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

ISBN 978 1 84844 673 1 (cased)

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

12 Approaching the nanoregulation problem in chemicals legislation in the EU and US

Markus Widmer and Christoph Meili

12.1 INTRODUCTION

A lot is at stake. Not only are there high hopes in the economic potential of nanotechnologies, but significant progress is also expected in areas such as medical treatments, energy efficiency and the environmentally friendly production of goods. The opportunities that will result from the use of the novel properties of manufactured nanomaterials are largely undisputed and have led to nanotechnologies being mentioned in the same breath with 'key technology of the 21st century' (see, for example, Smrcka, 2009). As more and more consumer products incorporating manufactured nanomaterials or nanotechnology processes enter the market, the broad and somewhat vague term of 'nanotechnologies' has also attracted continuous attention from a range of commentators including the public, the media and a number of civil society actors.

Exploitation of the novel properties of manufactured nanomaterials creates products with increased functionalities. Not surprisingly, these same properties of nanomaterials have also been identified as potentially being associated with novel risks. Of particular concern are tiny (nano) particles, which have been shown to be able to enter the body through unexpected paths and exhibit interactions with tissues that have previously not been observed. Toxicologists are concerned, not only by potential short-term effects, but even more by the potential of manufactured nanomaterials to harm humans and the environment over the long term. Awareness of nanotechnology risks has thus dramatically risen in recent years among researchers, the industry, lawmakers, regulators, environmental advocates and (to some limited extent) the broader public alike.

Whenever unquantified potential long-term effects are in play, insurance companies are among the first to be attentive. Exposure to dangerous substances today may accumulate into damage (both financial and to health) of unforeseeable dimensions over time. Specifically making reference to manufactured nanomaterials, the worst-case scenario of asbestos has recently been reactivated in the context of carbon nanotubes (Poland et al., 2008). Carbon nanotubes are tiny manufactured nanoparticles in a

tube-like shape, similar to asbestos fibres, with exciting new properties. The asbestos comparison has been invoked in order to point to potential hazards, which, in the case of asbestos, were not recognized until it was too late for thousands of workers exposed to it over many years. To underline this, Robert Landry, president and CEO of Zurich's Canadian operations concluded that, along with climate change, aging infrastructure and 'the unknown', nanotechnology is among the top four emerging risks facing insurers (Canadian Underwriter, 2007).

However, to date, there are no known cases of death that can be conclusively attributed to nanotechnologies or the use of manufactured nanomaterials. MagicNano,[1] the first 'case' where manufactured nanoparticles were first believed to be involved in a series of serious lung injuries, turned out to be caused by inhalation of conventional chemical substances, rather than being attributed to the use of nanomaterials. The manufacturer of the MagicNano product had intended to boost marketing by using the buzzword 'nano' on the product packaging.

These fears have led to a vivid and broad debate about the balance of potential benefits and risks of manufactured nanomaterials in recent years. Through continuous and rather balanced media reporting as well as dedicated information and dialogue events, the public has been involved in the debate, albeit to varying degrees (see, for example, Miller and Scrinis, 2010). From the course of previous technology debates, for example, nuclear power or genetically modified organisms (GMOs) in Europe, it has become evident that the late identification of health, safety and environment risks, as well as the late inclusion of the affected stakeholders, can dampen the sustainable and successful development of a new technology. It is therefore generally perceived that the acceptance of a technology by the broad public is of utmost importance and a precondition for a sustained development of nanotechnologies.

In the course of the ongoing debate, various stakeholder groups have issued differing calls for adequate risk governance and regulation. Questions arose as to which regulatory or policy instruments are most effective and appropriate for managing the potential risks associated with nanotechnologies. Despite the rapid commercialization of nanomaterials in consumer products, current laws and regulations in most cases do not explicitly refer to nanomaterials. However, it has to be clarified that the absence of explicit nano-regulation does not signify that nanomaterials exist in the legal black hole. Manufactured nanomaterials are implicitly covered by existing laws and regulations that apply to chemical substances, for example, the *Registration, Evaluation, Authorisation and Restriction of Chemical Substances* (EC 1907/2006) (REACH) in the European Union and the *Toxic Substances Control Act* (1976) (TSCA) in the US. However,

as will be discussed, the environment and the mood concerning nano-specific adaptations of existing laws and regulations has recently changed significantly.

The claims concerning regulation of manufactured nanomaterials differ depending on the respective stakeholder. They range from a moderate claim to review whether the existing legal frameworks are appropriate to effectively handle manufactured nanomaterials (this approach has been the predominant perspective of governments and governmental authorities so far), to a radical call for a moratorium on nanotechnology research and product marketing until the risk situation has been clarified (the position of some non-governmental organizations).

The obvious contrariety in assessing the current legal situation and deriving the necessary measures leads us to have a closer look at how under current legal frameworks in the area of health, safety and the environment manufactured nanomaterials are handled, and what uncertainties and problems regarding the role of manufactured nanomaterials in current regulatory frameworks have been identified.

12.2 HOW EXISTING REGULATORY FRAMEWORKS DEAL WITH NANOMATERIALS

Nanotechnologies comprise a set of enabling technologies, which, due to their distinct cross-sectional character, are expected to bring benefits in almost every area. However, some manufactured nanomaterials have been found to potentially expose humans and the environment to risks that are difficult to assess at this time because new, or unexpected, mechanisms are anticipated to be involved, and because the necessary methodology to quantify these risks is largely missing.

Regulations and legal provisions are fundamental and can serve several purposes. From the point of view of authorities and consumers, they can help to assure safety and protection of human health and the environment; for companies, while representing a restriction (compliance), regulations can serve as guidelines that facilitate strategic decisions (legal certainty). As long as it is uncertain what legislative requirements must be met in the near future, and what specific restrictions might be imposed, entrepreneurs are hardly interested in investing in the development of nanotechnologies. The industry reportedly relies on a predictable and relatively constant legal framework, which ensures long-term investments are optimally protected.

The regulatory sector, as a consequence of the novel properties of manufactured nanomaterials, has been identified as an area that should

be considered for the control and use of the technology. A regulator's role involves being able to set threshold values (define tolerable risks) and determine clear rules for exemptions. However, to be able to fulfil these far-reaching expectations, regulators need a profound level of knowledge to establish reasonable and sound regulations; it is commonly agreed that this prerequisite is not met today regarding the availability of scientific data about the potential risks of manufactured nanomaterials. Under these circumstances, national and international regulatory agencies have come to the conclusion that early regulation of manufactured nanomaterials is not a feasible option. On the other hand, according to stakeholder surveys, a moratorium on nanotechnologies is also deemed unreasonable.

In order to clarify regulatory questions at an early stage of technology development, a series of scientific advisory committees have been commissioned to examine the appropriateness of current legal frameworks to handle nanomaterials. Several industry and chemistry associations, as well as government agencies, have issued statements regarding existing legal frameworks, and, in the majority of cases, have came to the conclusion that, in principle, existing legal regulations and frameworks are capable of successfully handling manufactured nanomaterials and the potential effects resulting from their specific properties. It has been suggested that specific adaptations might be necessary only in individual cases and at the area of subordinated legislation. In June 2008, the European Commission (2008a: 3) in a Communication to the European Parliament stated that:

> Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation.

In Switzerland, the Federal Council in 2006 launched a comprehensive programme to assess the current knowledge about the risks of manufactured nanomaterials, to identify gaps, to review the existing legislation regarding its adequacy to effectively handle manufactured nanomaterials, and to derive appropriate measures. As a result of this analysis, the Federal Council agreed that:

> There is . . . no need at present for 'nanospecific' legislation. At the level of implementation ordinances, however, both provisions relating to products and those with safety as a goal need to be re-examined (Eidgenössisches Departement des Innern EDI, 2008).

Furthermore, since current legislation implicitly includes manufactured nanomaterials, the Federal Council concluded that:

> Only when the methodological foundations and well-grounded risk assessments of synthetic [manufactured] nanomaterials are available, can additional statutory framework conditions for the safe handling of synthetic nanomaterials be developed (Eidgenössisches Departement des Innern EDI, 2008: 2).

