

Introduction to the Special Issue

Why the elephant in the room appears to be more than a nano-sized challenge

Joel D'Silva [1] and Diana M. Bowman [2]

Abstract

This Special Issue devoted to 'The legal regulation of nanotechnologies' draws together contributions from some of the leading commentators in their respective fields. The Special Issue canvasses some of the most pressing philosophical, ethical and regulatory questions currently being debated around the world in relation to nanotechnologies and more specifically nanomaterials.

At this relatively early stage of development, there is considerable scientific uncertainty, for example, about the potential human health and safety risks of some 'free' nanomaterials and their use. In addition to the potential risks associated with various products themselves, a number of commentators have also raised concerns about the potential occupational and environmental risks associated with the manufacture and disposal of certain classes of nano-based products. Looking beyond the scientific safety questions, commentators have also expressed concern about the potential reaction of consumers to the technology and the market realities therefore. Indeed, it is not a given that consumers will readily accept the use of nanomaterials in, for example, foods, even if they offer a 'superior' alternative to their conventional counterpart.

Regulation has a significant impact on the development and trajectory of new technologies. Depending on its scope, applicability and interpretation it will affect research and development, types of products produced, commercialisation and finally consumption of the technology (and its products). This Special issue incorporates fourteen papers covering various aspects and issues pertaining to the theme across a number of jurisdictions.

1. Introduction

We have all heard the word by now. The word 'nano' or 'nanotechnology' has crept into our vernacular and is now often associated with everyday consumer products such as the 'iPod nano'. The term has been marketed, often hyped and sold. But behind this commercial facade is an ongoing and intense debate. From its promise-or indeed its potential peril-through to its perceived developmental trajectory and even on issues such as definitions, there is little about the technology that is not currently being contested, scrutinised or the subject of intense deliberation. While government, industry and the research community attempt to address the very knowledge-deficits that drive much of these debates, an increasing number of consumer products are making their way onto the market.

The ever-increasing interest in the technology lies in the novelty that exists at the nanoscale and the subsequent ability to exploit this. [3] It is a technology, which although defined by its scale, has the potential to blur traditional disciplinary boundaries, and one that offers arguably its greatest contributions through its convergence with other technologies such as biotechnology and information technologies. The mundane nano-based products largely seen today, such as tennis rackets and silver socks, shall soon be superseded by the use of sophisticated nanomaterials in, for example, drug delivery mechanisms and medical devices, through to construction materials and food contact materials.

Yet despite the immense potential nanotechnologies appear to offer, current debates and uncertainties have already shown us that some applications will, and indeed are, challenging existing perceptions, dynamics and standards relating to ethics, health and environmental safety and governance. [4] At this relatively early stage of development, there is considerable scientific uncertainty, for example, about the potential human health and safety risks of some 'free' nanomaterials and their use. [5] In addition to the potential risks associated with various products themselves, a number of commentators have also raised concerns about the potential occupational and environmental risks associated with the manufacture and disposal of certain classes of nano-based products. [6] Looking beyond the scientific safety questions, commentators have also expressed concern about the potential reaction of consumers to the technology and the market

realities therefore. [7] Indeed, it is not a given that consumers will readily accept the use of nanomaterials in, for example, foods, even if they offer a 'superior' alternative to their conventional counterpart.

Knowledge gaps, questions of expertise, effectual participation by various stakeholders and definitional issues all pose crucial challenges to the effective regulation of products and processes that incorporate nanotechnologies. [8] The current paucity of data (so called knowledge gaps) on the effects of some nanomaterials, particularly insoluble and/or biopersistent nanoparticles, on human health and the environment has led to increased concern. [9] According to Wiesner et al., 'definitive answers on the risks posed by nanomaterials are perhaps years away and, in any event, are likely to emerge on a case-by-case basis'. [10] With an increasing number of individuals being potentially exposed to certain classes of nanomaterials within their workplace, combined with an increasing number of consumers using, nano-based products on a regular or semi-regular basis as part of their lives, it is not surprising that some commentators have voiced their concerns. [11] Such dialogue has done little, if indeed anything, to stem the manufacturing of nanomaterials and the commercialisation of nano-based products. And while such concerns are increasingly being acknowledged by governments, safety regulators and indeed even within certain sectors of industry, from an outsiders' perspective it would seem that the stakeholders are often talking past each other and not to each other. It would seem that if 'we' are to get this right, the elephant in the room must not only be acknowledged - but dealt with in a collaborative, multi-disciplinary manner which prioritises the greatest needs of the elephant above all else.

