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Explaining Transatlantic Policy Divergence: The Role of Domestic Politics and Policy Styles in Nanotechnology Risk Regulation

*Ronit Justo-Hanani and Tamar Dayan**

Abstract

In this study, we seek to explain a growing divergence between the US and EU regulatory policies over nanotechnology environmental, health, and safety risks. Faced with significant scientific and regulatory uncertainties, incremental approaches have been taken in both regulatory systems, but substantial differences are evident in terms of both policy processes and stringency. While the EU exhibits a regulatory integration process with stringent adjustments of existing legislative frameworks, the US is far less engaged in regulatory adaptations. We have carried out a comparative analysis of the EU and US regulatory policies. We suggest that literature perspectives that focus on differing public attitudes, economic interests, and advocacy pressure groups do not suffice to explain the regulatory policy divergence. We argue that a combined effect of domestic politics and policy styles provides the most powerful explanation of why the US and EU currently differ with respect to their regulatory responses to nanotechnology risks and uncertainties.

This article is motivated by two related empirical puzzles. First, the US and EU have shown increasing policy divergence in recent years over nanotechnology[1] environmental, health, and safety (EHS) risks, despite the globalized nature of nanotechnology markets, technological innovation, and entrepreneurship trends.[2] Second, in the EU, despite a substantial economic burden, and in the

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1. Nanotechnology involves the manipulation of matter, discussed here in the context of chemicals or materials typically manufactured in the 1- to 100-nanometer size range that enter the market as industrial raw materials and components of consumer products.
2. For the benefits of policy coordination, see Breggin et al. 2009.

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absence of a policy crisis, intensive regulatory activity has occurred, including labeling requirements, regulatory recasts, and adaptations.

While nanotechnology is expected to transform the global industry arena, its EHS regulation poses similar challenges to regulators on both sides of the Atlantic. Better toxicity assessments, coherence between scientific developments and risk regulation, and legal clarity have become matters of dynamic politics. However, while the two regulatory systems are similar in their objectives (European Commission [EC] 2004; Sargent 2013)—protecting public health and the environment while promoting innovation—their regulatory policies exhibit divergent trajectories in terms of both policy process and stringency.

These patterns require the analysis of political factors that have influenced the EU and US regulatory responses with diverging policy effects. Domestic politics and policy-making factors, while not the only candidates for this role, are worth examining, since they can illuminate policy paths and may shed light on future transatlantic regulatory developments. However, although scholars have analyzed the regulatory dynamics of nanotechnology risks in Europe and the US, significantly less attention has been given to the growing differences in regulatory policies and the deeper political factors behind the apparent divergence. This study seeks to fill this gap.

What are the reasons and sources of the variations in the EU's and the US's nanotechnology regulatory risk policies? More specifically, what accounts for the more extensive, innovative, and stringent EU regulatory policy, when compared to the US? We recognize that the concept of policy divergence is multifaceted (Knill 2005; Steinberg and VanDeveer 2012), and that the US and EU have been engaged in cooperative efforts through international and bilateral forums on some technical areas of regulatory practices on nanomaterials (NMs); see, e.g., High-Level Regulatory Cooperation Forum (HLRCF) 2010. Nonetheless, we argue that with regard to international environmental politics, a marked divergence has occurred, and that a combination of domestic politics and policy styles provides the most powerful explanation for this growing regulatory difference.

This article presents three contributions. Analytically, it brings *policy process* to the fore, in addition to *stringency*, which has already been identified as a benchmark for transatlantic regulatory divergence (Vig and Faure 2004; Vogel 2003; Vogel 2012). A process-oriented approach to the question of regulatory divergence highlights the importance of institutional settings and policymaking patterns. It thus provides insight into the complex channels by which divergence is created (Schreurs et al. 2009; Steinberg and VanDeveer 2012, 5). It also expands upon Falkner and Jaspers's (2012) analysis, which infers potential transatlantic regulatory divergence on nanotechnology risks, providing a systematic comparative perspective in view of broader explanations for this phenomenon. Moreover, embedding the nanotechnology case within the broader divergence-convergence debate (Busch et al. 2012) creates new empirical insight and testing grounds for established comparative environmental politics theories.

The empirical analysis draws extensively on reviews of key policy documents and professional reports, analysis of rulemaking and policy actions across key policy areas, written material produced by industry alliances and the NGO community, as well as the nano-regulation and governance literature. Methodologically, we use a comparative analysis and process tracing across the EU and US case studies, assessing theoretical arguments against the empirical record, to identify which factors underlie the observed regulatory divergence. Process tracing is particularly useful for tracing the European roots of the regulatory policy, identifying key political players and institutional contexts that led to the acceleration of the policy process and stringency.

