LAW AND POLICY OF NANOTECHNOLOGY IN FOOD: GLOBAL COMMERCE PROMOTING GLOBAL HEALTH FROM FIELD TO FORK

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INTRODUCTION

Every day, humans and animals need and consume food to sustain their lives. Food is therefore subject to extensive regulation nationally, internationally, under customs law and trade agreements, and under some religious laws as well.[1] Few people are aware of how profoundly developments in nanotechnology in food impact their daily lives as consumers; moreover, remarkably little is understood about the potential long-term risks[2] of the nano-enabled changes to the food supply.[3] This gap in knowledge and awareness amplifies the risk of rapid unquantified exposure to nanotechnology in the food supply. In parallel, the absence of a shared legal vocabulary to describe nanotechnology makes it challenging for society to maximize the benefits of applying nanotechnology to food[4] while minimizing the risks posed to humans, animals, and the overarching ecosystem.

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[1] *See* Zahra Khoshdouni Farahani & Fatemeh Khoshdouni Farahani, *Biosensors as a Rapid Method for Detection of Non-Halal Ingredients in Food Products*, 1 J. HUM., HEALTH & HALAL METRICS 94, 95 (2020), https://doi.org/10.30502/jhhhm.2021.233755.1024; Deni Subara & Irwandi Jaswir, *Gold Nanoparticles: Synthesis and Application for Halal Authentication in Meat and Meat Products*, 8 INT'L J. ON ADVANCED SCI., ENG'G & INFO. TECH. 1633, 1633 (2018); M. S. Thakur & K. V. Ragavan, *Biosensors in Food Processing*, 50 J. FOOD SCI. TECH. 625, 625 (2013), http://dx.doi.org/10.1007/s13197-012-0783-z; Zhenyun He & Hongshun Yang, *Colourimetric Detection of Swine-Specific DNA for Halal Authentication Using Gold Nanoparticles*, 88 FOOD CONTROL 9, 9 (2018), https://doi.org/10.1016/j.foodcont.2018.01.001;; *see also Tackling Food Loss and Waste: A Triple Win Opportunity*, FAO (2022), https://www.fao.org/newsroom/detail/FAO-UNEP-agriculture-environment-food-loss-waste-day-2022/en [https://perma.cc/TLU3-NBRG].

[2] *See generally* Society of Toxicology, *SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety: The Toxicology of Nanoparticles*, VIMEO (Apr. 8, 2021), https://vimeo.com/539756902.

[3] *See* Stephanie Strom, *Study Looks at Particles Used in Food*, N.Y. TIMES, Feb. 5, 2013, https://www.nytimes.com/2013/02/06/business/nanoparticles-in-food-raise-concern-by-advocacy-group.html [https://perma.cc/J3SR-N6GE] ("Some companies may not even know whether nanomaterials are present in their products").

[4] *See* Ilise L. Feitshans, *Forecasting Nano Law: Defining Nano*, 8 NANOTECH. PERCEPTIONS 17, 17–34 (2012); *see also* Ilise L. Feitshans, *Forecasting Nano Law*, 704 UN SPECIAL 36, 36–37 (2011).

Nanotechnology[5]—a new approach to applied science in which particles are designed and engineered—has been used in the development of food since the late 20th century, yet its role in food production is largely under-recognized.[6] Therefore, its implications for food quality, quantity, and distribution have not been widely described, despite the impacts of nanotechnology on human health, livestock and domestic animals, and global trade.

The United States (U.S.) and the European Union (EU) have adopted starkly contrasting positions with respect to the question of how to regulate nanotechnology in food. Under the U.S. regulatory regime, the application of nanotechnology to food is largely ignored. In Europe, the application of nanotechnology to food is analyzed according to a "field to fork" framework. This model recognizes that nanotechnology may be applied to food up and down the supply chain: more effective formulation of fertilizers, pesticides, and herbicides; nanosilver as an antibacterial in food handling[7] and

[5] For a discussion of the challenges in defining the term "nanotechnology," see L. P. Balogh, *Why Do We Have So Many Definitions for Nanoscience and Nanotechnology?*, 6 NANOMEDICINE: NANOTECHNOLOGY, BIOLOGY, & MED. 397, 397 (2010) ("[M]ost experts seem to disagree on how to define and use nano-related terms. As a consequence, a surprising number of different definitions can be found both in the popular and the scientific literature for nanoscience and nanotechnology, not to mention nanomedicine. What's more, these definitions keep changing all the time."), http://dx.doi.org/10.1016/j.nano.2010.04.001.

[6] *See* Simon More, Vasileios Bampidis, Diane Benford, Claude Bragard, Thorhallur Halldorsson, Antonion Hernández-Jerez, Susanne Hougaard Bennekou, Kostas Koutsoumanis, Claude Lambré, Kyriaki Machera, Hanspeter Naegeli, Søren Nielsen, Josef Schlatter, Dieter Schrenk, Vittorio Silano, Dominique Turck, Maged Younes, Jacqueline Castenmiller, Qasim Chaudhry, Francesco Cubadda, Roland Franz, David Gott, Jan Mast, Alicja Mortensen, Agnes G. Oomen, Stefan Weigel, Eric Barthelemy, Ana Rincon, José Tarazona & Reinhilde Schoonjans, *Guidance on Risk Assessment of Nanomaterials to Be Applied in the Food and Feed Chain: Human and Animal Health*, 19 EUR. FOOD SAFETY AUTH. J., Aug. 2021, at 1, https://doi.org/10.2903/j.efsa.2021.6768.

[7] Silver recovery presents a historically major challenge. The same antimicrobial properties that make silver popular for servingware are also source of hazardous waste under long-established U.S. laws. Silver nanoparticles have an affinity to cell membranes, and there is a need to develop clear methodology regarding the persistence of nanosilver in gastric fluids. The role of nanosilver regulation under hazardous waste laws remains an open question. Resource Conservation and Recovery Act of 1976 § 3001, 42 U.S.C. § 6921.

refrigeration;[8] carbon nanotubes for secure and durable packaging;[9] titanium dioxide to make food white, fluffy, and attractive to consumers;[10] and nano-biosensors to detect temperature changes that might cause spoilage, thereby helping to prevent food loss.[11] The special corpus of law governing the application of nanotechnology in food in every jurisdiction therefore represents the

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[8] *See* Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, Holger Zorn, Laurence Castle, Emma Di Consiglio, Roland Franz, Nicole Hellwig, Stefan Merkel, Maria Rosaria Milana, Eric Barthélémy & Gilles Riviére, *Safety Assessment of the Substance Silver Nanoparticles for Use in Food Contact Materials*, 19 EUR. FOOD SAFETY AUTH. J., Aug. 2021, at 1, 5, https://doi.org/10.2903/j.efsa.2021.6790.

[9] *See* Enrico Bergamaschi, Giacomo Garzaro, Georgia Wilson Jones, Martina Buglisi, Michele Caniglia, Alessandro Godono, Davide Bosio, Ivana Fenoglio & Irina Guseva Canu, *Occupational Exposure to Carbon Nanotubes and Carbon Nanofibres: More Than a Cobweb*, 11 NANOMATERIALS 745, *2 (2021), https://doi.org/10.3390/nano11030745; *see also Guidance on the Protection of the Health and Safety of Workers from the Potential Risks Related to Nanomaterials at Work*, at 56, COM (Nov. 2014), https://ec.europa.eu/social/BlobServlet?docId=13087&langId=en [https://perma.cc/MTV4-Y9ZQ] (noting the "high tensile strength" of carbon nanotubtes, which is the property which makes carbon nanotubes unlikely to rupture or be otherwise damaged during shipping).

[10] *See* Strom, *supra* note 3. For a discussion of the nanotoxicity of carbon nanotobues, see also Maged Younes, Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Paul Fowler, Maria Jose Frutos Fernandez, Peter Fürst, Ursula Gundert-Remy, Rainer Gürtler, Trine Husøy, Melania Manco, Wim Mennes, Peter Moldeus, Sabina Passamonti, Romina Shah, Ine Waalkens-Berendsen, Detlef Wölfle, Emanuela Corsini, Francesco Cubadda, Didima De Groot, Rex FitzGerald, Sara Gunnare, Arno Christian Gutleb, Jan Mast, Alicja Martensen, Agnes Oomen, Aldert Piersma, Veronika Plichta, Beate Ulbrich, Henk Van Loveren, Diane Benford, Margherita Bignami, Claudia Bolognesi, Riccardo Crebelli, Maria Dusinska, Francesca Marcon, Elsa Nielsen, Josef Schlatter, Christiane Vleminckx, Stefania Barmaz, Maria Carfí, Consuela Civitella, Alessandra Giarola, Ana Maria Rincon, Rositsa Serafimova, Camilla Smeraldi, Jose Tarazona, Alexandra Tard & Matthew Wright, *Safety Assessment of Titanium Dioxide (E171) as a Food Additive*, 19 EUR. FOOD SAFETY AUTH. J., May 2021, at 1, 75.

[11] *See Food Wastage Footprint*, FAO (last visited Oct. 25, 2024), https://www.fao.org/nr/sustainability/food-loss-and-waste/en/ [https://perma.cc/XE9S-KT65H] ("Food loss refers to the decrease in edible food mass at the production, post-harvest and processing stages of the food chain."). Thus, food loss never reaches the consumer or the serving table. Food that is served and unused is food waste.

critical nexus of regulation, international policy, and global health law; nanoscience and nanotoxicology; and food science and technology.[12] The zone of convergence for these three disciplinary realms is quite small, but vital, to the future of humanity and the global environment for health and trade. In order for commerce to thrive, laws must be consistent and predictable across jurisdictions and also must make diligent efforts to protect global health. To foster the operationalization of the principle of *cura personalis* (caring for the whole person), this Article addresses key issues at the confluence of existing laws, emerging technologies, and the life cycle of food in commerce.

Therefore, before nanotechnology can successfully be applied to feed the world, an extreme conflict of law must be addressed: the U.S. and EU have polar opposite approaches to regulating nanotechnology in food. The U.S. approach largely ignores developments in food science that use nanotechnology. The EU laws and regulations of food, on the other hand, are informed by contemporary scientific research. While there is no question that these divergent approaches create a conflict of law which undermines the world's largest trade partnership, the question of whether or not the two regulatory paradigms can be reconciled has not yet been discussed. For this reason, even though harmonization is commonplace within the EU itself, this Article seeks to draw attention to the dearth of consistency between the two paradigms in the hope of inspiring some negotiations that will synthesize the concerns in Europe with the willingness to use nanomaterials without limits in foods created or consumed in the U.S.

This Article proceeds in seven Parts. Part I describes the role of nanotechnology in the lifecycle of food. Part II describes the natural link between food and the right to human health. Part III outlines key challenges that arise when defining nanotechnology in a legal document such as a regulation, statute, agency guidance, or treaty governing nanotechnology in trade under international law. Discussion includes the need to avoid the illusion that there is consensus about "what nano is" and some lessons for defining nano. Part IV examines the balancing of benefits and risks for nanotechnology in food, with examples from carbon nanotubes, nanosilver, and titanium dioxide (TiO_2). Part V compares how two major governmental systems, the U.S. Food and Drug Administration (FDA) and the EU European Food Safety Authority (EFSA), differ in their approaches to the regulation of nanomaterials in food, using nanoscale TiO_2 as a case study. The contrasting FDA and EFSA approaches to the use of TiO_2 at the nanoscale in food provide important regulatory lessons for the governance of

[12] *See infra* Figure 1.

nanotechnology worldwide. Although little controversy exists in the U.S. about the use of nanoscale TiO_2 in food, in the space of three years, TiO_2 has become a flashpoint for new laws and litigation in the EU.[13] Part VI emphasizes the necessity for harmonization among regulatory systems. Given the fact that the U.S. and EU are major trading partners that have remarkably different approaches to the regulation of nanoscale material in food, their conflict of laws, impacting millions if not billions of people, underscores the urgent need for harmonization of nanotechnology laws. Part VII offers recommendations to promote harmonization that will reduce the conflict of laws impacting food and enable the smooth flow of international trade: (1) by educating the public to galvanize political will to support harmonization of the law and (2) by designing an overarching forum for discussing the scientific basis for nano-regulatory problems. An oversight approach similar to the commission envisioned by the EU's Nanotechnology Risk Governance Project (NANORIGO) could guide the harmonization process.[14] This Article concludes that the global need to protect health demands harmonization and consistency across the hundreds of possible jurisdictions that are home to nanotechnology law.

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[13] *See* Cases T-279/20, T-288/20 and T-283/20, CWS Powder Coatings v. Commission, ECLI:EU:T:2022:725, ¶¶ 1–182 (Nov. 23, 2022).