2. Where is the elephant in the room?

Given the concerns associated with certain aspects of the technology, questions regarding the ability of current media-specific regulatory frameworks to effectively manage any potential risks and / or uncertainties have been voiced from all corners of the globe. Indeed, as review after review has now shown, nanotechnologies are regulated; nano-based products fall under existing frameworks in the same way that their conventional counterparts do. But how well will these frameworks apply, especially when applying mass-based metrics to thresholds or determining the adequacy of exposure limits, is not yet known. Indeed, given the need for more scientific risk data to be generated and standardised characterization reporting to be invoked, it may take many years before any *real* evaluation of the effectiveness of such regimes can be successfully undertaken. Until then, it would appear that speculation will continue to grow as to the adequacy of current arrangements and the implications of adopting different regulatory solutions rather than maintaining the status quo.

Definitions play an important role in regulation as they establish the subject matter and scope of what is to be regulated. [12] The absence of the term/s 'nano' or 'nanomaterial' in existing legislation has not, been, as noted above, a barrier to such products and processes falling under existing frameworks. As Stokes and Bowman contend, this process is simply one of regulatory inheritance, and is symptomatic of how such regimes have dealt with the emergence of other, older technologies. [13]

Moving forward, however, there is some debate over the need for consensus on fundamental terms such as 'nanotechnology', 'nanoparticle', 'nanoscale', and a 'nanomaterial.' Some of these debates have been played out in the public arena and have been complex and highly contested. [14] The International Standards Organization (ISO) may have started working on this several years back; however it is interesting to note that there is still no internationally recognised and accepted definition of a 'nanomaterial.' This is despite the fact that several definitions have been discussed and proposed by national authorities, scientific committees, international organisations, and other bodies. [15]

In the European Union (EU), the European Parliament has forged ahead with its attempt to regulate particular product areas in which nanotechnologies are used as well as introduce definitions. This can be seen in the EU's recast of the regulatory regimes for cosmetics. [16] The *Cosmetics Regulation* amongst others things, includes the introduction of a definition of 'nanomaterials', notification requirements regarding the use of nanomaterials in cosmetic products and labelling requirements for all products containing nanomaterials. According to the *Cosmetics Regulation* a nanomaterial is:

'an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm'. [17]

In March 2009 the European Parliament voted in favour of a proposal to update the *Novel Foods Regulation* [18] with special treatment for nanoparticles and nanomaterials. According to the proposal, besides including definitions for 'nanomaterials', nano-specific test methods should be developed and all ingredients present in the form of nanomaterials will have to be clearly indicated in the list of ingredients. [19] The European Union Council (EUC) and European Parliament (EP) however failed to reach a decision on this in March 2011. The failure of agreement on 'cloned meat and its offspring' led to the abandonment of the entire Novel Foods recast process, sending the European Commission (EC) back to the drawing board. [20] The Commission has however indicated that it intends to make a new proposal for the Novel Foods Regulation recast as soon as possible, focusing on those aspects that had already been agreed during the negotiation process. [21]

In 2010, the EC's Joint Research Centre (JRC), the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the EC respectively released various definitions of a 'nanomaterial' to be used as a broadly applicable reference term for any EU communication or legislation addressing nanomaterials. [22] Finally, in October 2011, the EC adopted a recommendation on the definition of a nanomaterial. [23] The recommendation encourages member states, EU agencies and economic operators to use the adopted definition 'in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies'. [24] According to the EC, a nanomaterial,

'means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %'. [25]

This definition has, however, received its fair share of criticism. The European Environmental Bureau (EEB) has, for example, claimed that the definition is 'too narrow', [26] while the European Chemical Industry Council (CEPIC) stated that the definition was too broad and would add to an 'unnecessary burden' for companies. [27] The various initiatives by the JRC, SCENIHR and the European Commission to define a 'nanomaterial' are definitely a move in the right direction, since having an accepted over-arching definition for regulatory purposes would be beneficial, to say the least. However, for all these bodies and regulatory agencies, 'one of the challenges raised by nanomaterials is to make balanced, sound decisions when relatively little nanomaterial-specific hazard and exposure data is available to inform such decisions, considering the fact that several products containing nanomaterials are already on the market'. [28] Also, regulators and manufacturers are in need of reliable data to determine whether, under specific conditions, certain nanoscale materials have the potential to create adverse impacts on workers, consumers and the environment. Such data needs to be developed accordingly for specific nanomaterials, or the means must be available to extrapolate reliably from data on other similar nanomaterials. [29] Defining terms such as a 'nanomaterial' for regulatory purposes is also as much a political endeavour as it is a scientific one. [30] There is also a strong need for consistency between European definitions and definitions developed by other jurisdictions and international bodies like the ISO and the Organisation for Economic Co-operation and Development (OECD). [31]

