International Handbook on Regulating Nanotechnologies

Edited by

Graeme A. Hodge

Director, Monash Centre for Regulatory Studies, Faculty of Law, Monash University, Australia

Diana M. Bowman

Senior Research Fellow, Melbourne School of Population Health, the University of Melbourne, Australia

Andrew D. Maynard

Director, Risk Science Center, University of Michigan, USA

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

FSC
www.fsc.org
MIX
Paper from
responsible sources
FSC® C018575

ISBN 978 1 84844 673 1 (cased)

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

16 Regulation of nanoscale materials under media-specific environmental laws

Linda K. Breggin and John Pendergrass[1]

16.1 INTRODUCTION

Nanoscale materials can be regulated under a host of media-based environmental laws. To date, however, most countries have not relied upon or fully assessed the use of media-based environmental laws to regulate nanoscale materials. Instead, as discussed by the authors of Chapters 12, 13 and 15, regulators have focused for the most part on laws that apply to chemical substances, food, and cosmetics as the primary vehicles for addressing potential risks posed by nanoscale materials. Widmer and Meili (2010) highlight how, for example, United States (US) regulators have focused their attention on the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) – the key US chemicals laws – and European Union (EU) regulators have focused on the newly-enacted Registration Evaluation and Authorisation of Chemicals (REACH), which governs the production and importation of chemical substances within the European market. In addition, regulators in jurisdictions such as the EU and Australia are using, or considering the use of, food and cosmetics laws to address risks posed by nanoscale materials (see, for example, Gergely et al., 2010; van Calster and Bowman, 2010).

This chapter examines the application of media-based environmental laws to nanoscale materials. It specifically excludes laws that govern chemicals, food, cosmetics, and worker safety, which are covered elsewhere in this Handbook.[2]

The reliance to date on laws that focus on chemical substances in particular is understandable, as discussed more fully below, because such laws typically attempt to address potential risks posed by chemicals prior to their release during or after manufacturing – before they can be released into the air and water, disposed of on land, or used in consumer products. The focus on food and cosmetics laws also makes sense because they are aimed at regulating potential risks posed by consumer products that typically have clear exposure pathways through ingestion or dermal exposure. In contrast, media-based environmental laws typically focus on preventing or regulating the extent of releases of pollutants into the air and water and on land during manufacturing, disposal, and, in some cases, during use. As a result, it is not surprising that far less attention has been paid to the use of media-based laws at this early stage in the regulation of nanoscale materials. Nevertheless, these laws should not be ignored indefinitely, as they represent potentially useful tools for addressing risk to human health and environment that may be posed by nanoscale materials. In fact, these laws are particularly important because they provide opportunities for addressing risks at a range of stages in the life cycle of nanoscale materials.

This chapter starts with a brief overview of media-based environmental laws and regulations in several key countries that have heavily invested in the development of nanotechnologies: the US, EU, Australia and Japan. These countries were selected for inclusion in this chapter because they are among the only countries that have released publicly available assessments of the use of their media-based environmental laws to regulate nanoscale materials. Furthermore, this chapter relies primarily on the authors' prior research on US environmental laws and also reports or assessments conducted by others. These assessments vary significantly in scope and depth and, therefore, our discussion reflects this variability. This variability is indicative of the early state of development of nanotech governance approaches.

The chapter then examines whether media-based environmental laws have been used or evaluated for purposes of regulating nanoscale materials. Next, the chapter turns to a general discussion of the barriers that may exist to using environmental laws to address potential risks posed by nanoscale materials, and offers examples that illustrate these challenges. The chapter closes with observations on the path forward for fostering the use of media-based environmental laws to regulate nanoscale materials.

16.2 APPLICATION OF MEDIA-SPECIFIC ENVIRONMENTAL LAWS

It is not possible of course to provide an overview of every country's efforts to apply or assess the application of environmental laws to nanoscale materials. Instead, this section provides an overview of the environmental laws in several key countries and describes their efforts to apply these laws to nanoscale materials.

As a threshold matter, our research indicates that to date none of the countries examined actually has applied its media-based environmental laws to nanoscale materials. In other words, regulators in these countries have not issued permits, taken enforcement actions, promulgated rules, or stated in policy or other official documents that a particular nanomaterial or class of nanoscale materials is covered by a particular media-based environmental law. Several countries, however, to varying extents have started the process of determining whether their environmental laws could be applied and if so whether any amendments to their laws or regulations would be needed.

It is also important to recognize that this chapter examines only government assessment and application of media-based environmental laws to nanoscale materials. The chapter does not address whether or the extent to which private firms have determined independently that emissions, discharges, or wastes containing nanoscale materials from their facilities are covered by a particular environmental law.

US

US federal environmental laws are relatively narrowly framed to deal with specific types of pollution that cross state lines or otherwise affect commerce, including air and water pollution and disposal and cleanup of hazardous substances.[3] The states retain general authority to deal with environmental issues and the federal pollution control laws typically allow states to implement the federal laws if they demonstrate that they will meet minimum standards of protection established in the federal law. The US Congress passed the major federal pollution control laws in the 1970s, starting with the Clean Air Act (CAA) in 1970,[4] followed by the Clean Water Act (CWA) in 1972,[5] and the Resource Conservation and Recovery Act (RCRA) (regulating disposal of solid and hazardous wastes) in 1976.[6] Although each of these laws has been amended and updated since their original enactment, none includes any provisions specifically intended to deal with nanotechnologies or nanoscale materials (see, for example, Environmental Law Institute, 2005; Breggin and Carothers, 2006; Davies, 2006). Each of these media-specific laws (CAA, CWA, and RCRA) delegates authority to the Environmental Protection Agency (EPA) to set standards and promulgate rules to implement the laws. The principal pollution control statutes,[7] the CAA, CWA, and RCRA, are broad enough to allow EPA to promulgate regulations covering nanoscale materials. Some have concluded, however, that such action would extend the agency's reach into new fields and could be controversial (Schierow, 2008).

In the US, there have been numerous efforts to assess the applicability of federal environmental laws to nanoscale materials and nanotechnologies. The Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies (PEN) (see, for example, Davies, 2007; Breggin and Porter, 2008; Breggin and Pendergrass, 2007; Greenwood, 2007), the Environmental Law Institute (ELI) (ELI, 2005), the American Bar Association (ABA) Section of Environment, Energy, and Resources (SEER) (ABA SEER, 2006a, 2006b, 2006c, 2006d, 2006e) and the Environmental Protection Agency (EPA) (EPA, 2007) all have analysed how nanoscale materials would be regulated under one or more environmental laws.

In the Clean Air Act, Congress established a model for federal environmental laws, followed in particular by the CWA and RCRA. Important features of the CAA model include:

- national minimum standards for pollutants in the environment
- technology-based pollution control limits applicable at the source
- requirements for polluters to obtain permits; authorization of states to implement the act if they demonstrate that they have the legal and administrative capability to carry out the provisions of the law; federal enforcement of the law through civil penalties, injunctive relief, and criminal prosecution
- federal oversight of states that are delegated authority to implement the act, and
- citizen suits to enforce the act in the absence of federal or state enforcement.

The CAA authorizes EPA to set National Ambient Air Quality Standards (NAAQS) for pollutants that the agency has determined cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare.[8] EPA could establish standards for nanoscale particles under these provisions or it could use existing standards for fine particulate matter to cover nanoscale materials (ABA SEER, 2006a). The first approach would require EPA to determine that specific nanoscale materials may reasonably be anticipated to endanger public health or welfare and then to set standards, which would necessitate detailed information about the risks of nanoscale materials and how those risks could be avoided or mitigated. The latter approach likely would require development of new monitoring technologies in order to determine compliance, as the existing rules, although technically including particles in the nanoscale range (1 to 100 nanometers), focus on much larger particles up to 2.5 microns (2500 nanometers). EPA also has authority to identify and regulate hazardous air pollutants (HAPs).[9] The existing rules regulate 187 HAPs, none of which is specifically identified as a nanoscale material (EPA, 2007). Other provisions of the CAA could provide additional authority by which EPA could regulate nanoscale materials, including their use as additives to gasoline or diesel fuels for use on roads (EPA 2007). Although EPA has authority under the CAA by which it could regulate nanoscale materials that caused air pollution, it has not done so to date.

