Research Policy 43 (2014) 169–178

Contents lists available at ScienceDirect

Research Policy

journal homepage: www.elsevier.com/locate/respol

The role of the state in regulatory policy for nanomaterials risk: Analyzing the expansion of state-centric rulemaking in EU and US chemicals policies

Ronit Justo-Hanani [a,*], Tamar Dayan [b]

[a] Department of Zoology, the George S. Wise Faculty of Life Sciences, and the Edmond J. Safra Center for Ethics, the Buchman Faculty of Law, Tel-Aviv University, Tel-Aviv 69978, Israel
[b] Department of Zoology, the George S. Wise Faculty of Life Sciences, Tel-Aviv University, Tel-Aviv 69978, Israel

ARTICLE INFO

Article history:
Received 18 January 2013
Received in revised form 14 June 2013
Accepted 24 June 2013
Available online 20 July 2013

Keywords:
State
Centralization
Regulatory policy
Nanomaterials risks

ABSTRACT

This paper explores the growing power of states in transnational regulatory policies for nanotechnology risks and thereby their impact on research and technology trajectories. Decentralization of governance structure has been reported by scholars, yet the role of the state is evolving and still underexplored. We draw on a case study of nanomaterials and chemicals policies, by analyzing recent regulatory developments in the EU and US. Using data-reporting and market-entry regulations as examples, the evidence demonstrates the expansion of state-centric market-oversight rulemaking, and 'stronger' patterns of centralization in the EU. We argue for a significant increase in regulatory power exertion, countering predominant views on decentralization as the prevailing governance response. These findings suggest the adaptation and strengthening of state-based regulatory systems in the context of scientific uncertainty and complexity of global nanotechnology settings; despite these challenges for policy making, the EU and the US are increasing government role in technology regulatory policy.

1. Introduction

What role do states play in transnational nanotechnology risk regulation and policies? In the past few years, most studies have examined the role of private rulemaking in transnational nanotechnology risk regulation and governance. Scholars have observed how global private actors seek to influence or work through states' regulatory systems, or how they create separate spheres of governance for themselves independently from existing states' regulation (Bowman and Hodge, 2008; Bowman and Gilligan, 2010; Forsberg, 2011). Yet, the role of states is evolving and their regulatory *power exertion* is still underexplored (exceptions include Falkner and Jaspers, 2012; O'Brian, 2012; Stokes, 2012). Scholars generally concluded that while states are likely to play an important role in the future, currently it seems difficult to reconcile state-centered regulation with the complicated structure of nanotechnology settings (Bowman and Hodge, 2008; Abbott et al., 2010). The relative role of states in transnational nanotechnology risk regulation may be referred to as 'the limited power' conception, a predominant view in nano-regulation studies. This paper aims to examine this role from an empirical perspective.

The 'limited power' conception rests on two arguments. First, state authorities lack a genuine regulatory capacity that would enable them to govern environmental and safety risks of nanotechnology through their own regulatory means (see, for example, Malloy, 2011, p. 6). Second, states have relied on private actors' rulemaking and, consequently, private actors retain substantial regulatory autonomy. While the first argument is not disputed in this paper, the second is challenged by examining a key example of the growing globalized market for manufactured nanomaterials[1] and transnational chemicals regulatory policies on their environmental and safety risks.

As nanomaterials are among the most rapidly developing products in the global nanotechnology industry, a request for global rulemaking on their environmental and safety risks has emerged (Hansen, 2010). In such an increasingly globalized regulatory environment there is a need to better understand how the EU and the US, the world's two most influential powers, see their role as environmental and safety risk regulators.

The aim of this paper is to examine the question: do states take a more active and expansive role in transnational regulatory policy-making on nanomaterials risk? We argue for significant expansion

* Corresponding author. Tel.: +972 50 8783548.
E-mail address: ronitjus@post.tau.ac.il (R. Justo-Hanani).

[1] The term "nanomaterials" is used in this paper to refer to chemicals substances or materials typically manufactured in the 1–100 nanometer (nm) size range, which enter the market as industrial raw materials and product segments.

0048-7333/$ – see front matter © 2013 Elsevier B.V. All rights reserved.
http://dx.doi.org/10.1016/j.respol.2013.06.008

of state-centric rulemaking in the EU and US. Global private actors still have considerable regulatory power, but the EU and the US strive to determine the shape and the level of transnational risk policies. As comparison of their initial efforts shows, the EU's centralization modes are 'more robust' than those of the US federal government. The empirical analysis is based on a comprehensive analysis of recent rulemaking by the European Commission and the US Environmental Protection Agency under REACH and TSCA regulatory policies, respectively,[2] which are most relevant to the global nanomaterials market. The subsequent analysis draws on literature from both legal scholarship and political science scholarship (nano-regulation and governance; globalization and governance from a state-centric perspective, respectively).

The significance of our findings goes beyond the nanotechnology policy domain. It is about providing empirical insight into one of the most fundamental questions in the study of 'global regulatory policies' and 'global politics of risk regulation': which governance-states relations exist in global regulatory spheres? (Rosenau and Czempiel, 1992; Peters and Pierre, 1998; Drezner, 2007; Bell and Hindmoor, 2009). Risk regulation is one of the most important power exercises of the modern state (Majone, 1996). The transnational arenas of risk regulation, with science, technology and innovation regulatory policies, are the major locus of expansion of the 'regulatory state' and more broadly of 'regulatory capitalism' (Levi-Faur, 2005; Faulkner, 2009). Hence Vogel (2003, 2012; see also Kelemen and Vogel, 2010) view global environmental and safety risks as key for analyzing the logic and historical transformation in the EU and the US regulatory states. Growing numbers of pluralistic legal scholars assert regulatory risk policies as increasingly 'decentered' from the state (Black, 2002; Abbott and Snidal, 2009). Finally, Majone (2004) has argued for the growing role of standard-setting organizations and the private sector in shaping international environmental and safety risk policies, given weaknesses in the EU and the US regulatory systems. The common viewpoint has become that states, in particular great powers, have experienced decreasing regulatory power in the process of setting transnational environmental and safety regulatory regimes (Abbott and Snidal, 2009; Büthe and Mattli, 2011; Hall and Biersteker, 2002; Potoski and Prakash, 2005).

Our analysis shows that regulatory activity in the EU and US takes an adaptive mode toward empowerment of their state-based regulatory systems with the aim of reducing uncertainties; moreover, it also constrains private actors' power to regulate, a highly political issue of power allocation. These findings counter a widespread understanding of decentralized, rather than formal state-centric rulemaking, as the prevailing governance response to global nanotechnology risks.

Our analysis does not aspire to provide a complete account of the EU-US regulatory relations or their role in international regulatory activity; by adopting a narrower focus, we provide an analysis of the expansion of state-centric rulemaking which leads to a conclusion that transnational nanomaterials risk regulation is now a policy field with a growing degree of states power, at least in the major pillars of the EU and US.

The paper is divided into three sections. First, we briefly introduce the global market for nanomaterials and current risks and challenges for technology policy making. The second section summarizes views from the nano-regulation literature on decentralized governance structure. The third section provides an empirical analysis and discussion of the expansion of centralized rulemaking in the EU's and US's chemical policies, focusing on data reporting and market entry regulations. This section also provides an initial comparison between the EU and the US on their early efforts toward state-centric rulemaking. Finally, we present our conclusions.

