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## Tiny Things with a Huge Impact: The International Regulation of Nanomaterials

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# TINY THINGS WITH A HUGE IMPACT: THE INTERNATIONAL REGULATION OF NANOMATERIALS\*

Dario Picecchi\*\*

## ABSTRACT

*Mounting evidence demonstrates that nanotechnology and nanomaterials impose severe environmental risks. To minimize these risks, the usage and handling of certain nanomaterials could be addressed under existing treaties such as the Rotterdam Convention, the Stockholm Convention, and the Basel Convention. However, even if existing treaties govern the handling of certain nanomaterials, no treaty effectively regulates all the specific challenges that nanomaterials pose to the global environment. Consequently, a completely new regulatory instrument is required. An international organization could take responsibility for developing and promoting such a nanospecific international legal framework. By incorporating the precautionary principle, a technology transfer, research cooperation, and a duty to promote transparency, the new legal framework would provide adequate measures to protect the environment from nanomaterials and their risks.*

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INTRODUCTION

Despite its origin in the 1960s, nanotechnology is a relatively young scientific field that gained prominence in the beginning of the 21st century.<sup>1</sup> In brief, nanotechnology is the science of ultrafine matter: the manipulation of particles smaller than 100 nanometers (“nm”).<sup>2</sup> To put that in perspective, the thickness of a piece of paper is 100,000 nm, and the thickness of a single strand of hair is 80,000 nm.<sup>3</sup> Although many scientific areas related to nanotechnology are still at the basic research stage, there are already multiple products on the market that contain nanomaterials or use nanotechnology in their manufacturing process.<sup>4</sup>

Since nanotechnology is a young and growing scientific field, few regulations pertaining to the control and management of nanomaterials exist. One of the main reasons for the absence of detailed regulations is the lack of comprehensive studies that carefully assess potential environmental risks of

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1. See generally Richard P. Feynman, *There is Plenty of Room at the Bottom*, 1 J. OF MICROELECTROMECHANICALSYS. 60, 60 (1992); Kristen Rodine-Hardy, *Nanotechnology and Global Environmental Politics: Transatlantic Divergence*, 16 GLOBAL ENVIL. POL. 89, 89 (2016). For further details regarding the origins of this young scientific field, see CHRIS TOUMEY, *Tracing and Disputing the Story of Nanotechnology*, in INTERNATIONAL HANDBOOK ON REGULATING NANOTECHNOLOGIES 46, 47 (Graeme A. Hodge et al. eds., 2010).

2. NAT'L SCI. & TECH. COUNCIL, THE NATIONAL NANOTECHNOLOGY INITIATIVE, SUPPLEMENT TO THE PRESIDENT'S 2015 BUDGET 3 (2014), [http://www.nano.gov/sites/default/files/pub\\_resource/nni\\_fy15\\_budget\\_supplement.pdf](http://www.nano.gov/sites/default/files/pub_resource/nni_fy15_budget_supplement.pdf).

3. Cf. VICTORIA SUTTON, NANOTECHNOLOGY, LAW AND POLICY: CASES AND MATERIALS 4 (2011).

4. Marina E. Vance et al., *Nanotechnology in the Real World: Redeveloping the Nanomaterial Consumer Products Inventory*, 6 BEILSTEIN J. OF NANOTECHNOLOGY 1769, 1770 (2015); see *infra* Section I.A.

nanomaterials.<sup>5</sup> The scientific community may have underestimated the need for a more careful risk assessment. However, there is enough scientific evidence showing that some nanomaterials cause serious adverse effects to the environment, including impacts on the health of humans and animals.<sup>6</sup> Consequently, scientific institutions and international organizations around the world are urging the international community to handle the assessment and regulation of nanomaterials with due care.<sup>7</sup>

This Note addresses the need for international commitment to the regulation of nanomaterials. First, this Note explains what nanotechnology and nanomaterials are. It also addresses the potential risks and harms nanomaterials may pose to the environment. Second, this Note provides an overview of existing treaties that could govern the usage and handling of nanomaterials, specifically the Rotterdam Convention,<sup>8</sup> Stockholm Convention,<sup>9</sup> and Basel Convention.<sup>10</sup> Additionally, this Note proposes how to regulate nanomaterials and their risks through a completely new regulatory instrument. It identifies an international organization that could take responsibility for developing and promoting an international legal framework to implement this regulatory instrument. Furthermore, this Note lists the key elements that this international legal framework could incorporate and discusses whether the framework should have a legally binding or non-binding character. Finally, the conclusion suggests the best approach for internationally regulating the potential risks of nanomaterials for the environment.

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5. JOHN F. SARGENT, CONG. RESEARCH SERV., RL34614, NANOTECHNOLOGY AND ENVIRONMENTAL, HEALTH, AND SAFETY: ISSUES FOR CONSIDERATION 1 (2011); Sci. Comm. on Emerging & Newly Identified Health Risks (SCENIHR), *The Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies* 6, SCENIHR/002/05 (Mar. 2006), [hereinafter SCENIHR], [http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_003b.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf); Volker Türk & Christa Liedtke, *Invisible but Tangible?: Societal Aspects and their Consideration in the Advancement of a New Technology*, in NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 67, 72 (Graeme A. Hodge et al. eds., 2007).

6. See *infra* Section I.B.1 (nanomaterials can cause cancer, cell mutations or infertility).

7. UNEP, *Emerging Challenges: Nanotechnology and the Environment*, in GEO YEAR BOOK 2007: AN OVERVIEW OF OUR CHANGING ENVIRONMENT 61, 61-62 (2007) [hereinafter UNEP 2007]; see also SCENIHR, *supra* note 5, at 6.

8. Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade art. 1, Sept. 10, 1998, 2244 U.N.T.S. 337 [hereinafter Rotterdam Convention].

9. Stockholm Convention on Persistent Organic Pollutants art. 1, May 22, 2001, 2256 U.N.T.S. 119 [hereinafter Stockholm Convention].

10. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal art. 1, Mar. 22, 1989, 1673 U.N.T.S. 57 [hereinafter Basel Convention].

## I. NANOTECHNOLOGY AND NANOMATERIALS

Before assessing how international environmental law could regulate the risks of nanomaterials, it is essential to understand what nanotechnology and nanomaterials are. Moreover, one should have a general understanding of the potential impacts of nanomaterials on the environment and the health of humans, animals, and plants. The following section first describes the general characteristics of nanotechnology and nanomaterials and then provides an overview of their potential risks.

### A. *A Definition and Recent Developments Regarding Nanomaterials*

Although scientists still heavily debate the exact definition of nanotechnology and nanomaterials,<sup>11</sup> they generally agree on the following definition: the terms “nanotechnology” or “nanomaterials” define a process or material solely with respect to size, namely everything between 1 and 100 nm.<sup>12</sup> Regarding their other characteristics, such as their shape, substance, or intended use, nanomaterials can vary greatly. Consequently, any material can be a nanomaterial if it has the required external dimensions.

To better understand this definition, it may help to think of a commonly known material: silver. Normally, silver in its regular dimensions is used for jewelry, silverware, or electronics. However, silver is also increasingly used as a nanomaterial known as nanosilver or silver nano-particles, which range from 1 nm to 100 nm.<sup>13</sup>

11. See LORNA BRAZELL, *NANOTECHNOLOGY LAW: BEST PRACTICES* 2, 6-20 (2012); TOBIAS JOHANNES SCHULZ, *NANOMATERIALIEN ALS RISIKO?, HERAUSFORDERUNGEN AN DAS EUROPARECHT: EINE UNTERSUCHUNG UNTER BESONDERER BERÜCKSICHTIGUNG DES WELTHANDELSRECHTS* 31 (2015); David Williams, *The Scientific Basis for Regulating Nanotechnologies*, in *INTERNATIONAL HANDBOOK ON REGULATING NANOTECHNOLOGIES* 107, 109 (Graeme A. Hodge et al. eds., 2010).

12. Lynn L. Bergeson, *Nanotechnology, Environmental Law, Policy and Business Considerations*, in *NANOTECHNOLOGY: ENVIRONMENTAL LAW, POLICY AND BUSINESS CONSIDERATIONS* 1, 3 (Lynn L. Bergeson ed., 2010); Steven Dawson, *A Proposal for an International Framework Convention to Assess the Environmental Risks of Commercially Available Nanomaterials*, 15 U. BALT. J. ENVTL. L. 129, 130 (2008); NAT'L SCI. & TECH. COUNCIL, *supra* note 2, at 3; Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCI. 622, 622 (2006); Lisa Larrimore Ouellette, *Economic Growth and Breakthrough Innovations: A Case Study of Nanotechnology* 2, 3 (World Intellectual Prop. Org., Working Paper No. 29, 2015), [http://www.wipo.int/edocs/pubdocs/en/wipo\\_pub\\_econstat\\_wp\\_29.pdf](http://www.wipo.int/edocs/pubdocs/en/wipo_pub_econstat_wp_29.pdf); UNEP 2007, *supra* note 7, at 62; Eugenia Val-sami-Jones & Iseult Lynch, *How Safe are Nanomaterials?: There is Still No Consensus on the Toxicity of Nanomaterials*, 350 SCI. 388, 388 (2015).

13. Fang Liu et al., *Effects of Silver Nanoparticles on Human and Rat Embryonic Neural Stem Cells*, *FRONTIERS IN NEUROSCIENCE*, Apr. 2015, at 1; SCENIHR, *Risk Assessment of Products of Nanotechnologies* 14 (Jan. 2009), [hereinafter SCENIHR, *Risk*], [http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scenihhr/docs/scenihhr\\_o\\_023.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihhr/docs/scenihhr_o_023.pdf); *Nanosilver: A New Name* -

Working with nanomaterials enables scientists to use materials in a way they do not naturally exist. Materials at a nanoscale usually have so-called nanospecific effects, which are effects the material only has at a nanoscale. For example, materials at a nanoscale may have a much larger surface area per volume unit, a different way of dissolving, or a higher reactivity compared to the same materials at their natural size.<sup>14</sup>

These nanospecific effects can be seen in nanosilver. As soon as scientists use silver at a nanoscale, the material develops nanospecific effects: compared to normal silver, nanosilver is significantly more reactive and toxic to bacteria.<sup>15</sup> Because of the antibacterial effects, scientists use nanosilver as a compound for wound dressings and the coating of surgical devices.<sup>16</sup>

Because of the new possibilities that nanomaterials offer, the scientific field of nanotechnology and nanomaterials has grown tremendously in the past decade. In fact, many scientists believe that nanotechnology and nanomaterials could have an enormous impact on the healthcare industry, social and economic developments, and even our daily lives.<sup>17</sup> At the same time, the Scientific Committee on Emerging and Newly Identified Health Risks (“SCENIHR”)—a scientific committee that advises the European Commission—points out that “these newly identified processes and their products may expose humans, and the environment in general, to new health risks.”<sup>18</sup>

Nevertheless, nanomaterials are widely used, not only in scientific research but also in the manufacture of consumer goods. Nanomaterials are present in various products, such as foods and beverages, fitness and health products, and even in goods for children. One can buy cookware, lotions,

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*Well-known Effects*, SCIENCE DAILY (Jan. 31, 2011), [hereinafter EMPA], <https://www.sciencedaily.com/releases/2011/01/1101311133005.htm>.

