Nanotechnology in Drinking Water Treatment Systems: Risk and Regulatory Compliance

DAVID STRIFLING,* JACOB DALTON,* AND VERONIKA FOLVARSKA**

ABSTRACT

Engineered nanomaterials ("ENMs") have shown promise in a variety of applications, including for drinking water treatment. But many uncertainties remain about utilizing ENMs for that purpose, including risks to human health and the environment and uncertain governance regimes. This article explains the reasons for the uncertainty surrounding ENMs, analyzing both technical and regulatory issues. It then examines several potential policy instruments to help mitigate the ambiguity. Although there is no one-size-fits-all solution, the information developed may prove useful not only for the governance of ENMs, but also for similar analyses of other emerging technologies.

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* Marquette University Law School.

** Marquette University College of Engineering. This research was made possible by a grant from the National Science Foundation Industry/University Cooperative Research Center for Water Equipment and Policy. The authors also wish to thank Monique Williams and Madlyn Rohr for their assistance.

INTRODUCTION

Engineered nanomaterials ("ENM") are products designed and manufactured at an extremely scall scale, measuring between 1 and 100 nanometers ("nm") in at least one dimension. ENMs have a very high surface to volume ratio and sometimes exhibit unique chemical and physical properties. ENMs have shown promise in a variety of applications, including for drinking water treatment. Specifically, ENMs have proven effective at contaminant removal and disinfection, as well as contaminant detection and corrosion control. However, despite their great promise, many uncertainties remain about utilizing ENMs in drinking water treatment products, including possible pathways of release into the environment, their fate and transport once in the environment, and unclear governance via voluntary and mandatory regulatory frameworks.

As nanotechnology advances and is incorporated in more products, questions have arisen surrounding the appropriate balance between protecting public health and the environment, on one hand, and incentivizing ENM-driven innovation and economic development, on the other. Although some authorities have begun to monitor and regulate the use of ENMs, these efforts have been fragmented and mostly unsuccessful. The resulting regulatory uncertainty negatively affects the ability of the regulated community to develop and use ENMs. In the worst-case scenario, these data gaps, content thresholds, and limited governance resources may result in two unwanted outcomes. First, some ENMs may never achieve their promise because industry will be reluctant to develop and use them. Second, on the other end of the spectrum, ENMs that are developed may escape regulatory oversight at one or more life cycle stages.

This article is intended to address and resolve some of this uncertainty to help streamline the implementation of ENMs in drinking water treatment applications. First, it examines existing literature related to the uses of ENMs in drinking water treatment applications and their ultimate fate and transport in the environment. In doing so, it identifies key knowledge gaps for future investigation. It then evaluates existing regulatory frameworks, especially in those jurisdictions that are farther along in regulating ENMs. Finally, it proposes a menu of policy options to help mitigate regulatory uncertainty related to ENM utilization in drinking water treatment applications. These policy options include both difficult-to-enact "hard" policy instruments such as statutes and regulations, as well as self-enabling but potentially less effective "soft" instruments such as industry or organizational codes of conduct, best practices, aspirational guidelines, voluntary reporting or risk management standards, nonbinding standards, and licensing or certification programs. The information developed in this article may provide a useful framework for similar analyses of other emerging technologies in the future.

I. SETTING THE BASELINE: A TECHNICAL PERSPECTIVE ON THE USE OF NANOTECHNOLOGY IN DRINKING WATER TREATMENT SYSTEMS

Nanotechnology, which is defined as technology that has structures spanning 100 nm or less in at least one direction,[1] is being researched and developed for many applications, including drinking water treatment.

One perceived advantage of nanotechnology is that at the nanoscale, material properties of materials or systems can be different than those of the corresponding

1. Ibrahim Kahn, Khalid Saeed & Idrees Khan, *Nanoparticles: Properties, Applications and Toxicities*, 12 ARABIAN J. CHEM. 908, 909 (2019).

materials and systems at the macroscale.[2] The comparatively higher surface area of ENMs can lead to high reactivity, strong adsorption capacity, and in some cases faster dissolution.[3] Many of these properties may prove useful for drinking water treatment applications. ENMs may even be released when affected by an external stimulus such as light, and after that, can enter biological systems.[4] This is significant, because some nanoparticles are more toxic than larger particles of the same type.[5]

A. THE USE OF NANOMATERIALS IN DRINKING WATER TREATMENT APPLICATIONS

Several types of ENMs are being studied for use in drinking water treatment. Carbon-based ENMs have shown promise and are discussed first below. Then, this section will discuss nanometals and nanometal oxides, before finally moving to nano-adsorbents.

1. Carbon-Based Nanotechnology

This category includes carbon nanotubes ("CNTs")[6] as well as graphene oxides ("GOs").[7] Certain forms of CNTs have been combined into a hybrid water filter leading to high bacterial reduction and high viral removal.[8] In addition to having antimicrobial applications, CNTs are also used as adsorbents for pollutant removal.[9]

In drinking water treatment, the specific focus of this article, CNTs have potential uses in contaminant removal, contaminant detection, and contaminant

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2. Ilka Gehrke, Andreas Geiser & Annette Somborn-Schulz, *Innovations in Nanotechnology for Water Treatment*, 8 NANOTECHNOLOGY, SCI. & APPLICATIONS 1, 2 (2015).

3. *Id.* Other differences include superparamagnetism (the magnetic orientation of sufficiently small nanoparticles can randomly flip direction), enhanced electrical fields near the particle's surface, and other changes to electronic and optical properties. *Id.*

4. Ankit Nagar & Thalappil Pradeep, *Clean Water Through Nanotechnology: Needs, Gaps, and Fulfillment*, 14 ACS NANO 6420, 6426 (2020).

5. Shahnaz Bakand, Amanda J. Haynes & Finance Dechsakulthorn, *Nanoparticles: A Review of Particle Toxicology Following Inhalation Exposure*, 24 INHALATION TOXICOLOGY 125, 125 (2012).

6. CNTs are an allotrope of carbon with a cylindrical nanostructure. Various forms of CNTs exist including single-walled CNTs ("SWCNTs") and multi-walled CNTS ("MWCNTs"). Both types can be applicable to drinking water treatment. Xitong Liu et al., *Application Potential of Carbon Nanotubes in Water Treatment: A Review*, 25 J. ENV'TL SCIS. 1263, 1272 (2013).

7. Graphene oxide and reduced graphene oxide ("rGO") are modified forms of graphene, a single layer of carbon atoms with a 2-D honeycomb structure. Graphene has beneficial properties such as a Young's Modulus of 1100GPa, breaking strength of 125GPa, electron mobility of 200,000 $cm^2/(V\bullet s)$, and a specific surface area of 2600m2/g. Yongchen Liu, *Application of Graphene Oxide in Water Treatment*, 94 IOP CONF. SERIES: EARTH ENV'T SCI. 1, 1 (2017). GO is different from graphene as it has oxygen-containing functional groups. *Id.*

8. Liu, *supra* note 6, at 1272.

9. *Id.* at 1268. Modified CNTs with functionalized groups such as hydroxyl, carbonyl, and carboxyl have shown stronger adsorption of low molecular weight, polar, and heavy metal contaminants than pristine CNTs.

quantification.[10] Thanks to their adsorption capabilities, CNTs are also a potential treatment option for per-and polyfluoroalkyl substances ("PFAS").[11] Whereas preliminary studies indicate CNTs may not work as well as conventional adsorbents for PFAS removal, that may change with electrochemical assistance and certain aspects of the PFAS itself.[12] CNTs can also degrade organic pollutants.[13]

GOs have the potential to be similarly useful in drinking water treatment applications. First, GO films can allow water to flow through while being impermeable to other liquids, vapor, and gas.[14] GO films used in desalination show several orders of magnitude higher flux compared to conventional reverse osmosis treatment methods, potentially leading to higher efficiency and cost savings.[15] Second, similar to CNTs, GOs are an effective adsorbent for metal and organic contaminants.[16] Moreover, graphene, GOs, and reduced GOs are also potential options for water quality sensors.[17] GOs also exhibit anti-corrosion properties because they do not allow the diffusion of small atoms or compounds.[18] These anti-corrosion properties are useful as a coating for certain materials and infrastructure used in the drinking water treatment process. Recent testing with 3-D

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10. CNTs used in sensors enable them to detect and quantify contaminants down to a few ions at the single particle level. Nagar & Pradeep, *supra* note 4, at 6425. This is because CNTS promote analyte-sensor interactions and electron transfer. Xiaolei Qu et al., *Nanotechnology for a Safe and Sustainable Water Supply: Enabling Integrated Water Treatment and Reuse*, 46 ACCTS. CHEM. RSCH. 834, 836 (2012).

11. Weilan Zhang, Dongqing Zhang & Yanna Liang, *Nanotechnology in Remediation of Water Contaminated by Poly- and Perfluoroalkyl Substances: A Review*, 247 ENV'T POLLUTION 266, 267 (2019). Although CNTs have stronger adsorption potential, PFAS adsorption by CNTs was lower compared to conventional adsorbents due to the prevention of micelle formation by the parallel alignment between the adsorbed PFAS chain and the CNT. *Id.*

12. *Id.* at 268. The pH and pKA (acid dissociation constant) of the PFAS are important in this respect. *Id.*

13. *See* Liu, *supra* note 6, at 1269 (finding CNTs function as photocatalysts through the formation of reactive oxygen species). CNTs' wide specific region, selective degradation, strong thermal stability, and acidic/basic media resistance all combine to make them an excellent support for catalysts. Bharti Arora & Pankaj Attri, *Carbon Nanotubes (CNTs): A Potential Nanomaterial for Water Purification*, 4 J. COMPOSITES SCI. 135, 142 (2020).

14. *See* Liu, *supra* note 7, at 3.

15. *See* Liu, *supra* note 7, at 4 (finding even with higher flow rates, Na+ and Cl- were still effectively retained).

16. *See* B.L. Dinesha et al., *Removal of Pollutants from Water/Waste Water Using Nano-Adsorbents: A Potential Pollution Mitigation*, 6 INT. J. CURRENT MICROBIOLOGY & APPLIED SCIS. 4868, 4870 (2017) (providing an example that rGO-magnetite and GO-ferric hydroxide have been used for arsenic removal, one of the many contaminants regulated by the EPA).

17. Ana Zubiarrain-Laserna & Peter Kruse, *Review—Graphene-Based Water Quality Sensors*, 167 J. ELECTROCHEM. SOC'Y 1, 3 (2020). While graphene allows for highly sensitive sensors due to the structure's ability to easily interact with surroundings and transduce the interactions into readable resistivity, graphene oxide offers sensors more selectivity allowing to target detection of specific contaminants. *Id* at 6.

18. Mădălina-Ioana Necolau & Andreea-Mădălina Pandele, *Recent Advances in Graphene Oxide-Based Anticorrosive Coatings: An Overview*, 10 COATINGS 1149, 1150 (2020). Furthermore, graphene oxide can be modified with hydrophobic features resulting in the improvement of corrosion resistance of composite materials. *Id.* at 1151.

printing technology has shown that GO nanotechnologies can be scaled up in size to be used in larger drinking water treatment facilities.[19]

2. Nanometal and Nanometal Oxides

Nanometals such as nanosilver are also potentially useful in drinking water treatment systems, and to date have been primarily used in point-of-use ("POU") water disinfection systems for their antimicrobial effects.[20] Antimicrobial performance of silver nanomaterials is dependent on a variety of factors and conditions including the size, morphology, and surface chemistry of the nanosilver, as well as the condition of the water to be treated.[21] Silver nanomaterials can also be added to filters at ceramic water filtration factories for higher pathogen removal: nano-enhanced filters remove 97.8–100% of Escherichia coli ("E. coli") and improve overall filter efficiency.[22]

Nano-titanium dioxide ("nano-TiO_2") is a nanometal oxide which, similarly to nanosilver, is used in drinking water treatment applications for its disinfection and decontamination abilities.[23] Disinfection using nano-TiO_2 is typically more effective than traditional water treatment technologies: three times stronger than chlorine and one and one-half times stronger than ozone.[24] In addition to the disinfection process, nano-TiO_2 can be used for arsenic removal.[25]

Nano zero valent iron ("n-ZVI") and magnetic nanomaterials also fall under the nanometal category.[26] N-ZVI can remove dissolved heavy metals, polychlorinated organic pollutants, and inorganic ions from water.[27]

19. Melvin Bankhead III, *Finally, 3D-Printed Graphene Aerogels for Water Treatment*, UBNOW (Apr. 16, 2021), https://perma.cc/CGL5-83VQ.

20. Gehrke et al., *supra* note 2, at 4–5.

21. Konstantinos Simeonidis et al., *Inorganic Engineered Nanoparticles in Drinking Water Treatment: A Critical Review*, 2 ENV'TL SCI.: WATER RSCH. & TECH. 43, 52 (2016).

22. Hongyin Zhang, *Application of Silver Nanoparticles in Drinking Water Purification*, 29 OPEN ACCESS DISSERTATIONS 1, 12–13 (2013); *see* Pooja Patanjali et al., *Nanotechnology for Water Treatment: A Green Approach, in* GREEN SYNTHESIS, CHARACTERIZATION & APPLICATIONS NANOPARTICLES 491 (2019).

23. *See* Adawiyah J. Haider, Zainab N. Jameel & Imad H. M. Al-Hussaini, *Review on: Titanium Dioxide Applications*, 157 ENERGY PROCEDIA 17, 26 (2019) (finding nano-TiO_2 disinfects pathogens through the production of reactive oxygen species when illuminated by UV light).

24. *Id.* Disinfection by nano-TiO_2 is more energy consuming compared to nanosilver as it requires a UV source for activation of the photocatalytic process. Zhang et al., *supra* note 11, at 269. However, some research shows that a UV source only makes the photocatalytic degradation ability of nano-TiO_2 stronger, and that nano-TiO_2 is toxic even in the dark. J. MICHAEL DAVIS ET AL., U.S. ENV'T PROT. AGENCY, NANOMATERIAL CASE STUDIES: NANOSCALE TITANIUM DIOXIDE IN WATER TREATMENT AND IN TOPICAL SUNSCREEN 1-13 (2010).

25. DAVIS ET AL., *supra* note 24, at 1-12 (highlighting that nano-TiO_2 can convert arsenite [As(III)] to arsenate [As(V)], a form more easily removed due to its lower solubility).

26. Both are used for groundwater treatment and remediation. Magnetic nanoparticles increase osmotic pressure of draw solutions used in the forward osmosis processes. Gehrke et al., *supra* note 2, at 5.

27. Patanjali et al., *supra* note 22, at 493. As with many nanotechnologies, modifications of nZVI improve performance. Specifically, modifications of nZVI may increase stability, mobility, and

3. Nano-Adsorbents

Some particles at the nanoscale have strong adsorption capabilities and are therefore categorized as nano-adsorbents. Some of the aforementioned technologies, such as CNTs and magnetic nanoparticles, fall into this category. Nano-silica has shown efficiency in removing lead,[28] as well as acting as a biosorbent.[29] Nano-alumina, another nano-adsorbent, has shown high removal efficiencies for lead, selenium, Fe(II), Cr(III), and aluminum.[30] Additionally, nano-alumina is used for defluorination.[31] Nano-adsorbents are currently being used in POU systems and decentralized applications.[32]

B. THE FATE OF NANOMATERIALS IN THE ENVIRONMENT

These property and capability differences have important implications for regulation and risk management of ENMs by policymakers, especially in the context of drinking water treatment applications. In part, this is because ENMs are difficult for traditional wastewater treatment processes to remove,[33] potentially resulting in permitting violations at high enough concentrations.[34] The presence of some nanoparticles may even inhibit traditional treatment processes such as activated sludge.[35]

Despite the importance of the issue, little attention has been paid to the possibility of whether and how ENMs are released, or the ultimate destination of

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reactivity, while reducing aggregation and passivation. Xing Chen et al., *Review on Nano Zerovalent Iron (nZVI): From Modification to Environmental Applications,* 94 IOP CONF. SERIES: EARTH ENV'T SCI. 51, 53 (2017).

28. Nguyen X. Huan, *Nanosilica Synthesis and Application for Lead Treatment in Water*, 9 J. VIET. ENV'T 255, 258 (2018). Extracted nanosilica from a chemical called tetraethoxysilane ("TEOS") has high lead removal efficiency—96.17% removal efficiency after an hour with an initial concentration of ten parts per million. *Id.*

29. Mohamed E. Mahmoud et al., *Immobilization of* Fusarium vericilliodes *Fungus on Nano-silica (NSi–Fus): A Novel and Efficient Biosorbent for Water Treatment and Solid Phase Extraction of Mg(II) and Ca(II)*, 134 BIORESOURCE TECH. 324, 329 (2013). Nano-silica from rice husk was also combined with a *Fusarium vertilliodes* fungus creating a new biosorbent. *Id.*

30. L. Kaledin, F. Tepper & H. Mowers, *Filtration of Soluble Metals and Organic Contaminants by Nanoalumina Fiber Filters*, 72 ANNUAL INT'L WATER CONFERENCE 361, 364 (2011).

31. Parimala Shivaprasad et al., *Synthesis of Nano Alumina for Defluoridation of Drinking Water*, 13 NANO-STRUCTURES & NANO-OBJECTS 109, 109 (2018). Fluoridation is the process of decreasing fluoride levels in drinking water. *Id.*

32. Gehrke et al., *supra* note 2, at 2.

33. *See* Zhihua Liang, Atreyee Das & Zhiqiang Hu, *Bacterial Response to a Shock Load of Nanosilver in an Activated Sludge Treatment System*, 44 WATER RSCH. 5432, 5437–38 (2010) (finding the nanoform of silver disrupted traditional wastewater treatment techniques more significantly than macroform silver).

34. *See* Lynn Bergeson, *Managing Nanotechnology Business Risks*, 39 ABA TRENDS 1, 1 (2010) (highlighting that ENMs may circumnavigate traditional barriers and cause biological harms).

