Emerging Nanotechnologies and Life-Cycle Regulation:
An Investigation of Federal Regulatory Oversight from Nanomaterial Production to End of Life

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**Definitions**

*Chemical Substances Inventory:*

The Chemical Substances Inventory catalogues all chemical substances manufactured or processed in the United States and is created and maintained under TSCA.

*General Duty Clause (under the OSHAct):*

The General Duty Clause under the OSHAct requires that employers furnish employees with a place of employment that is free from recognized hazards that are causing or are likely to cause serious physical harm and that employers shall comply with the occupational safety and health standards under the OSHAct, and all rules, regulations, and orders issued pursuant to the OSHAct.

*Unreasonable adverse effects:*

The term unreasonable adverse effects is used under FIFRA, and the EPA “Terms of Environment: Glossary, Abbreviations and Acronyms” Web site defines the term as “any unreasonable risk to man or the environment, taking into account the medical, economic, social, and environmental costs and benefits of any pesticide.” 1

*Unreasonable Risk:*

According to the TSCA Deskbook, the term unreasonable risk is not defined in the TSCA statute, nor does the statute specify the amount of evidence needed to support a finding that a chemical “may present” an unreasonable risk. However, the EPA explained in their earliest test proposals in 1981 that they would pursue the following policy with respect to the phrase “may present an unreasonable risk”:

“If there is substantial evidence that exposure to a chemical may lead to a serious health effect or increase in mortality and that people may be exposed to the chemical, EPA will presume that the activities in question (manufacturing, processing, using, transporting, disposing) ‘may present an unreasonable risk’ unless the rule is likely to result in a significant loss to society of the benefits of the substance. In the latter instances, if EPA's analysis shows that the costs of testing may cause manufacturers or processors to cease or severely restrict their commercial activities, EPA will weigh this potential adverse impact against the benefits of testing before presuming that the chemical may present an unreasonable risk.” 2

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Glossary of Abbreviations

CBI – confidential business information
CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act (commonly known as Superfund and administered by the EPA)
CPSA – Consumer Product Safety Act (administered by the CPSC)
CPSC – Consumer Product Safety Commission
CPSIA – Consumer Product Safety Improvement Act (administered by the CPSC)
EPA – Environmental Protection Agency
FCN – Food Contact Notification
FDA – Food and Drug Administration
FFDCA – Federal Food, Drug, and Cosmetic Act (administered by the FDA and by the EPA for pesticide residues on food only)
FHSA – Federal Hazardous Substances Act (administered by the CPSC)
FIFRA – Federal Insecticide, Fungicide, and Rodenticide Act (administered by the EPA)
GAO – Government Accountability Office
GRAS – generally recognized as safe
HPV – high-production volume challenge
LoREX – low-release, low-exposure exemption
LVE – low-volume exemption
NMSP – Nanoscale Material Stewardship Program
OSHA – Occupational Safety and Health Administration
OSH Act – Occupational Safety and Health Act (administered by OSHA)
PMN – Premanufacture Notice
PPPA – Poison Prevention Packaging Act (administered by the CPSC)
RCRA – Resource Conservation and Recovery Act (administered by the EPA)
SNUN – Significant New Use Notification
SNUR – Significant New Use Rule
TSCA – Toxic Substances Control Act (administered by the EPA)
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Executive Summary

Nanotechnologies promise many benefits for society, from modest improvements in consumer products to revolutionary changes in drug delivery and medical treatments. There are over a thousand nano-enabled products currently on the market in the US, and billions invested in future nanotechnologies. While nanotechnologies offer tremendous benefits for society, they may also pose significant risks. The same properties that enable novel applications may also lead to negative health and environmental consequences. These novel properties, coupled with a relative scarcity of information on nanomaterial hazards, make risk assessment and regulation a difficult task. This paper investigates the US federal regulations that apply to a nanomaterial along its life cycle, from initial creation to end-of-life. Drawing upon the growing literature that explores the regulatory challenges posed by nanomaterials, this analysis investigates which regulations are expected to apply at each life-cycle stage, and the ways that nanomaterials challenge the applicability or enforcement of these regulations.

This research found that one or more federal regulations may apply at each stage of a nanomaterial's life cycle. However, a high degree of uncertainty over hazards, a lack of nanomaterial-specific risk information, and high applicability thresholds mean that federally mandated risk assessments might not be conducted for many nanomaterials. Furthermore, several regulations are hindered by problematic definitions, inadequate authority for information requests or requiring testing, and a deficit of resources in the relevant regulatory agencies for adequately managing the growing influx of nanomaterials and nano-enhanced products. As a result of these challenges, many nanomaterials will not undergo a federally mandated risk assessment at any point in their life-cycle and may escape regulatory oversight entirely. For those materials that do undergo a risk assessment, a lack of consistent oversight at later stages of the life cycle (when nanomaterials are released into the environment or are discarded) mean that many nanomaterials will become less regulated or entirely unregulated as they move from one life cycle stage to another.

This research highlights the need for improved consistency in regulatory oversight along the entire nanomaterial life-cycle, as well as changes to definitions and applicability thresholds, vast improvements in regulations for nano-enhanced cosmetics, dietary supplements and consumer products, and an increase in agency resources directed at the growing field of nanomaterials and nano-enabled products.
Introduction

When renowned physicist Richard Feynman dreamed of writing the Encyclopedia Britannica on the head of a pin during his famous “There’s Plenty of Room at the Bottom” lecture in 1959, he captured the imagination of scientists worldwide who have since made feats of this scale possible.\(^3\) This new field of research and development, coined nanotechnology, involves manipulating materials one ten-thousandth the width of a human hair to make new nanomaterials with unique and often unexpected properties.

As defined by the National Nanotechnology Initiative, “Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers (nm), where unique phenomena enable novel applications.”\(^4\) A nanometer is one-billionth of a meter. To put this scale into perspective, if one meter were the distance between New York City and Los Angeles (approximately 2,462 miles), then one nanometer would be about the length of a grain of rice. Four water molecules would span the length of a rice grain, a strand of human DNA would be about two rice grains wide, a cold virus would be slightly larger than a basketball, and a red blood cell would be the height of a twelve-story building.

Materials with at least one dimension (length, width, or height) between 1 and 100 nanometers are considered to be at the nanoscale. These materials often exhibit exciting and unusual physical, chemical, or biological properties that are different from the properties of the same material in its bulk (non-nanoscale) form. As an example, aluminum in its bulk form is widely used for beverage containers, as it is stable, strong, and inert. However, nanoscale aluminum powder can be highly reactive and combustible, and is currently being tested as a rocket fuel.\(^5\) Such dramatic changes in properties at the nanoscale enable scientists to create previously impossible technologies that promise to revolutionize medicine, energy production, and consumer products. Some expected benefits from nanomaterials include the ability to specifically target and destroy cancer cells, to vastly improve solar-energy

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collection and water treatment, and to make consumer products lighter, stronger, fresher, and longer lasting. Over a thousand products in North America are now enhanced by nanotechnology, including sunscreens, cosmetics, cleaning products, sporting goods, and appliances. Current projections put the market for nanotechnology goods at between $1 trillion and $3 trillion by 2015.

It is expected that as nanotechnology matures, it will pass through four generations, from simple passive products to complex and novel structures and applications. In its current incarnation as an enabling technology, nanotechnology is in the first generation of “passive nanostructures.” In this generation nanomaterials are typically used as additives or components of more complex materials, bestowing on them unique properties that offer sizable benefits. Subsequent generations are expected to make a transition from “active nanostructures” that are biologically active (e.g., targeted drug delivery), to “systems of nanosystems” that involve the assembly of nanoparticles into more complex active materials, to “molecular nanosystems” that use nanomaterials as devices with fundamentally new functions. This evolution promises to further advance a myriad of technologies beyond what is possible today.

While nanotechnologies offer tremendous benefits for society, they may also pose significant risks. The same properties that make nanomaterials promising—those that make them behave quite differently from bulk forms of the same material—may lead to negative health and environmental consequences. Studies have shown that nanomaterials can be toxic to animals, plants, and microorganisms and that these toxic properties are difficult to anticipate given the known properties of the bulk form of a material. In one database maintained by the International Council on Nanotechnology, nearly 4,200 scientific articles related to the environmental, health, and safety implications of nanotechnology have been catalogued. Nanoparticles, owing to their extremely small size, have been shown to penetrate readily such natural biological barriers as the skin and the blood-brain barrier; they can also reach potentially sensitive organs, such as bone marrow, lymph nodes, the spleen, and the

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heart. Furthermore, nanoparticles can be more biologically active for a given mass than larger-sized particles, given that a greater proportion of their molecules are available on their surface. Finally, nanoparticles have been found to affect aquatic organisms in the environment and have proven difficult and expensive to monitor, measure, and control given currently available technologies.10

What we know about the environmental, health, and safety implications of nanotechnology is alarming, and many questions remain. Nanotechnology has taken the leap from the realm of research into a growing number of applications and consumer products, and yet the science of safety has lagged perilously behind. With mounting evidence that nanomaterials can cause harm in unexpected and potent ways, scientists and citizens alike are calling for better assessment and proactive management of the risks from nanotechnology.

This paper aims to investigate how risks from emerging nanotechnologies can be assessed and managed through current government regulations as they are created, used, recycled, and discarded. By understanding the challenges that nanotechnologies pose for health and environmental regulations and regulatory agencies, it will be possible to identify the key gaps that must be addressed if risks are to be managed effectively.

Risk and Life-Cycle Thinking

One promising method for negotiating the complexity of interactions between emerging technologies, society, and the environment involves a systems, or life-cycle, approach. From the early stages of product design and production to later use, recycling, and disposal, many different risks may be presented for both humans and the environment.

