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

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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

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[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.

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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.