International Handbook on Regulating Nanotechnologies

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Edward Elgar
Cheltenham, UK • Northampton, MA, USA

Published by
Edward Elgar Publishing Limited
The Lypiatts
15 Lansdown Road
Cheltenham
Glos GL50 2JA
UK

Edward Elgar Publishing, Inc.
William Pratt House
9 Dewey Court
Northampton
Massachusetts 01060
USA

A catalogue record for this book
is available from the British Library

Library of Congress Control Number: 2010925965

ISBN 978 1 84844 673 1 (cased)

Typeset by Servis Filmsetting Ltd, Stockport, Cheshire
Printed and bound by MPG Books Group, UK

26 Conclusions: triggers, gaps, risks and trust

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26.1 INTRODUCTION

Nanotechnologies are something of an enigma. On the one hand, it is hard to deny that the idea of working with matter at the nanoscale has stimulated significant new cross-cutting research and technology innovation. On the other hand, the essence of this emerging technology – that which determines its identity – becomes strangely elusive when specific questions on impact, harm and regulation are asked. Yet despite this, the debate over understanding and managing the potential health and environmental impacts of nanotechnologies has become an integral part of the technology's development – so much so that this Handbook addresses a very real desire for greater information and clarity on regulating nanotechnologies among stakeholders.

Questions over the regulatory path for nanotechnologies are confounded by different framesets within which challenges and options are discussed, varying interpretations of what 'nanotechnology' means, and confusion over the underlying science and its implications to risk and risk management (as discussed by, for example, Nordmann (Chapter 2), Williams (Chapter 6) and Chaudhry, Bouwmeester and Hertel (Chapter 7). The result has been the nanotech equivalent of the Tower of Babel – a lot of talk, but little constructive dialogue. This is at the heart of our 'wicked' public policy problem outlined in the Introduction – a problem that many stakeholders are interested in, but which remains complex, ill-defined, highly contested or perhaps even imaginary.

Clearly, if progress is to be made in ensuring the safety and success of nanotechnology-enabled products and processes, this is a problem that needs to be disentangled, clarified, and addressed in a systematic and grounded manner. Effective regulation cannot afford to be based on imagined futures that are not connected to scientific, social and economic reality. And as highlighted by the authors of Chapters 10 (which provides a business perspective), 13 (oversight of cosmetics) and 15 (oversighting food), there can be little doubt now that black letter regulations

specifically dealing with nanotechnologies will be increasingly introduced in some jurisdictions. These initiatives will no doubt be applauded by some and deemed unnecessary by others. And advocacy groups who usually seek to expand any policy problem to maximize their influence over government directions more generally will also likely claim that the responses do not go far enough. Indeed, 'regulating nanotechnology' will remain highly debated.

The consequences of misplaced speculative regulation are potentially severe – ranging from unnecessary barriers to economic growth to inadvertent harm to the public and the environment. Yet at the same time, there is clearly a need for creating regulatory approaches that are responsive to new and shifting risks.

With nanotechnologies – and indeed other emerging technologies – it has been hard to find this balance. Ludlow et al., (2009: 615) remarked, for example, that the

> regulation of new technology will always miss its mark because it is being used to address a complex and dynamic problem. The bullseye of appropriate regulation is small and ever-changing. This is partly because, as noted by Kapor, '[w]hat lies on the far side of the technology chasm is fundamentally unpredictable'.

It is only with hindsight that we will be able to judge whether or not any such regulatory response was effective or what the true costs of speculative regulatory responses were.

The emerging technology has been stimulated and 'sold' by imagined futures that have sometimes had only marginal grounding in reality. Nanotechnologies have been heralded as having the potential to stimulate economies, create jobs, solve a multitude of global challenges, and underpin the next 'industrial revolution' as several Handbook chapters emphasize. This enthusiasm for the nanotechnology 'brand' has not necessarily been a bad thing.[1] It has raised the political profile of complex scientific research needs, encouraged policy debates around nano issues and stimulated new interest and funding directed at understanding unusual behaviour at the nanoscale (Royal Society-Royal Academy of Engineering, 2004; European Commission, 2005). It has also encouraged innovative and effective cross-disciplinary research that has extended far beyond conventional science-based disciplines (Robinson et al., 2007). In short, it has energized a new generation of potential scientists and engineers, and brought stakeholders together in new ways to address common desires and fears (as noted in Chapters 19 and 20, for example).