The traditional risk-assessment paradigm involves determining whether a substance is hazardous (i.e., whether it can cause harm), to what extent people or the environment may be exposed to the substance, and whether that exposure will cause an adverse effect (i.e., whether it will make people sick or degrade the environment). In order to evaluate the risks posed by a substance along its life cycle, it is necessary first to understand the hazards (through lab testing or modeling) and then to determine the probable exposures to those hazards at each life stage. Given the many different ways that a substance may be handled throughout its life, exposure scenarios may differ dramatically from stage to stage.

Imagine a hypothetical nanoparticle designed to improve the durability of a consumer food-packaging product. Workers in a factory where nanoparticles are produced or incorporated into the packaging material may be exposed to airborne particles through inhalation. Consumers may ingest some of these particles as the material comes into contact with their food during use. Particles may wash off the container and into household wastewater, where they are carried out into the environment. Finally, incineration at the end of the container’s life may release the particles into the air or transform the particles into more hazardous products. The different situations at each stage of the life of this material create unique exposure scenarios. If the particle is known to be hazardous and exposures can be determined, then the risks posed at each stage can be managed appropriately. Without applying a life-cycle approach to risk assessment, however, understanding and managing risks as the material makes its way from production to final disposal is impossible.

Life-cycle thinking has been increasingly included in risk-assessment procedures carried out by governments, academia, nongovernmental organizations, and industry over the last decade or so, and several frameworks have been proposed for assessing
risk over the life cycle of new nanotechnology products.\textsuperscript{11} While the assessment of risks continues to advance, the management of risks over a product's life cycle has relied on a patchwork of stakeholder oversight and will require greater coordination in management efforts.\textsuperscript{12} Risk assessment and risk management for technologies and chemical substances are carried out in varying degrees by multiple stakeholders and at different stages of the life cycle. However, whether the current collection of government regulations provides adequate oversight for risk-assessment and risk-management efforts at each stage remains unclear. The following sections aim to investigate the state of current federal health and environmental regulations and how they apply over the life cycle of a nanomaterial.


\textsuperscript{12} Council of Canadian Academies, “Small Is Different.”
Life-Cycle Regulation

In the United States responsibility for the regulation of potentially toxic materials and products containing those materials spans several federal agencies. These agencies include the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Occupational Health and Safety Administration (OSHA), and the Consumer Product Safety Commission (CPSC). Each of these agencies is charged with enforcing statutes to control risks from specific types and uses of substances (i.e., chemicals, pharmaceuticals, and pesticides) at specific life-cycle stages.

The typical life cycle of a product—whether an industrial chemical, a consumer product, or a nanoscale material—involves a few key steps. These include 1) raw-materials acquisition (resource extraction), 2) raw-materials processing, 3) product fabrication, 4) transportation and storage, 5) product use and maintenance, 6) recycling and reuse, and, finally, 7) disposal and incineration. A simple schematic outlines this cycle in Figure 1.

Figure 1. Generic Life-Cycle Model

While the first step in a typical life cycle is the acquisition of raw materials, this stage is not included in this investigation. Since ‘engineered’ nanoparticles (those which are intentionally created, and hence the focus of this paper) generally do not come into existence until raw materials are transformed into the intended nanoscale...
form, this investigation will begin at the raw materials-processing stage. Traditional life-cycle analyses also include an investigation of the transportation and storage of products, but these stages have been omitted here to focus on the stages with the largest potential for risk.

The next section follows a nanoparticle though its life cycle and investigates the federal regulations that come into play at each stage. The intended applicability of each regulation is described, and mechanisms for risk assessment and management are explored. Further, the applicability of each regulation for the case of nanotechnology is investigated, considering both limitations in regulatory mechanisms regarding nanotechnology and the special challenges that nanotechnology poses. Finally, a review of how the regulations fit into the broader picture of the life cycle of nanomaterials is conducted.
Figure 2. Step 1: Raw-materials processing and product fabrication

The raw materials–processing and the product-fabrication stages, as displayed in Figure 2, provide the first stop along the life cycle of a nanomaterial. These stages represent the early development of nanomaterials, from the raw material up to the point where they either become products or are incorporated into other products to be marketed later. These two stages are grouped together here since the applicable federal health and environmental regulations tend to treat the processing of product ingredients and the fabrication of the product similarly.

Three key statutes come into effect at this stage, depending on the intended application of the nanomaterial. Chemical substances and pesticides are regulated under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), respectively. The Environmental Protection Agency (EPA) administers these two statutes. Food additives and drugs are regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA), which is administered by the U.S. Food and Drug Administration (FDA). Together, TSCA, FIFRA, and FFDCA apply to chemical substances, pesticides, food additives, and drugs primarily through a ‘premarket’ risk-assessment, registration, and management approach. In other words, each substance is evaluated and risk-management decisions are made before the product is released for use on the market. While these statutes do have various mechanisms for ‘postmarket’ evaluation of risks (such as when reports of adverse
effects surface), as well as some ability to manage such risks after a product is marketed, their primary mechanisms are at the premarket stage. Each of these statutes will be examined here for their applicability to nanomaterials as a means of identifying the challenges that such materials pose.

**Chemical Substances under the Toxic Substances Control Act**

TSCA, enacted in 1976, regulates all chemical substances produced or imported into the United States and focuses on the production, intended use, and disposal of chemicals, with the exception of pesticides (regulated by the EPA under FIFRA); food and food additives, cosmetics, and drugs (regulated by the FDA under FFDCA); and other materials, including tobacco, nuclear materials, or munitions.\(^\text{13}\)

A chemical substance is defined by TSCA as follows: “any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.”\(^\text{14}\) By this definition engineered nanomaterials currently being developed and marketed fall under the oversight of TSCA.\(^\text{15}\) Furthermore, owing to TSCA’s broad applicability to the production and use phases of a chemical’s life cycle, it is widely expected to be the main statute for regulating risks over the life cycle of emerging nanotechnologies.\(^\text{16}\) However, as nanotechnology matures and as nanomaterials make the transition from passive structures toward more complex active materials, such technologies may very well challenge the definition of a chemical substance. In such a case it is unclear whether nanotechnology will still be subject to the requirements of TSCA.

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13 Toxic Substances Control Act, U.S. Title 15, Chapter 53, Subchapter I (2009), § 2601-29
Under TSCA the EPA regulates chemicals by maintaining a Chemical Substances Inventory of substances manufactured or processed in the United States. The inventory lists approximately 62,000 substances that were in use before 1978, as well as approximately 20,000 substances added since then. Once a substance is listed on the inventory, it is considered an “existing substance” and is deemed safe and authorized for use. When a manufacturer intends to produce or import a substance, they must determine whether or not it is listed on the inventory. If the substance is listed and there are no specific rules or requirements issued for that substance, then the manufacturer does not need to notify the EPA. However, if a substance is determined to be a “new substance” (i.e., not on the TSCA inventory), or the substance is already on the inventory but is subject to a Significant New Use Rule (SNUR), then the manufacturer must submit a notice to the EPA for review. These two notice requirements, namely, the Premanufacture Notice (PMN) for new substances and the Significant New Use Notification (SNUN), are the primary triggers for determining whether a chemical substance will be reviewed and regulated under TSCA.

**New Substances and the Premanufacture Notice**

A manufacturer who produces a new substance must submit a PMN to the EPA for a ninety-day review. The PMN allows the EPA to determine whether the “manufacture, processing, distribution in commerce, use, or disposal [of a chemical substance] . . . presents, or will present an unreasonable risk of injury to health or the environment,” given the information required by the notice.

Several exemptions exist for new substances where the PMN requirements do not apply and for which the EPA has limited or no reporting requirements. Chemical substances, including nanomaterials, are eligible for these exemptions:

* research and development (R&D) exemption (substances manufactured in small quantities for research and development);
* polymer exemption (most types of polymers are exempted, as the EPA believes they “do not pose an unreasonable risk”);
* low-volume exemption, or LVE (substances manufactured or imported in amounts of 10,000 kilograms (10 metric tons) or less each year);

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20 Jeffords et al., “GAO-05-458 Chemical Regulation.”
The first two exemptions are “self-executing,” meaning that once an entity determines that the exemption applies, they can carry out manufacturing without a PMN provided they comply with any requirements stipulated by the exemption. The LVE, LoREX, and TME require EPA approval, and manufacturers seeking one of these exemptions must submit an exemption notice that is subject to a thirty-day EPA review and approval process.

Approximately 1,500 “new chemical” notices are submitted to the EPA under the PMN requirement each year, nearly half of which are exemption requests. Since 2005 the EPA has received and reviewed more than fifty new-chemical notices for nanoscale materials.\textsuperscript{21}

**Existing Substances and the Significant New Use Rule**

Existing chemicals on the TSCA inventory are authorized for manufacture and import and do not involve any additional reporting requirements or limitations, unless specified by a rule issued by the EPA. However, if the EPA determines that an existing substance is being manufactured or imported for a “new use,” it can issue a Significant New Use Rule, or SNUR. This rule requires any manufacturer using or intending to use an existing substance for a significant new use to submit a Significant New Use Notification (SNUN) to the EPA for review. The EPA’s SNUR authority is similar to its PMN authority, where both the notification requirements and ninety-day review process are essentially identical.\textsuperscript{22} The key difference is that before the EPA can issue a SNUR, it must first consider all relevant factors, including

\begin{itemize}
  \item the projected volume of manufacturing and processing of a chemical substance;
  \item the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance;
  \item the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance; and
  \item the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.
\end{itemize}

\textsuperscript{21} L. Breggin et al., “Securing the Promise of Nanotechnologies.”
The EPA shoulders the substantial burden of both identifying new uses and making a case for issuing a SNUR. However, the EPA does not have to make a legal finding with respect to the potential harm of a substance; rather, the agency only needs to demonstrate that it considered these relevant factors.

Figure 3 illustrates the applicability of TSCA for chemical substances, including nanomaterials. This schematic demonstrates the complexity of TSCA and provides an example of the complex applicability of many of the regulations investigated in this paper.

