1. Introduction: the regulatory challenges for nanotechnologies

Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard

1.1 INTRODUCTION

The past two decades have seen much debate about nanotechnologies. We have also been busy contemplating the regulatory implications of such new scientific frontiers. Indeed, we appear to have made real progress in these regulatory discussions as conversations have become progressively more professionalized, more careful and more rational. Or so some people assume.

Yet underneath this veneer remains a real paradox. Despite its ubiquity and the undoubted importance of nanotechnology over the coming decades, the ‘nanotechnology phenomenon’ is itself an enigma. Its definition, meaning and historical origins continue to be the subject of contest, so that the degree to which it is really a ‘new’ scientific frontier requiring fresh thinking remains unclear. Indeed, amid calls for renewed ‘upstream’ policy dialogue, greater public engagement and stronger regulation, we are still debating the degree to which nanotechnologies are new, or are merely a re-badging exercise. And amid calls for governments to step in and guard against the inherent risks of new technologies, we are still debating the degree to which such responsibility should be borne by industry, government and the community.

Moreover, in times of increased global economic uncertainty, the point at which the optimum balance is achieved in progressing forward and maximizing economic growth and sustainability while showing sufficient precaution remains as elusive as ever. So, are we on the verge of a revolutionary nanotechnologies platform? Or does the coming ‘nano-age’ simply amount to a cluster of exciting ideas sold to us by fervent investors, self-interested academics and politicians, each of whom are keen to make their name and mark their success through innovative new ways of solving current economic and sustainability challenges?

This Handbook assumes that nanotechnologies are an important part of today’s society, and will also play a significant role in tomorrow’s economies. But in saying this it is clearly science, or more particularly the
realm of the nanosciences, along with the knowledge and applications that they spawn, that is central to this future. It is the continuing challenge of governing technology, as well as its relationships to the public and to businesses that are all at stake.

This Handbook also acknowledges that, to a large degree, the challenge of regulating nanotechnologies is yet another ‘wicked’ public policy problem facing governments, including climate change and other emerging technologies such as synthetic biology. Wicked problems have been defined as problems which have a multitude of stakeholders showing interest, but an inability for stakeholders to agree on either the nature of the ‘problem’ (to the degree that it exists at all), or on the most desirable solution to be applied (Klijn, 2008). Stakeholders such as industry leaders, politicians and non-government organizations (NGOs) all have differing and competing motivations within debates. All appear to genuinely believe that they best represent the interests of citizens.

This Handbook takes up the challenge as well of regulation as a multi-disciplinary common ground in which stakeholders and other interested parties may meet to contest their understandings of the objectives of regulation and the best paths forward. Whether the contributor, or indeed the reader, comes to regulation from a background in public policy, science, law, public administration, business, engineering, economics or history, it may be argued that we share this common space because of our interests in encouraging more civilized behaviours in the arena of nanotechnologies. A central and challenging observation is the fact that very few people have formally undertaken tertiary training in ‘regulation’. So while wanting to influence regulatory design and the governance of nanotechnologies, most commentators actively engaged in these debates have minimal formal regulatory training behind them. This is a sobering observation. On these grounds, a more philosophical view of regulation rather than one limited to a particular discipline such as law or economics is clearly warranted.

Within this broader context, it is worth considering the observations of Levi-Faur and Comaneshter (2007). These two regulatory scholars noted that in relation to nanotechnologies,

 unlike other cases where the discussion of the associated risks has followed the development of new technologies, the discussion on the proper regulatory framework for the governance of nano-technology is accompanying the development of the technology and the associated products themselves (Levi-Faur and Comaneshter, 2007: 150).

Their observation was optimistic, but would appear to be also realistic given the array of government and industry efforts that have been initiated
in a number of different jurisdictions over the past five or so years. Their proposition therefore remains a great starting point for us today. Even when we start from this point, however, it is necessary to have a better understanding of the regulatory phenomenon and its relationship to nanotechnologies. Moreover, if we are to make progress in our quest, a series of challenges must be addressed. In order to conduct, for example, a dialogue on nanotechnologies, it is pivotal to first understand the multiple languages that underpin the phenomenon as well as the many policy and technical challenges facing us in moving forward.

This chapter proceeds by outlining the characteristics of the three languages crucial to nanotechnologies: the language of nanotechnology as a ‘phenomenon’; the language of nanotechnologies as a set of science frontiers; and the language of regulation. It then outlines a range of regulatory frontiers which currently face government, industry, civil society and members of the international community. We then articulate seven specific regulatory challenges.

Part I of the Handbook provides important conceptual foundations, while Part II aims to articulate just what is actually new in relation to nanotechnologies. Part III investigates a number of case studies viewed through a range of jurisdictional lenses, while Part IV looks to the future. Our conclusion ties together the themes articulated throughout this Handbook, paying particular attention to those related to the challenges initially posed.

In order to begin this journey it is prudent to first articulate how regulatory debates concerning nanotechnologies are typically constructed through three languages. It is through better understanding these three languages that appropriate regulatory solutions will ultimately lie.

