013). *Thirdly*, an informed customer with a tendency to have adverse health effects from a nano-enabled products can provide accurate information of exposures to materials to their physicians that could be critical for appropriate treatment; and nondisclosure of ingredients will likely prevent proper diagnosis possibly leading to inappropriate remedies, naturally inviting additional harm (Van Tassel 2013). *Fourthly*, parents with small babies sometimes have to avoid products that may cause allergies, and thus they have to heavily rely on the product warning, without which they and their young children could be victims of the nondisclosure in question (Van Tassel 2013) . *Fifthly*, consumers purchase products in good faith that unsafe products are not marketed, whereas nondisclosure helps manufacturers take advantage of consumers' uninformed trust and protects them from liability for the harm caused by the risky elements of their products (Van

Tassel 2013). This is so because consumers will not know the major cause of their harm, and therefore will be unable to identify the defendant. Thus, it will be safe-harboring the true culprits from liability (Van Tassel 2013). Also, failure to disclose material information renders a product misbranded, and violation of general product disclosure law (Van Tassel 2013). Further, such a nondisclosure also raises a question of fairness, justice and accountability (Van Tassel and Goldman 2011).

In sum, by relieving the supply chain from disclosure, regulators are effectively preventing the ability of consumers to protect themselves against the risks of harm, and in turn facilitating detriments to occur (Van Tassel and Goldman 2011). Hence, nondisclosure is unacceptable, unethical and inconsistent with law on many counts.

In view of the aforesaid risks of harm and recognised benefits, nanoparticles can be regarded as a double-edged sword, whilst the existing regulatory laxity or dichotomy rests on the apparent uncertainty of risks. However, waiting for the certainty of harm through further *in vivo* experiments may be unwise from the viewpoint of consumer predictable impairments. This is why plausible arguments for regulating these products have been advanced by researchers and commentators (Van Tassel and Goldman 2011), and already accepted and implemented by the EU. If considered cautiously, striking a balance between the risks and benefits through regulation is warranted. It is thus advisable that regulation should impose some precautionary requisites on the use of these nanomaterials by manufacturers at this stage of scientific development (Soliman and Yipt 2013), keeping in mind both the protection of consumers and the facilitation of the technology. A discussion of the current regulatory philosophies follows.

Regulatory policies currently in place

Current regulatory dominant policies for nano-sunscreens

Currently there are two dominating regulatory paradigms for engineered nano-products from the perspective of risk prevention: one based on ‘sound science’ or the ‘reasonable certainty of no harm’ standard; and another based on the ‘precautionary principle’ (WHO 2004). Although both approaches are reliant on science, they evaluate scientific evidence of risks differently giving different weightings and sensitivities to uncertainties and varying emphasis given to social and economic matters (WHO 2004). Of the two jurisdictions, Australia and the EU, the latter has invoked regulation whilst the former still allows nano-sunscreens to be released to the market without having to comply with any nano-specific regulatory requirements. It means Australia relies on the so-called ‘sound science’ or the ‘reasonable certainty of no harm’ principle, whilst the EU applies the ‘precautionary’ principle’ (Kraus 2015).

In view of the current approach, it might not be easy to impose regulation in Australia, if it continues to follow the US which apparently requires solid evidence of real harm ‘gathered through scientific methods’ (Marks 2017). In other words, nano-specific regulation is not needed until the risk of harm is categorically proven with certainty. Commentators argue, in the US context, that manufacturers have no obligation to generate safety data or provide risk information keeping the regulator uninformed of any potential risks attached to a chemical material (Shah and Taylor 2011). The situation led to a comment that ‘the use of chemicals in personal care products is allowed under current law with virtually no government-compelled testing’ (Kraus 2015). This leniency is unacceptable to many stakeholders, which triggered attempts to amend the legislation aimed at requiring rigorous safety testing and data disclosure, but all was in vain following strong lobbying in favour of self-regulation which has not been beneficial either (Kraus 2015). In the context of nanotech, self-regulation is not believed to be ‘the best route’ towards managing the risks posed by nanomaterials as it may not protect the public (Reese 2013). This successful resistance against a compulsory safety-check in the US reminds us of the mighty nature of the corporate world in a market economy.

Somewhat contrariwise, the ‘precautionary principle’ which is extensively adopted by the EU is relatively flexible and it solicits regulation be imposed even where uncertainty of human harm exists (WHO 2004). This principle is thus proactive to prevent known and unknown harm, given the existing limit of scientific knowledge of potential risks (WHO 2004). Marks articulates the precautionary principle in a logical way:

The principle is based on recognizing that people have a responsibility to prevent harm and to preserve the natural foundations of life, now and into the future. The needs of future generations of people and other species and the integrity of ecosystems are recognized as being worthy of care and respect. A precautionary approach asks *how much harm can be avoided rather than asking how much is acceptable*. It acknowledges that the world comprises complex, interrelated systems that are vulnerable to harm from human activities and resistant to full understanding. *Precaution gives priority to protecting these vulnerable systems and requires gratitude, empathy, restraint, humility, respect, and compassion* [Italics added] (Marks 2017).

The ‘precautionary principle’ is arguably beneficial for consumer protection, compared to its alternative, the so-called ‘sound science’.

