

Multi-level Governance of Nanotechnology in Europe: Policy Variation in Germany, the UK, and the Netherlands

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Within Europe, there has been the emergence of an EU-wide nanotechnology regulatory regime with regional authorities gaining greater decision-making power over a wide range of policy areas. However, despite the development of more comprehensive European nanotechnology policies, considerable variation remains in how member states implement these rules and regulations. In this article, we utilize a multi-level governance approach, to explore this seeming paradox in order to explain cross-national policy variation within a common European regulatory framework. This broader analytical approach allows us to account for the wide range of actors involved in European nanotechnology governance including, national governments, international organizations, research institutes, firms, and advocacy groups. Case study analysis of Germany, the United Kingdom, and the Netherlands emphasizes how differences in domestic policy styles explain variation in the implementation of nanotechnology regulations across states. At the same time, the engagement of national governments with European and international regulatory efforts highlights the important role that states play in contributing to the development of a common nanotechnology regime in Europe.

Introduction

Around the world, governments and stakeholders working in nanotechnology are engaged in deliberations on how best to regulate these emerging technologies. Despite great promise, much uncertainty remains about the long-term consequences of the manufacturing and use of nanomaterials. Such uncertainty poses challenges for

policymakers at local, national, and international levels about how best to promote economic growth and innovation while also ensuring the health and safety of citizens and protecting the environment. These challenges raise serious questions about which factors influence emerging international nanotechnology governance regimes, what role national governments play in shaping these regulations, and whether cross-border policy harmonization is necessary to achieve stated goals.

Within the European Union (EU), a nanotechnology regulatory regime has been emerging over the past two decades with regional authorities gaining greater decision-making power over a range of policy areas, including occupational health and safety, nano-chemical production, and environmental protection. However, despite the development of more comprehensive nanotechnology policies, considerable variation remains in how EU member states implement these rules and regulations. In this article, we utilize a multi-level governance approach, to explore this seeming paradox in order to explain cross-national policy variation within a common European regulatory framework.

The next section of this article examines three prominent theoretical models of governance. Unlike theories that focus solely on international influences or state-centric dimensions of policymaking, our multi-level governance approach accounts for the complex interactions that take place among a wide range of actors involved at the local, national, and supranational levels. This broader analytical approach provides an important account of EU governance that is not captured by alternative theoretical perspectives. The third section examines the wide range of non-state actors involved in nanotechnology governance within Europe, including international organizations, research institutes, firms, and advocacy groups. The fourth section explores case studies for Germany, the United Kingdom, and the Netherlands, three prominent EU member states with large nanotechnology markets.¹ These case studies emphasize how differences in domestic policy styles explain variation in the implementation of nanotechnology regulations across states. At the same time, the engagement of national governments with European and international regulatory efforts highlights the important role that these states play in contributing to the development of a common nanotechnology regime in Europe. The final section provides an overview of these findings and gives implications for future research and policy.

Models of Governance

To understand how the governance of nanotechnologies in Europe has evolved it is important to employ theoretical frameworks to explain what drives the policymaking process across states and at the international and European levels. Here, we examine three competing theoretical arguments, each focusing on different aspects of the emerging EU nanotechnology regulatory regime. For our main theoretical argument, we utilize a multi-level governance approach that emphasizes the importance of public and private actors at multiple levels in shaping governance outcomes. We also explore two prominent counter-arguments that offer competing explanations of EU nanotechnology regulatory development. First, liberalization theories focus on the

independent role that globalization and international market pressures play in shaping EU rules and domestic policies. Second, state-centric theories of governance highlight the singular importance that national governments and interstate negotiation play in EU policy development.

Multi-level Governance

Unlike theories that emphasize top-down or bottom-up explanations of European governance, the concept of multi-level governance focuses on the complex interactions that take place among national governments and non-state actors involved in policymaking at local, national, and supranational levels. Over the past several decades, authority has shifted away from the sole responsibility of nation states to include actors operating both within states and at the supranational level.² Jurisdiction over some policy areas has also been extended horizontally, beyond the traditional boundaries of the state to create cross-national regulatory frameworks.

A prominent example of this emerging form of multi-level governance is found in the EU, in which decision-making and control over different policy areas has become increasingly complex and in which the state, while still prominent, is no longer the sole governing authority. Regional European bodies, such as the European Commission, Council of Ministers, European Parliament, and the European Court of Justice, play important roles in policy development and implementation both independently and in conjunction with states and non-state actors.³ While member states retain some autonomy, national policymaking decisions are embedded within larger regional and international settings.⁴ Yet in this context, the domestic rules, regulations, and norms of member states influence EU policy. State policies in turn are influenced by other member states and by European-wide regulations and practices. Increasingly, non-state actors, such as networks of professionals with recognized expertise and competence in particular domains, non-governmental organizations, and firms, also influence decision-making by collaborating with and putting pressure on states and EU institutions (Ref. 3, p. 24; Ref. 4, p. 111). Ultimately, EU decision-making represents an important shift away from traditional state centric conceptions of authority to a complex model where authority is dispersed vertically and horizontally among various actors.