2. The global nanomaterials market: risk and challenges for technology policy making

Nanomaterials are among the most significant components in the total nanotechnology market (Cientifica, 2007; ReportsnReports, 2011). Produced for the last ten years mainly by the chemical industry, nanomaterials are now seen as the future of the global chemical sector, with the US, Japan, Western Europe, and Asia Pacific as leading industrial countries. The nanomaterials industry is considered a 'silent' or 'invisible' industry, yet with a most visible impact. Most of the manufactured nanomaterials are not sold directly to consumers but are produced as raw materials and basic building blocks in diverse industrial settings (i.e. used as product segments in green cleaners and lubricants, sunscreen lotions, wafer polishing and textile treatment). The total market size is therefore difficult to estimate, with only partial data released by companies and online 'polls'. For example, a market report from 2007 (Cientifica, 2007) estimated that the chemical sector is, and will continue to be a dominant player in the global nanotechnology market with predicted growth of over 100% by 2012. In 2010, the global Carbon Nanotubes industry alone turned over around US$668.3 million, and is forecasted to grow to US$1.1 billion by 2016 (NanoWerk NanoDatabases, 2011). Overall at least 21,500 tons of nanomaterials were manufactured commercially worldwide in 2010, a tenfold increase from 2002. Their production volume is expected to double and over by 2016. Their market value is estimated at US$ 2.64 billion and some estimates are much higher (Research and Markets, 2011; PRNewswire Reports, 2011).

As manufactured nanomaterials are among the fastest growing products in the global nanotechnology industry, a widespread exposure of humans and ecosystems is inevitable. As numerous scientific reviews have demonstrated, there are quite specific but highly diverse potential health and environmental impacts associated with nanomaterials, including inhalation, absorption, and release into terrestrial and aquatic environments (Aitken et al., 2009). Recent experimental studies (Sanderson, 2008; Kulinowski, 2009) have indicated that carbon nanotubes may induce a specific form of lung cancer (mesothelioma) and inflammatory reactions in mice which were previously observed in relation to asbestos exposure. The potential of nanomaterials reactivity in environmental settings is also acknowledged in view of several factors, such as their great surface area; a growing body of evidence found potential exposure to nanomaterials that have dispersed in air, aquatic environments, soil and sediments (see, for example, review by SCENIHR, 2009). Among industry workers, some evidence was found of exposure-related mortality from lung disease (Gilbert, 2009; Song et al., 2009); these observations, while contested, have triggered considerable anxiety and discussions about global regulatory response.

Although nanotoxicology studies have greatly increased in the last few years, this research branch is still in its infancy. While the toxicity of certain nanomaterials, most notably carbon nanotubes, silver nanoparticles, and titanium dioxide nanoparticles, is already well documented, the toxicity of others is largely unknown (Wijnhoven et al., 2009). There is still a great deal of uncertainty and inconclusive knowledge on the characterization of nanomaterials; there is even controversy regarding the accepted definition, which mainly relates to their intrinsic scientific complexity. There are problems with extrapolating traditional risk assessment methods to nanomaterials, and these limit the ability to calculate or make quantitative predictions regarding potential hazards (SCENIHR, 2007; Wijnhoven et al., 2009).

[2] European Parliament and Council (2006); the Toxic Substances Control Act (TSCA) 1976.

As a challenge for policy making, nanotechnology has caught the attention of scholars from both the natural and the social sciences; the debate on its risks has been increasingly focused around creating technology policy for uncertain risks, a multidisciplinary challenge involving regulators and risk assessors. Overall, nanomaterials policy making requires a 'regulatory science' (Jasanoff, 2005) in the form of a significant information base and risk assessment foundation, that may be achieved by tackling the following uncertainties: first, it is not clear whether potential hazards can be addressed with existing test methods and risk assessment approaches; second, a lack of exposure and hazard data on a wide range of materials, to allow the establishment of a detailed framework for assessment; third, related difficulties in assessing tradeoffs between manufacturing production, cost, and safety concerns (Linkov et al., 2009). These major uncertainties are widely recognized as demanding regulatory policy making at the international level, but such policy making is still dynamic and undergoing change.

3. A predominant view: a decentralized governance structure

Since the 1990s scholars in a wide range of fields have tended to view transnational environmental and safety regimes as systems of decentralized governance structure (Young, 1997; Falkner, 2003; Haas, 2004; Pattberg, 2005; Pollack, 2007; Bernstein and Cashore, 2007). Most scholars agree that regulatory power over global markets is neither completely monopolized by state actors, nor by private actors, but is shared between them. Most also agree that such allocation of regulatory power presents a changing architecture (but not eclipse) of the state, and differs markedly from traditional hierarchical power (Evans, 1997; Jayasuriya, 2001; Levy, 2006).

Transnational nanotechnology regimes can be seen as new examples of this structure. Since the mid 2000s, nano-regulation studies have viewed these regimes as hybrid, as the decentralized power concept suggests. Similar descriptions include 'hybridized', 'reflexive', and pluralistic' regulation (Bowman and Hodge, 2008; Abbott et al., 2010; Falkner and Jaspers, 2012). From states' perspective, the regulatory dilemma has been and still is whether and how existing regulatory policies can be used or adapted to the needs of nanotechnology (Stokes, 2012, 2013). Self-regulatory initiatives and voluntary approaches have evolved in recent years as attempts to deal with scientific and technical uncertainties. Examples include private standards by ISO, BSI and standardization organization alike on nano-terminology and toxicity guidelines (e.g. ISO, 2010); voluntary partnerships for risk management (e.g. ED-DuPont, 2007), and public-private initiatives (see discussion below on the NMSP). The advantage of these patterns, so their proponents argue, is their move beyond 'traditional' modes of formality and *reactive* policy making (which is usually identified with state-centric rulemaking) to more *proactive*, easily adopted response, which better fits to the highly dynamic situation characterized by uncertain risks (Marchant et al., 2012).

Core features of transnational regulatory policy for nanomaterials risk include control over products safety, consumer protection, market registration, and data disclosure. Descriptions of transnational rulemaking paths continuously show the many impediments faced by the EU and US regulatory systems in these key policy issues (Renn and Roco, 2006; Bowman and Hodge, 2008; Breggin et al., 2009; Bowman and Gilligan, 2010; Hansen, 2010; D'Silva, 2011; Forsberg, 2011; Falkner and Jaspers, 2012): both the EU and the US have been investing significant financial and expertise resources for independent policy activities in risk assessment, safety appraisal, standardized definitions, or generation of knowledge, but whether their level of investment is sufficient or appropriate to meet societal needs is still uncertain. Both the EU and the US have delayed adoption of new nano-specific regulation or amendments within their chemicals regulatory frameworks (REACH and TSCA, respectively) to capture all types of nanomaterials within their policy fields related to 'market creation' (registration requirements, thresholds triggers). For instance, registration requirements apply to chemicals produced in volumes of more than one ton per year; nanomaterials manufacturers might be excluded from registration since they produce below such volumes. Most coordination mechanisms in policy fields related to 'market safety regulation' (risk assessment, scientific evidence requirements, post monitoring) are led by specialized networks within intergovernmental forums, such as the OECD's Chemicals Committee and the OECD's Working Parties on Nanotechnology and Manufactured Nanomaterials (OECD WPN, OECD WPMN); although the US and the EU government agencies are well-represented, these forums are strongly controlled by private sector epistemic communities, such as trade organizations and R&D steering committees, with technocratic influence on international standard setting.

At least four different types of self-regulation have been developed by global chemicals industrial giants in the last 7 years on occupational setting and risk management related policies, including single-party and multi-partners initiatives (for detailed description, see Bowman and Gilligan, 2010). Standardization for risk management is pursued by ISO, besides its constant work on standardization of terminology and measurement. Although the EU and the US initiated individual processes, the private sector takes a pivotal role in their initiatives: EC closely follows the work in ISO by the European Committee for Standardization (CEN). The ISO standard on Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate (ISO/TS 27687:2008) has been approved by CEN (CEN/TS) in 2009 for a period of three years, in which its adoption as a European standard was considered; the data gathering process initiated by the EPA (see analysis below) was designed to have an important role in monitoring and enforcement of the global market, but the agency's limited role was reflected in heavy reliance on private sector collaboration.