Besides definitions, standardisation will also play a critical role in ensuring that the potential of nanotechnology is realised and safely integrated into society. [32] The production and availability of well-characterised and controlled nanotechnology products depends on the availability of documentary standards for terminology, nomenclature, measurement and characterisation. [33] Much of these standards however, will have to be anticipatory since many nanotechnological developments lie in the future. The developments of anticipatory standards however are likely to be plagued by two problems: a lack of sufficient scientific and technological knowledge required and differences in the way the standards may be developed. [34] Despite these, standards will become necessary to facilitate the inter-operability of nanoscale devices and systems. In addition to measurement and inter-operability standards, taxonomy standards will also be needed to ensure that everyone involved in the field is speaking the same language. [35]

The EU is by and large the first jurisdiction in the world to adopt a mandatory nano-labelling policy (*Cosmetics Regulation*). The labelling requirements will hence not only have implications within, as well as beyond, the EU. It is unclear at this time, for example, whether industry will-for economic reasons-keep the labels developed for the EU market on their products, even when selling outside of that market. As such, there is the potential to see voluntary positive labeling of cosmetic products in other jurisdictions as a direct result of the EU's stand. This has the potential to then circumvent the policy debates going on in countries such as the United States, where the Food and Drug Administration (FDA) has explicitly rejected calls for the introduction of nano-specific labelling requirements. [36]

Even so, it would appear that the debate over the need for mandatory labelling regimes for products containing nanomaterials is likely to intensify as the number of products available on the market increases. [37] Fundamental to these debates will be the questions of the purpose of any such regime and the nature that such a regime should take in order to meet its objectives. Each of these questions is highly contentious and is likely to represent significant battlegrounds, not only across stakeholder groups but also within stakeholder groups given the diversity of interests at play and their economic implications. [38]

The lines on these battlefields are still being drawn, and are likely to be redrawn time and time again as new data comes to the fore. But ensuring that the various key players are all on the same page, and are talking about the same issue, is critical to ensuring that answers are generated sooner rather than later.

3. The Special Issue: Brief introduction to articles

Regulation has a significant impact on the development and trajectory of new technologies. Depending on its scope, applicability and interpretation it will affect research and development, types of products produced, commercialisation and finally consumption of the technology (and its products). This Special issue of the *European Journal of Law and Technology* incorporates fourteen papers covering various aspects and issues pertaining to the theme - 'The legal regulation of nanotechnologies' across a number of jurisdictions. As these contributions highlight, the technical nature of

the debate and the jurisdictional undertones associated with them has ensured that there is incredible scope for commentators and stakeholders to inadvertently talk past each other. Such complexities are further amplified by the sheer breadth of discussions needed so as to ensure the safe and responsible development of the technology.

The scene for this Special Issue is set in the first article by one of the leading social science commentators in the field, David Berube. It is in this contribution that Berube seeks to remove the hyperbole surrounding much of the debate over emerging technologies-such as nanotechnologies-by instead drawing the reader to the real issues at hand. Using a humanistic analysis, Berube traces the emergence of the nanotechnology phenomena over a decade through ten key claims that have been made by both opponents and proponents of the technology during that period. He argues that 'trying to separate accuracies from hyperbole remains problematic'. Such a conclusion is, in our view problematic; if an expert in the field finds it hard enough to separate out fact from fiction, then how is the general public meant to interface with such a complex and highly dynamic technology? In his view, a re-examination of how we perceive the evolution of an emerging technology is needed if we are to ever de-couple the 'claims and counterclaims' underpinning its evolutionary path.

The second article employs a beneficence lens through which author, Hailemichael Demissie, examines the concept of regulatory virtue in relation to nanotechnologies. In his view, 'regulation in general and the regulation of modern technologies in particular remains a risk management specialization least concerned with the distributions of benefits'. Contrasting the concept of beneficence against the concept of justice, the article argues that beneficence, instead of the virtue of justice, is the appropriate regulatory virtue for the governance of nanotechnology.

These broad theoretical and philosophical articles provide the foundation for more focused articles, each of which examines a more discrete area of the nano-regulation debate. While the authors of these articles straddle disciplines and jurisdictions, their contributions highlight the complexities involved and how such questions must be answered in a systematic manner in order to make significant progress. In their article, Roger Strand and Kjølbjerg Kamilla focus on the way in which the EU is tackling the regulatory challenges posed by nanoparticles. The focus of the article is on scientific uncertainty and its relationship to both risk and the precautionary principle. The authors argue, for example, that the 'prevention of unintended harm, potentially disastrous harm, to health and the environment' will require more than simply 'filling in the regulatory gaps'. This current approach is, in their view, unsatisfactory in the management of uncertainty and is naive given the existing development and use of nanoparticles. The authors note that while a ban on their production and use is unrealistic, they argue that alternative regulatory strategies that promote a precautionary approach are warranted at this time.