Figure 3. TSCA applicability flowchart
TSCA and Nanoscale Chemical Substances

Low Production Volumes and Notification Exemptions

While at a distance TSCA appears to possess broad regulatory authority and multiple mechanisms for regulating emerging nanotechnologies, a closer look reveals that it is riddled with gaps. One such gap lies within the notification-exemption process. The existing LVE was originally designed with the assumption that substances produced in lower volumes pose less overall risk than those produced in higher volumes. While this assumption has served in the past to prioritize the higher-volume substances for assessment, nanotechnology now challenges its suitability.

Nanomaterials tend to be more reactive than their bulk counterparts and often require a smaller mass of material to have a desired effect. Similarly, nanomaterials are widely known to have larger toxic dose-response effects by mass, meaning that for an equivalent mass of a nanoscale material and bulk (non-nano) material, the nanomaterial can produce a greater toxic effect. Toxicologists generally agree that traditional dose measurements based on mass may not be suitable for nanomaterials because nanoparticles experience a dramatic increase in surface-to-volume ratio as particle size decreases; more atoms are available on the particle surface to react with their surroundings. Therefore, a measure that is reflective of the total surface area of the material may be a better measure of dose than mass. 23

Given what is known about the reactivity and potency of nanoscale materials, the LVE of TSCA does not appear to be appropriate. With a high-production threshold of 10,000 kilograms per year before TSCA comes into effect, low production-volume nanomaterials will not be regulated under TSCA. Requirements for reporting and prioritization for assessment ought to be based on such criteria as a substance-hazard profile or potential for exposure rather than on production volume alone.

Nanoscale Materials: New or Existing Substances?

Another contentious issue with TSCA is whether or not nanomaterials that are composed of substances already listed on the TSCA inventory (but in a non-nano...
form) should be regulated as new or existing substances. In a 2007 clarification document the EPA stated that it will apply the definition of “chemical substance,” as described above, to determine whether a nanoscale material will be considered new or existing under TSCA.24 Any nanoscale material that is composed of a substance with the “same molecular identity” as a substance already on the inventory will be considered an existing substance; a nanoscale material with a molecular identity that is “not identical” to any chemical substance on the TSCA inventory will be considered new. In addition to this clarification the EPA confirmed that it would not focus on such physical attributes as particle size when determining whether a substance is new or existing. The result of this determination is that nanomaterials created from existing substances—and there are likely to be many—will not require a PMN or reporting of any kind.

This determination has been criticized by Andrew Maynard of the Project on Emerging Nanotechnologies as ignoring “the scientific research evidence to date that different nanostructures with the same molecular identity present different hazards.”25 The assumption that the risk profile of a nanoscale version of a substance is identical to the risk profile of its bulk counterpart does not hold in light of the growing body of evidence showing how nanomaterials behave in unique ways. In fact, nanotechnology is widely popular and heavily funded owing to the reality that nanomaterials can have different properties than their bulk counterparts of the same molecular identity. By applying the EPA’s method of determining new versus existing, nanomaterials that are considered existing may be misclassified as safe and make it to market without adequate consideration of the associated risks.

For nanomaterials that are considered existing, the SNUR mechanism can, in theory, be used to require reporting as more toxicology data becomes available to the EPA. Using SNURs would require manufacturers to send in notices to report chemical data and known risks, as required by the SNUR for a particular nanomaterial. However, given the expected influx of new nanomaterials on the market, issuing SNURs for each of these products would be an extremely burdensome process for the EPA, taxing already strained resources. Furthermore, the EPA reports that the typical time-frame for issuing a SNUR, from the beginning of work until it goes into effect, is two years.26 Such a time lag means that nanomaterials can make it onto the market in consumer products with no risk review by the EPA for several years, despite growing

26 U.S. Environmental Protection Agency, "EPA Authorities under TSCA."
evidence of the toxicity of certain nanoscale substances.

In short, nanomaterials that are deemed existing will not require any additional reporting, testing, or limitation in production or use unless the EPA can build a case for issuing a SNUR, a process that is long and burdensome. Since TSCA’s inception in 1976, a total of only seven hundred SNURS have been issued.27

Information Requirements and the Burden of Proof

The PMN and SNUN are the primary mechanisms by which all relevant information is submitted to the EPA for a risk review. They are essentially identical in their information requirements. These requirements include

- chemical substance data (e.g., molecular structure, categories of use, estimated amount manufactured, estimate of the numbers of people exposed, and the method of disposal);
- any test data in the possession or control of the person giving such notice that are related to the effect on health or the environment; and
- descriptions of any other data concerning the environmental and health effects of such a substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.28

While companies are required to provide this information, according to a recent Government Accountability Office (GAO) report, “chemical companies are not required by TSCA, absent a test rule, to test new chemicals before they are submitted for EPA’s review, and companies generally do not voluntarily perform such testing.”29 The GAO report also states that the EPA estimates “about 15 percent [of PMNs] include health or safety test data.” In order for the EPA to require that a company test a product for toxicity, they must promulgate a test rule, which requires them to demonstrate that a chemical substance

- may present an unreasonable risk of injury to (human) health or the environment, OR
- is or will be produced in substantial quantities, and either (a) enters or may be reasonably anticipated to enter the environment in substantial quantities, or (b) may significantly or substantially allow for human exposure to such substance or mixture, AND
- that there are insufficient data and experience upon which the effects of the substance on health or the environment can reasonably be determined or predicted, AND
- that testing of the substance or mixture with respect to such effects is necessary to develop data.30

27 Breggin et al., “Securing the Promise of Nanotechnologies.”
30 Bergeson and Dassa, “TSCA and Engineered Nanoscale Substances”; U.S. Environmental Protection Agency, “EPA Authorities under TSCA.”
Given that a new material is likely to have very little information publicly available (by nature of it being new and not yet in use widely), it is easy to see that building a case for the necessity of a testing rule would be a sizable challenge for the EPA. Finalizing test rules under section 4 of TSCA can take from two to ten years and can require the expenditure of substantial resources. With these limitations the EPA has required testing through formal “test rules” for just 185 of the 82,000 chemicals on the TSCA inventory (as of 2005).  

**VOLUNTARY PROGRAMS FOR COLLECTING HAZARD INFORMATION**

To deal with such constraints the EPA often uses voluntary programs or consent agreements to encourage companies to submit information. For example, the EPA has entered into consent agreements with companies to develop tests for an additional 60 chemicals. Similarly, the EPA introduced the high-production volume (HPV) challenge, a voluntary-reporting program that challenged industry to provide testing information for chemicals produced in amounts over 1 million pounds per year. This program has resulted in test data being submitted for 2,800 chemicals, though much of this data is incomplete and companies have refused to submit data on 300 chemicals on the HPV list. A similar program was created for nanomaterials, titled the Nanoscale Material Stewardship Plan (NMSP), which resulted in information being submitted for 123 nanoscale materials based on 58 different chemicals. However, information on approximately 90 percent of the different nanoscale materials that are likely to be commercially available were not submitted through the NMSP, and very few submissions provided toxicity or environmental-fate studies. While the EPA has to bear a high burden of proof to require risk information through formal TSCA mechanisms, they do have some ability to collect a limited amount of information through voluntary measures.

In addition to the burden of proof required before the EPA can promulgate a test rule, a similar burden is placed on the agency before it can regulate or control a substance. In a report by J. Clarence Davies, former assistant administrator for policy, planning and evaluation at the EPA, one weakness of TSCA is that it “implicitly assumes that no knowledge about a chemical means there is no risk.” Without adequate information to demonstrate that a substance may present an “unreasonable risk of injury,” the EPA is severely limited in the actions the agency can take to regulate that substance. One mechanism for regulating a substance when information is sparse illustrates the difficulty that the EPA faces. For example, section 5(e) of TSCA states that if the available information is “insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance,” then

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31 Jeffords et al., “GAO-05-458 Chemical Regulation.”
32 Ibid.
33 Breggin et al., “Securing the Promise of Nanotechnologies.”
34 Davies, “Managing the Effects of Nanotechnology”, p. 11.
the EPA can prohibit or limit the manufacture of a chemical substance. However, in order to do this the EPA must clearly demonstrate that the chemical “may present an unreasonable risk,” which is precisely what Davies suggests it cannot show. The requirement for compelling information to make a case for regulating a new substance is a catch-22 scenario that is not easily overcome.

EPA reviews have resulted in some action taken to reduce the risks of over 3,500 of the 32,000 new chemicals submitted for review since 1976. More than half of these actions involved chemical companies voluntarily withdrawing their notices of intent, and the remainder included consent orders to produce a chemical under specified conditions or with the EPA requiring chemical companies to submit notices of any significant new uses (for 160 chemicals). In terms of limiting production only five chemicals or chemical classes have been banned or had limits placed on their production by the EPA since TSCA was enacted in 1976.

Since emerging nanomaterials, like other chemical substances, do not require testing by the manufacturer, and it is unlikely that a significant amount of publicly available risk information exists for these materials, the EPA would likely face a challenge in requiring testing or in regulating nanomaterials. With the growing attention on nanotechnology and with concerns by scientists and the public alike, significant resources have been focused on nanotechnology within the EPA. Two recent SNURs have been issued through an expedited process for single-wall and multi-wall carbon nanotubes; however, they have been withdrawn owing to the submittal of adverse comments. The EPA expects the SNURs to be reissued following the standard rulemaking process in the future.

**Life Cycle and TSCA**

TSCA is designed to assess health and environmental risks not just from the production stage but also from the use and disposal stage of a product. However, since many nanomaterials are unlikely to require a PMN or SNUN as described above, they will not benefit from such a risk analysis. For those that do, TSCA enables a one-time risk assessment, the accuracy of which is limited both by the information available at the time of assessment and by the production, use, and disposal scenarios identified by the manufacturer. These scenarios may change significantly over time, as it is difficult to anticipate all possible uses of a chemical.

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35 Jeffords et al., “GAO-05-458 Chemical Regulation.”
at the time of premanufacture. If at a later date additional use, hazard, or exposure information becomes available, there is no automatic mechanism for a reassessment of the risks by the EPA. Such a reassessment would occur only after a SNUR was issued or if the EPA were able to negotiate an agreement outside of the formal regulation framework.