Multi-level governance theory argues that globalization and liberalization increases the mutual interdependence of actors leading to more cooperative forms of governance.⁵ Demand for the harmonization of EU policies can be seen as primarily driven by policy interdependence.⁶ States may seek harmonization at the European level in policy areas where they lack the individual capacity to address an issue alone or see some benefit in cooperating with other states. Yet, amidst policy harmonization we should expect to see variation in domestic policymaking styles, regulatory capacity, and institutional structures (Ref. 5, p. 71). While states may have shared interests in the development of common policies, how these interests are translated into EU rules and regulations will depend upon the actors and institutions

operating at various levels and across jurisdictions, which are involved in the policymaking process (Ref. 6, p. 8). How these supranational policies are then applied at the national levels depends greatly upon the domestic actors and institutions involved in the implementation and monitoring of rules and regulations.

Liberalization and Globalization

Liberalization theories examine the ways in which the dynamics of globalization constrain and shape domestic policymaking.⁷ These theories posit that the expansion of global markets and adoption of free market principles lead to greater policy convergence across states as governments and firms adopt similar strategies and practices.⁸ Such arguments follow neoliberal assumptions predicated on the centrality of markets and economic power in shaping international outcomes. Based on these assumptions, economic strength drives policy harmonization across states. In other words, policies and practices that operate within the world's largest markets will, over time, become the global regulatory norm (Ref. 7, p. 628). Larger markets have greater power to protect their policy preferences and leverage their economic power to impose their policies on smaller markets.⁹ The underlying argument is that larger economies will attract more firms and investors seeking to gain market access. To do so, these actors are willing to adopt rules and regulations that exist within these markets.¹⁰ In turn, global firms seek harmonization of regulatory rules across markets as a way to ease their own burdens as they seek access to these markets. In doing so they may put pressure on their own (and other) governments for reforms that coincide with the policies of more powerful states.

In the case of the EU, integration has greatly reduced barriers to economic, political, and cultural exchange.¹¹ Proponents of liberalization argue that international market pressures will lead to the further convergence of European policy areas. Such convergence is not limited to economic governance, but to diverse policy areas such as environmental protection and public health. Such harmonization in time should lead to decreased variation in the structures and processes of policymaking across states.¹² Domestic policymaking, from this perspective, is largely shaped by exogenous pressure from powerful economic actors, institutions, and norms at regional and international levels.¹³ Hypotheses rooted in this theoretical perspective posit that accelerated globalization should lead to the convergence of policies across states.

State-Centric Governance

State-centric theories of policy development emphasize the importance of state decision-making. Rather than global economic pressures relentlessly driving policy convergence, these theories argue that states' preferences are the primary factor shaping global governance decisions. From this perspective, states as sovereign actors maintain control over policy decisions, and international bargaining is defined by interstate negotiation. While powerful states may be able to leverage their

preferences, smaller states retain a great deal of autonomy to resist such pressures. Existing domestic structures influence the incentives and behaviour of actors throughout the policymaking process.¹⁴ Differences in political and economic structures across countries therefore will produce divergent policy outcomes. The causal logic of such state centred analysis emphasizes the path dependent nature of national policy outcomes.¹⁵ The result is to constrain policy alternatives and reinforce the primacy of existing domestic structures and policy processes in the face of external pressures to harmonize.

The overall implication here is that policy outcomes are more powerfully affected by domestic dynamics than by the influence of international actors and norms.¹⁶ As a result, rather than convergence we should expect to see continued variation in national policies, reflecting domestic differences.¹⁷ In the case of the EU, heterogeneous political and economic structures will produce diverse policy outcomes across member states. Since states retain autonomy, policy convergence among them occurs through interstate negotiation, either when respective states see harmonization as mutually beneficial or, conversely, when more powerful states are able to coerce others to adopt their preferred policies. Either way, the results are obtained through processes of interstate bargaining, and not because of any effects of globalization per se. From this perspective the competencies that the EU has gained and the regulatory authority they have been granted, has been limited and further integration will be unlikely.¹⁸ In the case of nanotechnology, we should expect to see states maintaining primary policy control over the governance of nanotechnology in Europe.

The Emerging International and European Nanotechnology Regime

Various international and European organizations have taken active and deliberate steps to foster complimentary and comprehensive regulations to address the risks of nanotechnology. Initiatives such as the existing EU chemical regulations protocol (REACH), standard setting processes in the International Organization for Standardization (ISO), and Working Parties of the Organization for Economic Cooperation and Development (OECD) are highly influential in defining international rules and standards concerning nanotechnology development. The UK, Germany, and the Netherlands are all active members of each of these organizations and work together with the other members to shape and determine a common approach to nanotechnology development.