These findings suggest a decentralized regulatory structure, a key feature of which is horizontal power-sharing. According to Bowman and Hodge (2008): "incremental regulatory changes designed to improve the governance of nanotechnologies are beginning to emerge across numerous jurisdictions... these voluntary programs operate within the shadow of formal regulatory obligations and do not seek to 'roll back the state' or replace the regulatory frameworks in which they operate". With reference to the industrial chemicals sector, Bowman and Gilligan (2010) state: "it would therefore appear that nano-specific state-based regulatory regimes are likely to constitute only a small part of an evolving governance web. A more promising path for state involvement is likely to come under the umbrella of civil and hybrid regulation" (see also Bowman and Hodge, 2008, p. 478). Abbott et al. (2010) agree: "...regulation is increasingly 'decentered' from the state by the rise of self-regulation and of private schemes ... predominantly private institutions... are increasingly significant transnational rule-makers... such flexible forms of international actions are the most suitable ways to begin coordinating national nanotechnology regulation under current conditions".

The 'decentralized structure' is, however, controversial among nano-regulation scholars. While Abbott et al. (2010) have supported reliance on private actors in the development of transnational risk governance, Davies (2008) strongly criticized the 'decentralized approach'. Falkner and Jaspers (2012) also criticize: "international governance of nanotechnology risk as it exists today is mostly limited to scientific and technical standardization... no

deeper structures for global governance have been created despite the rapid globalization of nanotechnologies".

While scholars like Bowman and Van Calster (2007) have argued that the EU and US still maintain sovereignty over the regulation of nanomaterials along their life cycles, others, like Lin (2007), have objected to these claims. In the context of the US regulation Davies (2008) stressed: "Four federal regulatory bodies [...] have some authority, in theory, to regulate nanotechnology materials and products. However, there is a wide gap between having legal authority and actually being able to exercise oversight over nano... There is no official government-wide effort to deal with the regulation of nanotechnology."

In brief, there is little controversy among scholars on the following: (a) private actors retain substantial control in transnational risk policies on nanotechnology; (b) the decentralized approach is clearly evident in the EU and the US regulatory policies; (c) this pattern of hybrid, horizontal power-sharing has some attraction for risk regulation in the short to medium term given massive uncertainties of future technology trajectories. Still, the *way* decentralized risk regulation operates has been criticized in several policy issues; (d) the scope of transnational nanotechnology rulemaking is largely restricted to technical and more politically salient issues (testing methods, risk assessment criteria). Control of highly political issues of market creation (thresholds as trigger for regulatory control; reporting requirements) are left to EU and US authorities, but have met with limited success.

In the next section we demonstrate a move toward state-centric market-oversight modes of rulemaking.

4. Results and discussion: the expansion of state-centric rulemaking in the EU and US chemical policies

To challenge the 'limited power' conception, it is necessary to understand the role of the EU and US regulatory systems in the global nanomaterials market and the expression and exercise of power in their new environmental and safety regulatory policies.

The EU and US regulatory power on global markets' policy issues derives from their general competence for creating 'Single Markets' and mutual recognition regimes (Smith, 2010; Egan, 2012). To develop these markets, both are increasingly shaping transnational regulatory regimes across a broad range of sectors (Vogel, 2003; Bach and Newman, 2007; Drezner, 2007). As this section shows, the EU and the US use this power to assert considerable control over the global nanomaterials market.

We carried out empirical analyses of two regulatory risk policies for nanomaterials in the chemicals sector: Data Reporting and Market Entry regulations. There are several reasons for choosing these policies for illustration: these are hotly contested policy fields and are particularly instructive examples since they show the limits of decentralization and at the same time the most likely path toward state-centric rulemaking in technology regulatory policy. Moreover, they provide a contribution to two major themes in academic discussions on globalization and governance from a state-centric perspective (Drezner, 2007): state sovereignty and power-constrained nonstate actors. A preliminary study revealed that data-reporting policy is a locus of regulatory expansion in the US while market entry policy is undergoing adaptations in the EU, so we focused our study on these different but complementary policy areas.

Two rulemaking paths are particularly important in this regard: the regulations of the US Environmental Protection Agency under the TSCA regulatory system, and the regulations of the European Parliament and the European Commission under the regulatory system of REACH.

4.1. US: data reporting regulation

With the rapid diffusion of nanomaterials in the market, new commercial data needed to understand their risks are continuously created across the globe (production volumes, uses, toxicity, physical and structural characteristics). These data can be used by companies and governments for market segmentation and risk management. In the face of mostly incomplete or uncertain risk information, key issues remain unresolved: are the EU and the US able to regulate data disclosure through their own regulatory means? Should they delegate or privatize their administrative authority to the industry? Should states have disclosure risk regulation on the whole power industry through coercive mechanisms of their choosing? Alternatively, should states use regulation upon the industry acting with a common interest through a voluntary model of power-sharing? Governing data reporting duties has therefore become a contentious global regulatory issue (Hansen, 2010).

The EPA's leadership clearly recognized that risk regulation over the globalized market for nanomaterials and nanoscale chemicals substances requires data reporting policy, but was concerned to stabilizing the TSCA legislative authority in this area (Marchant et al., 2007). In the late 2000s, the TSCA regulatory system had two main policy tools for obtaining commercial data on nanomaterials: general reporting requests and a nano-specific reporting scheme. They provided some rulemaking powers to EPA institutions, but have strict functional and procedural constraints imposed upon them.

The general reporting system, the TSCA IUR rule, in place from 1986, mandated the EPA to require data reporting from industry, but with serious limitations: only once every-five-years (section 8; EPA, 2003). The expanded manufacture and use of nanomaterials in the past five years, when international policy debates occurred, are thus systematically excluded from the US general reporting policy.

Proposals for qualified reporting format under TSCA were closely monitored by autonomy-minded industry. The industry was dominant in the 'reporting discussions' and has effectively promoted a voluntary partnership model (Bergeson, 2007). The EPA's Nanoscale Materials Stewardship Program (NMSP), announced in January 2008 after over a year of consultation process, was a voluntary reporting scheme that was backed by the global industry commitment (EPA, 2007a; NLR, 2008).

Procedurally, the NMSP subjected reporting matters to the industry's autonomous decision making. EPA invited companies to voluntarily report some or all of the following information about nanomaterials manufactured or imported: physical and chemical properties, hazards, use, risk management practices or plans (EPA, 2007a). In effect, the EPA has informally delegated its regulatory power to the private sector in a number of areas affecting its data retention, including those serving legitimate purposes of market knowledge and public trust. Data collection, according to the GAO's extensive report to Congress, turned out to be a policy field with a low degree of federal government sovereignty in decision-making (GAO, 2010).

However, a year after the program began, the EPA registered its disappointment that approximately 90 percent of potentially commercially available nanomaterials were not reported (EPA, 2009). A political climate for regulatory reforms, as outlined in President Obama's vision for economic competition (The White House, 2011), together with the EPA's disappointment with the NMSP, terminated in December 2009, have provided the background for adaptations in EPA's reporting policy during 2010 and 2011. The TSCA amendments, particularly in section 8 (a) (Chemical Data Reporting [CDR] Rule) have actually lessened the bargaining power of the nano-industry; the EPA used regulatory power to achieve a few types of 'socially desirable' ends such as reduction of scientific uncertainty through prohibiting potential confidentiality claims on processing and use information, as well as stringent requirements for

Table 1
Developments on data reporting regulations under TSCA.[a]

Regulatory issue area	Year	Regulatory instrument	Policy tool	The extent or nature of state-centric market-constrained rulemaking
Pre-Manufacturing	2008	Administrative order (EPA, 2008a,b)	Clarifying the status of carbon nanotubes as 'new' chemicals	Increasing governmental regulatory scrutiny on the private market
	2010	Administrative order (EPA, 2010)	Identify priority for review and assessment: the two most commonly used nanomaterials structures has listed as 'chemicals of concern'	Placing limitation to industry power by restricting commercial activity
	2012	Administrative order (EPA, 2012)	More stringent reporting requirements for nongeneric use of infused carbon nanostructure	Placing limitation to industry power by restricting commercial activity
Post-monitoring	2009	Stewardship Program (NMSP) (EPA, 2009)	Withdrawing the voluntary data-reporting agreement with industry	Diminishing power-sharing with the private sector; increasing independence of federal government from private sector
	2011	Rule (EPA, 2011a)	Expanding the frequency and scope of reporting requirements	Enhancing the agency monitoring authority
	2011	Reporting standard (EPA, 2011a)	Replacing the "readily obtainable" with the "known to or reasonably ascertainable by" reporting standard	Decreasing the high bargaining power of the private sector

[a]Data reporting regulation refers to EPA's binding rules or expected final decisions in ongoing regulatory processes. Some rulemaking pertain to 'chemical substances' generally and apply to nanomaterials also.

full-manufacturing data and production volumes, that "will better address Agency and public information needs" (EPA, 2011a). The modifications for TSCA adopted with outside pressure from international EHS organizations and raised compelling industry concerns (for NGOs and Industry views see Denison, 2010, 2011; Lamprou, 2010). Table 1 presents an overview of major rulemaking activity on data reporting by the EPA since 2008.