[14] *See* EU NANORIGO, *NMBP 13 Final Online Event: Future-Proof Approaches for Risk Governance,* YOUTUBE (Mar. 1, 2023), https://youtu.be/JVYbFil9zao; *see also* Memorandum from NANORIGO, RiskGONE & Gov4Nano (Nov. 24, 2022) (available at https://www.gov4nano.eu/wp-content/uploads/2022/12/Memorandum-Risk-Governance-in-development-of-advanced-materials_final.pdf) ("Advanced materials like nanomaterials are prioritized as one of the Key Enabling Technologies within these policies. Meanwhile the Commission acknowledges in its 2019 Communication on Better Regulation the need 'to have regulation that fosters and, at the same time, harnesses innovation to the benefit of the environment, the economy and EU citizens.). The three H2020-projects Gov4Nano, NANORIGO, and RiskGONE (shortened as NMBP-13 projects) have gathered meaningful insights about challenges and issues in risk governance of nanomaterials. We regard these insights relevant for efficient and effective risk governance of advanced (nano)materials.").

I. THE ROLE OF NANOTECHNOLOGY IN THE LIFECYCLE OF FOOD

Nanotechnology is the science of studying phenomena at the very small nanoscale and then applying that knowledge to manipulate materials at the atomic, molecular, or macromolecular level.[15] Use of the prefix "nano" in this context refers to a nanometer (nm), which is one thousand-millionth of a meter, or about one one-hundred-thousandth of the diameter of a human hair. Some nanoparticles have been engineered or manufactured by humans, others occur naturally, and others are generated as a byproduct of industrial processes. Naturally occurring nanomaterials, such as volcanic ash, also have industrial uses. Unusual physical, chemical, and biological properties can emerge in materials at the nanoscale, and properties may differ in important ways from the properties of bulk materials and single atoms or molecules.

In the U.S., a major report produced by a Clinton Administration cabinet-level council advocated for funding nanoscience research.[16]

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[15] *See* Commission Recommendation of 10 June 2022 on The Definition of Nanomaterial, 2022 O.J. (C 229) 9–11 (EU) ("The term nanomaterial should address materials consisting of particles in solid state, present on their own or bound as constituent parts of aggregates or agglomerates. The term 'consist of' rather than 'contain' should be used to acknowledge that the nanoparticles are the principal component of the material. Other non-particulate components potentially present (e.g., additives necessary to preserve its stability or solvents that may be separated without affecting the particle size distribution) are part of the (nano-) material but should not be taken into account when assessing whether a material is a nanomaterial. The definition should exclude nonsolid (i.e., liquid and gaseous) particles. This should ensure that the highly dynamic nature of the external dimensions of non-solid particles, such as micelles or nanoscale droplets in emulsions or sprays, does not prevent the use of the external dimension as the defining qualifier in the definition. The definition should not cover large solid products or components, even when they have an internal structure or a surface structure at the nanoscale, such as coatings, certain ceramic materials and complex nanocomponents, including nanoporous and nanocomposite materials. Some of these products or components may have been manufactured by using nanomaterials and may even still contain them.").

[16] NAT'L SCI. AND TECHN. COUNCIL, COMM. ON TECH., SUBCOMM. ON NANOSCALE SCI., ENG'G & TECH., NATIONAL NANOTECHNOLOGY INITIATIVE: THE INITIATIVE AND ITS IMPLEMENTATION 13, 20 (2000), https://www.nano.gov/sites/default/files/pub_resource/nni_implementation_plan_2000.pdf. ("Developments in these emerging fields are likely to change the way almost everything—from vaccines to computers to automobile tires to objects not yet imagined—is designed and made. . . . Such new forms of materials and devices herald a revolutionary age for science and technology.").

The report, which forecasted key future developments and created the National Nanotechnology Initiative (NNI), set forth the blueprint for the extensive federal legislation that followed. Nanotechnology research in the U.S. was subsequently designed to provide people with greater access to many products in global commerce. Similar laws appeared soon thereafter in the EU and key industrial nations throughout Asia.[17]

Touching the economy globally, nanotechnology planning at the dawn of the 21st century has successfully traversed every industry, including food processing for retail markets, cosmetics, paintings and coatings, agriculture, equipment and packaging, housing, transportation vehicles, and most notably, telecommunications. Exceptionally influential thought leaders at the World Economic Forum viewed nanotechnology as the source of a fourth industrial revolution,[18] reshaping the global economy. Commercialized products applying nanotechnology could be found in everything from daily needs to nanomedicine[19] and meat grown in laboratories (or even in outer space) using animal cells. Nonetheless, no single harmonized definition of nanotechnology has emerged, and no scientific consensus could be incorporated into relevant law.

The lack of a unified definition did not slow the advent of nanofoods, nor did it quell the ethical debate surrounding their use. One example involved a new food product marketed as "vegetarian steaks," designed to cut costs for agricultural feed and reduce the carbon footprint from growing meat using live animals. This example was just one new approach to food production that launched a fascinating ethical debate about whether food derived from animals without slaughtering them can be considered vegetarian.

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[17] *See* Md. Md. Ershadul Karim & Abu Bakar Munir, *Nanotechnology in Asia: A Preliminary Assessment of the Existing Legal Framework*, 4 KLRI J. L.& LEGIS. (2014), https://dx.doi.org/10.2139/ssrn.2589995. *See also* DAVID AZOULAY, RYE SENJEN & GUILLERMO FOLADORI, SOCIAL AND ENVIRONMENTAL IMPLICATIONS OF NANOTECHNOLOGY DEVELOPMENT IN ASIA-PACIFIC (2013), https://ipen.org/documents/social-and-environmental-implications-nanotechnology-development-asia-pacific.

[18] Jane Onyanga-Omara, *Leaders to ponder 4th industrial revolution at Davos 2016*, USA TODAY, Jan. 18, 2016, https://www.usatoday.com/story/money/2016/01/17/davos-world-economic-forum-2016/78893596/ [https://perma.cc/836U-TCGB] ("Technology is the fourth industrial revolution.").

[19] *See* VARVARA KARAGKIOZAKI & STERGIOS LOGOTHETIDIS, HORIZONS IN CLINICAL NANOMEDICINE (2015) (statement of Dr. Varvara Karagkozaki, a leading researcher in nanomedicine at the University of Aristotle Greece) ("Nanotechnology represents the possibility of revolutionizing many aspects of our lives.").

Nevertheless, this merchandise would not be possible without nanotechnology. Commercialized nanotechnology has therefore offered a fascinating global package for transforming society by applying innovations to food.

Regardless of these debates, this use of nanotechnology impacts access to safe food and its global distribution. And because nanotechnology has been in use since the beginning of the millennium, it has been altering the physical properties of food materials whether consumers are aware of these changes or not. Indeed, there is a marked disconnect between common knowledge of nanotechnology being applied to food and the ubiquity of commercialized nano-enabled applications in this area. 3D-printed food, which relies upon nano-enabled technology, involves downloading and assembling the molecular recipe of foods. This technique has been used in some commercial foods for years. Countless additional examples of nanoscale materials change the process for growing, harvesting, transporting, storing, manufacturing, eating, and disposing of food.[20]

The reality is that no consumer is untouched by nanotechnology[21]: Nanostructures are in pesticides, nanosilver refrigerator linings, carbon nanotube food packaging, and transport of foods.[22] Nano-enabled packaging, for example, is lighter, cheaper to produce, and more secure; it reduces costs, ultimately impacting the pricing and insurability of food products. From the time crops are developed and harvested until their sale or disposal as food waste, nano-enabled products have so-called "contact transmission" with food in places people might not expect.

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[20] *See* Fahad Khan, Pratibha Pandey & Tarun Kumar Upadhyay, *Applications of Nanotechnology-Based Agrochemicals in Food Security and Sustainable Agriculture: An Overview*, 12 AGRICULTURE 1672 (2022); *see also* Ilise L. Feitshans & Philippe Sabatier, *Global Health Impacts of Nanotechnology Law: Advances In Safer Nano Regulation*, 67 MATERIALS TODAY: PROC. 985, 985–994 (2022).

[21] Strom, *supra* note 3.

("Only 26 out of 2,500 companies, including PepsiCo, Whole Foods and the corporate parent of Pizza Hut and Taco Bell, responded to a survey from As You Sow about their use of nanomaterials. 'Only 14 said they don't use nanomaterials, and of those only two had any policies on the use of nanomaterials,' said Andy Behar, chief executive of As You Sow.").

[22] FAO & WHO, FAO/WHO EXPERT MEETING ON THE APPLICATION OF NANOTECHNOLOGIES IN THE FOOD AND AGRICULTURE SECTORS: POTENTIAL FOOD SAFETY IMPLICATIONS: MEETING REPORT (2010), https://www.who.int/publications/i/item/9789241563932 [https://perma.cc/VMH2-JPB8].

So where does one turn to understand where their food comes from, or, more importantly, what is in it? The EFSA created a widely accepted model that is referred to as "Field to Fork."[23] Field to Fork's chronology of industrial food creation and processing also embraces concerns after the fork, such as the disposal of food that is damaged (food loss) or unused (food waste), as well as "contact transmission," which loosely defines the permissible ways food may come into contact with nanoscale materials that may migrate into food. Significantly, Food to Fork targets food quality and, therefore, does not differentiate between the sources of nanomaterials. In other words, concerns about contact transmission of nanomaterials are not prioritized according to whether the nanomaterial has been engineered, manufactured, or occurs naturally.

II. THE NATURAL LINK BETWEEN FOOD AND THE HUMAN RIGHT TO HEALTH

"Food is another pillar of our urban life, like housing and access to health care and education," according to Liz Neumark, who runs Great Performances, a caterer that partners with the local communities to prevent wasting unused food.[24] Most nations define "food" under their own specific legislation, and not every definition is like the other. Although the theoretical underpinnings of the human right to health are not unanimously accepted or engraved in every national constitution, the concept that nations provide protection for human health is operationalized in some form in a vast majority of countries through the control and inspection of food. There is a consensus that food is important, if not essential to

[23] Yann Devos, Edward Bray, Stef Bronzwaer, Barbara Gillani & Bernhard Url, *Advancing Food Safety: Strategic Recommendations from the 'ONE—Health, Environment & Society—Conference 2022'*, 20 EUR. FOOD SAFETY AUTH. J., 3 (2022), https://doi.org/10.2903/j.efsa.2022.e201101. ("Food systems need urgent and significant transformation if they are to meet sustainability targets. To be considered sustainable, food systems will need to operate within planetary boundaries. As part of the European Green Deal, the EU has put forward its Farm to Fork Strategy that sets unprecedented ambitions to make the EU food system more sustainable and resilient. In addition, the EU intends to adopt a legislative framework for sustainable food systems by the end of 2023 that will address the sustainability of both products and processes (e.g., circularity, food loss and waste reduction, promotion of more nutritious and sustainable diets). Consequently, food is now expected to meet the highest standards of nutrition and sustainability, in addition to being safe, accessible and affordable for all.").

[24] Kira Goldenberg, *Serving Community*, 111 BARNARD MAG. 29 (2022).

commerce, evinced by numerous laws that subsidize enterprises that grow or process food.

An impressive majority of nations agree that the right to health is enshrined as a "fundamental" right in the WHO Constitution which states: "Health is a *state of complete physical, mental, and social well-being* and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being."[25] Shared values about the right to health are articulated in the International Covenant on Economic, Social and Cultural Rights (ICESCR).[26] According to the plain meaning of that text, the right to health is rooted in governmental obligations to protect the health of its citizens.[27] Additionally, health rights are found in key human rights documents as well as the soft law of the Universal Declaration of Human Rights (UDHR)[28] and in piecemeal[29] and regional international human rights documents, such as the Council of Europe Charter for Human

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[25] Constitution of the World Health Organization, 1, July 22, 1946, https://www.who.int/about/governance/constitution [https://perma.cc/3P7Y-DKT8].

[26] G.A. Res. 2200A (XXI), International Covenant on Economic, Social and Cultural Rights, at 7, 12 (Dec. 16, 1966), https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights [https://perma.cc/4NW8-KV4M] ("State Parties . . . recognize the right of everyone to the enjoyment of just and favourable conditions of work which ensure, in particular…safe and healthy working conditions . . . the right of everyone to the enjoyment of the highest attainable standards of physical and mental health . . . [t]he improvement of all aspects of environmental and industrial hygiene . . . [and] [t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases"); *see also* CTR. FOR THE STUDY OF HUM. RTS., TWENTY FIVE HUMAN RIGHTS DOCUMENTS (1994).

[27] Frank P. Grad & Ilise L. Feitshans, *Article 12: Right to Health, in* UNITED STATES RATIFICATION OF THE INTERNATIONAL COVENANTS ON HUMAN RIGHTS 224 (Hurst Hannum & Dana Fischer eds., 1993).