1.2 THREE LANGUAGES IN REGULATING NANOTECHNOLOGIES

This chapter contends that there are three discourses which underpin the regulation of nanotechnologies. They may be summarized as follows:

1. the language of ‘nanotechnology’ as a societal phenomenon, and as a way of framing meaning in public policy and regulatory debates;
2. the language of nanotechnologies as a set of multiple frontiers emerging from scientific disciplines; and
3. the language of regulation, where although the single word ‘regulation’ is adopted, this word brings with it multiple meanings from different authors and in different contexts.
As a fundamental launch point for regulatory discussions on nanotechnologies, let us now briefly articulate each.

1 Nanotechnology as a Phenomenon

‘There is no such thing as nanotechnology’ (Sparrow, 2007: 2; see also Katz et al., 2005; and Sandler, 2007). While the phrase ‘nanotechnology’ was first coined in 1974 by Norio Taniguchi (1974), the term itself does not acknowledge the complexity of ideas and meanings now embedded in it. It has become a handy shorthand label for several phenomena. But the reality is that the singular word encompasses many scientific domains and applications. ‘Nanotechnology’ is not simply one discipline, or family of techniques, but rather a vast range of disciplines including engineering, materials science, biotechnology, medicine, physics, chemistry and information technology.

These areas are united by the fact that they deal with the nanoscale ($10^{-9}$ metres); this is the common denominator. Scientists though could just as well have labelled this new field ‘new developments in chemistry, physics, materials sciences, information technology, agriculture and biotechnologies at the atomic scale’. But this did not happen. Such a label would have been far too cumbersome. A simple shorthand solution was instead developed: nanotechnology. But this label² is not an accurate description of the immense range of technologies that fall under the nanotechnologies umbrella.

Is this distinction important? We contend that it is. Labelling fires both our imagination and emotion. For example, this labelling underpins science fiction stories such as Carver’s (1989) From a Changeling Star, Stephenson’s (1996) The Diamond Age: Or, a Young Lady’s Illustrated Primer, Ludlum and Larkin’s (2004) The Lazarus Vendetta, and Crichton’s (2002) Prey. It also enables movies, like The Six Million Dollar Man and Spiderman, to be re-invented and for ‘nanotechnology’ to become part of everyday vernacular. Moreover, it allows urban myths such as ‘grey goo’ to circulate, albeit to date within limited circles – all of which rely on the power of the ‘nanotechnology’ spectre. Of course nanotechnology is inherently diverse and far more difficult to describe or categorize because of this complexity. So labelling produces a paradox. While it is true in a sense that ‘there is no such thing as nanotechnology’, and it is ‘a ghost that we have created’ as Maynard (2008) put it, we nevertheless continue to employ this shorthand. In practice, the use of the term nanotechnology is now commonplace and the continued use of the label gives it its power, even though ‘nanotechnology’ itself doesn’t exist. This is the paradox. It is in habitual usage in much the same way as having adopted the phrase...
‘information technology’. But in the case of the latter, the public know that this term refers to an entire sector of our modern economy, and to the multiple useful practices and processes, business opportunities and policy challenges that it entails.

More importantly, labelling is one of the basic building blocks of public policy debates. Here, framing has always been a central quest in discussions. It has been a fertile ground in which the act of labelling itself creates meaning in the direction intended by the creator. The very choice of words transfers not only our intellectual argument, but also the intended emotional state. The word games played in the general public policy arena are legendary. We have seen nuclear warheads labelled as ‘peacemakers’, and instances where men, women and children killed in acts of war are simply labelled ‘collateral damage’. The overwhelming power of the phrase ‘Frankenfoods’ as it was applied in the genetic modification organism (GMO) food debate in the European Union (EU) is a further example, here, and one that the industry is unlikely to forget for some time. In short, labels are a crucial tool employed to influence policy initiatives.

Such labelling already exists in the nanotechnology arena. Both sides of the nano-debate use the ploy. One Australian newspaper recently reported that, ‘a clear majority of people now believe the benefits of nanotechnology outweigh the risks . . . [and that] only 3% believe the risks outweigh the benefits’ (Dayton, 2008: 30). It has also been suggested that over the next decade ‘the global value of revenues relating to nanotechnology is expected to increase from $US32 billion to $US2.6 trillion’ (Victoria Government, 2008: 4). Both examples employ a positive framing of nanotechnology, and do so by reference to economic growth and the implied benefits to human wellbeing. Through this lens, how could it possibly be opposed?

On the other side, though, there have been the critics who have framed nanotechnology as being risky to both human and environmental health and safety. Headlines say it all: ‘Women buying creams made of tiny particles “used as guinea pigs”’ (Fleming, 2006: 6), and ‘Nanotech [is] Unpredictable and Un-Regulated’ (ETC Group, 2004: 1). Critics have also linked nanotechnology with the sorry history of asbestos, and vowed that we need to have a moratorium on certain aspects of the technology. This alternative characterization frames nanotechnology as dangerous and implies that the organizations manufacturing and commercializing nanomaterials are untrustworthy. In this light how then could it possibly be supported by governments and other parties?