We begin by characterizing briefly what is meant by transatlantic policy divergence in the nanotechnology EHS risks context. Before outlining our particular approach, we review pervasive explanations for policy divergence that invoke differences in (a) public views, (b) economic interests, and (c) advocacy pressure groups. While much theoretical work on the patterns of transatlantic divergence has focused on these determinants, we argue that such explanations do not fully account for intriguing policy variations across regions for the nanotechnologies sector, and for the acceleration of EU policy process. In the following section, we introduce and discuss an explanatory approach that shows how the combined effect of domestic politics and policy styles drives policy divergence. The remainder of the study focuses on three derived explanatory variables—institutional politics, the degree of precaution reflected in regulatory approaches, and global leadership ambitions—through which we illustrate and assess the divergence argument. The three variables provide considerable differences in the EU's and the US's regulatory policies, offering an intriguing setting to scrutinize mechanisms for divergence at work. We find that domestic politics and policy styles drive the recent ascendance of the EU's regulatory process and stringency, adding, more generally, to research focused on the important link between international cooperation on EHS regulation and domestic policy dynamics (e.g., Busch et al. 2012).

Regulatory Policy Divergence: A Brief Overview

Nanotechnology is a new frontier of enabling technologies promising huge economic benefits; it allows the creation of structures and devices for diverse industries, including medicine, foods, electronics, and energy. The Project on Emerging Nanotechnologies currently lists 1,628 products available on the market, suggesting that numbers could be significantly higher.[3] Estimates suggest that revenues from products incorporating nanotechnology could reach $4.4 trillion by 2018 (Lux Research 2014; Sargent 2014). The US and EU are two of the world's largest nanotechnology manufacturers, investors, and traders; estimates show that the US, through its National Nanotechnology Initiative (NNI), has

3. Available at www.nanotechproject.org/cpi/.

invested approximately US$ 3.7 billion in R&D, the EU has invested US$ 1.7 billion, and Japan US$ 950 million (Lux Research 2014; OECD/NNI 2013).

However, toxicological and eco-toxicological reviews have challenged the safety of NMs; studies have demonstrated that nanoparticles can penetrate DNA and cause harm to lung, skin, brain, and digestive system cells (SCENIHR 2009). Some forms of carbon nanotubes (CNTs) could be as harmful as asbestos (Sanderson 2008). Nanoparticles enter ecological systems through materials taken to dumps, incinerated, or washed down the drain. Studies have shown that exposure to NMs dispersed in air, aquatic environments, soil, and sediments can cause harmful effects to key ecological groups (Oberdörster 2004; SCENIHR 2009). However, given the novelty of such materials, fundamental uncertainties remain regarding their effects. Policy advocates have expressed worries that the debate on regulating nanotechnology risks and uncertainties is lagging behind technological innovation, and they have questioned the adequacy of existing risk assessment and management frameworks. Technical issues—for instance, toxicity testing methods and exemption from regulation due to NM sizes that do not meet the existing thresholds—have become matters of concern among regulatory authorities (Linkov et al. 2009).

While regulatory strategies for handling NMs in both the EU and the US have drawn on an incremental approach using existing regulatory frameworks, a marked divergence is emerging in both their policy processes and stringency. Looking at the *stringency* of regulation, the EU has played an innovative role in the adoption of mandatory labeling and traceability requirements for cosmetics, food, and biocidal products by the end of 2013 (Hull and Bowman 2014; Pendergrass et al. 2010). For example, manufacturers of cosmetics products must list NM ingredients using identical terms across the EU, in addition to gaining premarket approval and providing information on particle sizes and percentages to regulatory authorities. These developments mark a significant deviation from regulatory tools in the US, which has not established any labeling requirements for nano-products or their ingredients. (For a detailed description and comparative analysis on EU and US regulatory systems for handling NMs, see Breggin et al. 2009; for nano-products labeling as a controversial issue on the transatlantic regulatory agenda, see Falkner and Jaspers 2012).

