

POLICY FORUM

How Should Engineered Nanomaterials Be Regulated for Public and Environmental Health?

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Abstract

A central ethical and policy issue regarding minimizing and managing risks of engineered nanomaterials (ENMs) is whether existing legal frameworks sufficiently protect public health and the environment. This article argues that policymakers should (1) use existing laws to regulate ENMs and the best available evidence to inform appropriate levels of regulation and (2) support additional research on risks of ENMs. Were they to do so, public health and environmental risks of ENMs could be minimized and managed without sacrificing their potential clinical, social, and economic benefits.

Growth of Nanomaterial Use in Health Care

The nanotechnology industry has expanded rapidly since the 1990s as scientists, engineers, and technologists have developed useful applications of nanomaterials in manufacturing, transportation, communications, energy production, waste treatment, consumer products, and medicine.^{1,2} Nanomaterials are solid, liquid, or gaseous substances typically between 1 and 100 nm in diameter or length. They are larger than subatomic particles (eg, protons, electrons) but smaller than the smallest microscopic ones seen through a conventional light microscope (eg, red blood cells). Nanomaterials occur naturally (for example, in ash from forest fires or volcanic dust) and as the products of manufacturing processes, also known as engineered nanomaterials (ENMs). Because nanomaterials are so small, they are influenced by quantum mechanical effects and often have unique physical and chemical properties (such as melting point, fluorescence, electrical conductivity, magnetic permeability, and chemical reactivity) that can change as a function of size.^{1,2} Nanomaterials are often highly reactive because they have a large surface area-to-volume ratio and chemical reactions occur on surfaces. Chemical engineers can use this property to design nanomaterials that catalyze chemical reactions.¹

Nanomaterials have medical and industrial applications. For example, silver nanoparticles (ie, nanosilver) have antimicrobial properties that make them useful in wound dressings, stents, catheters, and bandages.³ Bioengineers have created nanogold shells containing chemotherapy drugs that deliver their payload only to cancer cells, thus

sparing the patient most of the adverse effects of the medication.⁴ Since gold nanoparticles accumulate in tumors, biomedical researchers have been able to develop tests that take advantage of nanogold's optical properties to detect the presence of cancer in the body. Chemists also have developed assays containing nanogold that can detect various types of proteins in blood and other body fluids.⁵ Carbon nanotubes—cylindrical carbon molecules that conduct electricity and heat—have been used as materials in batteries, capacitors, boat hulls, water filters, and sporting goods and as coatings and films in various industrial applications.⁶ Many commercial sunscreens contain titanium dioxide and zinc oxide nanoparticles to enhance protection from UV radiation.⁷ According to one estimate, the global market for products containing ENMs will be \$3 trillion by 2020.⁸

Assessing the Risks of ENMs

Although ENMs have many potential benefits for society, they also pose some risks to human health and the environment that are not well understood at this time.⁹⁻¹² Most of the information concerning the risks of ENMs has come from in vitro cell studies, in vivo animal experiments, or computer modelling of physical, chemical, and biological processes related to exposure to and distribution, excretion, aggregation, and toxicity of ENMs. For example, some types of carbon nanotubes can induce inflammation, pulmonary fibrosis, and genotoxicity when inhaled and are potential carcinogens.¹² Factory workers might inhale carbon nanotubes during manufacturing, and consumers might inhale them when handling materials, such as tennis rackets or frying pans, which have been coated with these materials. Other ENMs, including titanium dioxide and nickel, can induce immune responses.^{11,12} Nanosilver can cause oxidative stress and can have toxic effects on marine species if it enters aquatic environments.^{13,14} Overuse of nanosilver, especially in nonmedical applications, could lead to the development of antibiotic resistance.¹⁵ Although human and nonhuman species have been exposed to naturally occurring nanoparticles throughout geological time, there is some concern that ENMs could pose greater risks than naturally occurring nanoparticles because organisms have not had sufficient time to adapt to their unique properties.^{10,11} Also, some types of ENMs might persist in the environment longer than naturally occurring nanoparticles.⁵

Exposure to ENMs can occur in many ways. The most direct forms of exposure can happen when ENMs are used in medicines, cosmetics, foods, or consumer products. Exposure can also occur, however, when manufacturing, distributing, selling, disposing of, or recycling products containing ENMs.¹² Nanomaterial waste products (or nanowaste), which can enter the environment at various stages of manufacture, use, and disposal, are another source of exposure to ENMs. For example, ENMs could slough off from consumer products and enter the soil, air, or [water](#). ENMs used in medications could enter sewage systems via urination or defecation. ENMs could also leach out of landfills and enter waterways, such as rivers, lakes, or estuaries.¹⁶

Numerous factors make it difficult to assess the risks of ENMs. First, ENMs are characterized only by size (approximately 1 to 100 nm) and origin (eg, human) and are therefore highly heterogeneous. Risk assessment must therefore focus not on the risks of ENMs as a class but on the risks of particular types of ENMs.¹² Second, research has demonstrated that many types of ENMs can enter the bloodstream, translocate through the body, accumulate in organs or tissues, cross the blood-brain barrier, and penetrate the cell nucleus.^{11,12} Contact with ENMs via the skin, lungs, or mouth could therefore lead to immune reactions or toxicity beyond the site of exposure.^{10,11} Third, since the properties of ENMs can change in relation to size, the risks of ENMs can vary accordingly when they aggregate or disaggregate in the body.¹⁰⁻¹² For example, a type of ENM that poses a low risk at 1 nm might pose a greater risk when it accumulates in a tissue and reaches 50 nm in size. Fourth, it can be difficult to measure exposures to ENMs or track their movement in the environment due to lack of reliable biomarkers of exposure and other methods of detection.^{10,16} Fifth, the risks of nanomaterials can vary across species and among individuals within the same species. For example, an ENM that produces no adverse effects in laboratory mice can pose significant toxicity risks in humans or other species.⁵ Such heterogeneity poses regulatory challenges.

