

# Principles for the Oversight of Nanotechnologies and Nanomaterials

The undersigned, a broad coalition of civil society, public interest, environmental and labor organizations concerned about various aspects of nanotechnology's human health, environmental, social, ethical, and other impacts, submit the following Declaration, *Principles for the Oversight of Nanotechnologies and Nanomaterials*.

## *Introduction*

Governments, universities, and businesses around the world are racing to commercialize nanotechnologies and nanomaterials. Already, hundreds of consumer products either contain nanomaterials (nano-scale chemicals) in the finished product, or are made using nanotechnologies. At the same time, mounting evidence indicates that this new materials revolution poses significant health, safety, and environmental hazards as well as profound social, economic, and ethical challenges. Those speeding the commercialization of nanotechnologies have barely begun the research needed both to clarify and reduce risks and to develop urgently needed ethical, legal and regulatory oversight mechanisms. These mechanisms are required if we are to avoid repeating failures of past "wonder" materials and technologies.

The current situation does not give us hope that we will "get it right" with nanotechnology. Manufacturing and laboratory settings operate without proper safety guidance or protection measures. Consumers are involuntarily exposed to unlabeled nanomaterial ingredients in products, without being informed of potential risks. Nanomaterials are disposed of and released into the environment despite unknown impacts and inadequate means to detect, track or remove the new materials. Governments and industry developers of nanotechnologies provide few meaningful opportunities for informed public participation in discussions and decisions about how, or even whether, to proceed with the "nano"-ization of the world.

This document declares eight fundamental principles that we believe must provide the foundation for adequate and effective oversight and assessment of the emerging field of nanotechnology, including those nanomaterials that are already in widespread commercial use.

## The Principles

- I. A Precautionary Foundation**
- II. Mandatory Nano-specific Regulations**
- III. Health and Safety of the Public and Workers**
- IV. Environmental Protection**
- V. Transparency**
- VI. Public Participation**
- VII. Inclusion of Broader Impacts**
- VIII. Manufacturer Liability**

A precautionary approach is fundamental. A precautionary approach requires mandatory, nano-specific oversight mechanisms to account for the unique characteristics of the materials. Within those mechanisms, the protection of public health and worker safety requires a committed focus on critical risk research and immediate action to mitigate potential exposures until safety is demonstrated. Similar emphasis and action must be taken with regard to safeguarding the natural environment. Throughout, oversight must be transparent and provide public access to information regarding decision-making processes, safety testing and products. Open, meaningful and full public participation at every level is essential. These discussions and analyses should include consideration of nanotechnology's wide-ranging effects, including ethical and social impacts. Finally, developers and manufacturers must be stewards responsible for the safety and effectiveness of their processes and products, and retain liability for any adverse impacts stemming from them. Governmental bodies, organizations, and relevant parties should implement comprehensive oversight mechanisms enacting, incorporating and internalizing these basic principles as soon as possible.<sup>1</sup>

## I. A Precautionary Foundation

The Precautionary Principle,<sup>2</sup> already integrated into many international conventions,<sup>3</sup> has been described as follows: “When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”<sup>4</sup> Such an approach requires preventative action in the face of uncertainty, assigns the burden of protection to those responsible for the potentially harmful activities, considers all alternatives to new activities and processes, and insists on public participation in decision-making. This would include prohibiting the marketing of untested or unsafe uses of nanomaterials and requiring product manufacturers and distributors to bear the burden of proof. Simply put, ‘no health and safety data, no market.’ Adequate lifecycle assessment of nanomaterials should be defined and the assessment conducted before commercialization. Adequate resources should be dedicated to discerning and using the safest possible feedstock, processes and products.

**The Precautionary Principle must be applied to nanotechnologies because scientific research to-date suggests that exposure to at least some nanomaterials, nanodevices, or the products of nanobiotechnology is likely to result in serious harm to human health and the environment.** The small size of engineered nanomaterials can imbue them with novel physical, chemical, and biological properties that are potentially useful; however, the comparatively high reactivity, mobility, and other properties that come with small size are also likely to impart novel toxicity.<sup>5</sup> Existing research on the impacts of nanomaterials on human health and the environment have raised red flags that warrant precautionary action and further study.<sup>6</sup> Because the potential toxicity of nano-scale materials cannot be reliably predicted from their toxicity profile in bulk (non-nano) form, regulations must require rigorous, accurate and comprehensive pre-market safety assessments that take into consideration the unique properties of nanomaterials. Regulations underpinned by a precautionary approach are critical for new technological

developments where long-term health and environmental impacts are unknown, inadequately studied, and/or unpredictable.<sup>7</sup> Lack of data or evidence of specific harm cannot substitute for a reasonable certainty of safety.

## II. Mandatory Nano-specific Regulations

**Current legislation provides inadequate oversight of nanomaterials. A modified or *sui generis*, nano-specific regulatory regime must be an integral aspect of the development of nanotechnologies.** Considering the already advanced and rapidly expanding development and commercialization of nanomaterials, a governmental assessment of current oversight mechanisms is urgently needed, taking into account the novel properties exhibited by nanomaterials.

