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ARTICLE

The Sources of EU's International Influence on Nanotechnology Risk Regulation and Governance

Ronit Justo-Hanani

The Department of Public Policy, and the Steinhardt Museum of Natural History, Tel Aviv University, Tel Aviv, Israel
Email: ronitjus@mail.tau.ac.il

Abstract

The European Union is a world leader in nanotechnology environmental, health and safety (EHS) risk regulation, and since its policy integration has been increasingly active in promoting international coordination and cooperation on nanotechnology risk governance. What affects its ability to influence nanotechnology risk regulation and governance internationally? This analysis focuses on the European Union (EU) level arguing that the EU's scientific and regulatory capacities have significant explanatory power. Empirically, the article examines three cases of EU influence in key areas of international nanotechnology risk regulation and governance – nanosafety research for regulatory purpose, science diplomacy, and multilateral risk governance, following its integrated policy.

Keywords: EU external affairs; international coordination and cooperation; nanotechnology risk regulation; regulatory capacity

I. Introduction

The European Union (EU) is a world leader in nanotechnology risk regulation, and since its policy integration has been increasingly active in promoting international cooperation on nanotechnology risk governance and shaping global market regulation for risks and uncertainties.[1] While the internal dimension of EU nanotechnology risk regulation has been extensively studied,[2] we know relatively little about the external dimension of EU nanotechnology risk regulation and governance. The few works that have examined the international influence of the EU in nanotechnology risk regulation have done so mainly in relation to the United States (US)[3] rather than international fora. Advancing literature on

[1] See, e.g., M Nielsen, L Skjolding, A Baun and S Hansen, "European Nanomaterial Legislation in the past 20 years – Closing the Final Gaps" (2023) 32 NanoImpact 100487; EU NanoSafety Cluster, "NanoHarmony OECD TG/GD Process Mentor Releasesd" (EU NanoSafety Cluster, 2024) available at <https://www.nanosafetycluster.eu/nanoharmony-oecd-tg-gd-process-mentor-releasesd/> (last accessed 17 July 2025).

[2] See, e.g., D Bowman, J D'Silva and G Van Calster, "Defining Nanomaterials for the Purpose of Regulation within the European Union" (2010) 1 European Journal of Risk Regulation 115; D Azoulay and V Buonsante, "Regulation of Nanomaterials in the EU: Proposed Measures to Fill in the Gap" (2014) 5 European Journal of Risk Regulation 228; S Smismans and E Stokes, "Innovation Types and Regulation: the Regulatory Framing of Nanotechnology as 'Incremental' or 'Radical' Innovation" (2017) 8 European Journal of Risk Regulation 364; Gazso et al, "Regulating Nanotechnological Applications for Food Contact Materials" (2019) 10 European Journal of Risk Regulation 219.

[3] See, e.g., B Laurent, *Democratic Experiments: Problematizing Nanotechnology and Democracy in Europe and the United States* (Cambridge, MA, The MIT Press 2017); R Falkner, L Breggin, N Jaspers R Porter and J Pendergrass,

EU international regulatory leadership, this article offers a fresh and comprehensive assessment of the EU's international influence on nanotechnology risk regulation and governance.

This research examines the question which factors affect the EU's international influence on nanotechnology risk regulation and governance? For the purpose of this research, the influence of the EU in international regulatory fora is defined as the ability of the EU to have its preferences incorporated into international forums and standards, coordination and cooperation with non-EU countries, and regulatory convergence.[4]

It is argued that the EU scientific and regulatory capacity have a significant explanatory power. EU influence is facilitated by its strong and capable regulatory institutions, and its coordinated policy in nanotechnology. To understand the EU's international regulatory influence, it is important to look closely at the context in which the EU promotes international risk regulation and governance. The EU was the first jurisdiction to regulate nanotechnology EHS risks, and thus, can have scientific and regulatory capacity in this relatively new policy area.[5]

This article offers three contributions. Analytically, it focuses on "coordination" and "capacity" in the EU's scientific and regulatory systems and contributes to the understanding of the EU's ability to exert an important influence on international debates. It also provides the first empirical data in this policy area, contributing to the literature on the EU's global regulatory influence. This article also extends the literature arguments on the EU effort to promote precautionary mindset beyond the EU. In the face of global knowledge gaps in the field of nanotechnology, the EU is leading and actively pursuing international coordination according to its norms.

This research proceeds as follows. It first reviews theoretically informed explanations of the resources that the EU can deploy in order to influence international EHS risk regulation. It then examines three cases of EU influence in international risk regulation and governance, with a view to assessing the analytical leverage of the explanations. The last section concludes.

II. State of the art and research design

The EU literature points out different resources that this regional jurisdiction can deploy in international EHS risk regulation. First, there is "market power."[6] That is the sheer size of the EU internal market. The causal mechanism is as follows: international standards or policy practices are not legally binding; they become so only when they are adopted and enforced by national jurisdictions. Consequently, the support of a jurisdiction with a large internal market is essential for the success of international standards and practices. Therefore, jurisdictions with large markets have more influence in international regulatory fora than smaller jurisdictions.