Regulating ENMs

The United States and many other developed nations have laws that can help to minimize and manage the public health and environmental risks of ENMs. For example, the [US Food and Drug Administration](#) has the statutory authority to regulate ENMs used in foods, drugs, biologics, medical devices, and cosmetics to protect the public from the toxic effects of ENMs.⁵ The [US Environmental Protection Agency](#) can regulate ENMs in the air and water, in solid and hazardous waste disposal sites, and in pesticides or other chemical products used in agriculture or industry.^{17,18} The US Occupational Safety and Health Administration has the authority to regulate exposure to ENMs in the workplace. States also have their own laws pertaining to public, occupational, and environmental health.^{17,18}

The central ethical and policy issue with respect to minimizing and managing the risks of ENMs is whether existing legal frameworks are sufficient to protect public health and the environment.^{17,18} Proponents of new regulations argue that ENMs are so different from existing substances and pose such far-reaching and poorly understood risks to public health and the environment that new forms of government oversight, such as regulations that address ENMs as a class, are needed.¹⁹ Nanowaste poses a particularly difficult problem for current legal frameworks because existing laws might not adequately account for the different ways that nanowaste can enter the environment.¹⁶ For example, existing laws might not address the risks of disposal of nanowaste from consumer goods (such as tennis rackets or sunscreens) or medical products (such as drugs or bandages). Opponents of new regulations argue that existing legal frameworks have been successfully applied to emerging technologies in the past (such as gene

therapy and genetically modified organisms), so there is no need for new regulations tailored to ENMs.²⁰ Opponents also point out that the heterogenous nature of ENMs makes it difficult if not impossible to develop regulations for ENMs as a class.¹⁷

Policymakers who are developing and applying regulations to protect public and environmental health face the dilemma of underregulation vs overregulation.²¹ Underregulation occurs when regulations are not stringent or extensive enough to adequately protect public and environmental health. For example, one might argue that dietary supplements were underregulated in the United States prior to passage of dietary supplement legislation in the 1990s because existing legal frameworks did not adequately protect the public from the risks of these products.²¹ Overregulation, by contrast, occurs when regulations are more stringent or extensive than is required to adequately protect public and environmental health. Overregulation can have negative effects on consumer autonomy, industry, and the economy that are not offset by positive impacts on public health or the environment. For example, HIV/AIDS activists argued in the 1980s and 1990s that the stringent Food and Drug Administration regulations and policies pertaining to drug testing and approval were preventing patients from obtaining access to life-saving medications.²¹

The dilemma of overregulation vs underregulation looms large in the societal debate of how best to minimize and manage the risks of ENMs. On the one hand, creating new regulations tailored specifically to ENMs could lead to onerous policies that interfere with the medical and industrial applications of nanotechnology without yielding compensating societal benefits. For example, regulations that seek to prevent nanosilver from entering the environment might interfere with its medical uses. On the other hand, failing to adequately regulate ENMs could have significant, long-term adverse impacts on public health and the environment. For example, failing to address the problem of nanowaste could lead to accumulation of various ENMs in the environment.¹⁶ However, since evidence of the adverse effects of nanowaste is currently lacking, more research is needed to determine the appropriate level of regulation.

Taking Reasonable Precautions Concerning ENMs

Critics of the current regulatory framework have argued that the precautionary principle provides a useful way of addressing the overregulation vs underregulation dilemma concerning ENMs.²² Since the 1980s, the precautionary principle has played an important role in policy debates concerning climate change, chemical regulation, food safety, and other public health and environmental issues.¹⁷ Early versions of this principle held that precautionary measures should be taken to prevent serious harms even when the scientific evidence concerning those harms is uncertain or incomplete.²² Although early versions of the principle were criticized for supporting risk-averse policies that stifle technological innovation, newer versions of the principle recognize that precaution has social and economic costs that must also be considered.²³ According to a version of the

principle favored by many, including this author, policymakers should take reasonable precautions to prevent, minimize, or manage risks that are plausible and significant.¹⁶ A precaution is reasonable if it appropriately balances competing moral and social values, such as protecting public health and the environment, on the one hand, and promoting industry, agriculture, and the economy, on the other.¹⁷

One could argue that since the risks of ENMs—and strategies for minimizing them—are poorly understood at this point, policymakers should (1) use existing laws to regulate ENMs and the best available evidence to set regulation levels without creating new laws or an overarching system to regulate ENMs and (2) support additional research on the risks of ENMs.^{22,24} These and other precautions can offer a way to minimize and manage the public health and environmental risks of ENMs without sacrificing their potential medical, social, and economic benefits.

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