The European Union

The European Commission, which has the power to enact EU-wide legislation among its 28 member states, has been at the forefront of regulatory action in elevating concerns about the gains and potential risks of nanotechnology. Early on, in 2005, the Commission adopted *Nanosciences and Nanotechnologies: An Action Plan for Europe 2005–2009*, a comprehensive plan for the development and regulation of nanotechnology in the region.¹⁹ The Action Plan provided impetus to further

nanotechnology research and development (R&D), establish an effective dialogue with various stakeholders, increase international collaboration within and beyond the EU, and protect public health and the environment. Importantly, the document focused on risk assessment at all stages of the technology life cycle, from R&D and manufacturing to distribution and disposal. In doing so, the EU established an authoritative path for future nanotechnology policy considerations.

In 2008, various EU directorates, at the request of the European Commission, prepared a regulatory review of EU nanotechnology legislation across sectors and concluded that the existing regulatory framework was capable of addressing any potential risks of nanotechnology.²⁰ A follow-up review in 2012 confirmed the Commission's view that the existing EU directive on the Registration, Evaluation, Authorization of Chemical Substances, or REACH (EC 1907/2006), would provide the best possible framework for risk management of nanomaterials.²¹ The incorporation of nanotechnologies into the existing REACH framework is significant as it has the potential to provide an extensive assessment of the risks associated with basic chemical properties of nanomaterials.

EU institutions have been instrumental in defining the nanotechnology policy agenda. Through various broad programmes, among these the seven framework programmes since 1984, the EU continues to fund a wide array of research. European Commission reports, in particular, legitimized a specific legislative path incorporating the precautionary principle – a preventative strategy that encourages action to be taken to address possible risks, such as harm to humans or the environment, in cases where scientific understanding is still uncertain – as an approach toward managing new and emerging risks.²² This regulatory approach is significant as it places the burden of proof on regulators and firms to establish the safety of nanotechnology products before bringing them to market, rather than assuming they are benign until proven otherwise. EU regulations also serve as a governance model for member states and in some cases enforce strict domestic adherence to new rules and standards. Yet, while EU institutions are active in shaping the policy agenda and decision-making, they do not exercise full control over the European policy process. Key member states and non-government actors have been highly involved in the development of nanotechnology regulation both within their respective domestic jurisdictions and at the European level.

The Role of International Organizations

Besides the EU, the ISO and OECD have been major platforms for international knowledge building on nanotechnology risk and regulation.²³ The ISO, for example, established a specific technical committee, TC 229 Nanotechnologies, in 2005, with the objective of establishing common standards, nomenclature and the characterization of nanomaterials.²⁴ Similar initiatives have been undertaken by the OECD, such as the Working Party on Manufactured Nanomaterials (WPMN) which was established in 2006 to advise governments on how best to formulate policies, coordinate research, and gather data for responsible nanotechnology development.²⁵ An important

WPNM objective is to define a minimum set of nanomaterial data, which manufacturers should supply in order to get approval for production and use in the market (Ref. 25).

Since membership in these three organizations often overlaps, there is an increasing demand for a consolidation of findings. Seeking increased harmonization of international standards, the European Commission recently approved the NANoREG project. NANoREG aims to develop a common European approach to test nanomaterials based on the findings of various OECD and ISO initiatives. It seeks to improve cooperation between regulators and industry in order to develop common tools for nanotechnology risk assessment by 2016.²⁶

Role of Sub-State and Non-Governmental Actors

In addition to international organizations, sub-state actors have made important contributions to the emerging EU nanotechnology governance regime. Non-governmental actors, such as research institutes, public interest groups, and firms, are influential in shaping the governance of nanotechnology in Europe through a range of activities including gathering data and disseminating information, raising public awareness about health and environmental concerns, participating in technical committees and stakeholder workshops, lobbying national parliaments and EU institutions.²⁷

The EU has welcomed this public participation in governance. For example, in 2008 the European Commission sponsored 'Framing Nano' a multi-stakeholder dialogue to address the responsible development of nanotechnology in Europe. The platform allowed various non-state actors, including, scientists, business representatives, environmental advocacy groups, and labour unions, to work together toward establishing common goals and objectives. The project proposed an 'inclusive' and reflective policymaking approach, allowing for multiple participants to be heard.²⁸

Supranational Harmonization, Domestic Variation

While there has been a harmonization of basic rules and regulations concerning nanotechnology risk at the European level, there continues to be significant variation in how these policies are implemented at the national level. Since nanotechnology has significant cross-sectoral applications, nanomaterials are not regulated under a single legislative framework. There continues to be a diversity of regulations covering a wide range of applications including foods, cosmetics, consumer products, textiles, and medical devices. In some cases there exists a governance gap at the European level and the regulation of nanotechnologies continues to fall under member state authority. Even in the case of REACH, which is arguably the most comprehensive framework to regulate nanomaterials in Europe and which represents a significant transfer of competencies to European authorities, there continues to be important national differences. While REACH provides a degree of harmonization, requiring states to comply with basic standards, it allows for individual countries to adopt more

rigorous rules and regulations as necessary (Ref. 2, p. 5). Such regulatory ‘spaces’ lead to differences in regulations across states as countries with more developed markets and regulatory capacity, such as Germany, the UK, and the Netherlands, build upon the existing requirements by implementing more stringent standards. These variations in domestic regulations reflect important differences in state policy preferences and attitudes toward risk. In order to gain a clearer picture of the development a European nanotechnology regime it is vital to examine these domestic differences.