The CWA establishes a goal of zero discharge of pollutants to US waterways and prohibits any discharge except in compliance with the statute.[10] Nanoscale materials could fall within the ambit of this goal, but EPA would need to determine that particular nanoscale materials were pollutants and then develop regulations setting the conditions under which discharge would be permitted (ABA SEER, 2006b). The Act requires the agency to establish technology-based effluent guidelines for discharges from point sources, which would require EPA to determine the best available technology economically feasible for dischargers. Other provisions of the Act also authorize EPA to regulate nanoscale materials. For example, the agency could determine that specific nanoscale materials were hazardous substances and then regulate their discharge (ABA SEER, 2006b). Thus, the CWA provides authorities to EPA that it could use to regulate nanoscale materials. Similar to the CAA, however, as discussed below in more detail, the agency would face scientific and procedural challenges to establishing appropriate and effective regulations covering specific nanoscale materials.

The RCRA regulates the disposal of solid waste and the generation, transportation, management, treatment, storage, and disposal of hazardous wastes (ABA SEER, 2006c). Nanoscale materials are covered by RCRA if they are solid wastes and subject to more stringent regulation if they are also hazardous wastes (Breggin and Pendergrass, 2007). The definitions of solid waste and hazardous waste are complicated and detailed, but if nanoscale materials are discarded they will very likely be regulated under RCRA (Breggin and Pendergrass, 2007; ABA SEER, 2006c). One exception to the regulation of hazardous waste that may be significant with respect to nanoscale materials is for household waste, which is regulated under the less stringent solid waste rules even when hazardous wastes are contained in the waste (Breggin and Pendergrass, 2007).

Hazardous wastes are defined by EPA either by specifically listing them in regulations (of which there are hundreds) or because they have one of four characteristics: ignitability, corrosivity, reactivity, or toxicity. EPA has not listed any nanoscale material as a hazardous waste due to its size, but it is possible that some listed hazardous wastes are being generated at the nanoscale and thus might be covered by existing RCRA regulations (Breggin and Pendergrass, 2007). EPA also has authority to respond to emergency situations by seeking injunctive relief to abate an imminent and substantial endangerment to health or the environment caused by solid or hazardous wastes.[11] Accordingly, EPA has authority under RCRA to regulate discarded nanoscale materials, but it may need to revise some of its regulations to address more effectively risks that may be specific to nanoscale materials, as discussed more fully below.

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund)[12] was enacted in 1980 to address inactive or abandoned hazardous waste sites, many of which were the product of decades of uncontrolled and undocumented methods of hazardous substance disposal. It also was intended, in part, to create incentives for proper future handling of hazardous substances (Percival et al., 2006; Pendergrass and Probst, 2005). In a 2007 report, ELI found that Superfund cleanup authorities are broad enough in theory to cover nanoscale materials. The threshold issue is whether any nanomaterial constitutes a 'hazardous substance.' Furthermore, even if nanoscale materials are not hazardous substances, the statute provides broad authority to EPA to address releases of pollutants and contaminants that present an imminent and substantial danger. ELI found that in theory this authority could be used to address nanoscale materials; but EPA would be limited to performing the cleanup itself and could not recover its cleanup costs from responsible parties (Breggin and Pendergrass, 2007).

Other statutes provide EPA with authority that could be used to regulate risks from nanoscale materials, including but not limited to the Emergency Planning and Community Right to Know Act (EPCRA)[13] and the Safe Drinking Water Act (SDWA).[14] EPA has not asserted its authority to regulate nanoscale materials under any of these statutes.

European Union

Most media-based and pollution prevention environmental laws in the EU are in the form of Directives (Institute for European Environmental Policy (IEEP), 2009). Directives set forth binding policy objectives, but they leave room for Member States to implement legislation that will achieve these objectives. Implementation not only requires the 'reproduction of the words of a Directive in national law, but also requires such additional provisions as may be necessary to ensure that national law as a whole properly achieves the result intended by the Directive' (IEEP, 2009: 7). Member States therefore have 'a measure of discretion . . . as to the means of achieving a particular result' (IEEP, 2009: 6–7).

The Water Policy Framework Directive (Directive 2000/60/EC) (the Water Directive) (European Commission, 2008a),[15] which entered into force on 22 December 2000, establishes a 'framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater' (Article 1). The directive requires Member States to identify individual river basins within their jurisdiction and to assign them to river basin districts (Article 3). Within four years after the date of entry into force of the directive, Member States must complete an analysis of each river basin district within their jurisdiction to determine:

1. the characteristics of the river basin district
2. the impact of human activity on surface and ground waters, and
3. water use economics (Article 5).

Taking into account the results of this analysis, Member States must establish a 'programme of measures' (Article 11).

The goal of this program is to achieve the environmental objectives set forth in the Water Directive. These include for surface water, for example, protecting, enhancing and restoring all bodies of surface water; achieving good chemical status and ecological potential for all artificial and heavily modified bodies of water within 15 years from the date of entry into force of the Directive; and reducing emissions from priority substances and priority hazardous substances (Article 4).[16] For groundwater, the objectives include:

- preventing or limiting the input of pollutants into groundwater,
- achieving good groundwater status within 15 years from the date of entry into force of the Directive, and
- implementing measures to reverse the 'significant and sustained upward trend' of pollutants resulting from human activities.

In addition, Member States are required to produce a river basin management plan for each river basin district lying completely within their jurisdiction (Article 13).

At the same time, pursuant to the Water Directive, the European Parliament and the Council are required to 'adopt specific measures against pollution of water by individual pollutants or groups of pollutants presenting a *significant risk* to or via the aquatic environment . . .' in order to ensure 'the progressive reduction and, for priority hazardous substances, . . . the cessation or phasing-out of discharges, emissions and losses' (Article 16, emphasis added). The term 'pollutant' is defined to mean 'any substance liable to cause pollution, in particular those listed in Annex VIII of the Water Directive (Article 2(31)). Annex VIII lists 12 categories of pollutants, including substances that 'have been proved to possess carcinogenic or mutagenic properties,' as well as 'metals and their compounds.'

The Ambient Air Quality Directive (Directive 2008/50/EC) (Air Quality Directive),[17] which entered into force on 11 June 2008, sets forth measures aimed at, among other things, 'defining and establishing objectives for ambient air quality designed to avoid, prevent or reduce harmful effects on human health and the environment as a whole' (Article 1). Pursuant to the directive, Member States must 'establish zones and agglomerations throughout their territory,' on the basis of which air quality assessment and management are carried out (Article 4).

The Air Quality Directive sets forth limit values[18] and, for certain pollutants, target values[19] to achieve (Articles 12 and 13). The pollutants covered under this directive include sulfur dioxide, PM_{10}, $PM_{2.5}$, lead, carbon monoxide, ozone, nitrogen dioxide and benzene. If the level of a pollutant exceeds a limit value or target value, plus any margin of tolerance, in the ambient air of any zone or agglomeration, Member States must establish an air quality plan in order to achieve the relevant limit value or target value (Article 23).

The Air Quality Directive does not currently contain any relevant limit values or measurement and control methods for nanoscale materials (European Commission, 2008a). As noted in the European Commission's (EC) (2008a: 34) report, while nanoscale materials are 'embedded' in particulate matter PM_{10} and $PM_{2.5}$, 'the metric related to total mass is unsuitable to ultra-fine particles.' It should be noted, however, that a '[r]eview process is set to reconsider the objectives and the appropriate PM metric by 2013' (EC, 2008a: 34). In addition, particulates are being regulated under other air quality laws. For example, the legislation relating to emissions from light passenger and commercial vehicles 'set[s] limit values on the number count of particulate matter emissions' (EC, 2008a: 34). The proposed standards for heavy-duty vehicles also contain similar provisions (EC, 2008a).

The Waste Directive (Directive 2008/98/EC) (Waste Directive),[20] which entered into force on 12 December 2008

> lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use (Article 1).