14. Priyanka Bhattacharya, *Environmental Effects of Nanotechnology*, AZONANO (Sept. 20, 2012), <http://www.azonano.com/article.aspx?ArticleID=3096>; SUTTON, *supra* note 3, at 130; UNEP 2007, *supra* note 7, at 62; Valsami-Jones & Lynch, *supra* note 12, at 388.

15. EMPA, *supra* note 13, at 2; Anita K. Patlolla et al., *Genotoxicity Study of Silver Nanoparticles in Bone Marrow Cells of Sprague-Dawley Rats*, 85 FOOD & CHEMICAL TOXICOLOGY 52, 52 (2015); UNEP, *Frontiers 2017: Emerging Issues of Environmental Concern* 27 (2017), [hereinafter UNEP 2017], [https://wedocs.unep.org/bitstream/handle/20.500.11822/22255/Frontiers\\_2017\\_EN.pdf?sequence=1&isAllowed=y](https://wedocs.unep.org/bitstream/handle/20.500.11822/22255/Frontiers_2017_EN.pdf?sequence=1&isAllowed=y).

16. Karla Chaloupka et al., *Nanosilver as a New Generation of Nanoproduct in Biomedical Applications*, 28 TRENDS IN BIOTECHNOLOGY 580, 585 (2010); Liu et al., *supra* note 13, at 2.

17. SALLY DALTON-BROWN, NANOTECHNOLOGY AND ETHICAL GOVERNANCE IN THE EUROPEAN UNION AND CHINA: TOWARDS A GLOBAL APPROACH FOR SCIENCE AND TECHNOLOGY 12 (2015); David A. Dana, *The Nanotechnology Challenge*, in THE NANOTECHNOLOGY CHALLENGE, CREATING LEGAL INSTITUTIONS FOR UNCERTAIN RISKS 3, 3 (David A. Dana ed., 2012); cf. ERIC GAFFET, *Nanomaterials and Nanoproducts: World Markets and Human and Environmental Impacts*, in NANOETHICS AND NANOTOXICOLOGY XXXIII, XXXIV (Philippe Houdy et al. eds., 2011).

18. SCENIHR, *supra* note 5, at 8.

makeup, deodorants, air filters, and baby bottles, all of which contain nanomaterials.<sup>19</sup> Manufacturers expect various benefits by adding nanomaterials to their consumer products. For instance, certain nanomaterials in cosmetics can help ingredients to more easily penetrate the skin and to more effectively protect the skin from UV light.<sup>20</sup> Another example is the use of nanomaterials in food packaging, which can help to reduce bacterial contamination of food.<sup>21</sup>

Since it is generally not required to officially label products that contain nanomaterials, scientific organizations have started databases of such products. One of those databases is the Consumer Products Inventory of the Woodrow Wilson International Center for Scholars and the Project on Emerging Nanotechnology, which was launched in 2005 and has steadily evolved since.<sup>22</sup>

As a matter of fact, the number of nanomaterial-containing products that consumers can readily purchase has increased by leaps and bounds. Between 2005 and 2014, the number of registered products on the Consumer Products Inventory rose from 54 to 1,814.<sup>23</sup> Since 2010, the number of products containing nanomaterials has risen by more than 75 percent.<sup>24</sup> These figures are likely higher today because databases on consumer goods containing nanomaterials are not comprehensive.<sup>25</sup>

Additionally, private and public funding for research and development demonstrates the increasing importance and rapid growth of the field of nanotechnology and nanomaterials. Between 2000 and 2010, global government funding rose from USD 1.2 billion to USD 18 billion.<sup>26</sup> In 2012 alone,

19. *All Products*, CONSUMER PRODS. INVENTORY, [hereinafter CPI Database], <http://www.nanotechproject.org/cpi/products/> (last visited Mar. 19, 2018).

20. Silpa Raj et al., *Nanotechnology in Cosmetics*, 4 J. PHARMACY & BIOALLIED SCI. 186, 186 (2012).

21. Alina Martirosyan & Yves-Jacques Schneider, *Engineered Nanomaterials in Food: Implications for Food Safety and Consumer Health*, 11 INT'L J. ENVTL. RES. & PUB. HEALTH 5720, 5728 (2014).

22. Todd Kuiken et al., *Public's Understanding, Perceptions, and Acceptance of Nanotechnology through the Lens of Consumer Products*, in NANOENGINEERING: GLOBAL APPROACHES TO HEALTH AND SAFETY ISSUES 151, 151-52 (Patricia E. Dolez ed., 2015); Vance et al., *supra* note 4, at 1770; CPI DATABASE, *supra* note 19.

23. Vance et al., *supra* note 4, at 1771.

24. *Id.*; cf. BRAZELL, *supra* note 11, at 15.

25. Kuiken et al., *supra* note 22, at 154; Rodine-Hardy, *supra* note 1, at 100.

26. CIENTIFICA, THE GLOBAL FUNDING OF NANOTECHNOLOGIES AND ITS IMPACT 4 (2011), <http://cientifica.com/wp-content/uploads/downloads/2011/07/Global-Nanotechnology-Funding-Report-2011.pdf>; Sabil Francis, *Public Funding of Nanoscale Science and Engineering*, in 1 ENCYCLOPEDIA OF NANOSCIENCE & SOC'Y 637, 637 (David H. Guston ed., 2010).

the U.S. and the EU each spent approximately USD 2.1 billion for research and development regarding nanotechnology and nanomaterials.<sup>27</sup>

In conclusion, nanomaterials are microscopically small materials that could have far-reaching impacts on our daily lives. Without a doubt, some of these impacts will be positive, such as the tremendous advances in the health industry that nanomaterials have brought.<sup>28</sup> For example, certain nanomaterials can help to deliver drugs directly into tumor cells, which provides a more efficient way of treating cancer.<sup>29</sup> However, despite the potential advantages and the growing interest in nanomaterials, they also impose new risks to our environment. Thus, society must pay due attention not only to the advantages of nanomaterials but also to their disadvantages.

### B. Possible Risks of Nanomaterials for the Environment

Although there has been a boom in the research and development of nanomaterials, the scientific data on the potential risks and harm of nanomaterials is anything but comprehensive.<sup>30</sup> Since nanotechnology is such a versatile and complex technology, and due to the young age of this scientific field, detailed and extensive scientific data is still lacking, particularly long-term studies.<sup>31</sup> In spite of this lack of comprehensive scientific data, various studies have shown strong evidence that nanomaterials bear certain environmental risks.<sup>32</sup> Besides addressing the potential risks and dangers of nanomaterials, this section discusses whether these risks rise to a level of global concern for the environment.

#### 1. Is There Anything the Environment has to Fear?

A closer look at the studies examining the potential harm caused by nanomaterials reveals four primary areas of concern: (1) the general toxicity of nanomaterials, (2) the accumulation of nanomaterials within biological

27. Bergeson, *supra* note 12, at 1; LarrimoreOuellette, *supra* note 12, at 17; *cf.* NAT'L SCI. & TECH. COUNCIL, *supra* note 2, at 9.

28. *Cf. supra* Section I.A (discussing nanomaterials' huge economic potential).

29. See UNEP 2017, *supra* note 15, at 26; Guifa Xi et al., *Convection-Enhanced Delivery of Nanodiamond Drug Delivery Platforms for Intracranial Tumor Treatment*, 10 NANOMEDICINE: NANOTECHNOLOGY, BIOLOGY & MED. 381, 389 (2014).

30. See *supra* Introduction.

31. See Robert Falkner & Nico Jaspers, *Regulating Nanotechnologies, Risk, Uncertainty and the Global Governance Gap*, 12 GLOBAL ENVTL. POL. 30, 31 (2012); Sebastian Heselhaus, *Nanomaterials and the Precautionary Principle in the EU*, 33 J. CONSUMER POL'Y 91, 93-94 (2010); Türk & Liedtke, *supra* note 5, at 71-72.

32. See *infra* Section I.B.1.



systems, (3) the non-biodegradability of nanomaterials, and (4) the trans-boundary harm<sup>33</sup> caused by nanomaterials.

First, various studies evidence that certain nanomaterials are toxic and are causing severe harm to humans, animals, and plants; for instance, nanomaterials can cause cancer, infertility, inflammation, allergic reactions, or autoimmune responses.<sup>34</sup> Some nanomaterials even possess effects similar to those of asbestos, which means that they could lead to inflammatory reactions and lung cancer.<sup>35</sup> In particular, there have been serious concerns related to carbon nanotubes—a new form of carbon molecules with a tubular structure—that have a similar fiber-like shape as asbestos and therefore similar respiratory toxicity.<sup>36</sup> Furthermore, studies show that, in certain species, exposure to nanomaterials can reduce the growth of plants, plant yield, and even the quality of plant seeds.<sup>37</sup> Additionally, various nanomaterials can dramatically change the cell structure of living organisms, which leads to unpredictable future damages.<sup>38</sup> The negative effects of nanomaterials on cell structure can affect the DNA of a cell, possibly resulting

33. In accordance with Principle 2 of the Rio Declaration, the term “transboundary harm” refers to “damage to the environment of *other States* or of *areas beyond the limits of national jurisdiction*” (emphasis added). U.N. Conference on Environment and Development, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I), annex I (Aug. 12, 1992) [hereinafter *Rio Declaration*].

34. See Haji Bahadar et al., *Toxicity of Nanoparticles and an Overview of Current Experimental Models*, 20 IRANIAN BIOMEDICAL J. 1, 2-4 (2016); Nel et al., *supra* note 12, at 622, 626-27; SCENIHR, *Risk*, *supra* note 13, at 8, 26-27.

35. See Rosana Simón-Vázquez et al., *Nanotoxicology*, in NANOBIO TECHNOLOGY: INORGANIC NANOPARTICLES VS ORGANIC NANOPARTICLES 441, 444 (Jesús M. De la Fuente & Valeria Grazá eds., 2012); Atsuya Takagi et al., *Induction of Mesothelioma in p53+/- Mouse by Intraperitoneal Application of Multi-Wall Carbon Nanotube*, 33 J. TOXICOLOGICAL SCI. 105, 114 (2008); UNEP 2017, *supra* note 15, at 29.

36. Robert J. AITKEN et al., *Regulation of Carbon Nanotubes and Other High Aspect Ratio Nanoparticles, Approaching this Challenge from the Perspective of Asbestos*, in INTERNATIONAL HANDBOOK ON REGULATING NANOTECHNOLOGIES 205, 205-06 (Graeme A. Hodge et al. eds., 2010). The similarities between nanomaterials and asbestos are especially alarming because, in the beginning, regulators did not take asbestos’ risks seriously enough. Although there were many suspicions regarding the health risks of asbestos, it took decades for legislators to introduce effective regulations for asbestos. See BRAZELL, *supra* note 11, at 18. Legislators are similarly overlooking the potential health risks of nanomaterials and are not establishing detailed nanospecific regulations.