35. Liang et al., *supra* note 33, at 5433.

ENMs in the environment.[36] There are various challenges that are currently inhibiting a strong understanding of the release and final destination of ENMs. One hurdle is difficulty identifying engineered nanoparticles, specifically when it comes to differentiating them from natural nanoparticles ("NNPs").[37] Other uncertainties include multiple points of potential release into the environment, various transformation processes of ENMs, and the often-classified nature of competitively developed nanotechnology.[38]

ENMs are typically released into the environment in modified forms. Some applications directly release ENMs into the environment, most notably direct injection of nano-TiO_2 for water treatment and n-ZVI for ground water remediation.[39] Because some ENMs, such as carbon and metal oxides, are nonbiodegradable, they aggregate and settle, meaning that their fate strongly depends on their solubility and dissolution rates in aquatic systems.[40]

ENMs also change and react to their surroundings, making the analysis of fate and transport even more complex. For example, ENMs are more likely to aggregate in hardwater and seawater, compared to freshwater.[41] Another consideration is that a receiving water itself has different conditions at different depths, so not only can a nanoparticle be altered when first making contact with the water, it can change again at various depths as it settles due to variations in temperatures, salinity, and natural organic matter content.[42] Moreover, ENMs are necessarily altered by the very purposes they serve. CNTs that adsorb water pollutants

36. Bernd Nowack, *Evaluation of Environmental Exposure Models for Engineered Nanomaterials in a Regulatory Context*, 8 NANOIMPACT 38, 42 (2017).

37. Chang M. Park et al., *Occurrence and Removal of Engineered Nanoparticles in Drinking Water Treatment and Wastewater Treatment Processes*, 46 SEPARATION & PURIFICATION REVS. 255, 259 (2016). Currently, fractionation techniques coupled with spectroscopy and microscopy are the most common options for identification of ENMs, however the ENM's ability to change when exposed to different environments and conditions makes the process more difficult. *Id.* at 259–60. Analytical methods to differentiate between ENMs and NNPs are relatively new. Westerhoff et al., *Low Risk Posed by Engineered and Incidental Nanoparticles in Drinking Water*, 13 NATURE NANOTECHNOLOGY 661, 661 (2018).

38. Park et al., *supra* note 37, at 257.

39. *Id.* at 257–58. nZVI easily aggregates resulting in a loss of reactivity and mobility. Xiaolei Qu et al., *Nanotechnology for a Safe and Sustainable Water Supply: Enabling Integrated Water Treatment and Reuse*, 46 ACCOUNTS CHEM. RSCH. 834, 838 (2012).

40. Mehrnoosh Ghadimi, Sasan Zangenehtabar & Shahin Homaeigohar, *An Overview of the Water Remediation Potential of Nanomaterials and Their Ecotoxicological Impacts*, 12 WATER (SWITZERLAND) 1150, 1161 (2020). In aquatic systems, the fate of a nanoparticle is primarily influenced by aquatic colloids, such as viruses/bacteria and inorganic fractions. *Id.*

41. Khan et al., *supra* note 1, at 927. When a nanoparticle is coated by a humic substance, the probability for aggregation is decreased due to the stabilization of the nanoparticle's surface charge. Ghadimi et al., *supra* note 40, at 1162. Several types of aqueous organic matter, such as tannic, fulvic, and human acids, not only impact aggregation, but also influence a nanoparticle's sorption ability to various surfaces. Konstantinos Simeondis et al., *Implementing Nanoparticles for Competitive Drinking Water Purification*, 17 ENVT'L CHEMISTRY LETTERS 705, 715 (2018).

42. Ghadimi et al., *supra* note 40, at 1162.

experience changes to their pore size, stability, hydrophobicity, surface, and functional groups.[43]

The ecotoxicity of ENMs is another open question, separate from fate and transport considerations. Several points seem clear. First, nanoparticles cause an effect when in contact with living organisms.[44] Second, these effects can be transferred to humans, either through accumulation in the food chain or trophic transference.[45] Third, toxicity varies depending on the type of nanoparticle, often depending on size, shape, and composition.[46] For example, metal nanoparticles seem to be more toxic than the metal ions themselves.[47] Contact with some types of nanoparticles impacts the development of lung fibrosis, mesothelial injury, and fibroblast formation in mice and rats.[48] Other ENMs can diffuse throughout a plant's structure, and impact plant functions such as photosynthesis, growth, and regeneration.[49] Although the risks to human health are not fully understood, some studies have suggested that certain ENMs may be toxic to humans—perhaps even more toxic than their macro-scale equivalents.[50]

To establish effective regulation that adequately accounts for risks to health and safety, decisionmakers need effective risk assessments to help provide information. Because ENMs exhibit unique behaviors, the risk assessments used to evaluate them should specifically account for certain considerations: (1) nanoform, (2) life cycle and exposure, (3) delivered dose, (4) bioaccumulation, (5) dissolution, and (6) durability.[51] In a 2018 study, researchers were only able to locate a single risk assessment framework which established these considerations and had the methods necessary for effective application; however, that framework was limited by current scientific knowledge.[52] This lack of data has led to governments applying established risk evaluation methods to ENM production. Three key remaining knowledge gaps related to ENM risk assessment include: (1) nanoparticles are currently identified using fractionation techniques in

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43. Rasel Das, Bey Fen Leo & Finbarr Murphy, *The Toxic Truth About Nanotubes in Water Purification: A Perspective View*, 13 NANOSCALE RSCH. LETTERS 183, 187 (2018).

44. *See* Simeondis et al., *supra* note 41, at 715. The resulting genetic damage can be transferred to future generations. Xun Luo et al., *Insights into the Ecotoxicity of Silver Nanoparticles Transferred from* Escherichia coli *to* Caenorhabditis elegans, 6 SCI. REPS. 1, 2 (2016).

45. Simeondis et al., *supra* note 41, at 715–16; Luo et al., *supra* note 44, at 1.

46. Das et al., *supra* note 43, at 184.

47. Sam Lekamage et al., *The Toxicity of Silver Nanoparticles (AgNPs) to Three Freshwater Invertebrates with Different Life Strategies:* Hydra vulgaris, Daphnia carinata, *and* Paratya australiensis, 6 FRONTIERS ENV'TL SCI. 1, 2 (2018).

48. *See* Simeondis et al., *supra* note 44, at 716. Similarly, TiO_2 NPs were shown to induce oxidative DNA damage, genotoxity, and clastogenicity in vivo in mice. Das et al., *supra* note 43, at 185.

49. Ghadimi et al., *supra* note 40, at 1163.

50. Bakand et al., *supra* note 5, at 125; Lekamage et al., *supra* note 47, at 2.

51. Agnes G. Oomen et al., *Risk Assessment Frameworks for Nanomaterials: Scope, Link to Regulations, Applicability, and Outline for Future Directions in View of Needed Increase in Efficiency*, 9 NANOIMPACT 1, 6–9 (2018).

52. *Id.* at 2.

combination with microscopy or spectroscopy. Analytical methods to differentiate between ENMs and natural nanomaterials ("NNMs") are relatively recent and still being developed. (2) The probability and path of ENMs being released into the environment during different stages—from production, product use, to product disposal—are essentially unknown. ENMs can be released into the environment from multiple points, requiring more intricate studies. (3) ENMs' ability to be altered by the surrounding environment and conditions makes predicting transport and final destination complex. ENMs' settling rate strongly depends on aggregation, which in turn depends on a variety of water characteristics. Additionally, ENMs can be altered by the contaminants they remove. More research as to what factors impact ENMs and how their fate can be accurately predicted is necessary.

The remainder of this paper explores current and future governance strategies for the use of nanotechnology in drinking water treatment applications.

II. GOVERNANCE REVIEW: USE OF NANOTECHNOLOGY IN DRINKING WATER TREATMENT SYSTEMS

In the face of uncertainty and data gaps coupled with inadequate governance, some ENMs may never achieve their promise. Innovators may be reluctant to develop and use them. Those which are developed may escape oversight at one or more life cycle stages.[53] Neither are good outcomes.

Effective governance of ENMs in drinking water treatment systems will require policymakers to overcome several unique challenges. Just as with macro-scale substances, concentrations of ENMs in the environment will likely increase in direct proportion to growing ENM usage.[54] Current water treatment plants remove more than 99% of naturally occurring particles on the nano-scale through physical processes.[55] However, the monitoring systems at most water treatment plants are designed to focus on larger particles in the 1–100 μm size.[56] Additionally, systems designed to focus on the nanoscale may have difficulty distinguishing NNPs, such as clays and organic fragments, from ENMs which have been intentionally introduced into water systems.[57] To further complicate identification and regulation, due to their size and properties ENMs are highly affected

53. Christian E. H. Beaudrie, Milind Kandlikar & Terre Satterfield, *From Cradle-to-Grave at the Nanoscale: Gaps in U.S. Regulatory Oversight along the Nanomaterial Life Cycle* 47 ENV'T SCI. TECH. 5524, 5529 (2013).

54. CATHRINE GANZLEBEN & STEFFEN F. HANSEN, ENVIRONMENTAL EXPOSURE TO NANOMATERIALS – DATA SCOPING STUDY i (2012).

55. Paul Westerhoff et al., *Overcoming Implementation Barriers for Nanotechnology in Drinking Water Treatment*, 3 ENV'TL SCI. NANO 1241, 1249 (2016).

56. *Id.*

57. *Id.*

by their surroundings which may give them a unique "environmental" identity.[58] These unique identities may cause the ENMs to interact differently than conventionally sized units of the same material in their movements through environmental systems.[59] Due to their small size and variability once introduced into ecological systems, an "upstream monitoring" approach to regulation, which regulates initial production instead of environmental concentrations, may be preferable.[60] In light of these challenges, existing governance efforts have produced results that are uneven at best, as described next.

A. EFFORTS AT FEDERAL GOVERNANCE

Currently, the Environmental Protection Agency ("EPA") is the federal agency in the United States that seems best suited to regulate ENM usage in drinking water treatment. The EPA has maintained that ENMs can be regulated under existing environmental statutes and regulations.[61] After the failure of EPA's voluntary Nanoscale Materials Stewardship Program ("NMSP"), the EPA has resorted to using mandatory, established programs for nanoscale monitoring. Of the EPA regulations that could affect water treatment, only the Toxic Substances Control Act[62] ("TSCA") has adopted changes focused on regulating ENMs,[63] while the Federal Insecticide, Fungicide, and Rodenticide Act[64] ("FIFRA") has proposed, but not adopted, nano-specific regulation measures.[65]

1. Voluntary Programs

The EPA garnered some support for a voluntary program after a specially created work group[66] recommended the creation of the Nanoscale Materials Voluntary Program ("NVP") in 2005. The NVP proposal was intended to apply to "pre-commercial new and existing chemical engineered nanoscale materials for which there is a clear commercial intent on the part of the developer,

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58. Iseult Lynch, *Water Governance Challenges Presented by Nanotechnologies: Tracking, Identifying and Quantifying Nanomaterials (the Ultimate Disparate Source) in Our Waterways*, 47 HYDROLOGY RSCH. 552, 556 (2015).

59. *Id.* at 556.

60. *Id.* at 559.

61. David A. Strifling, *Environmental Federalism and Effective Regulation of Nanotechnology*, 2010 MICH. ST. L. REV. 1129, 1170 (2010).

62. Toxic Substances Control Act, 15 U.S.C. §§ 2601–2692 (1976).

63. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 82 Fed. Reg. 3641, 3642 (Jan. 12, 2017) (codified at 40 C.F.R. pt. 704).

64. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y.

65. Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment, 76 Fed. Reg. 35,383 (proposed Jun. 17, 2011).

66. *See* Lynn L. Bergeson, *Good Governance: Evolution of the Nanoscale Materials Stewardship Program*, 4 NANOTECHNOLOGY L. & BUS. 473, 475 (2007) (explaining that the EPA requested assistance from the National Pollution Prevention and Toxics Advisory Committee in developing a voluntary pilot program for existing ENMs).

excluding such materials that are only at the research stage, or for which commercial application is more speculative or uncertain."[67] The NVP proposal included a Basic Program, which focused on risk management practices, and an In-Depth Program, which covered specific hazards of particular ENMs in addition to risk management practices.[68] The NVP would have required participants to sign up within six to twelve months, and then for Basic Program participants to submit risk management practice information within three months.[69] Remarkably, the NVP received near unanimous support in public meetings when the proposal was released.[70]

Upon the EPA's release of the NMSP for comment in 2007, certain industry leaders were still supportive of the idea of a voluntary program, but voiced a few reservations. The American Chemistry Council Nanotechnology Panel urged the EPA to enact more ambitious deadlines, with results being assessed in nine months instead of two years; the NanoBusiness Alliance supported the program but cautioned the EPA to be mindful of burdens a voluntary program places on small business; and the Dow Chemical Company supported the use of significant new use rules ("SNURs") to ensure risk reviews could be conducted on existing ENMs being used in novel ways.[71] The two year delay and modifications straying from the NVP's recommendations, including the lack of urgency showed by removing deadlines for groups to sign up, submit the required information, or apply basic risk management practices, led to criticism.[72] Additionally, critics pointed to lackluster voluntary programs that had been attempted in the United Kingdom and Denmark since the 2005 proposal.[73]

The EPA launched the NMSP in January 2008. Its stated intent was to encourage voluntary reporting of ENMs in production.[74] The goal was to provide the EPA with an understanding of which ENMs were being produced, in what quantities, how they were used, and what risks and hazards were associated with each ENM.[75] The NMSP was based on the NVP and included an option for ENM producers to participate in a Basic or an In-Depth Program.[76] Both the Basic and In-Depth Programs required participants to implement a risk management program and provide information about their practices.[77] All participants were required to report information about ENM production, with the In-Depth Program requiring

67. *Id.* at 476 (citing NPPTAC, Overview Document on Nanoscale Materials).
68. *Id.*
69. *Id.* at 478.
70. *Id.* at 480.
71. *Id.* at 481.
72. *Id.* at 480.
73. *Id.* (highlighting the United Kingdom's program had fewer than ten participants and Denmark's program yielded so little information there were no published results).
74. *See* Bergeson, *supra* note 66, at 478.
75. *Id.*
76. *Id.* at 479.
77. *Id.*

a greater amount of detail about subsets of the information reported in the Basic Program.[78] The EPA stated that it would review the data, that it *might* publish an interim program summary after one year, and that it *would* publish a detailed evaluation of the program after two years, including determinations about the future direction of the basic reporting phase.[79] In retrospect, there appear to have been few benefits to companies participating in the program.

Overall, the program ended in 2009 as a disappointment, having only received input from thirty-one companies on 132 ENMs on the market (less than 10% of available commercial ENMs at the time).[80] Only four companies participated in the In-Depth Program and a substantial portion of the Basic submissions did not include the requested exposure or hazard-related data.[81] Upon reviewing the failed program, it becomes clear that companies believed participation involved substantial costs but provided few benefits, especially given the uncertainty of how the EPA would use the data submitted. Meanwhile, the EPA did not have detailed information about which companies were creating ENMs, so it was unable to reach out to potential producers to encourage participation.[82] The program's failure led the EPA to move regulatory attempts away from voluntary programs and, instead, to modify existing mandatory regulations to include nanotechnology development.

2. Toxic Substances Control Act

The Toxic Substances Control Act ("TSCA") is the most robust means the EPA currently has to monitor the manufacture and distribution of ENMs in the United States.[83] TSCA is not limited by the medium or manner in which the chemicals are used.[84] Any chemical produced as a pesticide, food, food additive, drug, or cosmetic is not subject to TSCA.[85] TSCA defines "chemical substance" extremely broadly as: "any organic or inorganic substance of a particular molecular identity, including . . . (1) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (2) any element or uncombined radical."[86] This expansive definition, along with the EPA's historic application of TSCA, led a majority of scholars to find that ENMs would fall into the definition of chemical and be subject to TSCA

78. *Id.*
79. *Id.*at 480.
80. Kenneth W. Abbott, Gary E. Marchant & Elizabeth A. Corley, *Soft Law Oversight Mechanisms for Nanotechnology*, 52 JURIMETRICS J. 279, 292 (2012).
81. *Id.*
82. *Id.*
83. Gregory Mandel, *Nanotechnology Governance*, 59 ALA. L. REV. 1323, 1347 (2008).
84. *Id.* at 1347.
85. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 82 Fed. Reg. 3641, 3642 (Jan. 12, 2017) (codified at 40 C.F.R. pt. 704).
86. 15 U.S.C. § 2602(2)(A) (1976).

regulations.[87] With respect to drinking water treatment, TSCA would cover any ENMs designed for a wide range of commonly used treatment techniques, such as water filtration, pollutant separation and degradation, and the detection of contaminants.[88] The relevant sections of TSCA utilized by the EPA to monitor and control chemicals are sections four (testing for existing chemicals); five (pre-manufacture screening for new chemicals); six (controlling and limiting known risks); and eight (maintaining chemical inventories).[89] As discussed next, sections four, five, and six all have flaws that make regulation of ENMs difficult, although the EPA has found some success in gathering information under section eight.

TSCA section four authorizes the EPA to develop test data on existing chemicals when those chemicals either (1) "may present an unreasonable risk" during manufacture, processing, distribution, use, or disposal or (2) are produced in very large volumes that increases potential for substantial human or environmental exposure.[90] An Interagency Testing Committee ("ITC") is responsible for designating a candidate list of no more than fifty chemicals for test rules to the EPA every six months.[91] When determining if additional testing data should be required for a chemical, the EPA considers eight factors:

> (1) quantity of the substance to be manufactured, (2) quantity of the chemical in environmental releases, (3) number of people who will be exposed occupationally and the duration of exposure, (4) extent of non-occupational human exposure, (5) similarity of the chemical to any other chemical known to present an unreasonable risk, (6) existence of data concerning environmental or health effects of the chemical, (7) the quantity of information to be gained by testing, and (8) the availability of facilities and personnel for performing testing.[92]

The ITC released the seventy-fourth report in April 2021, the first since January 2014, and there are currently no nano-specific chemicals listed in recommendations for additional testing data.[93]

TSCA section five requires manufacturers of substances to provide a pre-manufacture notice for any new substance, or any substance being used in a

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87. *See* Reut Snir, *Regulating Risks of Nanotechnologies for Water Treatment*, 38 ENV'T L. REP. 10233, 10240 (2008); Mandel, *supra* note 83, at 1347; Bergeson, *supra* note 66, at 474; Michelle Reese, *Nanotechnology: Using Co-Regulation to Bring Regulation of Modern Technologies into the 21st Century*, 23 HEALTH MATRIX 537, 550–51 (2013).