Germany

Germany is home to the largest nanotechnology market in Europe with nearly 400 companies involved with the development, production, or use of nanomaterials (Ref. 1, p. 13). According to the Federal Ministry of Education and Research, nearly half of all EU nanotechnology firms are based in Germany (Ref. 1, p. 15). Throughout Europe, Germany has the highest levels of public and private sector investment in nanotechnology of any country, with government spending second only to the European Commission (Ref. 1, p. 15). The federal government has also made great strides to promote nanotechnology innovation and develop wide-ranging regulations to limit potential risks. Since the German economy is export oriented, it is important that products developed domestically are able to reach European and international markets, creating incentives for harmonizing regulatory standards across countries for safety and environmental concerns. In addition, Germany has a highly developed chemicals sectors with a comprehensive regulatory system to categorize and manage potentially harmful substances, which serves as a guide for nanotechnology regulation at the national and European levels.

Traditions of Governance

At the heart of German policymaking is a long-held belief in the value of policy conservatism, caution, and incrementalism.²⁹ Government intervention is seen as vital to ensuring social protection against possible harm to human health and the environment. Macrocorporatist³⁰ strategies provide formal representation for various stakeholders, and the heavy integration of firms within economic sectors allows policies and practices to be adopted across networks. The result is a policymaking process that takes place in numerous policy venues and incorporates various stakeholders throughout society.³¹

Environmental policies, for example, are largely shaped by industry actors, scientists and technical advisers, and government officials who collaborate to formulate policies and define goals.³² Government officials work with industry representatives to establish policies that will meet environmental, health, and economic concerns through voluntary agreements (Ref. 32, p. 128). Expert panels composed of scientific and industry specialists are highly involved in monitoring policy implementation, reflecting a risk-adverse technocratic approach. Structured representation is also extended to powerful NGOs, such as Friends of the Earth Germany.

While public policy in Germany is developed in an open manner through negotiations with interested stakeholders, policy implementation is a fairly rigid process in which the state imposes comprehensive standards across industries and jurisdictions. Environmental standards, for example, are applied uniformly to all firms across sectors (Ref. 32, p. 132). In other words, while public policy in Germany is developed through an inclusive process that incorporates a range of public and private stakeholders, it is then implemented in a more rigid and legalistic manner across all sectors (Ref. 31, p. 685).

German Governance of Nanotechnology

Nanotechnology risk assessment strategies in Germany have been exemplary of open policymaking combined with rigid implementation of industry-wide requirements. In an attempt to identify the potential negative health and environmental effects of nanomaterials, the German Federal Ministry for the Environment (BMU) and the Federal Institute for Occupational Health and Safety (BAuA) along with the Association of the Chemical Industry (VCI) held a stakeholder dialogue in 2005 and composed a joint questionnaire to be administered to firms throughout the country³³ This data collection exercise, undertaken by state officials and industry representatives, provided an overview of the production, protection measures, and handling of nanomaterials throughout the German economy with the aim of establishing universal regulations for all industries.

Application of the precautionary principle and risk adverse governance strategies are evident in several recent developments in German nanotechnology regulatory assessments. In 2011, the Federal Institute for Risk Assessment (BfR) issued a statement entitled 'Safety of Nano Silver in Consumer Products: Many Questions Remain Open' which recommended that, due to incomplete data on the health risks and toxicity of nano-silver, measures should be taken to prevent their use in foods and other products until a final assessment of possible harm can be obtained.³⁴ This recommendation has implications for a number of different sectors as nano-silver compounds are used for their anti-microbial effects in a wide-range of products, from cosmetics to textiles and medicines. In its Opinion No. 24/2010 the BfR indicated that nano-silver might have a different toxicological profile than other substances, including that of bulk silver, and advised that further evaluation would be needed to confirm its safety before nano-silver should be introduced in consumer products (Ref. 34).

This recommendation came out of a workshop that included industry representatives, scientific experts, and civil society groups. The inclusion of a broad range of participants highlights the inclusive nature of many German risk assessment initiatives. It also points to the influence of non-economic actors as this endorsement faced opposition by some industry representatives who argued that existing data were sufficient to permit introduction of nano-silver products into the marketplace. The BfR has also recently begun similar inquiries into the assessment of hazardous nanomaterials in cosmetic products.