37. Farzad Aslani et al., *Effects of Engineered Nanomaterials on Plants Growth: An Overview*, SCI. WORLD J., Aug. 2014, at 14, 16, <http://www.hindawi.com/journals/tswj/2014/641759/>; Mélanie Auffan et al., *Ecotoxicology, Nanoparticle Reactivity and Living Organisms*, in NANOETHICS AND NANOTOXICOLOGY 325, 349-50 (Philippe Houdy et al. eds., 2011).

38. See Bahadar et al., *supra* note 34, at 1, 5; Falkner & Jaspers, *supra* note 31, at 10; Valsami-Jones & Lynch, *supra* note 12, at 388.

in DNA alterations and genetic or chromosomal mutations.<sup>39</sup> Such mutations can lead to malformations, cancer, and an increase in cellular death, causing severe tissue damage.<sup>40</sup>

Second, there is a significant risk that nanomaterials can accumulate in organisms and ecosystems.<sup>41</sup> The risks of bioaccumulation of nanomaterials is particularly worrisome because of their size.<sup>42</sup> Since nanomaterials are even smaller than bacteria, they could accumulate in the smallest links of the food chain.<sup>43</sup> Moreover, nanomaterials can cross barriers in an organism that were formerly regarded as impenetrable.<sup>44</sup> For instance, studies with rats and *in vitro* studies have shown that nanomaterials can pass through the blood-brain barrier and thereby enter brain cells.<sup>45</sup> The ability of nanomaterials to pass through the blood-brain barrier is significant because the brain is one of the best-protected human organs.<sup>46</sup> The brain is shielded from potentially dangerous or harmful compounds by the blood-brain barrier. This barrier—a membrane between the neural tissue and the bloodstream—limits the transfer of compounds from the blood to the brain.<sup>47</sup> However, this protective barrier fails to shield the brain from certain nano-

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39. Alain Botta & Laïla Benameur, *Nanoparticle Toxicity Mechanisms: Genotoxicity*, in NANOETHICS AND NANOTOXICOLOGY 111, 118 (Philippe Houduy et al. eds., 2011).

40. Junchao Duan et al., *Toxic Effects of Silica Nanoparticles on Zebrafish Embryos and Larvae*, PLOS ONE, at 7 (Sept. 2013); cf. Nan Mei et al., *Silver Nanoparticle-Induced Mutations and Oxidative Stress in Mouse Lymphoma Cells*, 53 ENVTL. & MOLECULAR MUTAGENESIS 409, 417 (2012); Patlolla, *supra* note 15, at 58.

41. See SCENIHR, *Risk*, *supra* note 13, at 21; Min-Kyeong Yeo & Dong-Ha Nam, *Influence of Different Types of NanoMaterials on their Bioaccumulation in a Paddy Microcosm: A Comparison of TiO<sub>2</sub> Nanoparticles and Nanotubes*, 178 ENVTL. POLLUTION 166, 166 (2013).

42. Dong-Ha Nam et al., *Uptake and Bioaccumulation of Titanium and Silver-Nanoparticles in Aquatic Ecosystems*, 10 MOLECULAR & CELLULAR TOXICOLOGY 9, 11 (2014).

43. See SCENIHR, *supra* note 5, at 40-42; Yeo & Nam, *supra* note 41, at 167; cf. Carlos Medina et al., *Nanoparticles, Pharmacological and Toxicological Significance*, 150 BRIT. J. PHARMACOLOGY 552, 554 (2007).

44. Heselhaus, *supra* note 31, at 94, 104; see Željka Krpetić et al., *Nanomaterials, Impact on Cells and Cell Organelles*, in NANOMATERIAL, IMPACTS ON CELL BIOLOGY AND MEDICINE 135, 137 (David G. Capco & Yongshen Chen eds., 2014); see Medina et al., *supra* note 43, at 554; see also Nel et al., *supra* note 12, at 625.

45. Cláudia Saraiva et al., *Nanoparticle-Mediated Brain Drug Delivery: Overcoming Blood-Brain Barrier to Treat Neurodegenerative Diseases*, 235 J. CONTROLLED RELEASE 34, 36-37 (2016); see Myrtil Simkó & Mats-Olof Mattsson, *Interactions Between Nanosized Materials and the Brain*, 21 CURRENT MED. CHEMISTRY 4200, 4203-04 (2014); cf. Auffan et al., *supra* note 37, at 347.

46. Simkó & Mattsson, *supra* note 45, at 4202; see Svetlana M. Stamatović et al., *Brain Endothelial Cell-Cell Junctions: How to "Open" the Blood Brain Barrier*, 6 CURRENT NEUROPHARMACOLOGY 179, 179 (2008); cf. SCHULZ, *supra* note 11, at 263.

47. See Saraiva et al., *supra* note 45, at 35; Simkó & Mattsson, *supra* note 45, at 4202; Stamatović et al., *supra* note 46, at 179.

materials. As a result, nanomaterials could accumulate in novel places with unpredictable consequences.<sup>48</sup>

Third, the concern that nanomaterials could accumulate in biological systems goes together with the fact that many nanomaterials are non-biodegradable.<sup>49</sup> Non-biodegradable materials do not break down naturally and hence, are not dissolved into the earth. Consequently, non-biodegradable materials persist in the environment, and their toxicity can have a long-term, negative impact on living beings.<sup>50</sup> Since many nanomaterials are inorganic and non-biodegradable, they not only pose imminent risks to the environment but also impose long-lasting environmental consequences, which are currently not assessable.<sup>51</sup>

Fourth, due to the size of nanomaterials and their ability to accumulate in the smallest organisms, there is a risk that they are likely to travel long distances. Once nanomaterials are free in the environment, it is possible that water, winds, animals, and even bacteria could transport them across borders and countries.<sup>52</sup> As a result, it is likely that nanomaterials are transcending mere local dimensions and are imposing transboundary harm to the environment.

## 2. Should the Risks of Nanomaterials be a Global Concern?

Most nations currently lack specific legislation on nanomaterials. For example, China—the nation with the second highest spending on nanotechnology research after the U.S.—has not enacted any substantial nanospecific regulations.<sup>53</sup> Other countries, like the U.S., treat nanomaterials mainly like other substances and regulate them using existing statutes.<sup>54</sup> If

48. Importantly, crossing the blood-brain barrier carries both potential risks and great opportunities for human health. Nanotechnology enables scientists to overcome the blood-brain barrier for therapeutic purposes. Therefore, it could be possible to treat neurological diseases with nanosized substances that can cross the blood-brain barrier. See Saraiva et al., *supra* note 45, at 43-44; Simkó & Mattsson, *supra* note 45, at 4202.

49. See Simón-Vázquez et al., *supra* note 35, at 444; UNEP 2007, *supra* note 7, at 67-68.

50. Nel et al., *supra* note 12, at 624; Türk & Liedtke, *supra* note 5, at 72.

51. SCENIHR, *supra* note 5, at 37-38.

52. Heselhaus, *supra* note 31, at 94; see Valsami-Jones & Lynch, *supra* note 12, at 388 (noting that once nanomaterials are released into the human body or the environment, they are impossible to find again).

53. BRAZELL, *supra* note 11, at 222; DALTON-BROWN, *supra* note 17, at 3-4; Darryl S. L. Jarvis & Noah Richmond, *Regulation and Governance of Nanotechnology in China: Regulatory Challenges and Effectiveness*, 2 EUR. J. L. & TECH. 1, 4 (2011), <http://www.ejlt.org/article/view/94>.

54. Gary E. Marchant et al., *Nanotechnology Regulation: The United States Approach*, in NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 189, 208 (Graeme A. Hodge et al. eds., 2007).

at all, the Food and Drug Administration (“FDA”) and the Environmental Protection Agency (“EPA”) impose specific regulations on certain nanomaterials in accordance with their existing regulatory power.<sup>55</sup> For instance, the Toxic Substances Control Act (“TSCA”)<sup>56</sup> provides different regulatory measures the EPA can take. Under Section 4 of the TSCA, the EPA can regulate any chemical substance if it finds that the chemical imposes an unreasonable risk of injury to health or the environment.<sup>57</sup> Moreover, Section 5 of the TSCA gives the EPA the power to screen and track new chemical products before they are available on the market.<sup>58</sup> If necessary, the EPA can implement regulatory measures to control unreasonable risk imposed by new chemical products.<sup>59</sup>

Generally, the U.S. has a more market-oriented approach toward the regulation of nanomaterials.<sup>60</sup> In comparison, the European Union (“EU”) pursues a more precautionary approach toward nanomaterials, which enables the regulation of certain substances even without comprehensive and conclusive scientific data concerning their potential risks.<sup>61</sup> Because of this precautionary approach, the EU has introduced some nanospecific regulations.<sup>62</sup>

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55. In 2008, the EPA decided that carbon nanotubes fall within the definition of new chemical products and therefore will be regulated more strictly under Section 5 of the TSCA. For further details, see Rodine-Hardy, *supra* note 1, at 97-98.

56. Toxic Substances Control Act, Pub. L. No. 94-469 (1976) (codified as amended at 15 U.S.C. §§ 2601-97 (2012)).

57. *Id.* § 2605(a).

58. *Id.* § 2604(a)(1)(B)(i), (a)(3).

59. *Id.* § 2604(f). Since the EPA’s decision that carbon nanotubes fall within the category of new chemical products, they can be regulated more strictly under Section 5 of the TSCA. Cf. Julie A. Miller, *US EPA Finalizes SNUR on Carbon Nanotubes*, CHEMICALWATCH (Oct. 4, 2014), <http://chemicalwatch.com/59704/us-epa-finalises-snur-on-carbon-nanotubes>. For further details on how the TSCA could regulate nanomaterials and their risks, see Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVIL. L. REV. 349, 362 (2007); Rodine-Hardy, *supra* note 1, at 97-98.

60. Rodine-Hardy, *supra* note 1, at 96; cf. BRAZELL, *supra* note 11, at 193; Lin, *supra* note 59, at 361.

61. Falkner & Jaspers, *supra* note 31, at 7; Mireille Oud, *A European Perspective*, in NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 265, 267 (Graeme A. Hodge et al. eds., 2007); Rodine-Hardy, *supra* note 1, at 94; Heselhaus, *supra* note 31, at 104.