Harald Thorne-Holst and Arie Rip focus their contribution on the politically charged and complex issue of labelling. Moving beyond the theoretical, their article examines the issue of consumer labelling of nano-based products through the consumers' own voices. The authors report on the findings of two Norwegian focus groups that were conducted in 2006 and 2008. While acknowledging that labelling schemes 'offer consumers the possibility to make informed product choices', the authors go on to note the inherent complexities that are associated with any such regime; their findings suggest that a myriad of complexities overlay each other when talking about the labelling of nano-based goods. In this respect, a labelling regime-the authors note-is not in itself the only solution to addressing consumer concerns regarding transparency and accountability, and public education. Drawing on their empirical findings, the authors propose an alternative to a 'nano-based' labelling regime that is based on the concept of shared responsibility.

From consumers to workers; this is the direction that the Special Issue then takes. In her article, Bärbel Dorbeck-Jung explores so-called forms of soft regulation-including codes of conduct-that have been developed and rolled out by various actors in order to reduce potential employee exposure to nanomaterials. The article articulates the various tools that have been developed to date, with a focus on understanding 'how...soft regulation [can] contribute to responsible nanotechnological development'. The article not only sets out the regulatory landscape, but also goes beyond it through empirical research so as to begin constructing a framework on which these activities may then be evaluated against. Dorbeck-Jung concludes that continued vigilance and ongoing adaptation of the soft regulatory approaches will be needed in order to ensure that workers are the beneficiaries of 'best practices' within the occupational setting. This will not be an easy task, and as the author concludes 'more reflection is needed on the false sense of certainty concrete benchmarks may provide'.

The sixth article continues the examination of the European landscape. In their article, Steffan Foss Hansen, Catherine Ganzleben and Anders Baun examine an often-overlooked piece of legislation that has a close connection with nanomaterials - the *Water Framework Directive (WFD)*. As noted by the authors, 'it is inevitable that nanomaterials will be released into EU waters either directly or via soils', and thus as the volume of nanomaterials produced increases, so too will the importance of the WFD in regulating any potential release. The authors question whether or not nanomaterials should be considered in the list of priority substances and the challenges of doing so. As with the operation of other regulatory frameworks, scientific uncertainty in relation to the potential toxic nature-including ecotoxicological data-of some nanomaterials appears to be a limiting factor for the effective deployment of the legislative instrument. The authors conclude by providing readers with four concrete steps in order to assist in reducing some of the challenges identified in their analysis.

In their article, Hitoshi Nasu and Tom Faunce look at the regulatory debate on nanomaterials through the lens of security; security in terms of, for example, food security, defence and counter-terrorism. Their analysis of the recent recast of

the *Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical Equipment* in the EU provides the perfect vehicle for such a case study, and in doing so, eloquently highlights the competing policy agendas that were at play. By focusing on the implementation and operation of the precautionary principle, the authors note that 'the ambiguity of the...principle, and in particular the ambiguity of the risk to be evaluated in a risk assessment, does not ensure that regulatory decision-making will take into account the global implications of European nanotechnology regulation in the context of various security concerns shared by states internationally'. In light of the current debates over the adequacy of existing regulatory approaches, the authors argue for the adoption of a more tailored regulatory approach, which 'address[es] the competing safety and security concerns'.

Michael Reinsborough and Gavin Sullivan explore the thorny question of regulating nanomaterials under the EU's *Biocidal Products Directive*. Their focus is, however, on the way in which some civil society organizations have become involved in the regulatory and policy debates in the United Kingdom (UK) through the court process. In their article, the authors critically examine an attempt by several civil society actors to mount a public-interest legal challenge against the UK Health and Safety Executive for failing to properly enforce the *Biocidal Products Directive* in relation to nanosilver consumer products. As participants in the public-interest challenge, the authors provide intimate details of the objectives behind the challenge and the steps taken by the actors in order to prepare the legal challenge. The authors state, for example, that from the outset, the process of attempting to use public-interest litigation to contest the legality of the UK government's regulation of nanotechnology had two primary aims. First, that such a case would force a more robust regulatory approach to be adopted by the HSE and second, that by generating profile on the issue within and across the public domain, such a case might stimulate civil society and broader public engagement on the issue. While the article highlights some of the structural conditions underlying the contemporary regulatory balance of forces which limit public-interest litigation, it suggests that such action may be a viable alternative to more traditional mechanisms—at least in some instances—in an effort to open up such debates.

