United States Government Accountability Office

GAO

Report to the Chairman, Committee on Environment and Public Works, U.S. Senate

May 2010

NANOTECHNOLOGY

Nanomaterials Are Widely Used in Commerce, but EPA Faces Challenges in Regulating Risk

GAO
Accountability * Integrity * Reliability

GAO-10-549

May 2010

NANOTECHNOLOGY

Nanomaterials Are Widely Used in Commerce, but EPA Faces Challenges in Regulating Risk

GAO
Accountability·Integrity·Reliability

Highlights

Highlights of GAO-10-549, a report to Chairman, Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

Nanotechnology involves the ability to control matter at the scale of a nanometer—one billionth of a meter. The world market for products that contain nanomaterials is expected to reach $2.6 trillion by 2015. In this context, GAO (1) identified examples of current and potential uses of nanomaterials, (2) determined what is known about the potential human health and environmental risks from nanomaterials, (3) assessed actions EPA has taken to better understand and regulate the risks posed by nanomaterials as well as its authorities to do so, and (4) identified approaches that other selected national authorities and actions U.S. states have taken to address the potential risks associated with nanomaterials. GAO analyzed selected laws and regulations, reviewed information on EPA's Nanoscale Materials Stewardship Program, and consulted with EPA officials and legal experts to obtain their perspectives on EPA's authorities to regulate nanomaterials.

What GAO Recommends

GAO recommends that EPA complete its plans to modify its regulatory framework for nanomaterials as needed. EPA concurred with our recommendations and provided technical comments, which we incorporated as appropriate.

View GAO-10-549 or key components.
For more information, contact Anu Mittal at (202) 512-3841 or mittala@gao.gov.

What GAO Found

Companies around the world are currently harnessing the properties of nanomaterials for use in products across a number of sectors and are expected to continue to find new uses for these materials. GAO identified a variety of products that currently incorporate nanomaterials already available in commerce across the following eight sectors: automotive; defense and aerospace; electronics and computers; energy and environment; food and agriculture; housing and construction; medical and pharmaceutical; and personal care, cosmetics and other consumer products. Within each of these sectors, GAO also identified a wide variety of other uses that are currently under development and are expected to be available in the future.

The extent to which nanomaterials present a risk to human health and the environment depends on a combination of the toxicity of specific nanomaterials and the route and level of exposure to these materials. Although the body of research related to nanomaterials is growing, the current understanding of the risks posed by these materials is limited. This is because the manner in which some studies have been conducted does not allow for valid comparisons with newer studies or because there has been a greater focus on certain nanomaterials and not others. Moreover, the ability to conduct necessary research on the toxicity and risks of nanomaterials may be further hampered by the lack of tools to conduct such studies and the lack of models to predict the characteristics of nanomaterials.

EPA has undertaken a multipronged approach to understanding and regulating the risks of nanomaterials, including conducting research and implementing a voluntary data collection program. Furthermore, under its existing statutory framework, EPA has regulated some nanomaterials but not others. Although EPA is planning to issue additional regulations later this year, these changes have not yet gone into effect and products may be entering the market without EPA review of all available information on their potential risk. Moreover, EPA faces challenges in effectively regulating nanomaterials that may be released in air, water, and waste because it lacks the technology to monitor and characterize these materials or the statutes include volume based regulatory thresholds that may be too high for effectively regulating the production and disposal of nanomaterials.

Like the United States, Australia, Canada, the United Kingdom, and the European Union have begun collecting data to understand the potential risks associated with nanomaterials and are reviewing their legislative authorities to determine the need for modifications. Australia and the United Kingdom have undertaken a voluntary data collection approach whereas Canada plans to require companies to submit certain types of information. Some U.S. states, like California, have also begun to address the potential risks from nanomaterials by, for example, collecting information from manufacturers on a limited number of nanomaterials in use in those states and making some of this information publicly available.

Contents

Abbreviations

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
EPA	Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
ISO	International Organization for Standardization
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NNI	National Nanotechnology Initiative
OECD	Organisation for Economic Co-operation and Development
RCRA	Resource Conservation and Recovery Act
REACH	Regulation, Evaluation and Authorization of Chemicals
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act of 1976
UV	ultraviolet
Wilson Center	Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies

United States Government Accountability Office
Washington, DC 20548

May 25, 2010

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate

Dear Madam Chairman:

The term "nanotechnology" encompasses a wide range of innovations based on the understanding and control of matter at the scale of nanometers—the equivalent of one-billionth of a meter. For illustration, a sheet of paper is about 100,000 nanometers thick, a human hair is about 80,000 nanometers wide, and three gold atoms lying side by side are about 1 nanometer long. Unusual properties can emerge in materials manufactured at the nanoscale—including catalytic, electrical, magnetic, mechanical, optical, and thermal properties—that differ in important ways from the properties of conventionally scaled materials. Some of these new properties can enhance products and their applications across a number of sectors, including electronics, medicine, and defense. The world market for nanotechnology-related products is growing and is expected to total between $1 trillion and $2.6 trillion by 2015.