In reality, though, the breadth of activities encompassed within the nanotechnology phenomenon render these types of statements almost meaningless. And in any case, we know from experience that critics tend in their arguments to emphasize the worst failings of history (such as the
International handbook on regulating nanotechnologies

asbestos debacle) within their arguments, while the advocates tend to emphasize the best of history (such as economic growth or the positive role of science on technology).

The chance that we will all stop using the term ‘nanotechnology’ is remote. Today, it is unavoidable shorthand. But given the dangers of the nanotechnology label, we should at least acknowledge its linguistic proclivities as a pre-requisite to more sensibly discussing regulatory options for engineered nanomaterials.

2 Nanotechnology as a Set of Scientific and Technological Frontiers

We have already noted that nanotechnologies span a number of science frontiers, with each giving rise to a diversity of commercial and technical uses. These technologies are united in the sense that they are parts of ‘the science of the small’. But nanotechnologies have themselves been technically characterized in a variety of ways, with many variables being seen as relevant in addition to size. Hodge et al. (2007) outlined some 18 variations in how the technology is defined and in doing so, observed five reoccurring themes within those definitions examined. These included reference to scale (0.1 or 1.0–100nm), a range of technologies, multiple disciplines, size dependent properties, and purposeful control in certain circumstances. These days, we are also quick to recognize that when characterizing particular engineered nanoparticles, many physico-chemical characteristics are potentially important – only one of which is size (Oberdörster et al., 2005). These include, for example, crystalline structure, surface area, charge and chemistry. So, the same material can show different behaviour if prepared in smaller-size chunks. The manufacturing process and its associated impurities are also likely to be important. What is vital to acknowledge here is that there are clearly tricky syntax issues in simply defining nanotechnologies, and in defining the specific components of the technology. It is for this reason that consensus standards organizations such as the International Standards Organization (ISO) and ASTM International are so heavily invested in clarifying the language of nanotechnologies (see, for example, ISO, 2008a, 2008b; and ASTM International, 2007).

Having acknowledged the breadth of scientific frontiers as well as the breadth of potential uses of nanotechnologies we could also note, as Maynard (2006: 8) has, that there has been enough research to ‘reasonably conclude that there are some applications that will present problems’ and that ‘certain applications of nanotechnology will present risks unlike any that we have encountered before’. Indeed, it seems that since Forrest (1989) argued that nanotechnology would challenge existing regulatory regimes, an ever increasing number of stakeholders and commentators...
have been contemplating the characteristics and degree of regulatory challenge. There is now increasing concern over potential risks and an increasing debate over which aspects of nanotechnologies should be subject to more stringent or specific regulation.

Conceptually, a new technology that leads to products and materials with novel properties raises questions concerning unconventional behaviour and non-obvious risks. If new products exploit physical, chemical and biological properties that are only manifest through nanoscale engineering, will they also present new ways of causing harm? Will precisely engineered nanometre-scale particles be able to enter, penetrate to and affect regions of the body or environment that are normally inaccessible? Or will sophisticated nanoscale substances designed to exhibit multiple behaviours blur conventional distinctions between chemicals and devices? The relevance of these and similar questions will vary between different nanotechnologies. The issues surrounding nanoscale electronics for instance will differ from those associated with the intentional as well as unintentional environmental release of nanoparticles. And the oversight of potentially high-gain high-risk applications in areas such as cancer treatment will most likely take a different path to the safe use of nanomaterials in cosmetics. Nevertheless, aspects of emerging nanotechnologies are likely to increasingly challenge conventional approaches to oversight. This begs the question of the third language – that of regulation.

3 The Language of Regulation

Until relatively recently the notion of ‘regulation’ was simple. Regulations were rules made by government through legislation. Such ‘black letter law’ was enacted by Parliament through formal traditional processes. The idea of regulation, however, has been completely reconceptualized. Contemporary regulation is now viewed as covering multiple disciplines, as ‘decentralized’ and as crossing all sectors. Industry and civil society both regulate, as too does government. The traditional ‘command and control’ concept of regulation has since been broadened out to include instruments and activities which extend well beyond the law. According to Black (2002: 19), for example, regulation is

the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes.

Broad definitions of regulation such as this have of course been a challenge to traditional legal and public administration scholars. But while narrower conceptions may be easier to digest they are less helpful and do not explain
the broad range of modern efforts designed to influence behaviour. This reconceptualization of regulation has led to several important insights.

First, today’s concept of regulation includes a wider range of regulatory mechanisms and tools. These range from so-called black letter law and regulations through to codes, guidelines, standards, contracts, grants, economic incentives, information usage, markets, licences and accreditation schemes. There are a multitude of regulatory tools and techniques at our disposal, with black letter law from governments being only one option.

Taking an institutional perspective, the second insight is that the locus of regulation may be from inside government, through independent institutions, through hybrid mechanisms, or through co-regulation, self-regulation or even ‘meta’ regulation, where our regulatory bodies oversee others (as occurs with accreditation bodies for the professions) who do the detailed oversight. The last two decades have, for example, seen the rise of the independent regulator (Gilardi et al., 2006). They found that the number of independent regulators across 36 countries increased through the 1990s by two and half times the increase over the previous three decades. Importantly, too, this phenomenon has been observed not only in relation to economic regulators but also in relation to the social arena.