Even where legal authority exists, substantial regulatory changes in existing laws are likely to be necessary in order to adequately and effectively address the fundamentally different properties of nanomaterials and new challenges that nanomaterials present.<sup>8</sup> Current laws are even less equipped to oversee products and processes such as active nano-systems and nano-structures that are currently under development.<sup>9</sup> Government agencies thus far have failed to use their existing regulatory authority.<sup>10</sup> Current regulatory systems must be adjusted and applied to nanomaterials as a temporary response, until nano-specific oversight mechanisms can be formulated and put into place.<sup>11</sup> Regulatory actions should retroactively cover all nanomaterial products already on the market.

The adverse effects of nanomaterials cannot be reliably predicted from the known toxicity of the bulk material.<sup>12</sup> Some experts recommend that up to sixteen physicochemical parameters be evaluated -- a “far cry from the two or three [parameters] usually measured” for bulk materials.<sup>13</sup> **Because of their novel properties and the associated risks, nanomaterials must be classified as new substances for assessment and regulatory purposes.**<sup>14</sup>

**Voluntary initiatives are wholly inadequate to oversee nanotechnology.** Voluntary programs lack incentives for “bad actors” or those with risky products to participate, thus leaving out the entities most in need of regulation.<sup>15</sup> Under voluntary initiatives, companies may lack motivation to test for long-term or chronic health and environmental effects.<sup>16</sup> Voluntary initiatives often delay or weaken essential regulation, forestall public involvement, and limit public access to vital environmental safety and health data. For these reasons, the public overwhelmingly prefers mandatory governmental oversight to voluntary initiatives.<sup>17</sup>

## III. Health and Safety of the Public and Workers

**Adequate and effective nanomaterial oversight requires an immediate emphasis on preventing known and potential exposures to nanomaterials that have not been proven safe.** This is essential for both the public and nano-industry workers because some materials present potential hazards and others are largely untested. Free

nanoparticles (nanomaterials that are not bound up in other materials) are of particular concern because they appear most likely to enter the body, react with cells, and cause tissue damage.<sup>18</sup> Embedded nanoparticles also pose exposure concerns. Workers may be exposed to such materials throughout the manufacturing process, while disposal and recycling activities may expose the public and the environment.

Due to their size, nanoparticles can cross biological membranes, cells, tissues, and organs more readily than larger particles.<sup>19</sup> When inhaled, they can go from the lungs into the blood system.<sup>20</sup> There is growing evidence that some nanomaterials may penetrate intact skin,<sup>21</sup> especially in the presence of surfactants<sup>22</sup> or massaging or flexing of the skin,<sup>23</sup> and gain access to systemic circulation.<sup>24</sup> When ingested, nanomaterials may pass through the gut wall and into the blood circulation.<sup>25</sup> Once in the blood stream, nanomaterials can circulate throughout the body and can lodge in organs and tissues including the brain, liver, heart, kidneys, spleen, bone marrow, and nervous system.<sup>26</sup> Once inside cells, they may interfere with normal cellular function, cause oxidative damage and even cell death.<sup>27</sup>

Inadequate funding and the lack of a governmental emphasis on human health risk research enabled the current situation in which some people are exposed to manufactured nanomaterials daily despite a dearth of data on potential long-term or chronic effects of those materials.<sup>28</sup> The people that research, develop, manufacture, package, handle, transport, use and dispose of nanomaterials will be those most exposed and therefore most likely to suffer any potential human health harms. **As such, worker protection should be paramount within any nanomaterial oversight regime.** The U.S. National Science Foundation estimates that by 2015 nanotechnology industries will employ two million workers globally.<sup>29</sup> In addition, many researchers and students work with nanomaterials in academic laboratories. Despite the burgeoning nano-workforce, no existing occupational safety and health standard specifically addresses nanotechnologies and nanomaterials, and there are no accepted standard methods for measuring human exposure to nanomaterials in the workplace.

Any regulatory regime designed to protect workers from the health effects of nanomaterials requires written comprehensive safety and health programs addressing workplace nanotechnology issues. Employers should use the precautionary principle as the basis for implementing protective measures for assuring the health and safety of workers. The hierarchy of exposure controls—elimination, substitution, engineering controls, work practice/administrative approaches, and personal protective equipment—should be employed. Exposure monitoring, medical surveillance and worker training are necessary to ensure that workers receive the most up-to-date information on nanomaterials. **Workers and their representatives should be involved in all aspects of workplace nanotechnology safety and health issues without fear of retaliation or discrimination.** Finally, existing occupational, safety and health standards must be scrutinized for their applicability to nanomaterials.<sup>30</sup>

#### IV. Environmental Sustainability

A nanomaterial lifecycle<sup>31</sup> assessment – including manufacturing, transport, product use, recycling, and disposal into the waste stream – is necessary to understand how various statutory systems apply and where regulatory gaps exist.<sup>32</sup> **Full lifecycle environmental, health and safety effects must be assessed prior to commercialization.**

Once loose in nature, manufactured nanomaterials represent an unprecedented class of manufactured pollutants. Potentially damaging environmental impacts can be expected to stem from the novel nature of manufactured nanomaterials, including mobility and persistence in soil, water and air, bioaccumulation, and unanticipated interactions with chemical and biological materials.<sup>33</sup> The limited number of existing studies has raised red flags, such as exposure to high levels of nanoscale aluminum stunting root growth in five commercial crop species,<sup>34</sup> byproducts associated with the manufacture of single-walled carbon nanotubes causing increased mortality and delayed development of a small estuarine crustacean,<sup>35</sup> and damage to beneficial microorganisms from nanosilver.<sup>36</sup> The U.K. Royal Society has recommended that, “the release of nanoparticles and nanotubes in the environment be avoided as far as possible” and that, “factories and research laboratories treat manufactured nanoparticles and nanotubes as hazardous, and seek to reduce or remove them from waste streams.”<sup>37</sup>