Professor Stephen Hawking (1995: *xiii*) once wrote that, 'tomorrow's science is today's science fiction'. It is therefore not surprising in one sense

that these positive outcomes of the nanotechnology enterprise are driven by imagined futures that can afford to be speculative. Yet as questions of risk and regulation have arisen (see, for example, Chapters 6–8 and 10–11), they have also been informed by the same vision. And as a result, the risk-dialogue has often been driven by poorly grounded and ill-defined imagined futures. These have resulted in clouding the 'wicked problem' of nanotechnology regulation being faced today rather than clarifying it.

26.2 MOVING AHEAD TO MEET CHALLENGES

If progress is to be made, we believe that the discussion on risk and regulation now needs to be reframed. It needs to be decoupled from speculative visions of future technologies and informed by plausible emerging risks to people and the environment. It should be grounded in established approaches to identifying, assessing and managing risks. And it needs to be focused on finding solutions that will protect people and the environment in both the short and long term, while enabling technology innovation. In effect, we need to peel away the mystique of nanotechnologies to reveal the underlying issues – which may not always fit neatly into a 'nanotech' bucket. This is no small challenge.

This Handbook was designed with the intention of assisting us to disentangle the dialogue over nano-regulation, and to transform a wicked problem into a merely complex one. By focusing on the contexts, drivers, challenges and possible solutions to ensuring the safe development and use of nanotechnology-based products and processes, the various contributors have begun this journey to reframe the discussion. Rather than attempting to shoehorn regulation into a narrow nano-specific worldview, they have begun the long, but richer, process of asking what is important for ensuring the safety and wellbeing of people and the environment, and how developments in nanotechnology affect this. In doing so, they have helped illuminate the seven challenges posed in the Introduction to this Handbook. In drawing the Handbook to a close, it is worth revisiting each of these in order to draw out some of the common threads, and think about where the future paths and solutions might lie.

The Language Game

Nanotechnology-related regulation cannot afford to be driven by rhetoric, or misled by obfuscation. Imagined futures and elusive definitions have been exploited by both proponents and opponents of greater regulation in the past, slipping ideologies in under the cover of uncertainty and confusion

(see, for example, Chapters 2, 3, 6–8, 10–11). Moving past the 'language game' will indeed be a tough challenge, as positions and perceptions often become entrenched in policy debates. There is a continuing temptation, as well, for nanotechnology to be used as a 'lightning rod' to open up all sorts of debates, ranging from policy shortfalls to global inequities. Yet it is also essential if progress is to be made. To help get out of the nano-rut, three steps will be important. First, the regulation conversation needs to be decoupled from the nanotechnology conversation. Although the two are closely related, the drivers, language and actions of oversight are not the same as those of the nanotechnology promotion. Second, the conversation needs to be grounded in evidence. As authors in this Handbook have highlighted, we need to get back to basics and focus on sound science and workable solutions (see, for example, Chapter 7). Third, a common language for addressing risks is needed that avoids confusion and enables dialogue (as discussed, for instance, by Miles in Chapter 5 and Williams in Chapter 6). While this will overlap with the language of nanotechnology promotion, it should not be confused, driven or dominated by this language.

Filling the Science Gaps

As this Handbook has highlighted (see, in particular, Chapters 7, 9–16 and 22–23), greater efforts are needed to develop and implement research strategies that identify and fill critical gaps in our knowledge base on nanotechnology-related risks and risk management (Maynard et al., 2006; National Nanotechnology Initiative (NNI), 2006; National Research Council, 2008; International Council on Nanotechnology, 2008). A number of knowledge gaps have been identified that require filling if existing regulations are to be better informed by evidence and new regimes developed (see, for example, Organisation for Economic Co-Operation and Development (OECD), 2007; NNI, 2008). The barrier to progress here is not a lack of direction – it is relatively clear where we need to be – but a lack of a plan, priorities and resources to get there. Public and private, national and global efforts to fill these science gaps are growing (see, for example, Food and Agricultural Organization, 2008; OECD, 2008; Aitken et al., 2009), but still fall short of what is needed to underpin safe uses of nanotechnologies.