This brings us to the third insight. We have come to understand that regulation has not simply been a phenomenon which has resulted from the frequent privatization of essential public services. It has represented a more fundamental re-ordering of societal priorities and power. Regulation has, as argued by Majone (1999: 1), essentially been ‘a distinctive mode of policy making’ and an ‘alternative mode of public control’.

The fourth insight stems from the numerous regulatory instruments now available. Instead of focusing on the degree of perfection achieved in the text of legislative instruments, decision makers, policy makers and regulatory scholars have all shifted their attention to questions of how regulatory systems can be best designed, what mechanisms work most effectively in particular circumstances and the degree to which citizens and other stakeholders see regimes as having legitimacy and credibility (see, for example, Bartle and Vass, 2007; Black, 2008). As well, scholars rightly concern themselves with the responsiveness of regulators to dynamic environments and the overall effectiveness of the regimes in practice.

Fifth, the extent to which regulatory activity includes a range of activities from hard law through to soft law has been described in frameworks such as the enforcement pyramid first articulated by Ayres and Braithwaite (1992). The implication of this is that much regulatory time is spent on measuring and monitoring, in assessing and in reporting, and in regulatory conversations as opposed to formal court proceedings. And many of these activities are inherently cross disciplinary rather than belonging to
one specific discipline. Regulation has essentially become a cross disciplinary professional pursuit; it just has not yet been widely acknowledged as such.

The sixth insight is that regulatory activity is inherently political activity. Whether governments choose to regulate directly through, for example, legislation, through independent institutions, through monitoring and reporting regimes, through markets, or through the employment of incentives or contracts, the choice of mechanism and the content comprising the regulatory fabric are political decisions. Moreover, regulation is preceded by policy choices in the face of public interest debate and discussion. Such choices involve conflicts in values, by definition. Indeed, government itself, as Van de Walle (2009: 45) has stated, ‘is constantly dangling in an uneasy equilibrium between competing values’. As a consequence, there is unlikely to be one single ‘best approach’ to organize regulatory regimes to the advantage of citizens. Such choices on regulatory activity also involve discussions which continually move between today’s reality of ‘what is’, to differing conceptions of ‘what should be’ in a better world.

Overall then it is clear that today’s policy discussions and regulatory debates on nanotechnologies should begin by acknowledging that while the word ‘regulation’ is commonly used, it means different things to different people in different contexts. What is needed is a richer and more sophisticated approach to regulatory discourse. One that marries together equally the breadth, emotion and values of broad policy discourse with the knowledge and evidence base of science and other disciplines. A sensible starting point for such regulatory discussions and the analysis of nanotechnologies is the existing regulatory space occupied by such products. In other words, the regulatory requirements around, for example, existing products should logically be applicable to products containing nanomaterials as well as conventional materials. At least this should be an initial framework from which we can learn.

Products incorporating nanotechnologies, such as cosmetics and therapeutic goods, currently fall under existing regulatory regimes, which vary between jurisdictions and regulatory requirements. These frameworks do not – at least at this time – differentiate nanotechnology-based products from their non-nanotechnology counterparts. It is the adequacy of these acts, regulations, directives and codes, for example, for regulating the products and processes of the technology that is contested. Several jurisdictions including Australia, the European Union, Germany, United Kingdom and the United States have conducted reviews of existing regulatory regimes and these have proved both useful and necessary terrain mapping exercises (see, for example, Health and Safety Executive, 2006; Chaudhry et al., 2006; Food and Drug Administration, 2007; Ludlow et
al., 2007; Food Standards Agency (2008); and European Commission (2008a, 2008b)). But these also represent the tip of the iceberg in relation to the work that probably needs to be done.

1.3 REGULATORY FRONTIERS

Regulation, as we have said, is a political activity combining our past regulatory experience, current knowledge in policy making values, evidence-based science and the broader context of future expectations. If we take an inclusive view of regulatory activities, there are multiple frontiers on which we attempt to alter the behaviour of others.

Looking past traditional state-based legislative and regulatory regimes, a wide range of frontiers exists from insurance to international framework conventions and treaties, tort law, the use of co-regulatory and self-regulatory mechanisms and the adoption of transparent arrangements where information itself is used to encourage and steer corporate behaviour. Abbott et al. (2006) have suggested that how we regulate technology involves consideration of a huge diversity of potential risks over long time periods and through a range of dimensions and actors (see also Abbott et al., 2010). They suggest that a wide variety of regulatory mechanisms are possible and that new governance models incorporating soft law options can provide a pragmatic way forward so that, for example, at the international level, say, transnational actors, epistemic communities and self-regulatory mechanisms can contribute to the international regulatory fabric. In their view, such regimes can even be less costly, more focused on science and more flexible than traditional state-based, prescriptive ‘hard-law’ approaches.

The suggestion here is that short term risks may be adequately addressed by existing frameworks but that new regimes will progressively emerge. This may take any one of a number of different forms. It may be that in the medium term, as tangible problems begin to emerge, framework conventions are negotiated to deal with specific issues (in much the same way as the Vienna Convention has done on the protection of the ozone layer) (Abbott et al., 2006; Abbott et al., 2010). In the longer term, too, as concrete problems become clearer, such issues are eventually covered through a combination of hard and soft law.