The directive instructs Member States to apply a 'waste hierarchy' (that is, a priority order) in establishing waste prevention and management legislation and policy (Article 4). The Waste Directive also sets forth a system of permits and registrations, as well as requires Member States to establish 'one or more waste management plans [that] . . ., alone or in combination, cover the entire geographical territory of the Member State concerned' (Article 28). In addition, the Waste Directive contains specific provisions related to hazardous waste, which is defined as any 'waste which displays one or more of the hazardous properties listed in Annex III' (Article 3(1), Annex III). The hazardous properties listed in Annex III include harmful, toxic and mutagenic substances. Under the directive, Member States must

> take the necessary action to ensure that the production, collection, and transportation of hazardous waste, as well as its storage and treatment, are carried out in conditions providing protection for the environment and human health . . . (Article 17).

In 2008, the EC issued a *Communication on the Regulatory Aspects of Nanomaterials* (EC, 2008c), which 'was prepared in response to a commitment by the EC to conduct a regulatory review of EU legislation in . . . sectors of relevance to nanotechnology' (Pelley and Saner, 2009: 27). In that communication, the EC (2008c: 3) concluded that its 'current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework.' In reaching this conclusion, the EC (2008a: 4) reviewed 'selected EU legislation that seem[ed] most relevant and likely to apply to nanotechnologies and nanomaterials.' This review was summarized in the accompanying *Regulatory Aspects of Nanomaterials: Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures* (Accompanying Nano Document) (EC, 2008a) and included a review of several media-based environmental directives.

Although the EC concluded in its review that the risks of nanoscale materials 'can be dealt with under the current legislative framework,' it nevertheless recognized: 'Knowledge on essential questions such as characterisation of nanomaterials, their hazards, exposure, risk assessment and risk management should be improved' (EC, 2008c: 11). Some directive-specific examples are discussed in the following section of this chapter.

Australia

Australian environmental regulations are promulgated both on the national level and local level (Ludlow et al., 2007). Responsibility for regulating and enforcing environmental laws in each jurisdiction rests primarily with the individual states and territories. The Department of the Environment and Water Resources (DEW), however, administers certain Commonwealth environmental laws, such as the Environmental Protection and Biodiversity Conservation Act 1999, the Fuel Quality Standards Act 2000 and the Hazardous Waste (Regulation of Exports and Imports) Act 1989 (Ludlow et al., 2007).

In 2007, the Monash University Centre for Regulatory Studies issued an independent review of 'the effect of nanotechnologies on Australia's regulatory frameworks' (Ludlow et al., 2007: 5). The final report, entitled *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework* (hereinafter referred to as the review), was written by Karinne Ludlow, Diana M. Bowman and Graeme A. Hodge. It was developed in response to a request from the Australian Department of Industry, Tourism and Resources and was intended to advise the Health, Safety and the Environment Working Group, which is composed of Commonwealth federal agencies. The Monash University team reviewed relevant legislation, codes of conduct, guidelines and guidance materials and evaluated whether these frameworks could effectively regulate the health, safety and environmental impacts potentially presented by nanoscale materials (Ludlow et al., 2007). The authors performed the review by assessing the federal regulatory framework and Victoria's environmental regulatory framework as a state example. Among the Victoria laws reviewed were the Environmental Protection Act 1970, Environmental Protection (Prescribed Waste) Regulations 1998, Pollution of Waters by Oil and Noxious Substances Act 1986, Pollution of Waters by Oil and Noxious Substances Regulations 2002, and Environmental Protection (Vehicle Emissions Regulations), 2003 (Ludlow et al., 2007).

The authors concluded that much of Australia's regulatory regime is 'well-suited' to protect the public from health and environmental risks potentially posed by nanotechnology (Ludlow et al., 2007: 100). However, they also identified several gaps in Australia's current regulatory framework. These include, but are not limited to: lack of clarity as to 'whether new nanoforms of conventional products would be considered as "different" to traditional products,' regulatory triggers that exist on the basis of a threshold weight or volume; lack of knowledge about the risks posed by nanoscale materials; and references to international documents that may fail to address the possible health and environmental risks posed by nanoscale materials (Ludlow et al., 2007: 100).

For example, in their review, the authors examined the Fuel Quality Standards Act 2000 (FQS Act), which regulates the use of fuel in order to reduce the level of pollution and emissions that contribute to environmental and health problems (Ludlow et al., 2007). Additionally, the Fuel Standards (Petrol) Determination 2001 (FSD) sets the standard for additives in petrol. Restrictions on additives are created when there is sufficient evidence that the additive will 'adversely impact fuel quality and engine operability' (Ludlow et al., 2007: 56). The review found that fuel and 'fuel additives incorporating nanoscale materials will, by their very definition fall within the scope of the FQS Act and the FQS Regulations' (Ludlow et al., 2007: 58). It also concluded that the Commonwealth's 'broad ranging powers in relation to the creation of fuel standards, and the monitoring and enforcing of these standards . . . apply equally to fuel and fuel additives incorporating nanoscale substances, as to any other fuel or fuel additives' (Ludlow et al., 2007: 60).

Additionally, the review determined that the Hazardous Waste (Regulation of Exports and Imports) Act 1989 (HWREI Act) and accompanying regulations issued in 1996 could apply to nanoscale materials. The objective of the legislation is

> to ensure that exported, imported or transited waste is managed in an environmentally sound manner so that human beings and the environment, both within and outside Australia, are protected from the harmful effects of the waste (Ludlow et al., 2007: 56).

Specifically, the review found that 'a number of nanotechnology-based products, or waste streams associated with the manufacturing and production processes of the nanotechnology-based products, may fall within the definition of "hazardous waste"' (Ludlow et al., 2007: 57). The review also concluded that anyone who seeks to import, export or transit hazardous waste within Australia, 'regardless of whether or not it contains nanoscale materials,' will be subject to the enforcement powers of the Commonwealth, including its entry, search, inspection and monitoring authorities (Ludlow et al., 2007: 60).

As noted, the review used the State of Victoria's environmental laws and regulations to evaluate whether states have the potential to regulate nanoscale materials. For example, in Victoria, the State Environmental Protection Authority (VEPA) has the authority to regulate waste discharged into water, air and onto land (Ludlow et al., 2007). The review found that the applicable state law and regulations interpret waste very broadly. Thus, if engineered nanoscale materials were 'discharged into the environment in such a volume as to cause an alteration in the environment, they would fall within the definition of 'waste' (Ludlow et al., 2007: 63). Furthermore

> any nanotechnology-based product, including electronic goods, plastics or glass, which are for example, discarded, rejected, or abandoned, may fall within the definition of waste . . . regardless of whether or not they contained [nanomaterials] or were made using nanotechnology (Ludlow et al., 2007: 63).[21]

Japan

Japan's Ministry of the Environment (MOE) is responsible for government-wide environmental policy planning, drafting and promotion (MOE, undated a). Additionally, the MOE provides advice with respect to government measures that are not specifically aimed at conservation but may have environmental effects (MOE, undated a). Bureaus within the MOE address air, water, waste and other areas of environmental regulation (MOE, 2006). Additionally, seven regional environmental offices throughout the country address waste and recycling, conservation measures, including conservation and development of the natural environment, and protection and management of wildlife (MOE, undated b).

Japan has enacted the following environmental regulations for media-based pollutants: Air Pollution Control Law, Law No. 97 of 1968 (APCL); Waste Management and Public Cleansing Law, Law No. 137 of 1970 (WMPCL); Water Pollution Control Law, Law No. 138 of 1970 (WPCL); and The Basic Environmental Law, Law No. 91 of 1993 (BEL) (Bowman and Hodge, 2007). The APCL controls the emissions of 'soot, smoke and particulates' in order to preserve and protect human health and the environment (Chapter 1, Article 1). The WMPCL prescribes measures for 'restriction of waste discharge, appropriate sorting, storage, collection, transport, recycling, [and] disposal' to protect public health and the environment (Chapter 1, Article 1). The WPCL was enacted to prevent the deterioration of water quality by regulating effluent discharges and requiring compensation be paid for damages caused by polluters (Chapter 1, Article 1). Finally, the BEL intends to 'comprehensively and systematically promote policies for environmental conservation to ensure healthy and cultured living for both the present and future generations of the nation' by ensuring that basic environmental principles are included in all policy considerations (Chapter 1, Article 1).