Current regulation of sunscreens in the European Union

EU regulation of personal care products is more consumer protective than that of Australia. The European Commission (EC) has been enforcing its regulation of these products under the European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals – Regulation (EC) No. 1907/2006 (REACH) (EC 2006), and the Regulation on Cosmetic Products EC 1223/2009 (EU Cosmetics Regulation (EC 2009)). REACH stands for ‘registration, evaluation, authorisation and restriction of chemicals’. REACH replaced the former legislative framework for chemicals in the EU, aimed at mainly to protect human health

and environment proactively through timely identification of the intrinsic properties of harmful chemical substances by applying the defined processes (REACH) and enhancing competitiveness and innovation. (EC 2018a)

The previous EU legislative framework had required public authorities to assess and manage risks of relevant chemicals and disseminate adequate safety information to consumers. REACH made a paradigm shift by transferring that responsibility for assessment of risks and dissemination of information from public authorities or state agencies to the industry (EC 2018a). Thus, this unique policy of REACH imposes burden on companies including manufacturers, importers, and downstream users of the substance, that the chemicals are safe. Companies must demonstrate to European Chemicals Agency (ECHA) how the substance can be used safely, in addition they are obligated to communicate the risk management measures to the end users. If unmanageable risks are found, authorities are mandated to impose restrictions on the use of substance in different ways (ECHA, Understanding REACH [date unknown]). REACH goes far beyond managing the risks by requiring the manufacturers to gradually replace more dangerous substances with their less risky alternatives, as and when such materials are available (EC 2016). The policy contained in REACH is straightforward, 'no data no market' (Soliman and Yipt 2013), it is thus 'a true market-access regulation' (Soliman and Yipt 2013) and overtly pro-consumers.

Both manufacturers and importers have the obligation to register risk and safety related information in a central database in ECHA in Helsinki, the central point in the REACH system (EC 2016). Functions of the ECHA include: managing the databases necessary to operate the system; co-ordinating the in-depth evaluation of suspicious chemicals; and building up a public database for consumers and professionals (EC 2016). Appreciably, this system does give emphasis to evaluation of product safety and dissemination of safety information to the public as an attempt to prevent harm from occurring.

Once companies have registered risks of a chemical together with their assessment of those risks and the safety of the substance with the ECHA, it (ECHA) receives and evaluates individual registrations for their compliance, and the EU Member States evaluate selected substances to clarify initial concerns for human health or for the environment (ECHA, Understanding REACH [date unknown]). State authorities and ECHA's scientific committees then evaluate the compliance requirements for this registered material and carry out an examination of the accuracy of risks assessed by the company and whether the risks of a given substance can be managed (ECHA Understanding REACH [date unknown]). If the risks are found unmanageable, EC proper enforcement authorities, to be determined by EU Members States, have the power to ban that substance altogether, or to restrict use or make it subject to a pre-market authorisation (ECHA Understanding REACH [date unknown]). The EC regulation is thus quite stringent, still not considered sufficient to protect consumers, which led to additional regulation in 2009.

The EU Parliament in 2009 further strengthened the protective feature of the Cosmetics Directives (EC 1976), by introducing the EU Cosmetics Regulation, with most of its provisions effective from 11 July 2013 (EC 2009). The EU Cosmetics Regulation, as the name implies, deals with cosmetics and specific ingredients in those products, but it does not provide any general definition of cosmetics, leaving it open to be decided on a case-by-case basis (EC 2009). However, paragraph 7 in the preamble of the EU Cosmetics Regulation provides a list of cosmetics; and sunscreens fall within the defined product under 'products for external intimate hygiene, sunbathing products, products for tanning without sun'. Emphasis has been given to the safety of such products in the EU Cosmetics Regulation which pronounces that: 'Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health' ((EC 2009, preamble para 9). This safety requirement is emphatic in that the product has to be safe under

normal as well as reasonably foreseeable conditions. The manufacturer has a greater burden to ensure safety of products from the perspective of a reasonable person, meaning that whether a manufacturer breaches the requirements will be judged objectively. To this end, manufacturers need to exercise a high standard of care in conducting safety checks.

The EU Cosmetics Regulation requires manufacturers to assess safety of any cosmetics before marketing, and prepare a safety report including identification of presence of any nanoparticles and their expected exposure, which is required to be provided to the European Commission (EC 2009, art. 10.1, 13.1; art. 13.1(f), (g)) . Article 5.2 of the EU Cosmetics Regulation obligates the manufacturers and importers alike to take corrective measures to rectify nonconformity with this Regulation. In accordance with the above Article 5.2, such immediate measures may include withdrawing or recalling affected products, and instantaneously notifying national regulators when a product indicates a health risk. Article 6 places obligations on distributors of cosmetics similar to those of manufacturers and importers. The obligations imposed of manufacturers, importers, and distributors sound fair and reasonably protect consumers from known and unknown harm.

Further, Article 16.1 of the EU Cosmetics Regulation gives particular emphasis to nanomaterials in cosmetics by stating that '[f]or every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured.' Article 16.3 sets forth specific requirements of a manufacturer, which include identification of: (a) the 'size of particles, physical and chemical properties' of the nanomaterials; (b) an estimated amount of nanomaterials in cosmetics to be marketed per year; (c) the toxicological profile of the nanomaterial; (d) safety data of the nanomaterial; and (e) 'reasonably foreseeable exposure conditions.' Article 16.6 empowers the EC to categorise nano-products as restricted or prohibited ingredients that carry potential health risk or sufficient data about safety is unavailable. Article 23.1 goes further by obligating the manufactures, importers and

distributors to report to the regulator of ‘serious undesirable effects’ defined as ‘an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death in Article 2.1. Depending on the harmful effect, the regulator can ask manufacturers to withdraw or recall the product from the market, any failure of which can be legally enforced as a violation of the EU Cosmetics Regulation (EC 2009, art. 25.1; . art. 25.5(a)-(b)).