Similarly, in the US, the Federal Government in a memorandum for the heads of executive departments and agencies on the principles for nanotechnology environmental, health and safety oversight has decided that:

> The Federal government's current understanding is that existing statutory authorities are adequate to address oversight of nanotechnology and its applications (Office of Science and Technology Policy and the Council on Environmental Quality, 2007).

These conclusions, however, differed noticeably from how some political parties, consumer and trade organizations and many other non-governmental organizations have assessed the current situation. Representing the other, more sceptical view, members of the Green Party of Switzerland in 2006 and 2008 launched parliamentary initiatives in order to regulate manufactured nanomaterials specifically and explicitly.

On the European (REACH) level, in April 2009 the Parliament overwhelmingly adopted a report to the Commission in which the Members of the Parliament requested quick and thorough action to adapt REACH in terms of its adequacy to handle manufactured nanomaterials (European Parliament Committee on the Environment, Public Health and Food Safety, 2009). Also in the US, although not specifically mentioning manufactured nanomaterials, a Research Service report for Congress indicated that:

> The available evidence indicates that EPA has had limited success using TSCA to gather information about new chemicals (Schierow, 2008),

and the Government Accountability Office (GAO) in 2009 reported that:

> EPA's assessments of industrial chemicals under TSCA provide limited information on health and environmental risks . . . GAO has recommended both statutory and regulatory changes to, among other things, strengthen EPA's authority to obtain additional information from the chemical industry, shift more of the burden to chemical companies for demonstrating the safety of their chemicals (GAO, 2009a).

Although it remains open as to how responsive the corresponding governments will be to the above claims, these events have marked a significant disturbance in the prevalent 'official opinion' regarding the regulation of manufactured nanomaterials. It can be concluded that several central

issues have been identified and that it is not clear yet how well the existing regulatory frameworks will be suited to handle manufactured nanomaterials.

The following sections will present and discuss two characteristic approaches to handle the 'case of nanomaterials' at the level of chemical substances, exemplified by the REACH in the EU, and the TSCA in the US. Although these two regulations do not conclusively describe the regulatory environment that applies for manufactured nanomaterials and their manifold applications[2], they represent the basic framework for the regulation and control of chemical substances. These two pieces of legislation will first be presented using a general approach, reviewing the procedures and tools that are provided within each regulation, and in a more nanomaterial-oriented way in order to discuss how well these two approaches are able to cover the particularities resulting from a growing commercialization of manufactured nanomaterials.

The European Approach – REACH

REACH, the new European chemicals legislation that entered into force on 1 June 2007 and replaced a patchwork of over 40 legislative instruments, will be phased-in over 11 years. REACH provides the most important framework for activities at national level by the EU Member States; in general, national regulatory agencies are bound to align with EU regulatory legislation, with the possibility of implementing specific, more detailed or tighter regulation at national level.

REACH allows the European Chemicals Agency (ECHA) to regulate the manufacture, sale and use of chemical substances, whether those substances are on their own, in preparations or in articles. REACH is intended to ensure a high level of protection to human health and the environment, as well as the free circulation of substances on the internal market (Article 1(1)).

The provisions of REACH explicitly declare that the precautionary principle should be applied when administering the Regulation (Article 1(3)). The precautionary principle advocates taking precautionary action when chemicals pose possible threats to human health and the environment, rather than waiting for complete scientific evidence to be developed. This principle is of particular relevance in the context of manufactured nanomaterials since the methodology, tools and scientific database to assess the possible risks of nanomaterials are still missing or largely incomplete. The precautionary principle also underlies the safety assessment process, in that if there is uncertainty over scientific evidence (for example, conflicting or little data), the safety assessment should normally be based

on the evidence that gives rise to highest concern (worst-case scenario) (European Commission, 2004).

In close relation to the precautionary principle, REACH allocates the responsibility to prove that no unreasonable risks will result from the use of a chemical to those who advocate for its use. Therefore, under REACH, the so-called burden of proof is shifted from the authorities to manufacturers and importers as 'it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment' (Article 1(3)). The burden of having to demonstrate a risk before taking precautionary and preventive action has been one of the main reasons why the regulation of chemicals has been slow and resource intensive in the past (Hansen et al., 2007). Although Member States and the Commission can suggest immediate restrictions in case there are *indications* of severe risks associated with the use of a given chemical, it remains open how much power the precautionary principle and the aforementioned shift of the burden of proof will have in practice in restricting chemical substances on the basis of *concern* rather than scientific evidence. The dossier for the restriction of the manufacture, sale or use of a substance under REACH requires an 'assessment of hazards and risks' and evidence 'that implemented risk management measures are not sufficient'; requirements that are difficult to fulfil on the basis of concern (Annex XV).

As the central element of interaction between manufacturers and the authorities under REACH, manufacturers and importers have to submit a registration dossier for substances that they manufacture or import at or above one tonne per year. As increasing amounts of a chemical substance are produced or imported, more comprehensive safety data is required upon submission for registration. Above 10 tonnes per year, registrants have to produce a chemical safety assessment and submit a chemical safety report to the ECHA, and above 100 tonnes per year detailed toxicity testing is required. REACH Articles 10 and 14 contain detailed requirements as regards the composition of the technical dossier and the chemical safety reports.

The shift of the burden of proof to manufacturers and importers also includes the obligation that registrants have to autonomously register and update new information in relation to changes in quantities manufactured or imported, new uses or new knowledge of risks to human health or the environment of which they may reasonably be expected to have become aware.

REACH covers all chemical substances, independent of their size, shape or physical state. Although it is widely acknowledged that the properties of manufactured nanomaterials can differ significantly from those of the

same substance on the micro or macro scale, REACH currently does not contain requirements that are explicitly targeted at substances at the nanoscale.

Before REACH entered into force, the terminology of 'new' and 'existing' chemical substances had been used to distinguish substances that have or have not yet been listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). In the context of REACH, EINECS-listed 'existing' substances are classified as 'phase-in substances', while any substance that would have been subject to notification as a 'new' substance before REACH is regarded as a 'non-phase-in substance'. While chemical substances that are already listed in EINECS can benefit from extended registration deadlines, the principle of 'no data, no market' applies for non-phase-in substances, meaning that market introduction can only occur after registration is complete (Article 5).

The distinction between phase-in and non-phase-in under REACH is made on the basis of the structural formula of a substance. Properties, such as particle diameter or surface area that distinguish nanomaterials from their bulk form are not considered. Since many of the commercially used nanomaterials are the nanoform of an existing bulk material with identical structural formula (for example, many metal oxide nanoparticles such as titanium dioxide), their nanoform will run as a 'phase-in substance' under REACH and can benefit from the extended registration deadlines. Nevertheless, upon registration, all the available intrinsic information on the nanoform has to be included and updated in the registration dossier; this also includes specifying deviating classifications, labelling, chemical safety assessments, identified uses and exposure scenarios of the nanoform as compared with the bulk form of a substance.

Although it may therefore be safe to state that REACH implicitly covers manufactured nanomaterials and requires registrants to include the relevant data for a material on the nanoscale in the registration and updating process, more explicit mentioning of manufactured nanomaterials has already been proposed in the context of future adaptations of REACH. Although the prevalent opinion of the European Commission (2008a: 3) has been that the 'current legislation covers to a large extent risks in relation to nanomaterials and risks can be dealt with under the current legislative framework', the European Commission did not exclude possible modifications in the light of new information 'for example as regards thresholds used in some legislation'.

The first concrete step to amend REACH with 'nanospecific modifications' was made in October 2008 when the European Commission published a regulation (*Commission Regulation (EC) No 987/2008*) amending Annex IV of REACH to remove carbon and graphite from the list of

substances of minimum risk. Annex IV lists chemical substances of 'minimum risk due to their intrinsic properties,' which are, therefore, exempt from safety testing. The amendment was triggered by the fact that certain carbon nanomaterials were marketed under the same chemical identity as conventional carbon and graphite and have consequently avoided safety testing and due to concerns that the nanotechnology form of carbon, particularly carbon nanotubes, may pose risks to human health and the environment.