Douglas Robinson shifts the focus to the agri-food sector and the governance challenges facing that area of industry in relation to nanotechnologies. As a number of commentators have already observed, the use of nanotechnologies in food has the potential to be a lightning rod for consumer concern and public backlash. Acknowledging such concerns, Robinson provides a comprehensive analysis of how nanotechnologies may be used primarily in food packaging for the benefit of industry and consumers alike. Robinson does not however shy away from the issues and concerns posed by nanotechnologies in this sector, noting in particular the important interaction that occurs between consumers and the foods that they enjoy. He notes that 'consumer perspectives are and will play a strong role with regards to the commercial development of nanofoods. Engagement exercises stimulated by public agencies and other organisations are an important part of the nanofood landscape and the forms and functions of these interactions will play a strong role in the emergence and societal embedment/rejection of nanofood options'. In Robinson's view, foresight will be a fundamental tool for shaping consumer perception and informing emerging governance arrangements within the sector.

Margherita Poto's contribution to this Special Issue builds on that of Robinson, but focuses instead on food safety regulation systems in the People's Republic of China (China) and in the Special Administrative Region of Hong Kong (HK). Providing an overview of the regulatory structures and key legislative instruments, Poto notes that the current challenge underpinning these systems 'lie in the need to straddle the two worlds of traditional-produced food and wet markets, and the centralized food production network'. The introduction of foods utilizing new technologies, including nanotechnologies, appears to add several additional layers of complexities. Her article then goes on to examine the ability of these frameworks to effectively regulate nano-based foods and food contact materials within the two jurisdictions. In the two jurisdictions there is, according to Poto, a 'commitment' to strengthen their regulatory framework in order to protect consumers from unsafe food and this commitment can involve the field of nano-foods, as an integrated part of the novel foods regulation'. Key to the strengthening of the regulatory framework would, however, appear to be 'a bottom-up' approach.

The eleventh article comprising the Special Issue, authored by Darryl Jarvis and Noah Richmond, also focuses its attention on China, but does so from the perspective of the country's investment in (nano)science and technology. The authors highlight how the country's policies—including economic investment policies—towards nanotechnologies have evolved over several decades, and the institutions and agencies that have been instituted to assist the country in fulfilling this goal. The very fact that, as the authors argue, 'nanotechnology is tied intimately to a national political agenda', would appear to have negatively influenced the ability of stakeholders to raise concerns—albeit in relation to safety or regulation more generally—about the technology. The authors themselves argue that 'the command and control style approach to national economic planning and the development of nanotechnology creates elite, technocratic processes, limiting the spaces for wider consultation or public participation about the role, desirability, potential applications...or where risks and questions about potential harm from such technologies can be assessed'. Questions regarding the effectiveness of the regimes to potential risks to human and environmental health and safety remain largely unasked and unanswered.

The ability of the Indian state to manage potential risks associated with nanotechnologies is then examined by Shilpanjali Sarma. With India 'fueled by the aspiration to be amongst the frontrunners in the nanotechnology domain'—as highlighted by its positioning in the development agenda—the central focus of this article is to examine the country's regulatory and institutional capacity to deal with the uncertainties posed by nanomaterials. Given the limited resources of the government, and competing pressures on these resources, it is not surprising that Sarma argues that 'despite the growing efforts at risk assessment and management, India is still vulnerable to manifestation and amplification of risks from nanotechnology'. In particular, Sarma suggests that the government's delay in engaging in the risk-debate is likely

to make it more vulnerable to potential risks and that the process of risk assessment itself is likely to put a 'tremendous regulatory burden for underfunded risk management systems in India'.

William Ryan, Sho Takatori, Thomas Booze and Hai-Yong Kang turn readers' attention to the United States, with the authors providing an in-depth look at California's mandatory call-in program for nanomaterials. As employees of the Department of Toxic Substances Control (DTSC) in the California Environmental Protection Agency-the body that initiated the call-in-the authors provide a unique perspective on the aims and objectives of the program. As a 'nano-industry leader... [with a] large technical workforce already in place', Ryan et al note that a key rationale behind the initiative was 'to assure that nanomaterials and the nano-industry evolve in a manner that anticipates threats and avoids unnecessary risk'. Ryan et al. provide a comprehensive outline of the data-call in process for carbon-nanotubes, the first material of interest to the DTSC, and the key questions underpinning the data-call in. Pursuant to the provisions provided for under the California's Health and Safety Code, the DTSC sought information from manufacturers regarding analytical test methods, fate and transport in the environment, and other data. As explained by the author, 'the DTSC expects to develop an in-depth understanding of the nature of nanomaterials and their fate and transport in the environment' as a result of the data-call in. It is likely that other public authorities will be keeping a close watch on the program to see what data is derived as a result of the process and at what cost, in order to determine whether similar types of programs be rolled out in other jurisdictions.