62. For example, the EU has introduced nanospecific provisions for biocidal products (*inter alia* Regulation 528/2012, art. 19(1)(f) or art. 58(3)(d) 2012 O.J. (L. 167) (EU)) and for cosmetics (Regulation 1223/2009, art. 16 2009 O.J. (L. 342) (EC)). Besides these regulations, the EU has also introduced nanospecific provisions in its Novel Food Regulations, which require a special authorization process for food containing nanomaterials (*inter alia* Regulation 2015/2283, art. 10(4) 2015 O.J. (L. 327) (EU)). Rodine-Hardy, *supra* note 1, at 94; cf. BRAZELL, *supra* note 11, at 168; SCHULZ, *supra* note 11, at 106.

However, because of the sparse national legislation, there is a significant divergence between regions and countries in terms of how they regulate nanomaterials. This divergence could lead to a dangerous race to the bottom, wherein certain countries may try to gain a competitive advantage in nanotechnology by limiting regulatory restrictions to the bare minimum.<sup>63</sup>

Overall, nanomaterials impose countless potential risks and dangers, not only to humans but also to animals, plants, and even the smallest organisms at the end of the food chain.<sup>64</sup> Since scientific studies lead to the conclusion that nanomaterials will persist in the environment for decades and will travel across borders without issue, nanomaterials have the capacity to harm the entire global environment for a lengthy period of time.

Based on these facts, single nations alone cannot comprehensively regulate the risks and dangers of nanomaterials. Nanomaterials lead to global as well as interconnected threats, requiring response from the international community. Because of the global character of the risks of nanomaterials, less strict regulations in one state or region will ultimately affect the entire environment.<sup>65</sup> Therefore, the international community should avoid a regulatory divide between regions. Furthermore, the international community should also avoid making the same mistakes it made with other threats to the environment, such as asbestos or heavy metals, for which collective actions should have been initiated much earlier.<sup>66</sup>

In summary, nanomaterials impose potential intertwined and transnational risks to the environment, which national legislation alone cannot adequately regulate.<sup>67</sup> These characteristics render nanomaterials a global risk to the environment. Consequently, an effective risk management strategy requires common action and international cooperation, which “respect[s] the interests of *all* and protect[s] the integrity of the *global* environmental . . . system” as stated in the Preamble of the Rio Declaration.<sup>68</sup>

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63. Cf. Gary E. Marchant & Douglas J. Sylvester, *Transnational Models for Regulation of Nanotechnology*, 34 J.L., MED. & ETHICS 714, 717 (2006); SARGENT, *supra* note 5, at 28; SUTTON, *supra* note 3, at 234.

64. See *supra* Section I.B.1.

65. Cf. Marchant & Sylvester, *supra* note 63, at 716-17; SUTTON, *supra* note 3, at 234-35; Türk & Liedtke, *supra* note 5, at 71-72.

66. See Simón-Vázquez et al., *supra* note 35, at 444; cf. Arthur Lyon Dahl, *Environment and Globalization*, in UNDERSTANDING THE GLOBAL ENVIRONMENT 95 (Samir Dasgupta ed., 2009).

67. See *supra* Section I.B; *supra* Section I.B.2.

68. *Rio Declaration*, *supra* note 33, preamble (emphasis added).

## II. INTERNATIONAL TREATIES THAT COULD POTENTIALLY REGULATE NANOMATERIALS AND THEIR RISKS

Because nanomaterials will impact the global environment, a strategy must be formulated to regulate nanomaterials at the international level. The following section looks at international treaties regulating toxic chemicals, specifically the Rotterdam Convention, the Stockholm Convention, and the Basel Convention. For each of these treaties, this Note examines whether nanomaterials fall within the treaty's current regulatory mechanisms.

### A. Rotterdam Convention

The Rotterdam Convention or PIC<sup>69</sup> Convention, adopted in 1998, deals with international trade of certain hazardous chemicals.<sup>70</sup> The key component of the Convention is the prior informed consent procedure for certain chemicals and pesticides.<sup>71</sup> The Rotterdam Convention does not prohibit the trade of chemicals but creates a procedure designed to ensure that a member state must give prior informed consent ("PIC") before an exporting state can export certain chemicals to it.<sup>72</sup> According to Article 3 of the Rotterdam Convention, the Convention applies "to (a) *banned* or *severely restricted* chemicals; and (b) *severely hazardous* pesticide formulations."<sup>73</sup>

To be considered a banned or severely restricted chemical, a substance must be listed in Annex III of the Convention.<sup>74</sup> Under Article 5(5) of the Rotterdam Convention, adding chemicals to this list requires that nations in at least two regions propose the listing of a new chemical.<sup>75</sup> Subsequently, in accordance with Article 5(6) of the Rotterdam Convention, an expert Chemical Review Committee makes a recommendation to the Conference of the Parties whether or not to amend the list to include the new chemical.<sup>76</sup> Finally, as stated in Article 22(5)(b), the decision to list a chemical is

69. PIC stands for "prior informed consent," an important instrument of the Rotterdam Convention.

70. Rotterdam Convention, *supra* note 8, art. 1.

71. ULRICH BEYERLIN & THILO MARAUHN, INTERNATIONAL ENVIRONMENTAL LAW, 220 (2011); PATRICIA BIRNIE ET AL., INTERNATIONAL LAW AND THE ENVIRONMENT 446 (3rd ed., 2009); MARY ELLEN O'CONNELL ET AL., THE INTERNATIONAL LEGAL SYSTEM: CASES AND MATERIALS 573 (7th ed. 2015); *cf.* Rotterdam Convention, *supra* note 8, arts. 10, 11.

72. BIRNIE ET AL., *supra* note 71, at 446-47; EDITH BROWN WEISS ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 709-10 (2d ed. 2007); DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 926 (5th ed. 2015).

73. Rotterdam Convention, *supra* note 8, art. 3 (emphasis added).

74. *Id.* art. 6(1).

75. *Id.* art. 5(5).

76. *Id.* art. 5(6).

based solely on the consensus of all the parties to the Rotterdam Convention, which means that any party can veto the listing of a new substance.<sup>77</sup>

Applying these rules to nanomaterials, they would only fall within the scope of the Rotterdam Convention if they were listed in Annex III. However, there are two main obstacles for listing nanomaterials in Annex III of the Convention: first, nanomaterials are only defined by their size, which means that any chemical between 1 and 100 nm can be a nanomaterial.<sup>78</sup> Consequently, the parties would have to list countless chemical substances because they cannot simply refer to the size of substances in general. Second, comprehensive and in-depth scientific results regarding the risks of nanomaterials to health and the environment are still non-existent. The lack of comprehensive scientific documentation regarding the hazardous characteristics of nanomaterials provides an easy and convenient ground for vetoing its listing as a new substance in Annex III of the Convention.<sup>79</sup>

Even if certain nanomaterials were listed in Annex III, the Rotterdam Convention would only regulate the import and export of nanomaterials, not their risks and possible harm in general. However, regarding the new and specific threats nanomaterials pose to the global environment, it is essential to regulate these risks comprehensively rather than merely regulating the import or export of nanomaterials. In particular, more cautious and transparent use of nanomaterials in consumer products and stronger research cooperation are important issues that the international community must address and regulate.<sup>80</sup>

### B. Stockholm Convention

The Stockholm Convention or POPs<sup>81</sup> Convention was adopted in 2001. According to Article 1 of the Stockholm Convention, the Convention deals with the protection of “human health and the environment from persistent *organic* pollutants.”<sup>82</sup> Pursuant to Article 3 of the Stockholm Con-

77. *Id.* art. 22(5)(b).

78. *See supra* Section I.A.

79. The conclusion that the scientific evidence regarding nanomaterials’ risks would not be sufficient for a listing is supported by the practice of the Convention’s parties. For example, Canada vetoed the listing of chrysotile asbestos despite clear scientific proof of its severe health and environmental risks. For further information, *see* Kathleen Ruff, *Quebec and Canadian Governments End their Historic Support of the Asbestos Industry*, 18 INT’L J. OCCUPATIONAL & ENVIL. HEALTH 263, 266 (2012).

80. For further details on important issues that the international community should regulate with a new legal instrument, *see infra* Section III.B.

81. Persistent organic pollutants (“POPs”) are organic chemicals that remain intact in the environment. They pose long-term hazards to human and animal health over a wide regional or even global area. *See* BIRNIE ET AL., *supra* note 71, at 448-49.

82. Stockholm Convention, *supra* note 9, art. 1 (emphasis added).

vention, the Convention prohibits the use or requires the elimination of the production of certain chemicals listed in Annex A of the Stockholm Convention.<sup>83</sup> Furthermore, as set forth in Article 5 and Article 6 of the Stockholm Convention, the parties are required to prevent the release of listed POPs from waste, stockpiles, or other sources.

Like the Rotterdam Convention, the parties to the Stockholm Convention can add new chemicals to the Convention's scope with additional annexes.<sup>84</sup> Chemical experts assess proposals by the parties for new chemicals and make a recommendation to the Conference of the Parties in accordance with Article 8 of Stockholm Convention.<sup>85</sup> As under the Rotterdam Convention, the decision of the parties is ultimately a political one.<sup>86</sup> However, pursuant to Article 8(9) of the Stockholm Convention, parties shall decide "in a precautionary manner," which favors listing a potentially hazardous chemical even when there is a level of uncertainty with respect to its potential hazardousness.<sup>87</sup>

Regarding the potential application of the Stockholm Convention to nanomaterials, the Convention could deal with certain nanomaterials that fall within the category of persistent organic pollutants ("POPs"). However, many nanomaterials are inorganic, such as metals or carbontubes.<sup>88</sup> Therefore, a significant number of nanomaterials does not fall under the Stockholm Convention. Additionally, the Stockholm Convention, in any event, only prohibits the use of some nanomaterials but does not deal with the specific issues resulting from these new materials in general.<sup>89</sup>

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83. *Id.* art. 3.

84. *Id.* arts. 5-6; PHILIPPE SANDS ET AL., *PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW* 526 (3d ed. 2012); SUTTON, *supra* note 3, at 235; BROWN WEISS ET AL., *supra* note 72, at 711-12.

85. Stockholm Convention, *supra* note 9, art. 8.

86. Canada vetoing the listing of chrysotile asbestos under the Rotterdam Convention perfectly illustrates the political character of the decision to list certain chemical substances. Canada vetoed the listing of chrysotile asbestos primarily based on economic interests resulting from Quebec's asbestos mines and asbestos industry. *Cf.* Ruff, *supra* note 79, at 263; *supra* Section II.A, note 79.

87. Stockholm Convention, *supra* note 9, art. 8(9); BIRNIE ET AL., *supra* note 71, at 450; ALEXANDER GILLESPIE, *CONSERVATION, BIODIVERSITY AND INTERNATIONAL LAW: NEW HORIZONS IN ENVIRONMENTAL AND ENERGY LAW* 466-67 (2011); ELEN HEY, *ADVANCED INTRODUCTION TO INTERNATIONAL ENVIRONMENTAL LAW* 73 (2016).

88. *See also* Simón-Vázquez et al., *supra* note 35, at 443.

89. There has been a similar problem with respect to the Rotterdam Convention, which does not contain any nanospecific regulations. For more details on the Rotterdam Convention, *see supra* Section II.A.



