THE ROLE OF SOFT LAW IN GOVERNING NANOTECHNOLOGIES

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ABSTRACT: The entry of nanotechnology-based products into the market in the early to mid-2000s was accompanied by hype and hyperbole, along with cries of concern over the potential risks posed by the technology. Known unknowns and unknown unknowns about potential human and environmental risks associated with nanomaterials appear to have been key drivers for industry, government, and nongovernmental actors to proactively experiment with different governance mechanisms, which could help mitigate potential risk and prevent potential consumer backlash. This Article examines a sample of the soft law initiatives that were deployed by stakeholders in parallel with the commercialization of an increasing number of nano-products. As the Article illustrates, some approaches were more successful than others and have helped shape the nanotechnology landscape. This Article argues, though, that the significance of these actions goes beyond nanotechnology: governance of an emerging technology can occur in parallel with its maturation, and be continuously refined as the science or the market demand.

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Nanotechnologies—a ubiquitous platform technology defined primarily by its scale and the unique physico-chemical characteristics that occur at the nanoscale—and the products and processes they give rise to have been the subject of significant regulatory debate over the last two decades.[1] Discussion has persisted despite the fact that sectors such as the information technology sector have been working at the nanoscale since the late 1960s and early 1970s—at a time before the word *nanotechnology* had been coined.[2]

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This Article draws upon earlier published work by the author, including Diana M. Bowman & Graeme A. Hodge, *Counting on Codes: An Examination of Transnational Codes as a Regulatory Governance Mechanism for Nanotechnologies*, 3 REG. & GOVERNANCE 145 (2009); Diana M. Bowman & Lucille M. Tournas, *Science—Democracy—Industry: Who Is in Charge of Regulating Nanomaterials?*, *in* NANOTECHNOLOGY: REGULATION AND PUBLIC DISCOURSE 103 (Iris Eisenberger et al. eds., 2019); and Diana M. Bowman, *More than a Decade On: Mapping Today's Regulatory and Policy Landscape Following the Publication of* Nanoscience and Nanotechnologies: Opportunities and Uncertainties, 11 NANOETHICS 169 (2017).

1. *See, e.g.*, Andrew D. Maynard et al., *Safe Handling of Nanotechnology*, 444 NATURE 267 (2006); Craig A. Poland et al., *Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-Like Pathogenicity in a Pilot Study*, 3 NATURE NANOTECHNOLOGY 423 (2008); O. Renn & M.C. Roco, *Nanotechnology and the Need for Risk Governance*, 8 J. NANOPARTICLE RSCH. 153 (2006); Andrew D. Maynard, *Nanotechnology: The Next Big Thing, or Much Ado About Nothing?*, 51 ANNALS OCCUPATIONAL HYGIENE 1 (2007).

2. Adarsh Sandhu, *Who Invented Nano?*, 1 NATURE NANOTECHNOLOGY 87 (2006) (reviewing STEVE EDWARDS, THE NANOTECH PIONEERS (2006)).

Early interest in potential governance challenges posed by the technology can be traced back to the pioneering work of Professor Frederick A. Fiedler and Glenn H. Reynolds. In 1994, they penned the first law review article highlighting the potential breadth of legal issues that may arise as a myriad of nano-enabled products made their way onto the market.[3] At the time, nanotechnologies were a nascent technology, and very few products were on the market, with the exception of computer chips. Their article posed more questions than it answered, yet provided subsequent scholars, policy makers, and other key stakeholders with the beginnings of a road map for the governance challenges posed by nanotechnologies.

Between 1994 and 2004, much of the nonscientific literature focused on the economic implications of nanotechnologies with governments such as the United States viewing the platform technology as one of the key economic drivers for the twenty-first century.[4] Unsurprisingly, much of the policy debate during this ten-year period focused on the need to invest—or redirect—significant public funds into large scale initiatives for the purpose of catalyzing the commercialization of nanomaterials and nano-enabled goods.[5] In January 2001, the Clinton administration became the first national government to establish a coordinated cross-agency initiative, the National Nanotechnology Initiative (NNI), for the purposes of driving fundamental research and development (R&D) activities within the energy, materials, and defense sectors.[6] Analogous initiatives were quickly initiated in a number of other countries,[7] with very little concern being raised at the time regarding either real or perceived potential risks posed by the technology.

In 2004, the United Kingdom's Royal Society and Royal Academy of Engineering (RS-RAE) published what is now viewed as one of the seminal reports

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3. Frederick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593 (1994).

4. Zan Huang et al., *Longitudinal Nanotechnology Development (1991–2002): National Science Foundation Funding and Its Impact on Patents*, 7 J. NANOPARTICLE RSCH. 343, 343–44 (2005).

5. PRIME MINISTER'S SCI. ENG'G & INNOVATION COUNCIL, NANOTECHNOLOGY, THE TECHNOLOGY OF THE 21ST CENTURY: THE ECONOMIC IMPACT OF EMERGING NANOMETRE SCALE TECHNOLOGY app. 1 at 12–14 (1999); Erik Fisher & Roop L. Mahajan, *Contradictory Intent? US Federal Legislation on Integrating Societal Concerns into Nanotechnology Research and Development*, 33 SCI. & PUB. POL'Y 5 (2006), http://sciencepolicy.colorado.edu/admin/publication_files/resource-2452-2006.03.pdf [https://perma.cc/5NXT-ZLKV].

6. Neal Lane & Thomas Kalil, *The National Nanotechnology Initiative: Present at the Creation*, ISSUES SCI. & TECH., Summer 2005, at 49, 49; *see also* M.C. Roco, *International Perspective on Government Nanotechnology Funding in 2005*, 7 J. NANOPARTICLE RSCH. 707, 707 (2005).

7. Ikechukwu Ezema et al., *Initiatives and Strategies for Development of Nanotechnology in Nations: A Lesson for Africa and Other Least Developed Counties*, 9 NANOSCALE RSCH. LETTERS, 2014, art. no. 133, at 1, 2–3, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3994481/pdf/1556-276X-9-133.pdf [https://perma.cc/3QTB-PSYJ]; *see also* Roco, *supra* note 7.

on nanotechnologies.[8] Unlike earlier publications, the RS-RAE report provided, for the first time, an in-depth analysis of the current and evolving state of the scientific art for nanotechnologies, including potential areas of application. The report articulated potential risks to human and environmental health that may occur from manufacturing or end-of-life processes, and raised questions regarding the applicability of conventional risk assessment protocols for certain families of nanomaterials.[9] This comprehensive analysis of the scientific landscape for nanotechnologies allowed the RS-RAE to layer broader ethical, legal, and social dimensions into their analysis. Focusing on the regulatory frameworks of the European Union and United Kingdom, the report tested the robustness of these frameworks in relation to their applicability for the production and entry of nanomaterials and nano-enabled products into the market. The analysis highlighted several potential weaknesses, with the most significant one relating to the approval process for new chemical substances entering the market.[10] Unsurprisingly, the RS-RAE included eight recommendations for the U.K. government focused on regulatory issues. For example, the RS-RAE recommended modifying the existing chemical regulatory scheme so that chemicals in the form of nanoparticles or nanotubes would be treated as new substances under the existing Notification of New Substances (NONS) regulations and in the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH).[11]

The release of the report was met with significant debate across disciplines, sectors, and jurisdictions. The uncertainties and potential risks identified by the authors may have served as a catalyst for a number of nongovernmental organizations (NGOs), who responded to the report with calls for greater government regulation, a moratorium on the production and use of certain families of nanomaterials, and increased investment in fundamental research to better understand the toxicity and ecotoxicity of certain nanomaterials.[12] While some of these calls were met with support from the U.K. government—and, indeed, other governments over time—the more extreme calls, such as those calling for various forms of a moratorium largely fell on deaf ears.

Efforts to address the uncertainties identified by the RS-RAE and a myriad of other scientists, regulators, and industry experts has shaped national and international research agendas over the last fifteen years. The limited number of studies focused on—for example, risk, risk assessment, nano-toxicity, and nano-ecotoxicity—has now been replaced with a significant body of work that seeks

8. THE ROYAL SOC'Y & THE ROYAL ACAD. OF ENG'G, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004), https://royalsociety.org/-/media/Royal_Society_Content/policy/publications/2004/9693.pdf [https://perma.cc/TRF8-VVME].

9. *Id.* at 35–36.

10. *Id.* at xi.

11. *Id.* at 86.

12. News Release, ETC Group, Nanotech: Unpredictable and Un-Regulation: New Report from ETC Group (July 8, 2004), https://www.etcgroup.org/sites/www.etcgroup.org/files/publication/96/01/nrlivingcolour.pdf [https://perma.cc/W6YN-FNRM]; GEORGIA MILLER & RYE SENJEN, FRIENDS OF THE EARTH AUSTL. NANOTECHNOLOGY PROJECT, OUT OF THE LABORATORY AND ON TO OUR PLATES 46–47 (2d ed. 2008).

to examine these questions, along with the development of applicable standards, reference materials, and nomenclature.[13] Against this backdrop, and subsequently informed by these scientific advances, a number of governments have undertaken and commissioned independent reviews of their legislative frameworks for effectively dealing with nanotechnologies.[14] These have been further supplemented by a myriad of independent analyses, commentary, and critiques by leading scholars across the world.

The uncertainties raised by RS-RAE and others are contributing factors to government, industry, and NGO action more narrowly focused on regulation and governance. These include, for example, voluntary data call-ins by governments in the United Kingdom, United States, and Australia;[15] the passage of nano-specific legislative provisions by the European Parliament and Council for cosmetics and foods (including labeling); the proposed use of the Significant New Use Rules (SNURs) for certain nanomaterials by the U.S. Environmental Protection Agency (EPA); occupational health and safety guidance by the U.S. National Institute for Occupational Health and Safety;[16] and publication of a

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13. *See generally* NANOTECHNOLOGY ENVIRONMENTAL HEALTH AND SAFETY: RISKS, REGULATION, AND MANAGEMENT (Matthew S. Hull & Diana M. Bowman eds., 3d ed. 2018) [hereinafter NANOTECHNOLOGY ENV'T HEALTH & SAFETY].

