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European risk governance of nanotechnology: Explaining the emerging regulatory policy

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ABSTRACT

This paper explores political drivers and policy processes of the emerging EU's regulatory policy for nanotechnology risks. Since 2004 the EU has been developing a regulatory policy to tighten control and to improve regulatory adequacy and knowledge of nanotechnology risks. This regulatory evolution is of theoretical interest as well as of policy relevance, addressing the links between risk governance and technological innovation policy in Europe. Although nanotechnology is among the largest EU-regulated industries and a policy domain in which EU regulatory activities continue to grow, political perspective (actors, institutions and processes) remain underexplored. We explored the emergent policy at the EU-level from three theoretical perspectives and a set of derived testable hypotheses concerning the co-evolution of global economic competition, policymakers' preferences and institutional structure. We thus pave the way for developing grounded analytical accounts of this newly-created governance domain. We argue that all three are key drivers shaping the technology regulation policy and each explains some aspect of the policy process: motivation, agenda-setting and decision-making.

1. Introduction

Since 2004, the regulation and oversight of environmental, health and safety (EHS) risks associated with nanotechnology markets have been undergoing significant developments in the EU; many were intertwined with adaptations or recast of existing regulatory frameworks. Amendments of the chemicals policy occurred first (EC, 2008), followed by adaptations of the food policy (EP and Council, 2008), the recast of the cosmetics directive (EP and Council, 2009) and those of the electrical equipment policy (EP and Council, 2011). The European Commission (EC) also established two horizontal nano-specific measures, the code of conduct for responsible nanosciences and nanotechnologies (N&N) research (EC, 2008) and a recommended 'nanomaterials' definition for regulatory purposes (EC, 2011a). Key institutional arrangements for research and industrial activities have been substantially assessed, leading to the creation of an integrated regulatory policy[1] for nanotechnology risk at the EU-level.

This burst of policy activity occurred at relatively early phases of technology development, ahead of many other polities (especially the US); it was not prompted by scientifically well-founded risks or a policy crisis (Falkner and Jaspers, 2012) and it coincided with a fiscal and monetary crisis. At first blush, such a regulatory dynamic may come as a surprise, calling for understanding the full context in which it is embedded; yet, there has been little academic analysis of the drivers for this regulatory process and policy (exceptions include Hardy, 2010; Stokes, 2012).

The emergent regulatory policy is empirically and theoretically remarkable. Centralized, integrated nanotechnology risk regulation and management, has been a contentious area in the EU. Yet as the regulation of N&N safety is identified as a cross-cutting issue that needs to be addressed in order to promote growth of the nanotech industry, a request for further regulatory actions has emerged (Savolainen et al., 2013). It is therefore expected to remain a topic of considerable attention and ongoing regulatory activity. Moreover, this regulatory policy has a significant impact on markets outside the EU, placing Europe at the forefront of legislative developments in this area (NIA, 2014). In the face of current challenges for governments' oversight of nanotechnologies, there is a need to better

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[1] The OECD provides a useful definition of this term: 'regulatory policy is about achieving government's objectives through the use of regulations, laws, and other instruments to deliver better economic and social outcomes and thus enhance the life of citizens and business'. (http://www.oecd.org/gov/regulatory-policy/).

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understand the regulatory model put forth and how the EU sees its role as a nanotechnology risk regulator.

We examine the question: what accounts for the evolution of the EU regulatory policy on nanotechnology risk? We thus continue literature discussions on key drivers in EU regulatory policies on EHS risks, with science, technology and innovations policies therein. By testing a series of alternative hypotheses, we evaluate the explanatory power of three theoretical perspectives on key drivers of EU risk regulation and policymaking process: global economic competition, policymakers' preferences and institutional structure. An initial review of policy documents associated directly with EU-level N&N risk governance indicates the predominant role of these issues in recent regulatory debates. We argue that all three are key drivers shaping the emerging technology risk regulation and each explains better some aspect of the policymaking process: motivation, agenda-setting and decision-making.

This paper presents three key contributions. First, we begin to develop a theoretical analysis of this new technological innovation risk governance domain. Second, we provide an analytical account of the EU policy development and explore its characteristics – i.e., the distinctive features of the policy approach and its driving factors and actors. Third, we elaborate on theories of EU risk regulation and governance of science and technology domains.

We focus on policy dynamics in Brussels, with particular attention to policymaking in the EC and the Council of the EU (Council) as well as relations between the EC and the European Parliament (EP); all three are involved in creating regulations and laws relevant to N&N. Policymaking at the Member States level, although not a focus of our paper, affects the EU regulatory policy mainly through positions on risk and regulation taken by national governments and influential politicians; thus it is discussed as part of the 'policymakers' preferences' explanation. Finally, we note that the development of regulatory policy for nanotechnology risk is an ongoing process and will thus be subjected to new insights and future policy-turns.

The paper is organized as follows. The next section presents briefly the challenges for nanotechnology policymaking in the EU. This section also sets the analytical and theoretical frameworks, introducing the main features of the EU regulatory policy, and reviewing plausible explanations and deriving testable hypotheses. The third section provides an overview of the regulatory policy development over the 2004–2012 formative period. The fourth provides an explanation for the policy process and the features of the regulatory policy by applying theoretical hypotheses to the empirical record, and relying mainly on two methods – process tracing and policy analyses, using a variety of key policy documents and secondary literature. The fifth section concludes.

