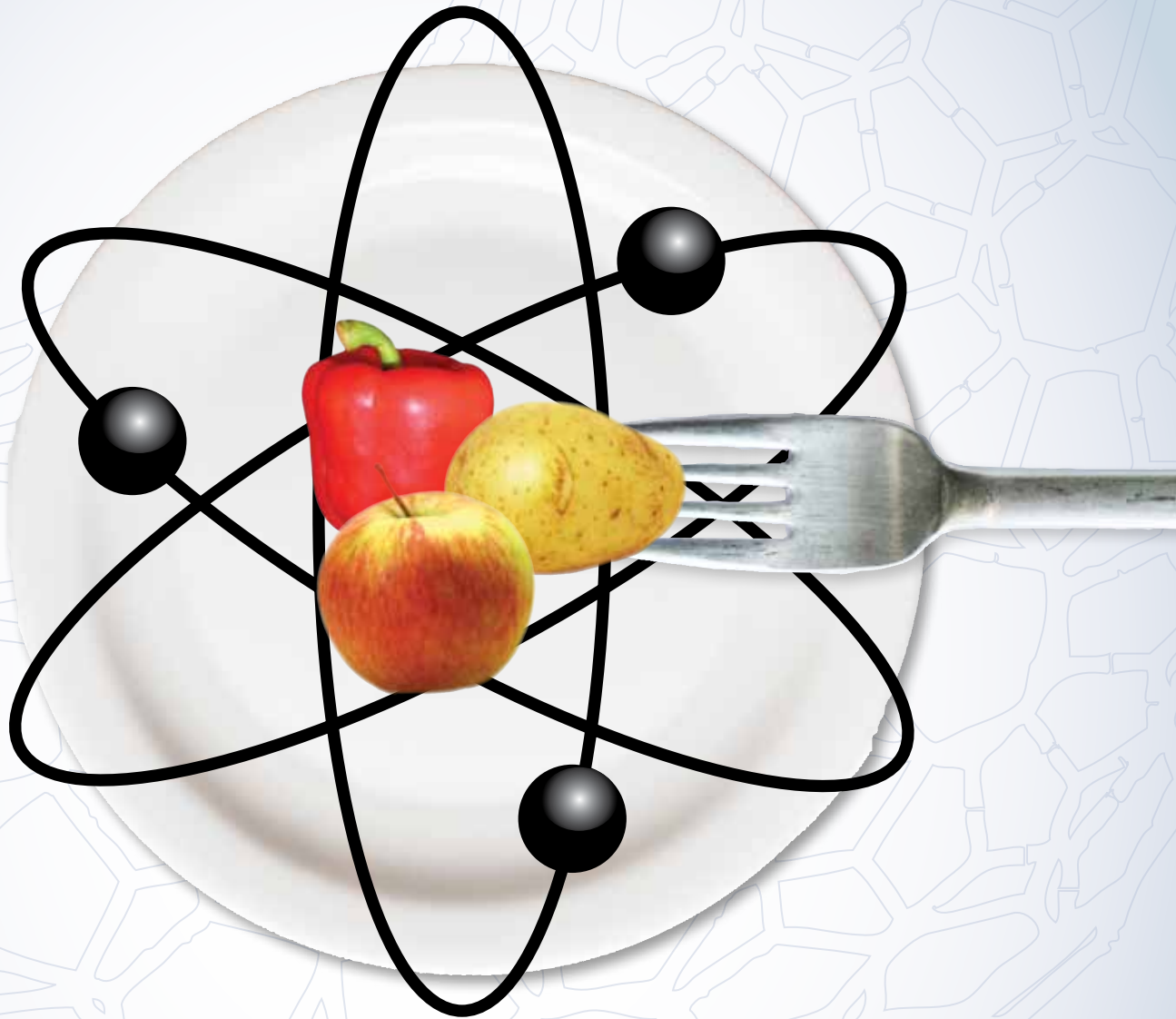


# Unseen Hazards

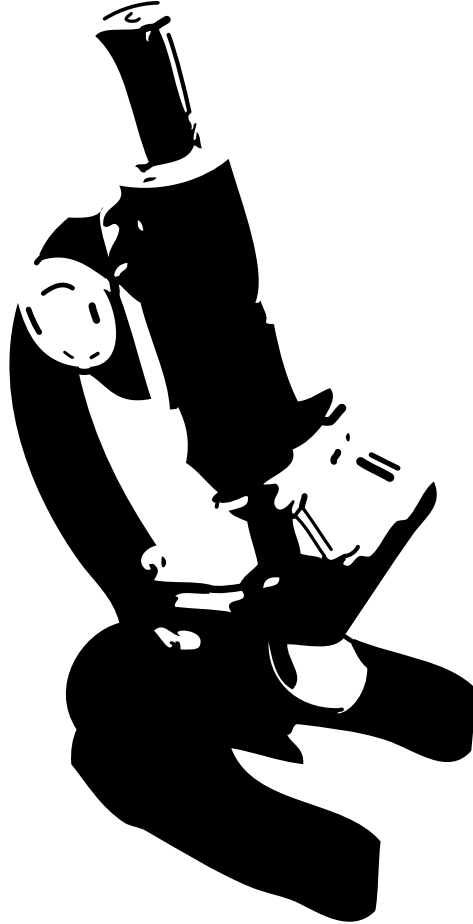


from **Nanotechnology to Nanotoxicity**

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## About Food & Water Watch

Food & Water Watch is a non-profit organization working with grassroots organizations around the world to create an economically and environmentally viable future. Through research, public and policymaker education, media and lobbying, we advocate policies that guarantee safe, wholesome food produced in a humane and sustainable manner and public, rather than private, control of water resources including oceans, rivers and groundwater. For more information, visit [www.foodandwaterwatch.org](http://www.foodandwaterwatch.org).

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# Unseen Hazards

## From Nanotechnology to Nanotoxicity

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### Executive Summary

Nanotechnology—engineering extremely small particles at the molecular level to create materials with new behaviors and chemical properties—is a powerful new scientific pursuit, one with the potential to produce the next electricity or combustion engine—the next thing to change everything.

Predicted by the National Science Foundation to be a trillion-dollar industry by 2015,<sup>1</sup> nanotechnology can already be found in hundreds of consumer products, including items related to food, like fertilizers,<sup>2</sup> kitchenware and tea.<sup>3</sup> Meanwhile, governments and corporations are plowing billions of dollars into research and development of nanoparticles, hoping to one day cure cancers and remedy the many inconveniences of the modern world.

Unfortunately, the enormous potential of nanotechnology to quell the world’s problems may be offset by its potential to cause harm. There is legitimate concern that the nano-sized particles employed in this new technology will have seriously damaging effects on the health of humans and the environment. Dozens of studies from the emerging field of nanotoxicity have already demonstrated hazards associated with nanoparticles.

On the nano-scale, particles of materials like silver and carbon exhibit qualitatively different behavior from larger-sized particles, behavior that makes scientists salivate and regulators tremble. As the Environmental Protection Agency states, “The same special properties that make nanoscale materials useful are also properties that may cause some nanoscale materials to pose potential risks to humans and the environment...”<sup>4</sup>

The very young field of nanotoxicity has already linked some nanoparticles to:

- Damage to DNA<sup>5,6</sup>
- Disruption of cellular function<sup>7</sup> and production of reactive oxygen species<sup>8</sup>
- Asbestos-like pathogenicity<sup>9</sup>
- Neurologic problems (such as seizures)<sup>10</sup>
- Organ damage, including significant lesions on the liver and kidneys<sup>11</sup>
- Destruction of beneficial bacteria in wastewater treatment systems<sup>12</sup>
- Stunted root growth in corn, soybeans, carrots, cucumber and cabbage<sup>13</sup>
- Gill damage, respiratory problems and oxidative stress in fish<sup>14</sup>