88. Snir, *supra* note 87, at 10235. Any ENMs designed to disinfect water would fall under FIFRA's purview. *Id.* at 10244.

89. David M. Bearden et al., *Environmental Laws: Summaries of Major Statutes Administered by the Environmental Protection Agency*, 7-5700 CONG. RSCH. SERV. 97–98 (2013).

90. *Id.* at 98.

91. *Id.*

92. *Id.*

93. *See* Seventy-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments, 86 Fed. Reg. 22414 (Apr. 27, 2021).

significant new way, at least ninety days prior to production.[94] When a manufacturer reports to the EPA, the following information about the substance must be disclosed: (1) specific chemical identity, (2) material characterization, (3) physical chemical properties, (4) production volume, (5) intended use, (6) methods of manufacturing and processing, (7) exposure and release information, and (8) existing information concerning environmental and health effects.[95] There are no standardized requirements for testing on environmental or health effects at this time, but TSCA only requires existing information or information the manufacturer reasonably should have known to be reported.[96] The EPA does not require blanket testing requirements for new chemicals out of a concern that it may stifle innovation by requiring unnecessary tests for all chemicals.[97]

TSCA section six gives the EPA the authority to limit the production of any substance that poses an unreasonable risk to health and safety or the environment.[98] However, the EPA bears the burden to provide substantial evidence that the chemical produces an unreasonable risk to the health and safety of the public or environment, which has been a historically difficult feat.[99] Additionally, the EPA is required to use the least restrictive means necessary in order to not unduly burden the industry.[100] *Corrosion Proof Fittings v. EPA* exemplifies just how difficult this burden is to meet after the court held the EPA failed to prove asbestos should be banned from manufacture due to unreasonable risk of injury.[101] During trial, the EPA provided the court with nearly ten years of research in a forty-five thousand page record when making its case in *Corrosion Proof Fittings*, but the court deemed there to be insufficient evidence to prove a complete ban was the appropriate remedy.[102] Due to the difficulty of showing the required danger, the EPA rarely attempts to utilize limits on manufacturing, much less an outright ban.[103]

Due to limited resources, the EPA often relies heavily on the testing done by manufacturers in making its determinations about a substance's safety.[104] Because nanotechnology is still in its infancy, there is not an established body of

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94. 15 U.S.C. § 2604.

95. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 82 Fed. Reg. 3641, 3645 (Jan. 12, 2017) (codified at 40 C.F.R. pt. 704).

96. 40 C.F.R. § 704.20.

97. Bearden et al., *supra* note 89, at 99.

98. 15 U.S.C. § 2605.

99. Bearden et al., *supra* note 89, at 99; Reese, s*upra* note 87, at 553.

100. Reese, s*upra* note 87, at 554.

101. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1123, 1229 (5th Cir. 1991), *opinion clarified* (Nov. 15, 1991).

102. Reese, s*upra* note 87, at 557.

103. Robert B Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, 6 ENV'T L. 99, 122 (1999). After *Corrosion Proof Fittings*, bans or limitations of specific chemical hazards generally require amendments to TSCA. *Id.*

104. Reese, s*upra* note 87, at 553.

knowledge for the EPA to effectively cross-reference information provided by the manufacturer when making a determination.[105] However, current health and safety studies rarely address nano-unique properties, and any current models used to predict ENM toxicity would likely compare the ENM to macro-sized chemicals with a similar molecular structure, but that would not account for any novel properties existing in the substance's nanoscale equivalent.[106] This could be problematic because many ENMs are manufactured or coated in ways that produce different properties than their macro counterparts.[107] Because the EPA relies on the manufacturers' risk information to determine if an ENM is unsafe, there is little incentive for manufacturers to engage in voluntary, in-depth risk assessments.[108] For these reasons, the EPA may have a particular difficulty in determining the true safety effects of an ENM and even more trouble proving it definitively to a court.

TSCA section eight charges the EPA with the task of developing and maintaining an inventory of all chemicals manufactured and processed in the United States.[109] In 2017, the EPA enacted an information gathering rule under TSCA § 8(a) to refine reporting requirements for manufacturers of ENMs.[110] Under the new EPA guideline, nanotechnology is defined as (1) a material that is solid at 25°C and standard atmospheric pressure, (2) is intentionally manufactured or processed to be at the 1–100 nm scale in at least one-dimension, and (3) exhibits a unique and novel property due to its size.[111] There is a one-time reporting requirement for any person intending to manufacture or process a new reportable substance.[112] Although the EPA has requested a report at least 135 days prior to manufacture if a producer is intending to make reportable substance, the regulation imposes a hard deadline of reporting at least thirty days before manufacturing can begin.[113] The rule also removed the mass and volume reporting thresholds for nanotechnology because ENMs are manufactured on a smaller scale and the current cutoffs were inappropriate to measure an appreciable amount of nanoscale production.[114]

There are several significant exceptions to the reporting requirements for nanotechnology. First, small manufacturers, defined as businesses with a gross income

105. Snir, s*upra* note 87, at 10241–42.
106. *Id.* at 10241.
107. *Id.* at 10246.
108. Reese, s*upra* note 87, at 553.
109. *See* 15 U.S.C. § 2607(a)(1) (2019); Bearden et al., *supra* note 89, at 100.
110. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 82 Fed. Reg. 3641, 3645 (Jan. 12, 2017) (codified at 40 C.F.R. pt. 704).
111. 40 C.F.R. § 704.20.
112. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 82 Fed. Reg. 3641, 3645 (Jan. 12, 2017) (codified at 40 C.F.R. pt. 704).
113. *Id.*
114. 40 C.F.R. § 704.20 (omitting any mass requirement threshold for reporting).

of less than $11 million per year (which includes any parent company income), are not required to report the manufacture of ENMs.[115] Second, any process where less than 1% of the manufactured substance (measured by weight) falls into the 1–100 nm scale does not meet reporting requirements.[116] Third, if the ENM's small size enhances existing properties but does not exhibit unique and novel properties, there is no reporting required for a separate nanoform.[117] Fourth, if a manufacturer is only making small quantities exclusively for the purposes of research and development, they are exempt from reporting the manufacture.[118] Fifth, ENMs that have already been reported on or after January 1, 2005 do not need to be reported again unless it is a new discrete form.[119] Finally, if a manufacturer participated in the NMSP, then any ENMs they reported at that time are exempt from requiring a duplicated report under TSCA, unless TSCA would require information about the ENM that was not required under NMSP.[120]

By modifying the information gathering rules regarding nanotechnology, the EPA has addressed some commentators' concerns on TSCA's efficacy in addressing nanotechnology. The EPA curtailed a significant concern as to whether ENMs would fall under TSCA's reporting requirements as new chemical substances. The EPA originally determined ENMs would not be treated as new chemical substances subject to premanufacture notification requirements if there was a similar macro chemical structure and composition listed.[121] Additionally, prior to the new rule adoption, reporting requirements to TSCA for a chemical were triggered by producing the chemical in excess of the mass threshold of more than 10,000 kg.[122] Due to their extremely small size, using mass production as a reporting requirement would create a large regulatory gap for ENMs.[123] The new rule focuses on the ENM's use and no longer requires a minimum amount produced to be enforced by the rule. By now requiring manufacturers of ENMs to report the chemicals produced, the EPA has compiled information specifically regarding ENMs they did not have access to for over a decade. Early industry

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115. 40 C.F.R. § 704.20.

116. 40 C.F.R. § 704.20.

117. 40 C.F.R. § 704.20.

118. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 82 Fed. Reg. 3641, 3642 (Jan. 12, 2017) (codified at 40 C.F.R. pt. 704).

119. 40 C.F.R. § 704.20 "Discrete forms" differ in one or more of the following characteristics: (1) A change is due to change in process to effect size change, size variation is greater than 7 standard deviations of mean particle size, and changes in a least one of the following properties: Zeta potential, specific surface area, dispersion stability, or surface reactivity that is greater than 7 times the standard deviation of measured value; (2) if there is a different morphology (ring/wire/sphere/fiber/etc.) of the same nanotech; and (3) if the substance is coated with another chemical substance or mixture at the end of manufacturing that consists of a different chemical substance or mixture. *Id.*

120. 40 C.F.R. § 704.20.

121. Mandel, s*upra* note 83, at 1350.

122. *Id.* at 1351.

123. Strifling, s*upra* note 61, at 1171.

reaction to the rule emphasized the potentially onerous nature of the recordkeeping and reporting requirements, with one group reporting an estimate of 175 hours to prepare a single report.[124]

3. Federal Insecticide, Fungicide, and Rodenticide Act

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") governs the sale and use of pesticide products in the United States. FIFRA broadly defines a pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."[125] In reference to water treatment, FIFRA could be used to regulate any ENMs designed to purify water by treating contaminants like bacteria, microbes, or algae.[126] The term pesticide includes antimicrobials (e.g., sterilants, disinfectants, sanitizers) in addition to various other substances used to control pests or nuisance growths in water.[127] Any pesticide or device that makes antimicrobial claims of efficacy must be registered under FIFRA.[128]

FIFRA defines a "pesticide device" as an instrument or contrivance (without a chemical substance) that is used to destroy, repel, trap or mitigate any pests such as insects, weeds, rodents, animals, birds, mold/mildew, bacteria and/or viruses.[129] Pesticide devices are regulated under FIFRA, but are not required to be registered as pesticides.[130] If a drinking water treatment device uses any substance intended to disinfect water and it does not work solely by a physical means (electricity, light, mechanics), then it is considered a product and must be registered as a pesticide device.[131] For example, if a device used ENMs for absorption purposes, but an ultraviolet light for disinfection, it would likely be categorized as pesticide device. However, if a device used nano-TiO_2 along with ultraviolet light for disinfection, it would require registration as a pesticide device.

Product manufacturers of a pesticide must register with FIFRA before the product is distributed or sold in the United States, which ensures that pesticides that are used properly will not cause unreasonably adverse effects on the environment or human health.[132] Registration involves collecting scientific data on the

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124. AM. COATINGS ASS'N, ACA GUIDANCE ON U.S. EPA'S NANOREPORTING RULE: NANOSCALE MATERIALS REPORTING AND RECORDKEEPING REQUIREMENTS UNDER TSCA 2 (2017), https://perma.cc/Y88D-HQ6H.

125. 7 U.S.C. § 136(u).

126. Snir, s*upra* note 87, at 10246.

127. Bearden et al., *supra* note 89, at 111.

128. OFF. OF PESTICIDE PROGRAMS, EPA, QUICK GUIDE FOR DISINFECTANT PRODUCTS FOR DRINKING WATER USE BY PUBLIC WATER SYSTEMS 3 (2017).

129. 7 U.S.C. §§ 136(h).

130. *See Pesticide Devices: A Guide for Consumers*, EPA, https://perma.cc/66X9-B95S (last visited Oct 25, 2021).

131. *See id.*

132. 7 U.S.C. § 136a(a); OFF. OF PESTICIDE PROGRAMS, *supra* note 128, at 1.

ENM's toxicity and behavior in the environment.[133] The EPA can demand strict testing requirements from manufacturers by requiring data from a battery of more than 100 different tests.[134] The same substance may be required to be registered for each unique application if used in multiple, different ways.[135] If any new health information arises after production and release, the manufacturer is required to disclose all new pertinent information as it would on the initial application.[136] Additionally, all registered pesticides are reviewed and must be re-registered every fifteen years.[137] For novel substances that may not have enough scientific data available, the EPA can temporarily register the pesticide for a reasonable period of time to generate the required information, but only if the use of the pesticide during the period will not cause unreasonable adverse effects on the environment and the use of the pesticide is in the public interest.[138]

Some attempts to use FIFRA to provide conditional registrations for types of nanosilver have run into resistance from the courts due to a lack of evidence to support the registration.[139] This lack of data to support the EPA's attempt to assist burgeoning ENMs could be a hindrance to innovation because courts have required a higher burden of proof to allow a conditional registration of the product.

The EPA issued a proposed rule for reporting requirements specific to ENMs under FIFRA on June 17, 2011.[140] The proposal included two potential approaches to obtain information about ENMs in already registered pesticide products.[141] The first, and EPA-preferred, option would have required reporting under FIFRA section 6(a)(2).[142] Section 6(a)(2) requires manufacturers to submit information regarding pesticides present in products and their potential effects on humans or the environment.[143] The reporting requirements would apply retroactively to existing pesticides and all future pesticide products that contain ENMs.[144] The second option would have allowed the EPA to obtain information using Data Call-In notices under FIFRA section 3(c)(2)(B).[145] Although no final

133. Bearden et al., *supra* note 89, at 111.
134. *Id.*
135. *Id.*
136. *See* 7 U.S.C. § 136a(c)(2)(B).
137. Snir, s*upra* note 87, at 10,246.
138. 7 U.S.C. § 136a(c)(7)(C).
139. Nat. Res. Def. Council v. EPA, 857 F.3d 1030, 1034 (9th Cir. 2017); Lynn L. Bergeson & Timothy D. Backstrom, *Appellate Court Vacates Conditional Nanosilver Registration*, A.B.A. SEC. ENV'T, ENERGY & RES. PCRRTK NEWSL. 9, 10 (Aug. 2017).
140. Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment, 76 Fed. Reg. at 35,383 (proposed Jun. 17, 2011).
141. *Id.* at 35,384.
142. *Id.*
143. 7 U.S.C. § 136d(a)(2).
144. Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment, 76 Fed. Reg. at 35,383 (proposed Jun. 17, 2011).
145. *Id.*

rule was adopted, there have been examples of the EPA using existing FIFRA regulations to control the use of nanosilver as a pesticide in multiple products, from washing machines to resealable food containers.[146]

When attempting to regulate ENMs, the EPA has relied on TSCA and FIFRA the most. Both would affect the production and implementation of ENMs to treat drinking water. TSCA would require registration before beginning to produce any ENMs that would be used for non-disinfectant purposes. FIFRA would require the ENMs be registered before use as a pesticide. Either way, manufacturers and producers would have to notify the EPA of any ENMs used, and their known risks, before a viable water treatment device could be marketed. The effectiveness of these provisions depends on the regulated community's compliance levels, the EPA's administrative ability to analyze and respond to the information submitted, and the EPA's enforcement capacity in the event of noncompliance.

4. Safe Drinking Water Act

The Safe Drinking Water Act ("SDWA") regulates contaminant levels in surface and ground water intended for human consumption. The SDWA is designed to control contaminant levels in drinking water.[147] The SDWA applies to all Public Water Systems ("PWSs") in the United States by setting Maximum Contaminant Levels[148] ("MCLs") and monitoring requirements[149] for water sources. Although there is potential for the EPA to include ENMs as controlled contaminants in the future, there are currently no MCLs set specifically for nanomaterials, natural or engineered, however there are MCLs set for elements commonly used in nanotechnology.[150] There is a concern that using ENMs in drinking water treatment will lead to their leaching into the drinking water supply. Due to their extremely small size and ability to bypass certain biological safeguards (such as the blood-brain barrier) there are understandable concerns that ENMs may have a disproportionate impact on health, even in quantities lower than the MCLs for their corresponding macro elements.[151]

Every five years, the EPA must make new regulatory determinations on a least five new contaminants to review for possible inclusion on the Drinking Water Contaminant List.[152] In addition to making determinations on regulation for five

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146. Snir, s*upra* note 87, at 10245; David L. Wallace & Justin A. Schenck, *EPA Targets Nanotechnology: Hi-Ho, Nanosilver, Away?*, 11 NANOTECHNOLOGY L. & BUS. 207, 208 (2014).

147. 42 U.S.C. §§ 300f–300j-26; Bearden et al., *supra* note 89, at 41.

148. 42 U.S.C. § 300g-1.

149. 42 U.S.C. § 300g-7.

150. Drinking Water Contaminant Candidate List 4-Final, 81 Fed. Reg. 81,099, 81,103–04 (Nov. 17, 2016).

151. Dario Picecchi, *Tiny Things with a Huge Impact: The International Regulation of Nanomaterials*, 7 MICH. J. ENV'T & ADMIN. L. 447, 455 (2018).

152. 42 U.S.C. § 300g-1.

contaminants, the EPA also issues a list of unregulated contaminants for PWSs to monitor every five years.[153] The most recent contaminant list ("CCL4") was finalized in November 2016.[154] There were ninety-seven chemicals and twelve microbial contaminants on the list.[155] Of the five contaminants on the CCL4, the EPA determined to add two to the regulation list in March 2021: perfluorooctanesulfonic acid ("PFOS") and perfluorooctanoic acid ("PFOA").[156] There have not been any nano-specific contaminants proposed for regulation as of CCL4, so there are currently no nanotechnologies being regulated or monitored under SDWA.[157]

For ENMs to thrive in the United States for water treatment use, developers must prove that the technology is able to effectively address contaminants to keep them below the MCLs set by the SDWA and remain cost effective while doing so. A PWS will not be able to incorporate nanotechnology into its treatment battery until it is proven effective and is unlikely to do so if the technology is overly expensive.[158] The EPA and state governments work together to ensure regulatory compliance for the PWSs.[159] A vast majority of PWSs in the United States serve less than 500 people.[160] These systems, although they individually serve a small portion of the population, account for a majority of violations each year.[161] These small PWSs may be where ENM based water treatment technologies are first implemented in the public sector.