The degree to which regulatory intervention is philosophically justified in the first place, the precise policy objectives sought behind regulatory intervention and the best methods to be adopted in such an intervention, though, are all widely contestable. Moreover, they are likely to remain so. That being said there is clearly a need to govern and appropriately control
any risks involved in the progressive rolling out of any new technologies in the abstract sense, and in this respect nanotechnologies are no different from any other emerging technology.

But how this might be best achieved practically and the point at which an optimum balance occurs are far more difficult and contested issues. We live in an age where ‘better regulation’ is sought, where governments actively seek to ‘reduce regulatory burdens’ and where policy advocates simultaneously press for new and stronger regulatory arrangements. Regulatory impact statements are also increasingly required before new regulatory arrangements are enacted (Better Regulation Taskforce, 2005). What is clear here is that there are several competing regulatory and policy directions to consider as well as questions of science and quantitative levels of risk. These broader contextual matters need to be considered alongside issues of risk regulation and evidence-based regulation, both of which have become catchphrases in recent times. One crucial starting point here is the simple question: to what degree are nanotechnologies ‘risky’? It is to this matter that this introductory chapter now turns.

### 1.4 RISK AND NANOTECHNOLOGIES

Concern over whether or not nanotechnologies are ‘safe’ and the potential risks posed by some applications of the technology are not new. However, with increasing numbers of innovative products incorporating the technology making their way into industrial and consumer markets, it is not surprising that debates over how these products and processes may be best regulated have grown (see, for example, ETC Group, 2003; Royal Society and Royal Academy of Engineering, 2004; Friends of the Earth Australia, 2006; Miller and Senjen, 2008; Standing Committee on State Development, 2008; Royal Commission on Environmental Pollution, 2008). But what exactly is meant by ‘safe’, and what is the real ‘risk’ being run?

Within many ‘hard law’ regulatory frameworks, risk describes a quantitative relationship between a person’s exposure to a particular situation or substance, and the harm caused as a result. Hazard represents the potential for something to cause harm, and varies from substance to substance and situation to situation. Exposure on the other hand, is what translates hazard into risk – the probability of harm occurring. Thus negligible exposure to a highly hazardous substance may lead to a low risk, or a low likelihood of loss, injury or damage occurring. While substantial exposure to a low hazard material could result in a relatively high risk.8

As a result, quantifying the risks associated with nanotechnologies
requires a teasing out of the nature of potential hazards and exposures for specific technologies and applications. There are few shortcuts to developing overarching risk assessments for nanotechnologies, and many dangers in generalizing discussions of risks over what is in essence a disparate collection of technologies. Rather, an evaluation of scientific risks (as opposed to broader societal risks) must consider:

1. exposure assessment;
2. hazard identification;
3. hazard characterization; and
4. risk characterization (Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 2006: 47).

Risk assessment, in relation to this perspective, is a complex and technical process involving analysis of exposure and hazard-related data (National Academies, 2009). The objective of a risk assessment is ‘to determine whether the level of hazard and risk arising from a substance or activity is acceptable, or whether more needs to be done to control or reduce the risk’ (Sweet and Strohm, 2006: 534). And while conventional risk assessments are hampered by varying degrees of uncertainty and the subsequent reliance on weighted data or assumptions, they are a fundamental tool for quantifying and prioritizing risks and provide a functional basis for risk management decisions (Anderson and Hattis, 1999).

Applying this conventional risk assessment paradigm to engineered nanomaterials in order to determine risks is conceptually simple. And as noted previously, several governments and government agencies have already undertaken reviews of their regulatory arrangements under mounting pressure to ensure that adequate safeguards are in place to protect human and environmental health and safety. These regulatory reviews have been further supplemented by a number of independent critiques of regulatory arrangements and their applicability to certain applications within specific jurisdictions (see, for example, van Calster, 2006; Fuhr et al., 2006; Davies, 2006, 2007; Taylor, 2006, 2008; Gergely, 2007; Ludlow, 2007; Hodge et al., 2007; and Marchant et al., 2008). But while simple in principle, the application of this conventional risk assessment paradigm to engineered nanomaterials is also unfortunately problematic at this early stage in the technology’s development. This is due to uncertainties in terms of both scientifically sound data relating to hazard and human exposure, including potential exposure pathways, as well as the duration of and anticipated level of exposure (Dreher, 2004; Oberdörster et al., 2007; SCENIHR, 2006).

It is crucial to acknowledge up front, therefore, that several leading
Introduction

Researchers within this field (including, for example, Aitken et al., 2004; Kandlikar et al., 2007; and Oberdörster et al., 2007) have argued that in light of the significant gaps in the science, it is impossible at this time to unequivocally determine what the risks are in relation to specific engineered nanomaterials. Moreover, in light of these inadequacies, Wiesner et al. (2006: 4343) have concluded that ‘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’.