Finally, as recognition to people’s right to know, Article 19 of the EU Cosmetics Regulation set out the labelling requirement, and it categorically provides that ‘All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets’ (EC 2009, art. 19(10(g)). This requirement has given effect since 2013 (ECHA, 2018). In addition, its Article 16.10(a) requires the EC itself to publicise a list of all available cosmetic products containing nanomaterials by 11 January 2014.

Clearly, the above-stated EU measures have embraced the ‘precautionary principle’ for the regulation of nanomaterials. Further, it is, as defined by Sachs (2011), the ‘strong’ precautionary principle which warrants:

- (1) regulation should presumptively be applied when an activity or product poses serious threats to human health or the environment, even if scientific uncertainty precludes a full understanding of the nature or extent of the threats; and (2) the burden of overcoming the presumption in favor of regulation lies with the proponent of the risk-creating activity or product (p. 1295).

Sachs (2011) adds that ‘the Strong Precautionary Principle advocates that some precautionary regulation should be a *default response* to serious risks under conditions of scientific uncertainty’ (p. 1295) and this form of regulation ‘could range from a blanket prohibition on a

proposed technology or a dangerous activity to less aggressive defaults, such as use of restrictions or warning requirements’ (Sachs 2011, p. 1295). The measure will vary based on the magnitude of the potential risk and merits of the scientific evidence (Sachs 2011). The proponents of risk creating activity can overcome the default regulation under this principle if they can prove that the risks in questions are acceptable or reasonable (Sachs 2011).

Given the rapid expansion of use of nanomaterials in consumer products and limitation of scientific knowledge of their harmful effects, it is argued that ‘some form of pro-active regulation is needed now in order to minimise future injuries which may be widespread and not remediable’ (Soliman and Yipt 2013, p. 146). It is to be noted that our lack of knowledge is unhelpful in preventing harm, thus it should not be a good ground for laxity in regulation. An utmost priority should be given to safety. Perceivably, safety may not be always guaranteed by any means; however, efforts need to be made towards achieving safety and continuously improving it. To this end, at this stage of nanotechnology, product labelling and re-evaluation of use and formulation of nano-sunscreens pending further *in vivo* research and scientific progress in the field of nanotechnology may be useful (Tran and Salmon 2011). While the EU has appreciably realised this need, Australia is still well away from such a policy and method of regulation.

Current regulation of sunscreens in Australia

Australian regulation has classified sunscreens into two: cosmetic sunscreens and therapeutic sunscreens. Cosmetic sunscreens are those which ‘contain an ingredient with suncreening properties but the primary purpose of the product is neither sunscreening nor therapeutic’ (TGA 2016). These products are regarded as cosmetics and regulated by the National Industrial Chemicals Notification & Assessment Scheme (NICNAS). These are excluded from the TGA regulation as they fall beyond the scope of therapeutic goods legislation, the *Therapeutic Goods Act 1989* (Cth), under the *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011* (TGA

2016). For a product to be a cosmetic sunscreen, it must satisfy the definition provided in the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth) as well as any requirements prescribed in the current *Cosmetics Standard* and *NICNAS Cosmetics Guidelines* (TGA 2016). Notably, the definition of ‘cosmetics’ provided in section 5 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth) is completely silent about use of nanomaterials in these products, accordingly the *Cosmetics Standard* and *NICNAS Cosmetics Guidelines* do not require disclosure or identification of nanomaterials, if used, in product labels (TGA 2016). Hence, consumers are unable to know about the true compositions of their cosmetics sunscreens under the regulation by NICNAS.

Product labelling of cosmetic sunscreens is further regulated by the *cosmetic ingredient labelling* regulation administered by the ACCC, the principal national watchdog for manufacturing consumer products in terms of competition in the market. Both NICNAS and ACCC follow the same policy, when it comes to sunscreens, as the ACCC regulation requires the labelling of ingredients on cosmetics without any specific requirements of disclosing nanoscale materials (ACCC 2014). ACCC administers the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*, which sets out the mandatory standard for ingredients labelling on cosmetics. It does not prescribe any rule specific to nano-products, and its Regulation 4 excludes therapeutic goods within the meaning of the *Therapeutic Goods Act 1989 from the scope of this regulation*. This regulatory inattention to nanoparticles exists arguably against the ‘right’ and ‘will’ of the people as alluded to earlier.

Therapeutic sunscreens are of two categories: listable sunscreens and registrable sunscreens. Listables are those sunscreens that carry sun protection factor (SPF) claims between SPF 4 and SPF 50+, and these are secondary suncreening products which fall within the definition of a therapeutic sunscreen. These sunscreens are required to be listed in the Australian Register of Therapeutic Goods (ARTG) under s26A of the *Therapeutic Goods Act 1989* (Cth) (TGA 2016).

Registrable sunscreens are identified as those which ‘make therapeutic claims other than sunscreens and/or reduction of risk of skin cancer, solar keratosis, sunspots or premature ageing’ (TGA 2016). Registration of these products is essential under s25 of the *Therapeutic Goods Act 1989* (Cth). The majority of the therapeutic sunscreens are listable, and their purpose should be sunscreens, excluding purposes such as ‘reduction of free radicals in or below the skin, or claims relating to reduction of UV induced immune suppression’ (TGA 2016). Sunscreens which claim these excluded purposes ‘and/or contain active therapeutic ingredients that are not included in the list of sunscreens agents permitted as active ingredients’ are not listed and they must be registered in the Australian Register of Therapeutic Goods (ARTG) to prescription medicines depending on their active ingredients (TGA 2016). Regardless of this classification, Australia has not yet imposed any nano-specific regulation, though therapeutic sunscreens need to be listed or registered with the TGA. Rather, negating the labelling requirement, the TGA promulgates that nanoparticles of TiO₂ and ZnO are commonly used in sunscreens, and those particles need not be declared as ingredients on product labels (TGA 2016). Appendix 1 of the *Australian Regulatory Guidelines for Sunscreens 2016* contains a labelling checklist which is neither mandatory nor exhaustive. It gives emphasis to a clearly visible and reasonably detailed label, and also reminds manufacturers of the prohibited descriptions on the label that include, amongst other things: false or misleading or likely to be misleading statements or picture; and indication or implication that the product cannot cause harm (TGA 2016). We have argued earlier that nondisclosure of nano-ingredients makes the labels misleading and deceptive. While false or misleading or deceptive labelling is prohibited, it is questionable as to why hiding nanoparticles from the public (this is something of public interest as evidenced previously) should not be sufficient to place the labelling within the defined proscriptions. Guideline 4.4 (TGA 2016) which explicitly negates the need for such disclosure arguably exists in conflict with the standard prohibitions concerning product