The second resource that the EU can deploy in international EHS risk governance is its "regulatory capacity" defined as "a jurisdiction's ability to formulate, monitor, and enforce

"International Coordination and Cooperation: The Next Agenda in Nanomaterials Regulation" in G Hodge, D Bowman and A Maynard (eds), *International Handbook on Regulating Nanotechnologies* (Cheltenham, UK and Northampton, MA, USA, Edward Elgar Publishing 2010) pp 508–24; K Rodine-Hardy, "Nanotechnology and Global Environmental Politics: Transatlantic Divergence" (2016) 16 Global Environmental Politics 89; R Justo-Hanani and T Dayan, "Explaining Transatlantic Policy Divergence: The Role of Domestic Politics and Policy Styles in Nanotechnology Risk Regulation" (2016) 16 Global Environmental Politics 79.

[4] See also Falkner et al, *supra*, 3.

[5] See M Nielsen et al, *supra*, 1.

[6] D Drezner, *All Politics Is Global* (Princeton, NJ, Princeton University Press 2007) 5; C Damro, "Market Power Europe" (2012) 19 Journal of European Public Policy 682.

a set of market rules."[7] With reference to the EU regulatory influence, Bach and Newman argue that market size is necessary, though not sufficient for global influence.[8] They claim that a sizeable market must be coupled with powerful and capable regulatory institutions to yield power over international governance. The main causal mechanism is that regulatory institutions translate latent power vested in the internal market into concrete international influence. Hance, jurisdictions with high regulatory capacity are more influential than other jurisdictions in international fora. There is also a link between policy integration, regulatory capacity and market size, in that the market power that derives from market size will be weakened if the EU does not have sufficient regulatory capacity or policy integration in that market.[9] More recently, Bradford examined the sequence of development of EHS regulations in different jurisdictions, which could give the EU a first-mover advantage by being the first to establish rules in a particular sector.[10] This so-called "Brussels Effect" has emerged as a leading explanation for the diffusion of EU EHS regulation. Here the causal mechanism is that a jurisdiction that develops regulatory models in a certain sector is better positioned to shape international rules. Not only does it have the expertise to interact effectively in international fora, it also has domestic regulatory models that can provide solutions to the regulatory issues that international fora and other countries seek to address. Bradford explains that the EU's ability to externalise its regulations to other jurisdictions – the "Brussels Effect" – results from a combination of a large domestic market that is important to foreign firms, the EU's considerable capacity as a regulator and enforcer, and its political will to adopt stringent regulation. Bradford adds two further conditions that increase the likelihood of policy diffusion: regulation of an inelastic market (i.e., immobile markets such as consumer markets) and the economic or technical non-divisibility of a business process (e.g., difficulties in maintaining different management standards in different markets).

Relatedly, Kagan investigated the international power played by the EU in international cooperation, focusing on the preference of negotiation, diplomacy, and persuasion, that is approaching problems with greater nuance and sophistication. The willing to work cooperatively with other nations enabling the EU to pursue common goals, usually through commercial and economic ties.[11]

Third, in EHS policy areas, the precautionary principle in EU law has been considered an important variable to explain its external influence. Vogel has argued that the EU actively seeks to extend its own internal concepts and precautionary approach for risk governance to international organisations and non-EU countries through processes of international norm diffusion or trading up.[12]

The dependent variable studied here is the EU's international regulatory influence. Regulatory influence is defined as the ability of the EU to have its preferences incorporated into international forums and standards, coordination and cooperation with non-EU

[7] D Bach and AL Newman, "The European Regulatory State and Global Public Policy: Micro-Institutions, Macro-Influence" (2007) 14 Journal of European Public Policy 831, 842.

[8] Ibid.

[9] Ibid.

[10] A Bradford, *The Brussels Effect: How the European Union Rules the World* (New York, NY, Oxford University Press 2020) pp 21, 25–65.

[11] R Kagan, "Power and Weakness" (2002) 13 Policy Review 3.

[12] D Vogel, *The Politics of Precaution: Regulating Health, Safety and Environmental Risks in Europe and the United States* (Princeton, NJ, Princeton University Press 2012) p 14. See also D Vogel and R Kagan (eds), *Dynamics of Regulatory Change: How Globalization Affects National Regulatory Policies* (Berkeley, CA, University of California Press 2004) p 11. For discussions on how the EU's application of the precautionary principle affects its relationship with international trade partners, see, e.g., R Falkner, "The Political Economy of 'Normative Power' Europe: EU Environmental Leadership in International Biotechnology Regulation" (2007) 14 Journal of European Public Policy 507; J Zandler, *The Application of the Precautionary Principle in Practice Comparative Dimension* (Cambridge, UK, Cambridge University Press 2010); A Young and J Peterson, "The EU and the New Trade Politics" (2006) 13 Journal of European Public Policy 795.

countries, and regulatory convergence. Moreover, this research understands regulatory influence to be a process rather than a specific outcome. It involves the development of cognitive environment for risk regulation and governance, the promotion of convergence in the principles and rules for risk assessment and management, and capacity building and greater involvement of developing countries in international processes.[13]

The cases examined in the empirical sections were selected because they share commonalities in terms of the dependent variable: they exemplify the EU regulatory influence internationally. The empirical material was gathered through a systematic survey of policy documents and press coverage. It also draws on a growing but fragmented literature on EU international influence in nanotechnology sectors, typically drawn from a variety of disciplines, including safety research, molecular sciences and law.