The EPA developed a protocol to help explore alternative technologies for PWSs that are having problems adequately monitoring or treating water.[162] In order for the state to determine if an alternative technology is a potential viable solution, the protocol recommends the PWS send the following to the state: (1) objective and verifiable test data to support a system's performance claims, (2) manufacturer's technical information and data, (3) verification of efficacy under site-specific conditions, and (4) availability of technical support.[163] There is an emphasis on estimates for operational and maintenance costs, as well as initial costs, because the continual upkeep of a cheaper system may not be economical in the long term.[164] Developers of alternative water treatment technologies would

153. 42 U.S.C. § 300g-1.
154. Drinking Water Contaminant Candidate List 4-Final, 81 Fed. Reg. at 81,100.
155. *Id.* at 81,102.
156. Announcement of Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 86 Fed. Reg. 12,272, 12,272 (Mar. 3, 2021) (codified at 40 C.F.R. pt. 141).
157. Drinking Water Contaminant Candidate List 4-Final, 81 Fed. Reg. at 81,103–04.
158. Deanna T. Ringenberg, et al., *State Barriers to Approval of Drinking Water Technologies for Small Systems*, 109 J. AM. WATER WORKS ASS'N E343, E344 (2017).
159. Bearden et al., *supra* note 89, at 42.
160. EPA, WSG 90, ALTERNATIVE TECHNOLOGY APPROVAL PROTOCOL 2 (1996).
161. *Id.*
162. *See Id.*
163. *Id.* at 4–5.
164. *See id.* at 5–6.

do well to keep these priorities in mind to help potential customers easily provide the required documentation.

For most drinking water disinfectants, FIFRA works in conjunction with SDWA. The pesticide must be registered with FIFRA, which regulates the manufacture of a product. To register the product, the pesticide must include the amounts that would not cause an unreasonable risk in the environment or humans.[165] Just because a product is registered with FIFRA does not ensure it meets requirements to be used in PWSs under SDWA.[166] SDWA and FIFRA both play a part in making sure the technology employed by PWSs are safe and effective. The following figure, produced by EPA's Office of Pesticide Programs, illustrates the relationship between the two laws in this context:

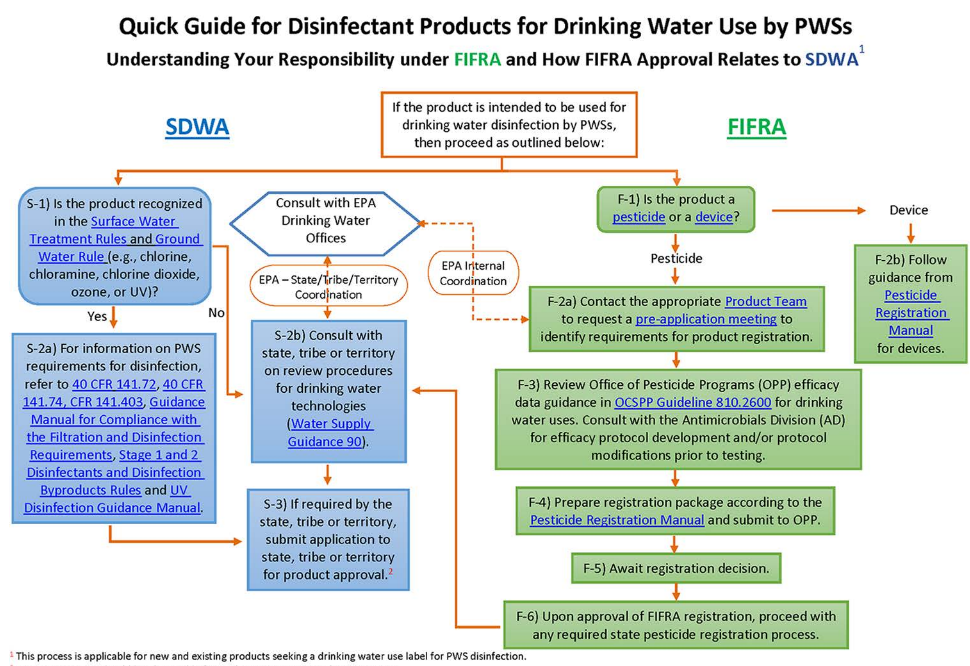

FIGURE 1[167]

165. 7 U.S.C. § 136a.
166. OFF. OF PESTICIDE PROGRAMS, *supra* note 128, at 1.
167. *Id.* at 2.

With respect to water treatment technology, SDWA would set the minimum standards that any ENM based drinking water treatment would need to meet. Any PWSs that wished to use a nanotechnology based POU or point-of-entry ("POE")[168] technology would need to be assured the technology would reliably meet or exceed all required standards set by SDWA before it could implement the technology. This process is typically subject to state approval requirements, as discussed in more detail below.

5. Other Potential Sources for EPA Authority

A few other laws may be a source for EPA authority over ENM use on a case-by-case basis. For example, the Clean Water Act ("CWA"),[169] Clean Air Act ("CAA"),[170] Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"),[171] and Resource Conservation and Recovery Act ("RCRA")[172] have all been used to regulate site specific pollutants. There are currently no nano-specific regulations in place in any of the above acts, but ENMs could still theoretically be regulated outside the drinking water context using the language of the acts as written, as is done with FIFRA. The main limitation in employing point-source enforcement currently is the lack of sensors which are precise enough to locate nanotechnology pollutants.

B. FOOD AND DRUG ADMINISTRATION REGULATIONS

In 2006, the Food and Drug Administration ("FDA") created a Nanotechnology Task Force to plan for nanotechnology regulation.[173] Unlike the EPA, where regulatory efforts are focused on the pre-manufacture stage of nanotechnology, the FDA utilizes a product-focused regulatory policy.[174] Most products are assessed based on the biological and mechanical context of the product and its intended use.[175] The exception to the FDA focusing on the end product is that food additives require a premarket review.[176] The FDA receives its authority to monitor bottled water and

168. EPA, 815-R-06-101, POINT-OF-USE OR POINT-OF-ENTRY TREATMENT OPTIONS FOR SMALL DRINKING WATER SYSTEMS 1-1 (2006). A point-of use device only treats water at a single source, usually with the intended use of consumption, such as a kitchen faucet. A point-of-entry device treats all the water entering a single building. *Id.*

169. 33 U.S.C. §§ 1251–1387.

170. 42 U.S.C. §§ 7401–7671q.

171. 42 U.S.C. §§ 9601–9675.

172. 42 U.S.C. §§ 6901–6992k.

173. John C. Monica, Jr., *FDA's Evolving Approach to Nanotechnology*, 67 FOOD & DRUG L.J. 405, 405 (2012).

174. *FDA's Approach to Regulation of Nanotechnology Products,* FDA, https://perma.cc/6FZF-DGUW (last visited Aug. 25, 2021).

175. *Id.*

176. *Id.*

food additives under the Federal Food Drug and Cosmetic Act ("FFDCA").[177] The FDA is much more limited in its regulation of water than the EPA after the passage of the SDWA in 1974.[178] The FDA's oversight is mostly limited to bottled water.[179] Additionally, the FDA regulates water used for food processing subject to the FFDCA.[180] However, a vast majority of the FDA's concern regarding ENMs is their relation to medicine, cosmetics, and food ingredients, not water treatment, and so regulation along those lines is not pertinent to the focus of this article.

C. STATE REGULATIONS

Whereas all companies that manufacture products in the United States are subject to the EPA's guidelines, some state and local governments have taken steps towards regulating nanotechnology. Multiple states have passed legislation peripherally touching on nanotechnology, but a vast majority of the laws passed are either aimed at defining nanotechnology or used to establish incentives funding research and development of emerging fields. The following states have passed some form of legislation regarding nanotechnology: (1) Arkansas,[181] (2) California,[182] (3) Connecticut,[183] (4) Florida,[184] (5) Illinois,[185] (6) Indiana,[186] (7) Kansas,[187] (8) Maryland,[188] (9) Massachusetts,[189] (10) Michigan,[190] (11) Minnesota,[191] (12) Missouri,[192] (13) Nebraska,[193] (14) New Jersey,[194] (15) New

177. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 348–49.

178. FDA & EPA, MOU 225-79-2001, MEMORANDUM OF UNDERSTANDING BETWEEN THE EPA AND THE FDA (June 22, 1979), https://perma.cc/LVZ5-3MMK.

179. *FDA Regulates the Safety of Bottled Water Beverages Including Flavored Water and Nutrient-Added Water Beverages*, FDA (Sept. 22, 2018), https://perma.cc/2KGF-P9BK.

180. MOU 225-79-2001, *supra* note 178.

181. ARK. CODE ANN. § 14-144-204 (2007).

182. CAL. PUB. RES. CODE § 26003 (2020); CAL. HEALTH & SAFETY CODE § 25254 (2009).

183. CONN. GEN. STAT. § 4-124hh (2017); CONN. GEN. STAT. § 32-7f (2012).

184. FLA. STAT. § 220.196 (2017).

185. 35 ILL. COMP. STAT. 5/220 (2021).

186. IND. CODE § 5-28-10-4 (2005).

187. KAN. STAT. ANN. § 74-99b03 (2011); KAN. STAT. ANN. § 74-99b33 (2014); KAN. STAT. ANN. § 74-99b63 (2011); KAN. STAT. ANN. § 74-99b83 (2004); KAN. STAT. ANN. § 12-1770a (2017).

188. MD. CODE ANN., ECON. DEV. § 10-445 (2020); MD. CODE ANN., ECON. DEV. § 10-449 (2020).

189. MASS. GEN. LAWS ch. 64H, § 6 (2021); MASS. GEN. LAWS ch. 62, § 6 (2021); MASS. GEN. LAWS ch. 23I, § 1 (2006); MASS. GEN. LAWS ch. 23I, § 2 (2008); MASS. GEN. LAWS ch. 23I, § 4 (2010); MASS. GEN. LAWS ch. 23G § 27 (2010); MASS. GEN. LAWS ch. 63, § 31M (2009); MASS. GEN. LAWS ch. 63, § 38M (2014); MASS. GEN. LAWS ch. 63, § 38U (2009); MASS. GEN. LAWS ch. 40J § 4F (2006).

190. MICH. COMP. LAWS § 125.2088a (2015).

191. MINN. STAT. § 116J.8737 (2021).

192. MO. REV. STAT. § 348.251 (2020).

193. NEB. REV. STAT. § 77-6302 (2017).

194. N.J. STAT. ANN. § 52:9X-12 (West 2006): N.J. STAT. ANN. § 52:27C-97 (West 2013).

York,[195] (16) Oklahoma,[196] (17) Pennsylvania,[197] (18) Rhode Island,[198] (19) South Carolina,[199] (20) Texas,[200] (21) Virginia,[201] (22) West Virginia,[202] and (23) Wisconsin.[203] There are additionally some states that have established regulations in their administrative codes to address nanotechnology with economic programs: (1) Arkansas,[204] (2) Florida,[205] (3) Illinois,[206] (4) Oklahoma,[207] and (5) Texas.[208] There are also states that have developed administrative regulations regarding educational requirements involving nanotechnology: (1) New Mexico,[209] (2) West Virginia,[210] and (3) Texas.[211]

Of the states listed above, California has taken the most appreciable steps towards utilizing established state legislation and regulations to monitor ENMs, which could potentially be utilized in drinking water technology.[212] The California Department of Toxic Substances Control ("CDTSC") has issued several required chemical information call-ins to gather information about ENMs produced in the state.[213] So far, the call-ins have required select manufacturers to provide chemical information if they produce carbon nanotubes, quantum dots, nanosilver, nano zero valent iron, nano cerium oxide, nano titanium dioxide, or nano zinc oxide.[214] The CDTSC and the California Department of Pesticide Regulation ("CDPR") have also taken joint steps towards regulating the use of

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195. N.Y. ECON. DEV. LAW § 352 (McKinney 2021); N.Y. ECON. DEV. LAW § 441 (McKinney 2019); N.Y. UNCONSOL. LAW § 6266-aa (McKinney 2017); N.Y. PUB. AUTH. LAW § 3154 (McKinney 2006); N.Y. EXEC. LAW § 209 (McKinney 2002).

196. OKLA. STAT. tit. 74, § 5060.1a (2013); OKLA. STAT. tit. 74, § 5060.4 (2013); OKLA. STAT. tit. 74, § 5060.43 (2006).

197. 72 PA. STAT. AND CONS. STAT. ANN. § 1725-B (West 2021); 72 PA. STAT. AND CONS. STAT. ANN. § 1725-F (West 2017); 72 PA. STAT. AND CONS. STAT. ANN. § 1725-H (West 2018); 72 PA. STAT. AND CONS. STAT. ANN. § 1725-J (West 2019); 72 PA. STAT. AND CONS. STAT. ANN. § 1725-L (West 2020); 24 PA. STAT. AND CONS. STAT. ANN. § 6250.902 (West 2002).

198. 1956 R.I. GEN. LAWS ANN. § 42-64.14-4 (West 2011).

199. S.C. CODE ANN. § 2-75-30 (2011); S.C. CODE ANN. § 2-75-90 (2008).

200. TEX. GOV'T CODE ANN. § 481.0296 (West 2003); TEX. GOV'T CODE ANN. § 489.213 (West 2003); TEX. EDUC. CODE ANN. § 111.122 (West 2009).

201. VA. CODE ANN. § 2.2-206.3 (West 2021); VA. CODE ANN. § 58.1-339.4 (West 2009).

202. W. VA. CODE ANN. § 18B-18A-1 (West 2014); W. VA. CODE ANN. § 18B-18A-6 (West 2008).

203. WIS. STAT. ANN. § 13.48 (West 2021); WIS. STAT. ANN. § 238.15 (West 2018).

204. ARK. ADMIN. CODE § 168.00.9-VII (2017).

205. FLA. ADMIN. CODE ANN. r. 12C-1.0196

206. ILL. ADMIN. CODE tit.14, § 531.60 (2018).

207. Oklahoma Nanotechnology Application Project, OKLA. ADMIN. CODE §§ 650:18-1-1–650: 18-1-15 (2021).

208. 10 TEX. ADMIN. CODE § 177.6 (2021).

209. N.M. CODE R. § 6.29.3 (2021).

210. W. VA. CODE R. § 133-48-4 (2021).

211. 19 TEX. ADMIN. CODE §§ 130.403 & 130.404 (2015).

212. *Chemical Call-in/Nanotechnology*, CAL. DEP'T OF TOXIC SUBSTANCES CONTROL, https://perma.cc/VXM3-VBQV (last visited Dec. 27, 2021).

213. *Id.*

214. *Id.*; EPA, OFF. LAND & EMERGENCY MGMT., TECHNICAL FACT SHEET – NANOMATERIALS 5 (2017).

nanosilver in products since 2010.[215] Additionally, the cities of Berkeley, California and Cambridge, Massachusetts have both taken steps to monitor the production of nanotechnology.[216]

The likely starting point for utilizing ENMs in water treatment in the United States lies in small, personal use systems or PWSs that only serve a single building. Some homeowners may not be served by a PWS or may want additional treatment for their home by using a POU system. Additionally, certain businesses may need to use a separate POE system to comply with SDWA standards if they are not connected to a larger PWS. These small PWSs, some serving as few as twenty-five people, must still comply with SDWA standards, despite the expense of maintaining treatment technology.[217] If cost effective, these small systems present an opportunity for an emerging technology to cut its teeth and prove reliability.

The EPA cannot regulate POU devices, but many states have regulations a treatment device must meet before it can be sold commercially. For example, all water treatment devices that attach to plumbing (carafe style filters are exempt) sold in Wisconsin must be reviewed by the Department of Safety and Professional Services and conform to the plumbing statutes.[218] They additionally must have approval from the Department of Industry, Labor, and Human Resources.[219] Finally, depending on the POU device's function, the Wisconsin Department of Natural Resources may be required to approve the installation.[220] Several states have adopted the International Plumbing Code ("IPC"), which requires that a drinking water treatment unit comply with National Sanitation Foundation International Standards 42, 44, 53, 55, 58, or 62 for all performance claims and be approved by an American National Standards Institute accredited listing agency.[221]

Although citizens could use a POU installation to supplement the treatment provided by a PWS, most states do not allow a PWS to use POU devices to meet compliance with MCLs under normal circumstances. However, many states commonly allow exceptions if centralized treatment options are not feasible and the PWS owns, installs, and maintains the POU systems.[222] These circumstances

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215. *Chemical Call-in/Nanotechnology*, *supra* note 213.

216. Stephen Chittenden, *State and Local Regulation of Nanotechnology: Two Opposing Methodologies*, 7 NANOTECHNOLOGY L. & BUS. 278, 281 (2010).

217. *Public Drinking Water Systems*, WIS. DEP'T NAT. RES., https://perma.cc/S3XV-FNY2 (last visited Dec. 6, 2021) (under "Is my business a public water system" dropdown).

218. ELAINE ANDREWS, CHRIS MECHENICH & LORETTA TRAPP, CHOOSING A WATER TREATMENT DEVICE 5 (2010). Devices which have already been approved by an American National Standards Institute agency are exempt from the Department of Safety and Professional Services' review. *Id.*

219. *Id.* at 5.

220. *Id.* at 7–8.

221. *2012 International Plumbing Code § 611*, INT'L CODE COUNCIL, INC., (2014), https://perma.cc/U884-B3SM.

222. ALASKA ADMIN. CODE tit. 18, § 80.365 (2019); CAL. DEP'T PUB. HEALTH, DIV. DRINKING WATER & ENV'TL MGMT., POINT OF USE COMPLIANCE 3 (2013).

may be met in areas where a PWS struggles to adequately treat enough water to meet its customers' demands. In 2013, California's POU Compliance Program estimated only 1–3% of water used in a PWS is used for direct consumption.[223] This means a centralized treatment system unnecessarily treats a massive percentage of water to drinking water standards.