2. The analytical framework

2.1. Background: challenges for nanotechnology policymaking in the EU

In recent years, hundreds of billions of dollars have been invested in Europe in N&N R&D, directly by the EU and national governments or indirectly via multilateral institutions; private investments have also been influential in some categories of EU R&D (Palmberg et al., 2009; OECD, 2013). Yet it was questioned whether these funds are sufficient to promote EU's innovation and economic competitiveness due to the challenging institutional and societal contexts of nanotechnology development. A substantial lack of information exists on how these R&D investments are distributed across nanotechnology sub-areas, including research on EHS risks and socio-economic issues; even shortcomings of relabeling already existing research complicate the R&D funding landscape. Moreover, concerns associated with risk management and regulatory inefficiency abound (Palmberg et al., 2009).

Nanotechnology in the EU currently faces many risk and uncertainty issues. Despite oversight by regulatory authorities and sustainability goals within the nano-industry (e.g., the International Dialogue on Responsible Nanotechnology R&D), ecotoxicologists and advocacy groups are concerned about potential EHS impacts associated with nanomaterials, including inhalation, absorption and capability of penetrating the blood–brain barrier. Specific concerns include potential reactivity and exposure to nanomaterials that have dispersed in air, aquatic environments, soil and sediments all leading to increased toxicity in combination with unrestricted access to the human body (SCENIHR, 2009; Savolainen et al., 2013; JRC, 2014). These issues challenge the growth and sustainability of nanotechnology markets, posing a challenge for policy makers. With the European debate on Genetically Modified Organisms (GMOs) as a backdrop, the debate on nanotechnology focuses on risk assessment structure and oversight capacities; the challenge of reducing regulatory and scientific uncertainties surrounding nanotechnologies may be even greater than that of GMOs (Falkner and Jaspers, 2012).

One of the greatest policy-concerns has to do with significant knowledge gaps on nanomaterials characterization. At the nanoscale, the properties of materials (e.g., mechanical, electrical and thermal) may differ significantly from their bulk behavior, but these size-effects aspects are still being investigated. Generally, nanotechnology policymaking requires a 'regulatory science' (Jasanoff, 2005) in the form of a significant data-base and risk assessment foundation for evaluating the safety of nanomaterials in EU-regulated products (EC, 2004; SCENIHR, 2007)[2]. This may be achieved by tackling the following uncertainties (Linkov et al., 2009): the lack of exposure data on a wide range of materials, to allow the establishment of a detailed framework for assessment; it is not clear whether potential hazards can be addressed with existing risk assessment approaches; related difficulties in assessing tradeoffs between production, cost and safety concerns. These issues are all relevant for European sectoral markets, recognized as demanding regulatory policy at the EU-level (SCENIHR, 2007). As one of the key technological drivers in building an 'innovation EU', the lack of regulatory clarity and scientific uncertainties could undermine the nanotechnology industrial exploitation potential; these were identified as major barriers to innovation in Europe (Savolainen et al., 2013).

Overall, the major challenge of regulation is to stimulate technological innovation and to ensure economic development as well as societal benefits from novel applications of nanotechnology, while protecting EHS quality (EC, 2004; Eisenberger et al., 2010). This challenge reflects the links between risk governance and technology innovation, stressing the key role that government plays in advancing dual and sometimes conflicting agendas in technology innovation policies (Bosso, 2010). Relatedly, a fundamental issue is whether and how existing regulations can be used or adapted to the complexity and scientific uncertainties of nanotechnology settings (Stokes, 2012).

2.2. The regulatory policy: distinctive features

To address the research question, it is necessary to understand the EU policy framework for regulation and oversight of N&N. Procedurally, decision-making power in the EU is shared between the EC, the Council and the EP. Their rulemaking mandate on nanotechnology matters derives from their general competence for creating laws and regulations by co-decision procedures (the treaty on the functioning of the EU [TFEU]). The EC develops proposals for law

[2] The scientific committee on emerging and newly identified health risks.

and policy that must be agreed by the Council and informs the EP on a regular basis. Most of its policy proposals are developed by different directorates-general (DGs), the executives departments within the EC, in their respective policy areas. Key regulatory measures for nanotechnology and nanomaterials risks include products safety-testing, market authorization, data-disclosure and labelling. Descriptions of rulemaking paths (e.g., Dorbeck-Jung, 2012) continuously point to the legal frameworks on chemicals (REACH)[3], biocides, food and cosmetics, which are currently at the forefront of regulatory and political developments. Occupational safety, electrical and medical uses are also important areas in which N&N risks have arisen. As this section shows, these policy areas are currently undergoing regulatory developments.

Between circa 2004 and 2008, the EU regulatory policy on nanotechnology was based on three features: (a) a non-distinct regulatory approach, where nanomaterials are covered by existing regulations, with minimal harmonization, either national or sectorial, through EU-level rules (although EU-level regulation was more developed in the cosmetics sector). (b) policy execution was assisted by technical cooperation, either by multilateral and bilateral forums (OECD's working parties on nanotechnology and manufactured nanomaterials – WPN, WPMN; EU–US nanoEHS dialogue), or in the form of European 'in-house' science services and committees (Joint Research Center – JRC; SCENIHR). Additionally, ongoing administrative links between the EC's various DGs facilitate information exchange. These include the DG Health and Consumers' Scientific Committee on Consumer Products (SANCO-SCCP), DG Environment (ENV) and DG Enterprise and Industry (ENTR). Moreover, independent advice for the EU President provided by the European Group on Ethics (EGE) has led to the adoption of a code of conduct for responsible nanosciences and nanotechnologies research (EC, 2008). (c) EU policy was conducted in absence of a European official definition or international regulatory agreement as to what 'nanomaterials' are (with the cosmetic product regulation as an exception; see Van-Calster and Bowman, 2010). This situation posed difficulties for domestic institutions in policy implementation and presented industry with lack of clarity on the data that they need to provide. In the long term, the EU predicted costs and delays in placing product into the markets (see Section 4 below). Yet there were international private definitions, available or in progress, such as standard on the vocabulary for nanoparticles (BSI, 2005). Additionally, a definition set by the International Organization for Standardization (ISO, 2008) was approved by the European Committee for Standardization in 2009 for a period of three years, in which its conversion into a European standard was considered (CEN/TC 352).