III. Coordinated nanosafety research: a new frontier for EU's international influence

The EU plays an important role in international coordination and cooperation on a number of key issues. This is clearly the case in nanosafety research for regulatory purposes, where the EU works to promote international coordinated strategy that is coherent and proactive.[14] Given the knowledge gaps on the appropriate tools for nanotechnology risk assessment, the EU is increasingly taking the lead in international research efforts, e.g., common testing methods and nano-specific risk assessment strategies and approaches.[15] By focusing on rare efforts in the nano-EHS community – such as harmonised terminology – its policy documents are attracting interest from parties in Europe and beyond. International organizations, as well as major economic powers such as the United States (US), China and Japan, have recognized that EU officials are often the right contacts to gain and share more knowledge on nanosafety for regulatory purposes.[16] With the European Commission's "safe-by-design" precautionary approach (see also discussion below), which ensures risk assessment at an early stage of product development before its release into the market, the EU's influence on risk assessment in global nanotechnology markets will increase in the coming years.[17]

European officials have learned a great deal about risk assessment issues in developing a common European approach to regulatory testing of nanomaterials and have applied this expertise in international fora. For example, the EU flagship project NANoREG has adapted standardised protocols for assessing the toxicity of nanomaterials in a regulatory

[13] See also R Falkner and N Jaspers, "Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap" (2012) 12 Global Environmental Politics 30.

[14] See, e.g., A Oomen, K Steinhäuser, E Bleeker et al, "Risk Assessment Frameworks for Nanomaterials: Scope, Link to Regulations, Applicability, and Outline for Future Directions In View of Needed Increase in Efficiency" (2018) 9 NanoImpact 1–13; L Soeteman-Hernandez, C Bekker, M Groenewold et al, "Perspective on How Regulators Can Keep Pace with Innovation: Outcomes of a European Regulatory Preparedness Workshop on Nanomaterials and Nano-enabled Products" (2019) 14 NanoImpact 100166.

[15] C Micheletti and JA Sips, "NANoREG Project Deliverable 6.1: Proposal to Monitor Innovations in New Nanomaterials and Their Applications" (NANoREG, 26 October 2017) available at <https://www.rivm.nl/en/About_RIVM/Mission_and_strategy/International_Affairs/International_Projects/Completed/NANoREG/deliverables/NANoREG_D6_01_DR_Proposal_to_monitor_innovations_in_new_nanomaterials_and_their_applications.org> (last accessed 17 July 2025).

[16] J Allan, S Belz, A Hoeveler et al, "Regulatory Landscape of Nontechnology and Nanoplastics from a Global Perspective" (2021) 122 Regulatory Toxicology and Pharmacology 104885.

[17] Ibid. See also L Soeteman-Hernandez, M Apostolova, C Bekker et al, "Safe Innovation Approach: Towards an Agile System for Dealing with Innovations" (2019) 20 Materials Today Communications 100548; M Miettinen, "'By Design' and Risk Regulation: Insights from Nanotechnologies" (2020) 12 European Journal of Risk Regulation 775; M Gulumian and F Cassee "Safe by Design (SbD) and Nanotechnology: a Much Discussed Topic with a Prudence?" (2021) 18 Particle and Fibre Toxicology 32.

context.[18] NANoREG was the first FP7 project to provide the safety answers needed by regulators by linking them to a scientific evaluation of data and testing methods. Just as the European Commission has been willing to engage in risk assessment over the past decade because it saw scientific and regulatory uncertainty as a threat to the innovative and economic potential of nanotechnology markets (see below), Commission officials expected other countries to pursue similar goals to Europe.[19] The European Commission clearly stated that this project and its associated documents should be useful to nanosafety stakeholders in Europe and beyond.[20] As described by NANoREG's project coordinators[21]:

> The innovative and economic potential of manufactured nano materials (MNMs) is threatened by a limited understanding of the related EHS (Environmental Health and Safety) issues. While toxicity data is continuously becoming available, the relevance to regulators is often unclear or unproven. The shrinking time to market of new MNM drives the need for urgent action by regulators. NANoREG is the first FP7 project to deliver the answers needed by regulators and legislators on EHS by linking them to a scientific evaluation of data and test methods."

An example of the external influence of this project is the international cooperation between Europe and other countries in the field of nanosafety. In Latin America, the Brazilian federal government signed a cooperation agreement with the EU's NANoREG project in May 2015. Brazil, the Czech Republic and South Korea have joined as partners, while the United States, Canada, Australia and Japan are associated to the project.[22] Brazil expected that this collaboration would provide the country with a regulation aligned with international regulations and takes into account the needs of society and industry. The goal was to translate the results of scientific research in a way that would be useful to its regulatory agencies.[23]

Overall, the EU NANoREG consortium has shown that it is possible to carry out a coordinated action on nano-specific risk assessment. The project has also shown that the willingness of partners to work together can be used to agree to make data publicly available to support the reliability and comparability of data. This will allow other partners and projects around the world to build on the results of NANoREG. In effect, this nanosafety dataset is now available to – and can be used by – the nanosafety community worldwide.[24] Its significance for the US is particularly pronounced[25]:

> First concrete step to implement a harmonized and user-friendly experimental data logging system for the nanoEHS community. Strong interest from the US counterparts has been expressed.