The difficulties of navigating the regulation surrounding drinking water is exemplified by a comparison of the PWS systems from three different states: Alaska, Tennessee, and Wisconsin. Alaska is one of the nation's largest and most rural states and currently ranks worst in the nation for PWS regulation violations,[224] despite having access to over 40% of the United States' surface water.[225] Tennessee has some of the fewest PWS violations in the nation, despite serving more than eight and a half times more citizens than Alaska.[226] Finally, Wisconsin has the most PWSs of any state and ranks around the midpoint in the nation for PWS violations.[227]

1. Alaska

In 2019, Alaska was home to 1,378 active PWSs that served approximately 850 thousand residents in the state.[228] Of the active PWSs, 531 of them were issued a total of 4,559 violations in 2019.[229] Most of these PWSs serve remote, rural areas that do not have a PWS employee anywhere nearby available for monitoring, so a majority of the violations are due to monitoring violations.[230]

Alaska's state drinking water requirements are codified under Title 18, Chapter 80 of Alaska's Administrative Code.[231] The drinking water code allows for the use of a POE device to meet water quality requirements if the device meets certain requirements.[232] However, POE devices not are authorized to be used to gain compliance for microbial contaminates.[233] Using POU devices to achieve

223. CAL. DEP'T PUB. HEALTH, *supra* note 222, at 3.

224. *See* ALASKA DEP'T ENV'TL CONSERVATION, DIV. ENV'TL HEALTH, ANNUAL COMPLIANCE REPORT 9 (2020) (finding 39% of PWSs had one or more violations for a total of 4,559 violations in the year).

225. D.F. MEYER ET AL., U.S. GEOLOGICAL SURVEY, WATER-DATA REPORT AK-03-1, WATER RESOURCES DATA ALASKA WATER YEAR 2003 4 (2004).

226. TENN. DEP'T ENV'T & CONSERVATION, DIV. OF WATER RES., 2019 ANNUAL COMPLIANCE REPORT 4 (2020) (finding only 214 violations in 2019).

227. WIS. DEP'T NAT. RES., WISCONSIN PUBLIC WATER SYSTEMS 2019 ANNUAL DRINKING WATER REPORT 16 (2020) (finding violations at 5.5% of PWSs, with a total of 1,036 violations for the year).

228. ALASKA DEP'T ENV'TL CONSERVATION, *supra* note 224, at 8.

229. *Id.* at 9.

230. *Id.*; MEYER ET AL., *supra* note 225, at 11.

231. ALASKA ADMIN. CODE tit. 18, § 80 (2019).

232. ALASKA ADMIN. CODE tit. 18, § 80.360 (2019) (requiring PWS owners to gain Department of Environmental Conservation approval that the POE device would produce water quality similar to that produced by a maintained central water treatment facility and is properly maintained by the PWS owner).

233. ALASKA ADMIN. CODE tit. 18, § 80.360(e) (2019).

compliance is prohibited, unless the devices are used on a temporary basis or if the owner of the PWS is granted a variance or exemption under the statute.[234] If an exception is granted, the PWS owner must "use [the] best available technology" and maintain the microbiological safety of the water at all times.[235] Once the POE or POU is approved and certified, the only plumbing code requirement is an application for a $1.50 permit to install the water treatment equipment.[236]

Despite how decentralized Alaska is as a state, there are still barriers to transitioning to a decentralized water treatment device on the PWS level. However, the exceptions to the statue, and vague language used, appear to provide a pathway for transitioning over to an ENM driven POU or POE system for water treatment needs on a small scale.

2. Tennessee

In stark juxtaposition to Alaska, Tennessee served more than 7.24 million residents in 2019, using only 780 PWSs.[237] Tennessee was able to serve over eight and a half times more residents with almost half the number of PWSs, and with only 214 violations in that year.[238]

Tennessee's regulations for PWSs also specify the requirements to use non-centralized water treatment devices for PWSs.[239] Similar to Alaska, Tennessee's regulations ban the use of POU devices to comply with MCLs except on a temporary basis, but there is no exception clause under Tennessee law in comparison to Alaska law.[240] POE devices are allowed if they are approved by the Department of Environment and Conservation and produce water with health protection "equivalent" to the water quality produced by well-operated central treatment plants.[241] Unlike Alaska, Tennessee does allow POE systems to account for microbiological safety.[242]

Moreover, there are also significant differences between Alaska's and Tennessee's plumbing code regulations that would affect implementation of ENM-based drinking water treatment. Tennessee has adopted the 2012 IPC, which requires much more than a $1.50 permit for a new treatment unit. The 2012 IPC requires any drinking water treatment units installed meet the National Sanitation Foundation ("NSF") codes NSF 42, 44, 53, 62, or BSA-B483.1.[243] NSF 42 and NSF 53 are particularly important for ENM treatment devices

234. ALASKA ADMIN. CODE tit. 18, § 80.365 (2019).
235. ALASKA ADMIN. CODE tit. 18, § 80.365(c) (2019).
236. ALASKA STAT. ANN. § 18.60.720.
237. TENN. DEP'T ENV'T & CONSERVATION, DIV. WATER RES., *supra* note 226, at 2–3.
238. *Id.* at 4.
239. TENN. COMP. R. & REGS. 0400-45-01-.29 (2012).
240. TENN. COMP. R. & REGS. 0400-45-01-.29(1) (2012).
241. TENN. COMP. R. & REGS. 0400-45-01-.29(2)(b) (2012).
242. TENN. COMP. R. & REGS. 0400-45-01-.29(4) (2012).
243. *2012 International Plumbing Code § 611*, *supra* note 221.

because they are the minimum requirements for non-health-related[244] and health-related[245] contaminants that ENMs would be suitable to remove.[246] These plumbing code requirements would apply to any PWS that installs equipment, but they would also apply to any private consumers who wished to add a water treatment device to their homes.

3. Wisconsin

Wisconsin has the most PWSs of all fifty states, with 11,525 PWSs that serve almost 4.25 million residents.[247] In 2019, there were 1,036 violations at 631 PWSs, mainly for failing to adhere to monitoring requirements and failing to notify customers of lead and copper test results.[248]

The Wisconsin Department of Natural Resources ("WDNR") has codified the Wisconsin Safe Drinking Water regulations under chapter NR 809 of the Wisconsin Administrative Code.[249] The regulations set the compliance requirements for each contaminant type and the monitoring requirements for those contaminants.[250] The code defines both POE and POU treatment devices, but there are no further specifications as to their use in the regulation.[251]

All water treatment devices that are sold in Wisconsin must be reviewed according to the Department of Safety and Professional Services Plumbing ("DSPS") requirements, unless they are certified under NSF International Standards 42, 44, 53, 55, 58, or 62.[252] Approval of water treatment devices through the DSPS are valid for five years before renewal, unless the product is revised, in which case it must be re-approved before the revision can be implemented.[253]

Additionally, all water treatment devices sold in Wisconsin require a letter of approval from the Wisconsin Department of Industry, Labor, and Human Relations ("DILHR").[254] Product approval requires the DILHR evaluate: (1) the device's ability to reduce aesthetic and health related contaminants, (2) the suitability of construction materials, (3) the ability of materials to withstand pressures

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244. NSF 42 certifies aesthetic-related contaminant reduction (chlorine, taste and odor, iron, total dissolved solids, etc.). *NSF/ANSI 42, 53 and 401: Filtration Systems Standard*, NSF INTERNATIONAL, (Dec. 2019) https://perma.cc/TN4Q-PX95.

245. NSF 53 certifies health-related contaminant reduction (over 50, but some common reductions include lead, *Cryptosporidium*, and chromium.). *Id.*

246. *See supra* section I.A.

247. WIS. DEP'T NAT. RES., *supra* note 227, at 6.

248. *Id.* at 16.

249. WIS. ADMIN. CODE NR § 809 (2018).

250. WIS. ADMIN. CODE NR §§ 809.07–53 (2018).

251. WIS. ADMIN. CODE NR § 809.04 (2018).

252. WIS. DEP'T SAFETY & PRO. SERVS., REV. 5/16 GWS, REQUIRED INFORMATION FOR THE REVIEW OF WATER TREATMENT DEVICES 1 (2014).

253. *Id.* at 4.

254. ANDREWS ET AL., *supra* note 218, at 5.

and temperature requirements, and (4) the availability of proper installation and operation instructions.[255] Whereas the EPA does not approve specific water treatment devices, any device that contains silver impregnated activated carbon must be registered with the EPA.[256] Therefore, any device utilizing nano-silver would also likely be required to register with the EPA under FIFRA as a pesticide.[257]

Finally, installing a device may require approval from the WDNR under certain conditions.[258] These include whether (1) the treatment device is intended to control bacteriological contaminants; (2) the treatment device is installed on or within a well or the treatment occurs in the well; or (3) the device is used to control chemical contaminants in a private water system when the contamination exceeds drinking water standards and the amount the treatment device can handle.[259]

4. Implementation Barriers

There are some recognized barriers to states approving new drinking water technology. As a whole, the public water sector is risk-averse and focuses heavily on public health concerns when inspecting possible technologies.[260] One recent study identified six factors that inhibit innovation: the risk-averse nature of water managers, the long life expectancy and significant complexity of most water systems, geographic and functional fragmentation, water pricing practices, absence of incentivizing regulations, and insufficient access to venture capital.[261]

Additionally, small PWSs often have difficulty retaining employees who are knowledgeable in specialized technology that would be required to maintain new technologies, such as ENM-based treatment options.[262] Small PWSs are often not as cost effective as larger PWSs, so the smaller PWSs prioritize technology that is known to be dependable and long-lasting due to limited funding concerns.[263] As exemplified above, manufacturers of new water treatment technology must obtain approval on a state-by-state basis, some of which have vastly enhanced regulations or specific limitations.[264] This could cause manufacturers to develop different models for each jurisdiction, raising costs associated with developing

255. *Id.*
256. *Id.* at 7.
257. *See supra* section II.A.3.
258. ANDREWS ET AL., *supra* note 218, at 7–8.
259. *Id.*
260. Ringenberg et al., *supra* note 158, at E344.
261. David Strifling et al., *Overcoming Legal and Institutional Barriers to the Implementation of Innovative Environmental Technologies*, 1 NOTRE DAME J. EMERGING TECH. 280, 282 (2020) (citing Newsha K. Ajami et al., *The Path to Water Innovation*, 2014-06 THE HAMILTON PROJECT 20 (Oct. 20 2014)).
262. Ringenberg et al., *supra* note 158, at E343
263. *Id.* at E343–44
264. *Id.* at E344.

and manufacturing products, and eventually resulting in a more expensive, less attractive option for small PWSs.

Although regulatory decisions are unlikely to move the needle on the water sector's risk-averse slant, there may be room to address some of the other barriers that hinder adoption of new technology. Subsidies and incentives related to ENM technology could potentially be aimed at assisting small PWSs in being able to afford to implement new technology and hire employees or consultants capable of properly maintaining them—especially if the technology is built with a focus on cheap and infrequent maintenance procedures. Additionally, programs to enhance cohesive regulations among the states or develop a baseline federal standard may aid manufacturers in producing functional technology that is applicable to a majority of states, resulting in more cost-effective production, and a cheaper treatment option for the PWSs. A standardized regulation would also assist in easier and more efficient monitoring and maintenance, likely resulting in fewer PWS violations and, ideally, safer water for public consumption.

D. EUROPEAN UNION REGULATIONS

Nanotechnology is prominent in the global market and will continue to be developed internationally as it becomes increasingly important in numerous spheres of life.[265] The European Commission has gone as far as to label nanotechnology as a "key enabling technology," meaning it will provide the basis for further innovation and development of new products.[266] The European Union ("EU") has recognized the need to regulate ENMs for the protection of human health and the environment. However, the properties and characteristics of ENMs have made it difficult for regulators in the United States and the EU alike to come up with an independent regulatory scheme for these materials. Because of this difficulty, the EU has opted to use pre-existing legislation to regulate ENMs, just as the US EPA did. In making this decision, EU regulators adopted an incremental approach to adapt some of the existing legislation to regulate ENMs.[267] The regulation that has been considered most heavily to control ENMs in the EU and could potentially have the greatest impact on the future of ENM use in drinking water treatment is the Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH").

1. Registration, Evaluation, Authorization and Restriction of Chemicals

REACH was enacted in 2007. Its purpose is to protect human health and the environment through the identification of the different properties of chemical

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265. *Communication from the Commission to the European Parliament, the Council, and the European Economic and Social Committee*, at 3, COM (2012) 572 final (Oct. 3, 2012).
266. *Id.*
267. Steffen F. Hansen & Anders Baun, *European Regulation Affecting Nanomaterials – Review of Limitations and Future Recommendations*, 10 DOSE-RESPONSE 364, 364 (2012).

substances.[268] The regulation places the burden on industry to provide information about chemical substances to ensure that they are safely used.[269] If the identified risks cannot be managed, use of the substance can be restricted.[270] The original language produced questions about whether an ENM is considered a unique substance or the same substance as its macro material counterparts.[271] In 2018, the EU Commission released an amendment to REACH to specifically include ENMs and update their reporting requirements.[272] The EU adopted its definition of a nanoform under Commission Recommendation 2011/696 as:

> a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm.
>
> . . . .
>
> . . . fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nano-materials.[273]

The 2018 amendment requires that nanoforms be identified in the registration so they can be documented separately from their macroforms.[274]

The required registration information is reported to the European Chemicals Agency ("ECHA").[275] For REACH regulation to apply to a particular entity, there is a threshold of one ton per year of a qualifying substance that the entity must either produce or import.[276] Due to the size of ENMs, it seems unlikely a significant portion of ENMs will be produced in the quantity required for the threshold amount to be reached.[277] However, if the registrant meets the threshold by producing macroforms of the same substance, it must also report details for any nanoforms of the substance it produces.[278] All registrations require (1) general

268. Commission Regulation 1907/2006, 2006 O.J. (L 396) 4.

269. *Id.* at 6; Sonia Desmoulin, *French and European Community Law on the Nanometric Forms of Chemical Substances: Questions About How the Law Handles Uncertain Risks*, 5 NANOTECHNOLOGY L. & BUS. 341, 347 (2008).

270. *Understanding Reach*, EUR. CHEMICALS AGENCY, https://perma.cc/DU28-G6H4 (last visited Dec. 22, 2021).

271. Hansen & Baun, *supra* note 267, at 365–66.

272. Commission Regulation 2018/1881, 2018 O.J. (L 308) 1–2.

273. Commission Recommendation, on the Definition of Nanomaterial 2011/696/EU, 2011 O.J. (L 275) 40.

274. Anna Pavlicek, Gloria Rose & André Gazsó, *Nano-Registries: Country-Specific Solutions for Nano-Regulations*, Nr.51 en NANOTRUST-DOSSIER 1, 2 (2019).

275. Commission Regulation 1907/2006, 2006 O.J. (L 396) 9.

276. *Id.* at 6; Desmoulin, *supra* note 269, at 347; Lucas Bergkamp, Geneviève Michaux & Nicolas Herbatschek, *Nanotechnology Regulation in Europe: From REACH and Nano-Registries to Cosmetics, Biocides, and Medical Devices*, 11 NANOTECHNOLOGY L. & BUS. 93, 94 (2014).

277. Diana Bowman & Geert van Calster, *Reflecting on REACH: Global Implications of the European Union's Chemicals Regulation*, 4 NANOTECHNOLOGY L. & BUS. 375, 379 (2007); QASIM CHAUHDRY ET AL., A SCOPING STUDY TO IDENTIFY GAPS IN ENVIRONMENTAL REGULATION FOR THE PRODUCTS AND APPLICATIONS OF NANOTECHNOLOGIES 12 (2006).

278. *Support Q&As*, EUROPEAN CHEMICALS AGENCY, https://perma.cc/65GE-KKDL (last visited Nov. 3, 2021).

registrant information; (2) substance identification; (3) information regarding the manufacture and use of the substance; (4) substance classification and labelling; (5) guidance on safe use; and (6) exposure information.[279]

When substance production reaches at least ten tons per year, the registrant additionally must produce a chemical safety report documenting the chemical's safety assessment.[280] The chemical safety assessment is used to determine hazards and risks to human health and the environment, as well as suitable risk management procedures.[281] The chemical safety assessment includes: (1) a human health hazard assessment; (2) a physiochemical hazard assessment; (3) an environmental hazard assessment; and (4) assessments to determine persistence, bioaccumulative, and toxic properties.[282] However, the testing required for a chemical safety report will likely result in toxicological test data that addresses the macroform of the substance, which may be different from toxicological test data of the nanoforms of the substance.[283] More in depth testing is required if the substance is produced at 100 tons per year and again at 1,000 tons per year.[284] Testing for qualities such as reproductive toxicity, toxicity across multiple generations, aquatic toxicity, and environmental fate are not required until the 100 ton threshold is met.[285] Registrants are required to conduct additional testing if relevant information about the substance is unknown.[286]

REACH also applies to what has been deemed "downstream users," which are companies that are not necessarily directly involved in the chemical business, but some part of the business involves qualifying chemicals.[287] The regulation creates procedures that industry must follow to identify the risks of the chemicals that they are working with as well as manage the risks associated with the identified risks.[288] The purpose of ECHA in this process is to evaluate the information to determine if the companies are in compliance with the requirements of REACH.[289]

Observers have acknowledged that REACH is likely going to be the most important existing regulation to address nanotechnology regulation, but there are many critiques and recommendations that have been proposed to mend the shortcomings of the regulation as it exists. The most frequently cited shortfall of

279. EUR. CHEM. AGENCY, GUIDANCE IN A NUTSHELL – REGISTRATION VERSION 3.0 11 (2017).
280. *Id.* at 14; Desmoulin, *supra* note 269, at 347.
281. EUR. CHEM. AGENCY, *supra* note 279, at 14.
282. *Id.* at 15.
283. Hansen & Baun, *supra* note 267, at 377.
284. *Id.* at 365.
285. Commission Regulation 1907/2006, 2006 O.J. (L 396) 93.
286. EUR. CHEM. AGENCY, *supra* note 279, at 12.
287. Commission Regulation 1907/2006, 2006 O.J. (L 396) 37.
288. EUR. CHEM. AGENCY, *supra* note 279, at 5.
289. *Id.* at 19–20.