### C. Basel Convention

The Basel Convention, adopted in 1989, deals with the transboundary movements<sup>90</sup> of hazardous wastes and their disposal. Under Article 3 of the Basel Convention, wastes are qualified as hazardous if they are listed in the annexes of the Convention or if parties of the Convention have declared them as hazardous under their domestic law and informed the Convention's Secretariat about this declaration.<sup>91</sup> According to Article 4 of the Basel Convention, the main duties of the Convention are the requirement of prior informed consent for transboundary movement of hazardous waste and an environmentally sound management of such movements, such as exports or imports of hazardous waste being moved in a manner that protects human health and the environment.<sup>92</sup>

Applying the Basel Convention's regulatory framework to nanomaterials, it is possible that certain nanomaterials can be listed in the Convention's annexes, or that parties to the Convention could declare them as hazardous waste under domestic law. Even if parties to the Basel Convention do not declare certain nanomaterials as hazardous waste, nanomaterials likely fall under existing categories listed in the annexes of the Basel Convention. For instance, according to Annex I, Y14 of the Basel Convention, "waste chemical substances . . . which are not identified and/or are new and whose effects on man and/or the environment are not known" fall within the scope of the Convention.<sup>93</sup> Additionally, pursuant to Annex III, sections H5.1, H6.1, H8 and H12 of the Basel Convention, the Convention also applies to waste that is "oxidizing," "poisonous," "corrosive," or "(eco)toxic."<sup>94</sup> Consequently, the Basel Convention can apply to nanomaterials if the nanomaterials fulfill these requirements, which, in fact, many nanomaterials do.<sup>95</sup> However, even if nanomaterials fall within the scope of the Basel Convention, the Convention merely regulates the transboundary movement of waste consisting of nanomaterials. Just as with the Rotterdam or Stockholm Convention, the

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90. Pursuant to Article 2(3) of the Basel Convention, the term "transboundary movement" means any movement of wastes "from an area under the national jurisdiction of one State to or through an area under the national jurisdiction of another State or to or through an area not under the national jurisdiction of any State, provided at least two States are involved in the movement." Basel Convention, *supra* note 10, art. 2(3).

91. *Id.* art. 3

92. *Id.* art. 4; *cf.* HUNTER ET AL., *supra* note 72, at 956; SANDS ET AL., *supra* note 84, at 569.

93. Basel Convention, *supra* note 10, Annex I, sec. Y14.

94. *Id.* Annex III, secs. H5.1, H6.1, H8, H12.

95. For further details on the effects and toxicity of different substances at a nanoscale, see Bahadar et al., *supra* note 34, at 2-5; *see also supra* Section I.A; *supra* Section I.B.1.

Convention does not deal with the other, more general issues regarding nanomaterials and their risks.<sup>96</sup>

### III. THE NEED FOR DEVELOPING SPECIFIC REGULATIONS WITH RESPECT TO THE RISKS OF NANOMATERIALS

Although the risks of nanomaterials constitute a global concern, most nanomaterials fall outside the scope of existing international treaties regulating hazardous substances. In any event, even where treaties apply, they do not provide adequate solutions to regulate the specific risks of nanomaterials.<sup>97</sup> Consequently, there is a need for specific regulations that effectively respond to the challenges and risks that nanomaterials pose to the environment. This section examines the possibility of developing such regulations. First, this section presents organizations that could potentially take responsibility for organizing and coordinating efforts to develop new regulations. Second, this section provides an overview of possible general approaches that could be implemented in nanospecific regulations. Third, this section explores whether the regulations should be legally binding or non-binding.

#### A. *Which Organizations Could Lead the Development of Nanospecific Regulations?*

Many countries have started selectively regulating some of the risks of nanomaterials.<sup>98</sup> Simultaneously, many international bodies have recognized that nanomaterials impose certain risks to the environment and human health. In 2008, the Intergovernmental Forum on Chemical Safety (“IFCS”)—a brainstorming forum for chemical safety—discussed nanomaterials on a global level for the first time.<sup>99</sup> Since then, countless international bodies have initiated reports and set up committees to assess the risks of nanomaterials. For instance, the Strategic Approach to International

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96. See *supra* Section II.A; *supra* Section II.B.

97. See *supra* Section II.A; *supra* Section II.B; *supra* Section II.C.

98. See *supra* Section I.B.2. Apart from domestic legislation, countries often establish intergovernmental cooperation mechanisms and scientific committees to assess possible risks and issues of nanomaterials. For example, the U.S. has started the National Nanotechnology Initiative, which aims to better understand nanotechnology and its risks. Similarly, the EU has the SCENIHR—a scientific committee advising the European Commission on various scientific issues, including nanomaterials. For more details, see *infra* Section III.B.2; NAT'L SCI. & TECH. COUNCIL, *supra* note 2; SCENIHR, *supra* note 5.

99. U.N. Inst. for Training & Research (UNITAR), Guidance for National Nanotechnology Policy and Programme 9 (2011), [hereinafter UNITAR], [http://www.unitar.org/cwm/sites/unitar.org.cwm/files/UNITAR%20nano%20guidance\\_Pilot%20Edition%202011.pdf](http://www.unitar.org/cwm/sites/unitar.org.cwm/files/UNITAR%20nano%20guidance_Pilot%20Edition%202011.pdf).

Chemicals Management (“SAICM”)—a policy framework that fosters the sound management of chemicals—is actively promoting research and international cooperation in the field of nanomaterials.<sup>100</sup>

Similarly, standardization bodies,<sup>101</sup> such as the International Organization for Standardization (“ISO”) or the European Committee for Standardization (“CEN”), have issued several documents for the standardization and classification of nanomaterials and nanotechnology. For example, ISO published a system that helps to classify and categorize nanomaterials, which should “prevent adverse health and safety consequences during the production, handling, use, and disposal of manufactured nanomaterials.”<sup>102</sup>

Furthermore, the United Nations Educational, Scientific, and Cultural Organization (“UNESCO”), the World Health Organization (“WHO”), the Food and Agriculture Organization of the United Nations (“FAO”), and the Organization for Economic Cooperation and Development (“OECD”) have all engaged in gathering information concerning nanomaterials.<sup>103</sup> The OECD, in particular, has taken a leading role in addressing potential challenges posed by nanomaterials to the environment. To address these challenges, the OECD has set up two bodies: the Working Party on Manufactured Nanomaterials and the Working Party on Nanotechnology. These two bodies assess the safety of manufactured nanomaterials, increase research pertaining to nanomaterials and develop policy advice.<sup>104</sup> Ultimately, the Inter-Organization Programme for the Sound Management of Chemicals (“IOMC”)—a program ensuring the coordination of any chemi-

100. See Falkner & Jaspers, *supra* note 31, at 22; UNITAR, *supra* note 99, at 10.

101. The term “standardization body” refers to any organization that develops and issues documents pertaining to the technical standards of a certain process or material. The American National Standards Institute is another example of a standardization body in addition to ISO or CEN. *About ANSI*, AM. NAT’L STANDARDS INST., [https://www.ansi.org/about\\_ansi/overview/overview?menuid=1](https://www.ansi.org/about_ansi/overview/overview?menuid=1) (last visited Mar. 18, 2018).

102. For further details, see Int’l Org. for Standardization, *Nanotechnologies: Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies*, ISO/TR 12885 (2008), <https://www.iso.org/standard/52093.html?browse=tc>; Int’l Org. for Standardization, *Nanotechnologies: Methodology for the Classification and Categorization of Nanomaterials*, ISO/TR 11360 (2010), <https://www.iso.org/standard/55967.html?browse=tc>.

103. Nupur Chowdhury, *Transnational Regulation of Nanotechnology: Institutional Diversity in Agenda Setting and State Support*, in *REGULATING TECHNOLOGICAL INNOVATION: A MULTIDISCIPLINARY APPROACH* 171, 171 (Michiel A. Heldeweg & Evisa Kica eds., 2011); Ludlow Karinne et al., *Conclusions: Big Regulatory Question—Something Old, Something New, Something Borrowed, Something Blue?*, in *NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY* 385, 399 (Graeme A. Hodge et al. eds., 2007); UNITAR, *supra* note 99, at 10.

104. Although the OECD consists of primarily Western countries, it makes sure that nations such as China, Russia, or Thailand and other organizations such as environmental NGOs or labor groups can participate in its nanomaterial working groups. See OECD, *Flyer on Nanomaterials at OECD 1* (2011), <http://www.oecd.org/science/nanosafety/45910212.pdf>; UNITAR, *supra* note 99, at 11.

cal issues among international organizations—must help coordinate the work of all the international bodies engaged in research and developments in the field of nanotechnology.<sup>105</sup>

These examples represent only a small overview of the most important work concerning nanomaterials on an international level. Nevertheless, this overview gives insight into the multiple, complex, and certainly confusing efforts of the international community in assessing nanomaterials and their risks.

The international community apparently prefers to work with a rather piecemeal approach than to coordinate its efforts. However, to establish an international regulatory framework for nanomaterials, it is highly advisable to combine all these efforts and to improve coordination between international bodies. Ideally, one international body should take the lead in the coordination of the development of nanospecific regulations.

However, it is unclear which international body would be appropriate for that role. One may think of the United Nations Environment Programme (“UNEP”), especially since “[d]eveloping international . . . environmental agreements and legal instruments” and “[p]romoting international cooperation” are two of UNEP’s official responsibilities.<sup>106</sup> Unfortunately, UNEP has not engaged in any work regarding nanomaterials apart from some small publications.<sup>107</sup> Nevertheless, if UNEP accepted a more relevant role in the field of nanomaterials, it could prove its relevance by regulating future dangers for the environment.

In contrast, the OECD has shown a much stronger involvement in developing nanospecific research and policy. However, the OECD, as an organization of mainly Western countries, may not be the ideal body to lead the development of global nanospecific regulations.

In the end, the international community must decide together which organization(s) should be in charge of developing a nanospecific international regulatory framework because such a decision also has a strong political component. Political considerations aside, a global environmental organization like UNEP seems to be the optimal choice because the coordination and the development of an environmental regulatory framework is part of UNEP’s core responsibilities. In any event, to benefit from existing know-how and past regulatory efforts, the future leading organization in developing a nanospecific framework can and should still work together with other international bodies.

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105. See UNITAR, *supra* note 99, at 10.

106. UNEP, *Organization Profile*, 18, 23 (2005), <http://staging.unep.org/PDF/UNEPOrganizationProfile.pdf>.

107. UNEP 2007, *supra* note 7, at 62; UNEP 2017, *supra* note 15, at 24.

## B. *What Would the Basic Regulatory Approaches Toward the Risks of Nanomaterials Look Like?*

The previous section has identified possible organizations that could lead the development of nanospecific regulations. However, the question remains which general rules or principles the international community should implement when it develops a nanospecific treaty. It is beyond the scope of this Note to provide detailed rules that could be implemented through international cooperation. Nevertheless, it is possible to provide general guidance and ideas on what the basic regulatory approaches toward nanomaterials should look like. The following section takes a closer look at three key elements that could help regulate the risks of nanomaterials: (1) the precautionary principle, (2) a technology transfer and research cooperation, and (3) a duty to promote transparency.