Potential environmental risks remain unidentified due to the failure to prioritize environmental impact research and the paucity of funding currently allocated for risk-relevant research.<sup>38</sup> **Government funding of environmental, health and safety research must be increased dramatically and a strategic risk research plan delineated.**<sup>39</sup>

Nanomaterials create immense difficulties for the application of existing environmental protection regimes.<sup>40</sup> Agencies lack cost-effective tools and mechanisms to detect, monitor, measure, and control manufactured nanomaterials, let alone the means to remove them from the environment. Industry shields even the scant data provided to government from public view by claims of confidential business information. The risk assessments, oversight triggers, toxicity parameters, and threshold minimums used by environmental laws in many countries, including the U.S. and E.U., are designed for bulk (non-nano) material toxicity parameters. The metrics used in existing laws, such as a relationship between mass and exposure, are insufficient for nanomaterials. Existing laws lack lifecycle analyses and fail to address existing regulatory gaps. Environmentally sustainable management of nanomaterials must address and remedy these failings.

#### V. Transparency

Assessment and oversight of nanomaterials requires mechanisms ensuring transparency, including labeling of consumer products that contain nanomaterials, installing workplace right to know laws and protective measures, and developing a publicly accessible inventory of health and safety information.

The public's right to know includes the right to be informed, in order to make educated choices. Polls show that the vast majority of the public lacks even basic information about nanotechnology or the presence of nanomaterials in consumer products.<sup>41</sup> In many cases, manufacturers have not publicly released health hazard and testing information concerning their products, or even labeled those products that contain nanomaterials.<sup>42</sup> As a result, the public cannot make informed choices about nanomaterial products. **The public's right to know requires the labeling of all products containing nanomaterial ingredients.**<sup>43</sup> Moreover, product labeling facilitates documentation of potential environmental releases, human exposures, and accountability for adverse impacts.

Safety testing data must be available for public scrutiny. In light of the poor record of industry in preventing workplace exposures and environmental releases of hazardous chemicals, effective oversight should include strictures on the use of confidentiality shields for nanomaterials. The provisions of international conventions on public access to information should be respected.<sup>44</sup>

## VI. Public Participation

**The potential of nanotechnologies to transform the global social, economic, and political landscape makes it essential that the public fully participate in the deliberative and decision-making processes.**<sup>45</sup> These processes must be *open*, facilitating equal input from all interested and affected parties. Government-corporate alliances (i.e., "public-private partnerships") undermine democratic ideals and oversight principles when they fail to be transparent and accountable to the public. The general public of every nation as well as future generations must be seen as stakeholders.

Participation must also be *meaningful*: it must proceed and inform policy development and decision-making, rather than be limited to after-the-fact, one-way public 'engagement' in which the government and/or industry 'educates' the public with the goal of quelling debate and smoothing public acceptance. Meaningful public participation requires a governmental commitment and sufficient funding.

Finally, *full* public participation requires democratic involvement for the entire range of processes by which nanotechnologies are developed and used and is necessary at each stage of development on a continuing basis to ensure that public concerns, values and preferences inform and guide nanotechnology oversight. Rather than beginning from the false presumption that technological change is inevitable and/or always beneficial, the processes of designing nanotechnology devices and systems should be driven by social needs that are identified through informed deliberation and open decision-making among the affected people. Special efforts must be made to include persons living in poor communities, who have suffered disproportionately from the development of new technologies in the past.

## VII. Inclusion of Broader Impacts

Consideration of nanotechnology's wide-ranging effects, including ethical and social impacts, must occur at each stage of the development process. Adequate assessment of both imports and exports containing nanomaterials is essential.

**In addition to posing health, safety and environmental risks, nanomaterials present broader socio-economic concerns.** For example, as new nanomaterials gain widespread use, they may disrupt markets for existing commodities, with potentially devastating consequences for the economies of commodity-dependent developing countries (i.e., the poorest countries).<sup>46</sup> The adverse impacts of granting patents for fundamental nanomaterials, which may amount to privatizing the building blocks of the natural world, must be considered and addressed. Moreover, the anticipated next generations of nanotechnologies, including the production of more sophisticated nanodevices for manufacturing, military or medical use – including enhancement of human performance – can be expected to pose complex risks as well as social and ethical challenges. Some laboratories are already engineering viruses, yeasts, and bacteria to make nanomaterials. Full public debate on all these issues will be crucial.

As with all new technologies, the allocation of research funding will shape nanotechnology's development trajectory. Social science analyses of nanotechnology's implications should take place alongside that of the health and environmental sciences. **Social impact, ethical assessment, equity, justice and individual community preferences should guide the allocation of public funding for research.** A significant proportion of this research should be community-based and designed to encourage public participation.<sup>47</sup> The current excessive funding of military research and meager funding for research on nanotechnology's social challenges, and possible risks to the health of the public, workers and the environment, is unacceptable.<sup>48</sup> More research on the EHS (environmental, health and safety) and socio-economic impacts of nanotechnologies is essential. This should include community action research that helps citizens understand the potential benefits and dangers of nanotechnology projects in their specific communities. That research should be publicly funded and commissioned by government agencies with clear mandates for oversight and research on EHS and socio-economic impacts. All results must be made available to the public.