14. *See, e.g.*, *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee Regulatory Aspects of Nanotechnologies*, COM (2008) 366 final (June 17, 2008), https://ec.europa.eu/research/industrial_technologies/pdf/policy/comm_2008_0366_en.pdf [https://perma.cc/99CS-SACZ]; *Accompanying Document to the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee Regulatory Aspects of Nanomaterials: Summary of Legislation in Relation to Health, Safety and Environment Aspects of Nanomaterials, Regulatory Research Needs and Related Measures*, SEC (2008) 2036 (June 17, 2008), http://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/sec/2008/2036/COM_SEC(2008)2036_EN.pdf [https://perma.cc/3EY2-NSAM]; *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee Second Regulatory Review on Nanomaterials*, COM (2012) 572 final (Oct. 3, 2012), https://ec.europa.eu/research/industrial_technologies/pdf/policy/communication-from-the-commission-second-regulatory-review-on-nanomaterials_en.pdf [https://perma.cc/ZE22-PJV2]; KARINNE LUDLOW ET AL., A REVIEW OF POSSIBLE IMPACTS OF NANOTECHNOLOGY ON AUSTRALIA'S REGULATORY FRAMEWORK: FINAL REPORT (2007), https://www.researchgate.net/profile/Graeme_Hodge/publication/265997359_A_Review_of_Possible_Impacts_of_Nanotechnology_on_Australia%27s_Regulatory_Framework/links/54b511d00cf28ebe92e4b974/A-Review-of-Possible-Impacts-of-Nanotechnology-on-Australias-Regulatory-Framework.pdf.

15. *See generally* U.K. DEP'T ENV'T FOOD & RURAL AFFS., UK VOLUNTARY REPORTING SCHEME FOR ENGINEERED NANOSCALE MATERIALS (Sept. 2006), http://www.defra.gov.uk/ENVIRONMENT/nanotech/policy/pdf/vrs-nanoscale.pdf [https://perma.cc/BGA3-SYY8]; News Release, U.S. Env't Prot. Agency, EPA Invites Pub. Participation in Dev. of Nanotechnology Stewardship Program (Oct. 18, 2006), https://archive.epa.gov/epapages/newsroom_archive/newsreleases/0edb5f39e2ed3c428525720b00629872.html [https://perma.cc/Y6MT-59SJ].

16. *See generally* NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUBL'N NO. 2014-102, CURRENT STRATEGIES FOR ENGINEERING CONTROLS IN NANOMATERIAL PRODUCTION AND DOWNSTREAM HANDLING PROCESSES (2013), https://www.cdc.gov/niosh/docs/2014-102/pdfs/2014-102.pdf?id=10.26616/NIOSHPUB2014102 [https://perma.cc/9FYN-DERK]; NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUBL'N NO. 2014-106, PROTECTING THE NANOTECHNOLOGY WORKFORCE: NIOSH NANOTECHNOLOGY RESEARCH AND GUIDANCE STRATEGIC PLAN, 2013–2016 (2013), https://www.cdc.gov/niosh/docs/2014-106/pdfs/2014-106.pdf?id=10.26616/NIOSHP

series of guidance materials for nanotechnologies by the U.S. Food and Drug Administration (FDA).[17] These actions have occurred alongside a wealth of industry and NGO initiatives ranging from the development of codes of conduct, risk assessment frameworks, certification schemes including the creation of a "Nano Mark," positive and negative labeling schemes, standards development, longitudinal studies focused on worker health, searchable nano-product databases such as that established by the Woodrow Wilson International Center for Scholar's Project on Emerging Nanotechnologies,[18] and even the voluntary removal of nano-ingredients from consumer products as illustrated by Dunkin' Donuts' removal of nano-ingredients in its donut glazes after a high profile backlash.[19] This form of self-regulation has also been witnessed in response to public outcry over the use of nanoscale titanium dioxide in food products.

Such actions would seem unprecedented given that the initiatives were propagated against a backdrop of *potential* risks and in the absence of any documented human and environmental harms outside laboratory studies. In 2007, leading regulatory scholars Levi-Faur and Comaneshter made the following observation in response to these activities:

> Unlike other cases where the discussion of associated risks has followed the development of new technologies, the discussion on the proper regulatory framework for the governance of nanotechnology risks is accompanying the development of the technology and the associated products themselves. The

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UB2014106 [https://perma.cc/RX9M-ELTM]; L. HODSON ET AL., NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUBL'N NO. 2019-116, CONTINUING TO PROTECT THE NANOTECHNOLOGY WORK FORCE: NIOSH NANOTECHNOLOGY RESEARCH PLAN FOR 2018–2025 (2019), https://www.cdc.gov/niosh/docs/2019-116/pdfs/2019-116.pdf?id=10.26616/NIOSHPUB2019116 [https://perma.cc/5ZUJ-PZ4G]; NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUBL'N NO. 2009-116, CURRENT INTELLIGENCE BULLETIN 60: INTERIM GUIDANCE FOR MEDICAL SCREENING AND HAZARD SURVEILLANCE FOR WORKERS POTENTIALLY EXPOSED TO ENGINEERED NANOPARTICLES (2009), https://www.cdc.gov/niosh/docs/2009-116/pdfs/2009-116.pdf?id=10.26616/NIOSHPUB2009116 [https://perma.cc/FF8L-FU7K]; NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, PUBL'N NO. 2013-145, CURRENT INTELLIGENCE BULLETIN 65: OCCUPATIONAL EXPOSURE TO CARBON NANOTUBES AND NANOFIBERS (2013), https://www.cdc.gov/niosh/docs/2013-145/pdfs/2013-145.pdf?id=10.26616/NIOSHPUB2013145 [https://perma.cc/7XT4-9JBU].

17. *See, e.g.*, U.S. FOOD & DRUG ADMIN., DOCKET NO. FDA-2010-D-0530, GUIDANCE FOR INDUSTRY: CONSIDERING WHETHER AN FDA-REGULATED PRODUCT INVOLVES THE APPLICATION OF NANOTECHNOLOGY (2014), https://www.fda.gov/media/88423/ download; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: SAFETY OF NANOMATERIALS IN COSMETIC PRODUCTS (June 2014), https://www.fda.gov/media/83957/download; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: ASSESSING THE EFFECTS OF SIGNIFICANT MANUFACTURING PROCESS CHANGES, INCLUDING EMERGING TECHNOLOGIES, ON THE SAFETY AND REGULATORY STATUS OF FOOD INGREDIENTS AND FOOD CONTACT SUBSTANCES, INCLUDING FOOD INGREDIENTS THAT ARE COLOR ADDITIVES (June 2014), https://www.fda.gov/media/115075/download; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: USE OF NANOMATERIALS IN FOOD FOR ANIMALS (Aug. 2015), https://www.fda.gov/media/88828/download; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: DRUG PRODUCTS, INCLUDING BIO- LOGICAL PRODUCTS, THAT CONTAIN NANOMATERIALS (DRAFT GUIDANCE) (Dec. 2017), https://www.fda.gov/ media/109910/download.

18. *See generally* NANOTECHNOLOGY ENV'T HEALTH & SAFETY, *supra* note 13.

19. A. Gergely et al., *Infinitesimal Ingredients: An Analysis of the Regulatory Dimensions of Nanotechnologies in Foods and Food Contact Materials*, *in* NANOTECHNOLOGIES IN FOOD 228–51 (Qasim Chaudhry et al. eds., 2d ed. 2017).

> discussion on the appropriate regulatory framework for this new technology advances hand in hand with the technology itself.[20]

Numerous new governance initiatives were launched after this time, adding support to Levi-Faur and Comaneshter's early observations.[21] This makes nanotechnologies somewhat unique from a regulation and governance perspective, given the breadth and range of hard and soft instruments employed since 2004. An examination of key initiatives, the motivations behind them, and their strengths and weaknesses can help inform responses to other emerging technologies including ubiquitous technologies such as artificial intelligence (AI).

This Article examines four of the better-known soft law initiatives that have been initiated and implemented in response to nanotechnologies. These initiatives include a unilateral code of conduct, a bilateral risk assessment framework, and government-sponsored voluntary requests for data and labeling activities. The four case studies selected by the author have been extensively reported on, have varying layers of documentation associated with their successes and failures, involve different governance mechanisms, and have had a lasting impact, albeit in one form or another, on the nanotechnologies landscape.[22] It is important to note, however, that these four initiatives are just a few of the scores

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20. David Levi-Faur & Hanna Comaneshter, *The Risks of Regulation and the Regulation of Risks: The Governance of Nanotechnology*, *in* NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 149, 150 (Graeme A. Hodge et al., 2007).

21. *See, e.g.*, *Code of Conduct Aims to Fill Tiny Retail Void*, SWI SWISSINFO (Apr. 22, 2008, 6:02 PM), https://www.swissinfo.ch/eng/code-of-conduct-aims-to-fill-tiny-retail-void/6605146 [https://perma.cc/F5DP-X4Q9]. *See generally* Bowman & Hodge, *supra* note *, at 54; Eur. Comm'n, *Commission Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research & Council Conclusions on Responsible Nanosciences and Nanotechnologies Research* (2009), https://ec.europa.eu/research/science-society/document_library/pdf_06/nanocode-apr09_en.pdf [https://perma.cc/S6UJ-5SS5]; *The EU Code of Conduct for Nanosciences and Nanotechnologies Research*, NANOWERK, https://www.nanowerk.com/spotlight/spotid=28850.php [https://perma.cc/SN2S-HUNF]; Lynn L. Bergeson, *European Commission Adopts Code of Conduct for Responsible Nanosciences and Nanotechnologies Research*, (Feb. 14, 2008), https://nanotech.lawbc.com/2008/02/european-commission-adopts-code-of-conduct-for-responsible-nanosciences-and-nanotechnologies-research/ [https://perma.cc/Z2HR-BCW6]; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY CONSIDERING WHETHER AN FDA-REGULATED PRODUCT INVOLVES THE APPLICATION OF NANOTECHNOLOGY (2014), https://www.fda.gov/media/88423/download [https://perma.cc/JM5G-PMAV]; LUDLOW ET AL., *supra* note 14; COLIN GAVAGHAN & JENNIFER MOORE, A REVIEW OF THE ADEQUACY OF NEW ZEALAND'S REGULATORY SYSTEMS TO MANAGE THE POSSIBLE IMPACTS OF MANUFACTURED NANOMATERIALS (2011), https://ourarchive.otago.ac.nz/bitstream/handle/10523/6162/Review%20of%20the%20Adequacy%20of%20NZ%27s%20Regulatory%20Systems%20for%20Nanomaterials.pdf?sequence=1&isAllowed=y [https://perma.cc/ER3R-44YS].