Table 1 presents three trends. First, the development of reporting regulation affecting the global nanomaterials market has greatly increased. While the NMSP was the only nano 'upgrade' of the US reporting system until 2008, at least four regulatory processes were issued since then. This is particularly significant in light of a general trend for improving environmental and safety rulemaking by the US administration as a key for continued global leadership, in accord with President Obama's regulatory agenda (The White House, 2011). Despite (or because of) a genuine scientific uncertainty, the adoption of rules and principles affecting global emerging technologies has become inevitably a routine in US politics (The White House ETIPC, 2011).

Second, amendments were made to disclosure regulatory policy. In 2006–2009 the 'nano-focus' in reporting regulation was primarily on the introduction of 'the shared-responsibility' system (NMSP) with the industry. Since 2009, policy has extended to improve the existing EPA authority to collect the needed information (EPA, 2007a, 2009). This trend reflects reduction of delegated enforcement by placing limitations to industry power; attempts to improve reporting regulation initially focus on identifying 'problem areas', and promoting specific reforms: in august 2011, the EPA entered an electronic reporting tool by amending TSCA IUR Rule (EPA, 2011a). Earlier review revealed that the lack of such a tool led to delay and inaccuracy in EPA's work (EPA, 2011b). In 2010, it entered stringent disclosure requirements by passing an administrative order on the two Carbon Nanostructures most commonly used in industrial commerce (Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes-CNTs). The required notification provided the EPA "with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs" (EPA, 2010). Thus, the two most important CNTs accounting for roughly 30 percent of global nanomaterials demand (NanoWerk NanoDatabases, 2011) are now specifically covered by the US reporting system. This burdensome regulatory initiative is particularly remarkable given the US strong incentive on retaining the global position of the US chemicals industry (CRS, 2008), which captured in 2010 the largest share, in terms of production capacity, of the carbon nanotubes global market (NanoWerk NanoDatabases, 2011). Also, heavily used regulatory loopholes have been specifically addressed by new provisions on confidentiality information claims (replacing the "not readily obtainable" loophole with the "not reasonably ascertainable") (EPA, 2011a). Finally, in 2012 rulemaking extended into generic use of Carbon nanostructures that were subjected to pre-manufacture review process (PMN), by the so-called 'chemicals of concern' order (EPA, 2012). Table 1 also shows that the majority of nano-reporting rulemaking is included within nonspecific regulation, with just a few nano-specific rules.

Third, the variety of regulatory tools has grown. Until 2009, *voluntary program* (NMSP) was practically the main tool for nanomaterials reporting. The role of voluntarism in reporting regulation seemed important as it reflected a commitment to data-sharing by industry sector, whereas a formal, coercive tool seemed an uncomfortable compromise by all parties (EPA, 2007a). Voluntarism was therefore the chosen pathway in US for governing a complex global regulatory issue, leaving discretion to manufacturers as to how they apply or exercise their power (CRS, 2008; EPA, 2007b, p. 63). However, since 2010 the number of regulatory tools has rapidly increased, including *Administrative Orders, Decisions, and Standard*. Finally, *coercive tools* have also become more common. Although the regulation appears to steer away from nano-specific data reporting, industry predictions expect many of the proposed changes to deeply impact the global nanomaterials market (see, for example, Nanotechnology Now, 2010).

In sum, the US influence over the global market rules has grown markedly. Amount, scope, and variety of data reporting regulation have markedly increased, especially in areas where US authorities and industry express divergent interests. The EPA systematically attempts to limit the industry's discretion and tries to increase the EPA's policy autonomy. It seems like a move toward global data reporting regulation that is a state-centric system of rulemaking. However, the *level* of centralization varies across issue

areas. For example, identifying priorities for review and assessment (the making of CNTs subject to strict notification requirements) is explicitly addressed by direct reporting regulation (EPA, 2010), but the administration of nano-industrial reporting is addressed by indirect regulation, under the CDR Rule (EPA, 2011a). In accord with others (Bosso, 2010; Stokes, 2013), we see the former type and subject of regulation as being essentially more socially and economy constructed, reflecting the progress in state regulatory capacity-building and exercise of formal government authority, especially in those areas in which the EPA has sound to support technological innovation and economic growth, while mindful of potential health and environmental risks of nanomaterials. Such regulatory dynamic reflects the key role that states play in advancing the dual and sometimes conflicting agendas of economic development and environmental quality.

4.2. EU: market entry regulation

A central concern is the ability of governments to control firms' entrance into market activity. Market entry (or access) regulation is most often favored for its perceived ability to offer a layer of protection for consumers (Svorny, 2000). Particular areas of interest for market entry regulation are initial Market ID (definition, classification), and registration requirements. Industry and regulators around the globe wrestle with the question whether and where new lines for market entry regulation should be drawn and concerns arise over governments' difficulty to define market entry policy (Bowman and Hodge, 2007). Should state institutions, the industrial community, or standardization organizations be positioned as the arbiter of a 'nanomaterial' regulatory definition? Should potentially dangerous substances be subjected to voluntary firms' self enforcement or to mandatory federal restriction and authorization procedures? Who has regulatory responsibility to maintain a global inventory and records of manufactured nanomaterials? How can government agencies literally reshape the access to global commercial production through regulatory means? Is it privatization and internationalization – or nationalization – that should instruct rulemaking on market entry? These are a few of the as of yet unresolved issues.

The REACH regulations, in force since 2007, have been accompanied by contentious discussions about their applicability to nanomaterials (Maynard, 2011). While the EU regulates the entry to the European market, the history of market entry regulation has been marked by state-private sector tensions and periodic proposals to strengthen state intervention (Selin and VanDeveer, 2006). Recent Parliament proposals (EP, 2009) to examine nanotechnology regulatory policies (food, workers protection, cosmetics and chemicals) have prompted another round of debate over the appropriate structure of Market entry regulation under REACH, the relative merit of privatization paradigms, and the *role of the state* in reconfiguration the role of private actors (see also Fisher, 2008; Heyvaert, 2010).

Table 2 provides an overview of major developments on market entry regulation for nanomaterials under REACH since 2008. While each regulatory issue area concerns the European market, the resulting regulatory policy is of 'macro-influence effect' (Bach and Newman, 2007), since EU establishes market entry standards for the global market as a whole (see also Selin and VanDeveer, 2006; Heyvaert, 2010).