[28] *See* G.A. Res. 217 (III) A, Universal Declaration of Human Rights, at 25 (Dec. 10, 1948), https://www.un.org/en/about-us/universal-declaration-of-human-rights [https://perma.cc/53QE-YCFJ] (bestowing rights as necessary to provide for "health and well-being of []self and . . . family").

[29] *See generally* Ilise L. Feitshans, *Chapter 4, Integrating Nanotechnology into International Laws Protecting Health, Section 4.1 An Abundance of International Laws: Resisting the Fad of Nanoregulation*, *in* GLOBAL HEALTH IMPACTS OF NANOTECHNOLOGY LAW: A TOOL FOR STAKEHOLDER ENGAGEMENT 153 (2018).

Rights[30] and regional agreements in South-East Asia.[31] Although the question of whether there is a human right to food has been the subject of extensive unresolved debate,[32] the role of food is so important in the global economy for international trade, for sustaining health, and for the right to life that it is the subject of a vast corpus of positive law. The presence of extensive food law nationally, internationally, and in trade agreements renders moot much of the need for any rights-based analysis.

III. CHALLENGES FACED WHEN DEFINING NANOTECHNOLOGY

Drawing bright lines between the different types of nanoparticles found in commercial products is difficult; such distinctions are essentially a moving target, changing with successive innovations. Evolving legal definitions may therefore eventually traverse several categories or bundle categories together based on their use, context, and function.[33] Key differences regarding material properties may become the basis for ultrafine legal distinctions between types of nanoparticles; the notion that any one definition that is widely

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[30] Article 11 links certain obligations of states to the end of protecting human health. Since this Charter was adopted in 1950, this has evolved into a well-established bundle of rights that the Council of Europe packages as the right to health. *See* Convention for the Protection of Human Rights and Fundamental Freedoms art. 11, Nov. 4, 1950, E.T.S. 5, https://www.echr.coe.int/documents/d/echr/Archives_1950_Convention_ENG [https://perma.cc/37N9-Y9JZ].

[31] *See generally The Right to Health in the Constitutions of Member States of the World Health Organization South-East Asia Regions*, WORLD HEALTH ORGANIZATION, SEA-HHR-02 (2011), https://iris.who.int/bitstream/handle/10665/205993/B4678.pdf?sequence=1&isAllowed=y. *See also* Inter-Am. Comm'n H.R., American Declaration of the Rights and Duties of Man art. 11 (1948), https://www.refworld.org/docid/3ae6b3710.html [https://perma.cc/CN8R-JGDV] (recognizing a "right to the preservation of health and to well-being [under which e]very person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care, to the extent permitted by public and community resources.").

[32] *See* Philip Alston, *Conjuring up New Human Rights: A Proposal for Quality Control*, 78 AM J. INT'L L. 607, 609–11 (1981) (Observing that human rights are something which must be created and citing the recognition of a right "to a healthy environment" as an example).

[33] *See generally* Martin Miernicki, Thilo Hofmann, Iris Eisenberger, Frank von der Kammer & Antonia Praetorius, *Legal and Practical Challenges in Classifying Nanomaterials According to Regulatory Definitions*, 14 NATURE NANOTECHNOLOGY 208 (2019).

accepted can or should become law is problematic.[34] It is extremely difficult, and perhaps impractical, to refine legal definitions in a manner sufficient to account for the various categories under which nanomaterials may fall and their various daily applications.

A. CRAFTING NANOREGULATIONS

With the vast applications of nanotechnology, governments are often given the difficult task of legislating the field, including defining the risks of the technology. Scientists and governments agree there are unquantifiable, presently unknown risks regarding the applications of nanotechnology to consumer products and have begun drafting guidance and approaches to address these uncertainties. Examples include the Swiss Federation,[35] the German Governmental Science Commission,[36] the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials,[37] International Organization for

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[34] *See generally* Memorandum from John P. Holdren, Dir., Off. Sci. & Tech. Pol'y, Cass R. Sunstein, Adm'r, Off. Mgmt. & Budget & Islam A. Siddiqui, Chief Agric. Negot., to Heads of Exec. Dep'ts & Agencies (June 9, 2011), https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/inforeg/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf [https:// https://perma.cc/TJX9-EZSJ].

[35] FED. OFF. OF PUB. HEALTH & FED. OFF. FOR ENV'T., SWISS CONFEDERATION, GUIDELINES ON THE PRECAUTIONARY MATRIX FOR SYNTHETIC NANOMATERIALS 6 (2023), https://www.bag.admin.ch/dam/bag/en/dokumente/chem/nanotechnologie/guidelines-precautionary-matrix-4.0.pdf.download.pdf/Guidelines%20Precautionary%20Matrix%204.0.pdf [https:// https://perma.cc/9W72-R4QX].

[36] The 2011 German report recommended a responsible and precautionary development of this new technology because the objective is to allow for innovation but also to identify and reduce risks at an early stage. GER. ADVISORY COUNCIL ON ENV'T, *Chapter 7: Conclusions and Recommendations, in* PRECAUTIONARY STRATEGIES FOR MANAGING NANOMATERIALS 4 (2011), https://www.umweltrat.de/SharedDocs/Downloads/EN/02_Special_Reports/2011_08_Precautionary_Strategies_for_managing_Nanomaterials_chapter07.pdf?__blob=publicationFile [https://perma.cc/93Q6-CCBZ].

[37] The OECD Working Party on Manufactured Nanomaterials (WPMN) "concentrates on the human health and environmental safety implications of manufactured nanomaterials, and aims to ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonized standard." OECD, DEVELOPMENTS IN DELEGATIONS ON THE SAFETY OF MANUFACTURED NANOMATERIALS AND ADVANCED MATERIALS—TOUR DE TABLE 5 (2023),

Standardization/Technical Committee 229 on Nanotechnologies (IOS/TC 229),[38] the World Health Organization (WHO) working group on workplace exposure to nanomaterials,[39] the Royal Commission on Environmental Pollution in the UK,[40] the U.S. National Institute for Occupational Safety and Health (NIOSH),[41] and non-government organizations that influence regulation.[42] Each entity, acting independently, has determined that the potential for risk exists, even though the precise nature and scope of risk within nanotechnology activities cannot presently be quantified.[43] These

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https://one.oecd.org/document/ENV/CBC/MONO(2024)1/en/pdf [https://perma.cc/7UZ6-Q9VR]. *See also* OECD, PHYSICAL-CHEMICAL DECISION FRAMEWORK TO INFORM DECISIONS FOR RISK ASSESSMENT OF MANUFACTURED NANOMATERIALS 11 (2019), https://www.oecd-ilibrary.org/physical-chemical-decision-framework-to-inform-decisions-for-risk-assessment-of-manufactured-nanomaterials_1fbbaf8c-en.pdf?itemId=%2Fcontent%2Fpublication%2F1fbbaf8c-en&mimeType=pdf [https://perma.cc/7TCJ-2ZX5].

[38] IOS/TC 229 works on standards for nanotechnologies by establishing several working groups, which include terminology and nomenclature; measurement and characterization; health, safety, and the environment; materials specifications; and products and applications. *ISO/TC 229 Nanotechnologies*, INT'L ORG. FOR STANDARDIZATION, https://www.iso.org/committee/381983.html [https://perma.cc/4J42-Q4MY].

[39] WHO, WHO GUIDELINES ON PROTECTING WORKERS FROM POTENTIAL RISKS OF MANUFACTURED NANOMATERIALS 10 (2017), https://iris.who.int/bitstream/handle/10665/259671/9789241550048-eng.pdf?sequence=1 [https://perma.cc/926Y-UWEU].

[40] U.K. ROYAL COMM'N ON ENV'T POLLUTION, REP. NO. 27, NOVEL MATERIALS IN THE ENVIRONMENT: THE CASE OF NANOTECHNOLOGY 14 (2008), https://assets.publishing.service.gov.uk/media/5a7c819ee5274a559005a573/7468.pdf [https://perma.cc/SMJ8-RX9X].

[41] *Occupational Exposure to Carbon Nanotubes and Nanofibers*, 65 NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH CURRENT INTEL. BULL., Apr. 2013, at iii, https://www.cdc.gov/niosh/docs/2013-145/pdfs/2013-145.pdf?id=10.26616/NIOSHPUB2013145 [https://perma.cc/NSX9-3WBW].

[42] *See* Fabio Boccuni, Diana Gagliardi, Riccardo Ferrante & Bruna Maria Rondinone, *Measurement Techniques of Exposure to Nanomaterials in the Workplace for Low- and Medium-Income Countries: A Systematic Review*, 220 INT'L J. HYGIENE AND ENV'T HEALTH 1089, 1089 (2017), https://tesble.com/10.1016/j.ijheh.2017.06.003 [https://perma.cc/N2YD-Q4S4].

[43] *See generally Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*, NAT'L NANOTECHNOLOGY INITIATIVE 23 (2008), https://www.nano.gov/sites/default/files/pub_resource/nni_ehs_research_st

quasi-legislative explorations by non-elected experts who are appointed by authorized officials, and subsequent regulatory activities, provide a veneer of consensus that nanotechnology can be controlled despite unquantifiable risks. Without long-term study and monitoring, however, nanotechnology's increased use poses risks of significant harm to presently exposed populations, the greater ecological environment, and public health.[44] But, the methods to be applied to measure the effect of these uses and subsequent exposures are the source of extensive scientific debate.[45] For example, engineered or manufactured nanomaterials can be more chemically reactive, have greater strength or elasticity, or have different electrical properties compared to material presently in commerce, and therefore ought not be controlled by the same rules as traditional matter. Switzerland therefore commissioned a committee of experts that was tasked with generating a detailed precautionary matrix.[46]

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rategy.pdf (explaining the National Nanotechnology Initiative's strategy for addressing research on environmental, health, and safety aspects of nanomaterials and the broad implications of nanotechnology for society, which can be grouped into two categories: environmental, health, and safety implications; and societal dimensions) [https://perma.cc/A3CR-54K4].

[44] *See* Yaping Liu, Shuang Zhu, Zhanjun Gu, Chunying Chen & Yuliang Zhao, *Toxicity of Manufactured Nanomaterials*, 69 PARTICUOLOGY 31, 31 (2022), https://www.sciencedirect.com/science/article/pii/S167420012100225X [https://perma.cc/E3CU-RBCX].

[45] *See, e.g.*, Ilise L. Feitshans, *Expert Paper: Nanotechnology's Revolutionary Changes in Commerce Will Transform Daily Life Throughout the Council of Europe Member States*, DOC. AS/Soc/Inf 03 (Jan. 17, 2013), https://assembly.coe.int/CommitteeDocs/2013/Asocdocinf03_2013.pdf [https://perma.cc/4MKT-SUB4]; *referenced in* Valeriy Sudarenkov (Rapporteur), Comm. on Soc. Affs., Health and Sustainable Dev., Eur. Consult. Ass., *Rep. on Nanotechnology: Balancing Benefits and Risks to Public Health and the Environment*, Second Part-Sess., DOC. 13117, 5–7 (Jan. 29, 2013), https://pace.coe.int/en/files/19261/html [https://perma.cc/X3D5-YMFG].

[46] FEDERAL COUNCIL, SWISS CONFEDERATION, ACTION PLAN: SYNTHETIC NANOMATERIALS 10 (2008), https://www.bag.admin.ch/bag/en/home/gesund-leben/umwelt-und-gesundheit/chemikalien.html [https://perma.cc/ZQS3-69ET] (select "Action plan for nanomaterials" hyperlink from menu; then select work from "Documents" panel). For the precautionary matrix which resulted from *id.*, see FED. OFF. OF PUB. HEALTH & FED. OFF. FOR THE ENV'T, SWISS CONFEDERATION, GUIDELINES ON THE PRECAUTIONARY MATRIX FOR SYNTHETIC NANOMATERIALS (2023), https://www.bag.admin.ch/dam/bag/en/dokumente/chem/nanotechnologie/guidelines-precautionary-matrix-

Their pathbreaking document enables manufacturers and industrial users of nanoproducts to plug key variables into a matrix, and then determine internally how important the risks are and whether they should be prioritized compared to other dangers. The Swiss matrix relies on self-assessment and requires very limited public disclosure to prioritize and manage nanotechnology risk.

By contrast, the Royal Commission on Environmental Pollution called for an approach based on functional analysis, using information about exposure assessment, risk assessment, and hazard analysis following reliable data collection.[47] According to this approach, risk management priorities are determined by external forces such as insurance companies, consumer preferences, input from academia and stakeholders, or regulations using the tools of risk mitigation and best practices. This approach is designed so that the manufacture, use, handling, transport, and safe disposal of nanotechnology applications is feasible and so that risks are understood by people exposed to risk.