[18] NANoREG, "NANoREG: A Common European Approach to the Regulatory Testing of Nanomaterials" (*NANoREG*, 3 June 2013) available at <https://www.rivm.nl/sites/default/files/2018-11/NANoREG_Press_release_Jun_2013.pdf> (last accessed 17 July 2025).

[19] NANoREG, "NANoREG: A Common European Approach to the Regulatory Testing of Nanomaterials" (NANoREG, 21 February 2017) available at <https://cordis.europa.eu/docs/results/310/310584/final1-20170518-nanoreg-final-report-part-1-overview-impact-evaluation-dow.pdf> (last accessed 17 July 2025).

[20] Ibid.

[21] NANoREG, *supra*, 18.

[22] I Malsch, M Lindorfer, I Wagner et al, "International Cooperation on Nanosafety between Europe and Latin America" in F Murphy, EM McAlea and M Mullins (eds), *Managing Risk in Nanotechnology: Topics in Governance, Assurance and Transfer* (Cham, Switzerland, Springer 2016) pp 71–92.

[23] Ibid.

[24] NANoREG2, "eNanoMapper Database" available at <https://enanomapper.adma.ai/projects/nanoreg2/> (last accessed 17 July 2025).

[25] NANoREG, *supra*, 19.

This has political implications. If scientific and regulatory capacities are coordinated, the EU has the opportunity to take an international leadership role. European regulatory authorities can make demands in international negotiations for harmonised and more stringent requirements that make sense in the context of the single market agenda but would not have been considered a priority by the international community. Coordination can also serve as an impetus for new scientific discoveries by providing a framework for more thorough risk analysis. The ability of regulators to define and validate a set of methods, testing standards and regulatory requirements has increasingly translated into a powerful regulatory lever at the international level.

IV. Nanosafety diplomacy: an evolving area of EU-international collaboration

At the EU level, science diplomacy has gained a lot of prominence in recent years, most recently through the call by the Competitiveness Council to develop a European agenda for science diplomacy.[26] Prominent examples of institutions established in Europe with both scientific and science diplomacy motivations include the Joint Research Center (JRC), founded in 1957, and the European External Action Service (EEAS), founded in 2011.

In the field of nanotechnology, the EEAS – the EU's diplomatic service – works closely with the EU NanoSafety Cluster, an initiative of the European Commission Directorate-General for Research and Innovation (DG-RDT), to develop international scientific cooperation and raise awareness of non-EU countries to European values and priorities.[27]

Since the establishment of the EU NanoSafety Cluster in 2010, international cooperation has been an important activity. The EU's goal in nanosafety diplomacy is to be at the forefront of international nanosafety research and to tackle scientific and societal challenges in areas such as environmental health, food and safe(r)-by-design.[28] The international influence of the EU is particularly evident in the work of the Organisation for Economic Co-operation and Development (OECD) on nanotechnology. The EU plays an important role, particularly in the development of international standards for the safety assessment of nanomaterials. As elaborated below, the EU JRC is actively involved in collaborative research projects and supports the development and implementation of EU policy on the safety assessment of nanomaterials. This includes exerting influence through the networking of researchers, twinning of projects, or the creation of research communities with the objective of sharing of best practices and harmonised testing methods. The main international platforms are the OECD Working Party on Nanotechnology (WPN), the International Organization for Standardization (ISO), the European Committee for Standardization (CEN) and the United Nations Institute for Training and Research (UNITAR), in which the NanoSafety Cluster, the JRC and the European Chemicals Agency (ECHA) together with the Member States are the main actors. These multilateral initiatives are also important to fulfill the EU's commitments to international goals such as the 2030 Agenda for Sustainable Development or COP21.[29]

In addition, the EU's approach to nanosafety diplomacy has broadened and become more strategic in recent years. Nanosafety diplomacy is part of the European Commission's

[26] European Union External Action, "Science Diplomacy at EU Level" (*European Union External Action*, 17 March 2022) available at <https://www.eeas.europa.eu/node/410933_fr> (last accessed 17 July 2025).

[27] EU NanoSafety Cluster, "Our Vision and Structure" (*EU NanoSafety Cluster*, 2024) available at <https://www.nanosafetycluster.eu/nsc-overview/> (last accessed 17 July 2025).

[28] K Savolainen, U Backman, D Brouwer et al, "Nanosafety in Europe 2015–2025: Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations" (Finnish Institute of Occupational Health, 1 January 2013) available at <https://archiv.szu.cz/uploads/nanosafety/nanosafety_eu_do_2025.pdf> (last accessed 17 July 2025).