22. Each of the initiatives presented in this Article is highly complex, with many internal and external factors playing a role in their ultimate success or failure. Some of these factors, and indeed actors, are well documented in relation to each case. Others, such as the pull (or push) of external funding, internal pressure from stakeholders or constituents, and relative ranking of nanotechnologies to other emerging technologies, for example, have all played a role in the success and failures of these initiative. They are therefore, not surprisingly, evaluated in relation to a relative importance in the eventual outcomes.

of soft-law activities that have been initiated, albeit to varying degrees of success, in response to nanotechnologies.

I. BASF'S CODE OF CONDUCT

The BASF Group's Code of Conduct: Nanotechnology (the Code) provides an example of a unilateral industry governance activity designed to guide internal decision-making and provide a vehicle through which the company could engage with stakeholders, including the public, around nanotechnologies.[23] Before examining the nature and efficacy of the Code, it is important to first put this initiative into context.

BASF was, at the time of the Code's publication,[24] and remains today, the world's largest chemical company when measured by annual revenue.[25] In 2004, the German-based company employed approximately 80,000 individuals in its global operations.[26] This figure was 122,000 in 2018,[27] which serves to highlight the global breadth of the company as well as its growth over the last sixteen years. BASF's core business is focused on the manufacturing of industry-grade chemicals, which are deployed across six sectors in over 90 countries.[28] As noted in its 2019 strategy brochure, the company's corporate values include being creative, responsible, open, and entrepreneurial.[29] "Responsible" is articulated by BASF to include the following: "We value the health and safety of people above all else."[30] BASF is committed to Responsible Care, the chemical industry's "voluntary initiative to drive continuous improvement in safe chemicals management and achieve excellence in environmental, health, safety and security performance."[31] It is one of 580 chemical companies (as of August 2020) to have signed up to the Responsible Care Global Charter.[32] As such, the

23. *Code of Conduct*, BASF, https://www.basf.com/global/en/who-we-are/sustainability/we-produce-safely-and-efficiently/resources-and-ecosystems/nanotechnology/safety/code-of-conduct.html [https://perma.cc/CZ6S-AFRS].

24. *Fortune Global Fortune 500: 2006*, CNN MONEY, http://money.cnn.com/magazines/fortune/global500/2006/full_list/ [https://perma.cc/47D3-H575]; *see also* BASF, SHAPING THE FUTURE: SHORT REPORT ON THE 2004 FINANCIAL YEAR (2005).

25. Joyce Chepkemoi, *The World's Largest Chemical Companies*, WORLD ATLAS (June 10, 2019), https://www.worldatlas.com/articles/which-are-the-world-s-largest-chemical-producing-companies.html [https://perma.cc/GS5W-WLPR].

26. BASF, SHAPING THE FUTURE CORPORATE REPORT 2004, at 62 (2004).

27. BASF, BASF REPORT 2018: ECONOMIC, ENVIRONMENTAL AND SOCIAL PERFORMANCE 18 (2019).

28. BASF, BASF GROUP 2019 AT A GLANCE 4 (2019).

29. *Id.* at 9.

30. *Id.*

31. *Responsible* Care, INT'L COUNCIL CHEM. ASS'NS, https://www.icca-chem.org/responsible-care/ [perma.cc/RHR8-8TJN].

32. INT'L COUNCIL CHEM. ASS'NS, RESPONSIBLE CARE® GLOBAL CHARTER: COMPANY SIGNATORIES 2, https://icca-chem.org/wp-content/uploads/2020/09/Signatories-of-RC-Global-Charter.pdf [https://perma.cc/49SD-J6EL]; *Responsible Care® Global Charter*, INT'L COUNCIL CHEM. ASS'NS, https://icca-chem.org/wp-content/uploads/2020/06/RC-Global-Charter-FINAL.pdf [https://perma.cc/WMG7-2BTW] ("As a signatory to the Responsible Care Global Charter my company will actively strengthen the Responsible Care initiative worldwide and is committed to: (1) A Corporate

company has a long history of engaging with voluntary initiatives that promote a higher standard of care around human and environmental health and safety. Given the nature and scale of its business interests, it is unsurprising that BASF identified the importance of nanomaterials to its value chain early in the technology's development cycle.

The Code, which was first published in 2004 and remains a living document on the company's website,[33] was designed to guide BASF's program of work and decision-making, and "reflects the principles of the German Federal Government."[34] The Code, and its overarching mission—the safe manufacturing and production of nanomaterials—is spelt out by four principles:

> 1. We, the employees of BASF, develop and use the potentials of nanotechnology to manufacture products with enhanced performance or new properties by specifically creating and using new, nanoscale materials. . . .
> 2. To the extent that new technologies are converted into concrete processes and products, the expertise required to weigh up the opportunities against the potential risks related to the use of new technologies in the form of innovative products and processes increases. This is also the case with nanotechnology. We take these risks seriously, and as technical advances are achieved, continuously evaluate their potential environment and health hazards. . . .
> 3. Nanotechnology-based products have long been part of our portfolio. We also plan to use the potential of nanotechnology in future to offer our customers products and systems that help them to be more successful. . . .
> 4. In our Values and Principles, we have committed ourselves to pursuing a dialogue with society based on openness and trust. We regard it as our duty to provide information about the opportunities but also the potential risks of nanotechnology. . . .[35]

The Code expands on each principle to suggest how BASF will operationalize it. For example, under principle two, BASF committed itself to "continuously developing a thoroughly researched scientific database for the assessment of

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Leadership Culture that proactively supports safe chemicals management through the global Responsible Care initiative (2) Safeguarding People and the Environment by continuously improving our environmental, health and safety performance; the security of our facilities, processes and technologies; and by driving continuous improvement in chemical product safety and stewardship throughout the supply chain (3) Strengthening Chemicals Management Systems by participating in the development and implementation of lifecycle-oriented, sound-science and risk-based chemical safety legislation and best practices (4) Influencing Business Partners to promote the safe management of chemicals within their own operations (5) Engaging Stakeholders, understanding and responding to their concerns and expectations for safer operations and products and communicating openly on our performance and products (6) Contributing to Sustainability through improved performance, expanded economic opportunities and the development of innovative technologies and other solutions to societal challenges." (emphasis omitted)).

33. *Code of Conduct*, *supra* note 23.

34. *Id.*

35. *Id.*

potential risks, and in improving and refining product-based testing and assessment methods. Furthermore, we actively debate the opportunities and risks of nanotechnology with partners from all areas of society."[36]

As documented on the company's website, BASF has undertaken an extensive array of safety testing internally, as well as contributed to a range of external safety research.[37] Principle 4 sets out the company's commitment to engaging in an open and ongoing dialogue on nanotechnology with society. The process for doing so, as well as the findings of a series of dialogue activities, is included in the BASF website.[38] These activities and their findings are further supported by the DaNa2.0 information portal, which provides interested parties with accessible "[i]nformation about nanomaterials and their safety assessment."[39]

The body of information published by BASF since 2004 (including details of its engagement across sectors, and its findings), suggest a level of ongoing commitment to the Code that is anything but tokenistic. Based on the extensive range of activities the company was involved in, its transparency in reporting, and its willingness to be held to account based on the Code, it can be argued that the company—through its highest levels of leadership—was committed to fulling its obligations to employees, customers, and the environment.

This can be contrasted with a number of analogous codes that, while created in the same time period as BASF's Code, seem to have little traction with the organizations involved in their creation. Such examples include the Coalition of Non-Governmental Organization's *Principles for the Oversight of Nanotechnologies and Nanomaterials*,[40] the United Kingdom's *Responsible NanoCode*,[41] or even relevant external parties. A partial explanation may be found in a number of factors that differentiate BASF's Code from other codes. For example, the very high-level nature of the principles set out by many other codes include very few, if any, clear and actionable objectives. Similarly, unlike BASF who

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36. *Id.*

37. *See, e.g.*, *nanoGEM–Nanostructured Materials–Health, Exposure and Material Properties*, DANA 2.0, https://www.nanopartikel.info/en/projects/completed-projects/nanogem [https://perma.cc/TH7X-K67N]; NANODEFINE, http://www.nanodefine.eu [https://perma.cc/4MPH-3QPM]; NANOSAFE' 20, http://www.nanosafe.org/cea-tech/pns/nanosafe/en [https://perma.cc/RLN8-G2XT]; *NanoCare*, DANA 2.0, https://www.nanopartikel.info/en/projects/completed-projects/nanocare [https://perma.cc/3D4Z-VEDT].

38. To view final reports, see *In Dialog with Society*, BASF, https://www.basf.com/global/en/who-we-are/sustainability/we-produce-safely-and-efficiently/resources-and-ecosystems/nanotechnology/dialog/with-society.html [https://perma.cc/WJ8B-3NPG] (follow hyperlinks to download individual reports).

39. *Data and Knowledge on Nanomaterials–Processing of Socially Relevant Scientific Facts*, DANA 2.0, https://www.nanopartikel.info/en/projects/completed-projects/dana-2-0 [https://perma.cc/965T-YQ3R].

40. INT'L CTR FOR TECH. ASSESSMENT & FRIENDS OF THE EARTH, PRINCIPLES FOR THE OVERSIGHT OF NANOTECHNOLOGIES AND NANOMATERIALS (2007), http://www.icta.org/files/2012/04/080112_ICTA_rev1.pdf [https://perma.cc/CF3U-V8TK].