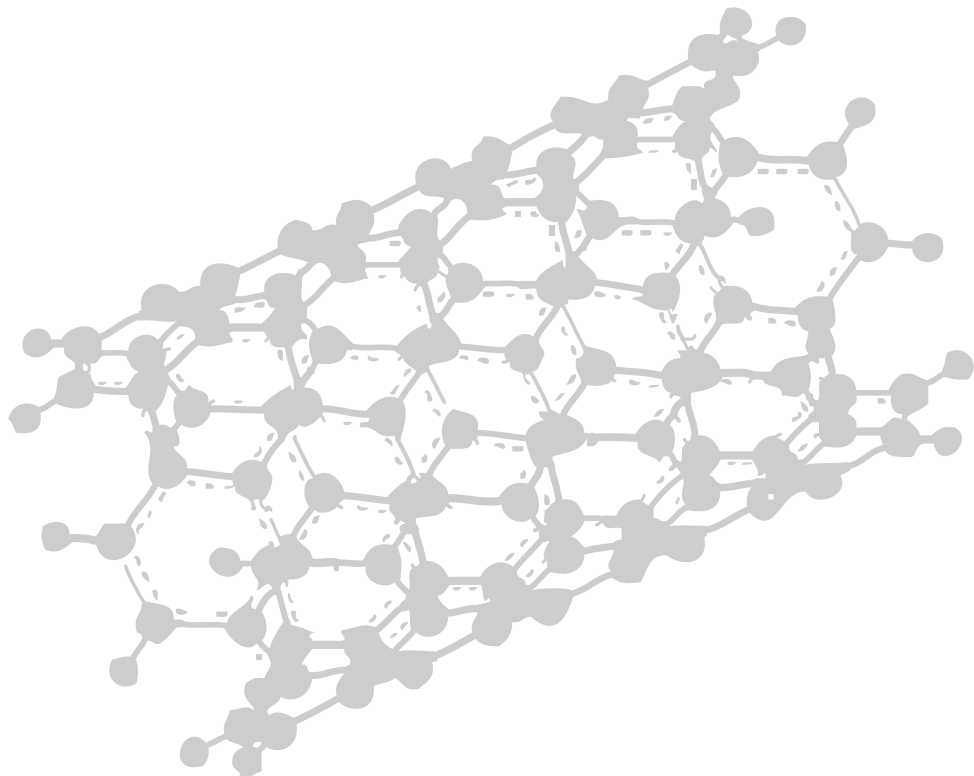
Though the potential threats of nanotechnology are widely acknowledged, regulations lag far behind the development and commercialization of products containing nanotechnologies. The Food and Drug Administration, which regulates 80 percent of the country’s food supply, has stated that “few resources currently exist to assess the risks that would derive to the general population from the wide-scale deployment of nanotechnology products.”<sup>15</sup>

The legacy of unregulated chemical and technological commercialization is, in some regards, one of man-made disasters. The track record of asbestos, DDT, PCBs and radiation—substances that were heralded as the technological breakthroughs that would change everything—should serve as a warning that we cannot continue to neglect the potential hazards associated with nanotechnology simply because it is the next big thing.

Though nanotechnology is showing enormous promise in fields like medicine and alternative-fuel generation, a great deal of development thus far relates to consumer products that offer little benefit to society given the potential costs associated with their potential toxicity. Slightly stronger, slightly lighter tennis rackets and bicycles make a small difference to sports enthusiasts, but the carbon nanotubes employed in their manufacturing might ultimately make a big difference to the health of humans and the environment. One insurance company, the Continental Western Insurance Group, reportedly went so far as to announce recently that it would no longer insure against injury caused by carbon nanotubes,<sup>16</sup> which have been linked to “asbestos like pathogenicity.”<sup>17</sup> This announcement was removed from its Web site shortly after its posting.

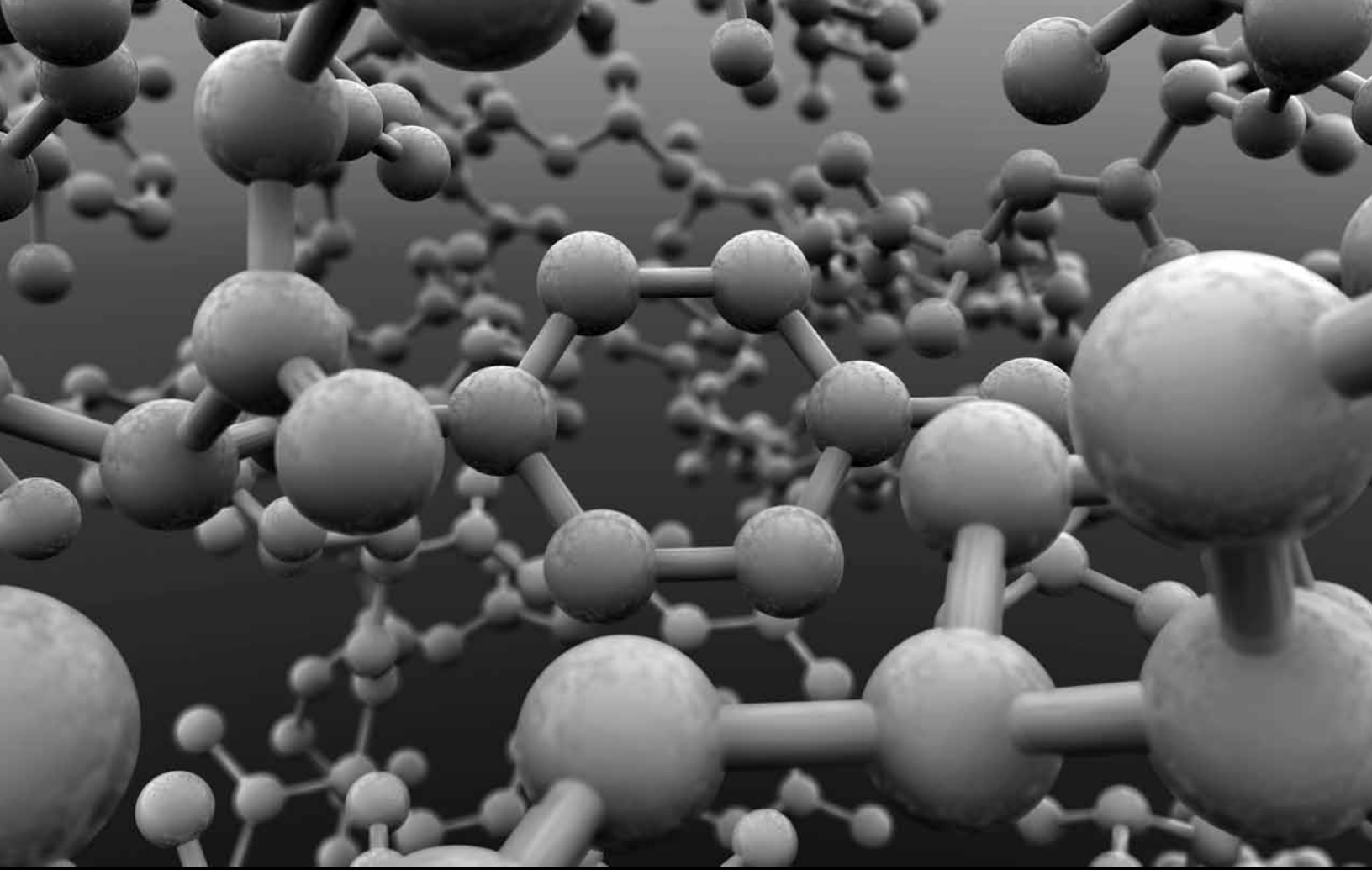
Regulators, including the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), should take action now to appropriately recognize the unique properties and distinct hazards that nanoparticles can pose, and develop nano-specific regulations that assess the safety of nanoparticles on a case-by-case basis. Legislators should foster a robust, public debate about nanotechnology and authorize a dramatic increase in funding for research into the toxic effects of nanoparticles. Lawmakers should also work to scale back the widespread proliferation of consumer products containing nanotechnologies until a robust regulatory program is in place. In the interim, it is essential that regulators require all consumer products containing nanotechnology to be labeled.

Given consumers’ increasing exposure to nanotechnology in grocery stores, around the dinner table and at their places of work—sometimes unknowingly—there is a clear need for legislators and regulators to put consumer protections in place now.



*“No matter how sophisticated knowledge is, it will always be subject to some degree of ignorance. To be alert to—and humble about—the potential gaps in those bodies of knowledge that are included in our decision-making is fundamental. Surprise is inevitable. Just as one basis for scientific research is the anticipation of positive surprises—‘discoveries’—so it will always yield the corresponding prospect of negative surprises. By their nature, complex, cumulative, synergistic or indirect effects in particular have traditionally been inadequately addressed in regulatory appraisal.”*

*– The European Environment Agency, from the 2001 report, “Late Lessons from Early Warnings: The Precautionary Principle 1896-2000”*



## Nano-Size

**A** nanometer is one-billionth of a meter, or about 1/50,000th the width of a strand of hair. Sub-microscopically small, nanoparticles exhibit unique properties that are different from even slightly larger sized particles. They express quantum mechanical phenomena and can go places that other particles cannot—some research suggests they are small enough to pass through your skin and even through the tight mesh of cells that comprise the blood-brain barrier.