labelling. Further, ‘indicating or implying that the product cannot cause harm’ can also contradict the aforesaid Guideline 4.4 in that silence about the presence of nano-particles which have the ability to cause harm may inappropriately and unfairly imply that the product is not harmful.

Furthermore, as its working process, the TGA is concerned with the risk assessment and management of therapeutic goods and aims to achieve this through different players which ‘have a role to play in maintaining a benefit-risk balance by making sure that products are developed, tested, manufactured, labelled, prescribed, dispensed and used in a way that maximises benefit and minimises risk’ (TGA 2011). Nonetheless, the TGA puts in place no requirement of disclosure of engineered nanomaterials as a way of minimising risk at least, perhaps fearing over-regulation.

Fearing over-regulation unjustified

Australia may currently have a fear of ‘over-regulation’ if mandatory nano-labelling requirements are imposed on the use of nanotechnology by manufacturers, importers and/or distributors. We are also conscious about the impact of any such excess, but at the same time, we do want to avoid any significant detriment to the public on a priority basis. We are anxious about consumer protection, and therefore we advocate that a ‘striking workable balance between so-called under- and over-regulation’ is needed to foster the technology paying due regard to consumer protection (Bowman and Bennett 2013). We also acknowledge that regulation should be designed to meet the specific needs of a given technology, hence we agree with the view that a combination of hard and soft approaches to the regulation of nanotechnologies is likely to help yield optimal benefits (Bowman and Bennett 2013). We are essentially recommending adoption of EU policies and modes of regulation, not anything beyond. We have a reason to believe that this adoption will not harm the industry, as no evidence of scaremongering in the EU has been found since the introduction of the labelling

disclosure of nano-materials. However, it is worth noting that whilst overwhelming demands for nano-disclosure exists in both Australia and elsewhere, misperception and misinterpretation of nano-labelling are sometimes relied upon in defending non-disclosure.

Misperception and misinterpretation of nano-labelling

There is a misperception of nano-labelling biased against disclosure of nanoparticles. Arguments against such a disclosure are based on misinterpretation of the meaning of labels and difficulties in implementation of labelling (Capon et al. 2015a). Capon et al. (2015a) have identified specific arguments against nano-labelling, some of these are: (a) negative perceptions (creating stigma, fear, reduced public acceptance and disinvestment); (b) additional costs involved in implementing labelling; (c) potential trade barriers between countries where some of them require nano-labelling and others do not; and (d) shifting the burden on supposedly informed consumers to determine the acceptability of potential risks. Prominent of these arguments are negative perceptions and implementation of nano-labelling. Difficulties concerning implementation of labelling, as summarised from several studies, are related to clearly defining nano-products, finding a reliable detection tools for the enforcement of the system, and setting out thresholds for nanoparticles to make a product contaminated (Capon et al. 2015a). However, such difficulties can be overcome by a given jurisdiction if these issues are carefully addressed with sufficient clarity.

In relation to fearmongering, it is important to note that such propaganda or publicity is not always true, because the mandatory labelling of nano-cosmetics including sunscreens within Europe has experienced a 'very little societal response'(Capon et al. 2015a). So the central argument against nano-labelling does not seem to be tenable, so the question is how much longer should be the waiting period for the adoption of the precautionary policy?

Delaying adoption of the precautionary policy

Australia is clearly lagging behind the EU in addressing the current safety concerns posed by nanotech as evident in its reliance on the ‘majority’ principle (TGA 2016, 2017). The harmful effects usually take a long time to be visible as mentioned earlier. According to the Australian Government statistics, a total of 124,465 cancer patients were diagnosed in 2013 and the number is estimated to be 138,321 in 2018 in the country with a population of 25 million (Cancer Australia 2018). The estimated most common cancers diagnosed in 2017 include melanoma 13,941 and lung 12,434 (Cancer Australia 2018). Consistent with the increasing number of patients, deaths from cancer are also rising, as the number was 44,171 in 2014, whereas the number is estimated to be increased to 48,586 in 2018 (Cancer Australia 2018). We have shown above that nanoparticles have the potential to cause cancers, and nano-sunscreens could be one of the causes of the increasing number of these largely incurable diseases (Ma et al. 2014). We also consider that ZnO can kill melanoma cells under normal conditions (without UV) (Wahab et al. 2013), whereas it has photo-toxicity as well (Ma et al. 2014). We need to rethink about the regulatory policy at hand in that public authorities have the responsibility to protect consumers from potential harm. Time is ripe to facilitate prevention of harm giving due consideration to the other side of the prevailing research.