41. *See, e.g.*, ROYAL SOC'Y ET AL., RESPONSIBLE NANOTECHNOLOGIES CODE: CONSULTATION DRAFT–17 SEPTEMBER 2007: VERSION 5 (2007); ROYAL SOCIETY ET AL., RECORD OF DELIBERATIONS: RESPONSIBLE NANOTECHNOLOGY CODE INITIATIVE WORKING GROUP MEETING SIX (2008).

could craft its code in a way that reflected the vision and mission of the business as a whole, one can hypothesize various multiparty initiatives that lack the ability to be adopted in this same wholesale way. BASF is also the world's leading chemical company. Therefore, not only does it have the resources to act on the commitments detailed in the code, but it also has reputational and economic incentives to do so. By showing the public and policymakers its willingness to go beyond legal requirements in a transparent way, the company would be less likely to suffer reputation harm should an adverse event involving nanomaterials come to public attention.

There are likely to be other factors at play here that go beyond reputational and economic incentives. One could argue, for example, that if these were the only factors at play, other leading chemical companies—and analogous companies—would have implemented their own successful self-regulatory activities. High-level support from leadership, development of clear and achievable objectives, the ability to monitor and report on meaningful measures, transparency with scientific data, active feedback loops that incorporate the evolving state-of-the-scientific art, and the ability to engage in a thoughtful and consequential manner with external stakeholders all play a role here. Indeed, the presence of these elements does not guarantee the legitimacy of such a voluntary instrument. But regulatory scholars would agree they add weight to the credibility of such instruments and, we would argue, are more likely to have a longer lifespan than purely aspirational codes that lack any degree of specificity and incentives for an organization to comply with such instruments.

II. ENVIRONMENTAL DEFENSE-DUPONT RISK FRAMEWORK

The partnership between the NGO, Environmental Defense Fund (EDF), and DuPont, for the purposes of creating a risk assessment framework for nanotechnologies, is one of the higher profile bilateral, cross-sector, initiatives that emerged in the mid-2000s. EDF is one of the United States' largest member-based environmental NGOs,[42] whose mission is to "find practical and lasting solutions to the most serious environmental problems."[43] In contrast to many NGO groups, EDF has a strong track record of working with industry partners, as the organization believes that one of the best ways to change corporate behavior and create long-term, sustainable change is "not through confrontation, but through partnership with powerful market leaders."[44] The extensive list of

42. In 2006, EDF had approximately 500,000 members. ENV'T DEF. FUND, 2006 ANNUAL REPORT 28 (2006) [hereinafter EDF 2006 ANNUAL REPORT], https://www.edf.org/sites/default/files/5752_2006AnnualReport_0.pdf [https://perma.cc/3Q9G-BDLC].

43. *Our Mission and Values*, ENV'T DEF. FUND, https://www.edf.org/our-mission-and-values [https://perma.cc/4DE7-AM6U].

44. EDF 2006 ANNUAL REPORT, *supra* note 42, at 6.

multinational companies that have partnered with EDF for the purposes of implementing environmental changes to their business practices is impressive and includes, for example, Fed-Ex and McDonalds.[45]

Having specifically identified nanotechnologies as a potential area of public health and environmental concern in EDF's *2005 Annual Report*,[46] EDF saw an opportunity to partner with a leading global industry player for the express purpose of "develop[ing] a framework for the responsible development, production and use of nanoscale materials."[47] In mid-2005, under the umbrella of its Corporate Partnership program, EDF announced a strategic partnership with DuPont, at the time the world's fourth largest chemical company, for the purposes of developing a freely available risk assessment framework for nanomaterials.[48]

A coauthored commentary in the *Wall Street Journal* by Fred Krupp and Chad Holliday, the CEO of DuPont, captured the objectives of the partnership and their underlying motivation for being at the forefront of the design and implementation of a risk assessment tool for nanotechnologies:

> An early and open examination of the potential risks of a new product or technology is not just good common sense—it's a good business strategy. With the right mix of voluntary corporate leadership, coordinated research and informed regulation, we can reap the benefits of this promising technology while reducing the likelihood of unintended consequences.[49]

Developed over a two-year period, with the assistance of more than a dozen experts, the risk assessment framework outlined four specific goals:

- Establish a process to ensure the responsible development of nanoscale materials
- Develop a tool to organize and share information with stakeholders
- Facilitate public understanding of nanotechnology

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45. *Id.*; ENV'T DEF. FUND, 2005 ANNUAL REPORT 6, 7 (2005) [hereinafter EDF 2005 ANNUAL REPORT], https://www.edf.org/sites/default/files/4963_2005AnnualReport_0.pdf [https://perma.cc/NNX6-YACA].

46. EDF 2005 ANNUAL REPORT, *supra* note 45, at 15.

47. J.M. Balbus et al., *Getting It Right the First Time—Developing Nanotechnology While Protecting Workers, Public Health and the Environment*, 1076 ANNALS N.Y. ACAD. SCIS. 331, 340 (2006).

48. ENV'T DEF. FUND—DUPONT NANO PARTNERSHIP, NANO RISK FRAMEWORK 11 n.1 (2007), https://nanotech.law.asu.edu/Documents/2011/06/6496_Nano%20Risk%20Framework_534_2973.pdf [https://perma.cc/3Z54-VAGF] (citing Press Release, Env't Def. Fund & DuPont, Global Nanotechnology Standards of Care Partnership Oct. 1, 2005, www.environmentaldefense.org/article/cfm?contentID=4821); Letter from Gwen Ruta, Dir. Corp. P'ships, Env't Def. Fund, to Linda Fisher, Vice President & Chief Sustainability Officer, DuPont (Aug. 30, 2005) [hereinafter Letter of Understanding] (on file with author); *see* ENV'T DEF. FUND—DUPONT NANO PARTNERSHIP, *supra*, at 7.

49. Fred Krupp & Chad Holliday, *Let's Get Nanotech Right*, WALL ST. J. (June 14, 2005, 12:01 AM), https://www.wsj.com/articles/SB111870930078058710 [https://perma.cc/439R-6B8Y].

- Provide input for government policy on nanotechnology safety.[50]

These were supported by the principles of sound science, engagement, and flexibility, and included risk identification, risk management, transparency and accountability, feedback, evaluation, and adaptability.[51]

Importantly (at least for the framework's vocal critiques), a fundamental aim of the partnership, as spelt out in the Letter of Understanding between the two parties, was to "disseminate the principles and processes of the framework to other companies, industry associations, framework-setting organizations and government entities . . . *and to promote it as a model to be adopted by other companies and/or by government*."[52] As such, while part of the motivation may have been altruistic, critiques of the partnership and subsequent framework, such as the so-called Civil Society-Labor Coalition, focused heavily on the aspiration of influencing policy and regulatory decision-making. For some, the framing of the partnership in this way had the effect of undermining the credibility and legitimacy of the initiative.[53]

This was illustrated with the release of the draft framework in February 2007. At the time of its publication, the six-step framework[54] was met with mixed responses and fierce criticism from NGO groups.

The Civil Society-Labor Coalition[55] was strident in its condemnation of the frameworks, arguing that

> the DuPont-ED proposal is, at best, a public relations campaign that detracts from urgent worldwide oversight priorities for nanotechnology; at worst, the initiative could result in a highly reckless policy and a precedent of abdicating

50. *DuPont-Safer Nanotech*, ENV'T DEF. FUND, http://business.edf.org/projects/featured/past-projects/dupont-safer-nanotech [https://web.archive.org/web/20191022142816/http://business.edf.org/projects/featured/past-projects/dupont-safer-nanotech].

51. Letter of Understanding, *supra* note 48.

52. *Id.* at 7 (emphasis added).

53. *See, e.g.*, Lotte Krabbenborg, *Deliberation on the Risks of Nanoscale Materials: Learning from the Partnership Between Environmental NGO EDF and Chemical Company DuPont*, 41 POL'Y STUD. 372, 384–85 (2020).

54. ENV'T DEF. FUND—DUPONT NANO PARTNERSHIP, *supra* note 48, at 8, 9.

55. The Coalition was comprised of the following organizations: (1) American Federation of Labor and Congress of Industrial Organizations; (2) Beyond Pesticides; (3) Brazilian Research Network in Nanotechnology; Society and Environment; (4) Center for Environmental Health; (5) Center for Food Safety; (6) Corporate Watch; (7) Edmonds Institute; (8) ETC Group; (9) Friends of the Earth Australia; (10) Friends of the Earth Europe; (11) Friends of the Earth United States; (12) Greenpeace; (13) Institute for Agriculture and Trade Policy; (14) International Center for Technology Assessment; (15) International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers' Associations; (16) Natural Resources Defense Council; (17) Sciencecorps; (18) Silicon Valley Toxics Coalition; (19) Third World Network; and (20) the United Steelworkers of America. Civil Society-Labor Coalition, *An Open Letter to the International Nanotechnology Community at Large—Civil Society-Labor Coalition Rejects Fundamentally Flawed Dupont-ED Proposed Framework*, ETC GRP. 2 (Apr. 12, 2007), https://www.etcgroup.org/sites/www.etcgroup.org/files/publication/610/01/coalition_letter_april07.pdf [https://perma.cc/WSL9-5PFS].

> policy decisions to industry by those entrusted with protecting our people, communities, and land.[56]

Similarly, the Coalition went on to argue that "voluntary regulations have often been used to delay or weaken rigorous regulation and should be seen as a tactic to delay needed regulation and forestall public involvement."[57]

Industry responses, however, were far more supportive of the draft framework. The Nanotechnology Industries Association, for example, stated that the voluntary tool "represent[ed] a timely and well-structured initiative to secure the advancement of nanotechnology in a responsible way."[58]

The final framework was released in June 2007 and has since been "applauded by representatives from a range of companies, industry associations, government agencies and non-governmental organizations"[59] from across the world. These include a number of important nanotechnology stakeholders such as the American Chemistry Council's Nanotechnology Panel, General Electric, Intel, the U.S. Nanotechnology Initiative, the European Union and Community, and the Organization for Economic Cooperation and Development.[60]

While these endorsements are important and speak to the credibility of the framework, the real test of the tool's legitimacy is arguably best measured by the level of dissemination and use across the public and private sectors—and by whom. In short, has a critical mass of organizations adopted the framework as a template within their operations? And, has the framework been used to inform the development of rules, regulations, or guidance materials by regulatory bodies?