A further problem is that a conventional application of the risk assessment paradigm that relies on mass concentration as an exposure metric may not be appropriate for calculating risks associated with engineered nanomaterials (Oberdörster et al., 2005; Maynard, 2006; Kandlikar et al., 2007). SCENIHR (2006: 47) has stated, for instance, that a focus on mass rather than particle size ‘may severely underestimate the potential contribution of nanoparticles to overall risk posed by the substance’. And while the science is not yet completely clear, it appears that the hazard presented by some nanomaterials may be characterized more appropriately using metrics such as surface area (Maynard and Aitken, 2007). Pinning down how hazardous emerging nanomaterials are – and how best to measure exposure – is complicated by difficulties in applying conventional toxicity tests to unconventional materials (Warheit, 2008; SCENIHR, 2009). Yet until it is determined which physico-chemical parameters and what combinations are important in determining the biological behaviour of specific classes of nanomaterials, scientists are unlikely to be able to accurately determine toxicity, and therefore risk (Oberdörster et al., 2005; Kandlikar et al., 2007). Even when consensus has been reached in relation to these parameters, reliance on multiple metrics will ensure that risk assessment is a complicated and time-consuming process. Until that point has been reached, scientists, industry and government must remain cautious in relying on current risk assessment data, and on measurement and risk assessment protocols. These uncertainties present huge challenges to regulators interested in protecting public health.

Another quite different perspective on risk comes from the notion of democratic rule and the right of citizens to be a part of deciding the most appropriate governance arrangements for new technologies generally. Indeed, matters of risk are inherently subject to how questions of ‘risk’ have been framed in the first place. Jasanoff (2005) noted, in the case of biotechnology, the huge difference between the framing of GMOs in the US in terms of narrow scientific harm compared to that experienced in Germany, where risk was framed more broadly as a democratic issue. What was observed was that in Germany risk was viewed in terms of the ‘relationship of science and technology to society, not simply the risks of...
biotechnology as contemplated by experts in the life sciences’ [as it was in the US] (Jasanoff, 2005: 39).

In other words, risk, too, is another ambiguous word which has multiple meanings. And when citizens call for greater upstream dialogue, risk to them may well represent a concern over being left out of the decision-making process rather than any notion of scientifically-determined risk. Put another way, we could say that as a minimum, citizens wish to regulate the application of science across the value chain and not just consume its products. But there is more to it than that. There is a significant body of regulation that exists because communities simply have a desire to encourage particular standards of behaviour; these may or may not relate to human and environmental health and safety risks. They may instead relate to social objectives and societal desires rather than any concept of health risk per se. In other words, ‘risk regulation’ is simply one part of the larger regulatory and public policy phenomenon. And in this context, labelling could also be viewed as one of the available policy tools, with a range of possible objectives – enabling a consumer to make an informed decision in relation to the product, while also promoting the movement of goods in the marketplace. These differing frames of why we regulate and how quantitatively defined risks fit into these frames continue to be relevant to today’s regulatory debates on nanotechnologies.

1.5 SEVEN REGULATORY CHALLENGES

In this context, we suggest that there are at least seven regulatory challenges that society will confront in relation to nanotechnologies in the coming years. These may be summarized as follows:

1. We need to move past the nanotechnology ‘language game’, or at least as a first step, acknowledge our use of such rhetorical games for advocacy and debating purposes. In a time in which increased policy dialogue is needed, how may we best achieve this?
2. There are clearly still huge gaps in scientific knowledge across the various scientific frontiers. As Maynard et al. (2006: 269) have suggested, two of their ‘five grand challenges’ for nanotechnologies are to ‘learn how harmful nano-materials are’ and to ‘evaluate the impact of engineered nanomaterials from cradle to grave’. Meeting these challenges will no doubt involve significant multi-disciplinary research over the coming two decades. What is the optimal way or rather ways that this may be achieved in a timely manner?
3. Developing appropriate metrology and standards for nanotechnologies
Introduction

will be crucial building blocks to the future of nanotechnologies. Drawing again on Maynard et al.’s (2006) work, how can we ensure that we find appropriate methods to measure air- and water-borne nanomaterials in a timely manner?

4. Establishing and clearly articulating the existence of so-called regulatory gaps and triggers in current legislation and regulation is itself a crucial step, and one that must be undertaken within each jurisdiction. How can we ensure that all governments openly undertake their responsibilities in this domain?

5. Governments now face the balancing act of supporting the nanosciences as a basis for future innovation and economic growth, while also enabling citizens to influence policy directions and protecting their health and safety. How can governments achieve a legitimate balance here?

6. Just as controversial as identifying any gaps or triggers in existing regulatory arrangements is the question of how effective alternative regulatory regimes may be in practice. While it is important to acknowledge the strengths and weaknesses of different regulatory approaches, evaluating what works in regulation is sensitive and highly contested territory. How can we proceed with appropriate precaution?

7. The challenge of ensuring appropriate transparency and trust continues across all areas of regulation, including in relation to nanotechnologies. Given the personal sensitivities around, for example, the use of engineered nanoparticles in foods and food contact materials as well as personal products such as cosmetics and sunscreens, there are significant immediate ‘trust-risks’ facing regulators responsible for ensuring the safety of these products. These may be exacerbated by an increasing distance between citizens and policy elites. In this context then, how, in the face of recent trust breakdowns from episodes such as the UK bovine spongiform encephalopathy (BSE or ‘mad-cow’ disease) outbreak, can regulators of products containing nanotechnologies build and maintain trust in the operation of both existing and evolving regulatory frameworks?