[29] EU NanoSafety Cluster, "International Cooperations: Enhancing Global Partnerships" (*EU NanoSafety Cluster*, 2024) available at <https://www.nanosafetycluster.eu/cooperation/> (last accessed 17 July 2025).

broader policy vision, which states that "in order to be successful in nanotechnology research, commercialisation and regulation, international collaboration is crucial".[30] The 2022 Action Plan of the International Network Initiative on Safe and Sustainable Nanotechnologies (INISS-Nano) sets targets for global collaboration in selected fields of action.[31] Based on the so-called "enabling collaboration without borders," the focus of the action plan has shifted from simply promoting new nanosafety research to tackling the international fragmentation of risk regulation and practices and placing greater emphasis on safe and sustainable innovation in line with the United Nations' Sustainable and Development Goals (SDGs) and the EU's Green Deal and Circular Economy.[32]

This is also in line with the general shift in EU research policy, which is no longer mainly focused on economic competitiveness, but also on grand challenges and the creation of norms for appropriate behavior.[33] Accordingly, future research priorities of the European NanoSafety Cluster include "harmonization" through the development of international nanosafety standards and harmonised testing guidelines to protect workers and consumers.[34] Another priority is to promote industry understanding of the means to promote commercial success, such as regulatory obligations that ensure public confidence. This is in line with the recent change in EU strategy aimed at supporting companies to implement EU precautionary requirements for nanomaterials, such as the updated REACH annexes.[35]

The NanoSafety Cluster also serves as an international coordinator for matters where the OECD is challenged. The Action Plan added a new point of coordination for industry and regulators in OECD and non-OECD countries and took the lead on Mutual Acceptance of Data (MAD)[36]:

> . . . whilst the OECD, including its Working Party on Manufactured Nanomaterials (WPMN), plays a vital role in disseminating information at a high level, knowledge about the underlying research and tools (i.e., testing guidelines) is not reaching all relevant levels of the factory floor effectively between regions . . . MAD is at least in place for many countries . . . INISS-Nano is an ideal position to disseminate information about tools developed across the globe in a manner that can be easily accessed and understood by all relevant units of factory. It has strong links to the

[30] A Falk, A Pogany, P Aungkavattana et al, "INISS-Nano: Revisited Concept and Action Plan" (2022), doi: 10.5281/zenodo.6818049 (last accessed 17 July 2025).

[31] Ibid.

[32] Ibid. See also Joint Research Center (JRC), "Contributing to a Greener EU with Safe and Sustainable Nanomaterials at the Design Stage" (*JRC*, 19 April 2021) available at <https://joint-research-centre.ec.europa.eu/jrc-news-and-updates/contributing-greener-eu-safe-and-sustainable-nanomaterials-design-stage-2021-04-19_en> (last accessed 17 July 2025); B Elzein, "Nano Revolution: Tiny Tech, Big Impact: How Nanotechnology is Driving SDGs Progress" (2024) 10 Heliyon e31393.

[33] S Borrás, *The Innovation Policy of the European Union: From Government to Governance* (Cheltenham, UK and Northampton, MA, USA, Edward Elgar Publishing 2003); V Mitzner, *European Union Research Policy: Contested Origins* (Cham, Switzerland, Palgrave Macmillan 2020); I Ulnicane, "Politics of Public Research Funding: the Case of the European Union" in B Lepori, B Jongbloed and D Hicks (eds), *Handbook of Public Funding of Research* (Cheltenham, UK and Northampton, MA, USA, Edward Elgar Publishing 2023) pp 55–71.

[34] EU NanoSafety Cluster, "2nd Harmonization & Standardization of Test Methods for Nanomaterials and Advanced Materials Workshop" (*EU NanoSafety Cluster*, 2024) available at <https://www.nanosafetycluster.eu/2024/08/07/> (last accessed 17 July 2025).

[35] A Falk, *supra*, 30.

[36] Ibid. In this context, see also the Malta Initiative, which is led by the Directorates-General of the European Commission, the NanoSafety Cluster and industry and focuses on amending or further developing the OECD test guidelines for nanomaterials. EU NanoSafety Cluster, "The Malta Initiative: Towards Safer Nanomaterials" (*EU NanoSafety Cluster*, 2024) available at <https://www.nanosafetycluster.eu/cooperation/the-malta-initiative/> (last accessed 17 July 2025).

> industrial, research and regulatory communities, meaning that it is ideally placed to support the development of protocols and schemes that promote the safe and sustainable expansion of nanotechnology across regions without the perception of vested interest.

In addition, the EU and the NanoSafety Cluster have several delegations and projects around the world.[37] The NanoSafety Cluster provides training and capacity building for governments in developing countries based on its action plan. Together with the European Commission and the EEAS, the NanoSafety Cluster has expanded international scientific cooperation through partnerships with countries in Latin America and the Caribbean, Asia, Africa and the Pacific.[38] Professor Kai Savolainen, coordinator of the NanoSafety Cluster, emphasized that:

> The strategic vision of the future direction of European nanosafety research may have a major impact on the future nanosafety research within and outside the European Union, and consequently, on the success of nanotechnologies."[39]

As for the role that business interests should play, in an article entitled 'Safety: An Opportunity, not an obstacle, for Nanotechnology', Savolainen reiterated this message, emphasizing that[40]:

> Manufacturers need to accept that the assurance of safety must be a key feature of all engineered nanomaterials and nanotechnologies, and they should see this as a business opportunity and not as an obstacle.