In June 2008, the European Commission (2008a) issued a Communication to the European Parliament on regulatory aspects of nanomaterials. Of particular interest therein has been the question whether the nanoform of a chemical substance should be generally regarded as a 'new' (non-phase-in) substance, regardless of its chemical identity (which may be identical to that of the bulk form of the same substance). However, the Commission Services and Member State Competent Authorities decided that 'more information is needed on the type of parameters that may be relevant (for example, particle size, geometry) for characterization of nanomaterials' and that 'the fact that a substance has different properties can in itself not be used to decide if it is a new substance' (European Commission, 2008b). As a consequence, many manufactured nanomaterials will benefit from the extended registration deadlines for 'existing' (phase-in) substances, and registration for manufactured nanomaterials of 'no particular concern'[3] that are produced or imported in volumes of less than 1 tonne per year may therefore be postponed until as late as 1 June 2018.

As another sign indicating potential change on the European level, in April 2009 the Parliament overwhelmingly adopted a report to the Commission in which the Commission's conclusion about the principal adequacy of current legislations regarding the handling of the risks of manufactured nanomaterials was challenged (European Commission, 2008a: 3) and the Commission was called

> to review all relevant legislation within two years to implement the principle 'no data, no market' for all applications of nanomaterials in products with potential health, environmental and safety impacts (European Parliament Committee on the Environment, Public Health and Food Safety, 2009: 10).

The Parliament also considered it 'particularly important to address nanomaterials explicitly within the scope of at least legislation on chemicals . . .' (European Parliament Committee on the Environment, Public Health and Food Safety, 2009: 10). Furthermore, the Committee proposed to implement a mandatory notification for all nanomaterials placed on the market (labelling) and requested a chemical safety report with exposure assessment to be submitted for all registered nanomaterials (which, according

to REACH, is only necessary if production or import exceeds 10 tonnes per year) (European Parliament Committee on the Environment, Public Health and Food Safety, 2009: 10).

Whether these recent developments can be regarded as a change of paradigm in the regulation of manufactured nanomaterials remains to be proved; in the meantime, REACH has to prove itself an efficient and viable regulatory framework (and not just for nanomaterials). While it seems clear that with the increasing importance of nanomaterials, they will be under close observation under REACH, a US GAO (2007) report was quite positive about REACH, concluding that:

> Assuming that the EU has the ability to review chemical information in a timely manner, specific provisions under REACH provide a means for addressing long-standing difficulties experienced both under TSCA and previous European chemicals legislation in (1) obtaining information on chemicals' potentially harmful characteristics and their potential exposure to people and the environment and (2) making the chemical industry more accountable for ensuring the safety of their products.

This leads on to an overview on the US TSCA, and how manufactured nanomaterials are handled under this legislation.

The US Approach – TSCA

The *Toxic Substances Control Act* (TSCA) entered into force on 1 January 1977. TSCA covers all chemicals produced, manufactured, imported, or exported, within the United States.[4] As TSCA applies to 'chemical substances', it is commonly agreed that manufactured nanomaterials also fall under TSCA regulations.

Under TSCA, the US Environmental Protection Agency (EPA) is given broad authority to control and restrict substances that are identified as posing a threat to human health or the environment, and require manufacturers to submit record-keeping, safety testing and data on health, safety and environmental impacts of any substance that has been determined to cause an 'unreasonable risk'[5] to public health or the environment. Core regulatory provisions include TSCA section 4 (testing of chemical substances and mixtures), TSCA section 5 (manufacturing and processing notices), TSCA section 6 (regulation of hazardous chemical substances and mixtures), and TSCA section 8 (reporting and retention of information).

Among others, TSCA provides the EPA with authority to:

- require a premanufacture notification (PMN) for new chemicals;
- issue Significant New Use Rules (SNURs), when it identifies a

'significant new use' that could result in exposures to, or releases of, a substance of concern;
- require testing of chemicals by manufacturers, importers, and processors where risks or exposures of concern are found[6];
- require manufacturers to keep records of and submit to EPA health and safety data concerning the chemical substances they manufacture[7]; and
- require manufacturers or importers to inform EPA if a substance is reasonably expected to present a risk of injury to health or the environment.[8]

Furthermore, the EPA is authorized under TSCA to maintain a Chemical Substance Inventory (TSCA Inventory), which contains all 'existing' chemicals produced, processed or imported for commercial purposes in the US (not only those substances with toxic or hazardous characteristics) (TSCA s.8(b)).

Similarly to the former EINECS registry in the EU, TSCA uses the terms of 'existing' and 'new' substances to distinguish substances that are or are not on the TSCA Inventory. Currently, the TSCA Inventory contains approximately 83 000 chemicals, identified by their chemical name and Chemical Abstracts Service (CAS) registry number (OPPT, 2009).[9]

If a substance is a 'new' chemical substance for the purposes of TSCA, it is subject to PMN reporting requirements (unless the substance meets a TSCA reporting exclusion, discussed below under Exemptions – Volume Based Thresholds). The PMN offers the EPA a limited timeframe to object before a new substance (or a significant new use of an existing substance) is released to the market and the environment. Manufacturers have to submit to the EPA, at least 90 days prior to the manufacture or importation of the new chemical substance, a formal report with information on chemical identity, production volume, by-products, information on the identified use, expected human exposure and environmental release of the substance in question. As PMN reporting does not require the development of new safety data, manufacturers have to submit what is in their possession at the time of submission and what is reasonably ascertainable – a fact that is important in the light of the prevalent uncertainties regarding the potential risks of manufactured nanomaterials.

Upon receiving and reviewing a PMN for a 'new' chemical substance, the agency can make use of several options:

- Do nothing: if after 90 days the EPA does not consider it necessary to place any restrictions on the chemical, and after providing a Notice of Commencement (NOC) to the EPA, the registrant may

begin production or importation of the new substance. As NOC is received by the EPA, the 'new' chemical is included in the TSCA Inventory and its status is changed to 'existing'.

However, in the case of the EPA, on the basis of the review of a PMN of a new substance, coming to the conclusion that further action is necessary, the EPA may apply a series of procedures to control and restrict manufacture and use, trigger safety testing or enforce submission of further data on health, environmental and safety impacts of a substance of concern.

- If the Agency determines that the information available to the authority for evaluation is insufficient and an unreasonable risk of injury to health or the environment cannot be excluded, the EPA may issue a TSCA section 5(e) consent order to restrict manufacture to specified conditions, limit certain uses and imply requirements. For example, the consent order may require personal protective equipment, monitoring, toxicity testing and/or recordkeeping. Consent orders, however, are only binding on the original PMN submitter.
- To bind all manufacturers, the EPA may promulgate a TSCA section 5(a) SNUR, often issued as direct final rules. Manufacturers intending to engage in a designated new use need to submit to the EPA a Significant New Use Notification (SNUN) 90 days prior to manufacturing. Often, SNUR are promulgated to bind all manufacturers to the new use designations prohibited by a section 5(e) Consent Order.

According to the EPA, approximately 10 per cent of PMNs and SNUNs submitted for EPA review are either restricted or regulated (OPPT, 2007).

In the case of the EPA deciding to act on an '"existing" chemical substance', the EPA may:

- Promulgate a TSCA section 5 SNUR, which designates a 'significant new use' of an existing chemical substance to notify the EPA at least 90 days before commencing that activity. The required notification will provide the EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs. This procedure, however, requires full notice and comment rulemaking and is used less often by the EPA.
- Issue a formal TSCA section 4 test rule, which requires companies to conduct testing on selected chemicals for which data is needed to

evaluate potential health or environmental hazards. This procedure commonly takes a long time (years) since it also underlies full public notice and comment procedures.