In March 2009, the MOE released a guideline that was 'formulated with the objective of reducing the health risk posed by environmental exposure to nanomaterials through the implementation of proper control measures by companies and other organisations that handle nanomaterials, as well as organising all available information on nanomaterials in anticipation of future issues' (MOE, 2009: 2). The guideline recognizes that although typically pollution-control regulations would be adopted to address substances that pose health and environmental risks, 'information on nanomaterials is not yet shared publicly.' It further reasons that 'companies who handle nanomaterials (for example, primary and secondary manufacturers, transporters and waste handlers) have the broadest knowledge on the physicochemical properties, potential health risks, and applications of nanomaterials' (MOE, 2009: 2). As a result the guideline states that companies 'are expected to voluntarily control and prevent the environmental release of nanomaterials, especially now that their use is expanding' (MOE, 2009: 2).

16.3 CHALLENGES

Environmental laws provide authorities that in theory can be used to address risks posed during various points in the life cycle of nanoscale materials and also to prevent pollution from nanoscale materials before it occurs. The importance of taking a full life-cycle approach, which could include, for example, basic research and development, manufacturing, and product use and disposal (ELI, 2005), is now well-recognized as a key aspect of developing effective governance approaches for nanotechnologies. Over the last several years, research and covenings by organizations such as the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies (PEN), the Royal Society and the Royal Academy of Engineering (RS-RAE), Environmental Defense Fund, and the ELI have highlighted the need for such a full life cycle approach to nanoscale materials regulation (see, for example, Davies, 2006; RS-RAE, 2004, Medley and Walsh, 2007). As explained by the Japanese Ministry of Environment:

> During the manufacturing or processing stage, nanomaterials are potentially discharged in the exhaust gas, effluent or waste depending on the handling method and type of nanomaterial. On the other hand, there is also a potential risk of environmental release when using products made of nanomaterials (MOE, 2009: 6).

The need to consider the use of media-based environmental laws is underscored by the myriad ways nanoscale materials can be released into the environment, many of which have been outlined on a media-by-media basis by the Japanese Ministry of Environment. For example, atmospheric releases could occur from the scattering of nanoscale materials from manufacturing or processing equipment. They could also be released during transport, packaging and unpacking. In addition, nanoscale materials in products, such as photocatalytic paints and sprays, can potentially be released into the atmosphere during use (MOE, 2009).

With respect to releases into water, the Japanese Ministry of the Environment (MOE, 2009: 8) explained that nanoscale materials

> contained in the effluent discharged during the manufacturing or processing stages and in wastewater generated during cleaning operations can potentially be released into the public water system.

Furthermore, although effluent is only discharged after it is treated, it noted that 'the removal efficiency for nanomaterials is not yet clear' (MOE, 2009: 8). Furthermore, nanoscale materials contained in cosmetics and household products ultimately may be released into general household sewage, which is typically treated at sewage treatment facilities. Again, however, 'the removal efficiency for nanoparticles is not yet clarified and they may potentially be released into the public water system' (MOE, 2009: 8).

There also are numerous ways that waste can contain nanoscale materials. Nanowaste can be generated during manufacturing and processing. In addition, work-site filters, cleaning paper and cloths, transport vessels and bags may be disposed of as waste. Furthermore, defective product and used test nanoscale materials may become waste. Exhaust gas, effluent, dust or sludge also may contain nanoscale materials that can be released into the environment. Finally, it is possible that in some cases nanoscale materials may be released into the environment during or as a result of disposal and treatment processes, such as shredding, incineration, composting and disposal in a landfill (MOE, 2009).

Thus, there are numerous ways at the various points in the lifecycle of nanoscale materials that releases into the environment can occur. Media-based environmental laws provide a means of addressing the risks that may be posed by these releases and yet, to date, these laws have not been used by regulators in the US, EU, Japan or Australia, for example. Studies suggest that major impediments exist to applying media-based environmental laws to nanoscale materials that should be addressed in order for these laws to be used effectively. In the following section some of these key challenges are examined, including knowledge and data gaps, monitoring and detection, quantity-based thresholds, overlap with and reliance on other laws, nanomaterials as new versus existing substances, next generation nanomaterials and time and resources.

Knowledge and Data Gaps

Perhaps the key challenge in using media-based environmental laws to address risks posed by nanoscale materials is the dearth of information on several key aspects of nanoscale materials. These data typically are needed for environmental laws to function effectively (Franco et al., 2007). In a recent report, the authors of this chapter, along with our co-authors Robert Falkner, and Nico Jaspers from the London School of Economics, and Read Porter from ELI, found that scientific uncertainty is a principal challenge in developing effective regulatory responses to the potential risks posed by nanoscale materials.

The report noted that:

> [r]ecent academic analyses and regulatory reviews by governmental institutions have revealed a number of areas in which scientific uncertainty is undermining the effectiveness of existing regulatory frameworks (Breggin et al., 2009: 85).

These studies emphasize uncertainties with regard to: classification of nanoscale materials; the definition of nanotechnology; identification of hazards and exposure levels and environmental and health effects (Breggin et al., 2009).

Specifically, the report cited the UK's RS-RAE (2004) report that pointed to existing gaps in knowledge and understanding of nanoscale materials and their associated risks. The report also emphasized the EC's (2008c) unequivocal statements in its Nano Communication of June 2008 report regarding the need for significantly increased scientific knowledge to support regulatory efforts, as well as the US EPA's (2007) *Nanotechnology White Paper*. The white paper recognized uncertainty with respect to chemical representation and nomenclature, environmental fate, environmental detection and analysis, human exposure models and toxicity testing of nanoscale materials (Breggin et al., 2009).

The Japanese government has made similar observations:

> In reducing the environmental risk posed by chemical substances, control measures are implemented according to the degree of hazard determined such that the amount released into the environment is maintained at a specific level that is unlikely to pose a health hazard. However, in the case of nanomaterials . . . the biological effects are not yet fully clarified . . . and it is not presently possible to establish an exposure control level for preventing environmental effects (MOE, 2009: 4).

The Monash University Review of Australian law reaches the same conclusion. It concludes that due to a lack of data regarding exposure and ecotoxicological properties of many nanoscale materials, it is unclear whether current methods are sufficient for the Australian Environmental Protection Authority to determine accurately the risks presented by nanoscale materials and products containing nanoscale materials (Ludlow et al., 2007).

Furthermore, in addition to scientific uncertainty, regulators face an important knowledge gap with regard to the presence of nanoscale materials in commercial products. This knowledge gap is closely linked to uncertainty about the environmental, health and safety (EHS) risks of nanoscale materials and complicates the development of effective regulatory approaches:

> Knowing as soon as possible what types of nanoscale products are on the market, what types of nanomaterials are used and how they move through possible product life-cycles provides some grounding for establishing research needs in the field of EHS risks (Breggin et al., 2009: xii).

These numerous data gaps may make it difficult in the near term, if not impossible, to use media-based environmental laws to address nanoscale materials. However, the ability to use environmental laws will vary considerably depending on the particular law and specific nanomaterial. To illustrate this point, this chapter now turns to examples of how in theory environmental laws can provide mechanisms for addressing risks of nanoscale materials but how their utility may be limited by data gaps.

US example

RCRA, which requires the identification, tracking, and safe treatment and disposal of hazardous wastes, could be a powerful tool for addressing risks posed by certain nanowaste. In a 2007 study, however, ELI concluded that regulators may find it difficult to use the authorities in RCRA to regulate nanowaste in part because they would need to make a determination as to whether a particular nanowaste has the characteristics of hazardous waste. For example, the toxicity characteristic component of the regulatory definition of hazardous waste may be the most likely to apply to nanowaste, but the toxicity characteristic leaching procedure may not be appropriate for nanowaste and may need to be revised to account for the different ways that nanoscale materials react in the environment compared with the bulk materials that were the basis of the current test (Breggin and Pendergrass, 2007).

ELI also concluded that further research is needed to determine whether existing practices for handling, treating, storing, and disposing of bulk forms of solid wastes are appropriate for nanoscale wastes of the same chemicals. Finally, ELI found that many generators of nanowaste may have insufficient information to provide to owners or operators of treatment, storage, and disposal facilities to enable them to manage such wastes appropriately (Breggin and Pendergrass, 2007).