In 2014, the BfR along with the BAuA and the Federal Environment Agency (UBA) proposed an amendment to REACH regulations for better identification and assessment of the potential hazards of nanomaterials, including ultra-fine powders and fibres.³⁵ If adopted, this amendment would also include the examination and testing of chemicals produced in lower quantities that do not currently fall under evaluation. Nanomaterials produced at a smaller scale may present greater risks as these chemicals have low density and higher potency than conventional bulk chemicals (Ref. 35). The EU is planning to review these proposed reforms to REACH by 2015.³⁶ These suggestions illustrate how government agencies shape EU regulations by advocating for harmonized requirements, which reflect domestic policies and preferences.

In sum, the German policy process provides structured access to a wide array of stakeholders, whose interests are reflected in state policy decisions. Representative of this broader political opportunity structure,³⁷ the nation's main nanotechnology strategy, the *German Federal Government Nanotechnology Action Plan 2015*, includes specific provisions to evaluate the effects of nanotechnology on human health and the environment, adopt a precautionary regulatory strategy, and to establish an inclusive dialogue with stakeholders (Ref. 28, p. 58). To this final point, the German government has promoted a stakeholder dialogues, including the 'Nano-Dialog 2006–2008' aimed at providing a platform for policymakers, researchers, industry representatives, and other societal stakeholders to discuss the advantages and risks of nanotechnology development (Ref. 28, p. 58).

The United Kingdom

The UK, with the second largest number of nanotechnology firms in Europe,³⁸ shares similar economic incentives with Germany to promote the growth of the nanotechnology sector while at the same time developing regulations to limit potential risks to public health, occupational safety, and the environment. However, compared with Germany, the policymaking process in the UK is more closed and tends to favour industrial interests over broader societal and environmental groups (Ref. 32, p. 88). However, policy implementation is much more flexible in the UK than in Germany, allowing firms to address risks according to their capacity under the best practicable means principle.³⁹

Traditions of Governance

The policy process in the UK is often defined as exclusive, in which state and industry representatives cooperate to formulate and implement policies largely at the exclusion of other social interests.⁴⁰ This process therefore favours major economic actors, such as industry representatives, who are able to provide technical advice and influence policy decisions, while civil society actors, such as environmental groups, have had greater difficulty accessing decision-making circles.⁴¹ This limited access to policymaking for non-economic interests is due in part to the unitary British state in which power is concentrated at the national level. Compared with the German federal

system, whose fragmentation and separation of powers allow for a greater number of policy access points, decision-making and lobbying efforts in the UK take place almost exclusively at Westminster, which provides fewer opportunities for public interest groups to influence policy outcomes (Ref. 31, p. 684; Ref. 32, p. 90).

While policymaking in the UK represents a more closed process, implementation is highly flexible and relies less on universal regulations applied across sectors (Ref. 31, p. 685). Monitoring and evaluating of environmental policy, for example, is typically based on the best practicable means principle, under which individual firms are required to limit their environmental impact to the highest degree possible given their resources and capacity (Ref. 32, p. 90). This process relies on voluntary compliance and self-monitoring by firms rather than government enforcement of universal standards across industries. Compared with their German counterparts, UK firms have much greater control over policy development, implementation, and evaluation.

UK Governance of Nanotechnology

As an example of this flexible relationship between government and firms, between 2006 and 2008 the UK's Department for Environment, Food, and Rural Affairs (DEFRA) implemented a voluntary reporting scheme in which firms and research organizations that choose to participate would provide the government with information about the potential risks posed by manufactured nanomaterials.⁴² During this two-year period, DEFRA received data from only 11 firms and two academic institutions⁴³ out of a pool of more than 640 firms and research organizations involved in the development of nanotechnologies.⁴⁴ This voluntary approach emphasizes the independence that firms have in monitoring their activities and shows that DEFRA could not compel firms to report. The DEFRA self-reporting also indicates that those firms and technical experts who did respond were able to have an influential role in informing government policy decisions since they were the main source of data on industry practices and assessments as to the potential risk of nanotechnology.

Advocates of this approach argue that, voluntary measures such as codes of conduct, data-sharing initiatives, and public engagement are less resource intensive and require less time to develop and implement than traditional regulations.⁴⁵ These measures are seen as an efficient means to generate information about the risks of nanotechnology and provide positive policy feedback. However, opponents argue that these voluntary measures lack mechanisms for independent evaluation or sanctions for poor compliance.⁴⁶ Sceptics also see these approaches as an industry strategy to prevent or delay the development of more rigorous regulations and limit public involvement (Ref. 47, p. 453).