From 2009, the EU regulatory policy developed into a more articulated and integrated structure, addressing the needs for legal clarity and consistency among EU, national authorities and economic operators in line with the multilevel innovation policy approach (CEPS, 2010; EC, 2010). The functional division of sector-specific regulations (chemicals, worker safety, food, cosmetics and environmental directives) is maintained, supported by adaptations in existing regulations and by a newly-created definition of what constitutes 'nanomaterials', to determine their fall within this legislative scope (EC, 2011a)[4]. Maintaining sector-specific regulation is compatible with regulatory adaptations via, for instance, equivalence or parity in the standard of care that manufacturers are to maintain across sectors. Likewise, while the recommended definition provides a broad coverage of nanomaterials, its consistent implementation by sector-specific regulation will play a critical role in determining how comprehensive this coverage will be. The definition, officially adopted in 20.10.2011, was already used in Biocides and Medical Devices regulation and it is expected to be incorporated into other Union and national regulations. EC's ongoing review of the definition is being undertaken, in light of accumulated exercise and scientific developments (JRC, 2014).

A second step is maintaining a comprehensive dialogue with industry and research communities, as well as emphasis placed on public engagement. Public and stakeholder consultation on 'nanomaterials' definition is a case in point. This dialogue went well beyond its original route for achieving consensus on meaningful *content* for the term 'nanomaterial' and includes discussions on *effectiveness* and *compliance* of the EC definition, i.e., how it can be applied in different sectors, and data disclosure needed for its regulatory review (JRC, 2014). Third is the ongoing process of reviewing existing regulatory frameworks and adapting them when necessary upon regular feedback and reports from the member states (Eisenberger et al., 2010; EC, 2012).

Overall, the most noticeable developments have been the broadening and deepening of integrated, centralized regulatory policy (Justo-Hanani and Dayan, 2014), mainly through maintaining a functional division of sector-specific regulation while increasing the profile of adaptive approach; separating risk assessment from risk management by creating a nano-definition for regulatory purposes and shaping collaboration relationship with industrial and scientific communities. The scope of EU regulatory activities has increased in the course of restructured risk control for the entire sector.

2.3. The explanatory framework

This section presents the hypotheses derived from alternative theories on the EU regulatory policies on EHS risks. We focus on three theoretical frameworks that constitute the most plausible alternatives derived from preliminary data investigation. These are: global competitiveness, EU institutional structure and policymakers' preferences (see Table 1 for summaries of hypotheses and their empirical testing).

2.3.1. The role of global economic competition

Competitive interests' explanations highlight the dynamics of the highly competitive global marketplace, which generates pressure for regulatory developments either at the national or transnational levels (Stigler, 1971; Vogel, 1995; Vogel, 1996; Jordana and Levi-Faur, 2004). Such explanations stress that risk regulation and policies cannot be referred to disregarding economic interests. With regard to emerging technologies, they highlight the presence of the EU as an economic actor and a trading market in the global arena (Kent et al., 2006; Faulkner, 2009). Economic interest is not necessarily about regulatory policies that disadvantage competing manufacturers (Vogel, 2012); some European regulatory policies on EHS risks promote economic interests of European firms, which then impact competitiveness inside global technology markets. Moreover, institutional capabilities in dealing with risks and inherent scientific uncertainties allow the EU to gain competitive advantage through demonstrated regulatory oversight (Bach and

[3] The regulation on the registration, evaluation, authorization and restriction of chemicals (EC no 1907/2006). The aim of REACH is to ensure EHS protection including promotion of methods for substances hazard assessments and to ensure the free circulation of substances in the single market, while enhancing competitiveness and innovations.

[4] According to the 2011 definition 'nanomaterial' means "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1–100 nm. In specific cases and where warranted by concerns for the EHS or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%".

Table 1
Explanatory framework and major empirical findings.

Theoretical explanations	Hypotheses	Empirical testing
Competitive interests	EU level: SM and N&N R&D increased technology development; inherent scientific uncertainties and information gaps.	Risk of regulatory or management failures (gaps); regulatory policy expected to generate economic advantages.
	Global level: competitiveness inside global nano-markets; international regulatory activities (private standardization).	Integrated regulatory policy needed for bolstering the EU ability to leverage its market power globally as well as maintaining its position as a global rule-exporter.
Institutional structure	EU institutions as risk-policy entrepreneurs.	**Motivating factors**. The commission and DG research played a pivotal role at the **agenda-setting** stage, acting as risk-policy entrepreneurs; The EP played a pivotal role in the **decision-making** phase.
	The regulatory policy reflects EU societal functions, and adheres to the competence of EU institutions in trust-building.	Substantial boost to the competence of the EU institutions in reducing scientific uncertainties; risk governance practices.
Policymakers preferences	Green parties played a crucial role.	Positions of green MEPs and national governments were most influential in the **decision-making** stage.
	The emergent regulatory risk policy conformed to the EP's preferences.	The emergent risk policy conformed to the EP's preferences, but also overlapped the EC's preferences.

Newman, 2007; Kelemen, 2010). Two complementary hypotheses can be suggested as;

H1. At the EU-level, technological risks and knowledge gaps exacerbated regulatory or management failures (gaps), jeopardizing the functioning of the single market. Hence, technological developments made it economically essential for the EU to establish integrated regulatory policy and risk regulation therein.