Using scientifically accepted definitions from key reports by the governments of the United Kingdom, Switzerland, or the multinational OECD, another problem becomes clear when applying the broad and vague term "nano": such definitions can be meaningless without criteria. When applying a definition that might include scientific criteria, such as "atomic, molecular, and macromolecular scales" or "properties differ significantly from those at a larger scale," there is no clear limit on the functionality of the nanomaterials used or the scope of the jurisdiction in its context. Attempting to craft "nano" definitions is further complicated by the many uses of nanomaterials. For example, the same materials often vary in their toxicity or risk management for exposure within different contexts: Functionalization of nanoparticles is typically achieved by different linkage methods such as covalent linkage (e.g., amide linkage, disulfide linkage), encapsulation, and entrapment. Nanoparticle formulations exist in some physical state (e.g., emulsion, hydrogel, powder) and are generally characterized as multicomponent systems containing nanoparticles, functionalizing agents, and the associated medium in which these components are contained. The same nanoparticle formulation can contain one or more different types of nanoparticles that vary in their structure, function, or chemical composition.[48]

4.0.pdf.download.pdf/Guidelines%20Precautionary%20Matrix%204.0.pdf [https://perma.cc/RSM9-ULYK].

[47] *See* U.K. ROYAL COMM. ON ENV'T POLLUTION, *supra* note 40, at 76–79.

[48] Dennis G. Thomas, Fred Klaessig, Stacey L. Harper, Martin Fritts, Mark D. Hoover, Sharon Gaheen, Todd H. Stokes, Rebecca Reznik-Zellen,

Consequently, the same nanomaterials in different uses may militate in favor of a different regulatory outcome. Both their use and quantity may differ on a grocery store shelf, a pharmacy, or a workplace. Should nanomaterials in tires that become routinely released as airborne particles during road wear be treated the same as nanomaterials in paints or coatings that largely remain intact after application simply because they are created from the same substance? From a risk perspective, it cannot be argued that the presence of nano-enabled materials in a car is without risk to the consumer population or overall society, or that the risk is not potentially lethal regardless of the dose of exposure. It is unclear whether the combined presence of nanotubes in paint coatings, fabric protection, headlights, and a variety of other parts of the car meets a possible threshold for nanoregulation. Not every government statement is law, nor should every guideline, request for data, voluntary compliance summary in annual reports, or draft legislation be accorded the weight of actual law.

The use of materials and the population placed at risk by its use are important legislative drafting issues shaped by the context and function of the nanomaterials and stakeholder views on risk acceptability. For the purposes of legislation, there is a need for flexible criteria that consider:

1. Properties that are important to risk compared to those that are likely inconsequential;
2. Robust methods based on scientific consensus about which criteria to apply in order to determine prioritization of potential consequences; and
3. Policy determinations that clarify priorities: At what moment in time does the regulatory framework capture the data that are used to make these determinations? The choosing of that temporal threshold must consider the value of flexibility, such that the regulatory framework can address unanticipated developments.

B. THE ILLUSION OF CONSENSUS: THE NANO THAT "EVERYBODY" KNOWS

Many experts meet in small committees to define the terms pertaining to nanoparticles and nanotechnology, but few meetings have been convened to produce one unified text. Experts may lack power, but powerful legislators may lack expertise. As discussion

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Elaine T. Freund, Juli D. Klemm, David S. Paik & Nathan A. Baker, *Informatics and Standards for Nanomedicine Technology*, 3 WIREs NANOMEDICINE & NANOBIOTECHNOLOGY 511, 512 (Sept./Oct. 2011), https://doi.org/10.1002/wnan.152.

slowly evolves to focus on precise concepts and precise language to give these terms meaning, the difficulty of the task becomes remarkably clear. To break these terms down into workable definitions, it might be suggested that the term nanoparticle refers only to "free nanoparticles," but there are no clear criteria for explaining this term or for differentiating this term from other uses of the term "nano." Consider for example, whether it is appropriate—or enforceable—to have laboratory-quality carbon nanotubes treated the same as a car or a toy under nanotechnology laws. The first step towards mapping a solution to the conflicts between U.S. and EU laws concerning the use and limits of nanostructures in food requires scientific consensus: a shared definition of nanotechnology that defines the problems to be resolved. Initially, defining nanotechnology terminology seems straightforward because "everybody" knows the answer to nanomaterial definitional questions—or at least "everybody" in the scientific community—since many of the substances used at the molecular level are already regulated under existing frameworks relating to health and human safety. But this still lends to different definitions technically, even if they are regulated the same practically. One definition may view nanotechnology as "encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale."[49] Another regulatory model categorizes chemical substances based on molecular identity, not on physical properties, such as particle size, arguing that their jurisdiction already exists to regulate nanomaterials, and uses an admixture of law from 2011 and its amendments in 2020 in order to generate requirements for specific substances on a searchable public database.[50] There is some consensus around a theme that

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[49] SUBCOMM. ON NANOSCALE SCI., ENG'G, & TECH., EXEC. OFF. OF THE PRES. OF THE U.S., NATIONAL NANOTECHNOLOGY INITIATIVE STRATEGIC PLAN 1 (2014), https://www.nano.gov/sites/default/files/pub_resource/2014_nni_strategic_plan.pdf [https://perma.cc/38T8-5QXT].

[50] Compare *Understanding REACH*, EUR. CHEMS. AGENCY (last visited Nov. 1, 2024), https://echa.europa.eu/regulations/reach/understanding-reach [https://perma.cc/EWZ3-FW2J] with The Toxic Substances Control Act of 1976, 15 U.S.C. § 2625(c) (defining the term and application of "category of chemical substance"). REACH and TSCA provide two examples of regulatory models that categorize chemical substances based on molecular identity, not on physical properties, such as particle size. Many nanomaterials are composed of chemical substances subject to TSCA. *See* 15 U.S.C. § 2625(c). REACH was designed to address highly toxic substances, but was amended in 2018 to include the extensive use of

nanoparticles and nanoproducts are those that are limited to 100 nanometers or smaller; however, this is problematic because the arbitrary cutoff fails to account for nanomaterials that may connect with each other through agglomeration, aggregation, or bio-nano interactions. At the same time, harmless materials that are smaller than 100 nanometers are caught in the regulatory web, needlessly diverting resources to compliance with this consensus-based, but imperfect bright line.[51]

Not all scientists may consider a given product to be "pure" nano, so society may reject the idea of labeling such products accordingly. Such a policy decision, in practice, is more problematic than it seems. Some of the definitions in respected references, such as the Royal Commission on Environmental Pollution, seem very straightforward initially but can easily expand into unwanted areas of industrial activity if applied in a workplace or to consumer products.

Actually, it is hard to posit a substance that does not vary significantly depending on its size, whether inanimate or organic.[52] The passage of time has not altered the baseline definition offered in 2010 by the International Standardization Organization (ISO) Technical Committee 229 on nanotechnologies issued a definition of nanotechnology that essentially has the same elements as those of its 1999 definition: "The application of scientific knowledge to manipulate and control matter in the nanoscale range to make use of size- and structure-dependent properties and phenomena distinct from those at smaller or larger scales."[53] Many widely quoted definitions of nanotechnology are inconsistent and seem simple but later prove to be overbroad. Few of these supposedly scientific definitions can easily transfer from one context of nanotechnology application to another. Therein lies one of the key challenges to creating a fair and predictable regulatory model that can be followed throughout product development and marketing.

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carbon, a substance that was previously viewed as safe because of widespread use of multiwalled and single walled carbon nanotubes. The Annex to REACH for carbon entered effect in 2020.

[51] This issue is exemplified by the evolution of EU definitions. *See generally* 2022 O.J. (C 229), *supra* note 15.

[52] *Cf.* Mark D. Hoover, Leigh J. Cash, Ilise L. Feitshans, Christine Ogilvie Hendren & Stacey L. Harper, *Nanoinformatics Approach to Safety, Health, Well-Being, and Productivity*, *in* NANOTECHNOLOGY ENV'T HEALTH & SAFETY 83, 98–100, 103 (Matthew S. Hull & Diana M. Bowman eds., William Andrew Publishing, 3d ed. 2018).

[53] Mihail C. Roco, *The long view of nanotechnology development: the National Nanotechnology Initiative at 10 years*, 13 J. NANOPARTICLE RSCH. 427, 428 (2011), https://doi.org/10.1007/s11051-010-0192-z.

Though it is not always clear, there has been some semblance of a consensus. One government defines nanotechnology as "the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications."[54] A research center defines "[n]anotechnology [as] the ability to measure, see, manipulate, and manufacture things usually between 1 and 100 nanometers. A nanometer is one billionth of a meter, a human hair is roughly 100,000 nanometers wide."[55] Another research project defined "nanomaterials" as possessing "chemical, physical and bioactive characteristics which are different from those of larger entities of the same materials" and as being able to "pass through body barriers."[56] Broader, overarching EU Commission recommendations, published in its official journal, use treaty-based language.[57]

Without creating definitions, the FDA uses several ambiguous terms for nanotechnology.[58] Applying these supposedly consensus-driven definitions to the FDA's present regulatory framework would accidentally include a wide variety of substances and end-products that may have nothing to do with the expected hazards posed by nanotechnology. Thus, many producers would be forced to comply with a regulation that, if implemented as required by law, would make no sense for their business or workplace. Overbroad legal terminology runs the risk of clogging the regulatory system with a litany of inventions and products, which would distract regulators, compliance officers, inspectors, and researchers from attacking the major emerging issues in nanotechnology's applications.

Anticipating this dilemma, the Royal Commission on Environmental Pollution in 2008 deliberately refused to develop clear language that would be useful to people untrained in the hard

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[54] SUBCOMM. ON NANOSCALE SCIENCE, *supra* note 49, at 1.

[55] Andrew Maynard, Nanotechnology: A Research Strategy for Addressing Risk*, in* PROJECT ON EMERGING NANOTECHNOLOGIES, WILSON CTR. (2011).

[56] *NanoImpactNet*, INST. OF NUCLEAR & RADIOLOGICAL SCIS. & TECH., ENERGY & SAFETY, https://inrastes.demokritos.gr/grants-list/european-network-on-the-health-and-environmental-impact-of-nanomaterials/ [https://perma.cc/P9YF-CHJM].

[57] *Nanomaterials*, Eur. Chems. Agency, https://echa.europa.eu/regulations/nanomaterials [https://perma.cc/84P7-PDU5].

[58] 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/83957/download [https://perma.cc/BG65-2E6V].

sciences. The following excerpt captures the technical complexity of the Commission's definition:

> In trying to assess the potential of manufactured nanoparticles to cause adverse effects in humans (and indeed other organisms), it is important to understand the relationships between their physical and chemical structures and their biological effects. Two criteria have been proposed to identify nanomaterials which may present a unique potential risk to human health: the material must be able to interact with the body in such a way that its nanostructure is biologically available; and the material should elicit a biological response associated with its nanostructure different from that associated with non-nanoscale material of the same composition.[59]

This description seems prescient if one were, for instance, to characterize the activity of TiO_2; but the statement does not offer a method for prioritizing the features it sets forth. Policy judgments, not science, must fill this void given the many contexts for nanomaterial use. It is also unclear whether such a definition would apply the relevant regulatory framework to materials that do not "differ significantly from those at a larger scale," regardless of their impact upon the environment and human health. In this regard, all existing working definitions of nanotechnology seem to have one thing in common: at first, their terms seem easy to understand and the subject of wide consensus. Consensus regarding the definition soon breaks down when applied to a new context.

Few substances behave the same way in a small quantity as they do in a larger scale quantity. The lack of precision in a definition for nanotechnology could bring organic substances also into the regulatory regime—regardless of whether the legislature wants to include them or not. Whether such an overflowing basis for the jurisdiction of the law is intended, good, unwanted, or bad, however, is a policy decision that may be derived from political compromise rather than scientific principles.