- Negotiate a consensus-based enforceable consent agreement, which requires certain signing parties to generate data and submit that data to the EPA. This procedure is quicker than formal rulemaking, but is still enforceable and based on a specified schedule.
- Rely on regular information updates under the Inventory Update Rule (IUR). The IUR is the standard data updating procedure for all existing substances listed in the TSCA Inventory.[10] In terms of the data submission requirements under the IUR, however, only basic information on manufacturing (company and site name, total production volume of the substance) and some information intended to estimate potential exposure needs to be submitted.

In order to control manufacture, processing, distribution, use or disposal of chemical substances, the procedures for rulemaking are all predicated on specific statutory findings made by the EPA. If the EPA wants to regulate a chemical substance, it has to demonstrate that there is a reasonable basis to conclude that the chemical 'presents, or will present an unreasonable risk of injury to health or environment' (s.6). This standard requires the EPA to have conclusive data on that particular chemical, and the EPA must consider risks, costs and benefits associated with the substance being regulated, including the availability of substitutes. TSCA requires the Administrator to impose the 'least burdensome' regulatory measure that provides adequate protections (s.6). In the case of the EPA wanting a company to conduct toxicity testing under a TSCA section 4 test rule, the EPA must make a statutory TSCA section 4 'A' (hazard) finding or a TSCA section 4 'B' (exposure) finding (see below under The Precautionary Principle and Burden of Proof).

The fact that manufactured nanomaterials already are an issue in the context of TSCA and the PMN review process is documented by various PMN submissions for nanomaterials. According to the EPA, it has 'received and reviewed numerous new chemical notices under TSCA for nanoscale materials' (EPA, 2009b). Receipt of PMN for carbon nanotubes (CNTs) and fullerenes (C_{60}), two novel manufactured nanomaterials, has been documented in a series of Federal Register Notices since mid 2008:

- In a 7 May 2008 Federal Register Notice, the use of single-walled CNTs has been announced in a PMN to the EPA as a property modifier in electronics and polymer composites (EPA, 2008a).
- In Federal Register Notices of 12 December 2008 and 13 April 2009,

the EPA announced that it has received PMN for fullerenes (C_{60}) in electronic applications (EPA, 2008b, 2009c).
- In several Federal Register Notices, the EPA announced receipt of PMN concerning multi-walled CNTs for use in composite materials and as electric conductive fillers (EPA, 2008c, 2009d; 2009e).

However, the three nanomaterials mentioned in the examples above without doubt only represent the tip of the iceberg of a much larger number of 'new' manufactured nanomaterials and 'existing' substances that are now used at the nanoscale. It will therefore be interesting to take a closer look at the EPA's stance on the handling of manufactured nanomaterials under TSCA.

Until recently, it was not clear what the EPA's approach on manufactured nanomaterials under TSCA would be. In a memorandum of November 2007 for the heads of executive departments and agencies, the Office of Science and Technology Policy and the Council on Environmental Quality published a strategic document summarizing principles for nanotechnology environmental, health, and safety oversight (Office of Science and Technology Policy and the Council on Environmental Quality, 2007). The Federal Government (Office of Science and Technology Policy and the Council on Environmental Quality, 2007: 2) concluded, among other things, that:

- 'Existing statutory authorities are adequate to address oversight of nanotechnology and its applications. As with any developing area, as new information becomes available the Federal government will adapt or develop additional oversight approaches, as necessary, to address the area of nanotechnology';
- 'Adequate information should be developed with respect to the effects of nanomaterials on human health and the environment'; and
- 'The Federal government should use standard oversight approaches to assess risks and benefits, and manage risks, considering safety, health and environmental impacts, and exposure mitigation. As experience is gained, these approaches can be refined.'

However, in terms of any specific regulatory path forward, the paper remained vague. The first concrete action with regulatory relevance in practice in relation to nanomaterials did not occur before September 2008, when the EPA signed the first manufacturing consent order with a manufacturer of CNTs upon submission of a PMN for the respective CNT nanomaterials to the EPA (EPA, Office of Pollution Prevention and

Toxics, 2008). According to the CNT manufacturer, the consent order was 'the result of several months of collaboration' (Thomas Swan & Co Ltd, 2008). Such 'contracts' need to be developed on a case-by-case basis and obviously represent a considerable burden to the EPA. Since the consent order is valid between the EPA and the corresponding manufacturer only, the restrictions therein do not apply to other manufacturers of the same CNT material; to generalize the requirements for all manufacturers of the same specific material, the EPA would need to negotiate separate consent orders for each manufacturer, or, alternatively, publish a SNUR on this particular (new) use of CNTs.

Some time later, the EPA confirmed the increasing concretization of its current approach on nanomaterials by announcing that some manufactured nanomaterials, under certain circumstances, must be considered 'new' substances under TSCA. In a Federal Register Notice on 31 October 2008, EPA clarified the TSCA inventory status of CNTs by stating that CNTs are 'chemical substances distinct from graphite or other allotropes of carbon listed on the TSCA inventory' (EPA, 2008c). This indicated to manufacturers and importers that CNTs are essentially considered 'new' chemicals under TSCA, and therefore are subject to PMN requirements.[11] Furthermore, the EPA under section 5 of TSCA promulgated SNURs for siloxane-modified silica and alumina nanoparticles (EPA, 2008d). As a consequence, any manufacturer of these two nanomaterials considering the manufacture or use of these nanomaterials must comply with the requirements of the SNUR (that is, it must notify the EPA 90 days prior to manufacture), or, if intending to engage uses outside the terms specified in the SNUR, report to the EPA under the TSCA PMN reporting requirements.

While these regulatory actions suggest that the EPA classifies nanomaterials as 'new' substances or at least considers them as 'new uses' of existing substances, it is of utmost interest to determine what procedures apply if a substance is already listed on the TSCA inventory (based on submission of information on the bulk form) and a manufacturer now intends to introduce the nanoform of the same substance. 'Existing' substances, even if now used at the nanoscale, will not be subject to PMN requirements. Therefore, they will not be reviewed before entering commerce, and the EPA will lack the opportunity to intervene before commercialization of the respective nanomaterial.

We remember that the EPA determines whether substances are 'new' or 'existing' for TSCA purposes based on a substances' molecular identity[12]; this approach has explicitly been confirmed to apply also in the case of manufactured nanomaterials (EPA, 2008e). The EPA, in fact, 'does not expect . . . that all nanoscale substances will qualify as new chemicals under TSCA' (EPA, 2008e: 2). The EPA further clarifies that 'when

manufacture or importation commences and the substance is added to the TSCA inventory, the listing is considered to encompass both nanoscale and non-nanoscale forms of the substance' (EPA, 2008e: 5), regardless of the fact that nanoparticles are commonly known to exhibit markedly changed properties and reactivity as compared to larger particles (the very properties that make them interesting for new applications).

Specifically, as related to manufactured nanomaterials, this implies that:

- Many of the most frequently used manufactured nanomaterials that result from a larger bulk material, for example, by mechanical grinding such as many metal (oxide) nanoparticles, are considered 'existing' substances since the corresponding bulk substance is listed in the TSCA inventory. The EPA considers those particles to be 'aggregates of molecules that have the same molecular identity' (EPA, 2008e: 4).
- Due to the 'allotrope rule',[13] CNTs and C_{60} are considered to have a different chemical identity than graphite or diamond (which are already on the TSCA inventory) and are thus to be considered 'new' substances for the purposes of TSCA. This stance has been confirmed by the Federal Register notice on the TSCA inventory status of CNTs and C_{60} (EPA, 2008c).

It seems obvious that despite the broad authority the EPA is given under TSCA, the EPA has had difficulty demonstrating that harmful chemicals meet the statutory requirement of presenting an unreasonable risk, and the tools and procedures currently in place only allow exploiting the given authority on a strict case-by-case basis. In fact, since Congress passed TSCA over 30 years ago, the EPA has issued regulations under the act to ban, limit or restrict the production or use of only five existing chemicals or chemical classes. In 1991, the EPA's 1989 regulation phasing out most uses of asbestos was vacated by a federal appeals court because it was reported to fail to meet the statutory requirement of being based on 'substantial evidence' (GAO, 2009b).