Indeed, business interests play an important role in the international harmonisation of nanotechnology regulations, as they both drive and influence this process. This involvement ranges from participation in standard-setting organizations to advocating for regulatory clarity across borders.[41]

The EU and the NanoSafety Cluster also strive to build and maintain links of all kinds (e.g., scientific, societal, regulatory, business-oriented) with nations around the world.[42] To achieve this, they have organized several rounds of workshops in South Africa, Asia, Iran, Brazil, Mexico and South Korea as well as regional forums (e.g., Asia Nano Forum) through scientific delegations and partnerships.[43] Under the title "creating global nanosafety network,"[44] science diplomacy activities include technical assistance to foreign regulators, information exchange on risk assessment and risk management, training sessions and workshops on nanotechnology risk regulation and governance, occupational health and safety issues and public awareness.[45] Switzerland's activities within the framework of the

[37] EU NanoSafety Cluster, *supra*, 29.

[38] K Savolainen, U Backman, D Brouwer et al, *supra*, 28.

[39] Ibid.

[40] K Savolainen, "Safety: An Opportunity, Not an Obstacle, for nanotechnology" (Horizon: The EU Research & Innovation Magazine, 2015) available at <https://research.fi/en/results/publication/0250298015> (last accessed 17 July 2025).

[41] UN Trade & Development, "Nanotech Diplomacy: Opportunities and Challenges for International Cooperation" (*UN Trade & Development*, 2024) available at <https://unctad.org/news/nanotech-diplomacy-opportunities-and-challenges-international-cooperation> (last accessed 17 July 2025).

[42] EU NanoSafety Cluster, "NSC International Delegations: Creating Global Nanosafety Network" (*EU NanoSafety Cluster*, 2024) available at <https://www.nanosafetycluster.eu/cooperation/eu-nanosafety-delegations/> (last accessed 17 July 2025).

[43] Ibid.

[44] Ibid.

[45] Ibid.

NSC are also an example of the EU's international impact. Switzerland is actively involved in this project through its research, its events and its national platform.[46]

More recently, the European Commission has also taken on the role of trainer of European nanoscientists in diplomacy, emphasising the importance of collaboration with regulators. In November 2021, InsSciDE (Inventing a shared Science Diplomacy for Europe) – Horizon 2020 research project – brought together a science diplomacy team for a training session for nanoscientists. In a panel discussion titled "Border-crossing scientists," nanosafety researchers emphasised the importance of a transdisciplinary approach to bridge the gap between innovators and regulators. Overall, participants agreed that nanosafety diplomacy is needed both in Europe and beyond, and that there should be a more structural approach in the strategy of nanosafety diplomacy to build trust in this technology.[47]

In sum, the institutionalisation of science diplomacy at EU level improves the EU's capacity and efficiency in leading international cooperation and coordinating risk management of nanotechnology. The European Commission has largely taken on the role of coordinator in this process. Its funding programs provide resources for the expansion of risk research and regulatory science and facilitate international partnerships and training. In the case of science diplomacy, EU influence was facilitated by its strong regulatory capacity in this field, and its coordinated policy in nanotechnology. In contrast to the relatively "technical" nature of international cooperation in the early 2000s, as described by scholars,[48] the current European strategy for scientific and regulatory capacity represents robust adaptive coordination, a strategic approach that supports the promotion of nanosafety in Europe and beyond.

V. EU and multilateral negotiations on precautionary risk governance

The continuous development of regulatory capacity in the EU has also strengthened the ability of the EU institutions to lead international discussions on the principles of nano-specific risk governance.[49] The EU is actively seeking to extend its own internal concepts and norms for risk governance to international organizations and non-EU countries. Through informal and formalised expert networks, bilateral and multilateral fora rely on the opinions of EC networks.[50] These EC networks have the authority to guide and monitor new concepts and values, highlight emerging precautionary norms and make recommendations to the international community on possible proactive solutions. The EU has played a key role in these negotiations by guiding several multilateral approaches to nanotechnology risk governance and concluding them with precautionary practices, as demonstrated below. In a number of thematic areas, such as risk assessment, risk management and communication, consultations with the European Commission "in-house" scientific services have been formally integrated into global risk governance efforts. The EC's JRC fulfills this task by providing interpretations and recommendations for the further development of safety regulations.

[46] EU NanoSafety Cluster, "US-EU NanoEHS Communities of Research (CORs)" (*EU NanoSafety Cluster*, 2024) available at <https://nsc-community.eu/cors-annual-workshop-2024/> (last accessed 17 July 2025).

[47] InsSciDE, "Nanoscientists in Diplomacy: Power of Many Individual Acts" (*InsSciDE*, 2024) available at <https://www.sabyna.eu/nanoscientists-in-diplomacy-power-of-many-individual-acts/> (last accessed 17 July 2025).

[48] See, e.g., R Falkner and N Jaspers, *supra*, 13.

[49] "Risk governance" is defined as the critical study of complex, interacting networks in which choices and decisions are made around risks and as a set of normative principles which can inform all relevant actors of society how to deal responsibly with risks. See M van Asselt and O Renn, "Risk Governance" (2011) 14 Journal of Risk Research 431.