1.6 THIS HANDBOOK

In the context of these observations, this Handbook seeks to provide an international perspective on the state of the art in regulating different products and processes of nanotechnologies. By drawing upon the expertise of
authors from a diverse range of disciplines and jurisdictions, the Handbook aims to provide new contributions to knowledge in this field. Irrespective of the definitions employed to describe nanotechnologies, current global circumstances cry out for clearer thinking and wiser direction setting as we shape future regulatory regimes for these technologies.

This chapter heads Part I of the Handbook which aims to provide some initial conceptual foundations. Other chapters in this part outline the intellectual histories of nanotechnologies and their contested views leading up the present age of regulatory governance. Part II investigates the evolving state of the art for nanotechnologies within the field of metrology and standardization, and the production and usage risks in terms of science and various disciplines. Part III tackles a range of case studies viewed through several jurisdictional and disciplinary lenses applied to occupational health and safety, industrial chemicals, consumer goods, cosmetics, therapeutic goods, foods and food contact materials, the environment, military activities and the intellectual property (patent) landscape.

Part IV focuses on the future regulatory landscape and looks towards scientific trajectories as well as the policy perspectives of industry and of NGOs. The potential future roles of self regulation and transnational regulation are also reviewed.

Our concluding part ties together the various themes articulated throughout the Handbook and makes some bold conclusions as to how the future regulatory landscape for nanotechnologies may evolve. The conclusion also speculates on how we will meet the seven big regulatory challenges posed within this chapter.

1.7 CONCLUSIONS

There are multiple challenges to be met in regulating nanotechnologies in the short to medium term. First, it is clear that we need to develop a more sophisticated understanding of the nanotechnology phenomenon and the various languages that are inherent in discussing the field. As this chapter suggested, the language of the phenomenon, the language of nanotechnologies as a set of new scientific frontiers and the language of regulation all matter as we set policy priorities. A more sophisticated understanding of the ways in which these languages are employed is also a fundamental part of translating scientific advances and understanding community concerns within the policy making process along with the subsequent development of any new regulatory arrangements.

Second, it is also clear that a wide range of regulatory frontiers are relevant to the future of nanotechnologies. Interestingly, the modern
conception of regulation presents us with a much richer mix of possibilities than our traditional command and control assumptions. Indeed, it may even be that we may be best to proceed with caution not through major changes to state-based regulatory regimes but through more innovative and flexible civil regulatory arrangements. But the question must equally be asked: to what extent do we dare to govern nanotechnologies without government?12

Third, this introductory chapter has suggested that we face seven major challenges and that each of these needs to be addressed if we are to move forward. Importantly, these challenges span the fields of science, engineering, public policy, business, politics, and the law; and they are not restricted to any one domain. The implication of this is that dwelling exclusively in one area would present significant limitations and be a hindrance in ensuring that the lessons are translated accessing across the specializations. There is little point in hiding behind our traditional disciplinary shields because in public debate, such narrow disciplinary defences are viewed as little more than a fig leaf.

Finally, legitimate regulatory regimes and those regulatory arrangements gaining the trust of institutional actors as well as civil society and citizens will be those which best marry together the values and priorities of multiple disciplines and align these with broader societal values and aspirations. To the degree that this Handbook can contribute to this longer term challenge, it will have succeeded.

NOTES

1. See, for example, Toumey (2008) who has questioned the traditional assumption that the nanotechnology pedigree descended from the 1959 Richard Feynman lecture.
2. We should, when contemplating our choice of the term nanotechnology, acknowledge the comment of Baird and Shew (2004: 150) who stated, ‘It is no accident that the NNI [the US National Nanotechnology Initiative] is a nanotechnology and not a nanoscience initiative’. They noted the compelling technological promise of work at the nanoscale and that ‘a central aim of the NNI [was] to quickly move nanoscientific discoveries into commercial development’. Citing the $US50 million grant to the Massachusetts Institute of Technology from the US Army to develop ‘nano-uniforms’ (which can stop bullets, monitor health, make the wearer stronger and can communicate), Baird and Shew (2004) quote Edwin Thomas who stated that the Army was not interested in papers, in Science and Nature: ‘They wanted real stuff’.
3. There is much written on this arena but see for example the work of Edelman (1964, 1985), Lasswell (1930, 1949) or Orwell (1954, 1984), as cited in Parsons (1995: 176).
4. This statement from government was derived from a more carefully worded statement (Lux Research, 2004), which referred to the global sales of products incorporating nanotechnologies (nanomaterials, nanointermediates and nano-enabled products).
5. Non-governmental organizations such as the ETC Group and Friends of the Earth Australia (FoEA) have called for a moratorium in relation to certain facets of the
6. We might note here that given the number of bodies and individuals endeavouring to alter the behaviour of others according to particular standards with public purpose in mind, much public regulation these days is undertaken through institutions and individuals which do not formally bear the title of ‘regulator’. Indeed, Grabosky (1995: 529) has suggested that ‘it is perhaps more useful nowadays to regard a regulatory system as consisting of layered webs of regulatory influence, of which conventional activities of regulatory agencies constitute but a few strands’.