H2. From a global perspective, the rapidly changing industrial markets created a need for the improvement of EU administrative regulatory capabilities. Integrated policy on risks and uncertainties was also driven by the need for leveraging the EU market power globally and for maintaining its position as a global rule-exporter.

2.3.2. The role of the EU's institutional structure

Another set of explanations looks directly at the policy-making process and explores how the formation of regulatory policy for nanotechnology risks is strongly affected by a broader European institutional context. This includes societal functions and objectives underpinning EHS policies as well as the Union's unique institutional set-up with its own special approach to policymaking and coordinated risk governance.

According to the EU institutional approach, which builds on the 'regulatory state' theory (Majone, 1996), the push factors of EU regulatory policies on EHS risk issues are: socially desired functions performed by regulation (e.g., norms enforcement, citizens protection), trust building in both government and technology and the entrepreneurship of well-established EU institutions focusing on the development of integrated, harmonized policies (Vogel, 2003, 2012; Jordan and Adelle, 2013).

Relatedly, the implementation of the Precautionary Principle (PP) as a social norm and an economic construct was identified as central to EU EHS policies. The PP constitutes an institutional constraint in risk management decisions which the EU institutions have to take into account when acting as policy entrepreneurs. Likewise, promotion of citizens' health and welfare is considered as one of the most important EU functions (Fisher, 2008; Heyvaert, 2010). As Vogel (2003) and others have suggested, public trust is to be achieved through demonstration of regulatory competence (Kent et al., 2006). Bell and Hindmoor (2009) argue that it can be achieved not only by strengthening state institutions but also by forging governance partnerships with a range of societal actors. Finally, an institutional approach highlights the importance of the EU institutions as policy entrepreneurs pushing their own regulatory agendas. EU institutions may address the challenge of developing regulatory policies by taking several approaches, e.g., problem identification, setting general and specific policy objectives and considering alternative policy options for reaching these objectives. In the case of nanotechnology regulatory policy, two testable assumptions can be produced.

H3. EU institutions, such as the EC, the EP and the Council played a pivotal role in driving the regulatory policy. Their role as policy entrepreneurs, plus their respective degree of influence, can be identified by process-tracing analysis.

H4. The regulatory policy reflects EU societal functions and adheres to the competence of EU institutions in trust-building.

2.3.3. The role of policymakers' preferences

Policymakers' preferences explanations portray the EU risk policies as the result of a series of policy choices made by EU policymakers reflecting interest groups' preferences, the positions taken by supranational institutions and by national governments and different views on risk regulation and management (Vogel, 2012; Jordan and Adelle, 2013).

There is a policy formulation process, in which powerful interest groups including European companies and industry articulate their preferences in EU fora to influence policy formation. Thus, the preferences of the EC are likely determined by these aggregated interests and they are also affected by a consultation process, which helps to explain the adoption of a certain policy. Moreover, like Vogel (2003, 2012), others have suggested that we are witnessing change in the political culture with competitiveness relationships among EU institutions and the growing power of the EP and green Members of Parliament (MEPs) in shaping regulatory policies on risk issues (Kent et al., 2006; Hix and Høyland, 2013). Hence, policy preferences of influential policy makers, the configuration of regulatory debate, together with a dynamic driven by 'green' or industry positions explain the regulatory process and outcome. Three alternative hypotheses can be derived:

H5. 'Green' positions (either green MEPs, or those taken by the 'green' member states), played a crucial role in the EU regulatory process.

H6. The regulatory policy conformed to the preferences of the EP.

H7. In the formation of EU preferences, economic interests of European firms, possibly from leading national markets, played an overriding role.

3. An overview of the European policy development

At the EU-level, the efforts to develop an integrated regulatory policy for nanotechnology risks formally began in May 2004 (albeit the 'integrated responsible' concept was conceived earlier during the EuroNanoForum, 2003). The EC proposed a European strategy for nanotechnology advocating integrated, safe and responsible approach, as part of the overall goal of transforming the EU into the world's most competitive, knowledge-based economy in accordance with the Lisbon strategy (EC, 2004: 338, 1.3). Ensuring 'appropriate and timely regulation in the area of public health, consumer protection and the environment' at the community level was marked in the strategy as essential (EC, 2004: p. 17). Given deep knowledge gaps on nanotechnology, the EC proposed: 'maximum use of existing regulation' together with an 'incremental approach' (review and possible amendments) (Franco et al., 2007). The competitiveness Council–a Council configuration–and the European Economic and Social Committee–an EU's consultative body, welcomed the EC's approach (Council, 2004; EESC, 2004).

The EC then used the working method of consultation to collect opinions on its proposed strategy plus inputs for future initiatives (Nanoforum, 2004). The consultation, the largest of its kind in Europe, used an online questionnaire and direct responses of a total of 750 stakeholders. Representatives invited to respond were from major research organizations, universities and industry, as well as other experts and journalists. Ninety-three % of respondents were Europe-based, a third from Germany and the UK (leading nano-markets). There was a broad consensus (over 75%) that risks, uncertainties and societal impacts must be addressed seriously at an early stage. A third of the respondents believed that the EU should regulate nanotechnologies while another third preferred international regulations. Additionally, revision of existing EU regulation rather than developing new regulation was preferred. Overall, it became clear that '[EU] regulators cannot afford to sit on the fence' (Nanoforum, 2004: p. 68–69, 76–78).

In June 2005 the EC adopted an Action Plan in line with its 2004 strategy (EC, 2005). The new Action Plan was directed at defining and strengthening EU markets for nanomaterials and nanotechnologies. The regulatory mandate for EHS risks included the following (EC, 2005; Eisenberger et al., 2010): to add employee health to the list of concerns; to review legislation for adequacy to nanomaterials; members states were called upon to modify national legislation, where necessary. It was clearly established that EHS concerns need to be addressed upfront, striking the right balance between reinforcing economic growth and managing risks.