REACH, as it would apply to ENMs, is the threshold amount.[290] Therefore, many researchers have suggested coming up with an appropriate threshold amount that considers the miniscule size of ENMs.[291] The current exception to the threshold is that an ENM could be selected for further evaluation by an EU member state or ECHA due to specific concerns, which would require manufacturers to develop a Chemical Safety Assessment specifically for the nanoform.[292]

In addition to concerns about the threshold requirements, commentators have identified other concerns REACH fails to address. Another critique of REACH is that it fails to require the industry to provide enough information to the ECHA before it can be approved and registered under REACH. Proponents of this idea would require the registrant to also provide the following information along with the information that is typical for registration: (1) shape, (2) crystal structure, (3) surface area, (4) chemistry, and (5) charge.[293] Other criticisms include that there is essentially no guidance for those who would be regulated under REACH, and there is a lack of information regarding products already in the market that contain ENMs. Finally, REACH does not mandate the establishment of a central database or registry for all member states to report chemical information about ENMs.[294]

There are several proposed legislative ideas that may address some of the deficiencies identified above.[295] The first of these is coming to an agreed upon definition of exactly who and what is regulated under REACH, as well as a more manageable threshold size to apply specifically to ENMs.[296] In addition, registration of nanoforms that currently benefit from the phase-in status would be necessary to obtain a clearer picture of what materials are already on the market and potentially in the water systems.[297] Finally, a different testing protocol for ENMs is likely warranted to fully determine hazardousness.[298] As ENMs interact with their surroundings, they can take on a variety of different characteristics, which affect how they interact with their surroundings in the future.[299] This means that a product that was initially hazardous may be nonhazardous once a part of a finished product and vice versa. The ideal legislative amendments to REACH would address all of these issues.

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290. Scientific Committee on Emerging and Newly Identified Health Risks, *Modified Opinion (After Public Consultation), on The Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies*, SCENIHR/002/05, at 55 (Mar. 10, 2006) [hereinafter *SCENIHR*]; Bowman & van Calster, *supra* note 277, at 378.

291. SCENIHR, *supra* note 290, at 55.

292. Hansen & Baun, *supra* note 267, at 366.

293. *Id.*

294. *See* Commission Regulation 1907/2006, 2006 O.J. (L 396).

295. Hansen & Baun, *supra* note 267, at 378.

296. *Id.*

297. *Id.*

298. *Id.* at 378–79.

299. Lynch, *supra* note 58, at 556; Kshitij Aditeya Singh, *Risk Governance in Nanotechnology*, INT'L RISK GOVERNANCE COUNCIL 1, 3 (2006).

2. Biocidal Products Regulation

There is sector specific legislation that specifically addresses nanotechnology regulations for cosmetics, novel foods, food contact materials, food additives, medical devices, and biocidal products.[300] The Biocidal Products Regulation requires specific assessment and approval of any ENMs produced to act as biocidal products.[301] The regulation covers biocidal products or treated articles that would be used for the disinfection of drinking water for humans and animals.[302] The regulation defines a biocidal product as:

> any substance or mixture, in the form in which it is supplied to the user, consisting of, containing, or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action

and includes any treated article that has a primary function of acting as a biocidal product.[303] Nanosilver, for example, must therefore be addressed specifically and does not fall under the assessment and approval of silver. Furthermore, the regulation requires the labeling of chemically active substances which are ENMs.[304]

Any product that is approved for use must be reapproved after an initial period of less than ten years.[305] The renewal of an approved active substance is fifteen years after approval unless specific provisions require a shorter renewal period.[306] There are several conditions required for approval, but the approval does not cover ENMs except where they are explicitly mentioned.[307] There is a simplified authorization procedure, but products containing ENMs are not eligible for consideration under the simplified procedure.[308] Any tests that are conducted for the approval of an active substance or biocidal product must adhere to the methods established in the European Union's Council Regulation 440/2008.[309] Whenever test methods are used for ENMs, an explanation for their scientific appropriateness must also be provided, along with a description of any adaptations that were required.[310]

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300. Pavlicek et al., *supra* note 274, at 2.
301. *See* Regulation 528/2012, of the European Parliament and of the Council, Concerning the Making Available on the Market and Use of Biocidal Products, 2012 O.J. (L 167) (EU).
302. *Id.* at 105.
303. *Id.* at 10.
304. Pavlicek et al., *supra* note 274, at 2.
305. Regulation 528/2012, of the European Parliament and of the Council Concerning the Making Available on the Market and Use of Biocidal Products, 2012 O.J. (L 167) 12 (EU).
306. *Id.* at 15.
307. *Id.* at 12.
308. *Id.* at 21.
309. *Id.* at 52.
310. *Id.*

Applications for approval require (1) a dossier for the active substance, (2) a representative biocidal product that contains the active substance, and (3) evidence that the exclusion criteria is not applicable.[311] When compiling the dossier, if a biocidal product contains ENMs, any principles in the dossier must be adapted and elaborated on to account for the most recent scientific developments.[312] ECHA then has thirty days to validate the data in the application but makes no determination as to its adequacy.[313] The evaluating competent authority makes a determination regarding the quality and adequacy of the data as soon as possible after ECHA validates the application.[314] If the evaluating authority requires additional information to process the application, the applicant has ninety days to provide additional information; the evaluating authority then has thirty days to review the additional information.[315] The evaluating authority then has one year to consider more in-depth analysis of the application's substance, such as concerns for human, animal, or environmental health.[316] Where ENMs are used in a product, risk to humans and the environment are assessed separately.[317] Upon completion of the evaluating competent authority's work, ECHA has 270 days to review and submit an opinion to the Commission regarding the approval of the substance.[318]

Any treated article that is placed on the market that contains an ENM must label the product to display the name of the ENM, followed by "nano" in brackets.[319] All biocidal products must be labelled to include any ENMs the product contains, the related risks for each ENM, and the word "nano" in brackets.[320] The regulation also requires member states to provide a report to the Commission every five years regarding implementation, which specifically includes information on the use of ENMs in biocidal products and their potential risks.[321]

3. Drinking Water Directive

The requirements for each EU member state to monitor drinking water quality are established in the Drinking Water Directive ("DWD").[322] Water supplies that are subject to the DWD are waters intended for human consumption that provide an average of ten cubic meters or more of water per day or serve fifty or more

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311. *Id.* at 13.
312. *Id.* at 109.
313. *Id.* at 13.
314. *Id.*
315. *Id.* at 14.
316. *Id.*
317. *Id.* at 18.
318. *Id.* at 14.
319. *Id.* at 35.
320. *Id.* at 40.
321. *Id.* at 38.
322. *See* Council Directive 98/83/EC, On the Quality of Water Intended for Human Consumption, 1998 O.J. (L 330) 35 (EU).

persons; all water supplied as part of a commercial or public activity fall under the DWD's overview.[323] Water sources must be free from any micro-organisms and parasites and a variety of listed contaminants must fall below certain concentrations in monitored water.[324] The annexes of monitored contaminants must be reviewed at least every five years and modified accordingly in light of scientific and technical progress.[325]

The DWD still provides for a great deal of variation between each member state for monitoring and enforcement.[326] Each Member State is permitted to add additional parameters to monitor any contaminant values as long as they are not less stringent than the ones specifically designated in the DWD.[327] Quality assurance is left to each member state to ensure that preparation and distribution of water does not allow for any contaminants to remain in the water when it is used for consumption.[328] When disinfection is used as part of water preparation or distribution, the member state must ensure contamination from disinfection by-products is kept as low as possible.[329]

Pursuant to a 2021 update to the DWD, member states are now required to ensure any treatment chemicals or filter media used for water treatment do not (1) compromise human health; (2) adversely affect the water's color, odor, or taste; (3) enhance microbial growth; or (4) unnecessarily contaminate water at levels higher than intended.[330] The listed contaminants do not include specific ENMs, but do include several macroforms that are commonly used in nanotechnology, such as cadmium, nickel, copper, and iron.[331] If ENMs were monitored under this regulation, the requirements would need to be adapted for the analytical methods that are used to monitor ENMs.[332] Characteristics of ENMs also pose a challenge in determining threshold amounts under this regulation, so more detailed study needs to be done to understand the potential toxicity in drinking water and better regulate drinking water treatment that has the potential to use ENMs.[333]

4. Water Framework Directive

The Water Framework Directive ("WFD") is akin to the American Clean Water Act; it establishes water quality objectives to manage pollutants in surface

323. *Id.*
324. *Id.*
325. *Id.* at 38.
326. *See id.* at 35–38.
327. *Id.* at 35.
328. *Id.* at 38.
329. *Id.* at 36.
330. Council Directive 2020/2184, 2020 O.J. (L 435) 24–25 (EU).
331. *Id.* at 35–42.
332. GANZLEBEN & HANSEN, *supra* note 54, at 121.
333. *Id.* at 122.

water and groundwater.[334] It does not directly regulate the use of ENMs as a treatment technology. Rather, the WFD governs the monitoring of priority substances that pose a risk to the aquatic environment or are required to be monitored by other regulations.[335] Chemical status, ecological status, and quantitative status are monitored under the WFD.[336] The potential discharge of ENMs used in drinking water treatment could trigger the WFD. A commission sets the environmental quality standards ("EQSD") for each identified priority substance, which are listed in Annex II of Directive 2008/105/EC.[337] The WFD refers to REACH for determining evaluation of priority substances, so amendments affecting REACH related to ENMs are automatically implemented in the Directive as well.[338]

As of this writing, no ENMs have been identified as a priority substance; however, there is potential for ENMs to be listed as priority substances to be monitored. Priority substances are picked based on scientific data from risk-based assessments that illustrate whether the substance poses a risk to aquatic environments.[339] The following are factors to be considered in determining if a substance should be classified as a priority substance: (1) evidence regarding the intrinsic hazard of the substance concerned, and in particular, its aquatic ecotoxicity and human toxicity via aquatic exposure routes; (2) evidence from monitoring of widespread environmental contamination; and (3) other proven factors which may indicate the possibility of widespread environmental contamination, such as production, use volume, and use pattern of the substance concerned.[340] Over time, the process of identifying priority substances has become broader to allow for the identification of substances with limited available information, such as ENMs.[341]

Currently, ENMs are not considered a priority substance, but rather as "other pollutants discharged in significant quantities."[342] There is also the issue that there are naturally occurring nanoparticles and there has not been a reliable method to determine how many nanomaterials present are naturally occurring as opposed to engineered.[343] The issue is further compounded because there are no member states that are currently monitoring ENMs or their accumulation in the environment.[344]

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334. Council Directive 2000/60, art. 1, 2000 O.J. (L 327) 1, 5 (EC); Stefen Foss Hansen, Catherine Ganzleben & Anders Baun, *Nanomaterials and the European Water Framework Directive*, 2 EUR. J.L. & TECH. 1, 1 (2011).

335. Council Directive 2000/60, art. 16, 2000 O.J. (L 327) 1, 17 (EC).

336. *Id.* at 12.

337. Council Directive 2008/105, annex II, 2008 O.J. (L 348) 84, 95 (EC).

338. Council Directive 2000/60, art. 16, 2000 O.J. (L 327) 1, 17 (EC).

339. *Id.*

340. *Id.*

341. *See* GANZLEBEN & HANSEN, *supra* note 54, at 104 tbl.11 (describing a variety of methodologies that could be used in determining whether to classify ENMs as a priority substance).

342. *Id.* at 108.

343. *Id.* at 109.

344. *Id.* at 110.

Although ENMs themselves are not considered priority substances, some of their base materials are.[345] These include cadmium and nickel, among others.[346] However, even if ENMs are being made out of listed elements, the acceptable emission limit values for macroform discharges may not be applicable to ENM discharge because the established toxicology doses for macroforms may vary greatly from how the ENMs interact in the environment.[347] Specifically adding ENMs to the list of priority substances would open up opportunities for research and data gathering in order to fully understand the impacts of ENMs in water and the environment.

5. Groundwater Directive

The Groundwater Directive works in conjunction with the WFD.[348] Like the WFD, the Groundwater Directive assesses the chemical status of groundwater and responds with remedial measures should the level of a priority substance exceed the quality standards set out for it.[349] As part of the Groundwater Directive, member states are charged with three main tasks: (1) assess the chemical status of groundwater, (2) identify upward trends in specific pollutants, and (3) establish starting points for trend reversal.[350] Currently, ENMs are not being monitored under this regulation, but they have the potential to be monitored under Annex II, Point 2 which relates to "manmade synthetic substances."[351] Again, there are challenges in using this regulation to regulate ENMs because of the size of the particles and the lack of information on the amount of naturally occurring nanoparticles in groundwater.

6. Classification, Labelling, and Packaging Regulation

The Classification, Labelling, and Packaging Regulation ("CLP") has similar information forcing goals to the REACH regulation. The CLP requires manufacturers, importers, and downstream users to label and package hazardous chemicals before they can go to market.[352] To be in compliance, industry participants must first provide the relevant information for a chemical or mixture of chemicals to determine the hazard class and category.[353] Once a chemical or chemical mixture is classified, the hazards have to be communicated throughout the supply

345. Hansen et al., *supra* note 334, at 6.
346. *Id.*
347. *Id.* at 7.
348. Council Directive 2006/118, art. 1, 2006 O.J. (L 372) 19, 21 (EC).
349. *Id.* art. 1–6, at 21–23.
350. *Id.* art. 4–5, at 22–23.
351. *Id.* at 27–28.
352. Council Regulation 1272/2008, art. 4, 2008 O.J. (L 353) 1, 10; Marla Alessandrelli & Marla Letizia Polci, *CLP Application to Nanomaterials: A Specific Aspect*, 47 ANN IST SUPER SANITÀ 146, 148 (2011).
353. Council Regulation 1272/2008, tit. II, 2008 O.J. (L 353) 1, 11–15.

chain and to consumers.[354] A chemical element or its compounds can be subject to the CLP in its naturally occurring state or in its manufactured state.[355] The CLP does not limit what size a compound must be to qualify for regulation, so ENMs can be regulated.[356] However, without a well-accepted definition of ENMs, CLP coverage of ENMs remains uncertain.[357]

The CLP creates an ongoing obligation for manufacturers, importers, and downstream distributors to keep up on the availability of new information pertaining to the chemical substances they are placing onto the market.[358] Once one of these groups becomes aware of this newly available information, it must reevaluate the safety of the chemical and complete whatever additional testing may be necessary.[359] A common issue that has plagued a smooth application of the existing EU regulations to ENMs is the lack of available testing to determine at what levels toxicity occurs and the level of toxicity; the CLP also suffers from this problem.[360] Although covered information might exist for a macroform material, it cannot be said with certainty that the information will be accurate or applicable to the analogous nanoform.[361] The CLP has great potential to address ENMs on the market; however, its language would have to be amended to expressly include ENMs as well as to account for the constant influx of information associated with increasing ENM use.

In summary, as in the United States, EU regulators have struggled to create an effective governance regime for ENMs and have instead relied on existing laws. Of these, the regulation that has the most potential for ENM control is REACH, which has some similarities to TSCA in that it requires industry users to provide information about chemical substances to ensure that they are safely used.[362] However, REACH has been subject to criticism on the grounds that it includes certain threshold requirements for regulation that ENMs may not meet; that it fails to require industry to provide enough information; that there is little to no regulatory guidance available; and that ENMs already in the market may escape regulation.[363]

E. EU MEMBER STATE REGULATION

The individual member states in the European Union have the power to create their own independent nanotechnology rules, applicable within their territories.[364]

354. *Id.* tit. 3, at 15–20.
355. *Id.* art. 2, at 9.
356. Alessandrelli & Polci, *supra* note 353, at 148.
357. *Id.*
358. Council Regulation 1272/2008, art. 15, 2008 O.J. (L 353) 1, 15.
359. *Id.*
360. Alessandrelli & Polci, *supra* note 353, at 148.
361. *Id.*
362. *See* Commission Regulation 1907/2006, 2006 O.J. (L 396) 47.
363. *See supra* section II.D.1.
364. Pavlicek et al., *supra* note 274, at 2.

For example, it is up to each member state to determine how EU-wide regulations, such as REACH, will be implemented.[365] One of the biggest critiques of REACH is that there is not a central database or registry for all member states to list the chemicals, particularly different ENMs within the EU.[366] Italy, Belgium, and France are working on national databases, but these countries also recognize the need for a "harmonization of national databases for nanomaterials on the market," and are working together to reach this common goal.[367] Although there still is not a single collaborative database amongst the member states, some are individually working on databases and projects that will suit the needs of their citizens because the goal is to ensure environmental protection and citizen safety.[368] Not every member state has published information about its efforts to fulfill its obligations under REACH, but the few that have released information on what they are doing should be highlighted.

1. France

France has been a leader in ENM registrations among the EU member states. It was the first country within the European Union to create a national registry for ENMs.[369] This registry entered into force in January of 2013 and is regulated in articles L. 523-1 through 523-5 of the French Code.[370] These articles establish a mandatory declaration procedure for nanoscale substances which are produced, distributed, or imported into France.[371] They also specify the definitions of nanomaterials and related terms and the minimum thresholds for and the frequency of these declarations.[372] Specifically, ENMs are subject to the registration requirements if they are artificially produced and circulated in quantities of at least 100 grams per year.[373] This registry is managed by the Agence nationale de sécurité sanitaire, de l'alimentation, de l'environenment et du travail [National Health, Food, Environment, and Labor Safety Agency] ("ANSES").[374]

In France, an established compulsory reporting scheme for ENMs applies to producers, importers, and distributors.[375] The annual declaration of the identity, quantity, and uses of the ENMs and the identity of the recipients down the supply chain are required to be disclosed in when registering ENMs.[376] These reporting requirements began in 2013, but they apply to any ENMs manufactured,

365. *Id.*
366. *See generally id.*
367. GANZLEBEN & HANSEN, *supra* note 54, at 34 tbl.4.
368. *See, e.g.*, *id.*
369. Pavlicek et al., *supra* note 274, at 3.
370. CODE DE L'ENVIRONNEMENT [CODE ENV'T] [ENVIRONMENT CODE] art. L523-1–523-5 (Fr.).
371. *Id.*
372. *Id.*
373. *Id.*
374. Pavlicek et al., *supra* note 274, at 3.
375. GANZLEBEN & HANSEN, *supra* note 54, at 34 tbl.4.
376. *Id.*

imported, and distributed since 2012.[377] The original law that created this database was passed in 2009, so members of industry were provided adequate time to gather the requisite information for reporting obligations.[378]

2. Belgium

Belgium also created a national registry, which entered into force on January 1, 2016.[379] Belgium requires registration when more than 100 grams per year of any substance enters the Belgian market.[380] This registry was amended in 2017 to include substances and mixtures produced in their nanoforms.[381] This led to the inclusion of substances such as paints and sunscreens, whose end product is no longer in the nano state.[382] This registry is managed by the Federal Public Service for Health, Food Chain Safety, and Environment.[383]

In Belgium, the Public Health, Food Safety, and Environment Ministry has created the framework for a compulsory ENM database.[384] This is in conjunction with the work the country is doing with the other member states to create a collaborative registry.[385]

3. Denmark

Denmark created a national registry for ENMs that entered into force June 18, 2014.[386] This registry was a follow-up to the Danish Chemical Action Plan which contained statements on ENMs that were nonbinding and also called for adjustments to include specificity on ENMs in REACH.[387] The national registry requires the disclosure and registration of all mixtures and products that contain

377. *Id.*

378. *Id.*

379. Koninklijk besluit betreffende het op de markt brengen van stoffen geproduceerd in nanoparticulaire toestand [Royal Decree concerning the placing on the market of substances produced in nanoparticular state] B.S. May 24, 2014; Pavlicek et al., *supra* note 274, at 3.