Another example is the CWA, which could be used to regulate nanoscale materials released into water. EPA would need to determine, however, that a particular nanoscale material is a 'pollutant' and then develop regulations setting the conditions under which discharge would be permitted (ABA SEER, 2006b). Furthermore, the act requires the agency to establish technology-based effluent guidelines for discharges from point sources. This would require EPA to determine the best available technology economically feasible for dischargers, which would be a difficult task given the uncertainty regarding nanoscale particles in the environment. The agency also could determine that specific nanoscale materials were 'hazardous substances' and then regulate their discharge, but it would need to demonstrate that specific materials present an imminent and substantial danger to the public health or welfare (33 U.S.C. §1321(b)(1)).[22] Thus, although the CWA provides authority to EPA by which it could regulate nanoscale materials, this would require scientific and technological advances to support the development of appropriate and effective regulations (ABA SEER, 2006b).

EU example

The EC's (2008a) report finds that the Waste Directive raises similar issues. The EC (2008a: 31) concluded that

> Community regulation as far as relevant for nanoscale materials and nanotechnologies can be presented under the general framework directives on waste and directives on specific waste streams and specific waste treatment techniques.

The EC (2008a: 33) recognized, however, that 'the central issue lies in the lack of understanding of the potential risks displayed by nanomaterials at the waste stage.'

Similarly, in a study on the lifecycle of certain commercial products that contain nanoscale materials, researchers noted that wastes are typically disposed of in landfills or incinerated, but 'very little is known about the long-term behaviour of nanoparticles in a landfill' and with respect to incineration the fate of nanoscale materials may vary depending on their structure. Furthermore, the study found that the 'lack of (eco) toxicological data makes it difficult to state if nanoparticles meet the criteria of hazardousness' (Franco et al., 2007: 178).

Finally, in its Accompanying Nano Document, the EC (2008a) recognizes that the manner in which the Integrated Pollution Prevention and Control (IPPC) Directive is currently implemented may not effectively regulate nanoscale materials. For example, implementation is currently focused on traditional pollutants. In order for the IPPC Directive to be an effective regulatory tool for nanoscale materials

> attention [must] be given to the assessment of the releases of [nano]materials from IPPC installations (noting that some such releases may be from industrial installations falling outside the scope of the IPPC Directive), their impacts, and control techniques that may be considered as [best available technology or] BAT (EC, 2008a: 29).

At the same time

> [t]he capacity of competent authorities to apply, monitor and enforce compliance with emission limit values or other types of permit conditions relating to nanomaterials would also need to be established (EC, 2008a: 29).

Australia example

The Environmental Protection and Biodiversity Conservation Act 1999, which aims to address action that will have or is likely to have a 'significant impact' on 'matters of national environmental significance,' may be difficult to apply to the manufacturing, processing, use or disposal of nanoscale materials due to scientific uncertainties (Ludlow et al., 2007). According to the above-referenced review:

> it would appear unlikely that the *EPBC Act* will be triggered by the manufacture, use, or disposal of [nanomaterials], or indeed, conventional scale substances. In relation to nanotechnology, current usage of nanotechnology and *deficiencies in knowledge* mean it is unlikely to be able to be shown that it has or will have, or even that it is likely to have, a significant impact on the matters protected under the Act (Ludlow et al., 2007: 55) (emphasis added).

Monitoring and Detection

Nanoscale materials present significant difficulties for environmental regulatory agencies because in many cases they are too small to be detected by current technology. A recent analysis of the 'incremental approach' adopted by the EU toward regulation of nanoscale materials concluded that one of the obstacles to management of risks under EU environmental laws was the lack of metrology tools (Franco et al., 2007: 171).

Methods and technologies for detecting, measuring, and characterizing nanoscale materials are still being developed (Denison, 2005). The International Organization for Standardization (ISO) Technical Committee 229—Nanotechnologies has a subcommittee that is focusing on measurement and characterization, but no standards are yet final (see, for example, Miles, 2010; Williams, 2010).

Much environmental monitoring is based on mass, yet particle count or surface area rather than mass may be more appropriate for measuring the health or environmental effects of nanoscale particles (EPA, 2007). Some technologies exist for measuring particle counts, but a variety of limitations may limit their usefulness. One such limitation is that the particles may change during the collection interval (ABA SEER, 2006a). Also complicating reliable detection is the difficulty in distinguishing manufactured nanoscale materials of interest from naturally existing nanoparticles and those created as a by-product of other activities such as coal and diesel fuel combustion or sewage treatment (EPA, 2007). Moreover, monitoring equipment must be capable of being used in the field and thus must be adaptable to different environments as well as affordable, easy to use, and durable. The US EPA claims that none of the existing instruments and methods satisfies these requirements (EPA, 2007).

US example

The ABA raised this issue in its analysis of the applicability of the US Clean Air Act to nanotechnology:

> Current air pollution monitoring methods, ambient air modeling methods, sampling and analytical methods, and control methods, do not perform adequately when applied to nanoparticles because they were created to identify, measure by mass, capture, and control elements or molecules of no particular

> physical shape or structure (other than size greater than 1000 to 1500 nanometers that behave in predictable ways both chemically and physically) (ABA SEER, 2006a: 8).

According to the US EPA (2007) some progress has been made so that some technologies have advanced to the point of being capable of separating and analysing nanoscale particles.

The unique physical structure and chemical properties of some nanoscale materials create challenges in addition to particle size. US EPA (2007) has also noted that chemical surface treatments on some nanoscale materials further complicate their detection and analysis. Nor are current technologies capable of differentiating between naturally occurring, incidentally-produced (that is nanoparticles in diesel exhaust) and manufactured nanoscale particles (EPA, 2007). The latter are of primary interest to policy makers and regulators concerned about environmental effects of nanotechnologies.

EU example

A recent study analysed the applicability of EU regulations to three products that incorporate nanotechnology: a badminton racquet using C_{60}, an oil lubricant containing C_{60}, and a baseball bat using carbon nanotubes (Franco et al., 2007). The authors analysed the Safety at Workplace Directives, Directive on Integrated Pollution Prevention and Control, REACH, and The Waste Management Directives and concluded that it was difficult to determine if the specific products were covered by the various laws for several reasons including the lack of metrology tools (Franco et al., 2007).

Quantity-Based Thresholds

A key barrier to using environmental laws to regulate nanoscale materials is quantity-based thresholds. In many cases, if these thresholds are not met, the law does not apply or imposes reduced requirements. These thresholds often make sense in the context of conventional materials, as *de minimis* amounts of pollutants often do not merit regulation. By providing such exemptions, the laws can be more efficiently administered and resources devoted to addressing the most serious risks. In the context of nano regulation, however, such mass-based exemptions may prevent regulation where it is appropriate.

This impediment to using environmental laws to address nanoscale materials was addressed in the above-referenced review of Australian law, which determined that weight or volumetric thresholds for regulating nanoscale materials are problematic for three reasons (Ludlow et al., 2007). First, given the lack of current scientific knowledge, it may not be known whether these thresholds are appropriate for nanoscale materials and products that incorporate them. Second, as it may be difficult to measure the presence of nanoscale materials, thresholds (such as mass) may not be meaningful or appropriate for preventing potential damage. Third, the current low production level of nanoscale materials means that they will not meet the threshold in regulations that set a ceiling for their application. Ultimately, the review found that a significant gap in Australia's regulations is that 'regulatory triggers currently exist on the basis of a threshold weight or volume' and there are currently 'real difficulties in simply measuring the presence of [nanomaterials] at this time' (Ludlow et al., 2007: 100).

US examples

In a 2007 report, ELI found that

> a fundamental underlying policy premise of RCRA is that the risk associated with hazardous waste is proportional to mass. This premise is significant in applying RCRA to nanomaterials because risks associated with them may be unrelated to mass, and because, at least in the short term, manufacturers of nanomaterials may not generate large quantities of solid waste from their operations (Breggin and Pendergrass, 2007: 22).