The prospect of manufacturers or retailers calling a product "nano" merely to make it more appealing to consumers creates a policy dilemma for regulators. If a product is merely called "nano" and not regulated, there is the possibility that it will offer any purchaser—large corporations or individual consumers—an illusion of safety, because purchasers know that "nano" products are subject to a vast apparatus of regulatory oversight. Although some consumers might not want every product burdened by regulation, it

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[59] U.K. ROYAL COMM'N ON ENV'T POLLUTION, *supra* note 40, at 45.

would be dangerous to allow ambiguity to govern self-proclaimed "nano" products that are not genuinely nano according to scientists. Without strong scientific consensus, legal definitions of nanotechnology and nanoscale activities have only elusive clarity beyond the laboratory bench in the realm of consumer exposure. Consequently, even with an abundance of caution, crafting workable definitions has proven very difficult.[60]

C. APPLYING THE NIOSH LOGIC MODEL TO FACILITATE LEGISLATIVE DRAFTING FOR NANOREGULATIONS

In an effort to offer a useful paradigm for resolving the policy dilemma surrounding nanotechnology definitions by embedding good science into regulatory frameworks, the U.S. National Institute for Occupational Safety and Health developed a "logic model" (NIOSH Logic Model).[61] As seen in Figure 1, the model uses a diagram to demonstrate the shared understanding of the path by which the research process leads to a reduction in injuries and illnesses. The NIOSH Logic Model is a useful tool for strategizing methods to transfer nanotechnology information from the scientific community to the general public. The logic model process begins with inputs from stakeholders, including scientists in government and academia, as well as production inputs, such as funding and infrastructure. Activities are based on the inputs and include internally- or externally-funded research and public health projects, often performed in partnership with stakeholders to accomplish select objectives. Outputs from these activities include scientific reports, such as peer-reviewed journal articles, technical reports, meeting presentations, book chapters, and review articles. This transfer fills the regulatory void for informing stakeholders who need information in order to implement and operationalize health and safety goals within nanoregulations.

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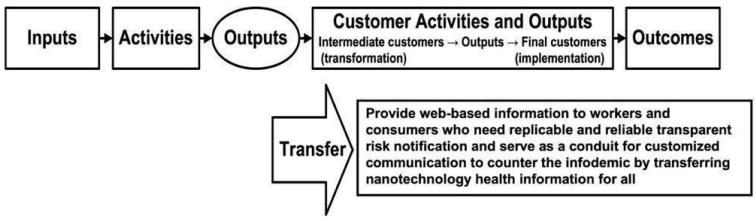
[60] *See generally* ILISE L. FEITSHANS, GLOBAL HEALTH IMPACT OF NANOTECHNOLOGY LAW: A TOOL FOR STAKEHOLDER ENGAGEMENT (Pan Stanford Publishing, 2018), https://doi.org/10.1201/9781351134477.

[61] *See* Sharon Newbill, Amanda Wickman, Carol Brown & Deborah Helitzer, *Hierarchical Logic Models as a Tool to Evaluate Programmatic Initiatives: Practical Solutions to Identified Problems*, J. OF CMTY. MED. & HEALTH EDUC. 3 (2017), https://doi.org/10.4172/2161-0711.1000522.

Figure 1. *NIOSH Logic Model for transferring information to the public.*



"Transfer of outputs" is a critical step in disseminating findings. Such a transfer can target either intermediate customers (trade associations, non-governmental organizations, government agencies, etc.), or final customers. Researchers and research agencies generally have few direct links to consumers, workers, or employers and rely heavily on the effective transfer of outputs to intermediate groups who have expressed stakeholder interest in solving the problem. Legislators frequently follow this path when uncertainty surrounds the decisions that need to be made at the time of drafting legislation.[62]

Policy questions concerning approaches to regulating in advance of cumulative doses that may present undue risks to the public—thereby increasing the global disease burden absorbed by public health systems—require careful forethought in parallel with support for economic development that will incubate nanotechnology industries. Unless the criteria are clear and there is a flexible regulatory framework, poorly drafted legislative text will result and can inadvertently unleash a bureaucratic nightmare and an unfair regulatory burden upon industries that may not consider themselves to be using nanotechnology. This conundrum is inherent in legislative drafting: "a draftsman [sic] should always bear in mind that he [sic] has an eventual responsibility to the public over and above his [sic] more obvious responsibility to the immediate

[62] *See generally* Jeff Morris, Jim Willis, Domenico De Martinis, Bjorn Hansen, Henrik Laursen, Juan Riego Sintes, Peter Kearns & Mar Gonzalez, *Science Policy Considerations for Responsible Nanotechnology Decisions*, 6 NATURE NANOTECH. 73 (2011); Diana M. Bowman, Geert van Calster & Steffi Friedrichs, *Nanomaterials and Regulation of Cosmetics*, 5 NATURE NANOTECH. 92 (2010); U.S. FOOD & DRUG ADMIN., *supra* note 58; OFF. OF INSPECTOR GEN., U.S. ENV'T PROT. AGENCY, EPA NEEDS TO MANAGE NANOMATERIAL RISKS MORE EFFECTIVELY (2011).

principal for whom he [sic] is working."[63] The plain meanings of the words used to define and regulate nanotechnologies and their applications to commercialized products inevitably go beyond the scope of the written words used in any nanoregulations.

Typically, disseminating relevant information using legislative tools such as laws, regulations, and governmental guidelines can be accomplished by avoiding defining the key terms in the law entirely. This quick-and-dirty approach, commonly applied to complex social issues that elude definition, involves writing laws about the subject without expressing a plain meaning definition of the problem. This legislative tool is often used to prohibit socially undesirable activities, such as discrimination. For example, both the United Nations Convention on the Prevention of Discrimination Against Persons with Disabilities[64] and the U.S. Americans with Disabilities Act,[65] which together formed the model pattern for international law, do not define disability. Instead, these laws define a host of contexts in which people are treated as disabled, regardless of what disease or illness they have and, in some cases, regardless of whether they are healthy or not. This allows those who draft the law to focus on crafting criteria for determining which problems are important enough to merit bureaucratic resources and attention, without inadvertently regulating minor situations that would distract from implementing the spirit of the law. In addition to avoiding the political compromises inherent in determining "who is in, who is out?" under the law, which can stall passage of a law or its implementation, this approach has the added value of enabling flexible frameworks that can address new problems that were beyond compromise or could not be anticipated at the time when the law was written.

D. LESSONS FOR DEFINING NANOTECHNOLOGY

The first lesson is that defining nanotechnology and identifying its applications necessarily confronts challenges under the law created by the many false declarations of consensus about the use of terms that "everybody knows." Because nanotechnology is ubiquitous in commerce, it is necessary that the words in its legal definition apply accurately in a variety of contexts. Thus, it is prudent for drafters of nanotechnology laws to avoid defining

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[63] JAMES CRAIG PEACOCK, NOTES ON LEGISLATIVE DRAFTING 2 (REC Found., 1961).

[64] G.A. Res 61/106, Convention of the Rights of Persons with Disabilities (Feb. 8, 2007).

[65] Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12111–12212, *amended by* ADA Amendments Act of 2008, 42 U.S.C. § 12101.

nanotechnology within their texts to ensure maximum flexibility in addressing problems based on empirical criteria instead of artificial cutoffs and line drawing that may not anticipate the context of nanomaterial use.

The second lesson is, given the complexity of assessing the toxicity of nanomaterials and the methods for measuring their impact, there is a need for agreement among regulatory authorities that has deeper texture than just a veneer of scientific consensus. Such agreement could allow for universally understood terms and conditions for the use of nanomaterials to ripen into workable instructions.[66] To achieve the goal of obtaining regulatory clarity, there is an urgent need for global harmonization of standards and approaches to regulating nanomaterials.

The third lesson is that the best way to produce coherent policies that offer predictable outcomes is to develop a unified forum for discussion. The conflicting laws and ambiguities discussed in this Article may be slight but are important and transcend international geographic borders. Political discourse about conflicts of law is often the linchpin of trade agreements, with multiplier effects on international commerce. Each of the elements discussed in this Article about the intersection of regulation, nanoscience, and food law have roles to play in the creation of such an entity. For this reason, legislation is needed to address the potential role of a science clearinghouse to direct laws or a science court as proposed by the EU-funded NANORIGO work package.

IV. BALANCING BENEFITS AND RISKS OF NANOTECHNOLOGY IN FOOD

Nanotechnology and its commercial products used in daily life have been major players in advancing millennial transformations of how people grow, sell, distribute, use, and discard food in society. Nanotechnology has added trillions of dollars of value to the global economy, and the European Union Observatory for Nanotechnology expects ongoing exponential growth in the future.[67] That economic value is a natural outgrowth of the early laws governing nanotechnology, which articulated the justification for funding nanotechnology research and provided the roadmap that future

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[66] *See* Mark D. Hoover, Leigh J. Cash, Ryan D. Hoover & Stephanie M. Matthews , *'Toxic' and 'Nontoxic': Context to Anticipate, Recognize, Evaluate, Control, and Confirm Protection from Risks*, 9 ENCYCLOPEDIA OF TOXICOLOGY (4th ed. 2024).

[67] EUR. CHEM. AGENCY, STUDY OF THE EU MARKET FOR NANOMATERIALS, INCLUDING SUBSTANCES, USES, VOLUMES AND KEY OPERATORS 48 (2022).

nanotechnology applications have consistently followed.[68] For every food container label made lighter because nanotechnology enables thinner paper with less glue and ink, there is reduced cost for transport—savings that are sometimes passed on to the consumer. For every container that is made thinner, stronger, and lighter, there is less chance of damage to the goods inside and a reduced cost for storage, transport, insurance, and cleaning of those goods before they are brought to market. Those cost savings are sometimes passed on to consumers, as well. Additionally, 3D printing of food holds the promise of victorious humanitarian relief efforts in wartime, pandemics, and during the aftershocks of any major natural disaster. 3D printing would make accessible to every person food that is tailored to their diet, regardless of religious laws, medical constraints, or food allergies. Food innovations built on foundational research in nanotechnology therefore hold the possibility of eradicating famine. If used correctly, these new tools can lower food costs despite national economic crises and ensure baseline nutrition that contributes to well-being. These are nanotechnology's "wonderful promises," holding the potential to revolutionize commerce and expand access to food, medicine, and consumer products that protect public health. Yet there is no conclusive evidence about the tradeoffs to society due to nanotechnology's underexplored downsides and the unsophisticated state of nanotechnology risk assessment and management.

Global health law and policy questions raised by carbon nanotubes in packaging that are lighter, indestructible, and preserve food longer therefore provide an excellent example of the two-edged sword that can both protect and harm stakeholders who use carbon nanotubes. Nano-enabled packaging is stronger than its predecessors, thereby protecting and increasing the food supply. However, using carbon nanotubes in packaging also raises issues of non-biodegradable waste that threatens human health and the environment. Food policy, including nanotechnology law, must examine these trade-offs, and an informed electorate should have the opportunity to participate as stakeholders in the policy decisions.

A. CARBON NANOTUBES

Carbon materials have a wide range of uses, ranging from composites for use in vehicles and sports equipment to integrated

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[68] *See generally* Mihail C. Roco, *The Long View of Nanotechnology Development: the National Nanotechnology Initiative at 10 years*, 13 J. NANOPARTICLE RSCH. 427 (2011), https://doi.org/10.1007/s11051-010-0192-z.

circuits for electronic components to packaging for food and other commodities. It is unclear whether carbon nanotubes disintegrate or stay in the human body with possible toxicological effects on human health. NIOSH, the leading occupational health research agency for the U.S. federal government, held hearings in 2011 regarding occupational exposure to carbon nanotubes and nanofibers. Shortly thereafter, NIOSH observed that carbon nanotubes "can be encountered in facilities" where products incorporating them are "processed, used, disposed, or recycled", with "potential for worker exposures."[69] In the same document, NIOSH concluded that carbon nanotubes "should be considered a respiratory hazard".[70]

B. NANOSILVER

Silver has antimicrobial properties that have been known for centuries, giving rise to the practice of referring to serving utensils as "silverware." It is known that nanosilver can migrate into human skin, and a risk assessment by the EPA regarding possible long-term impacts of nanosilver exposure has been the focus of litigation in the U.S.[71] On the other hand, the EU has already implemented legislation regulating the use of chemicals like nanosilver: a regulation called

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[69] *Occupational Exposure to Carbon Nanotubes and Nanofibers*, 65 NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH CURRENT INTEL. BULL., at ix, (Apr. 2013).

[70] *Id.* at xii.

[71] Nat. Res. Def. Council v. EPA, 857 F.3d 1030, 1034–35 (9th Cir. 2017) (holding, in response to petitioners seeking review of EPA's registration of the pesticide nspw-l30ss, an antimicrobial materials preservative that uses nanosilver as its active ingredient, that EPA failed to support the public interest finding with substantial evidence under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136a(c)(7)(c), because EPA's finding that current users of conventional silver pesticides relied on unsubstantiated assumptions); *see* Michael T. Novak, Eric P. Gotting & Kathryn M. Biszko, *NRDC v. EPA: The Ninth Circuit issues a narrow ruling on EPA's conditional registration of a "nano-pesticide",* 45 A.B.A. SEC. ENV'T, ENERGY & RES. 18, 20208 (2014) ("The U.S. Environmental Protection Agency's (EPA) first-ever conditional registration of a nanosilver pesticide was recently challenged on multiple fronts. . . . The Natural Resources Defense Council (NRDC) not only questioned EPA's approach to granting conditional pesticide registrations, but also the very safety of nanosilver itself. The U.S. Court of Appeals for the Ninth Circuit, however, largely rejected NRDC's suit. On November 7, 2013, the court upheld EPS's conditional registration with one narrow exception and remanded the registration decision back to EPA on that issue. EPA, working with the pesticide registrant, subsequently amended the pesticide label to address the grounds for remand, thereby permitting the conditional registration to stand.").