Nanomaterials can occur naturally, be created incidentally, or be manufactured intentionally. For example, naturally occurring nanomaterials can be found in volcanic ash, forest fire smoke, and ocean spray. Incidental nanomaterials are by-products of industrial processes, such as mining and metal working, and combustion engines, such as those used in cars, trucks, and some trains. In contrast, manufactured nanomaterials (sometimes called engineered nanomaterials) have been specifically designed for a particular function or property, such as improved strength, decreased weight, or increased electrical conductivity. Our review will focus on manufactured nanomaterials, rather than nano-sized materials that occur naturally in the environment or are incidentally produced, and for the remainder of this report, we will call such materials "manufactured nanomaterials," or simply "nanomaterials." While the use of nanomaterials holds promise for the future, their small size and unique properties raise questions about potential risks to people or the environment that might result from exposure to them during their manufacture, use, and disposal. Risk is usually defined as the potential for harmful effects to human health or the environment resulting from exposure to a substance—in this case, nanomaterials. In general terms, risk depends on a combination of the exposure a person or the environment has to the substance as well as the inherent toxicity of the chemical. In other words, the same exposure to two different substances each with their own toxicity would result in different levels of potential risk.

The Environmental Protection Agency (EPA) administers several laws that regulate chemicals, pesticides, pollutants in air or water, and wastes that may be composed of or contain nanomaterials.[1] These laws include the following:

- the Toxic Substances Control Act of 1976 (TSCA), which authorizes EPA to require chemical companies to report certain information about chemicals used in commerce and authorizes EPA to require testing of and control chemicals that pose an unreasonable risk to human health or the environment, among other things;
- the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which authorizes EPA to regulate the sale and use of pesticides and prohibits marketing of pesticides that have not been registered with EPA;[2]
- the Clean Air Act, which requires EPA to set standards for common air pollutants and to regulate industrial sources of hazardous air pollutants;
- the Clean Water Act, which authorizes EPA to regulate discharges of pollutants into federally regulated waters;
- the Resource Conservation and Recovery Act (RCRA), which establishes a framework for regulation of hazardous and solid wastes and authorizes EPA to issue administrative orders to address imminent hazards; and

[1]EPA is one of four key agencies that administer laws that regulate manufactured nanomaterials depending on how they are used. The other regulatory agencies include the Consumer Product Safety Commission, the Department of Health and Human Services' Food and Drug Administration, and the Department of Labor's Occupational Safety and Health Administration. We did not review these other agencies' regulatory authorities as part of this work.

[2]In addition, EPA has authority under the Federal Food, Drug, and Cosmetic Act to establish tolerances or exemptions for the requirement of a tolerance for pesticide residues that remain in food. Food is considered adulterated if, amongst other conditions, it contains any residue of a pesticide chemical for which there is no tolerance or exemption or which exceeds any established tolerance.

- the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly known as Superfund, which authorizes EPA to compel parties responsible for contaminating sites to clean them up or to conduct cleanups itself and then seek reimbursement from responsible parties.

On the international level, other national authorities are also concerned about the potential risks of nanomaterials and whether their current regulatory framework authorities are sufficient to address these risks. For example, Australia, Canada, the United Kingdom, and the European Union have begun to review their regulatory approaches for nanomaterials. Furthermore, the Organisation for Economic Co-operation and Development—a forum in which the governments of 30 developed countries, including the United States, work together to address economic, social, and environmental issues—has established a "working party" on nanomaterials. In addition to the international focus on this topic, some U.S. states have begun to explore ways to address the potential risks of nanomaterials.

In this context, you asked us to (1) identify examples of current and potential uses of nanomaterials, (2) determine what is known about the potential human health and environmental risks from nanomaterials, (3) specifically assess actions EPA has taken to better understand and regulate the risks posed by nanomaterials as well as its authorities to do so, and (4) identify approaches that selected other national authorities have taken to address the risks associated with nanomaterials. In addition, you asked us to identify any U.S. states and localities that have begun to address the risks from nanomaterials.

To identify examples of current and potential uses of manufactured nanomaterials, we analyzed documents and reports that discuss the current and future uses of manufactured nanomaterials, such as market research reports produced by Lux Research, an independent research firm that conducts market analysis of nanotechnology, among other things. In addition, we interviewed cognizant agency officials from the six U.S. agencies that conduct the majority of nanotechnology-related research.[3]

[3]These agencies are the Department of Defense, the Department of Energy, EPA, the Department of Health and Human Services' National Institutes of Health, the Department of Commerce's National Institute of Standards and Technology, and the National Science Foundation. These six agencies accounted for over 95 percent of federal nanotechnology research reported in fiscal year 2009.