380. Koninklijk besluit betreffende het op de markt brengen van stoffen geproduceerd in nanoparticulaire toestand [Royal Decree concerning the placing on the market of substances produced in nanoparticular state] B.S. at art. 3.

381. Koninklijk besluit tot wijziging van het koninklijk besluit van 27 mei 2014 betreffende het op de markt brengen van stoffen geproduceerd in nanoparticulaire toestand [Royal Decree amending the Royal Decree of May 27th 2014 concerning the placing on the market of substances produced in nanoparticular state] B.S. Dec. 27, 2017.

382. Pavlicek et al., *supra* note 274, at 3.

383. *Id.*

384. GANZLEBEN & HANSEN, *supra* note 54, at 34 tbl.4.

385. *Id.*

386. Bekendtgørelse om register over blandinger og varer, der indeholder nanomaterialer samt producenter og importørers indberetningspligt til registeret [Order on a register of mixtures and articles that contain nanomaterials as well as the requirement for producers and importers to report the register] n.r. 664 June 13, 2014 [hereinafter Denmark Order on Nanomaterials Registry].

387. Pavlicek et al., *supra* note 274, at 3.

ENMs that are produced in Denmark or imported into the country.[388] The Danish registry is managed by the Danish Environmental Protection Agency.[389]

In 2012, the Danish Environment Ministry announced a proposed order for a database of products that release ENMs.[390] The proposed order would also require that producers and importers of products that release ENMs or are made from ENMs to generate information about the risks that ENMs could pose to consumers and the environment.[391] The risks assessed would be the risks associated with use in Denmark, particularly to the Danish environment and Danish citizens.[392]

4. Sweden

Sweden created a national registry that entered into force on January 1, 2018.[393] Unlike the other listed countries whose registries are more regulation focused, Sweden's registry focuses more on data gathering with the goal of creating an overview of which ENMs, including their types and quantities, are being placed in the Swedish marketplace.[394] However, no notification or registration is necessary if the nanomaterial is naturally occurring or accidentally produced.[395] The second notable exception is that companies producing less than five million Swedish crowns annually do not need to register.[396] This registry is managed by the Swedish Chemicals Agency.[397]

5. Norway

Norway created a national registry that went into force shortly after France's did, in March 2013.[398] This registration requires that any individual or company within Norway who imports or manufactures more than 100 kilograms per year of products that are classified as hazardous, including some ENMs using hazardous metals or materials, report that product to the Product Register.[399] The registry is managed by the Norwegian Environmental Agency.[400]

388. Denmark Order on Nanomaterials Registry, *supra* note 386, at ch. 3.
389. *Id.* at ch. 4.
390. GANZLEBEN & HANSEN, *supra* note 54, at 34 tbl.4.
391. *Id.*
392. *Id.*
393. KEMIKALIEINSPEKTIONENS FÖRESKRIFTER [KIFS] [CODE OF STATUTES OF THE SWEDISH CHEMICAL AGENCY], OM KEMISKA PRODUKTER OCH BIOTEKNISKA ORGANISMER [CHEMICAL PRODUCTS AND BIOTECHNICAL ORGANISMS REGULATIONS] 2017:7.
394. *Id.*
395. *Id.*
396. *Id.*
397. Pavlicek et al., *supra* note 274, at 4.
398. DEKLARERINGSFORSKRIFTEN [DECLARATION OF REGULATIONS], FORSKRIFT OM DEKLARERING AV KJEMIKALIER TIL PRODUKTREGISTERET [REGULATIONS ON THE DECLARATION OF CHEMICALS TO THE PRODUCT REGISTGER] May 29, 2015.
399. *Id.*
400. Pavlicek et al., *supra* note 274, at 5.

6. Germany

In Germany, the Federal Environment Agency and the Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety took the approach of first supporting a research project.[401] The purpose of the project was to determine the legal feasibility of a nano product registry in the country.[402] The study concluded that a nano registry would be feasible.[403] Unfortunately, the members could not agree on the function or the goals of the register, so no registry has been enacted at this time.[404]

7. Italy

In Italy, the government is currently working on an ENM specific database, but the content that will be in the database is unclear at this point.[405] Unlike the schemes of its counterparts, Italy's database would be voluntary at the start but have the potential to become compulsory.[406]

III. POLICY CONSIDERATIONS MOVING FORWARD

A. FRAGMENTATION

There is both horizontal and vertical fragmentation when governments regulate PWSs. Drinking water treatment regulation involves every level of government.[407] Additionally, at each level there can be multiple agencies with authority to create regulations or rules that must coordinate with each other, resulting in a complex web of vertical and horizontal fragmented management authority. Some commentators argue that fragmentation results in unnecessary duplication that increases costs and reduces efficiency, while others believe fragmentation leads to more efficient utilization of resources due to specialization.[408]

Vertical fragmentation refers to the division of authority between international, federal, state, and local powers.[409] Currently, there is little vertical fragmentation regarding regulations of ENMs in the United States, because few government agencies outside of the EPA have utilized any ENM specific enforcement.[410]

401. GANZLEBEN & HANSEN, *supra* note 54, at 34 tbl.4.
402. *Id.*
403. *Id.*
404. *Id.*
405. *Id.*
406. *Id.*
407. *See supra* Part II.
408. *See* Christopher B. Goodman, *Local Government Fragmentation: What Do We Know?*, 51 STATE & LOC. GOV. REV. 134, 141 (2019); Alejandro E. Camacho, *Adapting Governance to Climate Change: Managing Uncertainty Through a Learning Infrastructure*, 59 EMORY L.J. 1, 27 (2009).
409. William W. Buzbee, *The Regulatory Fragmentation Continuum, Westway and the Challenges of Regional Growth*, 21 J.L. & POL. 323, 344 (2005).
410. *See supra* Part II. A notable exception being where the state of California and city of Berkley have enforceable ENM regulations. *See supra* section II.C.

However, drinking water regulation has multiple examples of vertical fragmentation, with drinking water requirements present at the federal level with the SDWA and common at the state level. Vertical fragmentation regarding ENM regulation is also an issue in the EU, where regulation exists at the international level in addition to regulation established by many member states.[411]

By contrast, horizonal fragmentation occurs when there are separate institutions within the same level of government which have authority to regulate a subject.[412] There is little horizontal fragmentation between agencies for nanotechnology regulation in drinking water treatment at the federal level in the United States, because the EPA is responsible for almost all applicable regulations.[413] In Wisconsin, there are multiple agencies involved in drinking water treatment, such as the WDNR, DSPS, and Department of Health Services ("DOH").[414] The WDNR regulates the PWSs, which treat drinking water,[415] the DSPS focuses efforts on product approval for home drinking water devices,[416] and the DOH provides information to residents and professionals on the appropriate way to address health concerns regarding drinking water.[417] Specialization in each of these topics is important and deserves an agency's dedicated efforts. However, these divisions can become overwhelming if the agencies begin to overlap in their responsibilities.

To highlight excessive fragmentation for water treatment authority, there are over 3,877 water districts that have been established in the western United States, each with their own authority to establish rules over water regulation in their district.[418] California's legislature tasked local governments to address water management decisions.[419] The intent was to create a flexible framework where each local government could customize their water management to the needs of their community, but what resulted was an expensive, confusing system that is difficult to navigate.[420] A glaring example is Tulare County, which has three separate urbanized areas and the highest nitrate contamination levels in the state.[421] Tulare County's water is regionally managed by the Central Valley Regional Water Quality Control Board at the state level, but there are thirteen separate water governance schemes at the local level.[422] Of these, the California Water Services is

411. *See supra* sections II.D & II.E.
412. Buzbee, *supra* note 409, at 347.
413. *See supra* section II.A.
414. *See supra section* II.C.3.
415. WIS. DEP'T NAT. RES., *supra* note 221, at 4.
416. WIS. DEP'T SAFETY & PRO. SERVS., *supra* note 252, at 1.
417. *Drinking Water*, WIS. DEP'T OF HEALTH SERVICES, https://perma.cc/C54Q-U99A (last visited Nov. 10, 2021).
418. Camille Pannu, *Drinking Water and Exclusion: A Case Study from California's Central Valley*, 100 CAL. L. REV. 223, 251 (2012).
419. CAL. WATER CODE § 380 (West 1982).
420. Pannu, *supra* note 418, at 252.
421. *Id.* at 253.
422. *Id.*

charged with providing drinking water to Tulane County, interacting with the other governing bodies in the county, and providing drinking water to Kern County as well, which has its own local regulations.[423] This level of vertical and horizontal fragmentation makes it difficult for the government to efficiently prioritize human health and satisfy every district's individual requirements when providing essential water services to the population.[424]

What may result from such hyper fragmentation is an inability for manufacturers of new drinking water technology to make a product that can be used by an appreciable number of customers. If different local bodies have conflicting regulations regarding requirements for ENM-based technology used to treat drinking water, it could quickly become cost prohibitive for a manufacturer to modify their product for each county level market.

B. "HARD" AND "SOFT" POLICY INSTRUMENTS

1. Characteristics of Hard Laws and Soft Programs

There are several techniques that society uses to regulate industries. Many of these can be categorized as either "hard instruments" or "soft instruments." Hard instruments are mainly comprised of statutes and regulations that require mandatory compliance.[425] The main characteristic defining hard instruments is that they are enforceable, with examples at the international level (treaties), national level (federal statutes and federal agency regulations), state level (state statutes and state agency regulations), and local level (local ordinances).[426] Soft instruments are comprised of a much more varied group of tools, including codes of conduct, best practices, aspirational guidelines, voluntary reporting programs, risk management standards, non-binding standards, licensing, and certification programs, among others.[427] The overall characteristic of soft law is that it attempts to establish influential standards of behavior through instruments that are not legally binding.[428] Soft instruments can be created and monitored by government agencies, industries, or even concerned citizens groups.[429] Soft instruments can cover subjects that affect local, state, national, and even international businesses or groups, but cannot be enforced without the participant's consent. This section will delve into the impacts that hard and soft instruments could make on nanotechnology, what has been used in the past, what is currently being developed, and potential for future developments. It will also outline recommendations for

423. *Id.*
424. *Id.*
425. Vincent R. Johnson, *Nanotechnology, Environmental Risks, and Regulatory Options*, 121 PENN ST. L. REV. 471, 497 (2016).
426. Abbott et al., s*upra* note 80, at 285.
427. Johnson, *supra* note 425, at 498.
428. Abbott et al., s*upra* note 80, at 285.
429. *Id.*

implementing certain instruments, along with the pros and cons for involved parties.

Several scholars have touted the benefits of implementing effective soft instruments in the nanotechnology sector. One of the significant challenges in regulating a burgeoning technology is that rapidly advancing technology will often outpace the regulations that have been put into place.[430] Soft law provides an ideal solution because the standards set by soft law can often be quickly updated to account for changes in technology as they arise.[431] This is especially important in an industry as varied as nanotechnology, where regulating ENM-based water treatment requires a different set of rules than regulating ENMs in other sectors, such as medicine or industrial fabrication.[432] This flexibility is also beneficial in allowing different industry groups to fine-tune the application of the regulations to their specific purpose, whereas hard regulations are often applied uniformly across a variety of sectors.[433] Finally, flexibility allows the regulation to "respond" to individual firms or industry groups by letting the responsible parties self-regulate and focusing efforts and resources on less responsible participants.[434]

Additionally, soft law is an effective precursor to hard regulations. Soft law programs can often be used as information-gathering platforms that give regulators the information required to establish effective, targeted hard regulations.[435] While gathering the required information, soft law can be used as a stopgap to help monitor and limit the risk of exposure to the public and the environment.[436] If done well, soft laws can fulfill the role of encouraging industry participants to develop effective risk assessment profiles and risk management techniques without stifling innovation and development.[437] If the techniques used are effective, they can be considered trial runs of what good policy looks like, and the regulators who eventually devise hard instruments can rely on these tested techniques when developing regulations.[438] If they are not effective, they can be adjusted before being cemented into mandatory instruments.

These benefits can be especially pronounced when the soft instruments are created and adopted by the industry participants themselves. A significant benefit of the soft instruments being created by the industry participants is that they are created by the topic experts themselves, not legislators relying on advice from

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430. Reese, s*upra* note 87, at 560.
431. Adam Thierer, *Soft Law in U.S. ICT Sectors: Four Case Studies*, 61 JURIMETRICS J. 79, 84 (2020); Abbott et al., *supra* note 80, at 301.
432. Abbott et al., s*upra* note 80, at 302.
433. *Id.*
434. *Id.*
435. *Id.* at 300.
436. *Id.* at 301.
437. *Id.*
438. Timothy F. Malloy, *Soft Law and Nanotechnology: A Functional Perspective*, 52 JURIMETRICS J. 347, 449 (2012).

knowledgeable parties.[439] This also often results in standards that can adapt effectively when changes are needed to bypass slow legislative processes.[440] When the participants are also the creators, there tends to be more vested interest in program success and outcomes are improved.[441] Finally, enhanced participation in programs lends legitimacy to the process which can improve public perception about the industry's regulation.[442]

Although implementing soft instruments has several benefits, it is not without downsides. A concern with using soft instruments for regulation is that the public and activist groups may not feel that these programs adequately protect public health or the environment.[443] The public may feel as though the programs are aimed towards promoting business' interests at the expense of the public, especially if the program was established by the industry participants themselves.[444] There are also concerns that soft laws are not effective because there is no way to enforce or ensure the quality of participation in soft law programs.[445] This can be mitigated to some degree if there are effective positive incentives for participation or negative incentives for lack of participation.[446]

Soft law established by a regulatory agency has a mix of the pros and cons of hard law and soft law established by industry participants. Because they have the authority and duty to work for the public's benefit, government programs, hard or soft, typically tend to garner more public confidence than those programs implemented by the industry.[447] Additionally, public programs tend to decrease the cost for participants because the government can provide funding to support implementation and incentives for participation.[448] However, public soft law programs, much like hard regulation, require the program be established and run by regulators, which may result in the program being less timely and less flexible.[449] Soft law established by agencies may also have the built-in incentive for increased participation known as "the shadow of the state," because a failed soft law program may lead to a hard law regulation which may be unwanted by the industry participants.[450] However, in order for a public soft program to be successful, the industry participants must trust the agency not to disclose information that could hurt them financially or politically in the future.[451] Therefore, public

439. Abbott et al., s*upra* note 80, at 304.
440. Reese, s*upra* note 87, at 560.
441. Abbott et al., s*upra* note 80, at 304.
442. *Id.*
443. Reese, s*upra* note 87, at 562.
444. *Id.*
445. Abbott et al., s*upra* note 80, at 302.
446. *Id.* at 303.
447. *Id.* at 307.
448. *Id.* at 306; Reese, s*upra* note 87, at 564.
449. Abbott et al., s*upra* note 80, at 304.
450. *Id.* at 303; *see also* Malloy, *supra* note 438, at 351.
451. Abbott et al., s*upra* note 80, at 303.

regulators must balance appropriately protecting business confidentiality while maintaining public understanding, despite the reduced transparency.[452]

2. Public Soft Law Programs

The NMSP, a public soft law program, failed after its attempted implementation, despite having garnered public and industry support.[453] This failure was likely due to a combination of lack of incentives, lack of trust, and lack of information. The United States was not the only country to have a failed data call-in program, as Australia, Denmark, and the United Kingdom also attempted to enact failed schemes around the same time as the NMSP.[454] After the failed NMSP, the EPA enacted modifications to TSCA, which were essentially just rolling the voluntary NMSP requirements into the mandatory TSCA. However, TSCA is only serving the basic role of information gathering and reporting, whereas an effective soft law program could vastly improve the industry's understanding of the benefits and risks of ENMs. If effectively designed, it could remedy the NMSP's shortcomings related to a lack of incentives for and information about the benefits of participation, leading to increased industry trust in the program and more information being provided.

Alternatively, the National Institute for Occupational Safety and Health ("NIOSH") produces best practice guides for workplace safety that have been widely adopted and is considered an effective example of a public soft law program. The NIOSH does not have rulemaking authority but does conduct research and release material that falls under the soft law umbrella.[455] Although they are not able to enforce their regulations, a 2015 study found that of forty-six companies visited, 89% were using the NIOSH suggested PPE and 83% were using some sort of containment-based engineering controls which the NIOSH recommended.[456] The NIOSH continues to release updated materials to assist in workplace safety as new information becomes available.[457] Industry participants can continue to help improve these materials by helping provide voluntary information that becomes available during their research and production.[458]

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452. *Id.*

453. See *supra* section II.A.1.

454. Diana M. Bowman, *The Role of Soft Law in Governing Nanotechnologies*, 61 JURIMETRICS J. 53, 67–68 (2020).

455. Elizabeth A. Corley, Youngjae Kim & Dietram A. Scheufele, *The Current Status and Future Direction of Nanotechnology Regulations: A View from Nano-scientists*, 30 REV. POL'Y RSCH. 488, 491 (2013).