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).[72]

REACH protects human health and the environment from the risks that chemicals can pose and applies horizontally to all chemical substances. Significantly, substances used as plant protection products or biocides must be registered under REACH Food contact materials (e.g., TiO_2, nanosilver, etc.). Nanomaterials in industrial sectors (e.g., TiO_2 in paints) are not exempt from registration under REACH. It should be noted that the resource recovery laws administered by the EPA identified silver recovery as one of the first targets for programs controlling hazardous waste in the 1970s, over half a century ago. Since nanosilver is heavily scrutinized under these parallel legal frameworks, any producer introducing a new product using nanosilver that risks contact transmission could face the burden of proving it is safe, or, in the alternative, distinguishing its processes from other uses. Even though the EFSA has studied contact transmission of nanosilver for food and determined it does not yet pose major risks,[73] the growing use of nanostructures in food foretells future scientific debate about non-food contact transmission impacting food safety and non-food packaging that threatens environmental health under hazardous waste laws.

C. TITANIUM DIOXIDE

Titanium dioxide (TiO_2) is an inorganic chemical substance primarily used in the form of a white pigment for its colorant and covering properties. TiO_2 is inexpensive and popular with food manufacturers because customers are attracted to its light, fluffy features. TiO_2 in skin creams, emulsifiers, color additives, flavor enhancements, and whiteners ranging from toothpaste to construction materials has been shown to pose several risks due to its inherent nanotoxicity.[74] Following a proposal from the competent French authority submitted to the European Chemicals Agency

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[72] Regulation 1907/2006, of the European Parliament and of the Council of 18 December 2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency, Amending Directive 1999/45/EC and Repealing Council Regulation (EEC) No 797/93 and Commission Regulation 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, O.J. (L 396) 1.

[73] Claude Lambré et al., *supra* note 8, at 9.

[74] Joanna Musial, Rafal Krakowiak, Dariusz T. Mlynarczyk, Tomasz Goslinski & Beata J. Stanisz, *Titanium Dioxide Nanoparticles in Food and Personal Care Products—What Do We Know About Their Safety?*, 10 NANOMATERIALS, June 4, 2020, at 14, https://doi.org/10.3390/nano10061110.

(ECHA) to classify TiO_2 as a carcinogen, ECHA's Committee for Risk Assessment (RAC) adopted an opinion classifying TiO_2 as a category 2 carcinogen, including the hazard statement 'H 351 (inhalation)'.[75]

The conflict of laws resulting from two very different approaches to risk presents an excellent example of the regulatory dilemma created by using products at the nanoscale in food. In the U.S., TiO_2 has been designated to be "Generally Recognized as Safe" (GRAS) and therefore allowed in food, but in the EU TiO_2 is prohibited. Although an EU determination is not binding under U.S. law, U.S. regulators may feel pressure to align with EU law that is designed to protect the lives and well-being of hundreds of millions of people. EFSA and EU parliamentary concerns about TiO_2 in food therefore transcend geographic borders, impacting food law in the U.S.

V. COMPARISON OF U.S. FDA AND EU EFSA APPROACHES

The world's two largest trading partners, the U.S. and the EU, have diametrically opposite pathways for analyzing nanostructures in food. This Part thoroughly compares these differences. Because cultural differences about food translate into the conceptual underpinnings of laws, it is unsurprising that laws in the U.S. and EU conflict on the appropriate uses for nanostructures in food. Both jurisdictions also have stern new laws about toxic substance controls across a broad range of environmental questions that impact human health and food. Note that a key difference between the FDA and the EFSA is that the latter provides recommendations to the EU in support of the development of regulations, rather than directly promulgating regulations itself.

REACH and the U.S. Toxic Substances Control Act (TSCA) both use stepwise analysis to operationalize preventive measures designed to control human exposure to hazardous substances.[76] Both REACH and the TSCA address methods for evaluating chemicals and their risks. TSCA was rewritten by the U.S. Congress in 2016. The modern 800-page law embraces nanomaterials by functional analysis based on the characterization of their use in a given context and the implications for human toxicity as hazardous waste. These

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[75] *See* cases cited *supra* note 13.

[76] *See* U.S. ENV'T PROT. AGENCY, HOW EPA EVALUATES THE SAFETY OF EXISTING CHEMICALS, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals (last visited Nov. 12, 2024) [https://perma.cc/QKD5-T7PT] (describing the step-wise analysis undergone pursuant to the TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, 15 U.S.C. §§ 2601–2629).

antecedents shape the EU's and the U.S.'s respective definitions of food, in turn implicating different legal issues arising from the regulation of nanostructures. Note that regulation of TiO_2 is only one example of differing approaches to nanomaterial use in food. Other nanoscale materials used in food raise unquantifiable scientific uncertainties about the migration of nanoparticles with potential impacts on global health. A review of these building blocks for nanoregulations in food holds several lessons for establishing safe and effective paradigms for using nanomaterials in a manner that promotes the benefits of innovation while protecting global health. The conflict of laws regarding methods for determining the toxicity, limits, and allowed uses for nanomaterials in food therefore reaches larger legal questions about global health.

A panel of experts at EFSA appointed to respond to requests for information from the European Commission has determined that nanoscale is potentially genotoxic and therefore not recognized as safe under EU law. In 2020, France became the first country to ban TiO_2 in food.[77] In May 2021, EFSA published an opinion that TiO_2 could no longer be considered safe when used as a food additive.[78] TiO_2 was then banned as a food additive, meaning it could be used exclusively for color in medicinal products in the EU.[79] Subsequently, the Court of Justice of the European Union banned TiO_2 based on EFSA's determination of carcinogenicity, although the November 2022 ruling does not apply to food.[80]

The FDA has remained silent about nanostructures in food, having determined decades ago that less than one percent of TiO_2 in

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[77] *Cf.* French Agency for Food, Evn't & Occupational Health & Safety, Opinion Letter on the Risks Associated with Ingestion of the Food Additive E171 (Apr. 12, 2019), at 27–28, https://www.anses.fr/fr/system/files/ERCA2019SA0036EN.pdf [https://perma.cc/6S79-T3QZ] (stating the need for further research into the hazardousness of E171 and concluding that workers, consumers, and the environment should generally have limited exposure to the substance). Note that ANSES's opinion was informed, in part, by its observation that EFSA had previously not found sufficient evidence that E171 was dangerous when it addressed the question in 2016. *Id.* at 6.

[78] Younes et al., *supra* note 10, at 5.

[79] Commission Regulation 2022/1396 of Aug. 11, 2022, Amending the Annex to Regulation (EU) No 231/2012 Laying Down Specifications for Food Additives Listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as Regards the Prescence of Ethylene Oxide in Food Additives, O.J. (L 211) 182, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R1396&qid=1731393032322 [https://perma.cc/VU4J-9SSQ].

[80] *Cf.* cases cited *supra* note 13.

food by volume is GRAS and does not require regulatory oversight.[81] But nothing in FDA regulations provides guidance to consumers who may be unaware of nanoscience and the debate that rages in the courts regarding TiO_2. Because the names of the products—e.g., whipped cream, donut fillings, and shaving cream—have not changed, consumers likely remain unaware of the use of TiO2 in the products they use each day. Nor has their composition been altered, so there is no question of misleading labeling or branding. Even though the function of the substance has changed dramatically: The FDA needs the opportunity to carefully examine this process-oriented function and characterization within a new framework appropriate for the nanoscale context.

Thus, there is an implicit, but perhaps inadvertent, exemption from FDA laws for nanoscale TiO_2, despite regulatory counterparts abroad finding that the substance poses unacceptable risks to human health. FDA regulations could be read to give rise to the false conclusion that if one percent of TiO_2 in food is safe, then surely a fraction smaller than one billionth of the same substance must also be safe. But the inherent properties of nanotechnology—enabling materials to become stronger and more potent at the smaller nanoscale—renders that logical conclusion untrue. TiO_2 is widely considered to be toxic even in its bulk form and is considered a carcinogen by ECHA. TiO_2 is subject to extensive regulation in the U.S. and abroad;[82] the amount of TiO_2 that is used is the actual linchpin of the safe use designation. FSA has concluded, "Overall, on the basis of all currently available evidence along with all the uncertainties, in particular the fact that genotoxicity concern could not be ruled out, the Panel concluded that E 171 can no longer be considered as safe when used as a food additive."[83]

A. FDA JURISDICTION OVER FOOD

The FDA has remarkably broad jurisdiction within the U.S. To understand the scope of that jurisdiction, consider that, according to the FDA:

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[81] *See* 21 CFR § 73.575 (stating that titanium dioxide can be safely used for coloring food, subject to restrictions including that "the quantity of titanium dioxide does not exceed 1 percent by weight of the food.").

[82] *See, e.g.*, Commission Delegated Regulation (EU) 2020/217 of Oct. 4, 2019, Amending, for the Purposes of its Adaption to Technical and Scientific Progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on Classification, Labelling, and Packaging of Substances and Mixtures and Correcting that Regulation, 2019 O.J. (L 44) 1.

[83] *See* Younes, et al., *supra* note 10, at 5.

- FDA is responsible for the oversight of more than $2.8 trillion in consumption of food, medical products, and tobacco.
- FDA-regulated products account for about 20 cents of every dollar spent by U.S. consumers.
- FDA regulates about 78 percent of the U.S. food supply. This includes all the foods sold or consumed in the U.S., except for meat, poultry, and some egg products.[84]

The FDA has nearly exclusive jurisdiction over food. It was created in the early 20th century in reaction to a host of unsafe and impure products in the U.S. marketplace that undermined public health by causing illness and death. The genesis of the Federal Food, Drug, and Cosmetic Act (FDA Act) was an uncontrolled market that harmed millions of people.[85] Products were either mislabeled as food or were sold after it was safe to eat them. The FDA Act defined food to be: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[86]

In 1960, Congress enacted Color Additive Amendments, which: defined the term "color additive"; established a listing and certification process for color additives; and eventually legalized food adulteration.[87] Those provisions reflected hard-won victories of lobbyists who maintained that it was impossible to control every molecule in food and that some stray materials are inconsequential. Those materials, according to the law, are not "adulteration" because they are "Generally Recognized as Safe." Hence the famous "GRAS List" was born.[88]

Although the FDA has a wide scope of jurisdiction, it rarely embraces premarket review of food products. Further complicating questions of food law and policy in the U.S., jurisdiction over the life cycle of food is fractured across several federal agencies: (1) the U.S. Department of Agriculture (USDA), which regulates crops,

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[84] U.S. FOOD & DRUG ADMIN., FDA AT A GLANCE (2020), https://www.fda.gov/media/143704/download [https://perma.cc/8LP6-DQ3F].

[85] *See* William W. Goodrich, *Safe Food Additives and Additives Generally Recognized as Safe—There is a Difference*, 16 BUS. L. 107 (1960).

[86] Federal Food, Drug, and Cosmetic Act § 321(f).

[87] Color Additive Amendments of 1960 Act, Pub. L. No. 86–618, §101, 74 Stat. 397, 399 (1960).

[88] *See* 21 C.F.R. § 73.1 (1977) (listing "[s]ubstances that are generally recognized as safe"); *see also id.* at § 73.1575 (stating that certification of titanium dioxide for use as a color additive "is not necessary for the protection of the public health").

including introducing new crop varieties, subsidizing preferred crops, and inspecting the quality of some livestock, crops, and related agricultural nonfood products; (2) the EPA, which regulates pesticide use, workplace health protection in the fields, and disposal of hazardous waste, including some food waste or discarded food packaging; and (3) the FDA, which regulates the quality and inspection of food products. These agencies tend to exercise their authority independently after the facts of food production have been revealed, rather than coordinating to divide up the jurisdictional pie. Consequently, there is often overlapping jurisdiction—sending mixed signals to food producers about which laws to follow—rendering compliance with U.S. food laws challenging.

B. EU EFSA JURISDICTION OVER FOOD

In the EU, the EFSA holds unified power that spans from "Field to Fork," as described at the outset of this article.[89] The EFSA embraces veterinary concerns due to its origins in the EU response to mad cow disease in the 21st century, which demonstrated the strong link between the safety of food for human consumption and animal health. Because of that historical concern with preventing the spread of diseases across species, the EFSA emphasizes precautionary regulation and control to a much greater extent than the U.S. agencies. The EFSA—viewing nanostructures as very important—has created a method for outlining the scope of restrictions on particular nanostructures on a case-by-case basis, using detailed stepwise analysis in its definitions of regulated nanomaterials.[90] Using contact transmission concerns as a tool for regulation, the EFSA exercises jurisdiction over many activities that at first might not appear to apply to food, such as livestock feed, storage, and pesticides, exemplifying the "From Field to Fork" model of regulation.