In such a situation, a valid question may arise, what measures can be taken into consideration to facilitate prevention and whether those measures can hinder the logical development of the technology. The EU has taken precautionary measures, have these measures affected the growth and benefits of the technology in Europe? We have not found any evidence of damaging the prospect of nanotech in the EU by these precautionary measures. We need to consider the extent of potential harm, if the ‘wait and see’ approach silently endangers human health and life. Public Health Association of Australia (PHAA) notes that the current legislative regime is inadequate to prevent the harm at hand (PHAA 2014). Commentators echo a similar view about the inadequacy of the present law (Bowman and Bennett 2013). PHAA (2014) in its

nanotechnology policy advocates a precautionary approach, rather than ‘wait and see’ until hard evidence of harm is established. PHAA (2014) is concerned because it observes that most common findings of nanotech studies affirm nano-size materials have different properties compared to their larger counterparts, and that increasing evidence indicates significant health and safety effects of engineered nanoparticles. Australian regulation does not presently distinguish between these two different sizes of the same chemical (Dalton-Brown 2016). Appreciably, a public awareness of nanotech program was introduced in February 2010 in Australia – however, making the situation arguably even worse, it had been discontinued in June 2013. The discontinuation was premised on the assertion that the way of presenting nanotech information to the public lacked balance (seemingly against nano-products) (PHAA 2014). It is questionable whether closing the program altogether was the best course of action, or it could have been modified in order to ensure the balance as the authority deemed appropriate. The closing of the program may imply an intention to keep the public uninformed and is likely a denial of their right to know, which may be unhelpful for the nano-industry and its reputation in the long run in that future litigation costs may outweigh immediate profits.

Denial of people’s right to know and apprehension of rejection

Technological innovations are historically seen suspiciously, and regulation is designed based on diverse thresholds of risk-tolerance within respective jurisdictions for consumer products, using labelling, quarantine, and complete bans in the worst-case scenario (Marks 2016).

This is the age of information. Almost all developed nations have legislation recognising people’s right to know. The disclosure philosophy is based on the stakeholders’ right to know, and it is the predominant regulatory principle worldwide, including Australia. The general public have the right to access information about any matters that affect them and to provide input into shaping policy and practice in relation to those matters. Nanotechnology is certainly one of them. When a new technology of genetically modified organisms (GMO) was

introduced into Europe without disseminating adequate information to the public, people rejected the technology (Devos et al. 2006). A continued lack of information on nano-products in disregard to people's right to know may result in a similar rejection by the society (Duncan 2011). Conversely, proper labelling will bring transparency to the product, may increase its market acceptability, enable its end-users to make an informed choice, and provide its traceability in respect of regulation and liability as found in various studies (Capon et al. 2015a). A sustainable strategy is needed before any public rejection of nanotech occurs, and striking a balance between consumer protection and product innovation seems an appropriate action to take at this point of time.

Striking a feasible balance between consumer protection and scientific innovations

Adopting any regulatory philosophy should follow careful assessment of its potential impacts on stakeholders, technology and the national economy. While protective measures should be given due consideration, fostering innovation and competitiveness in the industry should not be ignored in any way. Hence, we want a regulatory balance between protection and innovation. This is what REACH aims to achieve in the EU (Ouellette 2015), and to that end the EU has introduced nano-labelling requirement without having to thwart the growth of nanotech.

It is certainly encouraging that the Australian Government recognises the potential long term social and economic benefits of nanotechnology for the nation. However, its current regulatory approach adopted for nanotechnology seems biased towards innovation in which the facilitation of scientific and commercial development takes precedence over consumer safety amid uncertainty that nano-sunscreens are harmful (Bowman and Bennett 2013). Although an uncertainty as to the risk scientifically exists, Australian reviews of nanotechnologies so far suggest a sort of certainty that 'there is no need to panic', entailing no major changes to be brought about –though there is a feeling that reviews need to be continued whilst utilising

largely existing uniform regulation for both bulk and nanoscale products (Bowman and Bennett 2013).

Prominently, the 2007 Australian first comprehensive nanotech review report (Ludlow et al. 2007; Bowman and Hodge 2007a; Bowman and Hodge 2007b) noted that although no immediate major regulatory overhauls were needed, reforms would be needed as new knowledge about the safety concerns emerged (Ludlow et al. 2007; Dalton-Brown 2016). That new knowledge, earned through numerous *in vitro* and *in vivo* experiments as alluded to earlier, has now arguably developed. On the other hand, public attitude towards the ‘clean benefit’ of nano-products has changed over time in Australia as evident in recent studies. The public attitudes in Australia revealed in studies conducted in 2005, 2007 and 2008 witnessed a positive understanding of the potential benefits in general without concerns for harm, which resembled those in the US and EU during that early period (Dalton-Brown 2016). However, that trend arguably no longer persists, as a 2015 study focused on public perception of nanotech risks and benefits concludes:

The Australian public perceives *greater risks* from manufactured nanomaterials and shows *less trust* in scientists and the health department to provide *protection* from possible health effects than academic, business and government stakeholders in the nanotechnology sector. Food applications and *cosmetics/sunscreens* loom *high on the list of public concerns*, *Policy makers should be aware* of these risk [sic] ... and address public sentiment by treating nanotechnology applications in the *higher risk areas* with greater caution [emphasis added] (Capon et al. 2015b; DIISRTE 2013).