Additionally, the existing legislative hurdles make it difficult for the EPA to force the manufacturer or importer to test the chemicals and to develop safety data. In contrast to the information development and updating requirements under REACH, which include a statutory duty for companies to develop and submit new or changed data related to the potential environmental, health and safety risks of any substance they manufacture, there is currently no such requirement under TSCA (GAO, 2007).

The TSCA inventory itself is not designated to function as a hazard

database; for this purpose, the EPA's National Center for Environmental Assessment maintains the Integrated Risk Information System (IRIS), an electronic database that contains certain information on environmental and human health effects. However, the US GAO, which supports Congress in evaluating the performance of the Federal Government, recently identified TSCA and IRIS as 'new high-risk areas' with considerable flaws and inefficiencies in assessing and publicly documenting the toxicity of chemicals, and has suggested reforming or modernization of TSCA (GAO, 2009a).

In the emerging regulatory discussion on manufactured nanomaterials, many stakeholders, including the American Chemistry Council (ACC), either postulate or no longer reject a reforming process of TSCA (Dooley, 2009). A series of involved stakeholders have already contributed suggestions as to how such TSCA reform should look (see for example Applegate, 2008; Denison, 2009a). In January 2009, the Government Accountability Office in its 'high risk' priority document concluded that reforming TSCA should be a top priority in 2009 (GAO, 2009a). Beginning in February 2009, TSCA is being revisited in a series of hearings by the Subcommittee on Committee, Trade, and Consumer Protection of the US House of Representatives Committee on Energy and Commerce (House of Representatives, 2009), and nanotechnologies have been mentioned as an issue where many of TSCA's longstanding flaws are revealed (Davies, 2009, 2010).

12.3 COMPARING THE TWO APPROACHES – THE NANOREGULATION PROBLEM

The following section is dedicated to compare the two different regulatory approaches of REACH and TSCA in order to discuss some of the characteristics, issues and flaws that have been identified to be relevant in the process of governing manufactured nanomaterials, and possibly defining adaptations of the current regulatory frameworks in order that they are able to better handle the peculiarities of manufactured nanomaterials.

It may be regarded as unfair to compare REACH with TSCA, the latter being a regulation that has been in force since 1976 and since then has not been fundamentally amended. In addition, due to the only recent implementation of REACH in June 2007, and due to the only recent enactment of the stepwise (pre-) registration procedures, experiences are still very rare to judge the adequacy of REACH in identifying and handling toxic chemicals, not to speak of manufactured nanomaterials. Nevertheless, this comparison is based on the information already available and is intended to

identify both positive characteristics and flaws that might foster or hinder appropriate consideration of manufactured nanomaterials in (future) chemicals legislation.

Four issues of paramount importance are now focused on: the precautionary principle, the burden of proof, the differences in handling new and existing chemicals, and volume-based thresholds and exemptions.

A) The 'Precautionary Principle' and the Burden of Proof

Regulations are never imposed with a complete understanding of the risks, which is particularly true for new or emerging technologies. For the time being, sufficient scientific evidence to build sensible and enforceable evidence-based regulations on manufactured nanomaterials, to control their manufacture, processing, use and disposal, is not yet available. For example, a commonly accepted definition of the term 'nano', as well as valid methodologies to measure and characterize nanomaterials, are still missing for the greater part. In addition, as long as the lack of quantitative knowledge about exposure and the efficacy of existing protective measures persists, regulations to protect human health and the environment from manufactured nanomaterials are bound to a rather fundamental level of specifying principles of behaviour and allocating general responsibilities. These principles define the general approach to regulation where specific evidence is absent.

The precautionary principle and the burden of proof are two principles defining responsibilities, with a special relevance in the case of nanotechnologies where considerable uncertainties in quantifying potential risks exist. The precautionary principle advocates taking precautionary action, even when a chemical only poses a *possible* threat to human health or the environment, rather than waiting for complete scientific proof of cause and effect to evolve. This may prevent damage in the phase while new information is developed.

In a close relation to the precautionary principle, the burden of proof allocates the responsibility of proving by evidence a disputed charge or allegation. In the context of product safety and environmental laws, the term is often used to express a 'shift' in the burden of proof indicating a reallocation of the responsibility to demonstrate the safety of a substance or activity from the authorities to the proponent of this activity or substance (usually the manufacturer). This is intended to create a strong incentive for manufacturers to come forward with the required substance information to obtain permission to put it on the market. Historically, however, the public has typically carried the burden of proving that a particular substance or activity presents a risk, while those undertaking

potentially dangerous activities and the products of those activities were considered innocent until proven guilty (Tickner et al., undated).

The European Union's REACH legislation is explicitly based on (or, more precisely, 'underpinned by') the precautionary principle. As the precautionary principle is mentioned only once in the whole of REACH, 'underpinned' means that the precautionary principle has been taken into account when phrasing its provisions, and that the precautionary principle will provide a framework for the development of specific regulatory policies. A definition of how the European Commission understands the precautionary principle, particularly with reference to emerging technologies and nanotechnologies, can be found elsewhere – in February 2000, the EC adopted a *Communication from the Commission on the Precautionary Principle*, a document which aimed to outline the Commission's approach to using the precautionary principle, establishing guidelines for applying it and building a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully, while avoiding unwarranted recourse to the precautionary principle (European Commission, 2000).

The precautionary approach to nanotechnology in the EU has been substantiated in the Commission's communication on regulatory aspects of nanomaterials in June 2008 (European Commission, 2008a: 8):

> Where the full extent of a risk is unknown, but concerns are so high that risk management measures are considered necessary, as is currently the case for nanomaterials, measures must be based on the precautionary principle.

Although the US government ratified the Rio Declaration in 1992, which stated that a 'precautionary approach' should be widely applied by States according to their capabilities, the precautionary principle is not expressly mentioned in any legislative documents or policies in the United States. Likewise, TSCA in its current version does not mention any 'precautionary principle' or a 'precautionary approach', and the regulation requires the authority to make certain statutory findings by demonstrating that a given chemical 'presents or will present an unreasonable risk' in order to take action (TSCA section 6(a)). This is an evidentiary burden on the EPA, which in principle stands in contrast with a precautionary approach.

More recently, the implementation of some sort of 'precautionary approach' was discussed in the context of the TSCA reforming process in February 2009 (House of Representatives, 2009). However, it seems likely that the 'precautionary principle' will be interpreted in a weaker form than under REACH.

Contrary to the differences regarding a precautionary approach, both REACH and TSCA, in principle, place the burden to provide the necessary data to prove that a chemical does not present a risk on those who manufacture this chemical:

- TSCA section 2(b)(1) provides that '[i]t is the policy of the United States that adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures.'
- REACH Article 1(3) provides that '[t]his Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.'

The question, however, of who is responsible to demonstrate the safety of chemical substances (burden of proof) is handled differently under REACH and TSCA. Under REACH, instead of governmental authorities being required to prove that substances are dangerous in order to lay down restrictions, it is up to industry to provide evidence on the safe use of their products before they can be marketed. REACH requires manufacturers to collect, develop (if necessary) and submit data on a given chemical before it is put on the market. A registration dossier of a nanomaterial, or a bulk material that is used in the nanoform, has to include all relevant information on the nanomaterial as manufactured or imported, also covering specific properties, uses, effects and exposure-related information as well as the relevant classification and labelling, safety assessment and any relevant exposure scenarios. Once a chemical is registered at the European Chemicals Agency, registrants have an obligation to update and register new information in relation to changes in the quantities manufactured or imported, new uses of the chemical or new knowledge of risks to human health or the environment of which they may reasonably be expected to have become aware of (REACH Article 22). This article is particularly relevant in cases where a substance was already registered in its 'bulk' form and the substance is subsequently intended to be manufactured or imported in a nanoform (European Commission, 2008b).