Several public interest groups have called into question the effectiveness of the DEFRA voluntary reporting scheme citing disappointing levels of response (Ref. 46, p. 477; Ref. 47, p. 191). In fact, the perceived failure of voluntary reporting schemes in the UK has created pressure at the European level to promote mandatory reporting

schemes across states. The UK's Royal Commission on Environmental Pollution (RCEP) and the International Risk Governance Council (IRGC), along with several non-governmental European consumer groups, have suggested that a mandatory EU reporting scheme for industries be established and linked to existing REACH registration requirements. However, it seems highly unlikely that the UK will adopt a mandatory reporting scheme anytime soon. Instead, the government has sought to revise the existing voluntary reporting system to include products that contain nanomaterials and to request feedback from a larger scope of firms and organizations associated with nano development (Ref. 46, p. 479). In response to the RCEP and IRGC recommendation, the UK government issued a response suggesting that while a review should be conducted of existing structures for sharing information and stakeholder engagement, a 'light touch' approach should be maintained in order to limit the regulatory burden on firms and ensure economic competitiveness.⁴⁷

Occupational safety standards governing nanomaterials, regulated under the Control of Substances Hazardous to Health Regulations (COSHH), represents a similar style favouring voluntary and flexible approaches, which take into account individual firm capacity. COSHH requires employers to protect workers from exposure to harmful substances in the workplace, while granting companies the independence to decide which measures would be most appropriate and feasible to adopt.⁴⁸ These approaches reveal a regulatory logic, which seeks to address potential risk while at the same time limiting government intervention in market activities. In other words, it grants significant autonomy for firms to meet government specified targets, rather than requiring adherence to uniform rules and standards across sectors.

While policymaking tends to favour the interests of industry actors, some non-state groups unaffiliated with business, have been able to influence the policymaking process by providing technical and scientific expertise. In particular, the Royal Society and the Royal Academy of Engineering (RSRAE), two independent UK research institutions, put out a report in 2004 on nanotechnology regulation that was highly influential in furthering the discussion of risk assessment, standard practices, and recommendations for policy both domestically and throughout Europe.⁴⁹ This report served as a catalyst for discussion of nanotechnology governance in Europe and introduced the precautionary principle into the policy discussion. The RSRAE has been instrumental in elevating the issue of nanotechnology risk to the top of the European policy agenda and continues to be an influential actor providing technical expertise and policy recommendations.

In 2008, the RSRAE, in partnership with several other organizations, developed the Responsible NanoCode, a voluntary code of conduct for firms handling nanomaterials, intended to promote best practices in the research, development and production of nanotechnologies (Ref. 47, p. 453). The code, initially intended to be adopted by companies within the UK, has been designed so that it can be implemented more broadly in numerous countries and under different regulatory regimes.⁵⁰ The process of developing the code began with a business-focused workshop that brought together a representative group of 17 European companies with a commercial interest in nanotechnology. This consultation allowed companies

involved in nanotechnology production to provide input on how best to ensure that the code would reflect industry concerns and be realistic to implement. The code offers a voluntary principles-based rather than standards-based approach to promote common practices. In many respects, the approach taken towards developing the NanoCode is very much in keeping with the UK policy process of business engagement and flexible policy adoption. It is important to note that organizations such as the RSRAE have been able to influence legislation and provide recommendations to industrial actors due to the high levels of specialized knowledge and expertise that they hold, reflecting a more technocratic approach rather than a pluralistic one.

Notably, as a result of their limited access to policymaking at home, many other non-state actors such as environmental organizations have begun to create pressure for regulatory change at the European level rather than looking to domestic institutions (Ref. 32, p. 110). According to the European Commission's transparency register, there are currently over 300 British-based civil society organizations operating in Brussels focused specifically on environmental and public health policy issues.⁵¹ By circumventing the state, interest groups are able to gain access to policy venues at the European level, thus influencing regional regulations and creating demands for domestic legislative changes.

The Netherlands

As in the UK and Germany, economic incentives fuelled the growth of nanotechnology development in the Netherlands. Yet, the Dutch government early on stressed the need for the responsible development and use of nanotechnology. Over the past several years, Dutch nanotechnology rules and regulations have become more cohesive with potential risks being addressed by a unified approach. The notion of integrated and comprehensive policies has therefore become the norm and a condition for public funding of nanotechnology research in the Netherlands.

The Netherlands, a relatively small country with a strong tradition of international trade and engagement, relies heavily on transnational collaboration to maintain and grow its position, moving away from any state-centric approach. To the Dutch, international collaboration can yield faster and better results than a relatively small country like the Netherlands can achieve on its own. The emphasis on international collaboration has a clear neo-functional aspect: international collaboration is ultimately in the national interest. The Dutch are actively involved in shaping global governance, notably within the EU, to ensure that any international agreements and policies reflect Dutch interests.