In many cases, however, quantity-based exemptions do not apply if the waste or other pollutant is highly toxic. These exceptions could reduce the quantity-based barriers to using environmental laws to regulate nanoscale materials, but only if the data are available to establish toxicity. By way of example, small quantity generators under RCRA (who generate 100 kilograms or less of hazardous waste per month) must comply with the requirement to determine if their waste is hazardous,[23] because the exception does not apply to 'acute hazardous wastes.' Such wastes instead have a limit of one kilogram per month (as opposed to 100) above which the full regulations apply.[24]

The Superfund law takes a similar approach to small volumes of hazardous substances. As ELI explained in its 2007 report:

> To ensure some level of fairness from the risk of litigation for CERCLA liability, the statute encourages the government to reach expedited, final settlements with so-called *de minimis* parties. *De minimis* parties are defined [in part as] . . . waste contributors whose contribution to the hazardous substance release is minimal in volume and toxicity in comparison to the other hazardous substances at that site (Breggin and Pendergrass, 2007: 41).

ELI concluded in the report that because the relative *quantity* of nanoscale materials at any particular site could be minimal, '[a]s more is learned about nanoscale materials, it is possible that the statutory exception should be amended in some manner to take into account nanomaterials.' Again, however, the *de minimis* party protections do not apply if the *toxicity* of the nanoscale materials is not minimal compared to the rest of the hazardous substances at a facility (Breggin and Pendergrass, 2007: 41).

In addition, the release-reporting requirements under CERCLA could apply to releases of reportable quantities of nanoscale materials, provided the nanoscale materials released constitute hazardous substances under the law. The default reportable quantity of one pound, however, may limit the application of the reporting requirements to nanoscale materials in cases in which EPA has not established specific reportable quantities (Breggin and Pendergrass, 2007: 5–8).

Concerns about quantity-based regulation arise even in the context of the CAA standards for fine particulates, which set limits on the amount of particulates less than 2.5 micrometers (that is, 2.5 thousand nanometers) in diameter that can be present in the ambient air. As explained by one expert:

> The CAA standard, like almost all environmental standards, is premised on a direct relationship between volume and concentration on the one hand, and risk on the other. This relationship may not be valid for [nanomaterials]. In any case, volume and concentration may not be useful measures if [nanomaterial] is lumped together with larger-sized matter, because the volume and concentration will be dominated by the larger-sized material (Davies, 2006: 15).

EU examples

Concerns about quantity-based thresholds have been discussed extensively in the context of EU chemicals laws. For example, in a recent report, the authors discussed in detail the challenges presented by REACH, which ties its registration requirements at least in part to the volume of the chemical that is produced. The report explained:

> This [registration] requirement applies to a chemical substance produced by a company only if the total production or import quantity is above 1 tonne per year. While relatively unproblematic for conventional chemicals, this quantitative threshold raises the possibility that producers of newly introduced nanoscale substances are not required to register the chemical in nanoform and provide information that would be relevant to risk assessment. Because REACH's data requirements increase with growing production or import quantity, there is concern that the minimal requirements for low-quantity chemicals may not provide sufficient information to adequately evaluate a nanomaterial's risks (Breggin et al., 2009: 45).

Overlap and Reliance on Other Laws

Media-based environmental laws and regulations often cross-reference or overlap in some manner with other laws, such as those that address chemical substances, food, and cosmetics laws. As a result, media-based environmental laws may take a back seat to other laws as vehicles for regulating nanoscale materials.

First, as discussed in the Introduction to this chapter, nanoscale materials can be addressed under several types of laws and regulations, in addition to media-specific environmental laws. As a result, regulators may opt for a variety of reasons to use these other types of laws before they use media-specific environmental laws. For example, regulators in the US and EU have opted to rely primarily on the laws that regulate chemical substances, presumably in part because those laws are aimed at regulating substances prior to manufacture. In contrast, many environmental laws address emission, discharge, and disposal of substances during and after the manufacturing process. Thus, by initially using the laws that address chemical substances, regulators in some cases can review nanoscale materials prior to manufacture – before they are released into the environment. Similarly, cosmetics and foods that contain nanoscale materials may be regulated under separate laws that in some but not all cases provide for pre-market review of the safety of the product. In such cases, it also may make sense for regulators first to focus on regulating a product that contains nanoscale materials, particularly those with direct exposure pathways, rather than attempt to regulate releases of nanoscale materials during its manufacture.

Second, in some cases, in order for an environmental law to apply, regulators first must make a determination under another law or use the authorities under another law to gather data. As a result, the use of media-based environmental laws to regulate nanoscale materials may be delayed until such determinations are made and data are developed.

US example

Under CERCLA 'hazardous substances' are defined by reference to substances that are designated under other environmental statutes.[25] These include substances that are designated as 'hazardous wastes' under RCRA and 'imminently hazardous chemical substances or mixtures' under TSCA.

EU examples

Directive 2000/60 establishes a framework for Community action that aims to improve the aquatic environment and to reduce the emissions of hazardous substances to water. In addition to targeted risk-based assessment that focuses solely on aquatic eco- and human toxicology, priorities also are based on risk assessments carried out under chemicals regulation and also under other directives, such as the directive on biocidal products (EC, 2008a).

With respect to data collection, REACH promises to generate data on a range of chemicals that in theory could be used to make determinations that media-specific environmental laws apply to certain nanoscale materials. As ELI and LSE discussed in a recent report, however, in some cases REACH may not generate adequate data on nanoscale materials because REACH registration requirements are based in large part on the volume of a substance produced and were designed primarily for conventional chemicals:

> Because REACH will be an important first-step method of gathering relevant data that inform the risk assessment process throughout the life-cycle of nanomaterials, any gaps in its coverage of nanomaterials are likely to become an important issue in future regulatory review (Breggin et al., 2009: 45).

Furthermore, even if REACH registration requirements adequately cover many nanoscale materials, it may be years in some cases before full registrations must be filed because REACH will be phased in over an 11-year period (Breggin et al., 2009).

Australia example

Australian regulations governing the transportation of hazardous waste rely on the *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal* (Ludlow et al., 2007). This has led to the observation that there may be a potential regulatory gap if the Basel Convention does not adequately address health, safety and environmental concerns presented by nanoscale materials (Ludlow et al., 2007).

Nanomaterials as New Versus Existing Substances

Another challenge to applying media-specific environmental laws to nanoscale materials relates to a key question that has been discussed at length in the context of chemicals laws: whether and to what extent should a nanomaterial be treated the same as its conventional counterpart for regulatory purposes? This question has been the topic of much debate in the US under TSCA because the law provides for pre-manufacture review of new chemicals (and significant new uses of existing chemicals) but not of so-called ‘existing’ chemicals. Thus, because EPA has greater authority to review a 'new' nanomaterial prior to manufacture, the definition of what constitutes a 'new chemical' has received considerable attention and currently is under review by EPA.

Similar issues arise in the context of media-specific environmental laws. The need for regulatory determinations as to whether nanoscale materials are new or the same chemicals as their bulk counterparts is yet another impediment to using media-based environmental laws to address risk posed by nanoscale materials.

US example

One of the principal ways by which a nanomaterial could become subject to CERCLA is if EPA, or possibly a court interpreting EPA's regulations, decides that a substance currently subject to the statute includes the substance in its nanoform.

Australia example

The Monash University's review of Australian laws found that for many nanoscale materials 'uncertainty exists as to whether the nanoentity would be considered as "new" or "different" to or the same as its conventional counterpart' (Ludlow et al., 2007: 92). The review (2007: 92) stated that this was 'possibly the most significant potential gap because of its relevance, to varying degrees, to all regulatory frameworks.' The review also explained that the

> ramification of this is that either the regulatory framework as a whole, or parts of the framework, may not properly apply to [nanomaterials] or products incorporating [nanomaterials] or produced using nanotechnology (Ludlow et al., 2007: 92).

Finally, the review concluded that addressing the gap will require not only a decision as to whether nanoforms should be considered as a 'new' substance or product or as an 'existing' substance or product when compared to their conventional counterparts, but would then require revision of most frameworks to ensure this is made clear' (Ludlow et al., 2007).