The first implementation report of the 2005 Action Plan was presented by the EC in September 2007. It concluded that 'current regulations address in principle concerns about health and environmental impacts' (EC, 2007). It next focused on improving implementation rather than introducing regulatory changes, as a primary goal. Future modifications in community legislation were mentioned, but the EC conditioned changes on new information becoming available or regulatory needs ascertained by national authorities (EC, 2008a: p. 3).

This position was further substantiated in 2008 following regulatory review in relevant domains (occupational safety, chemicals, environmental protection and product safety). The EC led by DG ENTR (by virtue of its role in advancing regulations which guarantee coherence between EHS and business agendas) issued a communication on regulatory aspects of nanomaterials (EC, 2008a), stating clearly that there is currently insufficient knowledge available on nanomaterials risks. Simultaneously it reaffirmed its conclusions that current community legislation generally covers nanomaterials risks, apart from implementation that should be improved (i.e., testing methods) (EC, 2008a: p. 3,8).

These accounts led to a heated debate with the EP. The immediate cause was tensions over the *adequacy* of existing legislations to address nanomaterials risks, given that none are geared to specific nano-size effects and knowledge gaps. A draft report in the form of 'own-initiative procedure' was put forward in January 2009 by member of the Swedish Green Party Schlyter from the EP's Committee on the Environment, Public Health and Food Safety (ENVI) and one of the most active individual members (EP, 2009b). In the explanatory statement Schlyter noted that 'the commission's analysis is based on a one-dimensional, legalistic overview of the current rules, but those rules are about as effective in addressing nanotechnology as trying to catch plankton with a cod fishing net'. Seemingly, the ENVI worried that the EC, especially DG ENTR, where industrial views prevail, would push through regulatory arrangements that favor industry interests over consumers and environmental ones in nanotechnology marketization (EP, 2009b). Across the draft, there has been much criticism of the EC's passive (laissez-faire) approach. It questioned not only the position on the *adequacy* of the existing legislation, but also the lack of progress in assessing risks of products and issuing information on nanomaterials types and uses (Van-Calster and Bowman, 2010). The exact wording on the EC performance was 'effectively blind to its [nanomaterials] risk; and 'the same diversity [about future nanomaterials' benefits or applications] shrinks to zero when it comes to a regulatory discussion about nanomaterials' (EP, 2009b: 3). These wordings were toned down in the resolution eventually adopted (EP, 2009c). A specific concern was that the EC has not yet provided for clear rules on products containing nanomaterials (placing them in the market, special toxicology tests and labeling). Criticism was also directed towards the EC's regard of such rules merely as a question of *implementation*, especially since it is constantly seeking new knowledge from companies. Hence, the report called for subjecting the approval processes of nano-products or their discharges into the environment to the REACH-alike principle of 'no-data-no-market'.

Another obstacle identified was lack of accepted, specific definition for the term 'nanoparticle' in the context of REACH. Thereby, companies applying for registration could register the compound in whatever way they see fit. Clear and detailed legislation was intended not only to generate confidence among consumers, but also to provide legal certainty for manufacturers and to promote efficiency in the product approval process.

The debate on regulatory adequacy reached a turning point in 2009, with the adoption of the draft report. Only 4 MEPs opposed the draft resolution, 5 abstained, while 362 members voted for it (EP, 2009a). On April 2009 the EP issued a resolution (submitted jointly by the EP's five main groups), in which it rejected the EC's view on the adequacy 'in principle' of existing legal provisions. It stated that in absence of nano-specific provisions and given the lack of data and risk assessment methods, it is impossible to address their risks within community legislation. The EP then called for review of all relevant legislation within a two-year period and for drafting of new nano-specific amendments in REACH, food, workplace safety, air, water and waste regulations (EP, 2009c; Eisenberger et al., 2010). A requirement was set for a new definition of the term 'nanomaterial'. Once established, the community legislation will be adapted accordingly. An important objective of the definition was to promote harmonization, preferably at the global level, thus helping to resolve regulatory and scientific disagreements (EP, 2009c).

The EP resolution was both the trigger and the 'blueprint' for most recent EC's regulatory initiatives. Throughout the period of 2008–2012 two regulatory reviews, horizontal nanomaterials definition for regulatory purpose and nano-specific modifications, were established. The resolution pushed for articulated regulatory arrangements in two areas: marketing nano-products and setting

criteria for risk assessment (the scientific basis for risk regulation). The former gives priority to the stage prior to release into the market and the latter focuses on significant changes in production methods or in the starting materials used. In 2010, the EC amended the cosmetics directive to require safety assessment of nanomaterials in cosmetics products, pre-market notification, labeling and compulsory registration (Dorbeck-Jung, 2012). The manufacturer/importer has to assess their safety prior to placing them on the market. In 2012, the EC announced a review of REACH regulation, considering relevant nano-criteria for market entry. Earlier in 2008, the EC decided to withdraw carbon and graphite from the exemption list due to potential health risk at the nano-scale (EC, 2008b); consequently, their nano-forms require new chemical registrations. Between 2008 and 2011 amendments were made in food regulation. Nano-foodstuffs and additives are now subjected to specific authorization before they enter the market. During 2010–2011, the EC negotiated and approved a nanomaterials definition (EC, 2011a); the term was not designed for determining intrinsically hazardous materials; rather, it was meant to identify materials for which special provisions within existing regulations, such as requirement for risk assessment or labelling, might apply (EC, 2011a, 2012).