TSCA, on the other hand, although providing that it is the manufacturer's responsibility to develop data with respect to the effects of a chemical substance, allocates the burden to demonstrate harm to the EPA, rather

than require the manufacturers to demonstrate the safety of the products they manufacture and sell. Although under TSCA the EPA is given the authority to require manufacturers to test chemicals for health and environmental impacts and to control chemicals of concern, the EPA can use its rulemaking authority only after making a series of statutory findings about the substance involved.

If, for example, the EPA wants to regulate an existing chemical substance, it has to demonstrate that there is a reasonable basis to conclude that the chemical 'presents or will present an unreasonable risk of injury to health or environment' (TSCA section 6), which essentially requires the EPA to have conclusive data on that particular chemical, a prerequisite that in the context of nanomaterials is hardly achievable in the light of the many uncertainties regarding their potential risks.

In case the EPA wants a company to conduct toxicity tests under a TSCA section 4 test rule, the EPA must make a statutory TSCA section 4 'A' (hazard) finding or a TSCA section 4 'B' (exposure) finding. This means that the EPA must be able to demonstrate that:

- existing data shows that the manufacture, distribution, processing, use or disposal of the substance 'may present an unreasonable risk of injury to health or the environment' and that the probability of exposure to the subject chemical substance is more than just theoretical (TSCA section 4(a)(1)(A)), or
- a chemical substance 'is or will be produced or imported in substantial quantities' and either may reasonably be anticipated to enter the environment in substantial quantities, or result in significant or substantial human exposure (TSCA section 4(a)(1)(B)).

Additionally, the EPA must demonstrate that existing data are inadequate for risk assessment, and that testing is needed to develop the data. This evidentiary burden is regarded as one of TSCA's most significant flaws, particularly in regard to the handling of manufactured nanomaterials. The resulting situation is commonly referred to as a 'catch-22': the EPA must already have substantial information on a chemical in order to prove that it needs such information (Applegate, 2008; Denison, 2009b). These statutory requirements therefore essentially prevent the EPA from exercising its authority in cases when the scientific evidence is still fragmentary at best.

Overall, in a situation of uncertainty about the real risks of manufactured nanomaterials, the application of a precautionary approach and a shift of the burden of proof from authorities to manufacturers in chemicals legislation make sense from a series of perspectives:

- In an environment where the risks and benefits of emerging technologies are controversially discussed and the scientific and methodological knowledge to assess the risks is only about to evolve, classical regulation based on defining levels of tolerable risk taking and thresholds is usually not possible. The application of a precautionary approach – if a good balance between precautionary behaviour and still permitting innovation can be found – helps to avoid accumulation of unpredictable risks as long as conclusive evidence is lacking.
- The fear of unnecessarily hampering innovation and technology exploitation is often brought forward in the context of the application of a precautionary approach and a shift of the burden of proof from authorities to industry. Nevertheless, it has to be considered that a climate of uncertainty about the actual level of risk taking and the uncertainty about possible regulations in the future do not represent a good breeding ground for innovation, nor financial investment in a new technology.
- In the light of the lack of mandatory declaration for manufactured nanomaterials, authorities are struggling to keep pace with the rapid developments and the increasing market penetration of products containing (or claiming to contain) manufactured nanomaterials. It is therefore questionable whether regulators and control authorities will be able to reliably identify and assess manufactured nanomaterials in production and on the market. It may therefore be regarded as more efficient to have the necessary risk and safety data developed by those who are expected to have the best knowledge about the corresponding substance and its use: the manufacturers.
- Additionally, the assessment of the safety of chemical substances represents a growing burden to public authorities, both in terms of (over)loading the existing authorities with complex, new tasks and additional costs. If shifted from authorities to manufacturers, these burdens are divided according to the costs-by-cause principle; those who profit from using these substances will pay for the safety assessment. The role of the authorities is limited to an oversight function of checking and reviewing industry's assessments. On the other hand, however, there are also concerns over a shift of the burden of proof, as it is also expected to shift significant costs from authorities to industry and might consequently discourage further investment into nanotechnologies (Bowman and van Calster, 2007; Choi et al., 2009).

B) Identifying Nanomaterials, New and Existing Chemicals, Data Submission Requirements

Both REACH and TSCA adhere to similar criteria in order to distinguish different chemical substances. Under TSCA, it is a substance's molecular identity (TSCA section 3(2)(A)), whereas in the case of REACH, besides the molecular and structural formula, further properties are integrated into the 'sameness' analysis, such as spectral information (REACH section 2 of Annex VI). However, in neither case substance properties such as particle diameter or surface area that could be used to make a reliable distinction between conventional (bulk) materials and their nanoform are explicitly included. Therefore, in principle, any given substance under each law could stand for either the macroscale or the nanoscale form, or even both forms, and it will be difficult for administrators to identify nanoscale materials in the submitted registration or notification dossiers.

Regarding the different procedures and requirements that apply for 'new' and 'existing' substances under REACH and TSCA, key differences exist. Under TSCA, the decision whether a given substance will be subject to a pre-market safety review depends on the determination whether it will be considered a 'new' or an 'existing' chemical. Since many nanoscale materials currently used, however, do not have their own CAS numbers, or have CAS numbers that are already associated with the non-nanoscale chemical, and no information that would identify such materials as the nanoform need to be submitted upon pre-market registration, many nanomaterials are expected to be regarded as 'existing' substances for TSCA purposes and therefore would not undergo TSCA PMN requirements.

Even if a nanomaterial is considered a 'new' chemical for TSCA purposes, a PMN dossier must only include basic information on anticipated use, production volume, exposure and release, to the extent such information is known or reasonably foreseeable by the submitter at the premanufacture stage, but no health or ecotoxicity data or information on a chemical's environmental behaviour and fate is required. The EPA reportedly reviews about 1000 PMN every year, 67 per cent of which include no test data, and 85 per cent lack any health or ecotoxicity data (OPPT, 2007). It seems therefore reasonable to conclude that the EPA will not receive the necessary data to perform sound risk assessment on manufactured nanomaterials from regular PMN submissions. Other options to gather such data exist and have been discussed in this volume by Meili and Widmer (2010) in the context of voluntary measures.

Once a chemical is listed in the inventory of existing chemicals, unless the EPA issues specific rules, it is considered safe and it is not subject to

regular in-depth health, environment and safety reassessment. According to a 2005 Government Accountability Office report on the chemical review programme, 'EPA does not routinely assess existing chemicals, has limited information on their health and environmental risks, and has issued few regulations controlling such chemicals' (GAO, 2005: 18). While some of the most important chemicals (in terms of production volumes) have been subject to reassessment in programmes such as the HPV (High Production Volume) Challenge Program or the Chemical Assessment and Management Program (ChAMP),[14] these initiatives focus on chemicals produced in volumes of 11.3 tons (25 000 pounds) per year or more and therefore must be considered of rather limited relevance to most manufactured nanomaterials currently in use. This removes the designated means by which any government review of the affected nanoscale materials can be assured in a categorical approach (EPA, 2007, 2008e).

REACH, on the contrary, by requiring that all chemicals, whether formerly regarded as new or existing, be registered, tested and their uses identified and assessed, essentially eliminates the differences in the treatment of new and existing substances, and therefore mitigates the debate on whether nanomaterials should be regarded as new or existing substances, and how to distinguish nanomaterials from bulk substances for regulatory purposes. Through a tiered registration regime and extended registration deadlines for substances that have formerly been regarded as existing substances, the testing, registration and assessment effort is distributed over time. By principally requiring manufacturers to include in a chemical substance's registration dossier 'all relevant information of a nanomaterial' (such as its properties, use, effects, safety assessments and exposure-related information) (European Commission, 2008b), REACH also requires manufacturers to include information that allows the identification of a given substance as a nanomaterial.

In the case of already registered chemicals, registrants also have to update and register any new information in relation to issues such as new uses or new knowledge of risks to human health or the environment. With reference to the US TSCA system, this procedure has been termed an 'automatic Significant New Use Rule (SNUR) for all chemicals all of the time' (Denison, 2008), and it also includes any specific information concerning the nanoform of a substance.