What makes nanoparticles so unique is not simply their small size, but their large surface area relative to their small size. Like finely ground coffee beans, which have a different, more effective interaction with hot water than whole coffee beans, nanoparticles have much more surface area than larger particles, which can make them highly reactive.

As the International Center for Technology Assessment notes, “Carbon (like graphite in pencil lead) is relatively soft; but carbon in the form of carbon nanotubes (nano-scale cylinders made of carbon atoms) is a hundred times stronger than steel. An aluminum soda can does not burn; however, aluminum nanoparticles explode when used as rocket fuel catalysts.”<sup>18</sup>

As scientists continue to show that the properties and behaviors nanoparticles exhibit are different from larger-sized particles, there is an evident need for different regulations to address nanoparticles’ potential hazards. Unfortunately, regulators are attempting to address nanoparticles with rules designed years or decades ago for chemicals or food. These rules are frequently clumsy in their application to nanotechnology, rooted in metrics related to type of material instead of size, geometry or behavior. When an agency views a nano-sized particle of carbon the same way it regulates a piece of coal—or nanosilver the way it regulates silver dollar coins—it ignores the complexities and potential hazards surrounding nanoparticles.

Under this weak regulatory regime there has been an unchecked proliferation of products containing nanotechnologies into the commercial marketplace. One survey found that more than 800 consumer products containing nanotechnology had entered the market as of last year,<sup>19</sup> with as many as 20 new items entering every month.<sup>20</sup> In a 2008 report, the environmental group Friends of the Earth found more than 100 food and agricultural products containing nanoparticles.<sup>21</sup>

For a snapshot of nanotechnology in the food system, consider the following:

*At the farm, fertilizers and pesticides containing nanoparticles of clay and other materials are touted for their slow-release mechanisms and potency.<sup>22</sup>*

*Food itself can contain nanoparticles, such as cured meats and sausages,<sup>23</sup> nano-tea,<sup>24</sup> and the wide variety of nutritional supplements containing nanosilver. Research and development is underway to use nanotechnology in myriad aspects of food processing.<sup>25</sup>*

*In the kitchen, we prepare food using kitchenware and cutting boards that employ anti-microbial nanosilver technology,<sup>26</sup> and store food in refrigerators also coated with nanosilver.<sup>27</sup>*

*When we package food to put in the refrigerator or take with us to work, a large number of food containers and wrappings are incorporating nanotechnologies into their manufacture,<sup>28</sup> even though there is a threat that nanoparticles could actually migrate from the packaging into the food itself.*

## Unseen Hazards

Human exposure to nanoparticles, whether incidental or intentional, could have grave and lasting consequences, and scientists are just beginning to understand the real-world consequences of nanotechnology's widespread dispersion into the public sphere.

New research into nanoparticles of titanium dioxide—widely used in sunscreens, including Burt's Beeswax “chemical free” variety<sup>29</sup>—shows that though the nano-sized material helps protect your skin from harmful UV radiation, it may cause cell damage through the production of free-radicals.<sup>30</sup>

In many ways, titanium dioxide exemplifies the need for regulations specific to the nanoscale. At larger particle sizes, titanium dioxide is considered inert and benign and is used in many food products. The FDA reports having “fully up-to-date toxicology information” about titanium dioxide and has allowed its use as an additive to food.<sup>31</sup> Many sunblocks, which the FDA also regulates, have historically used titanium dioxide in larger particle sizes, too—particularly memorable are the white noses of so many lifeguards in decades past.

However, at particle sizes below 300 nanometers, nano-sized titanium dioxide particles have been shown to damage DNA<sup>32</sup>, disrupt cellular function,<sup>33</sup> produce reactive oxygen species,<sup>34</sup> and cause organ damage.<sup>35</sup> While skin products containing nanoparticles of titanium dioxide continue to be sold widely in the United States, the FDA is working with the National Institutes of Health and other government agencies to examine “the skin absorption and phototoxicity” of the material.<sup>36</sup>

Nano-sized copper particles have also been linked to unique hazards. Mice exposed to nano-sized copper particles exhibited “gravely toxicological effects and heavy injuries” to internal organs while those exposed to micro-sized copper particles—which are also very small particles, but still 1000 times larger than nano-copper—were relatively unharmed.<sup>37</sup> Nano-copper can be found in a variety of commercially available cosmetics and also in at least one nutritional supplement.<sup>38</sup>

In May 2008 the journal *Nature Nanotechnology* published a highly publicized study that linked carbon nanotubes to health problems similar to those produced from asbestos exposure.<sup>39</sup> Nanotubes, which are carbon atoms arranged on the nano-scale in the shape of tubes, are revered for their enormous strength and used in the manufacturing of things like tennis rackets. Some nanotubes also happen to be similar in shape and size to asbestos particles,







which have been proven to cause mesothelioma, cancer of the lung lining.<sup>40</sup>

Disturbingly, the *Nature Nanotechnology* study showed that nanotubes exhibit “asbestos-like pathogenicity” in mice whose abdomens were injected with carbon nanotubes.<sup>41</sup> One of the study’s authors noted that much more research needs to be done before a link can be established between carbon nanotubes and mesothelioma,<sup>42</sup> a challenge that the National Institute of Occupational Science and Health (NIOSH) seems to have taken up with compelling preliminary findings;<sup>43</sup> the group’s research, still in progress, has shown “inflammation in the lungs of the mice, and fibrosis in their lungs, which persisted following exposure.”<sup>44</sup>

In 2007, a review of nanotoxicology peer-reviewed publications found that of 38 studies of carbon-based and metallic nanoparticles, 24 indicated some negative biological impact such as cell death, DNA damage, oxidative stress, increased reactive oxygen species levels, pro-inflammatory response, and altered immune function.<sup>45</sup>

This growing body of nanotoxicological evidence is being published in peer-reviewed journals and also circulated among regulatory bodies, which readily acknowledge the potential harms of nanotechnology. An EPA report<sup>46</sup> notes:

*Studies assessing the role of particle size on toxicity have generally found that ultrafine or nanosize range (<100 nm) particles are more toxic on a mass-based exposure metric when compared to larger particles of identical chemical composition.*

*Studies examining the pulmonary toxicity of carbon nanotubes have provided evidence that intentionally produced nanomaterials can display unique toxicity that cannot be explained by differences in particle size alone.*

*Submicron particles have been shown to penetrate the stratum corneum of human skin following dermal application, suggesting a potential route by which the immune system may be affected by dermal exposure to nanoparticles.*

*[Researchers] have reported that in molecular dynamic computer simulations C60 fullerenes [a type of carbon nanoparticle] bind to double and single-stranded DNA and note that these simulations suggest that C60 may negatively impact the structure, stability, and biological functions of DNA.*

The widespread engineering and commercialization of nanotechnology, which is predicted to be a trillion-dollar industry by 2015,<sup>47</sup> means that the potential hazards of nanoparticles may soon become a facet of everyday life. Nanoparticles could have a hazardous effect in the home where nano-products are used, in the factories where the products are manufactured, and elsewhere in the environment, such as in the landfills and waterways where nanoparticles will likely accumulate.

## Occupational Health

A 2009 European survey of “emerging chemical risks” to worker health identified exposure to nanoparticles as the number one emerging health-safety risk European workers are likely to face.<sup>48</sup>

In the United States, the National Institute of Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) are the government agencies responsible for ensuring the safety of workers on the job. The 2009 budget for NIOSH, the research arm



of the federal occupational health program, includes \$6 million for nanotechnology research, earmarked for investigating issues associated with the environment, health and safety, commonly referred to as EHS.<sup>49</sup>

While this money should be spent on investigating how to protect workers from the potential threats of nanoparticles in the workplace, NIOSH apparently is finding ways to bring more nanotechnology into the work environment, with safety devices like “protective screens for prevention of roof falls” and “curtains for ventilation control in mines.”<sup>50</sup> This use of research money seems hasty, if not irresponsible, given the many unknowns surrounding the behavior and potential hazards of nanoparticles, and given the relatively small amount of money that NIOSH has to address what seems like the more pressing issue of worker exposure to nanoparticles.

Meanwhile OSHA, the regulatory body responsible for occupational health, has attempted to address nanotechnology through existing regulations, such as the Occupational Safety and Health Act.<sup>51</sup> The ability of the act to protect worker safety is weak, however, because the exact nature and scope of nanoparticles’ threat to worker health is not known, making it difficult to hold manufacturers accountable for safe handling of nanomaterials.