Traditions of Governance

Dutch governance builds on a long tradition of consensus building among stakeholders on important policy questions through structured consultation.⁵² Consociationalism historically has been a key aspect of the Dutch political system as a way to accommodate the preferences of different groups that made up the pluralist Dutch society until the late 1960s.⁵³ This Dutch model of governance is

inclusive and open, yet structured. Like Germany, the Netherlands has a long tradition of neo-corporatism in governance (Ref. 54). Although Dutch politics have become more pluralist in the last decades, much of the pre-existing set-up of consensus-seeking policymaking remains and enjoys high legitimacy. As a result, in many policy fields, multi-stakeholder consultation, between government representatives and a diverse set of non-government actors, remains the norm.⁵⁴

A General Approach to the Risks of Human Activities

In the early 2000s, the Dutch Cabinet adopted a general risk strategy to guide policymaking. According to this approach, the risk associated with human activities is based on the probability of incident, the level of uncertainty about the risk, and the scope and gravity of harm. This risk assessment also accounts for more social factors such as the level of potential controversy, the effort needed to respond to risks, and whether activities pose higher risks for specific populations. Activities associated with higher levels of risk require more public engagement and participation when assessing whether they are acceptable for society to bear.⁵⁵ In its risk approach, the Cabinet follows the precautionary principle as introduced by the EU (Ref. 22). To counter any unrealistic applications of the precautionary principle that might constrain scientific progress, the general risk approach applies a principle of utility or proportionality that aims to balance potential benefits of certain activities with the costs of limiting their risks.⁵⁶

Early Uptake of Nanotechnology

The development of nanotechnology in the Netherlands is marked by early initiation of interdisciplinary scientific research and by the early uptake of nanotechnology by Dutch industry, in particular by sizeable international corporations, such as Philips and Akzo-Nobel.⁵⁷ NanoNextNL, is the third in a series of public-private partnerships between universities, research institutes and companies, which started in 2002. It has been instrumental in advancing nanotechnology development in the Netherlands and lists more than 100 Dutch companies involved in its activities.⁵⁸ The Netherlands is also a global leader in nanotechnology R&D and regulation along with countries such as the United States, Germany, the UK and China.⁵⁹ This is surprising given its small size and market relative to other global leaders and reflects considerable investment on behalf of the Dutch government. For example, the NanoNextNL consortium and its linked network of facilities NanoLabNL have a budget of around €250 million to cover the years 2012 to 2016. Public funding covers half of the budget. The Dutch government has set two clear conditions for funding nanotechnology research through the consortia: it requires the partners to match the amount public funding and it requires that 15% of the budget is dedicated to risk-related research.⁶⁰

Nanotechnology plays a pivotal role in an ambitious broader programme aiming to expand the international competitiveness of the Netherlands: the goal of the *Top Sectoren* programme is to place the Netherlands in the worldwide top of

knowledge-based economies by 2020, by increasing the overall Dutch annual investment in research to 2.5% of GDP.⁶¹ These ambitions coincide with the European *Horizon 2020* programme for research and innovation. Both programmes stress that risks and uncertainties associated with nanotechnology are addressed in a more integrated approach.²¹

Dutch Governance of Manufactured Nanomaterials

Beginning in 2005, Dutch government advisory councils began to advocate for increased state involvement in the development of nanotechnology. The aim is to ensure that knowledge gaps about potential nanotechnology risks are addressed and that R&D of this emerging technology is done in a responsible manner.⁶² The Dutch Cabinet first presented its view on nanotechnologies in a 2006 vision statement entitled 'From Small to Great'.⁶³ The content of the document mirrored the outline of the EU's 2005 Action Plan, with sections on business and research opportunities; societal, ethical, and legal issues; public engagement; and risk assessment. The Cabinet focused on the uncertainty and risks associated with nano-materials and the lack of standardization of this technology. The Cabinet requested a group of stakeholders involved in Dutch nanotechnology production to put together a Strategic Research Agenda for nanotechnology, outlining research priorities and formulating a request for continuing funding.⁶⁴

In 2007, the Netherlands adopted REACH regulations that replaced all existing policies with regard to the use of materials and chemicals in the Netherlands, which may include manufactured nanomaterials.⁶⁵ Parliament discussed REACH implementation costs for the industry in 2006. Industry interests argued that the REACH requirements based on the precautionary principle may place an undue burden on firms. Partly in response to industry concerns, the Dutch Cabinet has promoted a more pragmatic interpretation of the precautionary principle in the form of 'no data, no exposure', meaning that workers or consumers should not be exposed to risks in the production and use of such materials.⁶⁶

In 2008, at the request of the Dutch Cabinet and other member state partners, the European Commission set up a subgroup under the REACH called the Competent Authority on nanomaterials (CASG Nano) to address the regulation of materials produced at the nano-scale (Ref. 62). Through participation in this group, the Dutch Cabinet aimed to encourage European collaboration in the development of a common strategy for the risk assessment of manufactured nanomaterials.⁶⁷ REACH therefore has become the main instrument wielded by the Dutch government to regulate the use of manufactured nanomaterials in the Netherlands.