A further complication to TSCA’s approach is that risk assessments do not take into account combinations of materials that may be present in a final product, which together could produce unreasonable risk to humans or the environment. In order to ensure that combinations of materials are evaluated together in products, there must be a mechanism for evaluating materials in their actual use at the “use, consumption, and maintenance” phase.

Finally, companies can claim a large amount of information submitted under TSCA as confidential business information (CBI), thereby limiting its availability outside the EPA. Information claimed as CBI is not available to other federal or state agencies or to the public. According to one GAO report, 95 percent of PMNs contain some information that chemical companies claim as confidential. The wide use of CBI claims limits the flow of valuable chemical property, use and exposure, or testing information to stakeholders and agencies along the life cycle of a material. Without such information other stakeholders are limited in their ability to conduct risk assessments or create risk-management or emergency-response plans. CBI claims are relatively easy for manufacturers to make but are difficult for the EPA to dispute, and therefore much of the data collected under TSCA is unavailable outside the agency.37

**Pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act**

FIFRA regulates all substances intended to be used as pesticides. First embodied as the Federal Insecticide Act of 1910, FIFRA came to life in 1947 under the auspices of the U.S. Department of Agriculture. FIFRA underwent a major revision in 1972, and responsibility was then transferred to the EPA, where it lies today. FIFRA is designed to regulate chemicals claimed to be “pesticides,” which are defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.38 While pesticides are often thought of as only insecticides, this

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37 Jeffords et al., “GAO-05-458 Chemical Regulation.”
term also refers to fungicides, herbicides, and other substances intended to control pests. FIFRA requirements are typically triggered based on the “intended use” of a substance, when a manufacturer makes a specific claim about the substances antimicrobial activities. Unlike TSCA, there is no mass- or volume-based trigger for applicability. According to a 2007 EPA white paper, pesticides containing nanomaterials are subject to FIFRA’s review and registration requirements.

In order for pesticides to be authorized for sale and distribution, they must first be registered with the EPA. Under FIFRA, manufacturers are required to submit an application along with scientific data on the toxicity and behavior of the pesticide in the environment. In contrast with TSCA, which places the burden on the EPA to prove that a substance poses an “unreasonable risk,” FIFRA places the burden on industry to prove that a pesticide will not cause “unreasonable adverse effects” to human health or the environment. The EPA has the explicit authority under FIFRA to require the manufacturer to provide substantial data to assess the benefits and risks of a pesticide and may require the applicant to conduct a battery of tests. After an assessment of the benefits and risks, the EPA can then ban the pesticide, permit the manufacture (possibly under limited use), or require further testing. If the registration is approved, the EPA will specify the approved uses and conditions of use, along with safe methods of storage and disposal, and will require that the pesticide is labeled appropriately with this information. Furthermore, pesticides must be reregistered every fifteen years and can be banned later if they are deemed harmful.

**FIFRA and Nanoscale Pesticides**

**Life Cycle and FIFRA**

Under FIFRA pesticides are assessed to determine both human-health and environmental risks from use, and manufacturers are required to supply test information

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39 Pelley and Saner, “International Approaches to the Regulatory Governance of Nanotechnology.”
43 Insecticides and Environmental Pesticide Control, U.S. Title 7 (2009), § 136(a), http://www.law.cornell.edu/uscode/7/uscc_07_136--a000-.html.
44 Breggin et al., “Securing the Promise of Nanotechnologies”; Mandel, “Nanotechnology Governance.”
NANOSCALE PESTICIDES AND UNSUBSTANTIATED CLAIMS

FIFRA has greater regulatory oversight than TSCA, but it covers only specific and limited contexts for chemicals and is expected to come into play only for nanomaterials intended to be used as pesticides. One well-known material with antibacterial properties has recently been the subject of some controversy as it made the leap into the world of nanotechnology. Silver was first registered as a pesticide in the United States in 1954, and several materials containing silver have been registered with the EPA since that time. \(^48\) Today nanosilver is the most common nanomaterial in consumer products and is typically used to endow products with antibacterial properties. \(^49\) However, the question remains as to how a nanoscale version of an existing pesticide will be regulated.

A handful of products that contain nanosilver have recently been subject to fines under FIFRA, although the EPA has been quick to clarify that its actions were not a move to regulate nanotechnology. Rather, action was taken solely to address unsubstantiated claims of antimicrobial activities. A fine of $205,000 was levied against Samsung in October 2009 for selling nanosilver-coated computer keyboards as “antibacterial,” and a lawsuit was filed against VF Corporation in September 2009 for claims that the AgION silver-containing footbed in their North Face product line has antibacterial properties. The VF Corporation is currently facing nearly $1 million in fines. \(^50\) These and other cases involving nanosilver resulted in the companies being required to remove any advertising that suggested that their products had antibacterial properties. However, the companies were not required to remove the silver material from their products.

The Project for Emerging Nanotechnologies’ Consumer Products Inventory currently lists 259 products containing nanoscale silver, including clothing that controls odor by “disinfection and deodorization,” wound dressings with “antimicrobial barrier protection,” and toiletries and equipment with “antibacterial” nanosilver coating. Although hundreds of products claim to use nanosilver for pesticidal purposes, the EPA has yet to receive a single application for registration under FIFRA. \(^51\) These recent lawsuits will likely encourage companies engaging in similar practices to consider registering their products under the act. Yet another effect is equally possible: the forced removal of pesticidal claims may result in greater difficulty in identifying which products contain nanotechnology.

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\(^{47}\) Insecticides and Environmental Pesticide Control, U.S. Title 7 (2009), 136(q).
Overall, FIFRA is comparatively well suited for assessing and managing risks from pesticides, including those containing nanomaterials. However, some harmful pesticide products have in the past made it to market, only to be removed after adverse effects have been identified. While FIFRA is not perfect, it does offer a greater level of oversight and a more precautionary approach than TSCA and several other statutes reviewed here.

**Food Additives and Drugs under the Federal Food, Drug, and Cosmetic Act**

FFDCA, originally created in 1938, charges the FDA with overseeing the safety of food, food additives, drugs, and cosmetics. Like FIFRA, FFDCA provides greater oversight of certain potentially toxic materials than TSCA, but it covers only specific and limited contexts. FFDCA handles products differently depending on their intended use. Food additives and drugs are managed primarily at the production or premarket stage of the product’s life cycle. Cosmetics and food additives that are considered dietary supplements are not regulated until after they enter the marketplace, and are reviewed in a later section.

**Drugs under FFDCA**

FFDCA defines drugs as “articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body.” Like pesticides under FIFRA, drugs are subject to an extensive premarket approval process by the FDA. This approval process requires manufacturers to demonstrate that a drug is safe and effective before it can undergo clinical trials and finally be sold on the market. To demonstrate safety, manufacturers must submit results of pharmacological and toxicological studies of a drug in animals or in vitro for review. This review process is the most stringent of all those investigated and places the burden of proof firmly on the drug manufacturer to prove safety rather than on the FDA to prove harm.

**Food Additives under FFDCA**

Under FFDCA, substances (including nanomaterials) that are either intentionally or unintentionally added to foods are considered food additives and require premarket approval. From the text, it appears that there is no blanket regulation of substances added to foods by FFDCA, but that substances are regulated if they are intended to affect the structure or function of the body.

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53 Breggin et al., “Securing the Promise of Nanotechnologies,” p. 74.
approval by the FDA. This definition includes substances used in food-contact articles (such as packaging) if they are reasonably expected to migrate into food.\textsuperscript{54} Similarly, pesticide residues in food (including residues of pesticide products containing nanomaterials) are regulated under FFDCA.\textsuperscript{55} In order to obtain approval for food additives, such as flavor enhancers or preservatives, a manufacturer must submit a petition along with specific testing data for review. The FDA then evaluates the composition and properties of the substances, including exposures through consumption, to determine the immediate and long-term (chronic) health effects. The FDA may approve a substance for use if “reasonable certainty” of no harm is determined, and limits and conditions can be set on the use of the additive if necessary.

This premarket approval process does not apply, however, if an additive is determined to be “generally recognized as safe,” or GRAS. A GRAS determination is the responsibility of the manufacturer rather than the FDA. If a manufacturer makes the determination that a substance is GRAS, they may notify the FDA of this determination or seek FDA review, but they are not required to do so under FFDCA. Similarly, substances that migrate from food-contact surfaces into food in small amounts may be exempted if their use poses “negligible safety concerns.”\textsuperscript{56} Producers may bypass the premarket petition for these substances by submitting a food contact notification (FCN) along with certain safety information. The FDA has a 120-day window to approve the FCN and can deny or revoke it at any time if the agency determines that the packaging is unsafe. According to a recent report by Breggin and colleagues, at least two FCNs have been approved to date for nanoscale materials, including titanium nitride and titanium aluminum nitride.\textsuperscript{57}

**FFDCA and Nanoscale Drugs and Food Additives**

**Nanotechnology in Drugs and Food Additives**

A recent FDA Nanotechnology Task Force report concluded that the agency’s authorities are generally comprehensive for products subject to premarket authorization requirements, including drugs and food additives.\textsuperscript{58} Because the


\textsuperscript{55} U.S. Environmental Protection Agency, “Nanotechnology White Paper.”

\textsuperscript{56} Breggin et al., “Securing the Promise of Nanotechnologies.”

\textsuperscript{57} Ibid.

\textsuperscript{58} U.S. Food and Drug Administration, “Nanotechnology Task Force Report 2007.”
agency is able to obtain detailed scientific information and testing to review safety of products, they are able to conduct a more rigorous assessment of potential negative effects than would be possible with limited information. It is unclear, however, whether the FDA would be aware of the presence of nanomaterials in a drug or food additive and whether it would likely have to request nanomaterial-specific information. As noted in the FDA report, the challenge for the agency is in understanding and identifying which properties of nanomaterials are of interest so as to focus data and testing requirements.