## VIII. Manufacturer Liability

Nanomaterials have exploded in the marketplace, billed as miracle substances with remarkable qualities that make them desirable in almost every sector of the economy. Like asbestos when it was first introduced to the market, the public health and environmental impacts of nanomaterials have been poorly studied. Even more so than asbestos, nanomaterials possess qualities (shape, size, chemical reactivity) that have the potential to make them especially risky. Nanomaterials are being sold to the public at large in consumer products, without any notice or warning of their potential hazard. In addition, like the tobacco industry, nano-industries seem content to market their products without fully understanding the potential risks or informing the public of those risks.

**All who market nano-products, including nanomaterial developers, handlers and commercial users, the makers of products containing nanomaterials and retailers who sell nano-containing products to the public must be held accountable for liabilities incurred from their products.** While product liability claims are the most likely liability for the nanomaterials industry, other forms of liability, including negligence, derivative liability, nuisance, fraud and misrepresentation are relevant. In addition, nanomaterial oversight regimes should include financial mechanisms, funded by manufacturers and distributors, ensuring that funds are available to compensate and/or remediate any potential health, worker, or environmental damages. Potential injured parties include individual members of the general public, classes of individuals who have experienced similar harm (such as workers or users of consumer products), federal, state and local governments (or units thereof), foreign nations, investors, insurance companies, and labor unions. Both those funding commercialization and those actively engaged in nanotechnology sectors are responsible for the adequacy of the product stewardship and any damage incurred because of failure to take precautionary protective actions to protect people or the environment.

### *Conclusion*

Proponents of a nanotech “revolution” predict that it will cause dramatic and sweeping changes in every aspect of human life.<sup>49</sup> We believe that a precautionary course of action is necessary in order to safeguard the health and safety of the public and workers; conserve our natural environment; ensure public participation and democratically decided social goals; restore public trust in, and support for, government and academic research; and permit long-term commercial viability. We call for all relevant bodies and actors to take actions to implement, incorporate, and internalize the above principles for nanotechnology and nanomaterial oversight immediately.

Executed on this day of July 31, 2007.

## Signatories

Acción Ecológica (Ecuador)  
African Centre for Biosafety  
American Federation of Labor and Congress of Industrial Organizations (U.S.)  
Bakery, Confectionery, Tobacco Workers and Grain Millers International Union  
Beyond Pesticides (U.S.)  
Biological Farmers of Australia  
Canadian Environmental Law Association  
Center for Biological Diversity (U.S.)  
Center for Community Action and Environmental Justice (U.S.)  
Center for Food Safety (U.S.)  
Center for Environmental Health (U.S.)  
Center for Genetics and Society (U.S.)  
Center for the Study of Responsive Law (U.S.)  
Clean Production Action (Canada)  
Ecological Club Eremurus (Russia)  
EcoNexus (United Kingdom)  
Edmonds Institute (U.S.)  
Environmental Research Foundation (U.S.)  
Essential Action (U.S.)  
ETC Group (Canada)  
Forum for Biotechnology and Food Security (India)  
Friends of the Earth Australia  
Friends of the Earth Europe  
Friends of the Earth United States  
GeneEthics (Australia)  
Greenpeace (U.S.)  
Health and Environment Alliance (Belgium)  
India Institute for Critical Action-Centre in Movement  
Institute for Agriculture and Trade Policy (U.S.)  
Institute for Sustainable Development (Ethiopia)  
International Center for Technology Assessment (U.S.)  
International Society of Doctors for the Environment (Austria)  
International Trade Union Confederation  
International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers' Associations  
Loka Institute (U.S.)  
National Toxics Network (Australia)  
Public Employees for Environmental Responsibility (U.S.)  
Science and Environmental Health Network (U.S.)  
Silicon Valley Toxics Coalition (U.S.)

Tebtebba Foundation - Indigenous Peoples' International Centre for Policy Research and Education (Philippines)  
The Soils Association (United Kingdom)  
Third World Network (China)  
United Steelworkers (U.S.)  
Vivagora (France)

Post-release Signatories to the Principles for the Oversight of Nanotechnologies and Nanomaterials (as of October 9, 2007)

Institute for Inquiry (U.S.)  
Mother Earth Foundation - Philippines  
International Science Oversight Board (U.S.)  
International Environmental Intelligence Agency (U.S.)  
Physicians and Scientists for Responsible Genetics (New Zealand)  
Center for Encounter and active Non-Violence (Austria)  
Observatori del Deute en la Globalització (Spain)  
Centro de Información y Servicios de Asesoría en Salud (Nicaragua)  
Comité Regional de Promoción de Salud Comunitaria, Centroamérica Movimiento de MOMS - Making Our Milk Safe (U.S.)  
Salud de los Pueblos (Latin America)  
Partners for the Land and Agricultural Needs of Traditional Peoples (U.S.)  
Sustainlabour - International Labour Foundation for Sustainable Development (Spain)  
Agricultural Missions (U.S.)  
Greenpeace International  
The Latin American Nanotechnology & Society Network  
Citizens Against Chemicals Pollution (Japan)  
Citizens Coalition on Nanotechnology (U.S.)  
Australian Council of Trade Unions  
Saskatchewan Network for Alternatives to Pesticides (Canada)  
Foundation Sciences Citoyennes (France)

## References

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<sup>1</sup> This declaration in no manner limits or binds the signatories from any other relevant actions or statements, including unilateral or joint superseding statements on nanotechnology policy. Each organization continues to fulfill their respective mission statements in accordance with their own fundamental guiding principles. This joint declaration supplements our organizations' work in this and related areas. This declaration is not intended to be a comprehensive statement of all possible oversight principles or to encompass all subsequent steps needed for their implementation; rather, it is a starting point from which future implementations of oversight policy can build.