Reflecting the interdependence between Dutch and European governance strategies, the 2008 'Nanotechnology Action Plan', which serves as the basis of Dutch nanotechnology governance, is modelled after the European Commission's 2005 Action Plan. According to this national Action Plan, the Dutch government seeks to create a climate for responsible and economically viable development of nanotechnology, based on four premises: (1) an ambitious agenda for research and

business opportunities; (2) an inclusive approach to address ethical, social, and legal issues pertaining to nanotechnology; (3) a programme to stimulate public engagement; and (4) an emerging regulatory model that recognizes the risks and uncertainty associated with nanomaterials. This government has also stressed that addressing the risks of nanotechnology within national boundaries would be ineffective and inefficient, as its production and use takes place in a wider European setting.⁶⁸ Therefore, the Dutch government has urged stakeholders to address these issues through international collaboration. This objective of international cooperation is made clear in the Action Plan, which states that, ‘the short term aim of the Cabinet is the embedding of European legislation’ (Ref. 62, p. 4).

The 2008 Nanotechnology Action Plan links to the 2008 ‘Strategic Research Agenda’ (SRA),⁵⁹ which has become the guideline of nanotechnology R&D priorities in the Netherlands. The SRA allocates 15% of the overall budget to risk-related research⁵⁹ at the explicit request of the government (Ref. 59, p. 11). In 2012, the Dutch Cabinet, looking to find ways to accelerate risk-related research for new manufactured nanomaterials proposed the NANoREG project to the EU.⁶⁹ The project aims to provide regulators throughout the EU with common instruments to assess the risks and remaining uncertainties of nanomaterials.²⁶ Membership of NANoREG is not limited to government representatives and the organization explicitly seeks collaboration between various non-state actors. Currently around 60 partners – many from independent research organizations and firms – from nearly 15 EU countries have joined the NANoREG project.²⁶ The overarching goal of this collaboration is for the various stakeholders involved to benefit from a multi-disciplinary approach to nanotechnology innovation. As a NANoREG leader, the Dutch Ministry of Infrastructure and the Environment is expected to present its results in 2016.^{26,69}

Overall, the Netherlands actively seeks to contribute to the harmonization of global nanotechnology regulations by integrating Dutch national interests and knowledge with broader European and international governance strategies. By engaging with various stakeholders at multiple levels the Dutch have sought to advance a common approach for the safe development of nanotechnology, while allowing for specific provisions for Dutch policy preparation and implementation. This collaborative policymaking approach has allowed the Dutch to emphasize economic growth while balancing the need for effective governance strategies to address the potential risks of nanotechnology.

Conclusion

Ultimately, the UK, Germany and the Netherlands case studies highlight the important role that member states play in the development of nanotechnology rules and regulations both domestically and at the European level. By engaging with EU institutions and non-state actors, states are able to identify best practices, guidelines, and common standards for the responsible development of nanotechnology throughout Europe that still meet domestic preferences. This multi-level engagement of

various actors has contributed to the regional harmonization of nanotechnology policies in Europe, such as common rules and regulations for nano-chemicals. At the same time, the European nanotechnology regime has allowed for flexible implementation of policies, allowing states to adopt and enforce policies according to domestic practices. As a result, we see both the expansion and harmonization of nanotechnology governance within Europe and continued domestic variation in how states implement these policies.

This divergence within convergence is not captured by state-centric nor liberalization governance theories. While we see the continued importance of national governments in domestic policy implementation and supranational policymaking efforts, state-centric arguments have difficulty accounting for the increased prominence and capacity of EU authorities and the increased harmonization of regional nanotechnology rules and standards. At the same time that we see an emerging European nanotechnology regime, we do not see a drive towards policy convergence across states anticipated by liberalization theories. Within these newly harmonized governance systems, there exists considerable variation in the policymaking processes, preferences, and implementation of nanotechnology regulations at the state level. In other words, both alternative theoretical approaches fail to capture important dimensions of the emerging EU nanotechnology regulatory framework.

In order to understand the complex and evolving nature of EU nanotechnology governance, we emphasize the utility of a multi-level governance framework. This approach offers a useful heuristic model that bridges the seemingly conflictual relationship that other theories identify between national self-interest and international pressures. Far from focusing solely on state-centric regulatory approaches, we argue that national governments willingly and deliberately choose to pursue a multi-level strategy in order to address concerns that are possibly beyond their own domestic capacity. This is apparent in the active role that governments in the UK, Germany and the Netherlands have taken in European nanotechnology policymaking. As part of this multi-level approach, states accept diminished influence in the emerging regime in return for a more effective and comprehensive regulatory response that still allows for national divergence.

Ultimately, the examination of the emerging European nanotechnology regime offers an important lens to understand the evolving nature of EU governance. This is of particular importance as EU institutions have gained more regulatory authority over different policy areas, such as occupational health and safety, immigration, and fiscal policies in recent years. Our expectation is that the multi-level and cross-sectoral dynamics that operate within the nanotechnology policy arena will have important parallels within other areas of EU governance that can better be understood through multi-level governance analysis. This approach offers exciting new opportunities to advance research about the complex interactions among governments, EU institutions, and non-state actors, which shape governance throughout Europe and beyond.

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