For food additives, since substances are determined to be GRAS by the food manufacturer and not by the FDA, it is possible that nanoparticles used as additives will be deemed safe and that the FDA may not even be aware that they are used as additives in foods. Owing to the large allowance for food manufacturers to use their own discretion in determining whether an additive is safe, the regulatory requirements for food additives are considered substantially voluntary. Furthermore, there is no mandatory labeling requirement for nanomaterials used as food additives; the FDA will consider labeling requirements on a case-by-case basis. As such, consumers may not have the ability to determine whether their foods contain engineered nanoparticles as additives.

**Life Cycle and FFDCA**

Under FFDCA both drugs and food additives receive a rigorous review for health risks posed by the use of these products. The FDA applies a product-by-product approach rather than a substance-based approach, so the agency is more likely to capture potential interaction effects from combinations of different substances in a product than other agencies. Furthermore, FFDCA is expected to be more stringent than other statutes in that the manufacturer must demonstrate a product’s safety before it is approved for use. Once a product is approved, the FDA also has the authority to recall products that demonstrate adverse effects. Finally, reassessment of tolerances for pesticide residues as “food additives” is authorized under FFDCA. A similar reassessment of other food additives and drugs is possible as information on adverse effects or potential hazards becomes available.

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FFDCA does not consider environmental risks owing to downstream disposal or inadvertent entry into the environment from such practices as the flushing of expired drugs. Furthermore, nanomaterial-based food additives may be exempted from regulation with a GRAS determination, given a paucity of available hazard information. Overall, however, FFDCA is considered to provide a high level of regulatory oversight and risk-management ability for food additives and drugs.
Use, Consumption, and Maintenance

The use, consumption, and maintenance stage represents the second stop along the life cycle of a nanomaterial and is the point at which the intended function of the material is realized. At this stage nanomaterials may be a component of cleaning products, clothing, food packaging, medical devices, pharmaceuticals, or any number of other products or technologies.

Regulations that come into effect at this life-cycle stage are primarily postmarket; in other words, they come into effect only after a product is marketed for use. While FFDCA was discussed in the previous section as it pertains to drugs and food additives, the act also includes oversight of dietary supplements and cosmetics at this stage. All other consumer products at the use stage are regulated under the Consumer Product Safety Act (CPSA), which is enforced by the Consumer Product Safety Commission (CPSC), a federal agency dedicated entirely to postmarket evaluation of products. These postmarket regulations and their applicability to nanoscale materials will be investigated here.

Dietary Supplements and Cosmetics under the Federal Food, Drug, and Cosmetic Act

In addition to managing risks from food additives and drugs at the premarket stage (as described above), FFDCA charges the FDA with regulating dietary supplements and cosmetics solely at the postmarket stage of their life cycle. Once a supplement
or cosmetic product is marketed for sale and use, FFDCA has several regulatory mechanisms available to assess and manage risks. However, the FDA’s oversight capacity for these products is less comprehensive than it is for food additives and drugs.62

**Dietary Supplements and FFDCA**

In contrast to the regulations for food additives under FFDCA, which require a full premarket evaluation by the FDA, the supplement manufacturer is responsible for determining whether a dietary supplement is safe before it is sold.63 With the exception of “new” dietary ingredients (those not marketed before 1994 or those not already present in the food supply), supplements do not undergo a safety review or registration with the FDA, and there are generally no notification requirements. The FDA, however, is responsible for monitoring the safety of dietary supplements once they are on the market, and the agency has the authority to take action against supplements that it can demonstrate are unsafe.64 According to the Nanotechnology Product Inventory, there are currently at least fifty-one dietary-supplement products on the market claiming to contain nanomaterials.

**Cosmetics and FFDCA**

Cosmetics are defined under the FFDCA as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance.”65 Cosmetics require no premarket registration or approval. Instead the FDA places the responsibility on cosmetics manufacturers to assess the safety of their products before marketing them. Furthermore, there are no reporting requirements for cosmetics, and so the FDA relies on voluntary programs for obtaining data on ingredients, registering manufacturing sites, and reporting cosmetics-related injuries. However, manufacturers are required to label products with a list of ingredients. When the FDA becomes aware of health or safety concerns, they have the authority under FFDCA to remove adulterated, unsafe, or unlawfully labeled products from the market through judicial action.66 There are currently over 130 cosmetics products on the market in the United States that claim to contain nanomaterials.67

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63 Breggin et al., "Securing the Promise of Nanotechnologies."
64 U.S. Food and Drug Administration, “Nanotechnology Task Force Report 2007.”
65 Ibid. p. 27.
66 Breggin et al., "Securing the Promise of Nanotechnologies."
67 Project on Emerging Nanotechnologies, "Consumer Products Inventory."
Dietary Supplements, Cosmetics, and Nanotechnology

No requirements currently exist for manufacturers of dietary supplements or cosmetics to declare that their products contain nanomaterials. While the FDA can require submission of data regarding particle size or other properties when relevant for establishing the safety of a drug or food additive, the agency has less ability for obtaining such information for cosmetics or dietary ingredients. The FDA may only learn of the use of nanomaterials in cosmetics or supplements if their use is noted in new-ingredients notifications (for dietary supplements only) or in adverse-effects reports. Neither of these notifications, however, requires the manufacturer to disclose the use of nanomaterials in their product.

The FDA also has a limited ability to collect the information required to justify the removal of a hazardous product from the market. Owing to the largely voluntary nature of reporting, the FDA may have far less baseline data for cosmetics or dietary supplements than it does for food additives and drugs. Until 2007 the FDA had only received voluntarily submitted adverse-event reports for dietary supplements, but the agency now requires by law that serious adverse-event reports be submitted. Similarly, there are no postmarket reporting requirements for adverse events associated with cosmetics, so the FDA only receives cosmetic adverse-event reports that are submitted voluntarily. According to the FDA Nanotechnology Task Force report, “the agency may have a comparatively difficult burden in assembling the necessary data to support a product remove action” for these products under the authority of FFDCA.

In addition, the FDA does not have the authority to delay a product from being marketed, regardless of whether nanomaterials are used or not. The agency is limited to postmarket mechanisms for regulating risky supplement products or cosmetics. In order for the FDA to remove a dietary supplement from the market, it must prove that the supplement “present(s) a significant or unreasonable risk of illness or injury,” which may be difficult to do given limited information. However, in the case of cosmetics, the FDA does not have postmarket recall authority at all and is limited to requesting a voluntary recall or taking legal action to remove adulterated or misbranded products from the market. Cosmetics and dietary-supplements manufacturers may use any ingredient that they (the manufacturers) consider safe until

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69 Ibid.
70 Breggin et al., “Securing the Promise of Nanotechnologies.”
73 Breggin et al., “Securing the Promise of Nanotechnologies,” p. 61.
the FDA demonstrates that it may be harmful to human health. But this process rarely occurs.\textsuperscript{75}

Nanomaterials have already found their way into nearly four hundred personal-care, cosmetics, and dietary-supplement products in the United States, including sunscreens, mascara, skin creams, vitamin sprays, and nano-mineral supplements.\textsuperscript{76} Given the largely voluntary basis for regulation of cosmetics and dietary supplements and the increasing use of nanomaterials in these products, it is apparent that oversight of nano-containing cosmetics and supplements products must be reconsidered.

\textbf{Life Cycle and FFDCA}

The regulations for dietary supplements and cosmetics are intended to apply only at the postmarket stage, and these products do not undergo any form of premarket assessment by the FDA. Dietary supplements and cosmetics receive the lowest level of oversight of all substances reviewed here, as the FDA has the authority to regulate a product only after adverse effects from use have been demonstrated. Furthermore, risk assessment is limited by a lack of product data and authority to collect relevant risk information. Finally, FDA’s oversight for these products is limited to health risks and does not extend to environmental risks posed by the use or routine disposal of these products. With limited authority to collect relevant risk information and to regulate these products, dietary supplements and cosmetics containing nanomaterials may pose a larger risk to society, especially given that nearly two hundred products are already on the market.

\textbf{Consumer Products under the Consumer Product Safety Act}

CPSA, enacted in 1972, charges the CPSC with protecting the public from risks associated with consumer products.\textsuperscript{77} The CPSC is an independent regulatory agency with jurisdiction over more than 15,000 types of consumer products, such as electronic devices, clothing, appliances, and toys.\textsuperscript{78} It has the authority to develop product-safety standards, to regulate consumer products that pose an “unreasonable risk of injury,” and to maintain the National Electronic Injury Surveillance System to

\textsuperscript{75} Mandel, “Nanotechnology Governance.”


collect, investigate, analyze, and disseminate product-injury data. These authorities do not apply, however, to pesticides regulated under FIFRA or to food, food additives, drugs, or cosmetics regulated under FFDCA.

Two additional statutes, the Federal Hazardous Substances Act (FHSA) and the Poison Prevention Packaging Act (PPPA), provide the CPSC with the authority to require appropriate labeling and safe packaging for poisonous and hazardous products. In addition, the recent Consumer Product Safety Improvement Act (CPSIA) of 2008 includes an expanded ability to regulate children’s products and has authorized $1 million for research on safety issues related to nanotechnology in consumer products.

The primary mechanisms for regulation through the CPSC include the setting of safety standards, the public disclosure of information (through an injury inventory and through product labeling), and product recalls. The commission may also ban products that create an “unreasonable risk of injury” when “no feasible consumer product safety standard” can adequately address that risk.

Products are not subject to premarket approval, and the CPSC does not have the authority to require safety testing of products before they go to market. Instead they rely on manufacturers to conduct their own tests or safety reviews. Companies are, however, required to notify the CPSC within twenty-four hours upon becoming aware of product hazards or defects. As a result of these requirements, the CPSC usually becomes aware of safety risks from nanomaterials in consumer products only after adverse effects have been reported. To date the CPSC has not taken regulatory action for any consumer products on the market that contain nanomaterials.