<sup>2</sup> See generally PERSPECTIVES ON THE PRECAUTIONARY PRINCIPLE (Ronnie Harding & Elizabeth Fisher, eds., 1999).

<sup>3</sup> See, e.g., RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT, June 14, 1992, 31 I.L.M. 874, 879 (“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”); CARTAGENA PROTOCOL ON BIOSAFETY, Jan. 29, 2000, 39 I.L.M. 1027 Art. 10(6) (“Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Part of import, taking also into account risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimize such potential adverse effects.”); U.N. FRAMEWORK CONVENTION ON CLIMATE CHANGE, May 9, 1992, 21 I.L.M. 849, (“The Parties should take precautionary measures to anticipate, prevent or minimize the cause of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures.”); THE WORLD CHARTER ON NATURE, G.A. Res. 37/7, ¶ 11, U.N. Doc. A/RES/37/7 (Oct. 28, 1982) (“Activities which might have an impact on nature shall be controlled, and the best available technologies that minimize significant risks to nature or other adverse effects shall be used.”); THE LONDON CONVENTION ON THE PREVENTION OF MARINE POLLUTION BY DUMPING WASTES AND OTHER MATTER, 1996 Protocol to the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, Mar. 24, 2006, art. 3, para. 1 (“Appropriate preventative measures are [to be] taken when there is reason to believe that wastes or other matter introduced into the marine environment are likely to cause harm even when there is no conclusive evidence to provide a causal relation between inputs and their effects.”); AGREEMENT FOR THE IMPLEMENTATION OF THE PROVISIONS OF THE UNITED NATIONS CONVENTION ON THE LAW OF THE SEA OF 10 DECEMBER 1982 RELATING TO THE CONSERVATION AND MANAGEMENT OF STRADDLING FISH STOCKS AND HIGHLY MIGRATORY FISH STOCKS, G. A. 164/37, art. 6, U.N. Doc. A/CONF164/37 (“States shall apply the precautionary approach widely to conservation . . .”).

<sup>4</sup> WINGSPREAD STATEMENT ON THE PRECAUTIONARY PRINCIPLE, January 1998; see also NANCY MYERS, ANNE RABE & KATIE SILBERMAN, LOUISVILLE CHARTER FOR SAFER CHEMICALS: BACKGROUND PAPER FOR REFORM NO. 4 (2005) available at [www.louisvillecharter.org/paper foresight.shtml](http://www.louisvillecharter.org/paper foresight.shtml)

<sup>5</sup> See, e.g., Andre Nel et al., Toxic Potential of Materials at the Nanolevel, 311 SCIENCE 622-27, 622, 623 Fig. 1 (2006).

<sup>6</sup> See, e.g., THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004); Andre Nel et al., Toxic Potential of Materials at the Nanolevel, 311 SCIENCE 622, 622-23 (2006); Holsapple et al., Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs, 88 TOXICOLOGICAL SCIENCES 12 (2005); Oberdörster et al., Nanotoxicology: an Emerging Discipline from Studies of Ultrafine Particles, 113 ENVIRONMENTAL HEALTH PERSPECTIVES 823 (2005); TRAN et al., INSTITUTE OF OCCUPATIONAL MEDICINE, A SCOPING STUDY TO IDENTIFY HAZARD DATA NEEDS FOR ADDRESSING THE RISKS PRESENTED BY NANOPARTICLES AND NANOTUBES (2005); EUROPEAN COMMISSION'S SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR), OPINION ON THE APPROPRIATENESS OF EXISTING METHODOLOGIES TO ASSESS THE POTENTIAL RISKS ASSOCIATED WITH ENGINEERED AND ADVENTITIOUS PRODUCTS OF NANOTECHNOLOGIES 6 (2005); Andrew Maynard, Nanotechnology: The Next Big Thing, or Much Ado about Nothing?, 51 ANNALS OF OCCUPATIONAL HYGIENE 1, 4-7 (2006); J. SASS, NATURAL RESOURCES DEFENSE COUNCIL, NANOTECHNOLOGY'S INVISIBLE THREAT, (2007); FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS, BIG RISKS (2006).

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<sup>7</sup> The European Union plans to apply the precautionary principle to issues that may have “potentially dangerous effects on the environment, human, animal or plant health.” EUROPEAN COMMISSION, COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE (2000).