EFSA rules address the need for precautions to prevent the migration of nanomaterials that may influence human health in the long term. Therefore, EFSA regulates contact transmission of nanomaterials to limit the presence of non-food nanostructures in food. Nanosilver in refrigeration, used because of its potent ability to kill microorganisms, is one permitted example. However, there remains an unquantified risk and scientific uncertainty about

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[89] *See supra* pp. 4–5. *See generally* EUR. FOOD SAFETY AUTH., *Nanotechnology*, https://www.efsa.europa.eu/en/ topics/topic/ nanotechnology [https://perma.cc/K7XA-DSDJ] (describing the role of EFSA with respect to nanotechnology).

[90] *See generally* Younes, et al., *supra* note 10 (using detailed stepwise analysis to define regulated nanomaterials).

whether nanosilver migrates and, if so, its impact on human health. Contact transmission of nanosilver therefore is subject to control following the EFSA requirement to prove that the use of materials is safe.

The EU approach deploys precautionary principles, aiming to prevent non-foods that are impure, mislabeled, or adulterated from reaching the market.[91] According to the Director of EFSA, the mantra remains that "[F]ood safety is the basis for everything. If it is not safe it is not food."[92] Under this construct, many items in commerce will not pass EFSA muster to be considered "food," even if those items are edible. Those items that are not food are something else, and—depending on the jurisdiction—may be subject to laws of hazardous waste.

Therefore, the EFSA approach is the exact reverse of the FDA approach. In the U.S., the regulatory jurisdiction encompasses any substance that purports to be food, but the EU approach requires that products be proven safe to be considered food. This subtle distinction between underlying cultural and philosophical approaches to nanoparticle risks is important.

Consequently, the cultural matrix underpinning these laws about food have produced a stark conflict of laws. The conflict of law raised by TiO_2 provides but one example of problems derived from these parallel cultures.

C. THE FDA APPROACH

The FDA has not stated a clear regulatory agenda or definition of nanotechnology.[93] Thus, it is unclear which nano-enabled products fall under its purview; the regulatory status of products ranging from mascara, lipstick, and whipped cream to high-tech Covid-19 vaccines, cancer-targeting drugs, and regenerative tissue medical devices remains ambiguous. The FDA allows long-standing use of TiO_2 as a color additive, placing it on the GRAS list.[94] The

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[91] "Only food additives included in the Community list in Annex II may be placed on the market as such and used in foods under the conditions of use specified therein." Moreover, "[f]ood additives shall comply with the specifications as referred to in Article 14" of that Regulation. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on Food Additives, 2008 O.J. (L 354) 16, 21.

[92] EFSAChannel, *A Chat with EFSA's Executive Director*, YOUTUBE (Sept. 12, 2022), at 08:36, https://www.youtube.com/watch?v=TLaT2DjVQ1I.

[93] *See* FDA, *supra* note 58, at 5 ("This guidance does also does not establish [a] regulatory definition[of nanotechnology].").

[94] *See* 21 C.F.R. § 73.575 (1977).

FDA has exclusive jurisdiction over food once the materials leave the part of the supply chain that is dedicated to crops. For example, food cannot be a hazardous substance subject to the jurisdiction of the Consumer Product Safety Commission (CPSC) because federal law defines hazardous substances and food to be mutually exclusive: "The term 'hazardous substance' shall not apply to . . . foods, drugs, and cosmetics subject to the Federal Food Drug, and Cosmetic Act . . ."[95] The U.S. Congress has repeatedly tweaked these definitions, for example, by establishing subcategories with special definitions, such as "food additives" and "dietary supplements" as subcategories of "food."[96] No one, however, has renounced the importance of the FDA's role in protecting public health regarding food. FDA regulations leave the impression that nanoscale TiO_2 is harmless despite empirical evidence that has moved regulators in other jurisdictions towards the opposite view. Indeed, nothing in FDA regulations suggests that TiO_2 poses any risk or danger.[97]

The color additives provision of the FDA statute governing adulterated food requires the agency to deem adulterated any food that bears or contains any color additive that is "unsafe."[98] According to the FDA, "safe" means that there is "convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive."[99] On the surface, this regulatory threshold may be characterized as less protective of public health than the EFSA's operationalization of precautionary principles. Furthermore, the FDA has not established any threshold for nanoscale use of TiO_2 that would justify regulatory action; the absence of any guidance by the FDA has resulted in the peculiar state of affairs whereby a substance identified as toxic and potentially carcinogenic by the EU remains essentially unregulated in the U.S.

This relative lack of vigilance on FDA's part is complicated by the fact that traditional FDA law involves self-activated statutory protections,[100] such that any claim by a manufacturer, distributor, or retailer that an article in commerce is "food" automatically subjects that article to FDA jurisdiction.

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[95] Federal Hazardous Substance Act, Pub. L. No. 86–613, 74 Stat. 372 (1960), see 15 USCA §1261 ("15 U.S.C.A. § 1261 (West 2008).

[96] *See* PETER BARTON HUTT, RICHARD A. MERRILL, LEWES A. GROSSMAN, NATHAN CORTEZ, ERIKA FISHER LIETZAN & PATRICIA J. ZETTLER, FOOD AND DRUG LAWS 555–565 (5th ed. 2022).

[97] *See supra* note 86 (noting that the exemption of TiO_2 from certification is premised on its safety).

[98] 21 U.S.C. § 342.

[99] 21 CFR 70.3(i).

[100] *See* HUTT, et al., *supra* note 96, at 555-66 (discussing the purposes of the Food, Drug, and Cosmetic Act).

Modern U.S. food safety is protected by the FDA's elaborate compliance system for oversight under the Food Safety Modernization Act (FSMA) of 2009, which requires traceability, import controls, performance standards, tracking, recordkeeping, and certification by specialists.[101] Ironically, this "modern" law ignores modern innovations in and concerns regarding food production enabled by nanotechnology, such as 3D-printed food and the migration of nanoparticles into food, which are the subject of EFSA concerns about contact transmission. Innovations in the industrial food-making process remove or dramatically alter key steps in the traditional process mapped out in the FSMA, rendering parts of the FSMA inapposite to modern food processes. Nano-enabled 3D food printers may soon be in every kitchen (whether factory, hotel, restaurant, hospital, or household),[102] thus bypassing statutory points of inspection and regulatory oversight in traditional food making, such as trucking, air cargo, and packing. When the FDA published guidelines about nanotechnology in June 2016, it stated, "These terms are discussed out of context, and without regard to the role of FDA proposed guidance as law or as mere suggestions to be followed."[103] Thus, FDA statements about nanotechnology do not squarely address the problem of whether its statutory mandate requires revisiting substances that behave differently at the nanoscale. One percent of food by volume using TiO_2 at the nanoscale represents more nanomaterial than one would use in several years. This example of reinvented matter in foods that are

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[101] Pub. L. No. 111-353, 124 Stat. 3885 ("Enhancing Tracking and Tracing of Food and Recordkeeping.").

[102] *See* Lynette Kucsma, *3D Food Printing*, YOUTUBE (Oct. 9, 2014), https://www.youtube.com/watch?v=Q7KquBN60f8 [https://perma.cc/5NN3-TC3E] (Kucsma boldly asserting that her 3-year-old and 5-year-old loved printed food she prepared even though they refused to eat the same ingredients when prepared traditionally; no laboratory testing regarding difference in nutritional value or sanitary conditions when comparing printed food with traditional food, a crucial distinction for determining human consumption); *see also* Jasper Tran, *The Law and 3D Printing*, 31 J. MARSHALL J. INFO. Tech. & PRIVACY L. 505, 508 (2015) ("3D printers can print out anything, from a lithium-ion microbattery to a human kidney, and can print in materials like plastic, metal, ceramic, cement, wood, food, and human cells. 3D printers print by setting raw ingredients into two-dimensional patterns on a platform and gradually raising to stack one layer on top of another until completion . . . 'A world in which everyone has advanced 3D printers at home or available in a public facility is a world in which manufactured goods no longer have to be produced in bulk and are no longer scarce'").

[103] ILISE FEITSHANS, GLOBAL HEALTH IMPACTS OF NANOTECHNOLOGY LAW: A TOOL FOR STAKEHOLDER ENGAGEMENT 38 (2018).

governed by FDA law is an unusual case of first impression, but it will not be the last. Whatever path the FDA eventually chooses has implications for nanotechnology and its offshoot technologies,[104] such as AI for health, Big Data, and mRNA vaccines.

D. THE EFSA APPROACH

The EU requires labeling of foods containing nanomaterials. In 2018, the EFSA published guidance for assessing nanomaterials in food and animal feed after extensive deliberation among experts, resulting in the prohibition of certain nanomaterials in food.[105] This decision resulted from a stepwise analysis to determine the presence and relative importance of nanostructures in food.

The EFSA "Field to Fork" regulatory framework includes nanostructures in food, soil, transport, packaging, and nanopesticides that may involve the use of or exposure to TiO_2. After conducting a review of all the relevant available scientific evidence, the EFSA concluded that a concern for the *genotoxicity* of TiO_2 particles (in the food additive E171) cannot be ruled out.[106] Based on this concern and because the experts could not establish an Acceptable Daily Intake (ADI) for E171,[107] the EFSA's experts no longer consider TiO_2 safe when used as a food additive:

> The European Commission [banned] titanium dioxide (E171) as a food additive . . . starting with a six-month phasing out period as of February 7, 2022, until August 7, 2022, after which a full ban applies. Following publication of Commission Regulation (EU) 2022/63 in the EU's Official Journal (OJ) on January 18, 2022, Annex II and III to Regulation (EC) No 1333/2008 on food additives [were] amended accordingly.[108]

These activities were consistent with the stepwise analysis of nanostructures in food required to prove a nanomaterial safe for use

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[104] DIANA DE LA IGLESIA, STACEY HARPER, MARK D. HOOVER, FRED KLAESSIG, PHIL LIPPEL, BETTYE MADDUX, JEFF MORSE, ANDRE NEL, KRISHNA RAJAN, REBECCA REZNIK-ZELLEN & MARK TUOMINEN, NANOINFORMATICS 2020 ROADMAP 6 (2011).

[105] *See generally* Younes, et al., *supra* note 10.

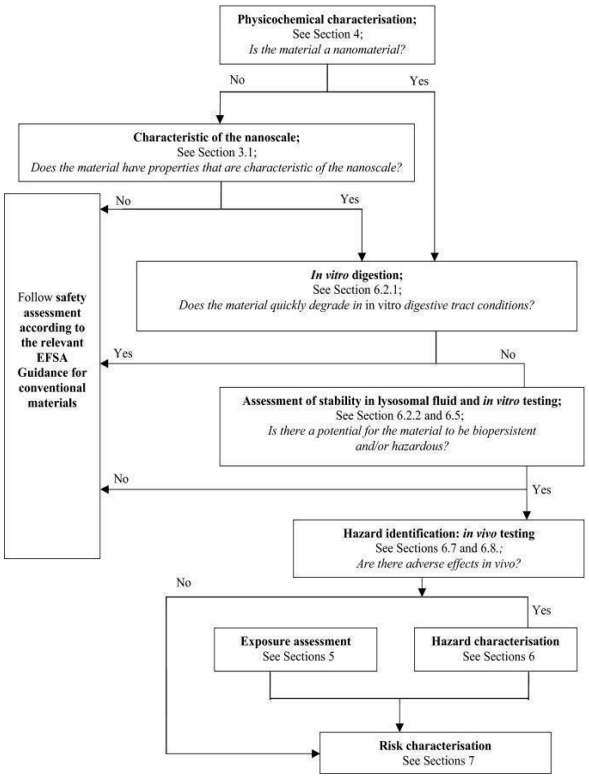
[106] Younes, et al., supra note 10, at 5.

[107] EUR. FOOD SAFETY AUTH., *infra* note 111.

[108] FOREIGN AGRIC. SERV., U.S. DEP'T OF AGRIC., E42022-0011, TITANIUM DIOXIDE BANNED AS A FOOD ADDITIVE IN THE EU (2022), https://apps.fas.usda.gov/newgainapi/api/Report/%20DownloadReportByFileName [https://perma.cc/9DBW-MG46].

in the EU market. While unfurling the entire EFSA stepwise process is outside the scope of this Article, Step 1[109] provides a representative example of the careful attention to detail that must be paid to the requirements. The attendant criteria in Step 1 of a detailed and comprehensive stepwise analysis offer concrete evidence of a transformation in regulatory analysis of risk, which may also be considered part of the nanotechnology revolution because of its remarkable impact upon governance.[110]

Figure 2. *Step 1 of the EFSA's stepwise analysis, determining the presence of a nanomaterial in food and next step tests to be performed.*



[109] *See infra* Figure 2 (providing an illustration of Step 1 of the analysis); More, et al., *supra* note 6, at 15.