In a recent statement the CPSC announced that nanotechnology-enhanced products would be treated the same as any other consumer product under CPSA. Approximately half of the consumer products containing nanomaterials currently on the market are believed to fall under the jurisdiction of the CPSC.

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81 Lin, “Size Matters.”
82 Satterstrom et al., “Considerations for Implementation of Manufactured Nanomaterial Policy and Governance.”
84 Breggin et al., “Securing the Promise of Nanotechnologies.”
CPSA and Consumer Products Containing Nanotechnology

Stretched Resources and Limited Expertise

The ability for the CPSC to effectively regulate nanomaterials depends on both adequate regulatory authority and the availability of resources to monitor and manage risks. In several reviews the CPSC has been portrayed as ineffective in carrying out its mandate for even simple, low-tech products and so will face a significant challenge with products containing nanomaterials. One reason for this challenge is a serious lack of budget and resources to carry out its mission. Until recently the CPSC’s budget had stayed at roughly the 1983 level, and while the commission had as many as 900 employees in 1981, that number had been reduced to under 400 by FY2007. When compared with the approximately 17,000 employees at the EPA and 14,000 employees at the FDA, it becomes apparent that the small staff and extremely limited budget of the CPSC makes it ill equipped to address its current backlog of consumer-product problem areas. The shortcomings of the CPSC’s regulatory efforts have been at the forefront of public attention in recent years, when tens of millions of lead-tainted children’s toys turned up on the market and regulators were forced to re-evaluate the agency.

One difficulty in providing oversight for consumer products is the overwhelming number and diversity of products on the market, most of which do not pose serious risks to health or environment. Sorting through these products to determine which pose serious risks requires significant resources that the CPSC does not have. This challenge is likely to be further complicated by nanotechnology since the CPSC has little experience in carrying out the sophisticated research and analysis that would be needed to evaluate the potential dangers of nanomaterials in consumer products. Finally, an insufficient enforcement staff means that it will be difficult to identify manufacturers that fail to report nano-product hazards to the agency. As a result, harmful products may not be removed from the market in a timely manner.

Limited Authority to Regulate

Several reports have argued that the CPSC does not have sufficient authority to promulgate mandatory safety standards and so must rely on voluntary measures to

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87 Breggin et al., “Securing the Promise of Nanotechnologies”; Lin, “Size Matters.”
89 Davies, “Oversight of Next Generation Nanotechnology.”
90 Lin, “Size Matters.”
ensure the safety of consumer products. In one report the CPSC is described as being crippled by amendments that prohibit the agency from imposing mandatory safety standards if the industry agrees to write its own voluntary standards. If such standards are found to be inadequate, the commission may establish mandatory standards but only as “reasonably necessary to prevent or reduce an unreasonable risk of injury.” The CPSC has a heavy burden of demonstrating that a substance is hazardous and that its use by consumers may cause substantial injury. Another report concludes that the thresholds for mandatory regulation are “at least as difficult to meet as the standards imposed by TSCA, and would be impossible to meet for nanotechnology given the paucity of existing data.”

Similarly, a 1981 amendment prohibits the CPSC from publicly reporting any information that identifies a brand or manufacturer by name without their permission. Further, the manufacturer must first approve every word that appears in a public recall before it can be released to the public. While manufacturers are under mandate to notify the CPSC of adverse effects or injuries related to the use of their product, product recalls are voluntary agreements negotiated between the CPSC and a manufacturer to notify retailers and the public to discontinue the sale and use of a product.

With little authority to regulate consumer products in the marketplace, and stretched resources that have prohibited the CPSC from effectively managing risks in products in the past, the CPSC’s ability to oversee the safety of more complex high-tech products is questionable. This combination of circumstances has led one critic to conclude that “the CPSC is so lacking in legal authority and financial resources that most consumer products in the United States are, for all practical purposes, unregulated.”

**Life Cycle and CPSC**

CPSA is well positioned in the life cycle of nanomaterials to enable the management of risks from nano-enhanced consumer products at the use, consumption, and

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93 Davies, “Nanotechnology Oversight.”
94 Lin, “Size Matters,” p. 369
95 Davies, “Nanotechnology Oversight.”
maintenance stage. The benefit of conducting a risk assessment on actual consumer products versus on nanomaterials at the production stage (as is done under TSCA) is that less speculation is required for understanding exposure pathways, combination effects, and affected populations. Unfortunately, given a scarcity of resources and a lack of authority to regulate, the CPSC cannot engage in proactive product-based risk management. This is especially troubling since it is the specific characteristics of consumer products that are likely to determine which adverse effects will occur from the use of nanomaterials.\textsuperscript{98} In addition, oversight of consumer products under CPSA is limited to health risks from the use stage and does not apply to environmental risks owing to use or disposal of products. Overall, CPSA provides minimal oversight and regulatory authority to assess and manage risks from consumer products, leaving a large gap in regulatory oversight at this stage in the life cycle of a nanomaterial.

\textsuperscript{98} Ibid.
Recycling, Disposal, and Incineration

Figure 5. Step 3: Recycling, reuse, disposal, and incineration

The “recycling, disposal, and incineration” stages represent the third stop along the life cycle of a nanomaterial and is the point at which the nanomaterial is transformed into a new product, is destroyed by incineration, or is otherwise disposed of. At this stage nanomaterials may already be incorporated into consumer products that have reached the end of their useful life, or may constitute a by-product solid or liquid waste from industrial or consumer use. One main waste-related regulation comes into play at this stage: the Resource Conservation and Recovery Act (RCRA). The applicability of RCRA to nanomaterial waste products will be investigated here. While an additional statute, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) can also come into effect for waste products, it deals with accidental releases into the environment that are not otherwise controlled under RCRA. Since CERCLA is not likely to come into effect until well after a nanomaterial has been released into the environment and deemed hazardous, it is not reviewed here in depth.

Hazardous Wastes under the Resource Conservation and Recovery Act

RCRA was created in 1976 to “regulate the generation, transportation, management, and disposal (other than to surface water) of secondary materials that become solid
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or hazardous wastes.” This statute makes the EPA responsible for ensuring that hazardous-waste materials do not pose a threat to human health or the environment. It is the first of the environmental laws explored here, and instead of regulating a product or a pollution source, it establishes standards for generators of waste and for waste-disposal sites. Under RCRA generators of hazardous wastes are required to identify such wastes and track them from the time they are generated until they reach a final treatment or disposal facility.

RCRA regulations define solid wastes as hazardous wastes if they display recognized hazardous characteristics (i.e., if they are corrosive, reactive, toxic, or ignitable). Examples include arsenic, benzene, mercury-containing compounds, sulfuric acid, and dry-cleaning solvents. The “hazardous waste” distinction also applies if a solid waste is specifically listed as a hazardous waste that is generated by certain industrial activities or by discarding of commercial chemicals. These rules apply to solid wastes based on the hazardous characteristics they display, regardless of whether the material is nanoscale or not. Therefore, RCRA is widely expected to apply to nanoscale wastes and solid wastes that contain nanoscale materials. In addition, if the hazardous characteristics of nanomaterials are novel and not covered by the current definition of hazardous characteristics, the EPA has the statutory authority to define new characteristics or to list problematic nanomaterials as hazardous waste so they can be regulated. The EPA can also use its emergency authorities if necessary to address hazards from particular nanomaterials. To date no nanomaterials have been defined as hazardous under RCRA.

**RCRA and Nanotechnology-Containing Wastes**

**Nanomaterials as Hazardous Waste**

While RCRA gives the EPA the authority to regulate wastes composed of or containing nanomaterials, several caveats apply. Before RCRA can be used to regulate a nanomaterial, it must first be listed as a hazardous waste or exhibit certain

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102 Breggin and Pendergrass, "Where Does the Nano Go?"; American Bar Association, "RCRA Regulation of Wastes from the Production, Use, and Disposal of Nanomaterials"; Powell et al., "Bottom-Up Risk Regulation?"
103 American Bar Association, "RCRA Regulation of Wastes."
hazardous characteristics. For three of the four characteristics required to consider a solid waste hazardous—namely, ignitability, corrosivity, and reactivity—relatively straightforward procedures are used to assess these hazards. The modeling techniques used by the EPA to assess toxicity and the potential for releases (from landfills), however, may not be applicable or accurate for nanomaterials. This is because little data exists on their behavior in soils and groundwater, and current assumptions for larger non-nanoscale materials may not be suitable for nanomaterials. Furthermore, as described above for TSCA, when little information exists to assess nanomaterial hazards, these substances will be assumed safe until significant evidence of harm can be compiled to support listing a material as hazardous. Therefore, RCRA gives the EPA the authority to regulate hazardous materials but limits the agency to reacting to harmful incidences to health or the environment rather than actively preventing such harm.

Despite these limitations the EPA is authorized to set out regulatory standards for handling all aspects of waste management and disposal, not just for hazardous waste. As such, solid-waste management practices required under RCRA may provide an adequate level of precaution for some substances. Similarly, the storage and disposal practices carried out by individual companies may also be sufficiently precautionary to avoid the release of materials for which little is known about safety.

Waste Exemptions and Nanomaterials

Two key exemptions exist that may enable certain nanomaterials to avoid regulation under RCRA. Small-quantity generators of nanomaterials (those that produce less than 100 kilograms annually) are not required to report their activities or waste-storage plans to the EPA. However, larger-quantity generators face more stringent requirements. As discussed for other statutes, nanomaterials are likely to be produced in smaller quantities because of their unique properties, and they may be quite toxic for their given mass. Releases of nanomaterials in amounts less than 100 kilograms may therefore pose a significant risk to human health or the environment. In addition, many consumer products containing nanomaterials are already on the market, yet they may be exempted from RCRA requirements as ‘household hazardous wastes.’ Facilities that manage or dispose of household solid wastes are bound to minimum standards, though hazardous-waste rules do not apply to the household

104 Mandel, “Nanotechnology Governance”; Powell et al., “Bottom-Up Risk Regulation?”
105 Powell et al., “Bottom-Up Risk Regulation?”
106 American Bar Association, “RCRA Regulation of Wastes.”
107 Powell et al., “Bottom-Up Risk Regulation?”
108 Breggin and Pendergrass, “Where Does the Nano Go?”
hazardous waste they collect. Together these two exemptions may prove to be sizable gaps in regulation, allowing significant amounts of potentially hazardous nanomaterials into the environment.