At the same time, further open-ended research is needed to help identify new science gaps. The challenges currently presented by simple nanotechnologies are reasonably clear; those that will be presented by later generation nanotechnologies, as set out by Davies in Chapter 25, are not (see also Chapter 8). Only through strategically supporting and evaluating exploratory research will these new challenges become apparent.

Developing Appropriate Standards and Metrology

Progress towards addressing nanotechnology-related risks depends on being able to define the problem appropriately (as discussed in Chapters 5 and 6), and having the tools to address it (Chapters 7 and 9). Appropriate standards and metrology are essential on both counts. Both of these are closely related to the two preceding challenges. They form a basis for a common – and precise – language for addressing potential risks. And they enable the generation of valid – and validated – data that will underpin evidence-informed decisions. Yet there is a danger of developing standards and metrology that are not fit for purpose – especially if the driver is nanotechnologies promotion, rather than nanotechnologies regulation. As well, extensive efforts are underway internationally to develop and implement nanotechnology-related standards and guidelines (International Organization for Standardization, undated; ASTM International, 2006; British Standards Institute, 2007; OECD, 2008). To be effective, these will need to share a common language and be supported by new research into identifying, assessing and managing potential nanotechnology-related risks. But they will also need to be assessed in terms of the added value they bring to policy and regulatory decision-making processes.

Identifying Regulatory Gaps

Regulatory bodies have their own inertia. Bureaucracy, resistance to change and a tendency to assume an unchanging world encourage the shoehorning of new challenges into old regulatory frameworks, rather than adapting regulations to emerging issues (Marchant et al., 2007). This is not necessarily a bad trait – regulations that shift with every technological whim or as a knee-jerk reaction to some kind of real or perceived regulatory failure may be burdensome, built on shaky foundations and potentially counterproductive. Yet new challenges do arise – with increasing frequency as the rate of technology innovation accelerates – and regulatory frameworks need to be responsive to these new challenges. Responsive regulation cannot afford to be based on ill-defined imagined futures. Rather, it needs to be grounded in current realities and probable developments (see, for example, Brownsword in Chapter 4; see also Levi-Faur and Comaneshter, 2007). Yet as increasingly novel materials, products and processes arise from technology innovation, foresight is needed to enable regulatory frameworks to adapt to emerging risks (Royal Commission on Environmental Pollution, 2008; Marchant et al., 2008; Miller, 2009).

Analyses in Chapters 14 and 15 suggest that current regulatory frameworks are reasonably robust when it comes to first generation products of

nanotechnologies, based largely on simple, passive materials. Admittedly there are clear weaknesses in existing regulations covering specific areas (see, in particular, Chapters 10–12 and 16–17) – but these are often weaknesses that exist for conventional products as much as emerging products and technologies (Ludlow et al., 2007; see also Taylor (2006: 28) who has noted that, for example, the 'FDA's legal tools for regulating cosmetics are among the most limited'). There is also considerable uncertainty over how existing frameworks apply to the products of nanotechnology, although here the challenge seems to lie predominantly with the interpretation and implementation rather than the regulations themselves (see, in particular, Chapter 25).

Yet it is equally clear that nanotechnologies are beginning to stress regulatory frameworks (as highlighted by Chapters 10–13, 16–17) and, as the technologies become increasingly sophisticated, these stresses may become significant and result in fractures. As nanotechnologies mature, products that cross multiple regulatory regimes are likely to lead to pressure coming to bear on the system. So-called 'borderline products', such as cosmetics that act as drugs, functional foods, and multifunctional drug/device combinations, will all challenge the applicability of existing frameworks. At a more basic level, nanotechnology-derived materials and products are already stressing regulations that are based on a chemistry worldview that is not overly responsive to the significance of form and functionality at the nanometre scale. Recognizing these stress points is a critical step to revealing weaknesses in existing regulatory frameworks and identifying triggers for change and adaptation.