Table 2 presents three trends. First, the absolute number of regulatory initiatives has grown. While the EC position in 2008 (EC, 2008a) stressed that REACH was sufficient to cover nanomaterials, since 2009 it processed at least three new regulatory and legal obstacles to industry's ability to enter the market, urged by the Parliament after disagreements with the EC position (EP, 2009, p. 10). A closer examination reveals control of highly political issues of market creation (e.g. registration thresholds, 'no data-no market' guiding principle). Incidentally, the number of initiatives under REACH concerning market entry enforcement has developed faster than those of alternative methods for risk assessment, though their promotion is a key purpose of the REACH regulatory regime (Selin and VanDeveer, 2006; Fisher, 2008). In the latter, a decentralization process of transnational regulation is still in progress, while much regulatory activity is being done by the OECD technical committee and market-driven forums, such as ISO (e.g. OECD, 2010). In other words, in Market entry the EU plays a central role in the global regulation of the market while in risk assessment it mostly rules in line with international initiatives.

Second, there is a mild trend toward revoking delegation of rulemaking from private actors in defining and enforcing criteria for market entry. Business rulemaking has played virtually the most important role in defining the European and the global markets semantics (EC, 2010; D'Silva, 2011). Almost all standardized vocabulary and core terms emanated from private international standards organizations with ISO at the forefront (including BSI, ASTM, IEC). Delegated rulemaking power to ISO on nano-related standards is provided by CEN (CEN/TC 352), which empowered CEN to propose the ISO documents for adoption as CEN documents using the Vienna Agreement process (EC, 2010). Recently, however, a European definition for the term 'nanomaterial' issued by the EC using the legal instrument of Commission Recommendation (EC, 2011a). The recommendation empowers the EC to implement existing EU legislation, including REACH, in line with the adopted definition. The new regulation, which deviated in central points from existing international standards (for a detailed review see EC, 2011b), actually recognized the failure of self-regulated private actors in defining nanomaterial, by direct supranational intervention (for industry comments see NIA, 2011). The EC itself recognized this point; in a 2011 policy press memo, it concluded that "the Commission has taken the ISO term 'nanomaterial' as the basis for its definition but has made a number of modifications which were deemed necessary to ensure its practical application in a regulatory context" (EC, 2011b). The EC's nano-team coordinator has also been quoted as saying that ultimately the decision on regulatory definition would be 'a policy one' rather than absolute scientific definition (Maynard, 2011). While the 'centeredness' of market entry regulation is limited, it is still remarkable that private rulemaking is underpowered, given the EC support on promoting self-regulation and market regulatory autonomy (for quotation of EC official Philippe Martin, see Monica, 2006).

Third, Table 2 indicates that market entry rulemaking is driven by two rationales: (1) promoting market integration, and (2) increasing administrative regulatory capacity. In 2011 the Commission agreed on a single definition for ensuring conformity across legislative areas and sectors and made a first legal step toward harmonizing the nanomaterials trade in EU markets (EC, 2010, 2011a; D'Silva, 2011, p. 85). As to the challenge of how to achieve adaptability in the new definition (Dana, 2010), one step is targeting technical assistance to the EC recommendation through the use of EU research institution – the European Research Initiatives (ERI). The Seventh Framework Program (FP7) is a broad initiative for research and technological development within the ERI, aimed primarily to increasing EU economic competitiveness (EC FP7, 2012). It also provides the development of technical assistance to relevant policies and instruments designed with an eye to boosting the 'innovation Union'. Technical assistance to the Definition was set in line with the requirements in the EC Recommendation (section 15) and includes 'Development of methods and standards supporting the implementation of the Commission recommendation for a definition of nanomaterial' (EC FP7, 2012, p. 3, 27).

Recently, a small but increasing number of decisions and regulations have focused on expanding the role of the new European

Table 2
Developments on market entry regulation under REACH.

Market entry policy area	Year	Regulatory issue area	Regulatory instrument	Policy tool	The extent or nature of state-centric market-constrained rulemaking
Substance identification	2011	Defining 'Nanomaterial'	Recommendation (European Commission, 2011a)	Supranational definition of a 'nanomaterial'	A constrain to the collective power of ISO and other private actors in defining and enforcing regulatory criteria for market ID
	2010	Substance detection	C&L Inventory (ECHA, 2012a,b)	Compile an inventory of nanomaterials by ECHA	Expanding the role of administrative agency (ECHA); improving the status of implementation and compliance over the global market
Registration	2008	Registration exemptions	Rule Amendment (European Commission, 2008b)	Carbon and Graphite were removed from the exemption list	Defining specific objects for active regulatory scrutiny over the global market
	2009	Information requirements	Resolution (European Parliament, 2009)	'No-data no market' guiding principle to apply under REACH	Reservation of decision-making power on market-entry policy at the EU level
	2009	Registration trigger	Resolution (European Parliament, 2009)	Call for (1) a change of criteria to trigger registration (threshold values); (2) a request for safety report for all registered nanomaterials	Enhancing regulatory implementation and compliance over the global market

Chemical Agency (ECHA) in registration mechanism: in 2009, the Parliament (EP, 2009) called to implement the 'no data no market' guiding principle by enforcing mandatory reporting system on nano manufacturers. In 2010, ECHA entered a 'nano inventory' under the new Parliament and Council regulation which supplements REACH (EP and Council, 2008). In 2009 and onwards, a systematic revision process (RIPoN) was launched by the Commission for advising ECHA in guidance to manufacturers, as the leading agency in REACH implementation. Moreover, in October 2012 the Commission adopted the Communication on the second regulatory review on nanomaterials, which describes the Commission's plans to improve EU law, including REACH and its application to ensure their safe use (EC, 2012). As a result, ECHA is expected to improve its power-imposing functions over the market (ECHA, 2012a). Finally, the publication of regulatory definition for nanomaterial has been welcomed by ECHA, reported as saying that nano definition will clarify responsibilities for ECHA and other players in the industry (ECHA, 2012b).

Bach and Newman (2007) argued that domestic administrative capacity and market integration are two institutional factors that augment EU's power on global rulemaking. The evidence suggests a clear trend toward enhancing these realms.

4.3. The EU's and US's centralized rulemaking compared

To fully appreciate the centralization in chemicals rulemaking we identified three essential differences between the EU and the US regulatory policymaking. First, the EPA lacks congressional support and leadership in shaping regulatory power over the global nanomaterials market through stressing relevant regulatory principles or practical needs. In the EU, by contrast, the Parliaments demands (specified in EP, 2009) serve as a 'blue print' for most of the recent EC regulatory initiatives. In a latest conference of the global chemicals industry, the EPA rulemaking was perceived as a collection of independently operating actors, as federal efforts to pass TSCA reform legislation are slowly proceeding (Sloan, 2012). Currently, US rulemaking seems as driven at the agency level rather than at the federal government level. Therefore, it might ultimately be challenged by the Congress.

Second, the US federal institutions have used their authority for external state sovereignty in a limited manner than the EU institutions. While the US continues to stall on domestic data reporting rules, European regulation has become the *de facto* international standard for market creation (EC, 2011a). Also, the Congress has rarely engaged in regulatory harmonization, which is a key feature of the EU regulatory policy. Cities and states have exercised regulatory power over nanomaterials issues, something that the Congress has been so far unwilling to do. These separate sources of regulatory power may represent a serious challenge for US leadership in risk regulation of the global nanomaterials market. A recent study (Kim et al., 2012) also reveals the US nano-scientists' disapproval from this regulatory path, with most scientists supporting federal-level or international nanotechnology regulation.

Third, the EU institutions have used more formal authority to reconfigure the role of global market actors than the US federal institutions. The EU independent policy choice on *political* definition of 'nanomaterial' (EC, 2011a) is a case in point. The EC declined a 'private global authorship (Hall and Biersteker, 2002) over the important issue of market ID by providing regulators with a simple legal reference to lean on. The EU institutions enjoy essentially unlimited authority under REACH to redefine state-market relationship affecting community safety. This includes the power to constrain the role of private actors and the market autonomy in the interest of sustainable development, but also the power to constrain the role of the state in the interest of privatization and market regulatory autonomy. By contrast, the mandate of the US federal authority under TSCA is limited, and the conceptual regulatory idea is that 'the market does not depend for its existence on the state (Fisher, 2008). Accordingly, the EPA's nano-policy focus is limited to enhancing regulatory compliance and does not include the restrictions on market creation or private actors' authority.