The fourteenth and final contribution to this Special Issue is written by Colin Gavaghan and Jennifer Moore. As the authors of a recent report for the New Zealand Government assessing the effectiveness of the country's current regulatory framework for managing the potential risks of nanotechnologies, this contribution draws upon that work. The focus of their article is, however, on hazardous substances and their regulation under the country's *Hazardous Substances and New Organisms Act of 1996*. In order to illustrate the operation of the Act to nanomaterials, the authors detail how the legislative instrument, on a strict reading of the Act, would treat a number of products containing nano-scale silver, such as the nano-silver washing machine manufactured by Samsung. The authors provide a step-by-step analysis of the Act, and in doing so, illustrate the current ambiguities that occur in relation to some nano-based substances. The authors articulate three potential levels at which regulatory gaps may arise in relation to the operation of the Act for nanomaterials, which are likely to be mirrored in analogous pieces of legislation around the world.

4. Concluding note

This Special Issue devoted to 'The legal regulation of nanotechnologies' draws together contributions from some of the leading commentators in their respective fields. The Special Issue canvasses some of the most pressing philosophical, ethical and regulatory questions currently being debated around the world in relation to nanotechnologies and more specifically nanomaterials. In this respect, and to borrow the words of Fielder and Reynolds-two of the leading thinkers in this space from 1994-the Special Issue has thus been designed to be 'more of a wakeup call than a road map, and it raises far more questions than it answers'. [39]

Many of the questions raised by the authors of these fourteen articles cannot be answered at this time; indeed, they may not be adequately answered for sometime to come. What is important, however, is that the elephant in the room is acknowledged; that we stop talking past one another and that concrete action is taken to prioritise our research and policy agendas. Only then may we start to address those knowledge gaps and begin to comprehensively address the multitude of questions being raised in this space.

Finally as guest editors of this EJLT Special Issue, we would like to express our gratitude to each of the contributors. We would like to thank Professor Philip Leith and Professor Abdul Paliwala for their on-going and unwavering encouragement and support.

[1] Joel D'Silva is Affiliated Researcher, Department of Legal & Economic Governance Studies (LEGS), University of Twente, Netherlands; Email: joel.dsilva@telenet.be

[2] Diana Bowman is Assistant Professor, Risk Science Centre and Department of Health Management and Policy, School of Public Health, The University of Michigan 1420 Washington Heights, Ann Arbor MI 48109-2029 and Faculty of Management and Governance, University of Twente. Tel: +1 734 647 1825; Fax: +1 734 764 4338; Email: dibowman@unimelb.edu.au. The authors would like to thank the NanoNextNL program for their on-going support.

[3] Balbus J et al (2005), Getting Nanotechnology Right the First Time, *Issues in Science and Technology*, 65; See also, Bowman D and Hodge G (2007), A Small Matter of Regulation: An International Review of Nanotechnology Regulation, 8 (1) *Columbia Science & Technology Law Review*, pp.3-4.

[4] See, D'Silva J and Van Calster G (2009), Taking Temperature- A Review of European Union Regulation in Nanomedicine. 16 (3) *European Journal of Health Law*, pp.249-269; Bowman D and Gilligan G (2007), How will the regulation of nanotechnology develop? Clues from other sectors, in Hodge G, Bowman D and Ludlow K (eds), *New Global Frontiers in Regulation: The Age of Nanotechnology*, Edward Elgar: Cheltenham, pp. 353-381; Bowman D and

Van Calster G (2008), Flawless or Fallible? A Review of the Applicability of the European Union's Cosmetic Directive in relation to Nanocosmetics, 2(3) *Studies in Ethics, Law and Technology*, pp.1-35; Marchant, G, Sylvester D, Abbott K and Danforth L (2009), International Harmonization of Regulation of Nanomedicine, 3(3) *Studies in Ethics, Law, and Technology*, Article 6; Wagner V et al (2006), The Emerging nanomedicine landscape, 24 *Nature Biotechnology*, pp.1211 - 1217; Stokes E (2009), Regulating Nanotechnologies: sizing up the options, 29 (2) *Legal Studies*, pp.281-304.