[50] See, e.g., L Soeteman-Hernandez, C Bekker, M Groenewold et al, *supra*, 14.

The concept of "Regulatory Preparedness" clearly illustrates this trend. The JRC developed this concept – about the readiness of regulatory authorities to deal with nanotechnology – as part of a Commission-funded project (EU Horizon 2020 NANoREG2).[51] At a workshop organized by the EC's JRC in Italy in 2017, Regulatory Preparedness was defined as the timely awareness of regulatory authorities on innovation, including the initiation of a revision of legislation applying the precautionary principle.[52] During the workshop, more than 60 regulators and risk assessors from the EU and the US, as well as representatives from non-governmental organizations and industry, discussed what is needed in regulatory risk assessment to deal with innovations. There was general agreement that proactive approaches are better than reacting and adapting to the information received, and that there is a need for more formalised innovation governance.[53] This also made sense from a business interests' perspective: consumers demand that companies think not only about their bottom line, but also about the safety of the environment and consumers.

The international significance of the European Commission's JRC ideas is also evident in the OECD's discussions on the Safe(r) Innovation Approach.[54] The JRC's foundational work on Safe(r)-by-Design, Regulatory Preparedness and Trusted Environments has been widely supported by the OECD and national regulatory bodies around the world. As the OECD explains[55]:

> RP can be seen as a way of applying the Precautionary Principle in a proactive and time efficient way: regulators acquire information about a new technology, its characteristics and potential safety concerns early enough while the technology is still in development so that the necessary regulatory tools, such as adapted legislation and appropriate safety assessment methodology, can already be in place when industry is ready to seek any necessary market approval.

The European Commission's JRC also continued to lead the development of working descriptions for these concepts in the OECD Working Party on Manufactured Nanomaterials (WPMN). The draft working descriptions of all four terms – Safe(r)-by-Design, Regulatory Preparedness, Trusted Environment, and Safe(r) Innovation Approach, were discussed and further developed in two teleconferences of the ad hoc group in May and June 2019, eventually reaching a common understanding and agreement among the group. These working descriptions to the WPMN were refined in the following months, and then forwarded to the WPMN in November 2019 for comments and agreement.[56] Although these concepts are not binding, they send a signal to government regulators, global industry, the media and civil society. Their precautionary nature therefore has a quasi-regulatory effect that diffuses through networks with industry stakeholders and regulators.

[51] NanoReg2 available at <https://cordis.europa.eu/project/id/646221> (last accessed 17 July 2025).

[52] L Soeteman-Hernandez, C Bekker, M Groenewold et al, *supra*, 14.

[53] JRC (2018), "Workshop on Regulatory Preparedness for Innovation in Nanotechnology" available at <https://op.europa.eu/en/publication-detail/-/publication/a4a55164-d7ff-11e8-90c0-01aa75ed71a1/language-en> (last accessed 17 July 2025).

[54] OECD (2020), "Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products," OECD Series on the Safety of Manufactured Nanomaterials and other Advanced Materials, OECD Publishing, Paris, <https://doi.org/10.1787/d68ef961-en> (last accessed 17 July 2025); OECD, "Sustainability and Safe and Sustainability by Design: Working Description for the Safer Innovation Approach" (2022a) OECD Series on the Safety of Manufactured Nanomaterials and other Advanced Materials, OECD Publishing, Paris, <https://doi.org/10.1787/a9a80171-en> (last accessed 17 July 2025).

[55] Ibid, OECD 2020.

[56] Ibid, OECD 2020.

Despite the diffusion of nano-specific regulations, recent adaptations have not simply copied European regulations. Some countries, such as Israel, have replicated the EU model for approval of certain products (see below). Others, such as South Korea, have combined a variety of regulatory tools, such as nanomaterials definition and nano-specific risk assessment.[57] In Switzerland, REACH-like requirements for registration apply to substances that are manufactured in or imported into the EU in nanoforms in quantities of one tonne or more per year.[58] These patterns of emulation and compilation are common in diffusion processes.[59] Nonetheless, these countries share an important commonality: more precautionary regulation is taking place, providing stricter nano-EHS protection.

The progress of the proactive and precautionary model does not mean that a "wait-and-see" approach has been eliminated as an option for regulating risks and uncertainties of nanotechnology. Several countries, such as the US, China, and Japan, have essentially limited regulatory policies. These countries may have argued that their existing sectoral regulations provide adequate nano-EHS protection.[60] Japan's regulatory policy, for instance, does not have a dedicated regulatory framework. Existing regulations are applied for the regulation of nanomaterials. However, in recent years, Japan has also begun collaborating with the European Medicines Agency (EMA) to develop guidelines and standards for nanomedicines. China has introduced technical standards, but most remain voluntary. In the US, nanomaterials are regulated by existing laws rather than nano-specific regulations. In line with efforts to reduce government interference, the US uses guidance documents for nanotechnology oversight.[61] While there is no politically supported cooperation between the US and the EU on nanotechnology risk regulation, both sides of the Atlantic engage in scientific and technical cooperation on nanotechnology in a number of multilateral forums, such as the OECD, ISO and the G20. A key area of this collaboration is the negotiation and formalisation of technical standards. The EU and the US have also held bilateral discussions on a common approach to these issues, such as the EU–US priorities in the area of nanosafety.[62] While these countries focus more on technological development than on the creation and dissemination of nanosafety regulations, the EU is the leading player in this field.