The risk inherent in nano-sunscreens is not negligible, rather is perceived to be the greatest, just after nano-foods – compared to the risks associated with medicines, pesticides and other products containing nanoparticles (Capon et al. 2015b). Notably, even highly regarded

scientists in the area of nanotech have sometimes expressed greater concerns than the public (Scheufele et al. 2007). There are several studies testifying that both public and high profile scientists alike are concerned about the risk associated with nanoparticles (Capon, et al. 2015b). We have shown earlier the public concern and desire to have nano-labelling on the products in Australia. In addition, PHAA (2014) is equally concerned about nanomaterials and states that these ‘could be inhaled, ingested or enter the body through the skin’ (p. 1). It thus recommends adoption of a precautionary approach to regulation and introduce nano-labelling (PHAA 2014). Beyond Australia, the public around the world are generally supportive of such labelling irrespective of their origins and ethnicity (Brown and Kuzma 2013; Capon et al. 2015a). Capon et al. (2015a) argue that ‘understanding societal perceptions of risk and risk values is important to ensure a balanced policy approach’. They conclude that ‘understanding the public’s tolerance of risk for nanotech and the factors that drive this risk will lead to a greater success in implementing a labelling policy’ (Capon et al. 2015a). Reference to international public support is relevant to Australian sunscreens when it comes to exporting these products. Having regard to the above discussion, we argue that striking a balance between consumer protection and nano-innovations is justified and highly desirable.

Balancing regulation between fostering nanotechnology and human protection

Over the past decades, researchers around the world have discovered extraordinary breakthroughs in nanoscale science and engineering with widespread applications in many fields (Ouellette 2015). As an emerging area of research, nanotoxicology explores the effects of nanomaterials within the human body (Reese 2013). Now a major issue is to bring the nano-usage and its consequences under a regulatory microscope that can arrest or at least minimise the harm and maximise its benefits, instead of forbidding its applications.

It would be unrealistic at this stage of nano-advancement to think about avoiding this technology, rather a balance between the risk and rewards needs to be struck in the greater interest of humankind. We agree with Reese's (2013) view that having regard to the extent of our exposure to nano-products, it is critical to ascertain potential risks and to impose regulation striking 'a balance between accessing the benefits of nanotechnology and limiting the foreseeable harm to the environment and public health' (p. 538).

In view of the absence of nano-specific regulation in Australia, one can assume or speculate that the government is waiting for greater certainty concerning the risks in question before making any policy shift (Bowman and Bennett 2013). Thus the regulatory laxity at hand is attributable largely to scientific uncertainty of safety risk of sunscreens. A lack of knowledge about certainty of harm could be a ground for imposing an outright ban, but should not be a decisive factor in regulating disclosure, from the perspective of harm prevention particularly with respect to sunscreens because ample evidence is available in support of potential detriment. No one should wait for harm to have occurred before attaching regulatory requirements to those products. At the very least, the consumers' right to know as to what they are using can be honoured by introducing accurate disclosure of ingredients in the product labels, even if no potential risk is incorporated into the disclosure. Instead of adopting a 'wait and see' policy, the knowledge gap may justify adoption of progressive regulatory approach (Kaddour 2013). So it may not be defensible to continue with the 'wait and see' approach to sunscreens regulation. Regulation should reflect the societal expectation, a common consideration in formulating laws.

A balanced and cooperative regulatory approach is needed which should be focused on ensuring disclosure, keeping a close watch on new developments in the area, and enhancing public awareness. It requires involvement of the government, the industry and the public.

Government regulation

Government has the responsibility to protect the public and facilitate the growth of beneficial technologies. The EU current regulation aims to protect human health and the environment from harmful chemicals alongside facilitating the development of alternative methods for the assessment of hazards of substances (EC 2006). Australia does have similar concerns, which are further magnified by the country's stronger UV radiation levels. A precautionary model of regulation is argued to be the optimal way of dealing with the nano-industry at this point of development, and the EU is obviously a pioneer in this direction.

Given the present knowledge gap surrounding nanoscale of TiO₂ and ZnO, the TGA as the principal government watchdog in Australia should set out disclosure requirements and increase public awareness through dissemination of scientific developments in relation to benefits and potential harm of nanomaterials used in sunscreens. The disclosure has to be nano-specific in simple and clear terms as part of mandatory product disclosure to be incorporated into the *product labels* as well as be published on manufacturers' websites. Under REACH, a three-stage assessment and evaluation of suspected products are carried out. First, the manufacturers assess and evaluate the risks before registration of a product with ECHA, then ECHA and member states separately conduct the safety check and manageability of the risks found. If assessed unmanageable, regulatory authorities may impose restrictions or even declare complete ban on the product, as they deem appropriate. This EU safety check practice could be followed in Australia. However, benefits of any regulation depend on compliance which essentially requires an effective monitoring system to operate proactively.

The TGA will need to ensure compliance with these regulatory requirements. An active monitoring system should be put in place. In this respect, the EU Cosmetic Regulation which is based on 'market surveillance model' could be adopted in Australia. The EU surveillance model assigns a responsible person to monitor the compliance of each product available on the market, and the person shall ensure compliance with the regulation, when any noncompliance

is detected, the responsible person ‘shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate’ (EC 2009, art 4, 5(2)). Article 6 of the EU Cosmetic Regulation places obligations on distributors of cosmetics similar to those of manufacturers and importers. As such, all major players in the supply chain have been brought under the regulatory umbrella.

Apart from regulating the actors in the supply chain, the demand side should also be educated. To this end, the TGA, as part of regulation, should update the public awareness information through their official websites and other appropriate outlets encompassing the current state of the art regarding nano-sunscreens, based on the credible research, as they are made available. Notably, Article 21 of the EU Cosmetic Regulation, provides for public access to information about composition of cosmetic products and hazardous substance by any appropriate means, without prejudice to the legitimate commercial secrecy. The significance of public awareness is discussed further briefly below.

This is a growing area of innovation and investigation. Thus, government regulation alone may not be always able to ensure public safety. Manufacturers and importers may be aware of particular information at the time of manufacturing the products or at a given point of time, before the information reaches regulators. Hence, the government regulation should be supplemented by self-regulation.