Next Generation Nanomaterials

A significant challenge will be applying existing laws to technologies that will be developing extremely rapidly. As a general matter it is often difficult for laws to deal with new technologies. Laws tend to be drafted to deal with problems identified from the past rather than anticipating new issues. The first generation of nanotechnologies has proved to be quite challenging for law, but the next generations are expected to be even more so (House of Lords, 2010).

The most significant challenge is that future technological developments are inherently unpredictable beyond a few years. One of the foremost analysts of nanotechnology policy, J. Clarence Davies, has pointed to the fact that the majority of all scientists who have ever lived are alive and working now, continually accelerating the pace of scientific and technological development (Davies, 2009, 2010). Thus while experts may have a vision of the next generation of nanotechnologies, the vast potential for innovation based on that generation makes it difficult to anticipate the characteristics of the following generations of nanotechnologies. There is agreement that current nanotechnologies are quite simple compared to what is expected. Current applications of nanotechnology are characterized as being passive in that a nanoscale material is incorporated in another material to improve its performance. Another way of characterizing current nanotechnologies is that they are essentially grinding existing materials into smaller particles and taking advantage of novel properties that result from the much smaller size. Examples are nanoparticles of silver used as antimicrobials in fabrics and other materials, carbon nanotubes to increase the strength of materials, and nanoparticles of titanium dioxide to make sunscreens clear.

The next generations of nanotechnologies will add complexity in several ways. They will move from simple and passive smaller particles of existing materials to nanostructures built at the atomic or molecular level to interact with the environment. Such nanoscale structures might change in response to exposure to light, magnetic or electrical fields, or the presence of specific types of molecules (Subramanian et al., 2010). Descriptions of generations of nanotechnologies beyond this are much more speculative, but involve complex systems at the nanoscale with multiple functions or combinations with other emerging technologies such as synthetic biology (Davies, 2009, 2010).

Another significant challenge that the next generations of nanotechnologies will pose for law is the incredible variety of applications they are expected to have. Among the fields where nanotechnologies are currently expected to have significant applications are: targeted drug delivery mechanisms; diagnostic devices; smart clothing; smart packaging; computer chips; batteries; adhesives; optical instruments; cloaking devices; energy efficiency; and energy production through biofuels, fuel cells, and even oil production (Davies, 2009). Policy makers are only beginning to consider appropriate means of managing risks that may arise from these future developments in nanotechnologies, but much deeper analysis will be required (Davies, 2009, 2010).

Time and Resources

For the reasons discussed above, the use of media-based laws to address risks posed by nanoscale materials requires a significant investment of time, staff expertise and resources – particularly on the front end. Certainly, efforts to address the scientific uncertainties that in many cases limit the effective use of environmental laws will take considerable time and resources. Many, including the authors of this chapter, have argued elsewhere that this investment should be stepped up as soon as possible (see, for example, Breggin et al., 2009: 88–9).

In addition, however, it takes time, resources and expertise to tackle many of the other impediments. For example, considerable resources are needed to determine whether quantity-based thresholds must be amended, to assess the implications of and prepare for regulating the next generation of nano, and to determine under a particular law whether a nanomaterial is the same chemical as its conventional counterpart.

Furthermore, even when these special impediments do not exist, the regular burdens associated with administering environmental laws exist and are not insignificant. For example, it is necessary under some laws to list or make determinations in order to apply the law to a new substance – regardless of whether the substance is in a nanoform. For example, depending on the law it may be necessary to determine whether a nanoscale material is a hazardous substance or to determine best available control technologies (see, for example, Franco et al., 2007: 177).

16.4 THE PATH FORWARD

In the US, the challenges of using environmental laws to regulate nanoscale materials have led some to call for new laws and approaches (Davies, 2009, 2010). Although new laws ultimately may be necessary, in the near term regulators and stakeholders should be encouraged to focus on removing existing barriers to the use of current laws. This includes continued efforts to address scientific uncertainties such as developing environmental, health and safety data and effective monitoring and detection approaches, without which these laws cannot function properly. Regulators should also thoroughly assess individual domestic laws for use in regulating nanoscale materials. Such assessments should identify impediments, such as quantitative thresholds for application, as well as include strategies for overcoming barriers. In addition, further investment is needed in the training of personnel, including inspectors, lawyers, and others, in how to use media-specific environmental laws to regulate nanoscale materials.

Furthermore, in addition to evaluation of domestic laws and regulations by individual countries, international collaborative entities, such as the Organisation for Economic Co-operation and Development and United Nations Environment Programme, should include on their agendas more in-depth consideration of how media-based environmental laws can be used to regulate nanoscale materials. This will enable regulators to share and benefit from implementation experience or assessments conducted by their counterparts in other countries, in much the same way they are now sharing information on related topics such as environmental, health and safety research.

The magnitude of the challenges associated with effective environmental, health and safety regulation of nanoscale materials are such that it is unwise to ignore any of the resources available. Media-specific environmental laws, which have been largely ignored to date, may represent much-needed governance tools for preventing pollution and for addressing potential risks at the various stages in the lifecycle of nanoscale materials.

NOTES

1. Teresa Chan and Emily Seidman provided essential research assistance and helped draft sections of this chapter.
2. For a discussion on these areas see Chapters 10–15.
3. Environmental law in the US is shaped by the constitution, particularly the *Commerce Clause* and the Tenth Amendment. The *Commerce Clause* authorizes Congress to regulate commerce among the states, while the Tenth Amendment provides that powers not specifically delegated to the federal government in the Constitution and not specifically prohibited by it to the states are reserved to the states or the people. As a result of these provisions and the absence of any provisions authorizing powers related to the environment, the federal government's regulation of the environment is based on the effect of pollution and other environmental issues on interstate commerce.
4. Clean Air Act, 42 U.S.C. §§7401–7671q.
5. Clean Water Act, 33 U.S.C. §§1251–1387.
6. Resource Conservation and Recovery Act, 42 U.S.C. §§6901–6992k (1996).
7. As noted in the introduction to this chapter, some US environmental laws seek to prevent pollution by regulating the production and use of materials that may present risks to human health or the environment if improperly handled or released into the environment. Chief among these are the Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which are covered in Chapter 11 (see Widmer and Meili, 2010). TSCA in particular has been a primary vehicle for regulating nanomaterials in the US.
8. 42 U.S.C. §§7408(a)(1)(A) and 7409(a)(1).
9. 42 U.S.C. §7412(b)–(d).
10. 33 U.S.C. §§1251(a)(1) and 1311(a).
11. 42 U.S.C. §6973(a).
12. 42 U.S.C. §§9601–9675 (1996). For a discussion of how nanoscale materials could be regulated under CERCLA see Breggin and Pendergrass (2007), at 30–51, ABA SEER (2006d), and EPA (2007).
13. The Superfund Amendments and Reauthorization Act (SARA), The Emergency

Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. §§11001–11050. For a discussion of how nanoscale materials could be regulated under EPCRA see Breggin and Porter (2008), EPA (2007) and ABA SEER (2006d).

14. Safe Drinking Water Act (SDWA), 42 U.S.C. §§300f–300j-26. For a brief discussion of the potential for regulation of nanoscale materials under the SDWA see EPA (2007).
15. The Water Directive progressively phases out the provisions of other directives related to water (see, for example, EC, 2008a).
16. See also EC (2008b).
17. The Air Quality Directive replaces several other directives related to air quality. These Directives will be repealed as of June 2010.
18. The phrase 'limit value' is defined under the Air Quality Directive as the 'level fixed on the basis of scientific knowledge, with the aim of avoiding, preventing or reducing harmful effects on human health and/or the environment as a whole, to be attained within a given period and not to be exceeded once attained' (Air Quality Directive, Article 2(5)).
19. The phrase 'target value' is defined under the Air Quality Directive as the 'level fixed with the aim of avoiding, preventing or reducing harmful effects on human health and/or the environment as a whole, to be attained where possible over a given period' (Air Quality Directive, Article 2(9)).
20. The Waste Directive replaces several other directives related to waste. These Directives will be repealed as of December 2010.
21. Victoria Environmental Protection Act 1970, section 4(1).
22. See also ABA SEER (2006b), at 7–8.
23. 40 C.F.R. §§261.5(f) & (g) and 262.11 (2007).
24. 40 C.F.R. §261.5(e)(1) (2007).
25. 42 U.S.C. § 9601(14) (2006). In addition, EPA specifically can designate hazardous substances under the Superfund program that may present substantial danger to public health or welfare or the environment, however, to date, this authority appears not to have been used. 42 U.S.C. § 9601 (14) (1980); 42 U.S.C. § 9602 (1996); 40 C.F.R. § 302.4 (2007).