As for the challenge of how to promote compliance with the regulation, one method is targeting technical assistance through the use of the seventh framework programme (FP7) and Horizon 2020. These broad initiative for research and technological development are aimed primarily at increasing EU economic competitiveness (EC FP7, 2012; Savolainen et al., 2013). They also support the development of technical assistance to relevant policies with an eye to boosting the 'innovation union' (EC, 2010). Technical assistance to the nanomaterials definition was set according to the EC recommendation (EC, 2011a) and included 'development of methods and standards for ensuring its reliable implementation' across specific legislative contexts (EC FP7, 2012: 27).

4. Results and discussion: explaining the emergent EU regulatory policy

This section explains the regulatory process and policy by evaluating the explanatory power of the hypotheses outlined above.

4.1. The role of EU's competitiveness

Two structural economic factors can be viewed as motivating the EU policy. First, the single market and the European N&N R&D funding increased technology development through research and nano-entrepreneurship. This changed rapidly European sectorial markets, triggering inherent scientific uncertainties and information gaps and challenging existing oversight of vital fields of R&D investment and manufacturing activities (e.g., nanomedicine, chemicals and space) (EC, 2004). The EU's investment horizons in technology infrastructure – 'poles of excellence', the advanced facilities and resources for the research community – plus private investments were expected to grow, as was the volume and heterogeneity of products commercialized (EC, 2004, 2005). Conversely, the ability of national and EU authorities to respond to technological risks was questioned, despite accumulating data on safety concerns (most notably at that time The Royal Society, 2004). A concern regarding nano-products traded in the EU was that production and quality standards to be met at the point of supply are tailored to conventional products and may be ill-equipped to their nano-equivalents (Stokes, 2012). Furthermore, reducing information gaps affecting the aggregated 'behavior' of the economy was essential to ensure that R&D spending will bring innovation and competitiveness for Europe. The improvement of risk management practices (risk assessment, measurement techniques and testing guidelines) was further stimulated by contributions to the reliability of future products and services (EC, 2004: 17). These issues promoted the pressure for appropriate and timely EHS regulation.

Additional powerful incentives were the 'wider economic payoffs' deriving from more EHS-targeted regulation, which would create a regulatory environment attractive to investors (predictable regulatory process), bring benefits for workers (higher confidence), consumers (reliability of products) and European firms, particularly start-ups, small and medium-sized enterprises (SMEs) (lower cost of regulatory burden) (EC, 2004: 1,3,17), so as to create jobs and wealth consistent with the Lisbon strategy (EC, 2005). Aside from ensuring a high-level public EHS protection consistent with TFEU, regulatory harmonization was expected to ensure the free movement of goods in the single market, avoiding market distortions emanating from different national treatment or interpretation (EC, 2004; Tomellini and Monk, 2005; TFEU).

Second, economic factors at the EU-level coincided with a global trend of technological innovation, entrepreneurship and trade liberalization. Actually, all studies pointed out that nano R&D and innovation targeted global markets from the outset (Auplat, 2012). The 'nano-revolution', which accelerated technological exchange and new industrial segments, implied that global industrial markets changed rapidly and that EU regulations lagged and therefore constituted a burden for the EU in the global economy, especially in competition with the US, Japan and South Korea (the volume of research, R&D investment and knowledge-base in nanosciences remain proportionally less than its main competitors; EC, 2004). This created the need for parallel regulatory instruments, starting with agreed definition, risk assessment methods and safety-testing, essential to turn the EU into a global leader in the development of key enabling technologies (EC, 2011b). Later in the policy process, the creation of a single 'nanomaterials' definition for regulatory purposes (EC, 2011a) was influential in 'upgrading' domestic regulatory capacities and strengthening the EU's voice in the international arena. The 2009 resolution clearly stated that the EP's objective was to promote its adoption at the global level to maintain a level playing field both within and beyond the EU, at a time when classification and meaning of 'nanomaterials' were being highly contested, generating disagreements and inconsistencies (EP, 2009c: F, 7–8; Maynard, 2011).

Overall, economic competition poses two challenges. First, knowledge exploitation and technology innovation policy were source of rapid EU's markets change, which existing regulatory systems were no longer able to cope with. Therefore, there is a need for appropriate regulation at the EU-level, including EHS policy as part of economic interests. Second, technological innovation activities still lag in the single market, posing an obstacle to the competitiveness of the EU in comparison with the USA, Japan and South Korea; hence, the necessity to promote integration in tune with targeting risks and scientific uncertainties in this sector through EU regulatory activity (EP, 2009c: E).

Bach and Newman (2007) specify that administrative regulatory governance over industrial markets in the EU interacts with at least three levels: the national, the single market and the global system. They also argue that integrated regulation is needed for altering the ability of the EU to leverage its market power globally. This makes 'global competitiveness' a precursor variable that can be linked to the next explanatory arguments.

4.2. The role of EU institutional structure

Regarding the third hypothesis, the EC and DGs played a pivotal role at the agenda-setting stage, which began with the EC's strategy (2004) with further advances by the action plan (2005). The EC and its DG research & innovation acted as regulatory pol-

icy entrepreneurs by defining the policy problem, namely, the lack of appropriate regulation on EHS safety issues and by proposing concrete solutions (EC, 2004: 17; 3.4.4.; EC, 2005: 10, 6.1.). Former commissioner for research Busquin stressed in the foreword of the communication 'towards a European strategy for nanotechnology' (EC, 2004: 1) that "any potential negative impacts on public health, safety, or the environment must be addressed up front as an integral part of the technological development process".