VI. Conclusion

This study examined the sources of the EU's international influence in nanotechnology risk regulation and governance. The main finding is that the EU's scientific and regulatory capacity has significant explanatory power. A coordinated policy is particularly important for the EU's scientific and regulatory capacity. The broadening and deepening of coordinated policy offer opportunities for the growth of new regulatory activities and

[57] OECD, "Important issues on Risk Assessment of Manufactured Nanomaterials," (2022b) OECD Series on the Safety of Manufactured Nanomaterials, OECD Publishing, Paris, available at <https://www.oecd.org/content/dam/oecd/en/publications/reports/2022/02/important-issues-on-risk-assessment-of-manufactured-nanomaterials_05cb9a3d/2f6e7c61-en.pdf> (last accessed 17 July 2025).

[58] Federal Office of Public Health, "Nanomaterials: Current EU Law," Swiss Federal Authorities (2025), available at <https://www.bag.admin.ch/en/nanomaterials-current-eu-law> (last accessed 17 July 2025).

[59] J Zeitlin (ed), *Extending Experimentalist Governance: The European Union and Transnational Regulation* (Oxford, UK, Oxford University Press 2015).

[60] D Bowman, "More Than a Decade On: Mapping Today's Regulatory and Policy Landscape Following the Publication of Nanosciences and Nanotechnologies: Opportunities and Uncertainties" (2017) 11 Nanoethics 169.

[61] AzoNano, "Global Nanomaterial Regulation: A Country-by-Country Comparison" (*AzoNano*, 2025) available at <https://www.azonano.com/article.aspx?ArticleID=6885#:~:text=In%202017%2C%20the%20EPA%20introduced,%2C%20and%208(d)> (last accessed 17 July 2025).

[62] EU NanoSafety Cluster, "EU–US priorities in nanosafety" (*EU NanoSafety Cluster*, 2019) available at <https://www.nanosafetycluster.eu/eu-us-priorities-in-nanosafety/> (last accessed 17 July 2025).

research projects in the field of nanosafety. This political move – the creation of a European regulatory state in the field of nanosafety – has not only changed regional policy. By creating an adaptive regime coordinated at the supranational level, the EU has influenced regulatory discussions and decisions at the international level.

This research has focused on the international regulatory influence of the EU by scientific and regulatory capacity. However, the EU can influence international nanotechnology risk regulation in other ways. Control of market access has played an important role in the exercise of international influence. Since 2008, the EU has adopted regulations with new nano-specific requirements in diverse sectors (such as chemicals, food, cosmetics, biocidal products) that have the practical effects of encouraging non-EU countries to change their domestic rules so as to make them equivalent to EU regulation, or increase the cost for non-EU countries and firms to export/import, causing them to adjust their regulation according to the EU.[63] The extraterritorial provisions of the EU Cosmetics Regulation (EC) No 1223/2009 are just one example of a broader trend where the EU is increasingly setting de jure international rules on nanosafety through its internal regulations. In New Zealand, for example, cosmetic products were originally covered by standards and were not subject to mandatory labeling. In 2015 – two years after the start of mandatory labeling in the EU – New Zealand introduced new labeling requirements for cosmetic products that are comparable to those in the EU. The Israeli adaptation process in the cosmetics sector is also an example of how the EU market has influenced the strengthening of nano regulations and shaped regulatory reform in non-EU countries. The removal of regulatory barriers to trade was crucial in reshaping the national cosmetics regime in Israel: market access control and EU exports led to EU-like regulation of nanomaterials in cosmetics.[64] The United Arab Emirates (UAE) is also aligning its nanotechnology regulations, particularly for cosmetics, with EU standards (although none of these countries is as stringent or comprehensive as the EU).[65] Moreover, the EU can influence self-regulation in nanotechnology firms.[66] Under self-regulation, many nanotech companies are taking a proactive stance to protect their workers in the face of the uncertainty, including risk management practices for occupational settings.[67] These are all interesting venues for future research.

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Biography. Ronit Justo-Hanani is an assistant professor of public policy and risk regulation. She has a multidisciplinary academic background which includes Law, Biology, Public Policy, and Politics. Theories of EU risk regulation, the EU as transnational and global risk regulator, and environmental policies and politics are central to her work.

[63] See R Justo-Hanani, *Governing Nanotechnology Safety: The Politics of Risk Regulation in Europe and the United States* (Cheltenham, UK and Northampton, MA, USA, Edward Elgar Publishing 2024) p 57.

[64] Ibid. pp 60, 69.

[65] Ibid. p 60.

[66] See, e.g., M Kurath, M Nentwich, T Fleischer and I Eisenberger, "Cultures and Strategies in the Regulation of Nanotechnology in Germany, Austria, Switzerland and the European Union" (2014) 8 NanoEthics 121.

[67] D Ramos and L Almeida, "Overview of Standards Related to the Occupational Risk and Safety of Nanotechnologies" (2022) 2 Standards 83.

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