## The Environment

As humans interact with products containing nanotechnologies—either in the workplace or at home with consumer products like cosmetics, clothing or food packaging—there is the worry that nanoparticles will eventually wash down our drains and into our water systems, creating problems with fresh water resources, fishing and farmland. Nanosilver—a widely used nanoparticle with antibacterial properties that is found in at least 260 consumer products<sup>52</sup>—has been shown to wipe out beneficial bacteria that neutralize ammonia in wastewater treatment systems.<sup>53</sup> Scientists also found nanosilver to be “extremely toxic,” able to “destroy the benign species of bacteria that are used for wastewater treatment” and halt “the reproduction activity of the good bacteria”<sup>54</sup> necessary to break down organic matter in waste water.

Other nanoparticles, like single-walled carbon nanotube byproducts in wastewater discharge, have been shown to cause increased mortality and delayed development of small estuarine (coastal marsh-dwelling) crustaceans.<sup>55</sup> Research has linked nanocopper with damage to gills and death in zebrafish,<sup>56</sup> while titanium dioxide has been associated with gill damage, respiratory problems and oxidative stress in rainbow trout.<sup>57</sup>

In addition to polluting waterways, nanoparticles could also have a negative impact on farmland, which is also serving as an unwitting testing ground for nano-sized innovations. Manufacturers of agrochemicals are reformulating existing pesticides to contain nano-sized versions of the active components,<sup>58</sup> which could result in other contamination

of the land and water. In one study, nano-aluminum was shown to stunt root growth in five commercial crops (corn, soybeans, carrots, cucumber and cabbage).<sup>59</sup>

The long-term consequences of engineered nanoparticles decomposing in the environment remain unknown. Many manufacturers claim that they “permanently embed” nanoparticles in their products, like plastic bottles made from clay nanoparticles or the ARC Outdoor’s X-System clothing, designed with nanoparticles to eliminate the scent associated with sweat, which can drive off deer during hunting season.<sup>60</sup> Generally, however, repeated washings of these types of products or their eventual disposal into landfills makes it likely that nanoparticles will leach out of them.<sup>61</sup>

As stated in an EPA white paper on nanotechnology:

Not enough is known to enable meaningful predictions on the biodegradation of nanomaterials in the environment and much further testing and research are needed.

The fundamental properties concerning the environmental fate of nanomaterials are not well understood (European Commission, 2004), as there are few available studies on the environmental fate of nanomaterials.<sup>62</sup>

## A Nanoparticle of Prevention Is Worth a Pound of Cure

The controversy surrounding nanotechnology’s potentially harmful impact on society has encouraged many stakeholders to question its widespread application in consumer products and invoke what is called the precautionary principle. The national academy of science in the United Kingdom, called the Royal Society, noted, “Until more is known about environmental impacts of nanoparticles and nanotubes, we recommend that the release of manufactured nanoparticles and nanotubes into the environment be avoided as far as possible.”<sup>63</sup>

A more succinct definition of the precautionary principle—adopted by the United Nations—reads, “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.”<sup>64</sup>

Even Lloyd’s of London, the insurance firm made famous by its capacity to extend insurance to those that are seemingly uninsurable, has identified nanotechnology as a major “emerging risk.”<sup>65</sup> As evidenced by their extensive partici-

pation at a health and safety conference on nanotechnology, insurance companies and lawyers are already taking a hard look at the liabilities associated with marketing nanotechnologies that have unknown, possibly hazardous impacts on society, which can lead to personal injury lawsuits.<sup>66</sup>

If ever there were a case to be made for the precautionary principle, it would seem to be with nanotechnology. A raft of problems face regulation of nanotechnology, however, not the least of which is the inexorable push for new applications of nanotechnology by scientists, businesses and governments.

Researchers this year released a report that estimated the time and costs associated with assessing the toxic potential of nanotechnology, concluding that the costs associated with testing existing nanoparticles in the United States “ranges from \$249 million for optimistic assumptions about nanoparticle hazards to \$1.18 billion for a more comprehensive precautionary approach....[and] the time taken to complete testing is likely to be very high (34–53 years) if all existing nanomaterials are to be thoroughly tested.”<sup>67</sup>

As the authors note, these numbers apply only to investigating *existing* nanoparticles—and just those in the United States—while thousands of new nanoparticles and nanotech innovations flood patent offices around the world. More than 5500 nanotechnology patents have already been claimed in the United States, and 3500 other applications are under consideration.<sup>68</sup> Factoring in nanotechnology development in other countries, these numbers would be even larger.

*“Not enough is known to enable meaningful predictions on the biodegradation of nanomaterials in the environment and much further testing and research are needed.”*

*– The U.S. Environmental Protection Agency*

The money and especially the time associated with assessing the potential hazards of nanomaterials would unquestionably impede research and development of nanotechnology. But as asbestos demonstrated, the model of promoting and peddling potentially dangerous innovations into the public sector without appropriate consumer and worker protections in place can be a recipe for disaster. For decades, asbestos provided jobs and what seemed like wonderful products, generating enormous revenues for manufacturers. But courtrooms today are still cleaning up the problems it caused, awarding huge settlements to those who unknowingly or unwittingly were exposed to the harm caused by the wonder material the government failed to regulate.

### National Nanotechnology Initiative: Environmental Health and Safety

In the United States, a government program called the National Nanotechnology Initiative (NNI) coordinates the billions of dollars that the federal government puts into research and development of nanotechnology. The NNI is “aimed at accelerating the discovery, development, and deployment of this technology,” and its budget reflects this.<sup>69</sup>

The 2007 and 2008 NNI budgets each totaled about \$1.5 billion, with almost all of that money focused on five government agencies.<sup>70</sup> In descending order, those agencies were the Department of Defense, the National Science Foundation, the Department of Energy, the Department of Health & Human Services (which oversees the Food and Drug Administration) and the Department of Commerce. The Environmental Protection Agency, which would have broad purview



over nanotechnology’s impact on the environment, receives less than one percent of the entire NNI budget.

In a review of the NNI, the Government Accountability Office found that less than 3 percent of NNI’s 2006 budget went to what are called EHS issues—assessing the potential negative impact of nanotechnology on the environment, health and safety.<sup>71</sup> Though the NNI claimed to be spending around \$38 million on EHS issues, the GAO found that around 20 percent of that amount had been improperly categorized and was actually being spent on other activities.<sup>72</sup>

The NNI also came under scrutiny from the National Research Council (related to the National Academy of Sciences), which made similar findings to the GAO and blasted the NNI’s push toward development without ensuring that adequate safeguards for the public are in place.<sup>73</sup>

The Council reported that the “NNI plan overstates the degree to which already funded studies are meeting the need for research on health and environmental risks... Probably less than half of the research projects described in the plan will ultimately yield useful data to support regulatory decision-making. If no new resources are provided, the research generated cannot adequately evaluate the potential risks posed by nanomaterials.”

It also notes that NNI’s plan for nanotechnology research is “missing elements crucial for progress in understanding nanomaterials’ health and safety impacts.”<sup>74</sup>

The National Research Council’s call for greater research into regulation of nanomaterials is just one voice in a mighty chorus that includes as diverse stakeholders as industry trade groups, like the Grocery Manufacturers Association,<sup>75</sup> and environmental groups, like Friends of the Earth. A 2006 report from the Project on Emerging Nanotechnologies—a think tank associated with the Pew Charitable Trust and the Woodrow Wilson International Center for Scholars—reported that Europe spends almost twice what the United States does on EHS issues,<sup>76</sup> while the United States historically has invested far more money in research and development of nanotechnologies.<sup>77,78</sup>

Given U.S. regulators’ apparent reluctance to enforce the precautionary principle or staunch the introduction of new nano-products into the marketplace, it seems imperative that they develop a substantial scientific understanding of EHS issues. The FDA and EPA are only just beginning this process, and their picayune contributions to EHS research remain woefully out of step with the production and proliferation of nanomaterials.



## Regulations

In 2005, the electronics corporation Samsung announced its new line of “silver magic” home appliances containing silver nanoparticles, boasting that “Silver Nano ions can easily penetrate ‘non-membrane cell’ of bacteria or viruses and suppress their respiration which in turn inhibit cell growth. On the other hand, Silver Nano is absolutely harmless to the human body.”<sup>79</sup>

Because nanotechnology regulations are very weak, consumers are essentially asked to trust a company’s own assessment of its product safety, a dangerous prospect.

Up to this point, American regulators like the FDA and EPA have largely demurred from confronting head-on the danger that nanotechnology poses to consumers, preferring to take a wait-and-see approach.

While regulators seem to acknowledge the unique properties that nanoparticles exhibit, they have failed to craft unique rules to address their potential hazards. Nanoparticles should be evaluated on a case-by-case basis, their proliferation limited by a regulatory regime that follows the precautionary principle.