Self-regulation

Although self-regulation, when standing alone, may not be generally effective to prevent harm mainly because of corporate culpability motivated by profit maximisation – it can be useful alongside the government regulation. Of course, all corporations should not be treated equally in terms of such culpability. Appreciably, recent studies suggest that some manufacturers, for example, Johnson & Johnson and Proctor & Gamble, have started phasing out toxic chemicals

from their personal care products (Kraus 2015). W.S. Badger Company, a US company, has stopped using nano-ZnO in sunscreens, instead it has been using ‘only uncoated non-nano sized particles of zinc oxide’ in its sunscreens, which has made the products popular (Cole et al. 2012).

Likewise, even some distributors and large retailers such as Walmart are planning to reduce toxic chemicals in their products (Kraus 2015). This positive action can be immediately rewarding for the company in that personal care products are marketed worldwide, so the removal of harmful chemicals will facilitate company’s greater access to the global market (Kraus 2015). We expect that these voluntary initiatives should stimulate others to follow suit. The nano-industry as a whole and each company individually need to have complete codes of conduct focusing on risk management and long-term commercial benefits or sustainability.

Risk management as part of self-regulation

Krow states that risk of injury by nano-products is directly proportional to exposure to them, and giving emphasis to risk management she provides prescription for achieving it (risk management) (Krow 2014). For the long term benefit of the industries which produce nano-products, they must not ignore implementing the risk management approach, because historically, a disaster in the end has occurred when companies produced new chemicals in a massive scale without having to fully investigate associated health effects of those products, and the socio-economic costs of those disasters have been overwhelming (Krow 2014). Amid uncertainty of the risks linked with nanoparticles, Krow suggests to follow traditional principles and ‘best practices’ - including due diligence, exposure control practices, and product stewardship - in order to manage the risks (Krow 2014).

Due diligence

Due diligence is said to be the cornerstone of risk management efforts, and it requires a dedicated and competent team to carry out proper investigation into legal, scientific and business aspects of the product in question staying abreast of the dynamics of the state-of-the-art in the relevant fields, in order to avoid any harm to all stakeholders and the company itself (Krow 2014). The team should be cautious that a product liability may arise at any stage of its lifecycle, which entails being informed of the entire supply, manufacturing, distribution, and disposal chain of a given product (Wernette 2010). To stay on the safe side, businesses should comply with the regulatory guidelines as well as the best safety practice recommendations, going beyond regulatory limitations and industry practices, where practicable (Krow 2014). This due diligence ‘should be viewed as an absolute *minimum* standard of care’ (Krow 2014, p. 160). The exercise of this standard of care should begin with designing of products, which is a critical aspect of risk management (Krow 2014). Controlling exposure to the potentially culpable substance is another way of minimising harm.

Controlling exposure

Having regard to the proportionate relation between exposure to products and extent of harm, controlling such exposure to harmful substance is generally a legal obligation of any entity anywhere, its individual enforcement practice regardless. Hence controlling such exposures should be taken seriously, and a failure in doing so may make companies indulged in the introduction of harmful products into the stream of commerce (*eg*, suppliers, distributors, manufacturers, and retailers) (Krow 2014). These products may cause harm to others for which the business may have to face strict liability, where good business intention will be irrelevant as a defence (Krow 2014). Although the exposure should be initially minimised from manufacturer’s workplace to protect workers, potential harm to consumers and other post-production handlers should be given equal emphasis (Krow 2014). So this relates to the

protection of sunscreens users as well. Product stewardship does help strengthen self-regulation and business sustainability.

Product stewardship

Consistently with the exposure control, product stewardship requires a broader consideration of harm prevention by ‘reducing the health, safety, and environmental impacts of consumer products across their lifecycle with a strong focus on sustainable end-of-life management’ (PSI 2018). The concept of product stewardship simply refers to the act of making products more sustainable through the protection of stakeholders across their life cycle (PSI 2018). This can be achieved in different ways, for example, by being proactive in conducting research and taking appropriate health and safety initiatives (Krow 2014). This stewardship has huge benefits for companies and their stakeholders in that it can prevent harm to others on the one hand, and keep companies immune from future litigation which is generally costly, on the other (Krow 2014). In addition, product stewardship can enhance the public image of companies contributing to increasing demand of their products and stocks and decreasing insurance cost (Krow 2014). As part of this stewardship, companies should invest in research in the area of nanotech, without which its further advancement and public safety are likely to be negatively affected, which cannot bring any good to anyone. We have to admit that nano-research aims to assist in the formulation of guidelines for safe and effective use of nanoparticles in different products (Cole et al. 2012).

Nanotechnology and nanosafety research thus aids in the development of guidelines for the safe and effective use of these materials in drug and therapeutic products, devices, foods, cosmetics, and dietary components, many critical aspects of human beings.

Alongside the government oversight and self-regulation, public awareness, as mentioned earlier, should be considered an integral part of preventing harm and nurturing nanotech in the present context.

Public awareness and educational initiatives

Public awareness empowers consumers to apply self-protection, and it is sometimes argued that such awareness is the best method of consumer protection (Kraus 2015). Where the product is potentially harmful, the awareness and consciousness of users is of paramount importance. This is particularly significant in relation to nano-sunscreens in that the existing body of nano-research overwhelmingly agree that nano-TiO₂ and ZnO can easily enter into the bloodstream through already dented, scuffed or itched skins, and thereby can cause life-threatening diseases. This awareness warrants disclosure of nanoparticles and rules of use. Any careless usage may result in serious harm including death.