Likewise, there is apparent divergence in *policy processes*. In the EU a thorough process of regulatory adjustments has been taking place and has gathered momentum since 2009 (Justo-Hanani and Dayan 2015). It is aimed at creating an integrated regulatory policy for nanotechnology at the EU level, followed by an action plan and implementation reports (EC 2004; EC 2007; EC 2008). The broadening and deepening of centralized, harmonized NM risk regulation have resulted so far in the creation of a "nanomaterial" definition for regulatory purposes; an increasing number of recasts and adaptations to existing EU legislation (related to chemicals, cosmetics, hazardous substances, waste electrical and electronic equipment, plastic food contact material, medical devices, and biocidal products regulations); new nano-specific rules in areas such as premarket safety testing, market

notification, and data disclosure; as well as an ongoing process of reviewing existing regulatory frameworks, especially the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation, upon regular feedback from member states (Bowman et al. 2010; EC 2011; EC 2012; Hull and Bowman 2014).

The EU has also moved to enhance *implementation of* and *compliance with* the new regulatory recasts and adaptations. Principally, a multilevel governance model was set to reinforce the EU's "safe, integrated, and responsible" (SIR) approach to nanotechnologies, by engaging national authorities, stakeholders, and citizens in the design and implementation of nano-regulation (EC 2004; Rodine-Hardy 2010). Regulatory capacity-building efforts are further targeted through the use of the EU FP7 and Horizon 2020 programs, including proactive cooperation between the competent authorities and industry on identifying needs within regulatory frameworks (e.g., NanoForce), the development of implementation methods for specific legislative contexts (e.g., i-Nanotool), and the facilitation of a common European approach to NM regulatory testing, with multiple partners (e.g., NANoREG). "In-house" scientific committees also provide the EC with technical advice on regulatory policy execution (JRC 2014; SCENIHR 2009).

In the US federal system, by contrast, there currently have been no legislative reform or comprehensive adjustments of regulatory frameworks (for critical views, see Bosso 2013; Nash 2012). Authorizations of NM applications are channeled through a long-established regulatory regime, in a case-by-case approach. Decentralized regulatory oversight has drawn mainly on the expertise of the Environmental Protection Agency (EPA), the Food and Drug Administration, and the National Institute for Occupational Health and Safety (NIOSH). During the Obama administration, some policy changes have taken place, including use restrictions for multi-walled CNTs under the Toxic Substances Control Act (TSCA) (EPA 2009; EPA 2014) and the establishment of exposure limits for CNTs and nanofibers (NIOSH 2013). However, these changes have focused on a narrow set of regulatory instruments on specific NMs rather than signifying a process of regulatory reform. This has led scholars to view US nanotechnology regulation as a piecemeal approach, arguing that "there is no official government-wide effort to deal with the regulation of nanotechnology" (e.g., Bawa 2013, 721; Davies 2008, 5). An OECD report on nanotechnology regulatory regimes has demonstrated that almost all respondents plan amendments to existing legislations, with the exception of the US (OECD 2014, 17).

Overall, the EU exhibits a much more proactive regulatory approach, in terms of both policy process and stringency, as compared to the US. The early-stage manifestations of these differences have not been characterized by high-profile regulatory disputes with a negative impact on trade relations, as was manifested in cases such as hormone-treated beef and genetically modified food (Busch et al. 2012). Yet, industry associations increasingly express concerns about the challenges facing US companies exporting NMs to the EU,

with "Europe at the forefront of legislative developments in this area" (NIA 2014, 1).

Possible Explanations for the Transatlantic Policy Divergence

Various attempts have been made to explain transatlantic regulatory divergence over EHS risks.

Advocacy Pressure Groups

Political economy perspectives emphasize the role of industry lobbies in US policymaking versus that played by environmental NGOs' lobbies in the EU (Bernauer and Meins 2003; Coen 2007; Rosendal 2005). As was previously argued, the diverging interests and influences of lobbying alliances ultimately explain the diminished rigor of EHS regulation in the US compared with the EU (Grant et al. 2000).