Whether current and future regulatory gaps can be filled through evolutionary adaptation, or whether radical changes in the regulatory landscape are needed – such as those proposed by Abbott, Sylvester and Marchant (Chapter 24) and Davies (Chapter 25) – is still unclear. What is becoming increasingly clear, though, is that if our regulatory frameworks are to keep up with emerging technologies, they need to shed some of their inertia, and become increasingly responsive, adaptive and proactive – at the national as well as the international level (such issues are canvassed in Chapters 17, 19–24).

Balancing Innovation and Safety

It is hard to imagine innovation leading to long-term sustainable progress without addressing the safety of the resulting products and processes at some point. At the same time, safety cannot be addressed effectively in the absence of products or processes arising from innovation. In other words, the two are inextricably intertwined. In the past, innovation has tended to

precede discussions over safety by a considerable margin, leading to reactive oversight and regulation. In contrast, nanotechnology has provided a unique opportunity to integrate the safety dialogue into the development and innovation process at an early stage. We began this Handbook with a quote from Levi-Faur and Comaneshter (2007), who observed that nanotechnology regulation was to an extent unlike other historical cases of regulation where the associated risks had followed the development of the technology. Their observation was that discussions as to proper regulatory frameworks for governing nanotechnology risks were accompanying the development of the technology. This important observation was echoed several times through this Handbook (see, for example, Chapters 12–13 and 15).

This early action raises the possibility of proactive oversight and the development of 'responsible innovation' (Owen, 2009; Owen et al., 2009). Yet, as discussed by Miller and Scrinis (Chapter 19) there are nonetheless concerns that the narrowly framed safety dialogue is merely an add-on to the innovation process, rather than integral to it (see also Ludlow and Binks, Chapter 8).

In part, these concerns arise from the dual roles of promotion and oversight taken on by governments and industry (Bowman and Hodge, 2007; Denison, 2008; Lyons and Whelan, 2010; see also Chapter 19). Governments have a strong interest in their considerable investments in nanotechnologies leading to economic stimulation and, while it can be argued that long-term gains depend on effective oversight and regulation, the short-term view is less clear. Likewise, industry has historically been reticent to unreservedly embrace safety measures that might potentially compromise productivity and profits. These perspectives do not necessarily do justice to progressive governments and industry taking a longer-term view on issues around the sustainability of technology innovation and its place in traditional industries. But there is also a question of accountability. Businesses are accountable to shareholders and other stakeholders. Government agencies are primarily accountable to their legislative objectives, missions and remits. Scientists are directly accountable to their funders and peers. As a result, the people likely to take the brunt of technology missteps are not necessarily those who the developers and implementers answer to directly (see Chapter 19). And as a consequence, the potential for conflicts of interest when addressing potential risks is far from trivial.

Re-balancing the innovation-regulation dialogue will depend on decoupling the risk conversation from the nanotechnology conversation, engaging stakeholders, and enabling citizens to play an active role in emerging technology policy (as discussed in Chapters 4, 8, 19 and 23). Given the

complexity and diversity of nanotechnologies, it is essential that there is close two-way communication between developments in the science and technology, and identifying and acting quickly and appropriately on emerging risks. Yet the risk conversation cannot afford to be only driven by the developers and promoters of the technology, or unduly influenced by them. Likewise, addressing potential risks will depend on pulling in expertise from different stakeholders, and acknowledging that each group has a valid role to play in developing future policies and strategies. Similarly, citizens – people affected by policy decisions – have a critical role to play in contributing to these decisions as highlighted by Miller and Scrinis (Chapter 19). Ethically, it is questionable to deny citizens the opportunity to be a part of the process of technology innovation where it potentially impacts on their lives and livelihoods. Pragmatically, developments in global communication are enabling citizens around the world to organize and wield considerable influence – ignoring this emerging voice would be a serious mistake, as was demonstrated with the introduction of genetically modified foods in Europe (Gaskell et al., 2000; Bauer and Gaskell, 2002; Tait, 2009). Engaging with citizens on science and technology faces many hurdles – few of which are ever overcome to everyone's satisfaction. However, finding new ways of bringing citizens into the process of developing responsible technology innovation is essential to striking an effective balance between innovation and safety (Tait, 2009).