The initial comparison between the EU and the US highlights the essential features of state-centric rulemaking in transatlantic nanomaterials risk regulation. Although at their early stages of

development, their trajectory already contrasts the 'limited power' conception.

5. Concluding remarks and future research

The globalization of nanotechnology markets is accompanied by transnational developments in their environmental and safety regulatory policies. Decentralization of governance structure has been reported by proponents and critics in the nano-regulation literature. Accordingly, most observers agree that decentralization is dominant so far in the transnational nanotechnology risk governance domain. We focused on developments in the EU's and US's behavior as risk regulators in a global regulatory environment, and showed that decentralization alone is insufficient to understand the transnational risk governance of nanotechnology. Findings from two case studies broadly support this claim by showing a political regulatory process toward centralization of regulatory power in nanomaterials risk policy fields. They also reveal that the EU and the US have chosen different regulatory pathways to meet transnational risk challenges through state-centric regulation. The study thus highlights more generally the limits of decentralization as a potential regulatory policy tool to increase oversight over global nanotechnology markets.

Future research should address an empirical scope beyond the cases and markets analyzed in this paper. Initial examination suggests that parallel state-centric rulemaking is underway in other nano-policy fields such as workplace safety and that those are beginning to affect global nanotechnology markets; a key example is the draft recommended exposure limits for carbon nanotubes and nanofibers established by the US National Institute for Occupational Health and Safety (NIOSH, 2010). It would be interesting to derive more general conclusions on whether the global challenge of nanotechnology risks and uncertainties is best met through state-centric regulation and through adapting existing regulation (see recent discussion by Stokes, 2012). In this context, further work should also examine whether the EU is increasingly replacing the US as the *de-facto* setter of global nano risk regulation, as already observed in other policy fields (Selin and VanDeveer, 2006).

Be that as it may, our findings are not consistent with the predominant view in the nano-regulation literature about the limited regulatory power of states over the global market and the emergence of private and decentralized rulemaking. These findings, however, are consistent with a growing body of literature that argues that it is important not to underestimate the collective power of states in defining global regulatory policies (Levy, 2006; Drezner, 2007; Bach and Newman, 2007). Much of the existing nano-regulation literature focuses on a lack of states' regulatory capacity or political will; the evidence shows an adapted path of regulatory policy making, in which the EU and the US institutions exercise centralized power within their policies to identify and influence technology trajectories in order to achieve socially desirable ends.

Early experiments in voluntary approach or market-based programs have paved the way for the increased role of governments in reducing – or controlling the understanding of – scientific uncertainties, a process which still leaves nano actors with significant regulatory impact. The EU and US regulatory systems are currently managed adaptively to determine their relationship with international industry and research communities. This is done by maintaining a dialog on accumulated scientific developments, prioritizing subjects for 'regulatory science' (supporting research on risk assessment methods and toxicity parameters), redressing information deficiencies, studying production volumes, and upholding the government role essential to sustainable technology and innovation policy.

Acknowledgments

Our sincere thanks to Prof. David Levi-Faur for sharing expertise and invaluable guidance. Thanks to the participants in the 2010 and 2012 conferences of the European Consortium on Political Research (ECPR) Standing Group on Regulatory Governance and participants in the 2010 conference of the Society for Risk Analysis-Europe (SRA-EU) for their insights at various stages of this research. Thanks to the Israeli Ministry of Science and Technology (MOST) for the generous funding of this research by the Levi Eshkol Fund for science policy research 2009–12. Finally, we thank the two anonymous reviewers for their helpful reviews. The authors are solely responsible for the conduct of this research and for the paper's content.

References

Abbott, K.W., Snidal, D., 2009. The governance triangle: regulatory standards institutions and the shadow of the state. In: Mattli, W., Woods, N. (Eds.), The Politics of Global Regulation. Princeton University Press, Princeton, New Jersey, pp. 44–88.

Abbott, K.W., Marchant, G.E., Sylvester, D.J., 2010. Transnational regulation of nanotechnology: reality or romanticism? In: Hodge, G.A., Bowman, D.M., Maynard, A.D. (Eds.), International Handbook on Regulating Nanotechnology. Edward Elgar, Cheltenham, pp. 525–544.

Aitken, R.J., Hankin, S.M., Ross, B., Tran, C.L., Stone, V., Fernandes, T.F., Donaldson, K., Duffin, R., Chaudhry, Q., Wilkins, T.A., Wilkins, S.A., Levy, L.S., Rocks, S.A., Maynard, A., 2009. EMERGNANO – a review of completed and near completed environment, health and safety research on nanomaterials. In: DEFRA Report CB0409 (downloaded on 15.01.2013 from http://www.iom-support.co.uk/Portals/3/SN_Content/Documents/EMERGNANO_CB0409_Full.pdf).

Bach, D., Newman, A.L., 2007. The European regulatory state and global public policy: micro-institutions, macro-influence. Journal of European Public Policy 14, 827–846.

Bell, S., Hindmoor, A., 2009. Rethinking Governance: The Centrality of the State in Modern Society. Cambridge University Press, Cambridge.

Bergeson, L.L., 2007. Good governance: evolution of the nanoscale materials stewardship program. Nanotechnology Law & Business 4, 473–483.

Bernstein, S., Cashore, B., 2007. Can non-state global governance be legitimate? An analytical framework. Regulation & Governance 1, 347–371.

Black, J., 2002. Critical reflections on regulation. Australian Journal of Legal Philosophy 27, 1–35.

Bosso, C. (Ed.), 2010. Governing Uncertainty: Environmental Regulation in the Age of Nanotechnology. Earthscan Press, Washington, DC.

Bowman, D.M., Hodge, G.A., 2007. A small matter of regulation: an international review of nanotechnology regulation. Columbia Science and Technology Review 8, 1–36.

Bowman, D.M., Hodge, G.A., 2008. Governing nanotechnology without government. Science and Public Policy 35, 475–487.

Bowman, D.M., Van Calster, G., 2007. Reflecting on REACH: global implications of the European Union's chemicals regulation. Nanotechnology Law & Business 4, 375–384.

Bowman, D.M., Gilligan, G., 2010. The private dimension in the regulation of nanotechnologies: developments in the industrial chemicals sector. UCLA Journal of Environmental Law & Policy 28, 1–39.

Breggin, L., Falkner, R., Jaspers, N., Pendergrass, J., Porter, R., 2009. Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation. Chatham House, London.

Büthe, T., Mattli, W., 2011. The New Global Rulers: The Privatization of Regulation in the World Economy. Princeton University Press, New Jersey.

Cientifica, 2007. Half Way to the Trillion Dollar Market? A Critical Review of the Diffusion of Nanotechnologies, Market Report (downloaded on 15.01.2013 from http://www.cientifica.com/WhitePapers/054_A%20Reassessment%20of%20the%20Trillion%20WP.pdf).

CRS, 2008. Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges. CRS Report for the Congress, Paper 50, January 1 (downloaded on 15.01.2013 from http://www.fas.org/sgp/crs/misc/RL34332.pdf).

Dana, D.A., 2010. Can the law track scientific risk and technological innovation? The problem of regulatory definition and nanotechnology. In: Working Paper, Northwestern University School of Law (downloaded on 15.01.2013 from http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1112&context=facultyworkingpapers).

Davies, C.J., 2008. Nanotechnology oversight: an agenda for the new administration. In: PEN 13, Project on Emerging Nanotechnologies, Washington, DC.

Denison, R.A., 2010. State-Level Nano Regulation: Yes, Indeed, the Industry Should Have Seen It Coming – It Caused It!, Available at: http://blogs.edf.org/nanotechnology/2010/09/10/state-level-nano-regulation-yes-indeed-the-industry-should-have-seen-it-coming-%E2%80%93-it-caused-it/last (accessed 15.01.2013).