However, while both American and European regulatory contexts have been dominated so far by strong nanotech coalitions, including manufacturers, trade associations, and international standards organizations (e.g., ASTM International and ISO), there is not yet strong evidence of environmental NGOs having overcome their influence in EU policymaking. For example, the EC rejected the Friends of the Earth's and Greenpeace's calls for a complete moratorium on nano-products' commercialization until they were proven safe (FramingNano 2009); the position of environmental NGO coalitions against the conclusion of the Second Regulatory Review on NMs (EC 2012a) did not prevail, nor did their proposal for a "nano-patch" for REACH annexes, including provisions for all NMs to be considered distinct from their bulk counterparts and for lower registration thresholds (Azoulay et al. 2012). Miller and Scrinis (2010, 437) argued that "despite the inclusion of NGOs in dialogue activities, it is apparent that NGOs are not accorded the same value attributed to other stakeholders in nanotechnology decision-making." Contrary to their prominent role in the debate on genetically modified organisms (Bernauer and Meins 2003), environmental NGOs' campaigns in Europe did not manage to drive a wedge between nano-industry and EU decision-makers. Hess (2010) attributes this to financial constraints and to "undone science," which, combined, seriously limit the influence of many environmental NGOs, especially smaller ones. Kearnes and Rip (2009, 8) have also proclaimed the ambivalent role of NGOs and civil society groups, which did not coordinate their strategies and action, and this possibly also hampered their influence on policy-making processes. The evidence, indeed, suggests both conflicts and collaborations between NGOs, civil society, and multinational nanotech enterprises. For example, Environmental Defense (EDF), an American environmental NGO, developed a partnership arrangement with DuPont, facilitating work with industry on voluntary oversight (EDF-DuPont 2007). In contrast, the ETC Group, a Canadian environmental organization, used

a different tactic of circulating petitions and publishing reports, but its campaigns have had little policy impact (e.g., calls for a global moratorium on all nano-research) (ETC Group 2006).

Interest group perspectives, however, also provide us with a more diversified and nuanced picture of the role played by trade unions, consumer groups, and nanotech coalitions in the formation of EU EHS policy. For example, Invernizzi (2012) suggests that it was trade unions' and NGOs' calls for moratorium that motivated some national governments to demand additional studies on risks (most notably, at that time, Royal Society and Royal Academy of Engineering 2004) and that contributed to pressurizing governments toward regulatory discussions. National trade unions campaigned in support of a precautionary regulatory attitude, and the European Trade Union Confederation has also advocated the same view (EC 2010, 117; ETUI 2010). The EC also strategically elicits input on nano-EHS issues from stakeholders and consumers as a constant feature of the policy process (EC 2010).

In sum, interest groups and lobbying activities have played a role in regulatory dynamics, with varying degrees of success, but they have been less significant, we argue, in explaining the policy divergence that is at the heart of this study, and the acceleration of the EU policy process.

Public Attitudes

Another set of explanations looks at public attitudes and their influence on policy-making. Like other issue areas in global politics, EHS policy debates often impinge on societal beliefs and cultural views. A core attitudinal view predicts greater European public concerns, outstripping the American public in perceived unacceptable risks (for a review, see Bodansky 2003; Stephan 2012). So far, however, there is little to support this hypothesis. A *Eurobarometer* survey found no significant differences in public opinions on nanotechnology between Europeans and Americans circa 2002–2005, the early phase of nanotechnology policy development. Gaskell and colleagues asserted that "it is invalid to claim that European public opinion is a constraint to technological innovation and contributes to the technological gap between the US and Europe…. Europeans are more or less as optimistic as people in the US and Canada about nanotechnology" (Gaskell et al. 2006, 7). Moreover, a Eurobarometer survey from 2010, the period when most significant regulatory developments in the EU occurred, found that "even though understanding of nanotechnology is low, Europeans feel that it should be encouraged" (TNS Opinion & Social 2010, 7). Gaskell et al. (2010, 25) asserted, "taken as a whole, perceptions of nanotechnology emerge as rather neutral in character." Another questionnaire further revealed that a vast majority of respondents in Europe, including citizens, expressed "high expectations" or "reasonable optimism" about nanotechnology (EC 2010). Such results provide no indication that the EU moved into intensive regulatory activity under pressure of public opinion. Moreover, there is no

evidence of a deeply rooted European disacceptance of emerging technologies (Gaskell et al. 2010; TNS Opinion & Social 2013). Perhaps even more noteworthy, nanotechnology risk perceptions appear to be inconsistent with the "knowledge deficit" model; studies have revealed that general knowledge about nanotechnology among lay people in Europe and America is low, and yet they hold moderately positive opinions, believing in the benefits of nanotechnologies even in the absence of information (e.g., Besley 2010; Currall 2009; Reisch et al. 2011; Satterfield et al. 2009). Overall, there is no strong evidence for a transatlantic difference in public attitudes on nanotechnology, suggesting that this has not played a pivotal role in driving differing regulatory processes.

Economic Interests

Another explanation focuses on the role of EHS regulation in bolstering economic competitive advantages, further suggesting that the EU's greater regulatory stringency may be consistent with the competitive interest of European firms (Baron 2000; for a review, see Bernauer and Meins 2003). Economic motivations are clearly associated with targeting nano-risks and uncertainties. The rationale here is that nanotechnology innovations change regional and global industrial markets, which then become a source for newly created risk and uncertainties. These concerns raise a need for regulatory developments, including EHS regulation which in turn may provide economic advantages (OECD/NNI 2013).