In addition to government initiatives, the public awareness program can be supplemented by private actors as well (Kraus 2015). Companies can publicise additional information on their research and health effects of the products in a reasonable detail on their websites. Understandably, many consumers may not care about such publicity, but some still may benefit from it. Reinforcing the significance of such programs, Kraus (2015) asserts that ‘Pending more stringent restrictions, consumer education remains the best form of consumer protection’ (p. 193).’

We do recognise the importance of risk management as managing the risks is obviously a key to preventing harm; however, all risks cannot be always successfully managed, and no one should be exposed to an unacceptable level of high risk. Hence it is critical to bear in mind that ‘prudent risk-taking is more important than carefully managing the risks taken unwittingly’ (Solaiman 2013, p. 669). The current regulatory leniency is an upshot of a lag time between the proliferation of nano-products and relatively a slow pace of scientific development in identifying the relevant risks (Van Tassel and Goldman 2011). Taking advantage of this gap, the supply chains have been marketing those products and consumers have been using them in the absence of true knowledge of the products’ benefits and detriments. The inherent harm of

such products is generally not noticeable instantly; rather it takes years or even decades sometimes (USA Today 2018; The Daily Star 2018).

Obviously, maintaining a registry of nano-products, enforcing reporting requirements to the regulator and labelling changes will involve cost, which is to be shared between the government, industry and society, as suggested by the Centre for International Economics (CIE), whilst the benefits in relation to health and safety are ‘very difficult to quantify’ (CIE 2011; Bowman and Bennett 2013). This report notes that the speculative costs will outweigh the potential benefits (CIE 2011). However, commentators argue that the cost-benefit analysis in the present context shall be abandoned (Van Tassel and Goldman 2011). In favour of this abandonment, researchers argue that the harm that can be caused by nanoparticles is cumulative, irreversibly damaging to human bodies, and may be life threatening in the long run (Van Tassel and Goldman 2011). Notably, it seems that the Australian Government has accepted the aforesaid CIE report, whereas many Australian NGOs have questioned its credibility and validity (Bowman and Bennett 2013).

Businesses will maximise their profits at the expense of all these costs including loss of life of stakeholders, comprising those of mostly innocent and uninformed consumers (Van Tassel and Goldman 2011). It is worth noting that the probability of risks in question does not rest on speculation any longer, and the cost of premarket testing, product labelling and post market surveillance is small, compared to potential harm (Van Tassel and Goldman 2011). This is a situation which defensibly entails regulation of nano-products. Van Tassel and Goldman assert that ‘risk mitigation strategies will fill the critical gaps in our public health system and will supply the accountability that is necessary to maintaining safe consumer products as each new nanotech product is introduced into the market’ (Van Tassel and Goldman 2011).

Conclusions

Although some nanoscale materials pose a threat to public health and the environment, the regulatory oversight failed to keep pace with the commercialisation of the nanoenabled products (Krow 2014). There is no gainsaying that engineered products containing nanoscale materials have the potential to help address several critical global problems encompassing energy, transportation, pollution, health, medicine, and food; however, our concerns lie in prevention of their hidden harm. This technology is a precious industrial resource with a huge potential to produce significant socio-economic benefits for the humankind, however, these benefits are attached to ‘undefined, unquantifiable risks that demand more than a “wait and see” approach’ (Krow 2014, p. 147). Investments in addressing these risks and maximising benefits should be counted as essential cost of doing business in using high profile nanoparticles including TiO₂ and ZnO (Krow 2014). Failure to appreciate and mitigate the risks at hand may cause a business failure ruining all investments by paying punitive damages in the end (Krow 2014). Rucinski (2013) predicts that the ever increasing use of nano-products, already integrated into our daily life, will continue to rise, and their harmful effects will gradually become more persistent with the likelihood of triggering a huge upsurge of litigation in the foreseeable future. She further adds that ‘Despite the dichotomous nature of nanotechnology’s public persona, the risk to human health and our environment is tangible’ (Rucinski 2013, p. 440). Therefore, regulation of the use of nanoparticles is the need of the time.

Government regulators alone cannot effectively address the risks without the industry’s own initiatives and public awareness about nano-products. Although everyone is affected by nano-products in varying degrees, public awareness of this technology is still awfully low (Krow 2014). The prevailing research literature undisputedly claims that nano-TiO₂ and ZnO can easily enter into the bloodstream through scratched and broken skin and cause life-threatening diseases. This is where users’ cautiousness is most needed.

We have recommended a cooperative model of regulation based on precaution by all stakeholders including government regulators, persons engaged with the nano-industry and consumers at this point of nanotech development. We submit that the government regulators should adopt a precautionary policy of regulation in line with the current regulatory approach of the EU which requires, amongst other things, mandatory nano-labelling, safety checks by the industry and state authorities, manufacturers to ensure product safety, and puts in place a close monitoring of compliance by the industry. Regulators should also conduct an ongoing public awareness program. The nanotech industry should develop a code of conduct for all parties in the supply chain targeting minimisation of use of harmful nanoparticles and discovering and designing safer products through accurate product disclosures online and facilitating continued research. Companies individually will need to develop their own code of conduct to reinforce the practice of self-regulation. Although intact skin may be fine for nano-sunscreens, already scratched or otherwise scuffed skins need to avoid using nano-sunscreen for safety purposes. For this to happen, consumers should first educate themselves from the product labels and official websites of the respective regulators and manufacturers. A combined collaborative effort of these three – regulators, supply chain and end users– can help prevent harm and foster the growth of the technology.

Finally, we agree with Rucinski's (2013) assertion that 'while more research and analysis still needs to be dedicated to this topic, legislators, analysts, and litigators should stay mindful of the fact that a body of materials to assist them in evaluating these nano-harms does exist—all they have to determine is under what haystack they should look' (p. 440).

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