A review of the project's homesite, *DuPont-Safer Nanotech*,[61] speaks directly to these questions. According to EDF, the framework has been distributed over 7000 times since its release[62] and has been incorporated into the practices of a number of leading global companies including General Electric, Procter & Gamble and Lockheed Martin.[63] A number of other companies are currently evaluating how to integrate the framework into their business practices. Of equal

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56. *Id*. at 1.

57. *Id.*

58. NANOTECHNOLOGY INDUS. ASS'N, NIA COMMENT UPON DRAFT FRAMEWORK BY ENVIRONMENTAL DEFENSE–DUPONT NANO PARTNERSHIP 3 (Feb. 2007); *see also* Lotte Krabbenborg, *DuPont and Environmental Defense Fund Co-Constructing a Risk Framework for Nanoscale Materials: An Occasion to Reflect on Interaction Processes in a Joint Inquiry*, 7 NANOETHICS 45, 51 (2013).

59. *DuPont Nanotech Project: Endorsements and Public Impact*, ENV'T DEF. FUND, http://business.edf.org/projects/featured/past-projects/dupont-safer-nanotech/dupont-nanotech-project-endorsements-and-public-impact [https://web.archive.org/web/20200109052652/http://business.edf.org/projects/featured/past-projects/dupont-safer-nanotech/dupont-nanotech-project-endorsements-and-public-impact].

60. *Id.*

61. *See DuPont-Safer Nanotech*, *supra* note 50.

62. *DuPont Nanotech Project: Coverage and Distribution*, ENV'T DEF. FUND, http://business.edf.org/projects/featured/past-projects/dupont-safer-nanotech/dupont-nanotech-project-coverage-and-distribution [https://web.archive.org/web/20191109203441/http://business.edf.org/projects/featured/past-projects/dupont-safer-nanotech/dupont-nanotech-project-coverage-and-distribution].

63. *DuPont Nanotech Project: Endorsements and Public Impact*, *supra* note 59.

significance is the degree of influence the framework has had on government policy. While this is likely to be a slower process than private sector uptake, the framework appears to be providing a reference point to a number of influential policy-making bodies and agencies, including the Organization for Economic Cooperation and Development, the International Standards Organization Technical Committee TG229 on Nanotechnologies and U.S. federal agencies.[64] While this level of influence and update may—at least at this time—fall short of EDF and DuPont's vision for the framework and impact, it is evidence of impact and credibility. Moreover, given the weightiness of those organizations that have utilized the framework in one way or another, the real impact of the tool is unlikely to be understood for some time to come.

In her analysis of the EDF-DuPont partnership, Krabbenborg points to key variables that appear to be important to the success of the partnership. They include a shared desire "to create a product"[65] and early consensus about what the product would be.[66] This early and shared focus allowed for rapid development of the risk framework, while minimizing potential for divergence and conflict. Krabbenborg also suggests that the public nature of the engagement was important to the partnership's success, especially given the unconventional nature of the partners involved.[67] While these are only three of many elements that contributed to the success of the EDF-DuPont's partnership, this Article argues that they are collectively fundamental to its success and durability over time.

III. VOLUNTARY DATA CALL-IN PROGRAMS

The third case study presented in this Article shifts to voluntary information gathering activities undertaken by government agencies in the United Kingdom, Australia, and the United States. The release of the RS-RAE's report highlighted, among other things, the deficiency of scientific data on nanomaterials and a general lack of knowledge about the types of nanomaterials in production, and the volumes at which they were being produced.[68] This included relevant regulators, such as those with oversight of industrial chemicals, who were not equipped with the necessary tools to differentiate between nanoscale chemical substances and their conventional chemicals counterparts.[69]

In direct response to the RS-RAE's findings and associated recommendations, the U.K. government recognized the need to build a robust evidence base on which scientifically sound decisions could then be made. The vehicle by

64. *DuPont Nanotech Project: Government Influence*, ENV'T DEF. FUND, http://business.edf.org/projects/featured/past-projects/dupont-safer-nanotech/dupont-nanotech-project-government-influence [https://web.archive.org/web/20191109203502/http://business.edf.org/projects/featured/past-projects/dupont-safer-nanotech/dupont-nanotech-project-government-influence].

65. Krabbenborg, *supra* note 53, at 384–85.

66. *Id.*

67. *Id.* at 386.

68. *See generally* THE ROYAL SOC'Y & THE ROYAL ACAD. OF ENG'G NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004), https://royalsociety.org/~/media/Royal_Society_Content/policy/publications/2004/9693.pdf [https://perma.cc/8HGV-3NE6].

69. *Id.* at 75–76.

which the U.K. government sought to do this was a "Voluntary Reporting Scheme for engineered nanoscale materials," which was formally launched by the Department for Environment, Food and Rural Affairs (DEFRA) in September 2006. The purpose of the scheme, as articulated in the Introduction, was

> to develop a better understanding of the properties and characteristics of different engineered nanoscale materials, so enabling potential hazard, exposure and risk to be considered. Building an evidence base in this way will allow for a more informed debate about the nature of appropriate controls.[70]

The scheme was entirely voluntary, and primarily focused on collecting data on "free" (i.e., nonembedded in other materials) nanomaterials.[71] The data request, as set out in Annex A of the September 2006 report, can only be described as onerous,[72] with the request covering, in sum, "information on material characterisation, hazard, use and exposure potential, risk management practices, and the techniques used."[73] An emphasis on existing datasets was stressed in the guidance documents. However, little information was provided on *how* the data would be used and by *whom*.

It is arguably not surprising that by the end of the sixth quarter (December 2007), DEFRA had received a grand total of nine submissions—seven from industry and two from academic institutions.[74] A subsequent review of the scheme by the Advisory Committee on Hazardous Substances led to the clarification of guidance materials, streamlining of the data request forms and the implementation of a telephone survey in an attempt to encourage additional submissions.[75] In setting out the revisions to the scheme, Minister for the Environment, Phil Woolas, noted that

> The future success of nanoscience will largely be determined by public trust. A high level of participation in the scheme will send a clear signal to all that industry, research communities and Government are working together to minimise risks and drive forward safe and responsible development in this important and promising area.[76]

Little was achieved through the amendments, with a total of thirteen submissions being reported at the end of the two-year trial.[77] The results of the trial

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70. DEP'T FOR ENV'T, FOOD & RURAL AFFS., UK VOLUNTARY REPORTING SCHEME FOR ENGINEERED NANOSCALE MATERIALS 3 (2006), http://ethics.iit.edu/NanoBank/docs/UK_Voluntary_Reporting_Scheme.pdf [https://perma.cc/3ADG-AAEL].

71. *Id.* at 5.

72. *See id.* at 6–8.

73. *Id.* at 6.

74. DEP'T FOR ENV'T, FOOD & RURAL AFFS., THE UK VOLUNTARY REPORTING SCHEME FOR ENGINEERED NANOSCALE MATERIALS: SIXTH QUARTERLY REPORT 1 (2008) [hereinafter U.K. DEP'T FOR ENV'T, FOOD & RURAL AFFS.].

75. *See* Letter from Phil Woolas, Minister for the Env't, U.K. Dep't for Env't, Food & Rural Affs., to a Colleague 2 (Mar. 20, 2008) (on file with author); U.K. DEP'T FOR ENV'T, FOOD & RURAL AFFS., *supra* note 74.

76. Letter from Phil Woolas to a Colleague, *supra* note 75, at 2.

77. *United Kingdom*, OECD, http://www.oecd.org/unitedkingdom/45989396.pdf [https://perma.cc/7WCF-RK6E].

are, arguably, best summarized by the Royal Commission on Environmental Pollution who elegantly stated, that

> [i]t is clear, for example, that the current voluntary reporting scheme for engineered nanoscale materials operated by Defra has not worked. . . . Hence, we recommend that Defra should make nanomaterials reporting mandatory.[78]

Against this backdrop, Australia's National Industrial Notification and Assessment Scheme (NICNAS)[79] and the U.S. EPA launched its own voluntary call, or stewardship program, for information.[80] In the case of Australia, in addition to placing the call in the *Chemical Gazette,* the agency took a targeted approach reaching out to over 200 companies involved in either the manufacturing or importing of chemical substances.[81] A total of 22 companies provided data on 21 nanomaterials.[82] This process was repeated in 2008, albeit with a somewhat different process and purpose, at which time the agency received seven submissions.[83] In reporting on the findings of the two calls, the NICNAS regulator acknowledged the shortcomings of the voluntary call, noting that the agency's own informal research had "an inconsistency between market information and the results of the voluntary calls for information."[84]

The U.S. EPA's Nanoscale Materials Stewardship Program (NMSP), launched in 2008, appears to have suffered from many of the challenges experienced in the United Kingdom and Australia. As noted in the program's interim report, within the first twelve months of the program a total of 29 companies had submitted data to the EPA, with four companies having agreed to participate in the In-Depth Program;[85] the EPA "considered [this] successful."[86]

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78. ROYAL COMM'N ON ENV'T POLLUTION, NOVEL MATERIALS IN THE ENVIRONMENT: THE CASE OF NANOTECHNOLOGY 70 (2008) (emphasis omitted), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/228871/7468.pdf [https://perma.cc/D673-HH46].

79. *Dep't of Health & Ageing NICNAS*, No. C 10, AUSTL. GOV'T GAZETTE CHEM., Oct. 7, 2008, at 8, https://nanotech.law.asu.edu/Documents/2009/07/2008oct_whole_165_2476.pdf [https://perma.cc/S7JC-DNNU].