### 1. The Precautionary Principle

The precautionary principle seeks to determine how to manage possible risks for the environment, although there is scientific uncertainty with respect to these risks.<sup>108</sup> In general, the precautionary principle requires appropriate action when there are reasonable grounds of a risk of serious harm despite the existence of scientific uncertainty.<sup>109</sup> According to Principle 15 of the Rio Declaration, “lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”<sup>110</sup> In short, the precautionary principle reflects a “better safe than sorry” approach toward possible environmental risks.<sup>111</sup>

As scientists have still not produced comprehensive and conclusive research concerning the risks of nanomaterials,<sup>112</sup> the precautionary principle is predestined to be a key element in a treaty regulating nanomaterials. Although there is some scientific uncertainty regarding the risks of nano-

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108. BEYERLIN & MARAUHN, *supra* note 71, at 47; TANJA EHNERT, THE EU AND NANOTECHNOLOGIES: A CRITICAL ANALYSIS 36 (2017); O’CONNELLETAL., *supra* note 71, at 533; Oud, *supra* note 61, at 276; David L. VanderZwaag, *The Precautionary Approach and the International Control of Toxic Chemicals: Beacon of Hope, Sea of Confusion and Dilution*, 33 Hous. J. INT’L L. 605, 607-08 (2011).

109. BIRNIE ET AL., *supra* note 71, at 157; Laurance Boisson de Chazournes, *New Technologies, The Precautionary Principle, and Public Participation*, in NEW TECHNOLOGIES AND HUMAN RIGHTS 161, 163 (Thérèse Murphy ed., 2009); see Heselhaus, *supra* note 31, at 92 (saying that there is a need to strike a balance between increasing wealth and reducing risk where uncertainty exists); see HUNTER ET AL., *supra* note 72, at 480-81 (saying that the precautionary principle should only be used after determining the level of uncertainty); SARGENT, *supra* note 5, at 16.

110. *Rio Declaration*, *supra* note 33, at 15.

111. SUTTON, *supra* note 3, at 240.

112. See *supra* Introduction; *supra* Section I.B.

materials, the current scientific results provide reasonable grounds to believe that nanomaterials can cause serious environmental harm.<sup>113</sup> Under the precautionary principle, it would be necessary to ensure that the potential risks of nanomaterials cannot materialize in reality.<sup>114</sup> Therefore, countries would need to take measures to protect the environment from potential risks. For instance, it could be appropriate to restrict the widespread use of certain nanomaterials in consumer goods, like cosmetics, if there is scientific evidence suggesting that these nanomaterials could cause serious harm.

The Principle 15 of the Rio Declaration provides a starting point for how the international community could formulate a norm to implement the precautionary principle.<sup>115</sup> However, there are more examples that could be considered as a template for a future precautionary norm: for instance, Article 8(9) of the Stockholm Convention has a weaker implementation of the precautionary principle than Principle 15 of the Rio Declaration. Article 8(9) of the Stockholm Convention only requires that the Conference of the Parties “shall decide, in a precautionary manner,” whether to list new chemical substances in the Convention’s annexes.<sup>116</sup>

Another example is Article 11(8) of the Biosafety Protocol<sup>117</sup>, which states that a “[I]ack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism” shall not prevent a party from making a decision on the import of the organism.<sup>118</sup> The Rio Declaration, the Stockholm Convention, and the Biosafety Protocol have an open approach toward the precautionary principle, which does not specify how to address a potential risk. Comparatively, the Agenda 21<sup>119</sup> has a more concrete approach toward the precautionary principle. For example, Arti-

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113. For further details on the possible harm for the environment, see *supra* Section I.B.1.

114. Cf. UNEP 2017, *supra* note 15, at 27, 31.

115. Cf. *supra* Section III.B.1.

116. Stockholm Convention, *supra* note 9, art. 8(9); cf. *supra* Section II.B.

117. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 2226 U.N.T.S. 208 [hereinafter Biosafety Protocol]. The Biosafety Protocol is an international convention that the Parties to the Convention on Biological Diversity initiated. Pursuant to Article 1 of the Biosafety Protocol, this Convention should ensure the safe handling, transport, and use of living modified organisms. The Biosafety Protocol provides different regulations with respect to the usage, transit, and risk assessment of living modified organisms. See *id.* arts. 6, 11, 15-16, 20.

118. *Id.* art. 11(8).

119. The Agenda 21 is an international plan of actions that the UN introduced after the Earth Summit in 1992. According to Article 1(3) and Article 2(1) of the Agenda 21, this plan should establish and support sustainable development on a global level. The Agenda 21 provides measures in various fields such as the environment, science, workspaces, education, and other social and economic areas. See U.N. Conference on Environment and Development,

cle 17(21) of the Agenda 21 lists possible “precautionary measures” to protect the marine environment, including “environmental impact assessments, clean production techniques, recycling, waste audits and minimization . . . [and] quality management criteria for the proper handling of hazardous substances.”<sup>120</sup>

Since the exact obligations under a general precautionary principle can be highly debated,<sup>121</sup> the international community should favor a more concrete approach for regulating nanomaterials.<sup>122</sup> With an enumeration of specific measures to protect the environment, there will be more legal certainty regarding the obligations that stem from the precautionary principle. Thus, it will be easier to ensure that all the parties comply with their precautionary obligations.

Although the precautionary principle is widely accepted among scholars and in international practice, there are also skeptical voices. Some authors suggest that the precautionary principle could hinder beneficial economic or social developments because it restricts innovative technologies due to mere scientific uncertainty.<sup>123</sup> Although innovative technologies inherently pose great opportunities for social welfare, the economy, and human health, they may also impose new risks. The difficult task is the balancing of potential risks and opportunities or—in the legal context—between the absence of any regulations and overregulation of innovative technology.

As part of this balancing, one should resist approving new technologies for the sake of technological progress. Instead, one must restrict and regu-

*Agenda 21*, U.N. Doc. A/CONF.151/26 (Vols. I, II, III), (Aug. 12, 1992), <https://sustainabledevelopment.un.org/content/documents/Agenda21.pdf>.

120. *Id.* art. 17(2).

121. BIRNIE ET AL., *supra* note 71, at 160-61; Floor M. Fleurke, *Catastrophic Climate Change, Precaution, and the Risk/Risk Dilemma*, in *RISK AND THE REGULATION OF UNCERTAINTY IN INTERNATIONAL LAW* 197, 205 (Mónika Ambrus et al. eds., 2017); O'CONNEL ET AL., *supra* note 71, at 534; BÉNÉDICTE SAGE-FULLER, *THE PRECAUTIONARY PRINCIPLE IN MARINE ENVIRONMENTAL LAW WITH SPECIAL REFERENCE TO HIGH RISK VESSELS* 119 (2013).

122. The exact formulation of a future norm should definitely be phrased in collaboration with several nations, scientists, NGOs, and as many other stakeholders as possible. Preferably, scientists could recommend precautionary measures that would help protect the environment and therefore would have a scientifically adequate basis for implementation in a treaty.

123. Fleurke, *supra* note 121, at 209; Mark E. Meaney, *Lessons from the Sustainability Movement: Toward An Integrative Decision-Making Framework for Nanotechnology*, 34 *J. L., MED. & ETHICS* 682, 682 (2006); Søren Holm & John Harris, *Precautionary Principle Stifles Discovery*, 400 *NATURE* 398, 398 (1990); Hailemichael Teshome Demissie, *Taming Matter for the Welfare of Humanity: Regulating Nanotechnology*, in *REGULATING TECHNOLOGIES: LEGAL FUTURES, REGULATORY FRAMES AND TECHNOLOGICAL FIXES* 327, 342 (Roger Brownsword & Karen Yeung eds., 2008); *cf.* SUTTON, *supra* note 3, at 241, 342.

late new technologies in accordance with scientific findings.<sup>124</sup> In any case, it is not the intent of the precautionary principle to have a “technology-freezing” effect.<sup>125</sup> Quite the contrary, the precautionary principle requires technological progress and especially further scientific research to identify and avoid potential risks of new technologies.<sup>126</sup> Only with more detailed and extensive scientific research can scientists evaluate potential risks of nanomaterials and conduct a proper risk assessment as the precautionary principle requires.<sup>127</sup> Consequently, the precautionary principle supports the improvement of new technologies and merely prevents the use of new technologies that are detrimental to the environment. In other words, the precautionary principle does not hinder new technologies. Rather, it establishes a more cautious balance between technological progress and environmental safety where the environment enjoys the benefit of the doubt.

## 2. Technology Transfer and Research Cooperation

The current international efforts to advance the knowledge about nanomaterials do not constitute a well-organized international cooperative effort but rather a fragmented approach involving single international bodies.<sup>128</sup> To successfully implement global regulations for nanomaterials and their risks, it is necessary to establish a general commitment toward research cooperation and a technology transfer mechanism.<sup>129</sup>

If international bodies combined their efforts in scientific research, policymaking, and risk assessment, it would advance the current state of scientific knowledge concerning nanomaterials. Particularly, it could help to comprehensively assess the potential risks nanomaterials have. Therefore, a dialogue between the various nations, scientific bodies, NGOs, and other stakeholders would allow the international community to address the envi-

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124. Establishing restrictions and regulations based on scientific findings is not as easy as it may seem. For example, there have been severe regulations for genetically modified organisms (“GMOs”), though scientists have shown that GMOs are not as dangerous as lawmakers and the public believe them to be. For further details on the regulatory approach toward GMOs, see Gregory Conko et al., *A Risk-Based Approach to the Regulation of Genetically Engineered Organisms*, 34 *NATURE BIOTECHNOLOGY* 493 (2016).

125. Holm & Harris, *supra* note 123, at 398.

126. Cf. DAVID A. DANA, *Conditional Liability Relief as an Incentive for Precautionary Study*, in *THE NANOTECHNOLOGY CHALLENGE: CREATING LEGAL INSTITUTIONS FOR UNCERTAIN RISKS* 144, 145 (David A. Dana ed., 2012).

127. Cf. BRAZELL, *supra* note 11, at 106; see DANA, *supra* note 126, at 153.

128. See *supra* Section III.A.

129. The term “research cooperation and technology transfer mechanism” means the institutionalized process of synergizing the national efforts and results in research and development pertaining to nanomaterials. Details of such a technology transfer and research cooperation can vary immensely. Cf. *supra* Section III.B.2.



ronmental risks of nanomaterials with well-informed judgment and broad support.<sup>130</sup>

Moreover, developing countries could benefit from global research cooperation and technology transfer. Continuing with the theme of global collaboration, the international community could also provide financial support to developing countries, NGOs, or research projects. As a result, the international community could avoid a knowledge or even regulation gap between certain regions. As stated above, nanomaterials could potentially cross long distances and even borders.<sup>131</sup> Hence, as many countries as possible must be made aware and capable of responsible risk management for nanomaterials. Otherwise, regional use of nanomaterials without due care could lead to cross-border harm and consequently weaken all global efforts to protect the environment from the risks of nanomaterials.