Yet, in the context of explaining the policy divergence on nanotechnology risks, it is worth noting that both the EU and the US administration have acknowledged the economic value of nano-EHS regulation, which seems to exclude this explanation as the main driver for the apparent regulatory divergence. EU decisions have attributed high economic value to a "reliable and stable regulatory framework" for investors and nano-industry confidence (Savolainen 2013). The US administration has followed this rationale as well; nanotechnologies were expected to benefit from clearer regulation, especially with relation to cautious investors (Sargent 2013). Improving EHS rulemaking within the US administration was outlined as a key for continued global economic leadership in President Obama's regulatory agenda (ETIPC 2011).

Moreover, the economic advantage of the EU's greater regulatory stringency was not a consensus shared among all European nanotech actors. Industry positions were mixed on adjusting existing regulation, especially REACH (Framing-Nano 2009). The REACH review generated deep, shared concerns within industry and national authorities regarding the cost burden of regulation on industry, in particular on startups and small- and medium-sized enterprises, in addition to delays in time to market (EC 2012). Ultimately, the differing regulatory trends across the Atlantic cannot be ascribed primarily to economic competitiveness motivations or to European nano-sectorial preferences.

The most persuasive explanation relates to the political economic mechanisms through which "institutional capabilities" (upgrading domestic regulatory

policies in dealing with risks and inherent uncertainties) have been influential in strengthening the EU voice in the international arena (Bach and Newman 2007). But this explanation is linked to domestic-political factors, which are discussed below.

Exploring the Roots of Divergence

Here we argue that the transatlantic policy divergence reflects stronger political support for more comprehensive regulatory standards in the EU, along with differing policy styles. Along these lines, several hypotheses have been proposed to explain the transatlantic divergence regarding EHS issues. These hypotheses are assessed against the empirical record, to validate the explanatory power of the argument. Through process tracing, we explain how the various factors have played out and influenced the regulatory process (and outcome), mapping the mechanisms for divergence at play.

Domestic Politics

This perspective addresses the policy-making process and examines how different regulatory institutions and policy-makers have influenced political decision-making. A central argument maintains that political structures together with institutional actors' relationships outlines the influence of political preferences and parties on political decisions (Adelle and Anderson 2013; Pollack and Shaffer 2009). While US states' role in the decision-making processes of federal agencies is limited, EU member states formally undertake a significant role in EU committees and Council. Moreover, scholars have identified competitiveness relationships among EU institutions, pointing to the growing power of the European parliament (EP) and of green MEPs in policy-making (Hix and Høyland 2013; Vogel 2003; Vogel 2012).

Differences in institutional politics on both sides of the Atlantic have played a critical role in shaping the respective positions of the EU and US over nanotechnology risk regulation. Since about 2009, the power of green MEPs and member states was magnified by the dynamic of regulatory politics at the EU level (Justo-Hanani and Dayan 2015). Initially, green member states pushed toward a more active, risk-averse approach and an acceleration of nanotechnology rulemaking. For example, in 2012 the Dutch Ministry of Infrastructure and the Environment led a call for urgent EC regulatory action on NM risks, supported by Austria, the Czech Republic, Denmark, France, Italy, Luxembourg, Spain, Sweden, and Croatia (Tajany et al. 2012). Then, a dynamic of "go-it-alone" with explicit national measures was recognized as jeopardizing the objectives of "ensuring free movement of goods by regulatory harmonization" (EC 2004), thus accelerating the EU policy process. For example, in 2010 France established a compulsory reporting scheme on nano-products; in Germany, the Green Party introduced a law banning all consumers' products using nanosilver. From the perspective of Germany and

France (leading nano-markets), integrated, EU-level action was required so as to supplement their domestic measures, if potential trade barriers were to be avoided (ETUI 2010; FramingNano 2009). Finally, member states with strict domestic disclosure requirements on NMs viewed the EU as a forum within which they could export their high standards to laggard member states (for the "leader-laggard" dynamic, see Liefferink and Andersen 1998). Led by the Belgian Presidency, green member states such as the Netherlands and Denmark, and later Sweden, Austria, and Finland, demanded that the EU adopt stringent environmental policies (European Presidency 2010). It was also the Belgian president's proposal on NM tractability (with the active support of France, Germany, Italy, and the Netherlands) that influenced the Council, which decided on "improving environmental policy instruments" by providing a mandate to the EC to review risk assessment and develop a compulsory database (Council 2010).