The EC also deliberately and strategically elicited input from stakeholders, primarily nanotech companies and researchers (Nanoforum, 2004). It also relied on independent scientific bodies, such as SCENIHR and SCCP to provide it with opinions on the need to develop new methodologies, in particular vis-à-vis risk assessment (SCENIHR, 2007). Overall, the emphasis placed on stakeholders and research community engagement has been a consistent feature in the development of nanotechnology EHS policy (see Section 4.3).

The EP, less involved at the beginning of the process (although it did support early on the idea of nano-regulation and pushed for it in its ENVI[5]), participated in the co-endorsement of the 2005 action plan with the Council.

EP was particularly active in the decision-making stage by keeping the incremental approach to EHS regulation in line with the PP (Calliess and Stockhaus, 2012). The EP did not welcome the EC's *adequacy* conclusion and its changing attitude toward more passive "wait and see" approach, making the case for enhancing the role of the PP on two grounds (EP, 2009c: O,Q; 2009a): first, it argued that it will promote the interests of social protection and public trust ('safe development of nanotechnology'; avoid 'recourse either to technology moratoria, or undifferentiated treatment of applications'); second, the EP pointed out to the EC communication from 2000 on the general role of the PP in community EHS policies (EC, 2000). It stated that applying the PP is about EHS research and nano-products regulation *before* their release into the market (with the focus on *government* regulation), as opposed to the EC's statement on applying the PP *after* release 'in the event that realistic and serious risks are identified' (with the focus on *market* regulation) (EC, 2004).

In the days since the approval of the 2009 resolution, the EP (mainly by its committee on environmental affairs) successfully influenced the design and formation of risk regulation by systematically proposing nano-specific modifications in various laws already reviewed or still under revision by the EC (cosmetics, food, biocides, RoHS), so as to ensure precautionary response to the challenge of regulatory and scientific uncertainties. Requiring updated registration under REACH whenever an approved bulk substance is introduced in nano-form, using the concept of 'no data, no market', is an example for a precautionary approach (Calliesse and Stockhaus, 2012).

With reference to the fourth hypothesis, the option chosen of regulatory review and adaptations constitutes a substantial boost to the competence of EU institutions in reducing uncertainties and contested problems, by explicitly addressing nanomaterials applications and the very nature of their potential EHS risks (EP, 2009c: 1). Several other features of the outcome fit well with the EU competence assumptions (Kent et al., 2006; Newell, 2003). The adoption of horizontal nanomaterials definition as a roadmap for consistent implementation within EHS national policies; the number of regulations adapted by the EU between 2009 and 2012, mainly attributed to risk assessment and information gathering; the recognition that European or national soft regulations, like the EU code of conduct on responsible research or the UK voluntary reporting scheme are of limited efficacy; and the ongoing process of reviewing existing regulatory frameworks and adapting them when necessary upon regular feedback and reports from the Member States (Paddock, 2010). Similarly, the emphasis placed on governments' public engagement activities (e.g., Nano-Cap 2006–2009) is central to strengthening EU competence by policy networks and smart regulation, ensuring that EU regulation is 'fit for purpose'.

The above analysis of regulatory competence is also compatible with the societal dimensions of EU risk regulation as suggested by Vogel (2003), Newell (2003) and Heyvaert (2010). The EP stressed that the overall objective for regulatory review was to build public and industry confidence in the technology, promoting EHS and gathering information (EP, 2009c). The support and funding of research on EHS impacts by DG research & innovation, DG ENV and DG SANCO; the extension of regular consultation with member states on risk assessment and labelling requirements; and setting clear criteria for nano-specific risk assessment, particularly in the context of REACH, are all indicators for activity with a view to safeguarding EHS management structure and maintaining the social function of protecting citizens within the community framework. Trust in government regulation is also promoted by promoting competencies (know-how) within the Member States to run their markets, through designing multilevel governance system orchestrated by the EU (Hardy, 2010). What impacts such governance model has on public trust is increasingly discussed but still unclear (EC, 2013).

In sum, the evidence points to three *types* of actions carried out by EU institutions, indicating their importance in the policy process. These are: setting the substantive agenda for the EU regulatory policy, through defining policy issues and presenting policy proposals (EC); actions for facilitating 'coordination' and 'capacities', through the EP proposed amendments to the EC revised policy in fields of risk assessment and scientific information; and actions for improving the social protection and common interests in relation to sustainable technology and innovation policy (EP).

4.3. The role of policymakers' preferences

As for the fifth hypothesis the empirical record suggests that 'green' MEPs and national governments were predominant in the decision-making phase, which was mainly characterized by pushing the EC towards a more active approach and acceleration of the rulemaking process, beginning circa 2010. Initially, the EP backed nearly unanimously the own-initiative report by green MEP Schlyter (see Section 4 above). Schlyter also repeatedly put pressure on commissioner Potočnik (draftsman of the 2004 strategy) for regulatory action, especially in REACH, following the EC's second regulatory review which 'does not meet the expectations of Parliament as expressed in its resolution of 2009' (Schlyter, 2012). Also, the proposal on tractability of nanomaterials of the Belgian Presidency of the Council influenced the Council, which resolved on 'improving environmental policy instruments' by providing the EC with a mandate to review risk assessment and develop a compulsory nanomaterials-database (Council, 2010). Several months earlier, the engineering of such a proposal was created during the workshop of the Belgian Presidency, with the active support of France and Germany (leading nano-markets), Italy, Belgium and The Netherlands (European Presidency, 2010). The EU's delay of the establishment of mandatory requirements for data-collection on the nanomaterials market led the above governments to invoke art. One example of this *go-it-alone* dynamic with explicit national measures is the French environmental code modified in 2010 to