Denison, R.A., 2011. A Sea of Red Herrings is Behind Opposition to EPA's Proposal to Enhance Chemical Reporting, Available at: http://blogs.edf.

org/nanotechnology/2011/04/07/a-sea-of-red-herrings-is-behind-opposition-to-epa%E2%80%99s-proposal-to-enhance-chemical-reporting/ (last accessed 15.01.2013).
Drezner, D.W., 2007. All Politics is Global: Explaining International Regulatory Regimes. Princeton University Press, Princeton, New Jersey.
D'Silva, J., 2011. What's in a name? Defining a 'nano-material' for regulatory purposes in Europe. European Journal of Risk Regulation 1, 85–91.
ECHA, 2012. ECHA Plans to Update its Guidance for Registration of Substances in Nanoform, News Alert, ECHA/NA/12/04.
ECHA, 2012. ECHA and MSCAa Pave the Way for Further Assessment of Nanomaterials Under REACH, News Alert, ECHA/NA/12/29.
ED-DuPont, 2007. Environmental Defense-DuPont. Nano Risk Framework. Nano Partnership. June 2007 (downloaded 15.01.2013 from http://apps.edf.org/documents/6496_nano%20risk%20framework.pdf).
Egan, M., 2012. Single Markets: Economic Integration in Europe and the United States. Oxford University Press, USA.
EPA, 2003. TSCA Inventory Update Rule Amendments. Federal Register 68 (848).
EPA, 2007a. Concept Paper for the Nanoscale Materials Stewardship Program Under TSCA (downloaded on 15.01.2013 from http://www.epa.gov/oppt/nano/nmsp-conceptpaper.pdf).
EPA, 2007b. Nanotechnology White Paper, EPA 100/B-07/001.
EPA, 2008a. Toxic Substances Control Act Inventory Status of Carbon Nanotubes. Federal Register 73 (212).
EPA, 2008b. TSCA Inventory Status of Nanoscale Substances – General Approach (downloaded on 15.01.2013 from http://www.epa.gov/oppt/nano/nmspfr.htm).
EPA, 2009. Nanoscale Materials Stewardship Program. Interim Report (downloaded on 15.01.2013 from http://epa.gov/oppt/nano/nmsp-interim-report-final.pdf).
EPA, 2010. Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules. Federal Register 75 (180).
EPA, 2011a. TSCA Inventory Update Reporting Modifications; Chemical Data Reporting. Federal Register 76 (158).
EPA, 2011. EPA Needs to Manage Nanomaterial Risks More Effectively. Interim Report (downloaded on 15.01.2013 from http://www.epa.gov/oig/reports/2012/20121229-12-P-0162.pdf).
EPA, 2012. Significant New Use Rules on Certain Chemical Substances. Federal Register 77 (80).
European Commission, 2008a. Regulatory Aspects of Nanomaterials. Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, COM (2008) 366 final.
European Commission, 2008. Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V, Official Journal of the European Union L 268/14.
European Commission, 2010. Considerations on a Definition of Nanomaterial for Regulatory Purposes. JRC Reference Reports. JRC58726.
European Commission, 2011a. Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial, Official Journal of the European Union L 275/38.
European Commission, 2011b. Questions and answers on the Commission Recommendation on the Definition of Nanomaterial, October 18, 2011 (downloaded on 15.01.2013 from http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/704&format=HTML&aged=1&language=EN&guiLanguage=en).
European Commission, 2012. Second Regulatory Review on Nanomaterials. Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, COM (2012) 572 final.
European Commission FP7, 2012. Seventh Framework Programme. 2013 Work Programmes. Cooperation (downloaded on 15.01.2013 from http://cordis.europa.eu/fp7/wp-2013_en.html).
European Parliament and Council, 2006. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Official Journal of the European Union L 396/49.
European Parliament and Council, 2008. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation), Official Journal of the European Union L 353/1.
European Parliament, 2009. European Parliament Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials (2008/2208(INI)). Texts Adopted, P6_TA(2009)0328.
Evans, P., 1997. The eclipse of the state? Reflections on stateness in an era of globalization. World Politics 50 (1), 62–87.
Falkner, R., 2003. Private environmental governance and international relations: exploring the links. Global Environmental Politics 3 (2), 72–87.
Falkner, R., Jaspers, N., 2012. Regulating nanotechnologies: risk, uncertainty and the global governance gap. Global Environmental Politics 12 (1), 30–55.
Faulkner, A., 2009. Regulatory policy as innovation: constructing rules of engagement for a technological zone of tissue engineering in the European Union. Research Policy 38, 637–646.
Fisher, E., 2008. The 'perfect storm' of REACH: charting regulatory controversy in the age of information, sustainable development, and globalization. Journal of Risk Research 11, 541–563.
Forsberg, E.M., 2011. Standartization in the field of nanotechnology: some issues of legitimacy. Science and Engineering Ethics, http://dx.doi.org/10.1007/s11948-011-9268-0.
GAO, 2010. Nanomaterials are Widely Used in Commerce, but EPA Faces Challenges in Regulating Risk. GAO-10-549 (downloaded on 15.01.2013 from http://www.gao.gov/assets/310/304648.pdf).
Gilbert, N., 2009. Nanoparticle safety in doubt. Nature 460, 937.
Haas, P.M., 2004. Addressing the global governance deficit. Global Environmental Politics 4 (4), 1–15.
Hall, R.B., Biersteker, T.J. (Eds.), 2002. The Emergence of Private Authority in Global Governance. Cambridge University Press, Cambridge.
Hansen, S.F., 2010. A global view of regulations affecting nanomaterials. Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology 2, 441–449.
Heyvaert, V., 2010. Regulating chemical risk: REACH in a global governance perspective. In: Eriksson, J., Gilek, M., Rudén, C. (Eds.), Regulating Chemical Risks: European and Global Challenges. Springer, Dordrecht, the Netherlands, pp. 217–238.
ISO, 2010. International Organization for Standardization. ISO 10808:2010. Nanotechnologies: Characterization of Nanoparticles in Inhalation Exposure Chambers for Inhalation Toxicity Testing. TC 229 Nanotechnologies.
Jasanoff, S., 2005. Designs on Nature: Science and democracy in Europe and the United States. Princeton University Press, Princeton. NJ.
Jayasuriya, K., 2001. Globalisation and the changing architecture of the state: regulatory state and the politics of negative co-ordination. Journal of European Public Policy 8, 101–123.
Kelemen, D.R., Vogel, D., 2010. Trading places: the role of the United States and the European Union in international environmental politics. Comparative Political Studies 43, 427–456.
Kim, Y., Corley, E.A., Scheufele, D.A., 2012. Classifying US nano-scientists: of cautious innovators, regulators, and technology optimists. Science and Public Policy 39, 30–38.
Kulinowski, K., 2009. Multi-walled Carbon Nanotubes and Meshothelioma. ICON Backgrounder, Available at: http://icon.rice.edu/resources.cfm?doc_id=12299 (last accessed 15.01.2013).
Lamprou, A., 2010. Nanotechnology Regulation: Policies Proposed by Three Organizations for the Reform of the Toxic Substances Control Act. Chemical Heritage Foundation, USA.
Levi-Faur, D., 2005. The global diffusion of regulatory capitalism. Annals of the American Academy of Political and Social Sciences 598, 12–32.
Lin, A.C., 2007. Size matters: regulating nanotechnology. Harvard Environmental Law Review 31, 349.
Linkov, I., Satterstrom, F.K., Monica Jr., J.C., Hansen, S.F., Davis, T.A., 2009. Nano risk governance: current developments and future perspectives. Nanotechnology Law & Business 6, 203–220.
Levy, J.D. (Ed.), 2006. The State after Statism: New State Activities in the Age of Liberalization. Harvard University Press, Cambridge, MA.
Majone, G., 1996. Regulating Europe. Routledge, London.
Majone, G., 2004. The Internationalization of Regulation: Implications for Developing Countries. Working Paper 57. Center on Regulation and Competition, University of Manchester (downloaded on 15.01.2013 from http://www.competition-regulation.org.uk/publications/working_papers/WP57.pdf).
Malloy, T.F., 2011. Nanotechnology regulation: a study in claims making. ACS Nano 5, 5–12.
Marchant, G.E., Sylvester, D.J., Abbott, K.W., 2007. Nanotechnology regulation: the United States approach. In: Hodge, G.A., Bowman, D.M., Ludlow, K. (Eds.), New Global Frontiers in Regulation: The Age of Nanotechnology. Edward Elgar, Cheltenham, pp. 189–210.
Marchant, G.E., Abbott, K.W., Sylvester, D.J., Gulley, L.M., 2012. Transnational new governance and the international coordination of nanotechnology oversight. In: Dana, D.A. (Ed.), The Nanotechnology Challenge: Creating Legal Institutions for Uncertain Risks. Cambridge University Press, New York, pp. 179–202.
Maynard, A.D., 2011. Don't define nanomaterials. Nature 475, 31.
Monica, J.R., 2006. EC Official Urges International Cooperation. Quotation of Philippe Martin, Principal Administrator for the EC's Nanotechnology and Policy Efforts. October 30, Available at: http://www.nanolawreport.com/articles/eu-1/#axzz21i9MXP26 (last accessed 15.01.2013).
Nanotechnology Industries Association (NIA), 2011. NIA Comments on the History of the EU's Definition of Nanomaterials, Available at: http://www.nanotechia.org/nia-press/nia-comments-on-the-history-of-the-eu-s-definition-of-nanomaterials (last accessed 15.01.2013).
Nanotechnology Now, 2010. 2010 To Be a Busy Year for Regulation of Nanotechnology. April 15, Available at: http://www.nanotech-now.com/columns/?article=437 (last accessed 15.01.2013).
NanoWerk NanoDatabases, 2011. Global Carbon Nanotubes Market – Industry Beckons, Available at: http://www.nanowerk.com/spotlight/spotid=23118.php (last accessed 15.01.2013).
National Institute for Occupational Safety and Health (NIOSH), 2010. Occupational Exposure to Carbon Nanotubes and Nanofibers. NIOSH Docket Number: NIOSH 161-A (downloaded on 15.0.1.2013 from http://www.cdc.gov/niosh/docket/review/docket161A/default.html).
NLR, 2008. Nanotechnology Law Report: First EPA Nanoscale Materials Stewardship Program Submission (downloaded on 15.0.1.2013 from http://www.nanolawreport.com/NanoLawReportJanuary2008.pdf).
O'Brian, F.P., 2012. An overview of the law of nanotechnology. In: Dana, D.A. (Ed.), The Nanotechnology Challenge: Creating Legal Institutions for Uncertain Risks. Cambridge University Press, New York, pp. 357–378.