80. News Release, U.S. Env't. Prot. Agency, EPA Invites Public Participation in Development of Nanotechnology Stewardship Program (Oct. 18. 2006), https://archive.epa.gov/epapages/newsroom_archive/newsreleases/0edb5f39e2ed3c428525720b00629872.html.

81. Austl. Gov't Dep't of Health, *Nanomaterials—Findings and Calls for Information—Summary: 2006 Call for Information on the Use of Nanomaterials*, NAT'L INDUS. CHEMS. NOTIFICATION & ASSESSMENT SCHEME, https://www.nicnas.gov.au/chemical-information/factsheets/chemical-name/nanomaterials-findings-and-calls-for-]nformation [https://web.archive.org/web/20190411211931/https://www.nicnas.gov.au/chemical-information/factsheets/chemical-name/nanomaterials-findings-and-calls-for-information].

82. *Id.*

83. *Id.*

84. *Id.*

85. U.S. ENV'T. PROT. AGENCY, NANOSCALE MATERIALS STEWARDSHIP PROGRAM INTERIM REPORT 3 (2009).

86. *Id.*

While additional data was submitted prior to the Program's close, the success of the NMSP has largely been described as underwhelming. Richard Denison of the Environmental Defense Fund described the outcome of the two-year program:

> Fewer than 10%—123 out of the more than 1,600 unique nanomaterials EPA estimates are already commercially available—were addressed in the basic program submissions. The submissions encompass only one-seventh (28 of 200) of the unique chemical structures on which nanomaterials in use or development are based.[87]

More formal steps have since been taken by the U.S. EPA to collect risk relevant data on nanomaterials. This has included, for example, the EPA proposing in 2017 a Significant New Use Rule (SNUR)—as provided for under §5 of the Toxic Substances Control Act—to require industry to provide additional information to the Agency on single-walled and multi-walled carbon nanotubes.[88] More recently, the EPA proposed, pursuant to its powers under §8(a) of the Toxic Substances Control Act, a rule that "involves one-time reporting for existing discrete forms of certain nanoscale materials, and a standing one-time reporting requirement for new discrete forms of certain nanoscale materials before those new forms are manufactured or processed."[89] Such formalized action has not been taken in the United Kingdom or Australia despite the acknowledgements by the respective agencies that their data sets are outdated and not reflective of the state of the commercial market for nanomaterials.

In sum, it appears reasonable to state that the three voluntary reporting schemes failed to achieve their objectives, and that despite the different frameworks and approaches employed by the regulators, the outcomes can only be described as disappointing. Or, more bluntly, failures. While there are likely many different hypothesizes as to why, this Article argues that the lack of clarity provided in the guidance materials, the lack of transparency in terms of how data would be used and by whom, and the onerous nature of the reporting requirement were all significant factors. It is also likely that the lack of incentives offered to organizations to participate in the programs, in addition to the attention it may draw to them and their nano-manufacturing activities—especially by high profile NGO groups—were weighty factors that contributed to the low rates of participation across the jurisdictions. In addition, these voluntary schemes should have been narrowly tailored in terms of scope and duration, with clearly defined rationales that address key issues for industry (including

87. Richard Denison, *Nano Confessions: EPE All but Concedes Mandatory Reporting and Testing Are Needed*, ENV'T DEF. FUND (Jan. 12, 2009), http://blogs.edf.org/health/2009/01/12/62/ [https://perma.cc/444T-LJJV].

88. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 82 Fed. Reg. 3641 (proposed Jan. 12, 2017) (to be codified at 40 C.F.R. pt. 704).

89. *Chemical Substances When Manufactured or Processed as Nanoscale Materials: TSCA Reporting and Recordkeeping Requirements*, *Docket ID EPA-HQ-OPPT-2010-0572*, REGULATIONS.GOV. (Jan. 11, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0137 [https://perma.cc/LF69-WDKB].

data sharing and intellectual property), while minimizing the burden and economic cost to those voluntarily providing the data.

IV. A NANO OR NON-NANO LABEL

For most people, product labeling is often viewed as a form of hard law, prescribed by governments as part of a broad suite of consumer product legislation. However, not all product labeling is prescriptive in nature: industry can use voluntarily labelling in a way to promote or differentiate its product from others on the market. This can be done through positive labeling regimes—that is, "organic," which is designed to build trust and confidence within the consumer[90]—or through negative labeling schemes, such as "BPA free" and "does not contain GMO," the latter of which has been heavily employed by the European and now U.S. food industry in response to consumer backlash against genetically modified (GM) crops.[91] With voluntary labeling having the potential to influence behavior and impact purchasing decisions, the fourth case study presented in this Article will focus on voluntary labeling as a soft governance tool for nanotechnologies.

The personal care sector—the cosmetics sector in particular—rapidly embraced the use of the "nano" term, along with specific types of nanoparticles, such as "nanosomes" and "nano-emulsions."[92] L'Oreal, a multinational company, rebranded and created new product lines expressly to embrace these nano-terms.[93] This use of the terms on packaging was framed in a positive way, often used to differentiate that product from its conventional counterpart through the subtle—or not so subtle—suggestion that the nano-ingredient made it a more

90. *See* Gabriele Jahn et al., *The Reliability of Certification: Quality Labels as a Consumer Policy Tool*, 28 J. CONSUMER POL'Y 53, 70; Meike Janssen & Ulrich Hamm, *Product Labelling in the Market for Organic Food: Consumer Preferences and Willingness-to-Pay for Different Organic Certification Logos*, 25 FOOD QUALITY & PREFERENCE 9, 9 (2012).

91. *See* BIOTECHNOLOGY: THE MAKING OF A GLOBAL CONTROVERSY 58–64, 87 (M. W. Bauer et al. eds. 2002). *See generally* Laura D. Scherer et al., *The Psychology of 'Regrettable Substitutions': Examining Consumer Judgements of Bisphenol A and Its Alternatives*, 16 HEALTH, RISK & SOC'Y 649, 658.

92. Another area that appears to have embraced positive labeling for nano-based products is the supplement industry. Products currently on the market include, for example, (1) Muscletech's NaNOX9 Next Generation Pre-Workout Amplifier, *See All Products*, MUSCLETECH, https://international.muscletech.com/products/?fwp_preworkout_intl=preworkout-intl [https://perma.cc/6GRC-AK7N]; (2) Allergy Research Group's Muscolyxir Nanotech Nutrients, *See Allergy Research Group, Mucolyxir Nanotech Nutrients 12 Ml*, NANOTECHOLOGY PRODS. DATABASE, https://product.statnano.com/product/6127/allergy-research-group-mucolyxir-nanotech-nutrients-12-ml [https://perma.cc/57D4-PJFD]; and (3) NuSkin's LifePak Nano nutritional supplements, *See LifePak® Nano*, NU SKIN, https://www.nuskin.com/content/nuskin/en_US/products/product.01003610.html [https://perma.cc/9RYB-LTDN].

93. Nell Greenfieldboyce, *Safety of Nano-Cosmetics Questioned*, NPR (Mar. 13, 2006), https://www.npr.org/templates/story/story.php?storyId=5257306 [https://perma.cc/N95G-82SC] (interview with Andrew Maynard, Sci. Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson Int'l Ctr. for Scholars); Nur Haziqah Che Marzuki et al., *An Overview of Nanoemulsion: Concepts of Development and Cosmeceutical Applications*, 33 BIOTECHNOLOGY & BIOTECHNOLOGICAL EQUIP. 779, 782.

superior product. A 2013 analysis of the Woodrow Wilson Center's online inventory of self-identifying nano products reinforces the positive use of nano terms in branding within this market sector.[94] The database has 1,628 products, but the largest category is "Health and Fitness" (n=788 making up 48.4% of products)[95] with the largest portion of that category being "personal care" (n=292 making up 37.1% of Health and Fitness category).[96]

That is not to say that personal care companies using nano-labels as part of their marketing agenda have done so without attracting negative attention and inciting various levels of controversy. The early use of buckyballs ("buckminsterfullerenes" also known as "buckyballs") within numerous cosmetic applications provide a case in point. Companies such as Zelens, which expressly noted the inclusion of fullerenes on their labels as part of their marketing pitch,[97] drew attention from NGOs[98] because of a growing body of work suggesting potential toxicity to living cells,[99] including human cells, even when present in low concentrations.[100]

However, concerns over the use of buckyballs in cosmetics were quickly overshadowed by apprehensions around the use of nonbiodegradable, metal oxide nanoparticles in sunscreening products. Australia saw the early entry of "clear" or "transparent" sunscreens—which contained nano-zinc or nano-titanium dioxide or both—including ZinClear Nano Zinc Oxide, which were marketed as offering better sunscreening solutions to conventional white/chalky products.[101] In response to concerns about the potential risks posed by active nano-ingredients in sunscreening products, in 2006 Australia's Therapeutic Goods

94. *Analysis*, PROJECT ON EMERGING NANOTECHNOLOGIES, (Sept. 13, 2019), https://web.archive.org/web/20190913220749/https://www.nanotechproject.org/cpi/about/analysis. It is important to note that these products are all self-identified nano-based products and that some products are counted twice in the database because they fall into multiple categories (i.e., a cosmetic that also functions as a sunscreen). *See generally* Marina E. Vance et al., *Nanotechnology in the Real World: Redeveloping the Nanomaterial Consumer Products Inventory*, 6 BEILSTEIN J. NANOTECHNOLOGY 1769 (2015) (providing an overview of the establishment of the inventory, the growth of the inventory in terms of product types and jurisdictions, and the subsequent revisions to the inventory in 2013).

95. *Analysis*, *supra* note 94.

96. *Id.*

97. Bethany Halford, *Fullerene for the Face*, CHEM. & ENG'G. NEWS (Mar. 27, 2006), https://cen.acs.org/articles/84/i13/Fullerene-Face.html [https://perma.cc/ZA2W-LZXQ]; *see also* FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS, BIG RISKS 22 (2006), https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/wpallimport/files/archive/Nanomaterials_sunscreens_and_cosmetics.pdf [https://perma.cc/N59G-VQWD].

98. *See, e.g.*, *id.* at 4–8, 17.