[5] De Jong W and Borm P (2008), Drug delivery and nanoparticles: Applications and hazards, 3(2) *International Journal of Nanomedicine*, pp.133-149; see also, Lin A (2007), Size Matters: Regulating Nanotechnology, 31(2)*Harvard Environmental Law Review*, pp.356-361; Xia T et al., (2009), Potential Health impacts of Nanoparticles, 30 *Annual Review of Public Health*, pp.137-150.

[6] DHHS (NIOSH) (2009), Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns associated with Engineered nanomaterials, 125, <http://www.cdc.gov/niosh/docs/2009-125/>; See generally Oberdörster, E (2004), Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass. *Environmental Health Perspectives*, 112(10), pp. 1058-1062; Maynard, A.D., Aitken, R.J., Butz, T. et al. (2006), Safe handling of nanotechnology. *Nature*, 444, pp. 267-269; and Kandlikar, M., Ramachandran, G., Maynard, A.D., et al. (2007), Health risk assessment for nanoparticles: A case for using expert judgment. *Journal of Nanoparticle Research*, 9, pp.137-156; Kimbrell G.A. (2006), Nanomaterial Consumer Products and FDA Regulation: Regulatory Challenges and Necessary Amendments. *Nanotechnology Law & Business*, 3, pp. 329-338; Davies, J. C. (2006), *Managing the Effects of Nanotechnology*. Washington, DC, Project on Emerging Nanotechnologies; Taylor, MR. (2006), Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs? Washington DC: Project on Emerging Nanotechnologies; Friends of the Earth Australia (2008), *Mounting evidence that carbon nanotubes may be the new asbestos*. Melbourne, FoE; Davies, J. C. (2010), From novel materials to next generation nanotechnology: A new approach to regulating the products of nanotechnology in Hodge, G.A., Bowman, D.M. and Maynard, A.D. (eds), *International Handbook on Regulating Nanotechnologies*, Cheltenham, Edward Elgar, pp.545-570; Breggin, L. and Pendergrass, J. (2010), Regulation of Nanoscale Materials under Media-Specific Environmental Laws, in Hodge, G.A., Bowman, D.M. and Maynard, A.D. (eds), *International Handbook on Regulating Nanotechnologies*, Cheltenham, Edward Elgar, pp.342-371.

[7] Petersen A, Seear K, and Bowman DM (2009), The Social and Economic Impacts of Nanotechnologies: A Literature Review, p.10, http://www.innovation.gov.au/Industry/Nanotechnology/NationalEnablingTechnologiesStrategy/Documents/SocialandEconomicImpacts_LiteratureReview.pdf

[8] D'Silva J and Bowman D (2011), The Regulation of Nanomedicine, in Hunter R & Preedy V (ed.), *Nanomedicine in Health and Disease*, Science Publishers USA, pp. 20-42.

[9] Miles J (2010), Nanotechnology Captured, in Hodge G, Bowman D and Maynard A (eds), *International Handbook on Regulating Nanotechnologies*, Cheltenham, Edward Elgar, p.85; see also, Maynard A and Kuempel E.D (2005), Airborne nanostructured particles and occupational health", 7 *Journal of Nanoparticle Research*, pp. 587-614; D'Silva J and Van Calster G (2009), Taking Temperature -A Review of European Union regulation in Nanomedicine, 16(3) *European Journal of Health Law*, pp.249-269.

[10] Dorbeck-Jung B et al (2011), Governing nanomedicine: Lessons from within, and for, the EU medical Technology Regulatory Framework, 33(2) *Law and Policy*, p. 219.

[11] Ibid Dorbeck-Jung

[12] Bowman D, D'Silva J and Van Calster G. (2010), Defining Nanomaterials for the Purpose of Regulation within the European Union, *European Journal of Risk Regulation*, Vol. 1 Issue 2, p. 115; see also, Williams D (2010), The Scientific Basis for regulating nanotechnologies, in Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard (eds), *International Handbook on Regulating Nanotechnologies*, Cheltenham, Edward Elgar, pp.109-111.

[13] Stokes E, Bowman DM (forthcoming), Looking back to the future of rugulation new technologies: the case of nanotechnology and synthetic biology *European Journal of Risk Regulation*.

[14] Ibid; see also D'Silva J (2011), What's in a name? Defining a 'nanomaterial' for regulatory purposes in Europe, 1 *European Journal of Risk Regulation*, p.85; See also, Hunt G (2004), Nanomaterials: Nomenclature, Novelty and Necessity, 56 *Journal of Materials*, p.13

[15] D'Silva J (2011), What's in a name? Defining a 'nanomaterial' for regulatory purposes in Europe, 1 *European Journal of Risk Regulation*, p.85.