[5] For example, former UK MEP Caroline Lucas expressed concern in 2003 that "innovation is running ahead of regulation", during international seminar on nanotechnology societal impacts (available at: ftp://ftp.cordis.europa.eu/pub/focus/docs/224en.pdf); proposals for amendments to REACH by Carl Schlyter, Caroline Lucas and Hiltrud Beyer were adopted by the environmental committee of the EP on 10.10.2006.

establish a compulsory registry to manufacturers and importers of nano-product in the French market (OECD, 2010: 30–31). This move reflected concerns that oversight is not adequately ensured under REACH. In Germany, the green party introduced a law into the national Parliament to ban all consumer products using nanosilver (European Presidency, 2010). These initiatives triggered the Belgian Presidency proposal for tractability of nanomaterials and for taking responsibility at the Member States level. While the compatibility of this measure with the EU law is subject of open debate, given the fact that it was taken in response to the EC's laissez-faire approach, it may be considered an intervention in a field not harmonized by REACH, jeopardizing the objective of 'ensure free movement of goods by regulatory harmonization' expressed in the 2004 strategy. This point is strongly linked to the explanation on potential regulatory failure previously discussed. Finally, former Dutch Minister of Infrastructure and the Environment, Joop Atsma, led a call in July 2012 for urgent EC regulatory action on nanomaterials risks, supported by Austria, Czech Republic, Denmark, France, Italy, Luxembourg, Spain, Sweden and Croatia. This indicated a convergence, or at least the congruence of risk-averse positions invoked by national governments and accelerated the EU-level decision-making process (Tajany et al., 2012). The aforementioned evidence indicates the significant influence that the green MEPs and member states have had in the policy process in term of pressure on EU-wide policy and risk-aversion.

Regarding the sixth hypothesis, the regulatory outcome is compatible with preferences of the EP, because it constitutes a substantial boost to the precautionary and proactive approach in its proposed resolution (EP, 2009c). By initially limiting the time period for a second regulatory review to two years, the EP and the Council managed to further push their preference for amendments at present. Additionally, by pushing through regulatory clauses before risks are scientifically understood or well-founded, the EP was successful in placing the role of precaution in nanotechnology policymaking, although not entirely accommodated by EU measures (no EU nanomaterials inventory, or compulsory register were agreed).

Similarly, although the EC was less successful in pursuing its preference for the preservation of the regulatory status-quo, it succeeded in affixing its first choice for the incremental adaptive approach as an effective regulatory policy rather than new regulatory frameworks (EC, 2004, 2005). Additionally, the EC managed to secure industrial influence on regulatory policy-making by industry participation in the relevant committees.

Regarding the seventh hypothesis, the regulatory process (e.g., the preparation of the 2005 action plan) deliberately encouraged input from nano-firms. It was dominated so far by strong industry lobbying and nanotech coalitions, including manufacturers, trade associations and international standards organization, e.g., ASTM International and ISO (Kearnes and Rip, 2009). In spite of recent proliferation in government public engagement activities (e.g., Nano-Cap 2006–2009), Miller and Scrinis (2010) argue that 'it is apparent that environmental NGOs are not accorded the same value attributed to other stakeholders in nanotechnology decision-making'.

As significantly, the industrial sector (including that of Germany and the UK) was favorably disposed to nano-regulation (EC, 2005); industry was expected to benefit from clearer regulation early in product development. Concurrently; however, industry's positions were mixed on adjusting existing regulation, especially REACH (FramingNano, 2009). An important point is that European firms, expected to benefit from the regulation, were actually global market actors with substantial activity and funding beyond their member state (see Bach and Newman, 2007 for the EU-global market linkages).

Overall, we found an enhanced EU-level effort with the regulation of risks related to sectorial activities involving N&N. This may be seen as supporting Vogel's (2012) characterization of the general trend toward increased stringency in risk regulation and management in Europe.

5. Conclusions

We analyzed the development of the EU regulatory policy on nanotechnology EHS risks in the crucial formative period of 2004–2012. It appears that a variety of factors and actors explain the regulatory policy process and its outcome. Different theoretical explanations may account for various stages of the policy process as well as for certain features of the regulatory policy. Our analysis suggests that competitiveness dynamics, which set the motivating factor and the background for the emergent regulatory policy, add to other theoretical explanations and explain the policy development timing. EU institutional approach may account for the pivotal roles played by the EC, the EP and the Council (with their authoritative bodies) at the agenda-setting phase and the significant growth in regulatory activity and pragmatic solutions for competence issues. This theory, however, does not explain the EC's limited success in promoting some of its preferences for policy-framing (e.g., the 'wait and see' approach). Policymakers' preferences largely explain the decision-making phase in which regulatory dynamics were driven by the EP's dominant members, who played a significant role in shaping the policy. A power of interest groups theory, which assigns significant impact to powerful green MEPs, may account for the preference of the EP. However, nano-industrial sectors are largely influential in the EC's activity, which secures industrial involvement in regulatory decision-making by participation in the relevant committees. The emergent policy does not entirely reflect the position of 'green pushers' because newly-created regulation or adaptive arrangements might not necessarily include proposed mechanisms for risk averseness (e.g., nano-products inventory).

Overall, this paper highlights direction of influence and a sequence of different theoretical explanations, tested as specific hypotheses. Examining nanotechnology public policy through different theoretical approaches, allows us to capture the ongoing regulatory activity in the EU. It can be understood as a combination of several influences: actions proposed in the global competitive interests of the EU; plus other influences which affect activities at the EU-level in practice, e.g., green political preferences and trade-offs in negotiation. While the policymaking track is still long and complicated and its final outcome remains to be seen, most regulatory activities reflect a public interest rationale and institutionalization of good governance principles and practices. Moreover, they reflect the key role that governments plays in advancing dual and sometimes conflicting agendas in sustainable technology innovation policies.

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