## Food and Drug Administration

The regulation of the food supply in the United States is a complex and disjointed affair, in large part because it is shared by at least 12 federal agencies, including the FDA, the EPA, the United States Department of Agriculture, and the National Marine Fisheries Service.

Though the FDA is charged with overseeing 80 percent of the food supply, it lacks the resources to be an effective regulator and has failed to address the threats that nanotechnology poses to consumers. In the agency’s assessment of its own capabilities to regulate nanotechnology, the FDA reports that “few resources currently exist to assess the risks that would derive to the general population from the wide-scale deployment of nanotechnology products.”<sup>80</sup>

With inadequate resources to regulate food safety, the FDA frequently is criticized for being a reactionary agency, one that waits to respond to food safety problems until after they manifest in foodborne illnesses that hurt or kill consumers. Evidence of the agency’s lax regulations surfaced during the 2009 recall of salmonella-tainted peanut products, which is believed to have caused nine deaths and hundreds of illnesses.<sup>81</sup> The FDA admits that “many products are regulated only if they cause adverse health-related events in use.”<sup>82</sup>

## Food

One regulatory device that the FDA may use to address nanotechnology is its Generally Regarded As Safe (GRAS) notification process, which concerns the use of additives to food and food packaging. Under GRAS, a company wanting to use a new ingredient conducts its own research to determine the ingredient’s safety. GRAS is called a notification system because the food producer, if it wants to, may then submit a notification to the FDA indicating that company research has found the new additive to be safe.

As a voluntary notification process—and not an approval process—GRAS does not require or compel producers to notify the FDA, nor does GRAS itself give the FDA the power to prohibit the use of an additive. Essentially, the process is entirely self-regulatory.

The current GRAS rule is an interim rule, designed to speed up the lengthy approval process that can be burdensome for food producers, while the FDA works on a final ruling. In comments submitted to FDA at its September 2008 public meeting on nanotechnology, former FDA official Michael Taylor noted, “From a consumer protection and public acceptance perspective, however, the GRAS concept, if not applied in the rigorous way intended by Congress, opens



the door to independent decision-making by technology providers and food companies to market truly new food technologies without a pre-market safety evaluation and approval by FDA.”<sup>83</sup>

Taylor also said, “I am concerned that the public credibility of the regulatory process, in the case of nanotechnology or any major new food technology, is jeopardized by the fact that the system includes, at least theoretically, the opportunity for technology developers and users to make independent GRAS determinations and go to market without even notifying FDA.”

In a more recent report, Taylor concluded that the FDA is “severely lacking in the resources required to prepare scientifically and otherwise for effective regulation of nanotechnology...”<sup>84</sup>

A controversial figure in the FDA’s history, Taylor has taken pro-technology stances that are the stuff of legend in American agriculture. As an FDA official he was involved in creating labeling rules that benefitted the producers and users of recombinant bovine growth hormone in dairy cows.<sup>85</sup> Many industrialized countries and some domestic dairies have banned its use because of health concerns.<sup>86,87</sup> Taylor was also involved in the FDA’s decision to allow genetically modified food to be sold without a label.<sup>88</sup> Additionally, Taylor worked for Monsanto, the biotech corporate giant, which, incidentally, has nanotechnology patents.<sup>89</sup>

If Taylor, an avowed proponent of technological interventions in agriculture and food processing, is advocating new regulatory approaches for nanotechnology, it should serve

as a clarion call to the public and its government representatives for the pressing need to increase the FDA’s oversight of nanotechnology.

For the time, however, the FDA has given no indication that it plans to make any serious changes or amendments to its regulatory regime regarding nanotechnology. Recently an FDA official publicly stated that the agency has the sufficient authority to regulate nanotechnology, but also noted, “It’s industry’s responsibility to make sure a product is safe and part of that is making sure that product is regulated.”<sup>90</sup> The FDA is working on a guidance—not a rule—on nanotechnology<sup>91</sup> that will be released in 2010,<sup>92</sup> and which will likely outline in broad, non-binding terms the agency’s thoughts on nanotechnology.

The new head of the FDA, Commissioner Peggy Hamburg, recently acknowledged the pervasive application of nanotechnology in products that her agency regulates, saying, “It’s in cosmetics, drug delivery, things I never would have imagined, like clothing... We need to understand more about that emerging technology and how to evaluate it.”<sup>93</sup>

For the moment, however, the FDA’s priorities regarding nanotechnology seem geared more toward allowing development than providing safeguards. Reportedly, the FDA is collaborating on nanotechnology research to develop a more sensitive detection device for anthrax.<sup>94</sup> Such a device, if successfully developed, could be a tremendous benefit to society; however, the agency’s expenditure of time and money on development of one specific application while failing to deal with potential negative impacts of other nanotechnology applications is irresponsible.

## Cosmetics

In addition to food and medicine, the FDA also regulates cosmetics in which nanoparticles are increasingly being employed because of their ability to cover and coat the skin. The FDA has called cosmetics “one of the fastest growing areas for application of nanotechnology.”<sup>95</sup>

Companies like Barney’s New York are employing nanotechnology in their “self-healing” Bionova cosmetics, while Chanel is marketing its “Calming Emulsion” and “Coco Mademoiselle Fresh Moisture Mix.”<sup>96</sup>

While these cosmetics advertise their use of nanoparticles, many others may not, for a variety of reasons, leaving consumers and the FDA in the dark about the scope of public exposure to nanoparticles. According to the FDA, “cosmetics are not subject to FDA premarket approval or mandatory establishment registration or ingredient reporting.”<sup>97</sup>

In an attempt to respond to the potential threats that certain products may pose, the FDA has initiated a Voluntary Cosmetics Registration Program, designed to encourage manufacturers to hand over ingredient information. In theory, this would give the FDA the ability to alert manufacturers should the agency discover potentially dangerous ingredients. However, as a voluntary regulatory device, the registration program offers little incentive for manufacturers to participate in the program.

More fundamentally, the voluntary registration fails as a consumer protection measure because it does not require the manufacturers to demonstrate the safety of their ingredients or disclose all nano-ingredients to the public.



## Environmental Protection Agency

The Environmental Protection Agency’s regulatory power extends broadly over water and land resources, and can overlap with the FDA’s regulation of food products and packaging. But like the FDA, the agency has done little to keep the proliferation of nanotechnologies in check or provide consumer protection from the hazards associated with nanoparticles.

In an attempt to understand the scope of nanotechnology use among private companies, the EPA in 2008 initiated the “Nanotechnology Materials Stewardship Program” (NMSP).<sup>98</sup> As commercial products are not required to be labeled as containing nanoparticles, the goal of this EPA initiative is to collect information on a voluntary basis from companies about their nanotech applications—not unlike the FDA’s voluntary registration program for cosmetics.

The stewardship program has, predictably, not elicited a huge response from the private sector,<sup>99</sup> whose financial success is tied to rapid research and development. Because the EPA is a regulatory body that can impose rules potentially delaying product development, there is very little incentive for a company to divulge proprietary information. At a nanotechnology conference in 2009, an EPA representative said that the voluntary registration program is “winding down,” and that the agency is considering pursuing a mandatory registration program because of the voluntary program’s limited success.<sup>100</sup>

The main regulatory tool which the EPA has to address nanotechnology is the Toxic Substances Control Act (TSCA), which gives the agency a framework for controlling the sale and use of new chemical substances that may impact public and/or environmental health.<sup>101</sup> Under TSCA, the EPA generally regulates nanoparticles according to their molecular composition, not their size. While most nanoparticles are regulated the same way as related larger particles, some nanoparticles, at the EPA’s discretion, are viewed as new “chemicals” and must be shown to be safe on case-by-case basis.<sup>102</sup> TSCA’s application to nanoparticles is still a work in progress, but it serves as a tool that, if strengthened, could vastly improve oversight of nanotechnologies.

For example, in October of 2008, the EPA issued a notice that manufacturers of “many” (but apparently not all) carbon nanotubes would need to submit information to government regulators under TSCA.<sup>103</sup> The EPA maintains a list of approved chemicals called its TSCA Chemical Substance Inventory,<sup>104</sup> to which manufacturers refer as they incorporate chemicals, including nanoparticles, into their products. However, until the EPA requires uniform regis-

tration of nanoparticles as new chemicals, the inventory—and the larger TSCA program—cannot effectively protect consumers.

In testimony submitted to Congress, J. Clarence Davies of the Project on Emerging Nanotechnologies notes that TSCA’s weak language, including its regulation of chemicals based on molecular composition instead of size or behavior, means the current act, “at least as currently interpreted by EPA, cannot regulate most nanomaterials as new chemicals and it cannot regulate any chemicals if they are not defined as new.”<sup>105</sup> TSCA is also weakened by its “no-data, no-risk” rule, which disallows the EPA from effectively regulating a company’s use of a chemical if the agency cannot produce data demonstrating a serious risk associated with the chemical, according to Davies.