A successful international technology transfer and research cooperation ought to incorporate three main instruments: (1) strong collaboration among scientists around the globe, (2) financial support for international research programs and for efforts toward regulation in developing countries, and (3) a complete and in-depth exchange and discussion of new findings pertaining to nanomaterials and their risks.

Existing programs that have already established a similar research and technology transfer can serve as a guide to create well-functioning international research cooperation as a part of an international treaty regulating nanomaterials. For example, the EU has set up an independent, scientific body: the Scientific Committee on Emerging and Newly Identified Health Risks (“SCENIHR”).<sup>132</sup> The SCENIHR is composed of scientists who may consult with other experts with specialized knowledge in a certain subject matter.<sup>133</sup> This group of scientific experts has the task of providing opinions, reports, and advice on emerging and newly identified health risks to the European Commission.<sup>134</sup> Thus, the European Commission can rely on scientific expertise to determine possible steps to be taken in regulating health risks. Besides the technology and research transfer for the European Commission, the SCENIHR’s work is also publicly available, and SCENIHR can collaborate with other scientific bodies to establish a dialogue with as many stakeholders as possible.<sup>135</sup>

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130. See Falkner & Jaspers, *supra* note 31, at 26-27; Marchant & Sylvester, *supra* note 63, at 717; Türk & Liedtke, *supra* note 5, at 69.

131. See *supra* Section I.B.1.

132. Commission Decision 2008/721, art. 1(1)(c), 2008 O.J. (L 241) (EC).

133. *Id.* arts. 3-4

134. *Id.* arts. 1(1)(c), 2(1), 2(3).

135. *Id.* arts. 1(13-14), 2(5).

Similarly, the U.S. has introduced the National Nanotechnology Initiative, which establishes cooperation between several federal departments, agencies, and commissions to increase knowledge and experience in dealing with nanotechnology.<sup>136</sup> The National Nanotechnology Initiative not only establishes cooperation between several governmental agencies but also develops a research program and fosters the transfer of scientific knowledge regarding nanomaterials into nanospecific regulations.<sup>137</sup> The National Nanotechnology Initiative has used over USD 25 billion to advance multidisciplinary and fundamental research concerning nanomaterials.<sup>138</sup> Moreover, this program has helped “to develop *science-based* regulations to protect human health and the environment” and to start a broader discussion about nanotechnology.<sup>139</sup>

Both the SCENIHR and the National Nanotechnology Initiative serve as prime examples of how to form and establish an international technology transfer and research cooperation. Thus, to establish international cooperation, it makes sense to rely on the existing experience of the SCENIHR and the National Nanotechnology Initiative when creating comparable programs or instruments on an international level.

### 3. A Duty to Promote Transparency

Although nanomaterials are frequently used in consumer goods,<sup>140</sup> many consumers may have never heard of nanomaterials and their associated environmental risks. At the same time, the current generation is more environmentally conscious than ever before.<sup>141</sup>

Why should one not take advantage of this fact? It seems likely that broader awareness and transparency concerning nanomaterials and their possible risks would encourage consumers to handle products with nanomaterials more cautiously. Better-informed consumers who are not willing to bear the risks of nanomaterials could lead to a generally more careful and

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136. NAT'L SCI. & TECH. COUNCIL, NATIONAL NANOTECHNOLOGY INITIATIVE: STRATEGIC PLAN iii (2016), [http://www.nano.gov/sites/default/files/pub\\_resource/2016-nni-strategic-plan.pdf](http://www.nano.gov/sites/default/files/pub_resource/2016-nni-strategic-plan.pdf).

137. See NAT'L SCI. & TECH. COUNCIL, *supra* note 2, at 19; NAT'L SCI. & TECH. COUNCIL, *supra* note 136, at 6, 10, 16, 22.

138. NAT'L SCI. & TECH. COUNCIL, *The National Nanotechnology Initiative: Supplement to the President's 2018 Budget* 11 (2017), <https://www.nano.gov/sites/default/files/NNI-FY18-Budget-Supplement.pdf>; NAT'L SCI. & TECH. COUNCIL, *supra* note 136, at 32.

139. NAT'L SCI. & TECH. COUNCIL, *supra* note 136, at 32 (emphasis added).

140. See *supra* Section I.A.

141. PEW RESEARCH CTR., THE GENERATION GAP AND THE 2012 ELECTION, ANGRY SILENTS, DISENGAGED MILLENNIALS 95-99 (2011), <http://www.people-press.org/files/legacy-pdf/11-3-11%20Generations%20Release.pdf>; Gwynne Rogers, *The Rise of Generation Y in the Sustainable Marketplace*, THE GUARDIAN (Feb. 4, 2013), <http://www.theguardian.com/sustainable-business/blog/rise-generation-y-sustainable-marketplace>.

restricted use of nanomaterials.<sup>142</sup> Additionally, greater awareness and caution among consumers could strengthen and reaffirm the precautionary approach toward nanomaterials.<sup>143</sup> However, increasing consumer's self-responsibility requires increasing awareness and transparency regarding nanomaterials.

Here, a duty to promote transparency could be crucial. If nations committed themselves at an international level to adopt rules that make their population more aware of nanomaterials, such awareness could have a positive impact on the handling and use of nanomaterials.<sup>144</sup> For example, the international community could agree on an official label for goods containing nanomaterials. Such a "nano-label" would be comparable to other labels that indicate, for example, whether a product is organic or contains genetically modified ingredients. As the EU has demonstrated with a duty to list nanomaterials in the ingredients of certain consumer goods, a label for nanomaterials could be a feasible first step toward a more transparent use of nanotechnology.<sup>145</sup>

Another step toward promoting transparency could be the implementation of a PIC-mechanism, similar to the PIC-procedure under the Rotterdam Convention.<sup>146</sup> Under a PIC-procedure for products containing nanomaterials, exporting nations would be required to inform importing nations about the import of products that contain nanomaterials. Thereafter, the importing nation would have to consent to the planned imports.

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142. For example, consumers' increased environmental consciousness regarding organic products and meat production has had positive effects on agriculture and animal farming. Cf. Meredith Cohn & Tim Wheeler, *USDA Takes Accounting of Organic Farms*, CHI. TRIB., <http://www.chicagotribune.com/ifestyles/sns-green-certified-organic-farms-story.html> (last visited Mar. 19, 2018); BETTY S. KING ET AL., FOOD AND AGRICULTURE, CONSUMER TRENDS AND OPPORTUNITIES: AN OVERVIEW, 3-4 (2000), <http://www2.ca.uky.edu/agcomm/pubs/ip/ip58a/ip58a.pdf>. Furthermore, a more transparent handling of nanomaterials would not only be favorable for the environment but also more appropriate and fair for the consumer's self-determination.

143. Cf. Boisson de Chazournes, *supra* note 109, at 163-66 (stating the precautionary principle requires increased transparency since precaution is symbiosis of technical, scientific, social, political, and legal agents and actions).

144. Experience has shown that more conscious consumers can have an impact on environmental issues. For instance, the growing awareness regarding the positive effects of organic products has tremendously increased organic and more sustainable agriculture. Cf. Jonathan H. Adler, *Labeling the Little Things*, in *THE NANOTECHNOLOGY CHALLENGE: CREATING LEGAL INSTITUTIONS FOR UNCERTAIN RISKS* 203, 208-15 (David A. Dana ed., 2012); Cohn & Wheeler, *supra* note 142; King et al., *supra* note 142.

145. Falkner & Jaspers, *supra* note 31, at 27; Rodine-Hardy, *supra* note 1, at 100; SCHULZ, *supra* note 11, at 106-07.

146. Dawson, *supra* note 12, at 147. For further details on the Rotterdam Convention, see *supra* Section II.A.

This PIC-procedure should help to protect importing nations from hazardous or dangerous substances.<sup>147</sup>

However, the initial concept of the PIC-procedure under the Rotterdam Convention is fundamentally different compared to a PIC-procedure for products containing nanomaterials. Chemicals that fall under the Rotterdam Convention are generally used by industrial companies or agriculturists in developing countries.<sup>148</sup> Moreover, since most of the chemicals under the Convention are pesticides, there is one main purpose for using them: to protect plants from pests.<sup>149</sup>

Comparatively, various companies manufacture or sell products that contain nanomaterials, and there are countless purposes for the use of nanomaterials.<sup>150</sup> Because of the various purposes and ways companies use nanomaterials, it would be difficult and costly to monitor and to ensure that countries gave their PIC to all imports of products that contain nanomaterials. Furthermore, compared to the 50 chemicals on the PIC-list of the Rotterdam Convention, the pure number of products that contain nanomaterials is extremely high.<sup>151</sup> Thus, the vast and increasing use of nanomaterials would lead to an immense paper chase for all imports and exports of products containing nanomaterials. At the same time, even nanomaterials that do not have any detrimental effects on the environment or human health would require a complex PIC-procedure.<sup>152</sup> As a result, the PIC-regulations could be disproportionate to the potential danger for importing countries.

To limit the time and effort exhausted by a general PIC-procedure for products containing nanomaterials, the international community would

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147. Dawson, *supra* note 12, at 147; *cf. supra* Section II.A.

148. *Cf.* Rotterdam Convention, *supra* note 8, art. 3; O'CONNELLETAL., *supra* note 71, at 573. It is noteworthy that, pursuant to Article 3(2)(h)(ii) of the Rotterdam Convention, chemicals that end users buy for their personal use do not fall under the scope of the Convention. There are two reasons why such imports do not fall under the Convention. First, a PIC procedure for end consumer imports could be expensive and time-consuming since there could be a substantial number of such imports. In addition, it would require significantly more effort to monitor whether consumer imports contain chemicals that fall under the Rotterdam Convention. Second, because of the small quantities of chemicals that are intended for personal use, there is only a small risk of negative impacts on the environment or health. As a result, the costs and efforts of a PIC procedure for end user imports would be disproportionate in comparison with the benefits of such a procedure.

149. Rotterdam Convention, *supra* note 8, annex III (35 of the 50 listed chemicals are pesticides); *cf.* O'CONNELLETAL., *supra* note 71, at 573.

150. For more details on consumer products containing nanomaterials, *see* Section I.A.

151. Rotterdam Convention, *supra* note 8, Annex III (there are 50 chemicals listed in Annex III); *see supra* Section II.A (there are countless substances at a nanoscale).