Moving Forward with Caution

The world today is a very different place from when many of the current regulatory frameworks covering materials and products were formulated (see, for example, Chapters 7, 10–12, 17 and 25). Indeed, one of the advantages of having conducted regulatory reviews for nanotechnologies has been the extent to which we now know more about the inadequacies of our current regulatory frameworks for existing materials and products. Advances in science and technology continue to challenge the robustness of these frameworks, and will continue to do so as technologies such as nanotechnologies and other emerging technologies like synthetic biology evolve and mature. At the same time social, political and technological changes are having their own impact on regulation. Social and economic globalization are challenging the relevance and utility of top-down, rigid and regionally constrained traditional regulation. Likewise, they are opening up new possibilities for developing alternate regulatory regimes and tools. The potential roles of insurance (Chapter 9), intellectual property rights (Chapter 18), voluntary programs (Chapters 20–21) and stakeholder partnerships (Chapters 22–24) in reducing risks are all becoming

increasingly prominent in discussions, leading to a shift in emphasis from the traditional hierarchical systems of control to distributed regulatory frameworks which are more timely and responsive.

Yet as we cautioned in the Introduction to this Handbook, evaluating what works in regulation is sensitive territory. As Ludlow et al. (2009: 615) noted, there have, with any new technology, probably been 'periods of so-called under- and over-regulation'. While regulatory evolution is essential, we would be remiss in throwing out the old and embracing the new, simply because it is there. Rather, the global community needs to proceed with caution in assessing where established regulatory regimes are stressed, and where alternate regimes can lead to more responsive – and more effective – regulation. This will require investment in multi-stakeholder initiatives at the national and international level that are tasked with evaluating regulatory barriers and options to emerging technologies – including nanotechnologies – and working with governments, industry and other stakeholders to implement viable solutions in priority areas (see, in particular, Chapters 4–7, 19–24). This will also require difficult assessments to be made by governments on the importance of nanotechnology regulation as against other regulatory priorities and on nano-risks as compared to other risks which exist more broadly. On this point, we might contrast Widmer and Meili's observation in Chapter 12 that there has to date been 'no known cases of death that can be conclusively attributed to nanotechnologies or the use of manufactured nanomaterials' against the reality of 34 017 road deaths which occurred in the US in 2008 (Fatality Analysis Reporting System, 2009) or the 26 000 children under the age of five who die each day around the world, mostly from poverty-related and preventable illnesses (UNICEF, 2008).

Transparency and Trust

Two critical factors in today's changing social and political landscape are the degree to which governments are increasingly applying regulation as a policy preference at the same time as individuals and citizen-communities are also seeking to increase their influence over regulatory decision-making (see Chapters 1 and 19). The continuing tensions between the European Parliament and the European Commission over future regulatory directions for nanotechnologies, for example, are indicative of both. They remind us that in western liberal democracies, citizen power, through their elected representatives, remains supreme.[2] They remind us as well that in the absence of business being willing to be more transparent and properly self regulate, government will step in. Lastly, they remind us that while trust in governments is not high today, it is nonetheless still

seen as having greater legitimacy than businesses regulating their own affairs behind closed doors. While harm to people and the environment has long been one of the important drivers of regulation, citizens have too often played a secondary role in the decision-making process. Over the past few decades, regulation of materials and products has typically been built on quantitative risk assessment – the purview of invisible experts – and quietly modulated by political and economic interests. The result has been a science-based regulatory approach that, while both professional and competent, nonetheless has tended to deal retrospectively with well-established risks. Increasingly though, citizens now expect to be able to challenge and influence regulatory decision-making which looks forward. Such citizen expectations produce new challenges in terms of transparency levels in public dialogue, but will need to be met if public trust of both governments and businesses is to be strengthened. Globally-organized consumers with considerable spending power and political influence have also begun to impact corporate and government policies, and to shape governance with their demands. This consumer power was perhaps most clearly seen in recent years with decisions on the use and labelling of genetically modified foods in Europe (Vogel, 2001; Gruère and Rao, 2007). But the trend towards organized citizens, whether as voters or as consumers, influencing risk-related policy is a general and growing one. Likewise, the expectation to increasingly influence regulatory policy on ethical and social grounds is without doubt.