In the US, by contrast, there is little evidence for states' activity or congressional support. This is particularly clear from regulatory developments in the chemicals sector. Currently, US rulemaking on NMs seems driven at the agency level, as Congress has rarely engaged in federalized restrictions. Nash (2012) argued that given the ongoing deadlocks in congressional efforts to enact TSCA reform, the role of state laws in NM regulation merits attention. Currently, however, the city of Berkeley, California, has been the first and only local government to regulate NMs. Cambridge, Massachusetts, also considered a municipal policy but did not enact an NM ordinance; also, California announced data call-in (DCI) for CNTs (Hull and Bowman 2014). With preferences for NM regulation under TSCA remaining divided between Congress and the EPA, Rodine-Hardy (2010) concluded that "we see so far a patchwork of risk governance at the local, state, and federal levels."

The domestic-politics approach further adds to our understanding of policy-making processes. Regulatory steps taken in the EU are generally driven by European parliamentarians who have become impatient with what they consider the Commission's *laisser-faire* attitude and its preference for status quo with respect to Community legislation that may apply to NMs (EP 2009; Justo-Hanani and Dayan 2015). The immediate cause for debate was the *adequacy* of existing legislations to address NMs. The first implementation report to the EU strategic plan on nanosciences and nanotechnology was published in 2007, with a clear position on the *adequacy* of existing legislation. The Commission concluded that "current regulations address in principle concerns about health and environmental impacts" (EC 2007). Subsequently it reaffirmed its conclusions and focused on improving *implementation*, rather than introducing regulatory changes, as a primarily goal (EC 2008). While the Commission argued that existing legislation was adequate, the parliament refused to accept it. A draft report in the form of an "own-initiative procedure" was put forward in 2009 by Swedish Green Party member Schlyter from the parliament's Committee on the Environment, Public Health and Food Safety, one of the most active individual members (earlier proposals for amendments to REACH by green MEPs Schlyter, Lucas, and Beyer

were also adopted by the Committee on the Environment, Public Health and Food Safety on October 10, 2006). The draft criticized the EC's "wait-and-see" approach. It questioned its position on adequacy and the lack of progress in product risk assessment, stating the EC was "effectively blind to [NM] risk"; Schlyter expressed concern that current rules "are about as effective in addressing nanotechnology as trying to catch plankton with a cod fishing net" (EP 2009a). This debate reached a turning point when the parliament backed this own-initiative report nearly unanimously. Only four MEPs opposed the draft resolution and five abstained, while 362 supported it (EP 2009b). On April 2009, the parliament issued a resolution, submitted jointly by the parliament's five main groups, in which it rejected the Commission's view on the adequacy "in principle" of existing regulations (EP 2009). It stated that in the absence of nano-specific provisions and given the lack of appropriate data, it was impossible to address their risks within European Community legislation. It then called for a review of all relevant legislation within a two-year period and for drafting new nano-specific amendments in REACH, food, workplace safety, air, water, and waste legislation. A requirement for a newly created definition of the term "nanomaterial" was also set; once established, the Community legislation would adapt accordingly.

Distinctive Policy Styles

Given that policy processes (rather than their outcomes) offer a credible description of transatlantic divergence, the policy styles hypothesis should be elaborated upon. A distinctive policy styles argument underlines differences in the criteria used by American and European policy-makers to decide whether and how to respond to particular risks and uncertainties (Vogel 2012, 35). A core analytical framework for comparing policy styles is the degree of precaution reflected in regulatory approaches (Sadeleer 2007). The implementation of the precautionary principle as a societal norm and economic construct was identified as being central to EU EHS policies. It became deeply embedded in EU laws and treaties, shaping both European regulatory debates and policy-making (Bernauer and Meins 2003; Falkner and Jaspers 2012; on the precautionary principle as a source for transatlantic tensions over EHS regulations, see Steinberg and VanDeveer 2012; Winickoff et al. 2005). Vogel (2003, 2012) claims that while formal risk assessment plays an influential role in the making of risk management decisions in the US, European policies reflect a willingness to impose more precautionary and stringent regulations in the face of scientific uncertainty. The mere fact that the regulatory strategies for handling NMs in both the EU and US were drawn on existing laws and regulations generates the need to explore this hypothesis.