**Life Cycle and RCRA**

How well wastes containing nanomaterials can be managed under RCRA remains unknown, owing to the need for the substance to be deemed hazardous waste before it can be controlled. Since the current information available for nanomaterials is insufficient to adequately estimate toxicity, model potential releases, and control releases, it is unlikely that nanomaterials will be specifically managed under RCRA until such information becomes available. Furthermore, the 100-kilogram and household-hazardous-waste exemptions may lead to many unregulated nanomaterials if they are produced in small quantities or are used in household products.

RCRA only applies at the point in the life cycle where a nanomaterial is considered a solid or hazardous waste, and it remains in effect until that material reaches a final treatment or disposal facility. Substances (including nanomaterials) that are released into the environment and are found to be hazardous at a later date will be subject to CERCLA. This act authorizes clean-up of contaminated sites when other regulations have proven insufficient to prevent the release of hazardous substances into the environment.
Regulations Across All Life-Cycle Stages

Figure 6. Step 4: Regulations across all life-cycle stages

This fourth stop along the life cycle of a nanomaterial consists of two integral components of regulation that apply to each stage: occupational safety and releases into the environment. The occupational-safety component applies to each stage of the life cycle where a nanomaterial is produced or processed. Depending on the inherent hazards of a nanomaterial and potential exposures during handling in the workplace, workers may face significant risks. Similarly, releases of nanomaterials through wastewater effluents or air exhausts can pose a risk to the environment. The three statutes that apply across all stages of the life cycle of a nanomaterial are the Occupational Safety and Health Act (OSHA), the Clean Air Act (CAA), and the Clean Water Act (CWA). These statutes are reviewed here to investigate their applicability to nanoscale materials in occupational settings and in industrial effluents.

Workplace Safety under the Occupational Safety and Health Act

The OSHA, enacted in 1970, initiated the creation of the Occupational Safety and Health Administration (OSHA), with a mission “to assure safe and healthful working conditions for working men and women.” OSHA is responsible for promulgating and enforcing safety and health standards for the workplace and provides research,
education, and training in the field of occupational safety and health.\textsuperscript{109} It also regulates hazardous materials by setting permissible exposure limits, recommends controls and personal protective equipment to ensure that worker exposures are within these limits, and communicates hazards and best protection practices to employers and workers.\textsuperscript{110}

Several reports find that owing to its broad language, the OSHAct could be used for managing exposure to nanomaterials in the workplace.\textsuperscript{111} According to one recent review of the act, four types of standards would apply to the protection of workers from exposures to nanomaterials. These include

- * substance-specific standards;*
- * general respiratory-protection standards;*
- * a hazard-communication standard; and*
- * the General Duty Clause.\textsuperscript{112}

OSHA has not yet issued a formal statement of guidance for nanotechnology as have other agencies; however, they outline applicable standards on their Web site.\textsuperscript{113} Furthermore, the National Institute for Occupational Safety and Health, the research body that informs OSHA decision making, has published several documents on nanotechnology risks and safe management practices.\textsuperscript{114} While OSHAct regulations are expected to apply to nanomaterials, a number of challenges exist as described below.

**OSHA and Nanomaterials in the Workplace**

**Nano Standards, Controls, and Communication**

Under the OSHAct several standards could be used for managing risks from nanomaterials in the workplace. First, OSHA has the authority to issue substance-specific standards, which would enable the agency to manage certain nanomaterials when a significant risk of harm can be demonstrated. However, given a lack of


\textsuperscript{110} Lin, "Size Matters."


\textsuperscript{112} Balbus et al., “Protecting Workers and the Environment.”


\textsuperscript{114} Pelley and Saner, “International Approaches to the Regulatory Governance of Nanotechnology”; Satterstrom et al., “Considerations for Implementation of Manufactured Nanomaterial Policy and Governance.”
toxicology data and the slow pace of research, it is unlikely that any standards specific to nanomaterials will be put in place in the next several years.\textsuperscript{115} One recent report states that the high level of uncertainty surrounding the health and environmental effects of nanomaterial exposure makes it “virtually impossible to meet the statutory thresholds for regulation” under the OSHAct.\textsuperscript{116} Furthermore, any standards that are set must be “supported by substantial evidence,” and uncertainty over potential risk is not sufficient to authorize a precautionary approach.

Without substance-specific standards the general respiratory-protection standards for “particulates not otherwise regulated” (a.k.a. nuisance dust) would apply, with a standard of 5 mg/m\textsuperscript{2} for inhalable particles. As discussed in earlier sections, however, mass-based bulk-material standards for dose are probably not appropriate for nanomaterials owing to their large surface-to-volume ratio and high potential for toxicity per unit mass.\textsuperscript{117} Such a general standard may therefore be inadequate for managing inhalation risks.\textsuperscript{118} Furthermore, any inhalable nanoparticle standard would be difficult to meet given current control and monitoring technologies.\textsuperscript{119} A lack of validated methods to measure and characterize nanoscale particles in air means that it will be difficult to ensure that personal protective equipment is effective at limiting worker exposure to nanoparticles.

A third regulation that could apply to nanomaterials is the General Duty Clause, which requires an employer to ensure that the workplace is free from recognized hazards that are likely to cause death or serious harm and that the company comply with OSHA standards.\textsuperscript{120} It is intended to be a broad requirement to protect workers from hazards known to be toxic and for which standards have not been created. However, the clause applies only to “recognized” hazards, which, given a scarcity of toxicological data, would be difficult to enforce for nanomaterials.\textsuperscript{121}

In terms of communicating risk the OSHAct requires that producers (or importers) of chemicals develop material safety data sheets (MSDSs) to communicate hazards and best handling practices for workers. As with the General Duty Clause, employers are only required to identify and warn workers of “known” hazards.\textsuperscript{122} A lack of available

\textsuperscript{115} Pelley and Saner, “International Approaches to the Regulatory Governance of Nanotechnology”; Satterstrom et al., “Considerations for Implementation of Manufactured Nanomaterial Policy and Governance.”

\textsuperscript{116} Balbus et al., “Protecting Workers and the Environment.”

\textsuperscript{117} Lin, “Size Matters,” p. 371.

\textsuperscript{118} Oberdörster et al., “Toxicology of Nanoparticles.”

\textsuperscript{119} Balbus et al., “Protecting Workers and the Environment.”

\textsuperscript{120} Occupational Safety and Health Act, U.S. Title 29 (2009), §§ 651-678, OSHA § 5(a)(1), http://www.law.cornell.edu/uscode/html/uscode29/usc_sec_29_0000654----000-.html.

\textsuperscript{121} Balbus et al., “Protecting Workers and the Environment.”

\textsuperscript{122} Lin, “Size Matters.”
data on properties specific to nanomaterials has led in some instances to the reporting of the bulk properties of a substance in place of nanomaterial-specific properties. One recent example involves the issuing of MSDSs by carbon-nanotube manufacturers that report hazards for graphite (both are carbon substances) without noting the dissimilarity in structure between the two. To remedy this situation a recent report by J. Clarence Davies suggests that MSDSs intended for nanotechnology workplaces should be required to provide information specific to nanomaterials rather than for the bulk forms of the substance.

**Resource Constraints**

As with other agencies, OSHA has been criticized as “understaffed, underfunded, and lacking personnel properly trained to handle pertinent emerging technologies.” With just 2,150 employees OSHA’s resources are stretched. In addition, OSHA’s budget has not changed significantly since 1980, and as of 2008 was approximately $238 million, a level that is considered by many to be insufficient to enable OSHA to effectively carry out its mission. These constraints have resulted in a slow pace in occupational standard setting and a necessary reliance on voluntary precautionary measures by industries.

Despite OSHA’s poor attentiveness in regard to nanomaterials, there are currently several efforts by governmental, nongovernmental, and research organizations to enable the safe handling of nanomaterials in the workplace. For example, the International Council on Nanotechnology develops and communicates information regarding the health and environmental risks of nanotechnology and maintains Web resources that provide guidance for best practices in the workplace. These resources allow companies to be proactive in managing potential risks given the slow development of nanomaterial standards under the OSHAct.

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123 Balbus et al., “Protecting Workers and the Environment.”
124 Davies, “Nanotechnology Oversight.”
126 Breggin et al., “Securing the Promise of Nanotechnologies.”
127 Davies, “Nanotechnology Oversight”; Mandel, “Regulating Emerging Technologies.”
128 Balbus et al., “Protecting Workers and the Environment.”
Life Cycle and OSHA

The OSHAct applies to all stages of a life cycle where a nanomaterial is created or processed in an industrial workplace. However, as described above, the act requires that OSHA demonstrate that there is a significant risk of health impairment from workplace exposure before standards can be set. As with most regulations reviewed here, a dearth of available hazard information makes standard setting for emerging nanomaterials a significant challenge.

In terms of risk assessment the OSHAct focuses solely on health risks and does not extend to environmental risks from occupational releases. Reassessment of risks and adjustment of exposure standards can occur when sufficient evidence becomes available to support a more or less stringent standard. In addition, communication of risk information is enabled through the MSDS requirements under the OSHAct. These efforts are also limited, however, by a shortage of nano-specific information and a reliance on hazard reporting for bulk forms of materials, which may be inaccurate.

Owing to the large potential for worker exposures, occupational risks have received much attention by researchers and nongovernmental organizations, and several resources for promoting best practices in the workplace have become available. Precautionary measures are likely to be brought into many workplaces through voluntary efforts.