26.3 CONCLUSIONS

Regulating nanotechnologies will remain a continuing challenge to governments, to businesses and to citizens. In an age when governments have become used to steering the media discourse and spinning their way out of troubled policy waters, regulating nanotechnologies will require new levels of trust and transparency as well as changing funding priorities. At a time when businesses face new global financial uncertainties and pressures, nanotechnologies regulation will require new openness and cooperation. And for citizens, regulating nanotechnologies will require strengthened patience as well as vigilance. But these are possible if a balanced approach is our priority.

As citizens become increasingly involved in influencing regulation, it is essential that they are given the tools to engage effectively with decision-makers in government and industry (Wilsdon and Willis, 2004). Citizens – as with other stakeholder groups – come to the table with a diverse set of values and will play important roles in decision-making. Yet herein lie

two dangers for future regulation. The first is that a blinkered adherence to a science-driven and hierarchical decision-making approach will ignore these values, leading to regulatory regimes that lack credibility, legitimacy and support. The second is that perceptions that are counter to current scientific understanding may have an undue influence on regulatory decisions, and lead to regulation that is not evidence-informed, and ultimately not fit for purpose. It is a question of achieving a new balance. And as we move ahead, including citizens and others effectively in evidence-informed and socially responsive decision-making will require new approaches to informing and engaging people. And in this process, transparency and trust will be paramount.

Innovative new ways of providing all stakeholders with relevant and accessible information will be essential to ensuring informed regulation (Wilsdon and Willis, 2004; Kearnes and Wynne, 2007). In the future, the challenge will be how to empower people to be an effective part of the decision-making process, rather than how to make decisions on their behalf. At the same time, the details of how regulations are crafted and enacted will of necessity remain the responsibility of a small number of experts. If regulation is to work within the changing social landscape, and in the face of emerging technologies, new levels of trust must be nurtured between citizens and decision-makers in industry and government.

Nanotechnologies represent the vanguard of a new era of emerging technologies. In many ways, they are a testbed for how as a society we respond to new opportunities and new challenges. From a regulatory perspective, the practical outcomes of the technologies have so far been evolutionary rather than revolutionary. But the 'wicked problem' of regulating nanotechnologies is now superimposed on a changing social and economic landscape, and it exists amid a climate of growing citizen expectation for influencing government policy directions. And even as we are learning to disentangle and address these problems, increasingly revolutionary technologies are waiting in the wings – active nanomaterials, smart nanodevices, synthetic biology, advanced robotics and information technology, together with synergistic convergence between these and other areas of innovation. These emerging technologies *will* challenge our ideas about, and frameworks for, identifying and managing risks. The only question is, are we prepared?

This Handbook highlights the complexity of the challenges we are facing. It also offers hope – because in the process of untangling the important questions, we also begin to reveal possible solutions. Ensuring the products of nanotechnology – and emerging technologies in general – are regulated effectively, without stifling innovation, remains a significant challenge. But by forging effective partnerships – between traditional and

non-traditional stakeholders – working together and learning from our experiences, we have the opportunity to learn and adapt – and transform the wicked regulatory problems presented by emerging technologies into challenges that are merely difficult.

NOTES

1. One way of viewing the nanotechnology phenomenon is not in terms of multiple and complex scientific frontiers, but as a brand. In consumer markets, brands identify commercial offers and differentiate them against those of competitors. They are defined not through any scientific or professional lens, but through the lens of consumer psychology and perception. The notion of nanotechnology as a 'brand' therefore, invites us to consider that 'nanotechnology', for example, identifies and differentiates a government's policies from those offered by opponents. In this case, 'nanotechnology' symbolizes positive business support, innovation and technological progress. And crucially, nanotechnology promises economic growth. But importantly, it is a hybrid idea that is by definition wonderfully ambiguous, and it aims to evoke images and emotions rather than precision. That is what has given it power (Hodge, Maynard and Bowman, 2010).
2. This statement might seem obvious. However, other sources of power in policy processes, while ever present, are too often not debated explicitly. Such sources of power in the current context might be sector-wide (such as private businesses), institutionally based (such as the power of professional public bureaucrats), or else be through professional groupings (such as economists, accountants, or scientists and technologists). Many other groupings are also possible, including a wide range of interest or policy advocacy groups (such as the green movement, security-based policy advocacy groups, or even ethical and religious groups).

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