A White House memorandum provides support for this interpretation. In June 2011, the Emerging Technologies Interagency Policy Coordination Committee released a document titled "Policy Principles for the U.S. Decision Making Concerning Regulation and Oversight of Application of Nanotechnology and

Nanomaterials," reemphasizing the message of regulation grounded in the best available science (ETIPC 2011). This memorandum is consistent with an earlier memorandum on US regulation of emerging technologies, stating "regulation should be based on risk, not merely hazard, and in all cases the identification of hazard, risk or harm must be evidence-based" (ETIPC 2011a, 5).

This evidence-based approach to NM regulation was echoed in the US-Canada Regulatory Cooperation Council report of 2014, in which both sides agreed to "base decisions on the best available scientific evidence … entirely in consistency with the US principles" (RCC 2014). Also, the updated NNI Strategic plan specifically refers to the two memoranda mentioned above; accordingly, it continues to guide federal agencies to intensify research and development primarily directed at risk assessment and risk mitigation methods, to inform their policies and regulatory decisions (NNI 2014, 6; Sargent 2014). Such an evidence-based approach reflects the idea of regulation evolving as the body of evidence grows.

By contrast, the parliamentary resolution, "Regulatory Aspects of Nanomaterials," which included explicit reference to the precautionary principle, became significantly influential in the formation of nano-specific provisions (EP 2009). The Resolution made the case for the use of the precautionary principle by stating its centrality to Community EHS policies [see the Commission Communication of February 2, 2000, on the precautionary principle: COM (2000) 0001]. Following the Resolution, a range of adaptations emerged, including precautionary clauses on traceability and mandatory labeling in the cosmetics, food, and biocide sectors; post-release monitoring; and updated registration for NMs under REACH [e.g., (EC) No. 1223/2009; (EU) No. 1363/2013]. The precautionary principle was also explicitly endorsed as the underlying foundation for nano-risk management in Europe by the "Code of Conduct for Responsible Nanosciences and Nanotechnologies Research" (EC 2009). Recently, the European Chemicals Agency (ECHA) made additional progress in promoting transparent documentation and authoritative risk assessment for NMs, in keeping with the precautionary principle (ECHA 2014, 8).

Notably, despite transatlantic cooperative effort regarding some regulatory practices on NMs, it seems that this does not refer to the precautionary principle. In a meeting of the EU-US regulatory cooperation forum, questions were raised as to whether the establishment of a risk-based approach to regulatory safety testing meant an agreement not to use the precautionary principle in Europe. The EC Director-General for Enterprise and Industry emphasized that "regulation on the basis of hazard *vs.* risk was a separate issue from the precautionary principle, which provides the ability to regulate when you don't know the risks and want to be on the safe side" (HLRCF 2010).

A related aspect of institutional analysis emphasizes regulatory path dependence in explaining policy divergence, claiming that regulatory regimes, once established, can become "locked in," thus constraining policies later on (Pollack and Shaffer 2009). In this context, the US reliance on the TSCA regulatory

scheme from the 1970s (together with the institutional environment mentioned above), as compared with the EU's more recently enacted REACH, is likely to deepen the regulatory divergence (for similar insights, see Bosso 2013; Falkner and Jaspers 2012).

A second part of institutional, policy style analysis emphasizes the variable of international regulatory leadership, by linking specific patterns of European policy-making, chiefly increasing administrative regulatory capacity and promoting single-market integration, with a strategic ambition for external effect (Bach and Newman 2007). This argument claims that existing EHS governance gaps at the global level shape the EU's ambition for regulatory leadership and provide a political opportunity for EU external effects consistent with its patterns of EHS domestic policies (Kelemen and Vogel 2010; Selin and VanDeveer 2006). The EU is pressing for ambitious and comprehensive regulatory policies to ensure high-quality regulation and maintain its position as a global rule exporter. Since EHS policies are an intrinsic part of the European market of goods and services, demonstrated regulatory oversight (through institutional capabilities for dealing with risks and inherent scientific uncertainties) allows the EU to gain regulatory competitive advantages. Undeniably, global governance gaps have emerged due to profound scientific and regulatory uncertainties that hinder international governance initiatives, in contrast to the rapid pace of nanotechnology commercialization (Falkner and Jaspers 2012, 19). Also, government regulators face challenges, as they must engage in "dynamic oversight" in response to a situation characterized by uncertainties (Marchant et al. 2012).