REFERENCES

American Bar Association (ABA) Section of Environment, Energy, and Resources (2006a), *CAA Nanotechnology Briefing Paper*, Washington, DC: ABA.

American Bar Association Section of Environment, Energy, and Resources (2006b), *Nanotechnology Briefing Paper Clean Water Act*, Washington, DC: ABA.

American Bar Association Section of Environment, Energy, and Resources (2006c), *RCRA Regulation of Wastes from the Production, Use, and Disposal of Nanomaterials*, Washington, DC: ABA.

American Bar Association Section of Environment, Energy, and Resources (2006d), *CERCLA Nanotechnology Issues*, Washington, DC: ABA.

American Bar Association Section of Environment, Energy, and Resources (2006e), *The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides*, Washington, DC: ABA.

Anton, D.K. (2008), *Australian Environmental Law: A Federal Overview*, accessed 23 November 2009 at http://ssrn.com/abstract=1141711.

Bowman, D.M. and G.A. Hodge (2007), 'A small matter of regulation: an international review of nanotechnology regulation', *Columbia Science and Technology Law Review*, **8**, 1–16, accessed at www.stlr.org/html/volume8/bowman.pdf.

Breggin, L.K. and L. Carothers (2006), 'Governing uncertainty: the nanotechnology environmental, health, and safety challenge', *Columbia Journal of Environmental Law*, **31**(2), 285–329.

Breggin, L.K. and J. Pendergrass (2007), *Where Does the Nano Go? End-of-Life Regulation of Nanotechnologies*, Washington, DC: Project on Emerging Nanotechnologies.
Breggin, L.K. and R.D. Porter (2008), *Application of the Toxics Release Inventory to Nanomaterials*, Washington, DC: Project on Emerging Nanotechnologies.
Breggin, L.K., R. Falkner, N. Jasper, J. Pendergrass and R. Porter (2009), *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation*, London: Royal Institute of International Affairs.
Davies, J.C. (2006), *Managing the Effects of Nanotechnology*, Washington, DC: Project on Emerging Nanotechnologies.
Davies, J.C. (2007), *EPA and Nanotechnology: Oversight for the 21st Century*, Washington, DC: Project on Emerging Nanotechnologies.
Davies, J.C. (2009), *Oversight of Next Generation Nanotechnology*, Washington, DC: Project on Emerging Nanotechnologies.
Davies, J.C. (2010), 'From novel materials to next generation nanotechnology: a new approach to regulating the products of nanotechnology', in Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard (eds), *International Handbook on Regulating Nanotechnologies*, Cheltenham UK, and Northampton, MA, USA: Edward Elgar, pp. 545–70.
Denison, R.A. (2005), *Environmental Defense, a Proposal to Increase Federal Funding of Nanotechnology Risk Research to at Least $100 Million Annually*, April, accessed 9 November 2009 at www.environmentaldefense.org/documents/4442_100milquestionl.pdf.
Environmental Law Institute (ELI) (2005), *Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up To the Job?*, Washington, DC: ELI.
Environmental Protection Agency (EPA) (2007), *Nanotechnology White Paper*, Washington, DC: EPA, accessed 2 December 2009 at www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf.
European Commission (2008a), *Regulatory Aspects of Nanomaterials: Summary of Legislation in Relation to Health, Safety and Environment Aspects of Nanomaterials, Regulatory Research Needs and Related Measures*, Brussels: EC, accessed at http://ec.europa.eu/nanotechnology/pdf/.
European Commission (2008b), *Summary of Water Framework Directive*, accessed 18 November 2009 at http://europa.eu/legislation_summaries/agriculture/environment/l28002b_en.htm.
European Commission (2008c), *Regulatory Aspects of Nanomaterials*, COM(2008) 366 final, 3, Brussels, EC, accessed at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:en:PDF.
Franco, A., S.F. Hansena, S.I. Olsen and L. Buttic (2007), 'Limits and prospects of the "incremental approach" and the European legislation on the management of risks related to nanomaterials', *Regulatory Toxicology and Pharmacology*, **48**(2), 171–83.
Gergely, A., Q. Chaudhry and D.M. Bowman (2010), 'Regulatory perspectives on nanotechnologies in foods and food contact materials', in Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard (eds), *International Handbook on Regulating Nanotechnologies,* Cheltenham, UK and Northampton, MA, USA: Edward Elgar, pp. 321–41.
Greenwood, M. (2007), *Thinking Big About Things Small: Creating an Effective Oversight System for Nanotechnology*, Washington, DC: Project on Emerging Nanotechnologies.
House of Lords, Science and Technology Committee (2010), *Nanotechnologies and Food*, accessed 11 January 2010 at www.publications.parliament.uk/pa/ld200910/ldselect/ldsctech/22/2202.htm.
Institute for European Environmental Policy (2009), *Source on EU Environmental Law*, accessed 24 November 2009 at www.eib.org/attachments/strategies/sourcebook-on-eu-environmental-law.pdf.
Ludlow, K., D.M. Bowman and G.A. Hodge (2007), *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework*, Melbourne, VIC: Monash University.
Medley, T. and S. Walsh (2007), *Nano Risk Framework: Environmental Defense – DuPont*

Nano Partnership, accessed 9 December 2009 at www.edf.org/documents/6496_Nano%20 Risk%20Framework.pdf.
Miles, J. (2010), 'Nanotechnology captured', in Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard (eds), *International Handbook on Regulating Nanotechnologies,* Cheltenham, UK and Northampton, MA, USA: Edward Elgar, pp. 83–106.
Ministry of the Environment (undated a), *Environmental Conservation Policy of the Government and the Task of the Ministry of the Environment*, accessed 9 November 2009 at www.env.go.jp/en/aboutus/pamph/html /index.html.
Ministry of the Environment (undated b), *Regional Environment Offices*, accessed 9 November 2009 at www.env.go.jp/en/aboutus/pamph/html/index.html.
Ministry of the Environment (2006), *Outline*, accessed 9 November 2009 at www.env.go.jp/en/aboutus/pamph/html/index.html.
Ministry of the Environment (MOE) (2009), *Guideline for Preventive Environmental Impact from Industrial Nanomaterials*, Tokyo: MOE.
Pelley, J. and M. Saner (2009), *International Approaches to the Regulatory Governance of Nanotechnology*, Ottawa: Carleton University.
Pendergrass, J. and K.N. Probst (2005), *Estimating the Costs of Institutional Controls*, Washington, DC: ELI and Resources for the Future.
Percival, R.V., C.H. Schroeder, A.S. Miller and J.P. Leape (2006), *Environmental Regulation: Law, Science and Policy*, New York: Aspen Publishers.
Royal Society and Royal Academy of Engineering (RS-RAE) (2004), *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*, London: RS-RAE.
Schierow, L.J. (2008), *Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges*, Congressional research service report for Congress, Washington, DC.
Subramanian, V., J. Youtie, A.L. Porter and P. Shapira (2010), 'Is there a shift to "active" nanostructures?', *Journal of Nanoparticle Research*, **12**(1) 1–10.
van Calster, G. and D.M. Bowman (2010), 'A good foundation? Regulatory oversight of nanotechnologies using cosmetics as a case-study', in Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard (eds), *International Handbook on Regulating Nanotechnologies,* Cheltenham, UK and Northampton, MA, USA: Edward Elgar, pp. 268–90.
Widmer, M. and C. Meili (2010), 'Approaching the nanoregulation problem in chemicals legislation in the EU and US', in Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard (eds), *International Handbook on Regulating Nanotechnologies*, Cheltenham, UK and Northampton, MA, USA: Edward Elgar, pp. 238–67.
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, UK and Northampton, MA, USA: Edward Elgar, pp. 107–23.