This contrasts with new European regulations that take a “no-data, no-market” approach, which theoretically requires companies to provide evidence of the safety of their chemicals before they can enter the marketplace.

The EPA has found other regulatory approaches to address nanotechnology, including a token stand it took in 2007 against the widespread proliferation of nanosilver in commercial products. Because it is used as an anti-microbial, nanosilver can be deemed a pesticide by the EPA. The EPA initiated a lawsuit against IOGEAR, a maker of keyboards and mouse instruments, based on the company’s “unsubstantiated public health claims” that its products were germ-resistant because of a nano-coating they contained.<sup>106</sup> IOGEAR settled the suit with the EPA for \$208,000.<sup>107</sup>

In its announcement of the settlement, the EPA stated that “products that kill or repel bacteria or germs are considered pesticides, and must be registered with the EPA prior to distribution or sale. The Agency will not register a pesticide until it has been tested to show that it will not pose an unreasonable risk when used according to the directions.”<sup>108</sup>

Unfortunately, the EPA has weakened its regulatory stance, deciding to apply this registration requirement to only those products that advertise the anti-microbial properties of nanosilver,<sup>109</sup> such as IOGEAR had done on the exterior of its packaging. In reality, consumer products employ nanosilver almost exclusively for the material’s anti-bacterial properties, whether or not they loudly advertise this fact.

In late 2007, the EPA made a similar ruling that “ion-generating equipment”—thought by many at the time to include Samsung’s controversial home appliances that use “Silver Nano ions”—would have to register with the EPA

as pesticides. However, the EPA continually weakened its stance, explicitly stating at one point that the registration requirement “does not represent an action to regulate nanotechnology.”<sup>110</sup> The agency also made public note that washing machines (such as a model produced by Samsung, which continues to be sold as of this article’s publication) would not necessarily fall under the new registration requirements.<sup>111</sup>

In 2008, Food & Water Watch joined the International Center for Technology Assessment and a dozen other organizations in filing a legal petition with the EPA, requesting greater regulation of nanosilver as a pesticide.<sup>112</sup> In response to the petition, the EPA invited public comments, and an official from the EPA in 2009 acknowledged that the agency may rule favorably on some points found in the petition.<sup>113</sup>

While the EPA hammers out the details of its regulatory stance, nanosilver appears to be the most popularly employed nanoparticle in consumer products,<sup>114</sup> found everywhere from food packaging to kitchen knives to clothing—everyday household products that put consumers in close contact with nanoparticles that seem to cry out for oversight.

*See nanosilver appendix on page 16.*

*Nanosilver appears to be the most popularly employed nanoparticle in consumer products, found everywhere from food packaging to kitchen knives to clothing — everyday household products that put consumers in close contact with nanoparticles.*



## International Regulation

With a combination of more willing legislators, more vocal constituents and more comprehensive regulations, Europe is offering the most promising regulatory approach toward nanomaterials thus far. It does this through its Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) program. Theoretically regulating on a case-by-case basis, REACH follows a “no data, no market” approach, requiring producers to provide evidence of the safety of their chemicals before they can reach consumers.

While REACH faces limitations similar to the EPA’s Toxic Substances Control Act—it fails to apply the robust precautionary principle that many researchers are calling for—it is continually being fine-tuned by legislators to better address the hazards associated with nanomaterials.

Designed to regulate chemicals produced in quantities of one ton or greater, REACH does not automatically apply to many nanoparticles, which even in large quantities weigh very little. Additionally, some materials like carbon and graphite, whether small or large in particle size, were initially excluded entirely from REACH because they were deemed to be safe materials, even though some carbon nanotubes have been shown to pose a danger to human health.

However, in 2008 the European Parliament took note that on the nano-scale, carbon and graphite have not demonstrated themselves to be risk-free, and it requested their removal from the exclusion list.<sup>115</sup> Additionally, members of the European Parliament have issued a call for mandatory labeling of products containing nanomaterials, and asked the European Commission to regulate nanoparticles more broadly under the “no data, no market” principle of REACH.<sup>116,117</sup>

While the final regulatory power that REACH will have over nanomaterials remains to be seen, the course of the legislation seems destined to provide stricter oversight than American regulations. And because American manufacturers will likely want to export their nanotechnology abroad, stronger regulations in Europe could force multinational companies to comply with the EU’s regulatory requirements.<sup>118</sup> In this way, European regulations can have a larger net effect by influencing development and commercialization of nanomaterials internationally.

In an attempt to foster an international understanding of nanotechnology’s potential hazards, the Organization for Economic Cooperative and Development (OECD) has created an international “working party” that delegates nanotoxicity research of different nanoparticles to different countries.<sup>119</sup> As part of U.S. involvement, the EPA is sponsoring research into the “environmental effects and



fate testing of fullerenes, single walled carbon nanotubes, multi-walled carbon nanotubes, silver nanoparticles and cerium oxide.”<sup>120</sup>

Scientists and toxicologists from Europe, Japan and the United States have come together to form a group called the International Alliance for NanoEHS Harmonization (IANH),<sup>121</sup> motivated by the lack of agreement on procedures for determining how nanomaterials interact with biological systems. Their approach is to conduct identical testing at their various locations—a “round-robin” method that uses identical batches of nanoparticles—until they get matching results.

At the same time, the International Organization of Standardization (ISO) is developing standardized terminology, specifications for reference materials, and testing methods for nanotechnology that could be useful for bringing different regulatory regimes on to the same page.<sup>122</sup> As an example of this, in 2007, the FDA and regulators from Canada, Europe and Japan made a consensus decision to follow the ISO’s “good manufacturing practices” over cosmetics, where nanoparticles are increasingly being used.<sup>123</sup>

At a 2009 conference on health and safety issues in nanotechnology,<sup>124</sup> a major theme that emerged among scientists was the lack of standards surrounding the field of nanoscience, particularly as it relates to consistent manufacturing of nanoparticles. Because it is extremely difficult to measure things like the purity of a given nanoparticle, it is also difficult for scientists to study their behaviors and properties—and risks and rewards. This lack of standardization underlines the many unknowns that plague the field of nanoscience, even as the commercialization of nano-products continues unabated and unregulated.

## Nanotechnology and the Food Supply

While toxicologists make note of the potential threats associated with human exposure to nanoparticles, the food industry touts nanotechnology's potential to make food safer and healthier. Reports suggest that anywhere from 150 to 1000 nano-foods and nano-food packagings have been developed.<sup>125</sup> These uses include:

- Biosensors constructed from nano-sized proteins and carbohydrates that could be used in food packaging to indicate when, for example, meat spoils or is unsafe to eat.<sup>126</sup> (Biosensors could also be used to track food as it travels around the globe.)<sup>127</sup>
- Encapsulation of food ingredients with nanomaterials that would fight degradation during shipment;<sup>128</sup> in contrast, pesticides could be nanoencapsulated and released only once they are inside an insect's stomach<sup>129</sup>
- Food packaging that prevents gas and moisture losses and enhances shelf life.<sup>130</sup>
- Improved functionality and potency of food ingredients to reduce amounts required.<sup>131</sup> (Food giant Unilever is reportedly working on a low-fat ice cream in which fat molecules have been nano-sized.)<sup>132,133</sup>
- Controlled-release systems for food nutrients (sometimes referred to as nutraceuticals or functional foods) that enhance the ability of the body to use the nutrient.<sup>134</sup>

The European Commission is sponsoring billions of euros for research into nanotechnology, including its use in food and agriculture to "stimulate European competitiveness across the food chain."<sup>135</sup> Among other endeavors, this European "Food for Life" program intends to research nanotechnology's ability to improve food quality and manufacturing;<sup>136</sup> innovate food packaging that can monitor food quality and safety during transport, storage and processing;<sup>137</sup> and introduce "bioactive food constituents" from plants, animals and microorganisms into food.<sup>138</sup>

The United States Department of Agriculture, which is the government agency responsible for ensuring the safety of the country's meat and poultry products, is funneling millions of dollars into similar research. With the tens of millions of dollars it has secured through the National Nanotechnology Initiative,<sup>139</sup> the USDA has invested in the following food applications:<sup>140</sup>

- *Nanosensors*—used in food packaging to detect pathogens and heavy metals



- *Identity preservation and historical tracking of products*—also called "little brother technology," the goal of these nano-devices is to detect "pesticides, fertilizers and biological events significant to the final product quality....of agriculture commodities."
- *Smart Treatment of Delivery Systems*—to "improve digestibility and flavor of food"
- *Novel Tools*—devices used to improve development of compost systems and gene-therapy in the veterinary sciences
- *Nanomaterials*—investigating self-assembly of nanomaterials in biological systems, such as plants and animals
- *Agro-Environment*—nanocatalysts for fuel production
- *Education*—supporting graduate-level research in nanotechnology.