OECD, 2010. Risk Assessment of Manufactured Nanomaterials in a Regulatory Context. Report of the Workshop on Environment Directorate. Joint Meeting of the Chemicals Committee, 16–18 September 2009 (ENV/JM/MONO(2010)4). OECD, Paris (downloaded on 15.0.12013 from http://search.oecd.org/officialdocuments/displaydocumentpdf/?doclanguage=en&cote=ENV/JM/MONO(2010)4).

Pattberg, P., 2005. The institutionalization of private governance: how business and nonprofit organizations agree on transnational rules. Governance 18, 589–610.

Peters, B.G., Pierre, J., 1998. Governance without government? Rethinking public administration. Journal of Public Administration Research and Theory 8, 223–243.

Pollack, M.A., 2007. Regulating risk in a global economy: law, politics and the struggle to govern genetically modified foods. In: Paper Presented at the European Union Studies Association Biennial International Conference, Montreal, Canada, 17–19 May 2007.

Potoski, M., Prakash, A., 2005. Green clubs and voluntary governance: ISO 14001 and firms' regulatory compliance. American Journal of Political Science 49, 235–248.

PRNewswire Reports, 2011. Global Nanomaterials Industry, Available at: http://www.prnewswire.com/news-releases/global-nanomaterials-industry-115089444.html (last accessed 15.01.2013).

Renn, O., Roco, M.C., 2006. Nanotechnology and the need for risk governance. Journal of Nanoparticle Research 8, 153–191.

ReportsnReports, 2011. Nanotechnology: A Realistic Market Assessment, Market Report (downloaded on 15.0.12013 from http://www.slideshare.net/linda3395/nanotechnology-a-realistic-market-assessment-9353577).

Research and Markets, 2011. Nanomaterials Production 2002–2016: Production Volumes, Revenues and End User Market Demand, Available at: http://www.nanotech-now.com/news.cgi?story_id=43497 (last accessed 15.01.2013).

Rosenau, J.N., Czempiel, E.O. (Eds.), 1992. Governance Without Government: Order and Change in World Politics. Cambridge University Press, Cambridge.

Sanderson, K., 2008. Carbon nanotubes: the new asbestos? Nature News, Available at: http://www.nature.com/news/2008/080520/full/news.2008.845.html (last accessed 15.01.2013).

Scenihr, 2007. The Scientific Committee on Emerging and Newly Identified Health Risks. The Appropriateness of the Risk Assessment Methodology in Accordance with the Technical Guidance Documents for New and Existing Substances for Assessing the Risks of Nanomaterials (downloaded on 15.0.1.2013 from http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_004c.pdf).

Scenihr, 2009. The Scientific Committee on Emerging and Newly Identified Health Risks. Nanomaterials, Available at: http://ec.europa.eu/health/scientific_committees/opinions_layman/nanomaterials/en/l-3/6.htm (last accessed 15.01.2013).

Selin, H., VanDeveer, S.D., 2006. Raising global standards: hazardous substances and e-waste management in the European Union. Environment: Science and Policy for Sustainable Development 48 (10), 6–18.

Sloan, L., 2012. Speech by Lawrence Sloan, President & CEO. In: Synthetic Organic Chemical Manufacturers Association (SOCMA) Global Chemical Regulations Conference, March 6, Baltimore, MD, Available at: http://www.socma.com/pressRoom/?subsec=13 (last accessed 15.01.2013).

Smith, M.P., 2010. Single market, global competitions: regulating the European market in a global economy. Journal of European Public Policy 17, 936–953.

Song, Y., Li, X., Du, X., 2009. Exposure to nanoparticles is related to pleural effusion, pulmonary fubrosus and granuloma. European Respiratory Journal 34, 559–567.

Stokes, E., 2012. Nanotechnology and the products of inherited regulation. Journal of Law and Society 39, 93–112.

Stokes, E., 2013. Demand for command: responding to technological risks and scientific uncertainties. Medical Law Review 21, 11–38.

Svorny, S., 2000. Licensing, market entry regulation. In: Bouckaert, B., De Geest, G. (Eds.), Encyclopedia of Law and Economics. Edward Elgar, Cheltenham, pp. 296–328.

The White House, 2011. Executive Order 13563 of January 18, 2011. Improving Regulation and Regulatory Review. Federal Register 76 (14).

The White House ETIPC, 2011. Memorandum: Principles for Regulation and Oversight of Emerging Technologies. March 11. Washington, DC (downloaded on 15.0.1.2013 from http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf).

Vogel, D., 2003. The politics of risk regulation in Europe and the United States. In: Somsen, H. (Ed.), The Yearbook of European Environmental Law, vol. 3. Oxford University Press.

Vogel, D., 2012. The Politics of Precaution: Regulating Health, Safety and Environmental Risks in Europe and the United States. Princeton University Press, Princeton, NJ.

Wijnhoven, et al., 2009. Nano-silver – a review of available data and knowledge gaps in human and environmental risk assessment. Nanotoxicology 3, 109–138.

Young, O.R. (Ed.), 1997. Global Governance: Drawing Insights from the Environmental Experience. MIT Press, Cambridge.