152. As highlighted before, nanomaterials also can have positive effects. *See supra* Section I.A; *supra* Section I.B.1, note 48.

have to agree on a list of certain nanomaterials that require a PIC. However, the international community can already do that under the existing Rotterdam Convention.<sup>153</sup> There would be no need for a separate PIC-procedure in a convention dealing with the risks of nanomaterials.<sup>154</sup>

In conclusion, a general PIC-procedure for products containing nanomaterials would establish a complex and costly bureaucratic mechanism that is not necessarily justified for every nanomaterial. Furthermore, it is already possible under the existing Rotterdam Convention to list nanomaterials for a PIC-procedure.<sup>155</sup> Consequently, it seems advisable to use the existing mechanisms with respect to a possible PIC-procedure for certain nanomaterials.

### *C. Should Nanospecific Regulations Have a Legally Binding or Non-Binding Character?*

For any international regulatory framework, there are two main possibilities with respect to its legal character. There is the classic approach of a legally binding regulation, which is also called “hard law.” The legally binding character of hard law is based on the legal obligation to fulfill and or to comply with a regulation.<sup>156</sup> Non-compliance with hard law can result in legal actions aimed at enforcing the breached regulation.<sup>157</sup> Comparatively, a law or regulation can also have a legally non-binding character, resulting in a so-called “soft law.” Soft law is the opposite of hard law because there is no legal obligation to comply with soft law regulations.<sup>158</sup> Consequently, the major advantage of hard law is its legally binding and coercive character. Thus, one may, at first sight, question the usefulness of soft law.

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153. See *supra* Section II.A.

154. For the new legal framework regarding nanomaterials and their risks, one may think of introducing a PIC procedure for end user imports that do not fall under the existing Rotterdam Convention. However, as demonstrated, monitoring all end user imports of (products containing) nanomaterials seems neither feasible nor appropriate. See Rotterdam Convention, *supra* note 8, art. 4.

155. See *supra* Section II.A.

156. JÜRGEN FRIEDRICH, INTERNATIONAL ENVIRONMENTAL “SOFT LAW:” THE FUNCTIONS AND LIMITS OF NONBINDING INSTRUMENTS IN INTERNATIONAL ENVIRONMENTAL GOVERNANCE AND LAW 7-8 (2013); Jon Birger Skjærseth, *Exploring the Consequences of Soft Law and Hard Law: Implementing International Nutrient Commitments in Norwegian Agriculture*, 10 INT’L ENVIL. AGREEMENTS 1, 3 (2010); Gregory C. Shaffer & Mark A. Pollack, *Hard vs. Soft Law: Alternatives, Complements, and Antagonists in International Governance*, 94 MINN. L. REV. 706, 713-14 (2010).

157. BEYERLIN & MARAUHN, *supra* note 71, at 290; BIRNIE ET AL., *supra* note 71, at 36.

158. Rebecca Byrnes & Peter Lawrence, *Can “Soft Law” Solve “Hard Problems?”: Justice, Legal Form and the Durban-Mandated Climate Negotiations*, 34 U. TASMANIA L. REV. 34, 36 (2015); HEY, *supra* note 87, at 6.

However, legally non-binding regulations have many advantages that binding regulations lack. First, it can be easier to reach a consensus on a certain subject because parties generally have a lower inhibition threshold to agree to non-binding regulations.<sup>159</sup> This lower inhibition threshold can be very helpful in initiating a common discourse over possible regulations.<sup>160</sup> Second, soft laws are less costly and more flexible with respect to their negotiation and implementation.<sup>161</sup> Third, the coercive character of a law is no guarantee that the affected individuals will comply with it. In fact, there are many reasons why individuals comply with legally non-binding rules, such as their socialization, their self-interests, their society's moral conception, or a simple internal motivation.<sup>162</sup> Thus, soft laws can help strengthen social and behavioral norms in our society.

Because of the advantages of soft laws, there are countless examples of legally non-binding regulations in environmental law.<sup>163</sup> One of the best examples of an environmental soft law is the voluntary PIC system established in 1989. This voluntary PIC system was the precursor to the Rotterdam Convention.<sup>164</sup> In fact, the voluntary PIC system led to international discourse about the need for legally binding regulations for certain hazardous chemicals and pesticides.<sup>165</sup> Moreover, the voluntary PIC system has had a substantial influence on the PIC procedure of today's Rotterdam Convention. The voluntary PIC system, with over 150 nations participating, showed that a legally binding PIC procedure could be possible and feasible.<sup>166</sup> Without the voluntary PIC system, it is highly unlikely that the international community would have agreed on today's Rotterdam Conven-

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159. BEYERLIN & MARAUHN, *supra* note 71, at 47; BIRNIE ET AL., *supra* note 71, at 35; Byrnes & Lawrence, *supra* note 158, at 44.

160. Shaffer & Pollack, *supra* note 156, at 720-21; cf. Timothy F. Malloy, *Soft Law and Nanotechnology, A Functional Perspective*, 52 JURIMETRICS 347, 349 (2012).

161. Byrnes & Lawrence, *supra* note 158, at 718; Birger Skjærseth, *supra* note 156, at 4.

162. Birger Skjærseth, *supra* note 156, at 2; FRIEDRICH, *supra* note 156, at 245-49.

163. For instance, there are several legally non-binding UNEP and OECD guidelines as well as non-binding codes and guidelines of the International Maritime Organization (IMO), the North Sea Conference Declarations, and most regulations issued by the treaty bodies of the Convention on Biological Diversity. See FRIEDRICH, *supra* note 156, at 22-51.

164. O'CONNELLETAL., *supra* note 71, at 573. For more details regarding the Rotterdam or PIC Convention, see *supra* Section II.A.

165. See Rotterdam Convention, *supra* note 8, art. 3.

166. Nancy S. Zahedi, *Implementing the Rotterdam Convention: The Challenges of Transforming Aspirational Goals into Effective Controls on Hazardous Pesticide Exports to Developing Countries*, 11 GEO. INT'L ENVTL. L. REV. 707, 709 (1999).

tion.<sup>167</sup> This example demonstrates that soft laws can have an immense impact on hard law regulations and even initiate their development.<sup>168</sup>

Regarding a nanospecific legal framework, it would be ideal to agree on a widely accepted and legally binding treaty. However, in reality, it can be difficult to establish a legally binding framework for regulating a highly complex issue such as nanomaterials. To establish international consensus on the regulation of nanomaterials could be especially challenging because many countries have different regulatory approaches toward the potential risks of nanomaterials.<sup>169</sup>

Consequently, a soft law can be the first step in laying the groundwork for a legally binding international framework for regulating nanomaterials and their risks. With this groundwork, the international community would have an established consensus as a basis for discussing and agreeing to details for a hard law framework. Additionally, legally non-binding regulations for nanomaterials could strengthen general awareness of the risks of nanomaterials. As a result, stakeholders, such as state legislators, scientists, entrepreneurs, and product developers, could become more cautious about the potential risks of nanomaterials and thus start handling them with due care.

## CONCLUSION

This Note shows that there are many uncertainties pertaining to the young scientific field of nanotechnology and the use of nanomaterials. Nevertheless, it is apparent that nanotechnology and nanomaterials will have a huge impact on our future, including on science, healthcare, the economy, and our daily lives.<sup>170</sup> Simultaneously, it is evident that certain nanomaterials will also carry a negative impact on our environment, including humans, animals, plants, and the ecosystem in general.<sup>171</sup> Because of the characteristics of nanomaterials, their negative effects on the environment transcend

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167. See FRIEDRICH, *supra* note 156, at 165.

168. Another way soft laws can play an important role in regulating a certain subject is their direct incorporation in national laws or, at least, references from national laws to soft laws. An example of this national incorporation or reference process is the Good Clinical Practice (“GCP”) Guideline provided by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (“ICH”): a legally non-binding standard for clinical trials. Because so many national laws have incorporated or referred to the GCP Guideline, they have become “the internationally accepted gold standard” for clinical trials. For further details, see Vischer Nerina et al., *The Good Clinical Practice Guideline and its Interpretation: Perceptions of Clinical Trial Teams in Sub-Saharan Africa*, 21 TROPICAL MED. & INT’L HEALTH 1040, 1040 (2016); cf. MICHAEL HERSCHEL, DAS KLIFO-BUCH, PRAXISBUCH KLINISCHE FORSCHUNG 33 (2d ed., 2013).

169. See *supra* Section I.B.2.

170. See *supra* Section I.A.

171. See *supra* Section I.B.1.

local dimensions, which means that nanomaterials can cause cross-border harm.<sup>172</sup> Thus, the risks posed by nanomaterials to the environment rise to the level of a global concern, which requires internationally coordinated efforts to protect the environment.<sup>173</sup>

The lack of comprehensive research regarding the risks of nanomaterials makes it difficult to assess and prevent their potential environmental harm. Therefore, the international community must increase research and technological developments on the environmental risks of nanomaterials. The international community cannot just wait until scientists can provide conclusive scientific results. Rather, it needs to establish a precautionary approach toward nanotechnology and nanomaterials.

The precautionary principle is the ideal legal instrument to deal with the scientific uncertainty of the potential risks of nanomaterials. Applying the precautionary principle to nanomaterials will enable the international community to take protective measures without waiting until the potential environmental risks of nanomaterials become reality.<sup>174</sup> Furthermore, the precautionary principle goes hand-in-hand with two other proposed regulatory approaches: research cooperation and a duty to promote transparency.<sup>175</sup>

Only with advanced scientific knowledge and a broader awareness among the general population will it be possible to determine and promote adequate measures to protect the environment from nanomaterials. Ideally, these measures should have a legally binding character. However, a soft law that regulates nanomaterials can be a promising start to initiate a legally binding international framework dealing with the environmental risks of nanomaterials.<sup>176</sup>

To guarantee well-organized and coordinated protection of the environment, international institutions must take the lead in developing the instruments and principles that could regulate nanomaterials and their risks. The OECD's current strong commitment toward regulating nanomaterials seems to be an ideal basis on which the international community could build. However, it is advisable to establish broader international support for regulation of nanomaterials because the OECD is an organization with primarily Western member states.<sup>177</sup> Thus, a joint effort of the OECD and another international environmental organization, like UNEP, would be ideal for developing an international regulatory framework. This joint effort

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172. See *supra* Section I.B.1.

173. See *supra* Section I.B.2.

174. See *supra* Section III.B.1.

175. See *supra* Section III.B.2; see also *supra* Section III.B.3.

176. See *supra* Section III.C.

177. See *supra* Section III.A.



could pave the way for uniting and unifying the approaches of single nations into an international effort to regulate nanomaterials and their risks.

To conclude, future regulations of nanomaterials are highly dependent on successful international cooperation. The international community should not only keep in mind the importance of protecting the environment from the negative impacts of nanomaterials but should also think of future regulations for other new technologies. Since the risks of new technologies will be one of the main environmental challenges in the future, the international community must demonstrate its ability to successfully deal with the challenges stemming from such new technologies. Hence, effective international regulations for the risks of nanomaterials will be a key step toward a new era in environmental law.