Environmental Releases under the Clean Air and Clean Water Acts

CAA and the CWA were enacted in 1970 and 1972, respectively, and were designed to regulate releases of pollutants to the environment. The two acts are ‘end-of-pipe’ statutes, meaning that rather than managing the production or use of potentially harmful materials, they aim to prevent and control discharges of such materials to the air and water during or after production.130 These two statutes charge the EPA with the responsibility for setting standards for pollutant levels in effluent emissions or in the ambient environment and for regulating releases into the air or water based on facility-control permits. CAA standards deal mostly with ambient concentration and emissions, whereby facilities are allowed to emit certain levels of pollutants into the air. CWA standards, however, are mostly technology based and relate to the

130 Powell et al., "Bottom-Up Risk Regulation?"
amount of emissions that can be reasonably controlled given currently available technology.

Several analyses suggest that CAA and CWA have adequate authority for regulating nanomaterials. CAA already has programs in place for dealing with ultrafine particles (unintentionally released nano-sized particles typically formed during combustion). Therefore, some regulatory mechanisms are already set to handle nanoparticles released into the air. CWA, however, does not specifically address nanoscale particles in effluents.131

Nanomaterials Released into the Air and Water

While several recent analyses claim that the EPA has the authority to regulate nanomaterials in air and water emissions, various substantial data and technology gaps exist that will probably allow nanomaterials to go unregulated by CAA and CWA.

As is the case with TSCA, CAA and CWA face catch-22 situations that require specific data to be available to the EPA before it can consider a nanomaterial a pollutant and build a case for regulation. Central to this data challenge is the current limitation in technology for sampling and analyzing nanomaterials in air or water effluents. In order for the EPA to regulate a pollutant, the agency must first be able to distinguish between different types of nanomaterials and to identify those that pose a risk.132 However, existing monitoring technologies may not be appropriate for this task, requiring further research to demonstrate that these technologies work for nanoscale materials. Ultimately, if nanomaterials cannot be detected in effluents, CAA and CWA are inoperable.133

In addition, even if emissions can be measured and monitored and if standards can be set through rulemaking, current emissions-control technologies may not be effective for reducing nanomaterial releases into the environment.134 CWA in particular requires that emissions-control standards are based on currently available technologies and are economically feasible. However, it may take a long time before new appropriate technologies are developed for controlling nanomaterial releases into water. Similarly, CAA requires that emissions levels are based on the performance of available control technologies, yet these technologies have not been demonstrated to be effective for managing nanomaterial releases into the air.

131 Ibid.
133 Davies, "Managing the Effects of Nanotechnology.
134 Powell et al., "Bottom-Up Risk Regulation?"; American Bar Association, "ABA SEER CAA Nanotechnology Briefing Paper."
In short, the regulation of nanomaterials under CAA and CWA is possible given the authorities granted to the EPA. However, without advances in monitoring and control technologies, these regulations will be ineffective for managing nanomaterials in air and water effluents.

**Life Cycle and CWA and CAA**

Similar to the OSHAct, CAA and CWA apply to every stage of the life cycle where nanomaterials are created or processed in an industrial setting. As with other statutes, CAA and CWA require that hazards be clearly demonstrated before a material can be regulated and that measurement and control technologies are available in order for regulation to be effective. Clearly, these statutes are not likely to play a role in regulating nanomaterial releases to air and water until more research is conducted and monitoring and control technologies mature.

Despite the challenges to the applicability of CAA and CWA to nanomaterials in air and water effluents, environmental releases are considered to pose minimal exposure risks to humans and the environment compared with current occupational exposures and the use and disposal of products containing nanomaterials.\(^{135}\) However, as nanomaterial production increases, releases into the environment may become a significant threat.

\(^{135}\) Davies, “Managing the Effects of Nanotechnology”; Lin, “Size Matters.”
The Lifecycle in Review

This analysis of federal regulations over the life cycle of emerging nanomaterials reveals that many statutes come into play at different life stages. In almost all cases the statutes focus on specific materials, applications, or life stages and do not overlap in authority. Most regulations come into play for a short period in the life of a material, and another regulation will typically take over once that material has moved to the next stage in its life. These regulations combine to cover all stages of the life cycle, as illustrated in Figure 7.

Figure 7. Collection of regulations across the life cycle of a nanomaterial

As found throughout this investigation, however, there are significant and sizable deficiencies in both the regulatory authority provided by several statutes and the resources available to agencies charged with enforcing these statutes. These deficiencies make it difficult for regulatory agencies to manage risks in general; the unique properties of nanomaterials combined with a high level of uncertainty over health and environmental hazards make it nearly impossible for some agencies to manage risks at all. The result is that in many cases, nanomaterials will go largely unregulated.
Conversely, if the nanomaterial is a chemical substance, it may undergo a risk assessment (under TSCA), but only if it is a “new” substance (or is a significant new use of an existing substance) and is not subject to the low-volume exemption. In addition, the risk assessment will be limited to available information: hazard testing is not required under TSCA. The EPA is then put in the position of demonstrating that a substance is hazardous, an undertaking that is seriously challenged by a lack of hazard information available for nanomaterials. On the other end of the spectrum dietary supplements and cosmetics receive no risk review at this stage, and control is limited entirely to voluntary risk-management measures by manufacturers.

Once these nanomaterials reach the market at step 2, they may continue to be regulated under FIFRA and FFDCA using various tools for collecting information on adverse effects and for removing materials from the market. However, at this stage many nanomaterials (other than pesticides, drugs, additives, supplements, or cosmetics) are likely to be a component of consumer products and are not subject to FIFRA or FFDCA requirements. These consumer products receive the lowest level of regulatory oversight; that is, they are largely unregulated until adverse effects are reported. This missed opportunity for assessment opens the door for unanticipated problems, particularly where the interaction of multiple substances may pose unique risks.

At step 3, when products are reused, recycled, or disposed of, RCRA comes into play, but only if a nanomaterial displays hazardous properties or is a listed hazardous waste. No nanomaterials are currently identified as hazardous under RCRA, and so none will be regulated at this end-of-life stage unless they are corrosive, reactive, toxic, or ignitable.

At step 4 environmental and occupational exposures are considered. However, current environmental (air and water) regulations do not apply specifically to nanomaterials and are not expected to play a role until specific nanomaterials are considered hazardous. Similarly, in occupational settings current regulations are seriously challenged by a lack of hazard information, and workplace safety measures are likely to be undertaken only voluntarily with the help of various best-practice guides for nanomaterials.

This analysis demonstrates that some materials or products such as cosmetics, dietary supplements, “existing” chemical substances, and consumer products, receive a very low level of regulatory oversight along their life cycles and may pose a significant risk to human and environmental health. There are currently hundreds of
such products on the market that contain nanomaterials, and risk management is limited to voluntary measures taken by manufacturers.

In addition to the limitations for certain materials or products, it is clear that some life-cycle stages receive very little regulatory coverage owing to gaps and a lack of hazard information. The end-of-life stage (recycling and disposal) will receive relatively little oversight until specific nanomaterials are categorized as hazardous. This gap means that health and environmental risks from most nano-enhanced products on the market today will not be managed once they are discarded. Furthermore, environmental releases and occupational exposures will receive relatively little oversight until hazards from particular nanomaterials are clearly demonstrated.

In short, significant regulatory gaps exist for nanomaterials at each step along their life cycles, which will effectively allow some potentially hazardous nanomaterials to go without risk-assessment and risk-management measures. There is also little overlap between regulations at different life-cycle stages, resulting in a patchwork of oversight with relatively little coordination. Finally, the sharing of information for many of these materials is limited by CBI claims by manufacturers, thereby restricting the ability of third parties or downstream users of nanomaterials to conduct risk assessments or to redesign products or materials to reduce hazards. Overall, significant gaps exist in the current collection of regulations through which many nanomaterials are likely to fall.
Conclusion

This life-cycle approach to understanding federal regulations has identified significant regulatory gaps for nanotechnology products at all stages of a product’s life. For all statutes reviewed, several reports have affirmed that each statute provides sufficient regulatory authority for managing risks from emerging nanomaterials. However, this analysis highlights the many ways in which the unique properties of nanomaterials, a high level of uncertainty surrounding potential hazards, and resource constraints can limit the ability of those statutes to assess and manage risks effectively. Many types of nanomaterials are therefore likely to fall through the wide gaps within regulations.

Furthermore, this analysis has identified a lack of consistent oversight along the life cycle of nanomaterials, which may result in potentially hazardous materials becoming less regulated or entirely unregulated as they move from one life-cycle stage to another. The largest gap, however, will potentially occur at the use stage, where actual hazards are likely to be manifested in products owing to combinations of materials and the complexity of nanotechnologies employed. These product-specific hazards would be difficult to assess using the current material-by-material approach to risk management and will become more prominent as nanotechnologies move from simple passive materials to complex active structures.

Several reports and analyses have brought forward recommendations for improving regulatory oversight for nanomaterials including increasing funding for risk research, limiting the use of CBI claims, and expanding authority for requiring testing to demonstrate safety. Many of these recommendations have been included in a recent Senate bill\textsuperscript{136} and a House discussion draft\textsuperscript{137} proposing TSCA reform, so improvements in the management of chemical substances will likely be realized in the near future. However, this analysis highlights the need for further updates to regulations, particularly for cosmetics, dietary supplements, and consumer products. Furthermore, investments in additional resources are needed to enable regulatory


agencies to manage the rapidly expanding field of nanotechnologies. Finally, improvements in the harmonization of regulations are necessary to prevent nanomaterials from falling through regulatory gaps as they move through different stages in their life cycle.

Nanotechnologies promise to offer tremendous benefits for society, but these benefits cannot be fully realized unless the risks are effectively managed along a product’s life cycle. With advances in risk research and timely improvements in regulatory oversight for nanomaterials, current and future nanotechnology products can be brought to market safely.


——. U.S. Title 7 (2009), § 136(a), http://www.law.cornell.edu/uscode/7/uscode_sec_07_00000136---a000-.html.


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