The fundamental requirements for manufacturers under REACH to submit and update any kind of relevant data including health and safety information for all substances means that authorities can be expected to be able to make informed 'guesses' on whether a given chemical is used in its nanoform or not, and that considerable health and safety information on nanomaterials will be gathered.

C) Volume-Based Thresholds and Exemptions

Another issue of controversial discussion in the context of manufactured nanomaterials and chemicals regulation concerns the statutory exemptions from reporting requirements under REACH and TSCA. Both regulations, besides excluding broad material categories, for example radioactive substances which are regulated in detail elsewhere, they also provide exemptions from reporting requirements based on certain thresholds, such as annual production volume.

TSCA provides a series of criteria which, if they apply to a new substance, discharge manufacturers from either reporting new substances under PMN reporting requirements or updating information on existing substances under the Inventory Update Rule (IUR). With particular relevance to manufactured nanomaterials, such exemptions include:

- Low Volume Exemptions: The PMN rule exempts certain categories of new chemical substances from full PMN review if produced or imported in quantities of less than 10 tons per year per manufacturer (40 CFR §723.50). If 11.3 tons (25 000 pounds) per year or less of an existing substance are manufactured or imported, it is exempted from the IUR requirements (40 CFR §710.48).
- Low Release and Low Exposure (LoREX): The substance is expected to have low environmental release and human exposure and is therefore exempted from PMN reporting (40 CFR §723.50).
- Small manufacturer: Substances are exempted from IUR reporting if manufactured by a company that has either less than $US40 million annual sales and less than 45.4 tons (100 000 pounds) production/import, or less than $US4 million annual sales (regardless of the quantity) (40 CFR §704.5(f)).

Manufacturers must be expected to be tempted to seek such exemptions under TSCA to reporting requirements if they have the necessary data to support such exemptions.

Under REACH, registration and risk assessment requirements are also triggered by increasing annual production volumes. With increasing production volumes, registrants need to include more detailed information on toxicity and exposure assessment (see above at The European Approach – REACH). However, under REACH only chemicals with an annual production less than or equal to one ton per year are exempted from registration and chemical safety assessments, which is still considerably lower than under TSCA.

Obviously, mass-based thresholds and exemptions means that chemicals produced in small amounts essentially slip through the net of chemical regulations, a fact that is subject to strong criticism particularly regarding manufactured nanomaterials. Nanoparticles often exhibit increased activity per unit of mass if compared with conventional bulk materials, and they are often manufactured in much smaller amounts than conventional chemicals. It is therefore argued that a chemical's mass (annual production volume) alone is neither a suitable parameter to predict a nanomaterial's negative effects on human health and the environment, nor should it be used as a general threshold to define requirements or to trigger regulatory actions (see, for example, Oberdörster et al., 2007). The traditional volume-based exemptions have also been criticized because they are expected to put many nanomaterials, which are produced in low quantities, outside the requirements of legislation.

The European Commission has recognized the problem of referring to volume-based thresholds in the context of nanomaterials, but it was the European Parliament that first stated clearly in its communication to the Commission that 'the tonnage thresholds might not be adequate, as the properties and potential risks of nanomaterial are determined to a greater extent by particle number, surface structure and surface activity than by their tonnage', thereby charging the Commission with reviewing the corresponding system of volume-based triggers and exemptions under REACH within two years (European Parliament Committee on the Environment, Public Health and Food Safety, 2009: 8).

12.4 CONCLUSION

Considerable uncertainties persist as to how effectively existing regulatory frameworks will be able to handle manufactured nanomaterials, their unique properties and the corresponding issues arising from commercially exploiting them. In the ongoing debate about the current US and EU chemicals legislations, a series of questions and problems on how to reliably identify, adequately handle and regulate manufactured nanomaterials have emerged, there is internationally still little consensus concerning the nature and form which regulatory frameworks for nanotechnologies should take (Bowman and Hodge, 2009). Nanospecific adaptations of current regulatory frameworks are subject to intense discussions in both the US and in Europe, and the discussions on this issue will certainly accompany us for some time.

NOTES

1. In March 2006, two cleaning and sealing agents (MagicNano spray applications), which had been in trade for a short time, were removed from the market due to evidence proving health hazards in more than 70 cases. The affected people, after inhalation of components of the spray, suffered from respiratory distress, and in six cases pulmonary oedema had to be clinically treated.
2. Besides REACH and TSCA, regulations with a more limited focus in terms of the substances or applications covered exist, for example, in the area of food and food additives, cosmetics, medical products, pesticides and others. These regulations are also of particular relevance for manufactured nanomaterials, and in these cases, often more specific and more stringent reporting and authorization procedures apply.
3. Chemical substances that are of no particular concern are those which are not carcinogenic, mutagenic or toxic for reproduction (CMR).
4. With the exception of pesticides, tobacco (products), firearms and ammunition, nuclear material, and food, food additives, drugs, cosmetics which are covered under other legislations.
5. TSCA's central regulatory standard of 'unreasonable risk' is not defined in TSCA. The legislative history, however, indicates that unreasonable risk involves the balancing of the probability that harm will occur and the magnitude and severity of that harm against the effect of a proposed regulatory action on the availability to society of the expected benefits of the chemical substance (EPA, 2009a).
6. TSCA § 4(a): '. . . the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.'
7. TSCA § 8(c): 'Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment . . . alleged to have been caused by the substance or mixture.'
   TSCA § 8(d): 'The Administrator shall promulgate rules under which the Administration shall require any person . . . to submit . . . lists of health and safety studies.'
8. TSCA § 8(e): 'The Administrator shall promulgate rules under which . . . any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information . . .'
9. In some cases, if the identity of a chemical is claimed to be confidential business information (CBI), an accession number replaces the above identification information of the chemical.
10. Beginning in 1986, the Office of Pollution Prevention and Toxics Programs has been updating the TSCA Inventory at intervals of every four years to obtain basic information about those chemicals that are actively being manufactured, produced, processed or imported during a specified reporting period. The inventory updates are intended to provide a more contemporary picture of a smaller subset of the total 83 000 chemicals in the Inventory and are also used for priority setting.
11. With the same intention, under REACH, carbon and graphite have been removed from the REACH Annex IV for substances of minimum risk to ensure that CNTs undergo full safety testing.
12. The EPA views molecular identity as being based on such structural and compositional features as the types and number of atoms in the molecule, the types and number of chemical bonds, the connectivity of the atoms in the molecule, the spatial arrangement

of the atoms within the molecule. Additionally, the EPA clarified that different allotropes of the same element are considered to have different molecular identities. The EPA considers chemical substances that differ in any of these structural and compositional features to have different molecular identities (EPA, 2008e).

13. The EPA clarified that different allotropes of the same element are considered to have different molecular identities (EPA, 2008e).
14. For more information on the efforts to assess and manage existing chemicals, see EPA (2009f).

REFERENCES

Applegate, J.S. (2008), 'Synthesizing TSCA and REACH: practical principles for chemical regulation reform', *Ecology Law Quarterly*, **36**(4), 721–69.

Bowman, D.M. and G.A. Hodge (2009), 'Counting on codes: an examination of transnational codes as a regulatory governance mechanism for nanotechnologies', *Regulation and Governance*, **3**(2), 145–64.

Bowman, D.M. and G. van Calster (2007), 'Does REACH go too far?', *Nature Nanotechnology*, **2**(9), 525–6.

Canadian Underwriter (2007), *Nanotechnology, Climate Change, Infrastructure among Top Risks*, accessed 1 July 2009 at www.canadianunderwriter.ca/issues/ISArticle.asp?aid=1000072059&issue=11222007.

Choi, J.Y., G. Ramachandran and M. Kandlikar (2009) 'The impact of toxicity testing costs on nanomaterial regulation', *Environmental Science & Technology*, **43**(9), 3011–19.

Davies, J.C. (2009), *Testimony of J. Clarence (Terry) Davies before the Subcommittee on Commerce, Trade and Consumer Protection*, accessed 2 July 2009 at energycommerce.house.gov/Press_111/20090226/testimony_davies.pdf.