7. Insurance as a regulatory mechanism is not widely acknowledged. What is also not often recognized is that in the abysmal global story of asbestos, Canadian insurance companies refused to insure asbestos workers due to the health hazard of asbestos in 1918, two and a half decades before the German Government deemed asbestos lung cancer to be an industrial disease, and therefore, compensatable in 1943 (Gee and Greenberg, 2002) (see also Mullins, 2010). This insurance refusal also occurred several decades before asbestos became widely accepted as a cause of mesothelioma (in the 1960s), and asbestos became a populist political issue in the UK and US (Hodge et al., 2007).

8. In making these observations, we acknowledge that terms such as hazard, exposure and risk continue to be contested. Moreover, differing definitions are often adopted in different contexts and for different purposes.

9. Whether such reviews are those by, for example, the Health and Safety Executive (2004), Davies (2006, 2007), Taylor (2006, 2008), Chaudhry et al. (2006), Ludlow et al. (2007) or the European Commission (2008a, 2008b), there is a common challenge facing jurisdictions in defining and articulating the degree to which regulatory triggers operate effectively. Ludlow et al. (2007), for instance, summarize the doubts on regulatory triggers in five ways:

1. Uncertainty as to whether new nano-forms and conventional products will be treated as ‘different’ to traditional products by regulatory regimes.

2. The fact that current regulatory triggers exist on the basis of a threshold weight or volume and yet such thresholds may not be appropriate for nanoscale materials.

3. The current reliance on risk assessment protocols as a means for ensuring human or environmental safety, while we know that these protocols may not be appropriate for determining potential future risks of nano-materials. We clearly have little else at present but communities expect little or no lag between our knowledge discovery on the one hand and tight regulatory regimes to ensure public and consumer safety on the other.

4. The traditional specific gap relevant to research and development uses of conventional materials, of course, will continue with nano-materials. This gap itself opens the floor for debate in the case of nano-materials which for any given mass may involve risks greater than those experienced to date.

5. International arrangements and the documentation underpinning these also form the basis for much regulation across jurisdictions. The degree to which such arrangements are optimal is uncertain.

10. Initiatives such as the Responsible NanoCode, Environmental Defense-DuPont Nano Risk Framework, voluntary reporting schemes, and the European Commission’s Code of Conduct for Responsible Nanosciences and Nanotechnologies Research are a few of the many options for future regulatory regimes as well as the more formal, traditional command and control regimes of government. Given the embryonic nature of these initiatives, the likely effectiveness of each has been questioned.

11. Legal mandate aside, regulatory institutions essentially depend on their credibility and legitimacy for power. This requires not only professionalism and policy sophistication from those within the organization but a sense of transparency, accountability and trust.
between regulatory bodies, other political and bureaucratic actors, civil society players and citizens.

12. See, for example, Bowman and Hodge (2008, 2009) and International Risk Governance Council (2008).

REFERENCES


Anderson, E.L. and D. Hattis (1999), ‘When and how can you specify a probability distribution when you don’t have much?’, Risk Analysis, 19(1), 47–68.


Black, J. (2008), ‘Constructing and contesting legitimacy and accountability in polycentric regulatory regimes’, Regulation & Governance, 2, 137–64.


European Commission (2008a), Regulatory Aspects of Nanomaterials, Brussels: EC.


Friends of the Earth Australia (2005), Submission from Friends of the Earth Australia – To the Senate Community Affairs Committee Inquiry into Workplace Exposure to Toxic Dust, Melbourne, VIC: FoEA.

Friends of the Earth Australia (2006), Nanomaterials, Sunscreens and Cosmetics: Small Ingredients, Big Risks, Sydney, NSW: FoEA and FoEUS.

Friends of the Earth Australia (2008), Mounting Evidence that Carbon Nanotubes may be the New Asbestos, Melbourne, VIC: FoEA.


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


International Organization for Standardization (2008a), Nanotechnologies – Terminology and Definitions – Core Terms, London: ISO.


International Risk Governance Council (2008), Risk Governance of Nanotechnology Applications in Food and Cosmetics, Geneva, Switzerland: IRGC.

Introduction


Oberdörster, G., A.D. Maynard, K. Donaldson et al. (2005), ‘Review: principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy’, Particle and Fibre Toxicology, 2(8), 1–35.


Royal Commission on Environmental Pollution (2008), Novel Materials in the Environment: The Case of Nanotechnology, London: RCEP.

International handbook on regulating nanotechnologies


Scientific Committee on Emerging and Newly Identified Health Risks (2006), The European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks Opinion on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies, Brussels: EC.

Scientific Committee on Emerging and Newly Identified Health Risks (2009), Risk Assessment of Products of Nanotechnologies, Brussels: EC.

Sparrow, R. (2007), Widespread Hypocrisy about Nanotechnology is a Worrying Sign, Melbourne, VIC: Monash University.

Standing Committee on State Development (2008), Nanotechnology in NSW, Sydney, NSW: NSW Legislative Council.