<sup>8</sup> J. CLARENCE DAVIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, MANAGING THE EFFECTS OF NANOTECHNOLOGY (2006); J. CLARENCE DAVIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21<sup>ST</sup> CENTURY, (2007); MICHAEL TAYLOR, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, REGULATING THE PRODUCTS OF NANOTECHNOLOGY: DOES FDA HAVE THE TOOLS IT NEEDS? (2006); American Bar Association, Section of Environment, Energy, and Resources, Nanotechnology Project, at <http://www.abanet.org/environ/nanotech/>; George Kimbrell, The Environmental Hazards of Nanotechnology and the Applicability of Existing Law, in NANOSCALE: ISSUES AND PERSPECTIVES FOR THE NANO CENTURY, (Nigel Cameron, ed. 2007); George Kimbrell, Nanomaterial Consumer Products and FDA Regulation: Regulatory Challenges and Necessary Amendments, 3 NANO L. & BUS. 329 (2006); Steffen Hansen et al., Limits and prospects of the “incremental approach” and the European legislation on the management of risks relating to nanomaterials, 48 REGULATORY TOXICOLOGY AND PHARMACOLOGY 171-83 (2007).

<sup>9</sup> See generally Mihail C. Roco, National Science Foundation and National Nanotechnology Initiative, Presentation at Science and Technology for Human Future, April 28, 2006; M. C. Roco, *Nanotechnology’s Future*, SCIENTIFIC AMERICAN Aug. 2006.

<sup>10</sup> J. CLARENCE DAVIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21<sup>ST</sup> CENTURY 32 (2007) (“What I have described in this section is the entire experience that EPA has reported to date with regulating nano. One would not guess, based on this experience, that nano is a major new technology being commercialized at a very rapid pace. ... Rather, it reflects the rapidly widening gap between the adoption of the technology in the private sector and the government’s lagging attempts to understand nano and to ensure that it does not harm humans and the environment.”); George Kimbrell, Nanomaterial Consumer Products and FDA Regulation: Regulatory Challenges and Necessary Amendments, 3 NANO L. & BUS. 329 (2006).

<sup>11</sup> See note 8 *supra*.

<sup>12</sup> THE ALLIANZ GROUP AND THE ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, SMALL SIZES THAT MATTER: OPPORTUNITIES AND RISKS OF NANOTECHNOLOGIES, § 6.4 (2005) (“Experts are overwhelmingly of the opinion that the adverse effects of nanoparticles cannot be reliably predicted or derived from the known toxicity of the bulk material.”); EUROPEAN COMMISSION’S SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR), *OPINION ON THE APPROPRIATENESS OF EXISTING METHODOLOGIES TO ASSESS THE POTENTIAL RISKS ASSOCIATED WITH ENGINEERED AND ADVENTITIOUS PRODUCTS OF NANOTECHNOLOGIES*, 6 (2005) (“Experts are of the unanimous opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics.”); Royal Society Report, *supra* note 6 at 49 (“Free particles in the nanometre size range do raise health, environmental, and safety concerns and their toxicology cannot be inferred from that of particles of the same chemical at a larger size.”); TRAN ET AL., A SCOPING STUDY TO IDENTIFY HAZARD DATA NEEDS FOR ADDRESSING THE RISKS PRESENTED BY NANOPARTICLES AND NANOTUBES, INSTITUTE OF OCCUPATIONAL MEDICINE 34 (2005), at 34 (“Because of their size and the ways they are used, [engineered nanomaterials] have specific physical-chemical properties and therefore may behave differently from their parent materials when released and interact differently with living systems. It is accepted, therefore, that it is not possible to infer the safety of nanomaterials by using information derived from the bulk parent material.”).

<sup>13</sup> Andrew Maynard, Nanotechnology: The Next Big Thing, or Much Ado about Nothing?, 51 ANNALS OF OCCUPATIONAL HYGIENE 1, 7 (2006); Nel et al., *supra* note 6; Oberdörster et al., Principles for Characterizing the Potential Human Health Effects From Exposure to Nanomaterials: Elements of a Screening Strategy, 2 PARTICLE AND FIBRE TOXICOLOGY 8, 1.0 (2005). Additional tests should include testing for pharmacological properties; absorption, distribution, metabolism, excretion studies; genotoxicity; effects on the development of embryonic and fetal organisms, immunotoxicity, and carcinogenicity. Physico-chemical properties additional to size, including shape, surface structure, polarity etc, influence the toxicity of nanomaterials and therefore must also be assessed. Exposure metrics must

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include surface area, number and concentration of particles not just mass. Jaydee Hanson, Nano Matters: Environmental and Safety Concerns, Speech to Nanotechnology and Biotechnology in Society Conference, (Mar. 29, 2006). Physico-chemical properties additional to size, including shape, surface structure, polarity etc, influence the toxicity of nanomaterials and therefore must also be assessed. Exposure metrics must include surface area, number and concentration of particles not just mass.

<sup>14</sup> See, e.g., THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 6, 43, 73, 83 (2004); NRDC et al., Comments to EPA, Re: EPA Proposal to regulate nanomaterials through a voluntary pilot program, Docket ID: OPPT-2004-0122, July 5, 2005; ICTA et al., Petition to FDA on Regulation of Nanomaterial Products, FDA Docket 2006P-0210/CP1, May 2006, at <http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf>

<sup>15</sup> See, e.g., British Department for Environment, Food, and Rural Affairs, [www.defra.gov.uk/environmental/nanotech](http://www.defra.gov.uk/environmental/nanotech) (voluntary program launched in September 2006, and as of April 2007, has received only six submissions).

<sup>16</sup> J. CLARENCE DAVIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21<sup>ST</sup> CENTURY 18 (2007) (“It is hard to see what will motivate manufacturers to carry out chronic and environmental testing if regulation does not require it.”).