Specific research that the USDA is funding includes a nanotechnology device that would help detect mad cow disease.<sup>141</sup> The agency is also funding the synthesis of bioactive nanoparticles that can be used to flush out the intestines of live poultry,<sup>142</sup> removing bacteria that commonly cause food-borne illnesses in humans.

The real source of food safety issues like mad cow disease and poultry-related bacteria, however, is in the industrial model of meat production, which relies on problematic feeding practices and confinement methods, and the use of artificial hormones and antibiotics. These problems necessitate sweeping changes in the system of food production; the USDA's attempting to treat these food safety problems with untested nanotechnological interventions, which in themselves could cause health problems in animals or the consumers who eat them, demonstrates how the development of nanotechnology is being mishandled by government agencies.

Using nanotechnology in food could have some theoretical benefit to consumers, but it also serves to increasingly process food—using potentially hazardous nanoparticles. For decades, food processing has been innovating at a fever pitch, creating new foods and food products that put more distance between consumers and unprocessed, fresh food, like fruits and vegetables. Consumers may well already be unknowingly buying, using or eating unlabeled, unregulated products containing nanoparticles.

Food packaging in particular is an increasingly popular destination of nanotechnology, because anti-microbial coatings on plastic (containing nanosilver, for example) purportedly

can help fight bacteria. The FDA recognizes that chemicals in food packaging (plastics, etc.) can “migrate” into the food itself,<sup>143</sup> but current FDA testing procedures may not be effective at measuring the migration of nanoparticles from food packaging into food, or the unknown health risks associated with that migration.<sup>144</sup> Additionally, the FDA has allowed food-packaging manufacturers to take advantage of the Generally Regarded As Safe notification process—the problematic, self-regulatory system that does little to protect consumers.

One organization that has taken a stand against the use of nanoparticles in consumer products is the Soil Association in the United Kingdom, which certifies as much as 80 percent of that nation's organic products.<sup>145</sup> In 2008, the group announced it would no longer certify as organic any product incorporating nanotechnologies, saying, “There should be no place for nanoparticles in health and beauty products or food. We are deeply concerned at the government's failure to follow scientific advice and regulate products. There should be an immediate freeze on the commercial release of nanomaterials until there is a sound body of scientific research into all the health impacts. As we saw with GM [genetic modification], the government is ignoring the initial indications of risk and giving the benefit of the doubt to commercial interest rather than the protection of human health.”<sup>146</sup>

The Soil Association's decision helps protect consumers of organic food in the United Kingdom, but the vast majority of consumer food products have no certifying body or regulatory agency requiring the labeling of nano-ingredients. It is difficult to know exactly how widely nanotechnologies are used in food production, but some of the biggest corporate producers—Kraft, Unilever and Nestle—reportedly are all investing in nanotechnology research.<sup>147</sup> In 2009, the National Organic Standards Board in the United States started discussions on nanotechnology but has yet to developed a formal policy regarding its use in food that is certified organic.

In 2000, Kraft helped launch an ambitious Nanotek Consortium, bringing a dozen universities and research institutions on board with a goal of manufacturing better food with nanotechnology.<sup>148</sup> That consortium has reportedly changed names and leadership since, with Kraft stepping away from the organization, possibly in reaction to the growing controversy around the application of nanotechnology to food.<sup>149</sup> While the big food producers have an obvious interest in developing nanotechnologies that could more effectively and safely process and deliver food to the public, in an unregulated environment consumers cannot expect profit-minded multi-national corporations to always have the public's interest in mind.



## Nanotechnology and Energy

Nanotechnology also may have a potential impact on agriculture through its application in biofuel production, an area of increasing interest as scientists continue to explore more efficient ways of turning cellulosic material (like wood and corn stalks) into fuel.<sup>150</sup> A major stumbling block in the development of cellulosic fuels at the moment is the great amount of energy needed to break down cellulose so that it can be converted into alcohol for fuel use.

A number of university researchers and private ventures are investigating ways that nanotechnology can help this process, through increasing catalyst efficiency<sup>151</sup> and improving water removal.<sup>152</sup> At the University of Illinois, researchers are attempting to engineer new yeast strains that can help convert cellulosic biomass into useable fuel,<sup>153</sup> while Iowa State University researchers have formed a startup company to investigate using “nanosphere catalysts” to increase biodiesel production.<sup>154</sup> The USDA is also investing in nanocatalyst research.<sup>155</sup>

Nanotechnology will likely help make better solar cells, too, as researchers envision inventive paints and sprays that could be easily applied to roofs and act as solar collectors.<sup>156</sup>

Regulation of energy, which would include biofuels, falls under the Department of Energy (DOE), which has secured more than \$1 billion in research money through the National Nanotechnology Initiative.<sup>157</sup> Though researchers have been working with nanomaterials for years, it wasn't until January 2009 that the agency issued guidelines for the safe handling of nanomaterials for DOE offices and contractors.<sup>158</sup> The wellbeing of researchers and those working in manufacturing—as well as the health of the environment—should weigh heavily against the potential benefits of nanotechnology as regulators consider safe practices.

## Nanotechnology and Water

Millions of people without access to clean drinking water could benefit enormously from an inexpensive breakthrough in water filtration, another emerging destination of nanotechnologies.<sup>159,160</sup>

A recent report by the nonprofit group Science Development Network found more than a half-dozen nanotechnology applications to water filtration, which incorporated nano-silver, carbon nano-tubes and nanoparticles of iron oxide to help clean water of pesticides, heavy metals or salt.<sup>161</sup>

A company called Seldon Technologies is marketing consumer-ready nano-filtration products like the Waterstick,<sup>162</sup>



a lightweight nano-carbon filter that fits into water bottles and retails for \$95.<sup>163</sup> And the Ford Motor Company is testing nano-filtration at its plants in Germany in an effort to eliminate industrial wastewater.<sup>164</sup>

While these applications may indeed turn out to be noble and innovative applications of nanotechnology, given the many unknowns associated with the fate of nanoparticles in our waterways and given the poor regulatory regime over nanotechnology, it may be premature to embrace these applications.

The Argonne National Laboratory in Chicago is working on numerous nanotechnology projects with regards to both energy and water, including “nanotechnology-based remediation technologies for groundwater contamination.”<sup>165</sup> Argonne is one of five Department of Energy Nanoscale Science Research Centers that, when completed, “will provide the Nation with [nanotechnology] resources unmatched anywhere else in the world,” according to the department.<sup>166</sup>

The Argonne Laboratory, however, has acknowledged the difficulty of working with nanotechnology, saying, “There has been little if any research on exposure, and there are virtually no data on the potential ecological effects of nanomaterials. While no laws or regulations address nanotechnology specifically, some existing regulatory structures could apply to nanotechnologies. However, because of definitions, exclusions, and other factors, many nanomaterials may escape formal regulation. The understanding of nanotechnology ES&H [environmental, safety and health] risks is likely to come slowly because of relatively low federal funding levels.”<sup>167</sup>

## Conclusion

Consumer products containing nanotechnologies have been entering the commercial market at a rate of about 20 a month<sup>168</sup> for the last year, while the government is granting new patents for nanotechnology at a rate of about 10 a week, trying to work its way through 3500 pending applications.<sup>169</sup> Current financial revenues from nanotechnology, which were predicted to contribute to \$166 billion worth of products in 2008,<sup>170</sup> are dwarfed by predictions for 2015, which foresee sales of one trillion dollars.<sup>171</sup> J. Clarence Davies, a senior advisor to the Project on Emerging Nanotechnologies and a senior fellow at Resources for the Future, has predicted that “twenty years from now, most of the products we use are likely to have some nanotechnology component.”<sup>172</sup>

The unchecked proliferation of nanotechnologies into everyday consumer society is a dangerous prospect given the number of studies showing the potential, lasting harm to human and environmental health posed by nanoparticles. With what seems like the inevitable exponential growth of nanotechnology’s addition to consumer products, it is imperative that regulators address its potential hazards now. In the current absence of sufficient government regulation, it is imperative that consumer products containing nanotechnology be labeled.