[16] *Regulation (EC) No. 1223/2009 - Cosmetics Regulation Recast*, OJ L342/59.

[17] *Regulation (EC) No 1223/2009*, OJ L 342/59 - Article 2(1)(k).

[18] *Regulation (EC) 258/97 concerning Novel Foods and Novel Food Ingredients*

[19] Bowman D, D'Silva J and Van Calster G. (2010), p. 117.

- [20] Nanotechnology Industries Association (2011), Clone wars: End of the Novel Foods Regulation Recast, <http://www.nanotechia.org/global-news/clone-wars-and-the-return-of-the-nanomaterial>; See also, European Parliament (2011), Novel Foods talks collapse on Council refusal to label clone-derived products, <http://www.europarl.europa.eu/en/pressroom/content/20110328IPR16525/html/Novel-Foods-talks-collapse-on-Council-refusal-to-label-clone-derived-products>
- [21] Ibid FN 20 NIA
- [22] D'Silva J (2011), What's in a name? Defining a 'nanomaterial' for regulatory purposes in Europe, 1 *European Journal of Risk Regulation*, pp.85-86; For the debate on the need for such a definition see also, Maynard A (2011), Don't define nanomaterials, 475 *Nature*, pp.30-31; Maynard A et al (2011), The problem of regulating sophisticated materials, 10 *Nature Materials*, pp. 554-557; Stamm H (2011), Nanomaterials should be defined, 476 *Nature*, p. 399; see also, Joint Research Centre (EU) Reference Report EUR 24403 EN (2010), Considerations on a Definition of Nanomaterial for Regulatory Purposes http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf; European Commission (2010), Proposal for a definition of the term 'nanomaterial' that the European Commission intends to use as an over arching, broadly applicable reference term for any European Union communication or legislation addressing nanomaterials, http://ec.europa.eu/environment/consultations/pdf/recommendation_nano.pdf; SCENIHR (2010). Scientific Basis for the Definition of the Term 'Nanomaterial', http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_030.pdf
- [23] European Commission (2011), Recommendation on the definition of nanomaterial, http://ec.europa.eu/environment/chemicals/nanotech/pdf/commission_recommendation.pdf
- [24] Ibid, FN 23 p.5.
- [25] Ibid FN 23
- [26] EEB (2011), Press release- Nano definition too narrow, <http://www.eeb.org/EEB/index.cfm/news-events/news/nano-definition-too-narrow-says-eeb/>
- [27] CEFIC (2011), Practical nanomaterials definition needed to push forward next great innovation breakthroughs, <http://www.cefic.org/PressReleases/Press%20statement%20nano%20definition.FINAL.pdf>
- [28] Morris J et al. (2010), Science Policy Considerations for responsible nanotechnology decisions, *Nature Nanotechnology*, Commentary:doi:10.1038/nnano.2010.191, p. 3.
- [29] Ibid FN 28 p.4.
- [30] D'Silva J (2011), What's in a name? Defining a 'nanomaterial' for regulatory purposes in Europe, 1 *European Journal of Risk Regulation*, p.91.
- [31] Ibid, p.90.
- [32] Miles, J (2010) Nanotechnology captured, in Hodge G et al (eds), *International Handbook on Regulating Nanotechnologies*, Edward Elgar, Cheltenham, p.83.
- [33] Miles, J (2007) Metrology and Standards in Nanotechnology, in Hodge, G et al. (eds), *New Global frontiers in Regulation: The Age of Nanotechnology*, Edward Elgar, Cheltenham, p. 344.
- [34] Ibid, FN 33 p.348.
- [35] Rashba, E. et al (2004), Standards in Nanotechnology, 1(2) *Nanotechnology, Law & Business*, p.192.
- [36] See, Jaspers N (2010), How to avoid International Trade disputes, 1(2) *European Journal of Risk Regulation*, p. 169.
- [37] Falkner R, Breggin L, Jaspers N, Pendergrass J and Porter R (2009), Consumer Labelling of Nanomaterials in the EU and US: Convergence or Divergence?, EERG Briefing Paper, London: Chatham House, pp. 3-4.
- [38] D'Silva J and Bowman D (2010), To Label or not to Label? Its more than a nano-sized question, 4 *European Journal of Risk Regulation*, pp.426-427.
- [39] Fiedler F.A. and Reynolds G. H (1994), Legal Problems of Nanotechnology: An Overview, 3 *Southern California Interdisciplinary Law Journal*, p.595.