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. (2008), 'Fixing TSCA for nano: don't forget all the other chemicals!', Environmental Defense Fund blog on chemicals and nanomaterials, accessed 3 July 2009 at www.blogs.edf.org/nanotechnology/2008/07/28/fixing-tsca-for-nano-dont-forget-all-the-other-chemicals/.

Denison, R.A. (2009a), *What should TSCA reform look – and not look – like?*, Environmental Defense Fund blog on chemicals and nanomaterials, accessed 2 July 2009 at www.blogs.edf.org/nanotechnology/2009/04/15/what-should-tsca-reform-look-and-not-look-like/.

Denison, R.A. (2009b), 'Ten essential elements in TSCA reform', *Environmental Law Reporter*, **39**(1), 10020–28.

Dooley, C. (2009), *Testimony of Cal Dooley on behalf of the American Chemistry Council Before the Subcommittee on Commerce, Trade and Consumer Protection*, accessed 2 July 2009 at energycommerce.house.gov/Press_111/20090226/testimony_acc.pdf.

Eidgenössisches Departement des Innern EDI (2008), Eidgenössisches Volkswirtschaftsdepartement EVD, Eidgenössisches Departement für Umwelt, Verkehr, Energie und Kommunikation UVEK, report of the Upper House of Parliament of 9 April, Aktionsplan Synthetische Nanomaterialien.

Environment Protection Agency (2007), *Concept Paper for the Nanoscale Materials Stewardship Program under TSCA*, accessed 3 July 2009 at www.epa.gov/oppt/nano/nmsp-conceptpaper.pdf.

Environmental Protection Agency (2008a), 'Certain new chemicals; receipt and status information', *Federal Register*, **73**(89), 25696.

Environmental Protection Agency (2008b), 'Certain new chemicals; receipt and status information', *Federal Register*, **73**(240), 75709–11.
Environmental Protection Agency (2008c), 'Toxic Substances Control Act Inventory status of carbon nanotubes', *Federal Register*, **73**(212), 64946–7.
Environmental Protection Agency (2008d), 'Significant New Use Rules on certain chemical substances', *Federal Register*, **73**(215), 65743–66.
Environmental Protection Agency (2008e), *TSCA Inventory status of nanoscale substances – general approach*, accessed 2 July 2009 at www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf.
Environmental Protection Agency (2009a), *Making a Finding on Unreasonableness of Risk*, in the New Chemicals Program, accessed 1 July 2009 at www.epa.gov/oppt/newchems/pubs/unrerisk.htm.
Environmental Protection Agency (2009b), *Nanotechnology under the Toxic Substances Control Act*, Pollution Protection and Toxics, accessed 2 July 2009 at www.epa.gov/oppt/nano/.
Environmental Protection Agency (2009c), 'Certain new chemicals; receipt and status information', *Federal Register*, **74**(69), 16861–6.
Environmental Protection Agency (2009d), 'Certain new chemicals; receipt and status information', *Federal Register*, **74**(2), 280.
Environmental Protection Agency (2009e), 'Certain new chemicals; receipt and status information', *Federal Register*, **74**(73), 17856.
Environmental Protection Agency (2009f), *Chemical Assessment and Management Program (ChAMP)*, Pollution Protection and Toxics, accessed 3 July 2009 at www.epa.gov/champ/.
Environmental Protection Agency, Office of Pollution Prevention and Toxics (2008), *Regulation of a New Chemical Substance: Pending Development of Information*, accessed 2 July 2009 at www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf.
European Commission (2000), *Communication from the Commission on the precautionary principle*, accessed 1 July 2009 at ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf.
European Commission (2004), *Questions and Answers on Reach, Part II*, accessed 1 July 2009 at http://ec.europa.eu/environment/chemicals/pdf/qa_reach_part2-2004_11_22_en.pdf.
European Commission (2008a), *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on Regulatory Aspects of Nanomaterials*, Brussels: EC.
European Commission (2008b), *Follow-up to the 6th meeting of the REACH Competent Authorities in the implementation of Regulation (EC) 1907/2006 (REACH): Nanomaterials in REACH*, Brussels: EC.
European Parliament Committee on the Environment, Public Health and Food Safety (2009), *Report on Regulatory Aspects of Nanomaterials (2008/2208(INI))*, Brussels: EC.
Government Accountability Office (2005), *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, Washington, DC: GAO.
Government Accountability Office (2007), *GAO Report of Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect Against the Risks of Toxic Chemicals*, Washington, DC: GAO.
Government Accountability Office (2009a), *Report to Congress: High-Risk Series – An Update*, Washington, DC: GAO.
Government Accountability Office (2009b), *Testimony Before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, House of Representatives: Chemical Regulation, Options for Enhancing the Effectiveness of the Toxic Substances Control Act, Testimony of John Stephenson, Director Natural Resources and the Environment*, accessed 2 August 2009 at www.gao.gov/new.items/d09428t.pdf.
Hansen, S.F., L. Carlsen and J.A. Tickner (2007), 'Chemicals regulation and precaution:

does REACH really incorporate the precautionary principle?', *Environmental Science & Policy*, **10**(5), 395–404.
House of Representatives (2009), Committee on Energy and Commerce, *Revisiting the Toxic Substances Control Act of 1976, Hearings – Subcommittee on Commerce, Trade and Consumer Protection*, accessed 27 August 2009 at www.energycommerce.house.gov/index.php?option=com_content&view=article&id=1505:revisiting-the-toxic-substances-control-act-of-1976&catid=129:subcommittee-on-commerce-trade-and-consumer-protection&Itemid=70.
Meili, C. and M. Widmer (2010), 'Voluntary measures in nanotechnology risk governance: the difficulty of holding the wolf by the ears', 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. 446–61.
Miller, G. and G. Scrinis (2010), 'The role of NGOs in governing nanotechnologies: challenging the 'benefits versus risks' framing of nanotech innovation', 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. 409–45.
Oberdörster, G., V. Stone and K. Donaldson (2007), 'Toxicology of nanoparticles: a historical perspective', *Nanotoxicology*, **1**(1), 2–25.
Office of Pollution Prevention and Toxics (2007), *Overview: Office of Pollution Prevention and Toxics Programs*, accessed 6 July 2009 at www.epa.gov/oppt/pubs/oppt101c2.pdf.
Office of Pollution Prevention and Toxics (2009), *OPPT Accomplishments Report January 2007–January 2009: Managing Existing Chemicals*, United States Environment Protection Agency, accessed 1 July 2009 at www.epa.gov/oppt/ar/2007-2009/managing/index.htm.
Office of Science and Technology Policy and Council on Environmental Quality (2007), *Memorandum for the Heads of Executive Departments and Agencies, Principles for Nanotechnology Environmental, Health and Safety Oversight*, accessed 1 July 2009 at www.ostp.gov/galleries/default-file/Nano%20EHS%20Principles%20Memo_OSTP-CEQ_FINAL.pdf.
Poland, C.A., R. Duffin, I. Kinlock et al. (2008), 'Carbon nanotubes introduced into the abdominal cavity of mice show asbestos like pathogenicity in a pilot study', *Nature Nanotechnology*, **3**, 423–8.
Schierow, L.-J. (2008), '*CRS Report for Congress, The Toxic Substances Control Act (TSCA): Implementation and New Challenges*, updated 18 July 2008.
Smrcka, K. (2009), *Nanotechnology – the key technology of the 21st century*, Engineering News Online, accessed 1 July 2009 at www.engineeringnews.co.za/article/xxx-2009-06-19.
Thomas Swan & Co Ltd (2008), *Swan pioneers nanomaterial controls with EPA*, accessed 2 July 2009 at www.thomas-swan.co.uk/ASP/News_Events/News_Events.asp?Type=News&ID=195&Arc=&DLT=Swan%20pioneers%20nanomaterial%20controls%20with%20EPA.
Tickner, J., C. Raffensperger and N. Meyers (undated), *The Precautionary Principle in Action – A Handbook*, accessed 2 July 2009 at www.biotech-info.net/handbook.pdf.