<sup>17</sup> JANE MACOUBRIE, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, INFORMED PUBLIC PERCEPTIONS OF NANOTECHNOLOGY AND TRUST IN GOVERNMENT 14 (2005).

<sup>18</sup> See, e.g., THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 36, 79-80 (2004); Oberdörster et al., Principles for Characterizing the Potential Human Health Effects From Exposure to Nanomaterials: Elements of a Screening Strategy, 2 PARTICLE AND FIBRE TOXICOLOGY 8, 29 (2005).

<sup>19</sup> See, e.g., Holsapple et al., Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs, 88 TOXICOLOGICAL SCIENCES 12 (2005).

<sup>20</sup> Id. at 829, 837.

<sup>21</sup> Monteiro-Riviere N. et al., Penetration of Intact Skin by Quantum Dots with Diverse Physicochemical Properties, 91 TOXICOLOGICAL SCIENCES 159 (2006); Rouse J et al., Effects of Mechanical Flexion on the Penetration of Fullerene Amino Acid-Derivatized Peptide Nanoparticles through Skin, 7(1) NANO LETTERS 155 (2007).

<sup>22</sup> Monteiro-Riviere N. et al., Skin Penetration of Fullerene Substituted Amino Acids and their Interactions with Human Epidermal Keratinocytes, 827 THE TOXICOLOGIST 168 (2006).

<sup>23</sup> Rouse J. et al., Effects of Mechanical Flexion on the Penetration of Fullerene Amino Acid-Derivatized Peptide Nanoparticles through Skin, 7(1) NANO LETTERS 155 (2007).

<sup>24</sup> Toll R. et al., Penetration Profile of Microspheres in Follicular Targeting of Terminal Hair Follicles, 123 THE JOURNAL OF INVESTIGATIVE DERMATOLOGY, 168 (2004).

<sup>25</sup> Florence A. et al., Transcytosis of Nanoparticle and Dendrimers Delivery Systems: Evolving Vistas, 50 ADV DRUG DELIV REV S69 (2001); Hussain N. et al., Recent Advances in the Understanding of Uptake of Microparticulates Across the Gastrointestinal Lymphatics, 50 ADV DRUG DELIV REV 107 (2001); Hillyer J. F. et al., Gastrointestinal persorption and tissue distribution of differently sized colloidal gold nanoparticles, 90 J PHARM SCI 1927-1936 (2001).

<sup>26</sup> See, e.g., Oberdörster et al., Nanotoxicology: An Emerging Discipline From Studies of Ultrafine Particles, 113 ENVIRONMENTAL HEALTH PERSPECTIVES 823-839 (2005).

<sup>27</sup> Borm PJ, Kreyling, W, Toxicological hazards of inhaled nanoparticles--potential implications for drug delivery, 4 J NANOSCI NANOTECHNOL 521-531 (2004).

<sup>28</sup> See, e.g., Rick Weiss, Nanotechnology Risks Unknown; Insufficient Attention Paid to Potential Dangers, Report Says, WASH. POST, Sept. 26, 2006, at A12.

<sup>29</sup> See, e.g., Mihail C. Roco, Nanotechnology's Future, SCIENTIFIC AMERICAN, Aug. 2006.

<sup>30</sup> See Occupational Safety and Health Act (OSHA) standards (29 CFR). Specific attention should be given to Hazard Communication (1910.1200), Respiratory Protection (1910.134), Personal Protective Equipment (1910.132), Access to Medical And Exposure Records (1910.1020), Hazardous Chemicals in Laboratories (1910.1450), and Chemical-specific standards where applicable (1910, Subpart Z).

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<sup>31</sup> A lifecycle assessment is the “systematic analysis of the resources usages (e.g., energy, water, raw materials) and the emissions over the complete supply chain from the cradle of primary resources to the grave of recycling or disposal.” THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 32 (2004).

<sup>32</sup> See, e.g., THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 46 (2004) (“Any widespread use of nanoparticles in products such as medicines (if the particles are excreted from the body rather than biodegraded) and cosmetics (that are washed off) will present a diffuse source of nanoparticles to the environment, for example through the sewage system. Whether this presents a risk to the environment will depend on the toxicity of nanoparticles to organisms, *about which almost nothing is known*, and the quantities that are discharged.”) (emphasis added); see, also Wardak et al., The Product Life Cycle and Challenges to Nanotechnology Regulation, 3 NANOTECHNOLOGY LAW & BUSINESS 507 (2006). Scientific experts estimated that it might take until 2012 to have “the ability to evaluate the impact of engineered nanomaterials from cradle to grave.” Maynard et al., *Safe Handling of Nanotechnology*, Vol 444 NATURE 267-69 (November 16, 2006).

<sup>33</sup> See, e.g., U.S. ENVIRONMENTAL PROTECTION AGENCY, NANOTECHNOLOGY WHITE PAPER 11 (2006).

<sup>34</sup> Yang L. et al., Particle surface characteristics may play an important role in phytotoxicity of alumina nanoparticles, 158(2) TOXICOL LETT. 122-32 (2005).

<sup>35</sup> Templeton R. et al., Life-cycle Effects of Single-Walled Carbon Nanotubes (SWNTs) on an Estuarine Meiobenthic Copepod, 40 ENVIRONMENTAL SCIENCE AND TECHNOLOGY 7387-7393 (2006).