The EU leadership ambition is manifested in issues such as the adoption of a "nanomaterial" definition for regulatory purposes and the ongoing adaptations to REACH that will affect global NM markets (EC 2011). Regarding the "nanomaterial" definition, an important objective was to promote *harmonization*, preferably at the global level. The April 2009 Resolution stated the parliament's objective to create a level playing field within and beyond the EU by resolving regulatory challenges posed by the "significant lack of knowledge and information, leading to disagreement starting at the level of definitions" (EP 2009, F, 7–8). Despite the efforts of both sides to advance internationally agreed-upon definitions through the OECD and ISO, various aspects remained unsettled. The EC concluded that "no internationally harmonized definition yet exists that would fulfil the requirements for entering into legislation, even though a wide range of definitions have indeed been discussed and proposed" (JRC 2010, 6). This gap may have played a catalytic role in paving the way for the new, ambitious EU goal (EP 2009). The creation of a practical, generalized definition for NMs was influential in "upgrading" domestic regulatory capacities (by providing regulators with a simple legal reference to lean on) and in strengthening the EU's voice in the international arena (Maynard 2011). Domestically, it became meaningful, as in 2012, a new regulation for biocidal products was adopted, the first to include the new definition [Regulation (EU) 528/2012]. While its practical implementation faces many challenges, when it comes to international EHS

politics, the EU definition plays an important role, reflecting a political leader's effort to shape global risk governance and guide the question of NM risks. Moreover, implementation challenges can be seen, through an interpretive lens, as a by-product of leadership ambitions, which would require adjustments as part of a learning-by-doing process (for an ongoing review of the definition in light of accumulated experience, see JRC 2014).

By contrast, the relatively slow development of regulatory activity in the US, and a lack of congressional support or political will for nanotech regulation, present challenges for US regulatory leadership. As was noted by Bosso (2013), US oversight capacities are at odds with what the technology needs today, because political actors are unable or unwilling to make changes in the absence of a perceived EHS crisis. For example, the Government Accountability Office (GAO) report to the Congress pointed out that data collection on NM risks is a policy field with a low degree of federal sovereignty (GAO 2010). In the 110th, 111th, and 113th Congresses, bills related to these issues were introduced but not enacted, or no further action was taken (Sargent 2013; Sargent 2014). At the end of 2011, the office of the EPA Inspector General Office concluded that "the EPA does not have sufficient information and processes to effectively manage the human health and environmental risks of NMs" (EPA 2011). Recent developments under TSCA, in which the EPA has expanded the frequency and scope of reporting requirements and identified priorities for the assessment of NMs (Justo-Hanani and Dayan 2014), have opened a window for regulatory reform, but may be ultimately challenged by Congress, as the debate over TSCA reform is ongoing.

Conclusions

We have sought to explain why regulatory handling of nanotechnology risks and uncertainties in the US and EU has evolved differently, and why in the last few years the EU has exhibited a burst of regulatory activity promoting stringent policy. We showed that existing cultural and public-opinion explanations, while useful and relevant, cannot fully explain the emerging transatlantic policy divergence. During the early and rapid period of nanotechnology development (2002–2010), public risk perceptions were generally positive, or at least not resistant, among both American and European citizens. Likewise, we showed that the US's and EU's diverging policies are not simply a product of their respective commitments to environmental and industry lobbying alliances. Also, we showed that their differing policy paths cannot be attributed principally to economic competitive interests or the interests of European firms.

We then explored the role played by domestic politics and policy styles. We concluded that the most powerful explanation links the policy preferences of influential policy-makers and parties to the importance of regulatory oversight principles, shedding light on the causes and dynamics of nanotechnology policy divergence. The global leadership impact of policy-making also added

independent explanatory power. In response to significant governance gaps at the international level, EU nanotechnology rule-making has been driven by ambitions for external effect, through improving regulatory integration and capacity building.

Analyzing divergence in the nano-regulatory domain through the policy process lens thus helps us understand the complexity of the transatlantic divergence phenomenon, as it manifests in the context of globalization in the EHS regulatory arena; simultaneously, it provides additional insights into domestic policy choices regarding the content, extent, and design of regulatory responses to these globally conceived governance challenges. Moreover, an analysis of the policy process helps clarify the meaning of the regulatory divergence. Beyond stringency (an outcome), it includes the capacity to assess, adjust, and foster adaptive regulatory capacities regarding newly created risks and uncertainties.

Our analysis is aligned with literature predictions regarding the prospects for convergence versus divergence in the context of globalization and EHS governance, indicating that the role played by domestic dynamics can have significant and often counteracting consequences for international cooperation and the harmonization of regulatory approaches (e.g., Busch et al. 2012; Falkner and Jaspers 2012, 2). Our analysis of nanotechnology regulation provides further support for the important role of domestic institutional settings and policy-making patterns in shaping policy divergence.

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