99. *E.g.*, Eve Oberdörster, *Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 ENV'T HEALTH PERSP. 1058, 1058–62 (2004).

100. *See generally* Christie M. Sayes et al., *The Differential Cytotoxicity of Water-Soluble Fullerenes*, 4 NANO LETTERS 1881 (2004).

101. *ZinClear™ Nano Zinc Oxide*, PROJECT EMERGING NANOTECHNOLOGIES, https://www.nanotechproject.org/cpi/products/zincleartm-nano-zinc-oxide-2/ [https://web.archive.org/web/20200207011713/https://www.nanotechproject.org/cpi/products/zincleartm-nano-zinc-oxide-2/].

Administration (TGA) conducted a review of the available scientific literature,[102] concluding that

> [t]here is evidence from isolated cell experiments that ZnO and TiO_2 can induce free radical formation in the presence of light and that this may damage these cells (photo-mutagenicity with ZnO). However, this would only be of concern in people using sunscreens if the ZnO and TiO_2 penetrated into viable skin cells. The weight of current evidence is that they remain on the surface of the skin and in the outer dead layer (stratum corneum) of the skin.[103]

Despite this conclusion, a 2006 publication by the Friends of the Earth's (FoE) Nanotechnology Project sought to move the safety debate around the use of nano-scale ingredients in personal care products—and sunscreens in particular—into the public spotlight. The report sought to highlight gaps in the scientific literature and information being provided to regulators, as well as the lack of labeling laws for nano-based products. The report concluded, among other things, that

> [b]ased on this report, Friends of Earth believes there should be a moratorium on the further commercial release of sunscreens, cosmetics and personal care products that contain engineered nanomaterials, and the withdrawal of such products currently on the market, until adequate public, peer-reviewed safety studies have been completed, and adequate regulations have been put in place to protect the general public . . . .[104]

In August 2007, the NGO published a document that specifically focused on its concerns about nano-based sunscreens.[105] Drawing from product labels and manufacturer claims, FoE created a traffic-light system for sunscreens in the Australian market, with nano-free sunscreens being given a "green light," sunscreens that may contain nano-ingredients being classified as "yellow," and those containing nano-ingredients being given a "red light."[106] The document,

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102. *See* AUSTL. THERAPEUTIC GOODS ADMIN., A REVIEW OF THE SCIENTIFIC LITERATURE ON THE SAFETY OF NANOPARTICULATE TITANIUM DIOXIDE OR ZINC OXIDE IN SUNSCREENS (Jan. 16, 2006), https://www.tga.gov.au/npmeds/sunscreen-zotd.pdf [https://web.archive.org/web/20060829142806/http://www.tga.gov.au/npmeds/sunscreen-zotd.pdf] (reviewing a total of 24 studies, although at least one was not reviewed as it was not in English).

103. *Id.* at 15. The TGA has updated the review twice since 2006, with the second iteration of the review being released in 2013 and the third in 2016. Each iteration of the review has included additional scientific studies. In line with the earlier review, the 2016 review concluded that

> on current evidence, neither TiO_2 nor ZnO NPs are likely to cause harm when used as ingredients in sunscreens. The current state of knowledge strongly indicates that the minor risks potentially associated with NPs in sunscreens are vastly outweighed by the benefits that NP-containing sunscreens afford against skin damage and, importantly, skin cancer.

AUSTL. THERAPEUTIC GOODS ADMIN., LITERATURE REVIEW ON THE SAFETY OF TITANIUM DIOXIDE AND ZINC OXIDE NANOPARTICLES IN SUNSCREENS 15 (version 1.1 Aug. 2016), https://www.tga.gov.au/sites/default/files/nanoparticles-sunscreens-review-_2016_1.pdf [https://perma.cc/CW9M-4MDH].

104. FRIENDS OF THE EARTH, *supra* note 97, at 17.

105. *See generally* FRIENDS OF THE EARTH, NANOTECHNOLOGY & SUNSCREENS: A CONSUMER GUIDE FOR AVOIDING NANO-SUNSCREENS (2007).

106. *Id.* at 10–12.

which was widely distributed, suggested that "[c]rucially for the use of nano-sunscreens, the jury is still out on how readily and how deeply nanoparticles penetrate skin."[107]

The intent, arguably, of the report was to nudge the Australian public into buying non-nano sunscreens. However, the report, along with associated media activities and other outreach activities by FoE, had a notable unintended effect. A survey conducted by the Australian Department of Industry, Innovation, Science, Research and Tertiary Education and presented at the 2012 International Conference on Nanoscience and Nanotechnology (ICONN) suggested that some consumers, based on their unease and a misunderstanding, may stop using sunscreen products altogether. [108] With Australia having the highest rate of melanoma in the world,[109] any reduction in the rate of sunscreen usage has the potential to result in adverse public health outcomes.

The debate around the potential benefits and risks of nano-ingredients in sunscreening products in Australia (in particular) coincided with the emergence of a "non-nano" label for such products. Reminiscent of the non-GMO label found across the European Union's food sector,[110] it actively seeks to differentiate the product from others on the market—regardless of whether these other products contain nano.**[111]** At the same time, the label seeks to alleviate concerns over potential risks, regardless of whether these risks are real.

In the absence of a universally accepted definition of what nano or nanomaterials are, the use of such labeling—albeit positive or negative—has the potential to mislead. It is therefore not surprising that with the increased use of the nano label, combined with concerns over potential risks by certain types of nanomaterials, a number of NGO's and other stakeholders lobbied governments for the introduction of mandatory labeling regimes.[112] These calls focused primarily on personal care products (i.e., sun screening products and make-up) and

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107. *Id.* at 4.

108. *See* Science in Public, *Australians Risking Skin Cancer to Avoid Nanoparticles*, PHYS.ORG (Feb. 9, 2012), https://phys.org/news/2012-02-australians-skin-cancer-nanoparticles.html [https://perma.cc/2HLM-FC8L].

109. *Skin Cancer Statistics: Melanoma of the Skin Is the 19th Most Common Cancer Worldwide*, WORLD CANCER RSCH. FUND, https://www.wcrf.org/dietandcancer/cancer-trends/skin-cancer-statistics [https://perma.cc/JW4P-QRKU].

110. Julie A. Caswell, *Labeling Policy for GMOs: To Each His Own?*, 3 AGBIOFORUM 53, 54 (2000), http://agbioforum.org/v3n1/v3n1a08-caswell.pdf [https://perma.cc/9TNJ-9V24].

111. *See, e.g.*, *Search Our Store: Non-Nano*, BABO BOTANICALS, https://www.babobotanicals.com/search?type=product&q=non-nano [https://perma.cc/RM9T-ENPB]; *Kids & Babies Sunscreens*, BADGER BALM, https://www.badgerbalm.com/c-47-kids-baby-sunscreens.aspx [https://perma.cc/9J6N-8VCR].

112. *See, e.g.*, INT'L CTR FOR TECH. ASSESSMENT & FRIENDS OF THE EARTH, *supra* note 40, at 3; FRIENDS OF THE EARTH AUSTL., SUBMISSION FROM FRIENDS OF THE EARTH AUSTRALIA TO THE NATIONAL FOOD LABELLING REVIEW (2009) [hereinafter FOE, NAT'L FOOD LABELLING REV. SUBMISSION] (on file with the author); FRIENDS OF THE EARTH AUSTL., SUBMISSION FROM FRIENDS OF THE EARTH AUSTRALIA TO THE HOUSE OF LORDS SCIENCE AND TECHNOLOGY COMMITTEE NANOTECHNOLOGIES AND FOOD INQUIRY 5 (2009) [hereinafter FOE, SUBMISSION TO HOUSE OF LORDS], https://www.parliament.uk/documents/lords-committees/science-technology/st132friendsoftheearthaustralia.pdf [https://web.archive.org/web/20121128015613/https://www.parliament.uk/

foods.[113] While much of this advocacy fell on deaf ears,[114] the arguments did gain some traction within the European Union, as evidenced by the passage of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products (the Cosmetic Regulation).[115] That Regulation provided for, among other things, the mandatory labelling of nanomaterials in cosmetic products on the European market.[116] While nano-specific provisions made their way into the Cosmetic Regulation, it is important to note that the recast of the regulatory frameworks for cosmetic products was not triggered by the debate and concerns around nanomaterials in such products, but rather as part of a broader agenda to streamline the regulatory process and enhance human safety requirements.[117]

For the purposes of the Cosmetic Regulation, a "nanomaterial" was narrowly defined as "an insoluble or bio-persistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm."[118] As such, soluble nanomaterials including, for example, solid lipid nanoparticles which are common in cosmetic products, are not considered to be a "nanomaterial" for the purposes of the Cosmetic Regulation. This definition and distinction are important, as the labelling requirement set out in Article 19(1)(g) of the Cosmetic Regulation—which requires that any cosmetic product containing nanomaterial ingredients to indicate as such by using the word *nano* after its listing on the packaging—will only capture a small set of nanoscale materials used in products.[119] Moreover, as suggested in my earlier piece, the narrow definition means that "[u]nless the benefits of using nanomaterials outweigh these costs, it is possible that some companies may reformulate existing nanobased products so that the particles fall outside—even slightly—the size range specified in the regulation."[120]

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documents/lords-committees/science-technology/st132friendsoftheearthaustralia.pdf]; *Greens New Century Australia Senate Agenda*, GREENS (Aug. 25, 2008), http://greens.org.au/node/2169 [https://web.archive.org/web/20130426211640/http://greens.org.au/node/2169]. *See generally* John C. Monica, Jr., *FDA Labeling of Cosmetics Containing Nanoscale Materials*, 5 NANOTECH. L. & BUS. 63 (2008); Joel D'Silva & Diana Megan Bowman, *To Label or Not to Label?—It's More than a Nano-sized Question*, 1 EUR. J. RISK REGU. 420, 420–27 (2010); Guillaume P. Gruère, *Labeling Nano-Enabled Consumer Prods.*, 6 NANO TODAY 117 (2011).