[110] More, et al., *supra note* 6 ("Where the data have been derived from appropriately conducted studies using validated methods and considering nanospecific issues where relevant, there may be no reason to use uncertainty factors for a nanomaterial that are any higher than those used for a conventional material. However, where data are either insufficient or have been derived from inadequate tests . . . for nanomaterials, applying additional uncertainty factors may be considered for safety assessment of a nanomaterial.")

On November 30, 2021, the European Commission published *Commission Implementing Regulation* (EU) 2021/2090 in the OJ, denying the authorization of TiO_2 (E171) as a food additive.[111] Although the EFSA does not have the authority to institute a ban—which must come from the European Parliament itself—the EU Commission appears to have given significant weight to the EFSA's determination that TiO_2 does not have a safe ADI. Furthermore, that determination was subject to court review in the Luxembourg Court's opinion.[112] The commercial food industry in the EU brought a case in the Court of Justice to arrest these developments, motivated in part by the belief expressed by Simon Norman, Head of Product Development for Food and Beverage at Leatherhead Food Research, who said:

> In many ways [TiO2] is the perfect ingredient: available for cheap in bulk from many different suppliers, inert and highly stable, mostly flavourless [sic], and very, very white. There are a variety of different grades available with optimised [sic] properties for particle sizing and surface chemistry to ensure compatibility in [for]mulations. Although there are other options for white pigments, product developers are likely to have to trade-off some performance criteria against cost as they go through their reformulation processes.[113]

In a remarkably technical opinion,[114] the European Court weighed in on the quality of EFSA conclusions based on the agency's

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[111] Commission Implementing Regulation (EU) 2021/2090 of 25 November 2021 concerning the denial of authorisation of titanium dioxide as a feed additive for all animal species 2021 O.J. (L 427). *See also Titanium Dioxide: E171 No Longer Considered Safe When Used as a Food Additive*, EUR. FOOD SAFETY AUTH. (May 6, 2021), https://www.efsa.europa.eu/en/news/titanium-dioxide-e171-no-longer-considered-safe-when-used-food-additive [https://perma.cc/Q8ZF-NWJT].

[112] *See generally* Joined Cases T-279/20, T-288/20 & T-283/20, CWS Powder Coatings GmbH v. Comm'n, ECLI:EU:T:2022:725 (Nov. 23, 2022).

[113] Andy Coyne, *The Complexity of Removing 'Unsafe' Food Additive E171: How Easy Will It Be For Manufacturers To Reformulate Products Containing E171?*, JUSTFOOD, (May 21, 2021), https://www.just-food.com/features/the-complexity-of-removing-unsafe-food-additive-e171/?cf-view [https://perma.cc/W6HZ-PCRJ].

[114] *See generally* Joined Cases T-279/20, T-288/20 & T-283/20, CWS Powder Coatings GmbH v. Comm'n, ECLI:EU:T:2022:725 (Nov. 23, 2022).

evidence: "First, the Commission made a manifest error in its assessment of the reliability and acceptability of the study on which the classification was based and, second, it infringed the criterion according to which that classification can relate only to a substance that has the intrinsic property to cause cancer."[115]

The implications of this opinion suggest that the next steps for nanostructure regulation require further complex science policy analysis using multidisciplinary tools such as the NIOSH Logic Model.[116] The European Court also suggested detailed scientific analysis is part of the law's future trajectory, even in courts where judges are not necessarily scientists. The next steps, therefore, involve multidisciplinary regulatory discussion about non-law variables that create the social, economic, and cultural dimension of food.

VI. HARMONIZATION IS KEY

The regulation of nanotechnology in food represents a transformative agent to address perennial global health issues about food and explore legal issues raised by the new technology. This includes issues such as how food should be distributed so that society can overcome wars, economic crises, pandemics, and class differences to prevent famine. The religious notion that humanity must be served by advancing and protecting the whole person invites a discussion of the transformations that nanotechnology has brought to society in tandem with concurrent scientific and demographic changes.[117] As noted by religious leaders, the global obligation to serve the needs of people goes beyond the charitable act of feeding the poor and includes a concern for feeding all of humanity in the future.

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[115] Court of Justice of the European Union Press Release: The General Court Annuls the Commission Delegated Regulation of 2019 in so far as it Concerns the Harmonised Classification and Labelling of Titanium Dioxide as a Carcinogenic Substance by Inhalation in Certain Powder (Nov. 23, 2022), https://curia.europa.eu/jcms/upload/docs/application/pdf/2022-11/cp220190en.pdf [https://perma.cc/H6PL-KWZP].

[116] *See supra* Figure 1.

[117] *See, e.g.*, Heather Wilpone-Welborn, *Georgetown Students Provide Practical Nutritional Information to Families In DC Food Deserts*, GEO. UNIV, (Sept. 2, 2022), https://som.georgetown.edu/news-stories/georgetown-students-provide-practical-nutritional-information-to-families-in-dc-food-deserts/ [https://perma.cc/MVY9-4B9Q] (last visited November 22, 2024) (describing how medical students operationalized the concept of *cura personalis*).

The demographic and geopolitical dimensions of food distribution chains across society therefore represent a fundamental global equity and justice concern that takes center stage for future capacity building of global health infrastructures. The regulatory challenges posed by nanostructures in food, nanomaterials for food transportation and storage, and nano-enabled foods may be new to many. Yet, food is essential and these are vital worldwide issues. The regulatory challenges are becoming increasingly important as the use of nanomaterials increases. Although nanotechnology applications in the food industry—from field to fork—are largely unknown in the U.S., nanostructures in food are intensely regulated in Europe. Existing nanoregulations, environmental laws, international treaties, and trade agreements exemplify the transnational character of nanotechnology jurisprudence that underscores the global need for clear limits and permissions regarding the use of nanomaterials in commerce—permissions that only unified governance and harmonized laws can provide.

Harmonization across jurisdictions is not a new challenge, but acceptance of a harmonized regime for nanotechnology law must be built on more than consensus. Achieving harmonization requires that governments forsake a piece of their sovereign power for the sake of bending to a common will. Only through such mutual abdications can a nanoregulatory process emerge under one unified law.[118] The new unified body for international nanomaterial scrutiny and regulatory governance should be empowered with a flexible mandate to examine the scientific underpinnings of nanostructures in commerce, including the origins, use, consumer contact, and hazardous waste disposal questions raised by TiO_2, nanosilver, carbon nanotubes, and the hundreds of additional substances already in global food commerce.

Legal analysis of these rules within the larger superstructure can also yield important policy benefits by not only indicating gaps where new laws may be required, but also by demonstrating where duplicative or useless provisions can be removed. Oversight by a commission composed of an admixture of experts and novices across a wide spectrum of stakeholders would provide the requisite range of relevant perspectives, including the public in nanotechnology regulation while also allowing for open discussion on technical points. Ultimately, the result of these long discussions will enable

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[118] For an example of a harmonized tiered approach, see OECD, *Harmonized tiered approach to measure and assess the potential exposure to airborne emissions of engineered nano-objects and their agglomerates and aggregates at workplaces*, ORG. FOR ECON. COOP. & DEV. (2015), https://one.oecd.org/document/ENV/JM/MONO(2015)19/en/pdf [https://perma.cc/F798-4LW5].

manufacturers, employers including government entities, and consumers to know where they stand in relation to risk management when making choices about products that deploy nanotechnologies or nano-enabled offshoots of baseline nanotechnology. An overarching structure with transparency and accountability may be required to organize existing laws, guidelines, and standards to help discover gaps between new laws and provide such information to stakeholders.

Harmonization of the existing and emerging nanotechnology laws requires a hierarchical superstructure to account for society's need for predictability in trade, data collection regarding risks, and consistent requirements regarding risk communication. Inevitably, some laws will take center stage and others will stay on the periphery once there is a framework with clear priorities. It is not easy for governments to relinquish sovereignty, but the benefits of harmonization compel them to do so. For example, the proposed NANORIGO (Nanotechnology Risk Governance)[119] approach in the EU offers oversight by stakeholders in academia, the judiciary, and the public, thereby harmonizing around international law. While plenty of global efforts towards harmonization exist, there is no clear indication of which harmonized body of nanoregulations will become the most important. Simultaneously, well intentioned researchers in academia, governments, and private industry are filling the regulatory void with scientific guidance and guideline development aiming for a risk testing framework. In sum, the rapidly changing nanoregulatory situation cries out for harmonization, transparency, and consistency across hundreds of possible jurisdictions that are home to legitimate and enforceable laws. The next substantive steps are to coordinate on a risk management framework and to employ best practices, such as exposure assessment and tools for risk communication. Adequate risk communication will include discussions of liability and other foreseeable harms, as well as anticipating the existence of unforeseeable problems.

Therefore, a foundation is needed to ensure (1) the flow of data throughout the process of nanotechnology commercialization, (2) sound and replicable risk management (exposure assessment, risk assessment,[120] and risk mitigation through education and training), and (3) the ongoing flow of data for stakeholder feedback in a

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[119] *See* sources cited *supra* note 14.

[120] *See Integrated Approaches to Testing and Assessment (IATA)*, ORG. FOR ECON. COOP. AND DEV., https://www.oecd.org/en/topics/sub-issues/assessment-of-chemicals/integrated-approaches-to-testing-and-assessment.html [https://perma.cc/2PL6-PPX5] (last visited Oct. 29, 2024).

cyclical process. Developing a flexible risk governance framework in this context is necessary because risks associated with the application of such technologies are much slower to emerge than the many new vistas of prosperity and efficiency that nanotechnology promises to humanity. Law and science successfully partnered together throughout the 20th century to take on "Big Science" projects that were fraught with risk, but succeeded in harnessing atomic energy and decoding the human genome without blowing up the world or unleashing mutant monsters. Each of those innovative projects were fraught with risk, but promoted new industries and improved the quality of life for humanity. The key point, however, is that the discoveries produced by each were guided by strong overarching legal frameworks. Without such frameworks and proper oversight, it is tremendously difficult to ensure compliance with precautionary principles.

VII. RECOMMENDATIONS

A roadmap across the legal landscape of nanoregulations concerning food can discern gaps in those laws that must be filled. In addition, the presence of overlapping rules must be identified and resolved to avoid a conflict of laws. Recognizing the global need for harmonization and consistency across the hundreds of jurisdictions that are home to nanotechnology, the following recommendations are proposed:

1. *Develop and provide meaningful education initiatives*:
   Educate the public and policymakers so that they may have meaningful discourse about the relevant laws governing nanotechnologies applied to food in the U.S. and abroad (EU).[121]

2. *Set forth a roadmap for harmonization and a global nanotechnology review commission for oversight*:
   Forecast aspects of the law that require harmonization across jurisdictions and comment upon the relevance of this regulatory superstructure for new nano-enabled foods such as so-called

[121] Devos et al., *supra* note 23, at 4 (discussing how special importance was given to how to advance communication and engagement in the field of food safety, and how to adopt social sciences and follow an Open Science approach in the context of regulatory science) ("There is a need to rethink the way we communicate science. Putting greater efforts into educating the public through one-way communication has not been an effective strategy for ensuring the trustworthiness of science. Instead, efforts must focus more on better listening, and more inclusive and meaningful collaboration.").

"vegetarian steaks" grown in the spacelab.[122] A new global nanotechnology review commission could achieve these recommendations by offering transparent and accessible information about nanotechnology in food to stakeholders and the judiciary, thereby protecting public health while promoting innovation.

CONCLUSION

Ultimately, global agriculture and food security needs cry out for harmonization of the law across the hundreds of jurisdictions that are, or soon could be, home to nanotechnology. Without an agreed-upon hierarchy to prioritize the conflicts of law that have been explored here regarding the use of nanotechnology in food, disjointed regulations and conflicting laws present an immediate obstacle to sound international commerce, thereby undermining global health. The most logical and useful first step in the path forward begins with an international negotiating entity, such as a trade commission that will be empowered to exercise oversight of the food quality, pre-market and after commercialization, and then will harmonize the laws of these two major trade partners. Under this new construct it will be possible to use nanotechnology to feed the world by exercising consistent and predictable regulation of nanoscale materials in food across jurisdictions.

[122] *See* Aleph Farms, https://aleph-farms.com [https://perma.cc/7FQE-AWDM] (last visited November 22, 2024).