<sup>36</sup> R. SENJEN, FRIENDS OF THE EARTH AUSTRALIA, NANOSILVER – A THREAT TO SOIL, WATER AND HUMAN HEALTH?, (2007) available at <http://nano.foe.org.au/>; J. SASS, NATURAL RESOURCES DEFENSE COUNCIL, NANOTECHNOLOGY’S INVISIBLE THREAT (2007).

<sup>37</sup> See, e.g., THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 46 (2004).

<sup>38</sup> See, e.g., Rick Weiss, Nanotechnology Risks Unknown; Insufficient Attention Paid to Potential Dangers, Report Says, WASH. POST, Sept. 26, 2006, at A12.

<sup>39</sup> See generally ANDREW MAYNARD, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, NANOTECHNOLOGY: A RESEARCH STRATEGY FOR ADDRESSING RISK (2006).

<sup>40</sup> George Kimbrell, The Environmental Hazards of Nanotechnology and the Applicability of Existing Law, in NANOSCALE: ISSUES AND PERSPECTIVES FOR THE NANO CENTURY, (Nigel Cameron, ed. 2007); J. CLARENCE DAVIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21ST CENTURY (2007); American Bar Association, Section of Environment, Energy, and Resources, Nanotechnology Project, (2006), at <http://www.abanet.org/envIRON/nanotech/>;

<sup>41</sup> DAN KAHAN ET AL., WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, NANOTECHNOLOGY RISK PERCEPTIONS 2 (2006) (“Consistent with past surveys (Peter D. Hart Research Associates, 2006), the results suggested that Americans are largely uninformed about nanotechnology: 81% of subjects reported having heard either “nothing at all” (53%) or “just a little” (28%) about nanotechnology prior to being surveyed, and only 5% reported having heard “a lot.”).

<sup>42</sup> See, e.g., CONSUMER REPORTS, NANOTECHNOLOGY: UNKNOWN PROMISE, UNKNOWN RISK 40 (2007) (Consumer Reports asked an outside lab to test for nanoparticles of zinc oxide and titanium dioxide in eight sunscreens that listed either compound on their label. All eight contained the nanoparticles, yet only one disclosed that use of nanotechnology).

<sup>43</sup> See, e.g., Paraco Inc v. Dept of Agriculture, 118 Cal. App. 2d 348, 353-54 (1953) (holding that the public “have a right to know what they are buying”); Fredrick H. Degnan, The Food Label and the Right-to-Know, 52 Food & Drug L.J. 49, 50 (1997) (Pursuant to the ‘consumer’s right to know’, “the public has a basic right to know any fact it deems important about food or a commodity before being forced to make a purchasing decision.”).

<sup>44</sup> United Nations Economic Commission for Europe (UNECE), AARHUS CONVENTION, CONVENTION ON ACCESS TO INFORMATION, PUBLIC PARTICIPATION IN DECISION-MAKING AND ACCESS TO JUSTICE IN ENVIRONMENTAL MATTERS, adopted June 25, 1998.

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<sup>45</sup> See, e.g., NATIONAL SCIENCE AND TECHNOLOGY COUNCIL, NATIONAL NANOTECHNOLOGY INITIATIVE, NANOTECHNOLOGY: SHAPING THE WORLD ATOM BY ATOM 4 (1999) (proclaiming nanotechnology as “a likely launch pad to a new technological era because it focuses on perhaps the final engineering scales people have yet to master.”); id. at 8 (“If present trends in nanoscience and nanotechnology continue, most aspects of everyday life are subject to change.”); id. (“The total societal impact of nanotechnology is expected to be much greater than that of the silicon integrated circuit because it is applicable in many more fields than just electronics.”); id. at 1 (stating the nanotechnology revolution will result in “unprecedented control over the material world.”); see also ASIA-PACIFIC ECONOMIC COOPERATION INDUSTRIAL SCIENCE AND TECHNOLOGY WORKING GROUP, NANOTECHNOLOGY: THE TECHNOLOGY FOR THE 21ST CENTURY. VOL II: THE FULL REPORT 24 (2002), (“If nanotechnology is going to revolutionize manufacturing, health care, energy supply, communications and probably defense, then it will transform labor and the workplace, the medical system, the transportation and power infrastructures and the military. None of these latter will be changed without significant social disruption.”).

<sup>46</sup> See, e.g., THE SOUTH CENTRE, THE POTENTIAL IMPACT OF NANOTECHNOLOGIES ON COMMODITY MARKETS: THE IMPLICATIONS FOR COMMODITY DEPENDENT DEVELOPING COUNTRIES (2005).

<sup>47</sup> Richard E. Sclove et al., Community-Based Research in the United States: An Introductory Reconnaissance (1998).

<sup>48</sup> In 2006, the United States government allocated 33% of the US\$1.3 billion National Nanotechnology Initiative budget to military applications. However the Woodrow Wilson Center estimated that only US\$11 million (0.85% of the 2006 NNI budget) was dedicated to highly relevant research into health and environment risks. At a nanotechnology workshop held in 2005 by the United Kingdom’s Royal Society and the Science Council of Japan, representatives from the United States National Science Foundation indicated that they would spend only US\$7.5 million (0.58% of the 2006 NNI budget) on research into nanotechnology’s ethical, legal and social issues.

<sup>49</sup> See note 45 supra.