113. *See, e.g.*, FoE, NAT'L FOOD LABELLING REV. SUBMISSION, *supra* note 112; FoE, SUBMISSION TO HOUSE OF LORDS, *supra* note 112, at 5. *See generally* Monica, *supra* note 112; Gruère, *supra* note 112.

114. *See generally* U.S. FOOD & DRUG ADMIN., NANOTECHNOLOGY: A REPORT OF THE U.S. FOOD AND DRUG ADMINISTRATION TASK FORCE (2007), https://www.fda.gov/media/74257/download [https://perma.cc/UC2C-PELU]; Monica, *supra* note 112, at 64.

115. Commission Regulation 1223/09 of Nov. 30, 2009, art. 19, On Cosmetic Products, 2009 O.J. (L 342) 59, 72–74 (EC) [hereinafter Regulation 1223/09].

116. *Id.*

117. Diana M. Bowman et al., Letter to the Editor, *Nanomaterials and Regulation of Cosmetics*, 5 NATURE NANOTECHNOLOGY 92, 92 (2010).

118. Regulation 1223/09, *supra* note 115, art. 2(1)(k), at 65.

119. *See id.* art. 19(1)(g), at 73.

120. Bowman, *supra* note 117, at 92.

The Cosmetic Regulation does not prohibit positive labelling that goes beyond the scope set out by the nano-specific provisions, nor does it limit the use of negative labelling by companies wishing to place their cosmetic products onto the E.U. market. Nor has it created a uniform definition of what a nanomaterial *is* for the purposes of E.U. law, with the E.U. Council and Parliament adopting a different definition within the text of the Regulation (EU) No. 1169/2011 of the European Parliament and the Council of 25 October 2011 on the provision of food information to consumers (the Food Labeling Regulation).[121] Pursuant to the Food Labeling Regulation and as amended by Regulation (EU) 2015/2283 on novel foods (the Novel Foods Regulation), an "engineered nanomaterial"

> means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.[122]

Properties that are characteristic of the nanoscale include

> (i) those related to the large specific area of the materials considered; and/or
> (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.[123]

New Zealand is the only other jurisdiction, at least to date, to have passed legislation requiring any form of nano labeling; its nano-labeling law only covers cosmetic products[124] and does not go as far as the European Union in addressing the use of nanomaterials in foods. This Article argues that it is highly unlikely that any other jurisdiction will move forward with the passage of mandatory nano-labeling laws given the decreasing concern over the presence of most nanomaterials in consumer products, such as personal care products and food. Further, the shift of many of the most vocal NGOs and commentators from nanotechnologies to other newer, and more pressing, emerging technologies such as gene editing/CRISPR, makes the passage of such laws unlikely. As such,

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121. Commission Regulation 1169/11 of Oct. 25, 2011, On the Provision of Food Information to Consumers, 2011 O.J. (L 304) 18 (EU).

122. *Id.* art. 2(2)(t), at 26; Commission Regulation 2283/15 of Nov. 25, 2015, art. 3(2)(f), On Novel Foods, 2015 O.J. (L 327) 1, 9 (EU).

123. Commission Regulation 2283/15, *supra* note 122, art. 3(2)(f), at 9. As provided for by Article 2(1)(h), which states that "the definition of 'engineered nanomaterials' as established by point (f) of Article 3(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council." *Id.* art. 33(1), at 21.

124. *See* N.Z. ENV'T PROT. AUTH., COSMETIC PRODUCTS GROUP STANDARD 2017–HSR002552 5 (2017), https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/2017-Group-Standards/7f18a92020/Cosmetic-Products-Group-Standard-2017-HSR002552.pdf [https://perma.cc/37T3-Q6XX]. For the purposes of the Standard, a "nanomaterial means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100nm." *Id.* at 8 (emphasis omitted).

consumers will be left to navigate a myriad of voluntary nano labels, along with a few mandatory regimes, with very little consistency or continuity between the different approaches.

This patchwork approach to consumer product labeling, albeit by design or default, is not without precedent. It mirrors many of the debates, activities, and actions taken in relation to the labeling of genetically modified (GM) food in the European Union and other jurisdictions. Widespread and intense backlash to GM foods across nations resulted in not only moratoriums of their entry into specific markets, but also the rise of the "non-GMO" label.[125] At the same time, intense debate ensued at the international level around how to define a GMO for the purposes of mandatory labeling regimes,[126] which failed to result in any one single definition being adopted by Codex members.

In cases of both biotechnology and nanotechnologies, responsibility is placed consumers to navigate the myriad of labels, assess their varying definitions, and exercise informed consent in relation to their purchasing. Commentators such as Shelley-Egan and Bowman have been critical of this shifting of responsibility to the consumer, arguing that such approach was

> problematic given current uncertainties about what a "nano label" actually means, and doubts around the capacity to furnish the consumer with sufficient information to allow them to make a fully informed decision about the product in question.[127]

Throne-Holst and Rip have similarly expressed concern with this shift with nano-based products,[128] arguing instead for a greater sharing of responsibilities

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125. *See* Caswell, *supra* note 110, at 54; *see also* Carmen Bain & Tamera Dandachi, *Governing GMOs: The (Counter) Movement for Mandatory and Voluntary Non-GMO Labels*, 6 SUSTAINABILITY 9456, 9456–58 (2014); Carmen Bain & Theresa Selfa, *Non-GMO vs Organic Labels: Purity or Process Guarantees in a GMO Contaminated Landscape*, 34 AGRIC. & HUM. VALUES 805, 805–18 (2017) (describing how the GMO label framing debate morphed into a debate around the term *organics* for the purposes of labeling within the United States).

126. Nicholas Kalaitzandonakes & Peter Phillips, *GM Food Labeling and the Role of the Codex*, 3 AGBIOFORUM 188, 188–91 (2000); Sara Poli, *The European Community and the Adoption of International Food Standards within the Codex Alimentarius Commission*, 10 EUR. L.J. 613, 626 (2004). *See generally* Jack A. Bobo, *Two Decades of GE Food Labeling Debate Draw to an End—Will Anybody Notice*, 48 IDAHO L. REV. 251 (2012); JEAN-MICHEL WAL, IMMUNO-ALLERGIE ALIMENTAIRE, TOPIC 9: POST-MARKET SURVEILLANCE OF ALLERGENICITY, JOINT FAO/WHO EXPERT CONSULTATION ON FOODS DERIVED FROM BIOTECHNOLOGY (2001), http://www.fao.org/ag/agn/food/pdf/bi11al.pdf [https://perma.cc/KN7R-T2UW] (for a discussion on the science underpinning the potential risks posed by GMOs).

127. Clare Shelley-Egan & Diana Megan Bowman, *The Challenge of Distributing Regulatory Responsibilities for Unknown Risks: 'Nano'-Cosmetics and the EU Cosmetics Regulation as a Case Study*, 6 J. CLINICAL RSCH. & BIOETHICS, no. 2, 2015, art. no. 1000212, at 1, 2, https://www.longdom.org/open-access/the-challenge-of-distributing-regulatory-responsibilities-for-unknown-risksnano cosmetics-and-the-eu-cosmetics-regulation-as-a-case-study-2155-9627-1000212.pdf [https://perma.cc/3J3L-QA4L].

128. H. Throne-Holst & Arie Rip, *Complexities of Labelling of Nanoproducts on the Consumer Markets*, 2 EUR. J. L. & TECH., no. 3, 2011, at 1, 3, http://www.ejlt.org/index.php/ejlt/article/view/83/175.

for labeling between the parties.[129] Their proposed approach would require consumers and the private and public sectors to play an active role in the governance process, rather than abdicating responsibility to any one sector. Based on the above analysis, such an approach for the labeling of nanotechnology products would help build legitimacy, credibility and transparency to what is currently an opaque and highly complex decision-making process.

This Article sought to highlight a few of the numerous soft law initiatives that have been initiated across the nanotechnologies landscape and to do so across jurisdictions and time. While a comprehensive review and evaluation of the catalogue of these soft law instruments is beyond the scope of this Article—although clearly warranted—it has illustrated the preemptive and proactive approached adopted by different actors in relation to an emerging technology.

The known unknowns and the unknown unknowns around potential human and environmental risks appear to have been key catalysts for this early experimentation with different soft law approaches—especially when combined with the economic potential promised by the technology. Given the uncertainties associated with nanotechnologies at the time of their emergence onto the market, this experimentation should be viewed as constructive for the commercialization, and consumer acceptance, of the technology and its products. Importantly, the simultaneous testing of different codes, certification schemes, guidance documents, data call in schemes and the like—across industries, jurisdictions and actors—can be said to have provided real time data around what may or may not work as a governance approach. Soft law instruments may then, owing to their flexibility and agility, quickly pivot to respond to this new information. As this Article has sought to highlight, dexterity has been important in minimizing consumer backlash to the technology.

This Article argues that this heterogeneity in approaches is important for any emerging technology, but even more so in relation to those that are considered to be platform technologies, such as AI, given their potential impact across all sectors of the economy. And while not all initiatives were successful—however measured—the failures, along with the success, provide valuable insights for the development and deployment for other emerging technologies as they enter into the market. As the BASF and DuPont-EDF examples illustrate, incentives—in the form of reputation, economic or political influence—can be key drivers for success. On the flipside, the absence of clear incentives—especially when combined with a lack of transparency and costs—can be seen as significant barriers for private sector participation in the government initiative programs, such as the voluntary call-in programs discussed in this Article. For producers and manufacturers of nano-based products, these calculations are likely to be far more nuanced, being highly dependent on the jurisdiction in which they are placing their product, the culture and social sensitivities to

129. *Id.* at 8.

emerging technologies and risks, and the nature of the product itself. Such calculations will be dynamic, meaning a decision to positive label a product may change rapidly in response to new scientific data or market reactions.

Twenty years of nanotechnology commercialization provides a rich history of soft and hard law approaches on which to draw lessons learned for the technology's governance. Of these, arguably the most important lesson—which echoes the early observations of Levi-Faur and Comaneshter—is that such instruments can be developed successfully in parallel with an embryonic technology and refined as the science or the market demand.