In collaboration with more than 70 other consumer and environmental groups from around the globe, Food & Water Watch supports the “Principles for the Oversight of Nanotechnologies and Nanomaterials.”<sup>173</sup> These principles are:

- **A precautionary foundation:** Agencies should operate on the basis of withholding approval for the technology until it has been proven safe.
- **Mandatory nano-specific regulations:** Agencies should recognize that existing regulatory frameworks are insufficient and must develop effective oversight to protect human, animal and environmental health.
- **Prevention of exposure to nanomaterials that have not been proven safe:** Current funding levels and government emphasis on Environmental, Health and Society (EHS) concerns are not sufficient. A major increase in EHS funding is needed to make up for the disparity in development funding over EHS over the past decade; a minimum of 40% of the current NNI budget should be allocated to EHS-based research.
- **Environmental sustainability:** Full lifecycle assessments of nanomaterials are necessary prior to commercialization.

- **Transparency:** Mechanisms to ensure transparency throughout the regulatory process are essential. This includes labels on consumer goods, access to safety data, workplace information and public right to know measures.
- **Public participation:** Steps must be taken to include and recognize public debate and input to the decision-making process.
- **Inclusion of broader impacts:** Ethical and social impacts of the technology must be accounted for and funded at each phase of development and regulation.
- **Manufacturer liability:** Companies that make and market nano-containing products must be held accountable for liabilities that result due to their products.

Furthermore, regulation of nanotechnology in consumer goods should be primarily administered under the auspices of two agencies, the FDA and EPA (ideally with support from the Occupational Safety and Health Administration to ensure worker safety, and the Consumer Product Safety Commission to ensure safety of non-food related consumer goods).<sup>174</sup> Food & Water Watch supports defining of nanomaterials as “new” substances under both the Toxic Substances Control Act and the Federal Food Drug and Cosmetics Act in order that the EPA and FDA respectively may adequately assess nanomaterials.

Finally, FWW calls for increased efforts to engage the public in the discussion on nanotechnology. Estimates suggest that less than a quarter of the population is familiar with nanotechnology,<sup>175</sup> though most people may be interacting with engineered nanoparticles on a daily basis.

In 2001 the European Environment Agency put forth a report titled “Late Lessons from Early Warnings: The Precautionary Principle 1896-2000”.<sup>176</sup> The team of experts commissioned by the agency made the following statement: “No matter how sophisticated knowledge is, it will always be subject to some degree of ignorance. To be alert to—and humble about—the potential gaps in those bodies of knowledge that are included in our decision-making is fundamental. Surprise is inevitable. Just as one basis for scientific research is the anticipation of positive surprises—‘discoveries’—so it will always yield the corresponding prospect of negative surprises. By their nature, complex, cumulative, synergistic or indirect effects in particular have traditionally been inadequately addressed in regulatory appraisal.”

It is time for U.S. regulators to heed this advice and implement a robust regulatory program over nanotechnology.

## Appendix: Nanosilver

Nanosilver has become a widely used nano-particle in consumer products, found in at least 260 commercially available items<sup>177</sup> and touted for its anti-bacterial properties.

Products containing nanotechnology range from a Chinese-made female foam prophylactic called the Nanometer-silver Cryptomorphic Condom; Sharper Image’s Antibacterial Silver Athletic and Lounging Socks; and Remington’s CleanX-change electric razor.<sup>178</sup>

Nanosilver does indeed demonstrate veritable anti-bacterial properties, but it also has demonstrated links to a host of health problems in humans and environmental damage.

A peer-reviewed study showed “...an apparent increase of mutation frequency caused by silver nanoparticles during DNA replication *in vitro* [in a laboratory] and *in vivo* [in live animals].” Noting the widespread use of nanosilver in consumer products like food-storage packaging, the authors sounded a “call for a review of the long-term biohazard issues of silver nanoparticles.”<sup>179</sup>

Disconcertingly, the life cycle of nanosilver could be as long as it is potentially hazardous, posing threats to the health of humans and the environment at every stop. As the

nanoparticles wash away from nanosilver socks in nanosilver washing machines—or as nanosilver pass through the human digestive system—there is concern that the nanoparticles could have deleterious effects on waterways and farmland.

Silver nanoparticles have been shown to generate more unique chemicals, known as highly reactive oxygen species, than their larger counterparts<sup>180</sup> and silver itself has been classified as a toxicant by the EPA and its use as a pesticide must be labeled with warnings, including: “This pesticide [silver] is toxic to fish and aquatic invertebrates.”<sup>181</sup> Processed sewage from wastewater treatment plants (often referred to as sludge) is used as fertilizer on agricultural lands, and if high levels of silver nanoparticles are present in the sludge, soil quality may suffer.

One researcher noted, “We found that silver nanoparticles are extremely toxic. The nanoparticles destroy the benign species of bacteria that are used for wastewater treatment. It basically halts the reproduction activity of the good bacteria.”<sup>182</sup>

Silver is also being used as a colloidal—suspended silver particles of varying sizes, from one to one-thousand nanometers, in a liquid.<sup>183</sup> Colloidal silver is a popular nutritional supplement, touted for its ability to cure disease



and restore health. A nutritional supplement called Utopia Silver advertises the “anti-microbial” properties of colloidal silver, including its ability to inhibit growth of “one-celled organisms.”<sup>184</sup>

However, government agencies like the National Institutes of Health (NIH), the FDA and the EPA have cautioned consumers about possible health effects of ingesting colloidal silver. The NIH notes “animal studies have shown that silver builds up in the tissues of the body” and that “side effects from using colloidal silver products may include neurologic problems (such as seizures), kidney damage, stomach distress, headaches, fatigue, and skin irritation.”<sup>185</sup>

When consumers take colloidal silver as a supplement, however, they are at least knowingly ingesting nanosilver. The bigger threat of nanosilver is the widespread commercialization of consumer products like food packaging and clothes that may expose consumers unknowingly to nanosilver and release large amounts of it into the environment.

For example, chemicals in food packaging have been shown to “migrate” into food itself,<sup>186</sup> so there is concern that nanosilver from food packaging could unintentionally be ingested by humans, potentially having a destructive effect on health. The FDA has said that its research plans for 2010 “include studies to quantify the migration of nanosilver from food-contact materials, and determine the conditions under which migration will occur.”<sup>187</sup> Reportedly there are between 400 and 500 food packaging products containing nanomaterials.<sup>188</sup>

The EPA, like the FDA, is also increasingly under pressure from consumer advocacy groups, environmentalists and members of the public to regulate nanoparticles. In 2008, Food & Water Watch signed on as a petitioner with the International Center for Technology Assessment and other groups, asking the EPA to regulate nanosilver more broadly as a pesticide. Included in that petition were more than 100 pages of evidence of the risks associated with nanosilver and arguments for the EPA’s obligation to regulate the material. The EPA is currently considering public comments made on the petition but as of September 2009 has not acted on them.

The petition asked the EPA to:

- I. Classify nanosilver as a pesticide and require the registration of nanosilver products as pesticides
- II. Determine that nanosilver is a new pesticide that requires a new pesticide registration

- III. Analyze the potential human health and environmental risks of nanosilver

- IV. Take regulatory actions against the class of nanosilver products illegally sold without EPA FIFRA approval, including issuing stop sale, use or removal orders for illegal and unlabeled nanosilver pesticide products

- V. If any nanosilver pesticide registration is approved, apply and/or amend to specifically apply the FIFRA pesticide requirements to the class of nanosilver pesticides

- VI. Take other EPA FIFRA actions necessary for adequate oversight of nanosilver pesticides

*The big threat of nanosilver is the widespread commercialization of consumer products like food packaging and clothes that may expose consumers unknowingly to nanosilver and release large amounts of it into the environment.*

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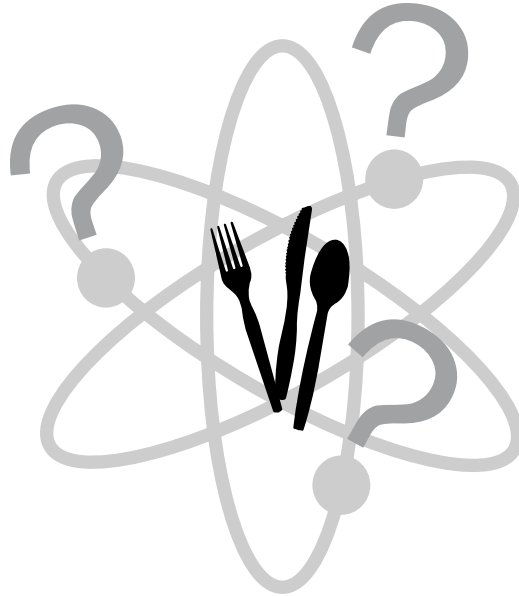
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