456. Mary K. Schubauer-Berigan et al., *Characterizing Adoption of Precautionary Risk Management Guidance for Nanomaterials, an Emerging Occupational Hazard*, 12 J. OCCUPATIONAL & ENV'TL HYGIENE 69, 69 (2015).

457. NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, CONTINUING TO PROTECT THE NANOTECHNOLOGY WORKFORCE: NIOSH NANOTECHNOLOGY RESEARCH PLAN FOR 2018–2025 7–14 (2019).

458. *See generally* NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, CURRENT INTELLIGENCE BULLETIN 70: HEALTH EFFECTS OF OCCUPATIONAL EXPOSURE TO SILVER NANOMATERIALS (2021).

Local government agencies have also developed public soft law programs to increase understanding and safety regarding ENM development. In 2007, the City of Cambridge, Massachusetts commissioned a report for recommendations on how to address the development of ENMs in the city.[459] The result of the report was a recommendation not to enact any ordinances at the time, but to develop soft law programs instead.[460] The report laid out the following as priorities for the city:

> (1) Establish an inventory of facilities that manufacture, handle, process, or store engineered nanoscale materials in the city, in cooperation with the Cambridge Fire Department and the Local Emergency Planning Committee.
> (2) Offer technical assistance, in collaboration with academic and nanotechnology sector partners, to help firms and institutions evaluate their existing health and safety plans for limiting risk to workers involved in nanomaterials research and manufacturing.
> (3) Offer up-to-date health information to residents on products containing nanomaterials and sponsor public outreach events.
> (4) Track rapidly changing developments in research concerning possible health risks from various engineered nanoscale materials.
> (5) Track the evolving status of regulations and best practices concerning engineered nanoscale materials among state and federal agencies, and international health and industry groups.
> (6) Report back to City Council every other year on the changing regulatory and safety landscape as it relates to the manufacture, use, and investigation of nanomaterials.[461]

These recommendations were adopted in lieu of potential hard regulations the city had approved in 2006.[462] The city's decision to forgo regulation in favor of information gathering has led to "longer-term and positive working relationships with the university and private sector institutions essential to the City's economic health."[463]

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459. Sean A. Hays et al., *Recommendations for a Municipal Health & Safety Policy for Nanomaterials*, 3 NANOTECHNOLOGY, BRAIN, & FUTURE 333, 333 (2008). For a comprehensive summary of the Cambridge program, *see* David A. Strifling, *Environmental Federalism and Effective Regulation of Nanotechnology*, 2010 MICH. ST. L. REV. 1129, 1168–69 (2010).

460. Hays et al., supra note 459, at 334.

461. CAMBRIDGE NANOMATERIALS ADVISORY COMM. & CAMBRIDGE PUB. HEALTH DEP'T, RECOMMENDATIONS FOR A MUNICIPAL HEALTH & SAFETY POLICY FOR NANOMATERIALS 1 (July 2008).

462. Lynn L. Bergeson, *City of Cambridge Adopts Recommendations for a Municipal Health and Safety Policy on Nanomaterials*, NANO & OTHER EMERGING CHEM. TECH. BLOG (Aug. 2, 2008), https://perma.cc/48FX-7T8W.

463. Christopher J. Bosso & Caitlin McAllister, *Local Government and Conditions of Uncertainty: Cambridge and the Regulation of Nanomaterials* 17 (Third Biennial Conference of the European Consortium on Political Research, Standing Group on Regulatory Governance on "Regulation in an Age of Crisis, 2010).

3. Private Soft Law Programs

There have also been several examples of private soft law programs related to nanotechnology. The BASF Group published a Nanotechnology Code of Conduct in 2004 and it has been updated multiple times to reflect updates in company knowledge.[464] BASF has published several documents that indicate the company is trying to be transparent in their commitment to following the Code.[465] The Code provides BASF the ability to show it has taken steps beyond those required by hard regulations and has likely garnered a buffer to reputational harm in the event a problem regarding nanotechnology occurs in the future.[466] A large player in the industry publicly providing a blueprint and showing the positive benefits of following this type of code likely results in other companies adopting similar codes.

Another example is the Environmental Defense-DuPont Risk Framework, which was a collaboration to provide a freely available risk assessment framework for ENMs.[467] The framework was developed to accomplish four specific goals: (1) establish a process to ensure the responsible development of ENMs, (2) develop a tool to organize and share information with stakeholders, (3) facilitate public understanding of nanotechnology, and (4) provide input for government policy on nanotechnology safety.[468] Although the framework received criticism from non-government organizations as a tactic to "delay or weaken rigorous regulation," the industry response was quite supportive.[469] The framework has been distributed over 7,000 times and incorporated into a number of prominent companies' practices.[470]

4. Hard Policy Instruments

Regulations, although they can be slow in coming and unwieldy if overreaching, serve several important functions. Laws, especially at the federal level, help establish uniform standards to protect public health and the environment from known hazards.[471] Regulations passed at the state or local level may be faster to implement but can create a patchwork that can be difficult for industry participants to navigate.[472] However, state and local regulations can be effective gap

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464. Bowman, *supra* note 454, at 60; *see* BASF, OUR CODE OF CONDUCT (2021), https://perma.cc/KCG7-3D24.
465. Bowman, *supra* note 454, at 61.
466. *Id.* at 62.
467. *Id.*
468. *Id.* at 63–64.
469. *Id.* at 64–65.
470. *Id.*
471. SUELLEN KEINER, WOODROW WILSON INT'L CTR. FOR SCHOLARS, ROOM AT THE BOTTOM? POTENTIAL STATE AND LOCAL STRATEGIES FOR MANAGING THE RISKS AND BENEFITS OF NANOTECHNOLOGY 32 (2008).
472. *Id.* at 17.

fillers if federal regulation does not address a specific safety aspect that needs an efficient solution.[473] A certain amount of regulation may also help promote innovation by providing boundary guidelines for companies (especially small companies) to operate within and help manage risks associated with new technology.[474]

Another reason for state and local regulation is to help address public opinion and concern at a smaller level. Berkeley, California had concerns regarding ENM regulation and—taking a different approach than the city of Cambridge—enacted ordinances to help address health and safety concerns.[475] Because it is easier to gauge public opinion and concerns at a local level, and usually faster to enact legislation at the local level, this may be an important tool to help provide legitimacy in the communities' view. However, if these regulations become abundant and demanding, it may create a patchwork of regulations from place to place, which manufactures may have difficulty navigating.

A significant consideration for hard regulations is which party bears the burden regarding harmfulness. The "precautionary principle" is when regulation places the burden on the producer to prove a lack of harmfulness when there is a suspected, but not proven, risk of harm.[476] TSCA is an example of regulation that does not follow the precautionary principle, as the burden to prove harmfulness is on the EPA, not the producer. If regulations are overly cautious and place a large burden on the producer, they may impede innovation. However, regulations that force the high burden of proving harm on a governing body may result in undesirable public health results, as exemplified by the health risks that continued after *EPA v. Corrosion Proof Fittings*.[477]

A concern with hard regulation, besides potentially stifling innovation if overly burdensome, is the potential to stigmatize ENMs by labelling the subject matter as hazardous unnecessarily. If regulations label ENMs as a "hazardous material" when the risks are still unknown, it may inhibit development out of fear of an increase in litigation over hazardous exposures.[478] It could also lead to an unwarranted stigmatization by the public, similar to the one faced by genetically modified organisms ("GMOs") when they were introduced into the public in the 1990s.[479] GMO companies have mostly moved past this stigmatization, but the

473. *Id.* at 22.

474. *Id.* at 15.

475. COUNCIL OF THE CITY OF BERKELEY, ORDINANCE NO. 6,960N.S., AMENDING BERKELEY MUNICIPAL CODE (BMC) SECTION 15.12.040 TO ADD SUBSECTION I AND AMENDING BMC SECTION 15.12.050 TO ADD SUBSECTION C.7, REGARDING MANUFACTURED NANOPARTICLE HEALTH AND SAFETY DISCLOSURE (2006).

476. Johnson, *supra* note 425, at 492.

477. *See supra* section II.A.2 (showing the court's holding that the EPA's had not met its burden allowed for the continued production of asbestos products).

478. John C. Monica Jr., Michael E. Heintz & Patrick T. Lewis, Commentary, *The Perils of Preemptive Regulation*, 2 NATURE NANOTECHNOLOGY 68, 70 (2007).

479. Leroy C. Paddock, *Reform Efforts in Environmental Protection Law, in* 3 LAW OF ENVIRONMENTAL PROTECTION § 26:32 (2021).

effects still resulted in a substantial delay in moving GMO products to Europe.[480] So, while some amount of governance may be required to maintain public confidence, regulation that erodes public trust in the industry is counter-productive to all parties if it prevents legitimate products from being developed.

C. PRODUCTS REGULATION AND MATERIALS REGULATION

A primary consideration moving forward is whether nanotechnology regulation will focus on the ENMs themselves or the end products. Because nanotechnology is not confined to a specific industry, hard instruments intended to apply to all ENMs are likely to result in unwieldy laws that do not apply uniformly across sectors. As a result, some suggest the focus of regulation should be on the final products, not the materials that make up the product.[481] This approach also gives policymakers the ability to create laws that are reasonably modified for applicability to individual sectors instead of making the drinking water sector create technology that complies with the same rules that govern automotive manufacturing or medical device production.

Currently, federal regulation of ENMs in the United States focuses primarily on reporting the ENMs through TSCA; the products using ENMs are not subject to any additional scrutiny.[482] Clarence Davies laid out the requirements of an adequate oversight system: (1) identify and assess potential risks and (2) prevent or minimize the adverse effects resulting from those risks while (3) minimizing burdens to technological innovation and (4) supporting public confidence and allowing public opinion to be heard.[483] In order to effectively regulate, proposed legislation needs to be properly linked to the target outcomes.[484] Ideally, the regulation is able to meet these outcomes while minimizing negative impacts on innovation or the market.[485] Davies suggested that nanotechnology regulation needs to address all stages of ENM utilization: (1) the manufacture of materials, (2) the products, and (3) the wastes produced.[486] Under that view, focusing on product regulation instead of material regulation is the most effective way to manage risks and utilize resources.[487] If products were the focus of regulation, there would need to be adequate risk assessments for the product's entire life cycle to determine risks during manufacture, use, and disposal.[488] Davies hypothesizes that by

480. *Id.*
481. J. CLARENCE DAVIES, OVERSIGHT OF NEXT GENERATION NANOTECHNOLOGY 27 (2009); Roger Hanshaw, *Regulation of Nanomaterials: What Are They? How Are They Regulated? And Who Decides?*, 29 NAT. RES. & ENV'T 1, 9 (2015).
482. Raj Bawa, *FDA and Nanotech; Baby Steps Lead to Regulatory Uncertainty*, *in* 1 BIO-NANOTECHNOLOGY: A REVOLUTION IN FOOD, BIOMEDICAL & HEALTH SCI. 720, 720–721 (2013).
483. DAVIES, *supra* note 481, at 20.
484. Johnson, *supra* note 410, at 488.
485. *Id.*; Davies, *supra* note 463, at 20.
486. *Id.* at 21–23.
487. *Id.* at 27.
488. *Id.*

having companies produce a sustainability plan that overviews potential risks for each of their products, regulatory resources could be focused on those products that have some probability of risk or those that showed unanticipated risks after release.[489]

There are several issues scholars have identified when regulatory agencies attempt to develop effective regulations. Agencies are often chronically underfunded, which makes it difficult to gather the resources and information required to create ideal regulation for complex problems.[490] Second, agency heads are often political appointees, so regulatory decisions may be made with a political objective in mind that does not appropriately account for the scientific or economic impact of the regulation.[491] Third, agency personnel are often recruited to higher paid private positions, so there are sometimes decisions made by employees with an eye looking towards potential employment, not the best decision for overall societal welfare.[492] Finally, regulatory agencies often attempt to implement traditional solutions to novel issues; nanotechnology is novel technology and traditional solutions may not provide adequate oversight.[493]

D. INSURANCE

The soft laws that will affect the development of nanotechnology are not confined to the industries that directly produce ENMs. The insurance industry is likely going to play a role in how the field moves forward, as manufacturers are unlikely to develop novel technologies if they cannot insure the risks associated with them. Major insurers already recommend taking a cautious approach towards insuring nanotechnology production.[494] Because the risk assessments for ENMs are not directly compatible with their macro counterparts, insurers face exposure concerns with little data to help predict exposure outcomes.[495] Nanotechnology will also affect many sectors, so a company that produces water treatment technology using ENMs will need insurance to protect against claims like environmental damages, workers compensation, personal injury, and product recalls.[496] The most significant concerns involve the risk of long tail claims, which do not become apparent until long into the future, like asbestos.[497] Because many insurance claims look back to the general liability policy that was in effect at the time the injury occurred, insurers may have to defend products that were

489. *Id.* at 28–29.
490. Johnson, *supra* note 425, 488–89.
491. *Id.* at 489.
492. *Id.*
493. *Id.* at 490.
494. Amy J. Fink, *Getting the Big Picture on Nanotechnology Insurance Issues: Addressing Coverage Issues for Long Tail Claims Can Help Prevent Big Headaches*, 19 ENV'TL CLAIMS J. 17, 18 (2007).
495. *Id.* at 21.
496. *Id.* at 21–22.
497. *Id.* at 22.

used decades before the claim was filed.[498] Current insurance industry recommendations include limiting coverage to preclude long tail claims that require the policyholder's insurer at the time of the claim to cover the incident.[499] This could mean that manufacturers might be unable to find coverage for certain products.[500] "Businesses using nanotechnology, and in particular, those involved in the manufacture, use or disposal of nanoparticles, should conduct careful risk analysis in order to address potential areas of loss, and in particular, long tail liabilities, and take precautions to ensure that appropriate loss-shifting risk management mechanisms are in place."[501]

E. APPLICATION TO NANOTECHNOLOGY IN DRINKING WATER

Although soft law provides some rapid, flexible solutions to governing the development of nanotechnology for the water industry, the rules regulating their application in PWSs seem likely to remain mostly hard law. Drinking water is widely recognized as a basic necessity, and governments and regulatory agencies often have the burden of ensuring safe drinking water to citizens.[502] Government water sectors are therefore quite risk-averse, and the regulations used are often strict and binding hard laws to ensure compliance.[503] These hard laws will likely continue to dominate the regulation of drinking water for several reasons. First, the government has a substantial interest in ensuring they are providing safe, potable water for their residents. Hard laws, such as the SDWA, with enforcement consequences help ensure water quality standards, where non-binding soft law may result in the inability to adequately protect water resources. Second, it is important that there is strong public trust that the water citizens receive is safe, and public hard law regulation is likely to inspire more public trust than any type of soft law regulation.[504] Third, drinking water is not strictly controlled by a single government agency, so hard law helps clearly define each involved agency's roles and responsibilities to ensure there are not significant gaps.[505]

Although a majority of laws regulating drinking water are (and will likely remain) comprised of hard laws, that does not mean there is no place for soft law in the industry. There are opportunities for public soft law programs that encourage and incentivize individual adoption of smaller, ENM-based products on the market. Additionally, industry participants can work to ensure drinking water products yield results that exceed the mandatory requirements. Private soft law programs like these would help assure both regulatory agencies and the public

498. *Id.* at 23.
499. *Id.* at 25.
500. *See id.*
501. *Id.*
502. *See supra* section II.A.4.
503. Ringenberg et al., *supra* note 158, at E344.
504. *See supra* section III.B.4.
505. *See supra* section III.A.

that new nanotech products are effective and may help encourage their adoption into the sector more readily.

Additionally, both hard and soft regulations may be used in concert across international boundaries utilizing a transnational regulatory framework. This framework would utilize soft regulations at first and gradually use those to transition to a hard regulatory framework, creating a consistent regulatory scheme across all participating nations. The soft regulations would be much like those discussed above, including voluntary reporting, internationally suggested limitations for quantities and types of ENMs, and suggested best practices to give corporations guidance on standards while also allowing them the time necessary to adjust to these changes. These soft regulations would be followed by hard regulations being implemented internationally. These regulations would be strict and include penalties for violations including fines, fees, and potentially criminal punishments depending on the severity of the violation.

Despite transnational regulations likely being simpler for private and public entities to abide by, there are many challenges facing this framework. The first of these challenges is the extended amount of time necessary to implement the framework and transition from soft regulation to hard regulation. Additionally, the feasibility of transnational regulation is in question due to its reliance on stable political relationships and willingness for countries to work together. Finally, the question exists as to who would enforce these regulations and how that enforcement would be carried out.

IV. MENU OF POLICY OPTIONS

Intended regulatory outcomes and goals should drive the selection of future policies. Because ENMs represent a diverse group of technologies and uses, it will be difficult to tailor policies to effectively apply to all industry groups and use cases. For example, information gathering, data reporting, and pollution control might be best overseen via federal regulation, which will promote high compliance rates because of their nature as command-and-control rules. But such broadly applicable rules could be difficult to enact in the face of pressure from both business and environmental groups. Command-and-control regulation could also be put in place at the state or even (in some cases) the local levels to address areas of high public concern over ENMs.

In the meantime, soft instruments can be useful to incentivize voluntary development of risk assessments, best practices for risk exposure and prevention, and more involved voluntary reporting programs. Such efforts must be tailored and well publicized to encourage uptake among the regulated community. High participation in such voluntary programs could reduce the need for more restrictive hard regulations. They would, however, require extensive public resources (both human and financial) to establish.

Industry groups involved with ENMs in the drinking water treatment industry could also develop private soft law programs to establish codes of conduct and licensing and certification programs throughout the industry. This could help establish public confidence related to the safe use of ENMs in the drinking water treatment industry. Establishing a viable program will also enable the regulated community to work together with government and other private organizations to help ensure smooth adoption of ENMs into products.