We also interviewed knowledgeable stakeholders, including officials from the National Nanotechnology Initiative, the Wilson Center, the National Academy of Sciences, Lux Research, and the NanoBusiness Alliance—a nanotechnology-related business association. We used an iterative process, often referred to as "snowball sampling," to identify knowledgeable stakeholders, and we selected for interviews those who would provide us with a broad range of perspectives on the current and potential uses of nanomaterials.

To determine what is known about the potential human health and environmental risks of manufactured nanomaterials, we reviewed documents that had been published by peer-reviewed journals, government agencies, and international nonprofit organizations. In conducting this review, we searched databases, asked knowledgeable stakeholders to identify relevant studies, and reviewed studies from article bibliographies to identify additional sources of information on the potential risks. Our review focused on 20 such studies, selected in part because they provided a synthesis of available research related to nanomaterials' risks and covered a variety of nanomaterials. For the purposes of this report, all the documents, studies, and synthesis studies we reviewed will be referred to as "studies." We also spoke with a variety of knowledgeable stakeholders representing industry, academia, nongovernmental organizations, and the regulatory community. These knowledgeable stakeholders were also selected using a snowball sampling method.

To assess actions EPA has taken to better understand and regulate manufactured nanomaterials and its authorities to do so, we analyzed selected laws and regulations, including TSCA, FIFRA, the Clean Air Act, the Clean Water Act, RCRA, and CERCLA. We also reviewed data and reports on EPA's Nanoscale Materials Stewardship Program, which EPA developed to encourage companies to voluntarily develop and submit information to the agency on the characteristics of nanomaterials. Furthermore, we consulted with EPA officials and legal experts to obtain their perspectives on EPA's available authorities to regulate manufactured nanomaterials.

To identify the approaches that other selected national authorities–Australia, Canada, the United Kingdom, and the European Union—have used to address the potential risks associated with manufactured nanomaterials, we analyzed these authorities' laws and regulations that would be applicable to regulating manufactured nanomaterials. We selected these authorities based on interviews with knowledgeable stakeholders who identified them as having taken actions related to better understanding, assessing, or regulating the potential risks of nanomaterials. To identify any states that may be taking action with regard to nanomaterials, we spoke with federal regulators; industry and environmental groups; and other knowledgeable stakeholders, including the Environmental Council of States.

A more detailed description of our scope and methodology is presented in appendix I. We performed our work between May 2009 and May 2010, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

In fiscal year 2009, federal support for nanotechnology research totaled about $1.7 billion. Cumulatively from fiscal year 2001 through fiscal year 2009, federal agencies have devoted over $10.5 billion to nanotechnology research. To guide federal development of nanotechnology, the National Nanotechnology Initiative (NNI) was established in 2001 to support long-term research and development aimed at accelerating the discovery, development, and deployment of nanoscale science, engineering, and technology. The NNI is a mechanism to coordinate the nanotechnology-related activities of the 25 currently participating federal agencies that fund nanoscale research or have a stake in the outcome of this research, such as those agencies that may regulate products containing nanomaterials. While the NNI is designed to facilitate intergovernmental cooperation and identify overarching goals and priorities for nanotechnology research, it is not a research program and has no funding or authority to dictate the nanotechnology research agenda for participating agencies or to ensure that adequate resources are available to achieve specific goals. Instead, participating agencies develop and fund their own nanotechnology research agendas. In fiscal year 2009, six NNI agencies accounted for over 95 percent of federal nanotechnology research reported. These are the Department of Defense, the Department of Energy, EPA, the Department of Health and Human Services' National Institutes of Health, the Department of Commerce's National Institute of Standards and Technology, and the National Science Foundation.

Nanomaterials can take a variety of forms and can generally be organized into four types:

- *Carbon-based materials.* These nanomaterials are composed mostly of carbon, and are most commonly spherical, elliptical, or tubular in shape. Spherical and elliptical carbon shapes are referred to as fullerenes, while tubular ones are called nanotubes.

- *Metal-based materials.* These nanomaterials include nanoscale gold, nanoscale silver, and metal oxides, such as titanium dioxide. They also include quantum dots, which are closely packed semiconductor crystals comprised of hundreds or thousands of atoms, on the scale of a few nanometers to a few hundred nanometers.

- *Dendrimers.* These nanomaterials are nanoscale polymers built from branched units. The surface of a dendrimer has numerous branch ends, which can be tailored to perform specific chemical functions. Also, some dendrimers contain interior cavities into which other molecules can be placed, such as for drug delivery.

- *Composites.* These materials combine nanoparticles with other nanoparticles or with larger, conventional-scale materials. For example, nanoparticles, such as nanoscale clay can be combined with other materials to form a composite material.

EPA uses a risk assessment process to estimate the extent of harm, if any, that can be expected from exposure to a given substance throughout its life cycle and to help regulators determine whether the risk meets the requirements for taking action under its statutory authorities, such as banning the substance's production or limiting its use. The basic risk assessment paradigm includes the following:

- an evaluation of scientific information on a substance's hazardous properties—or toxicity—which may potentially affect human health or the environment;

- the dose-response relationship—the relationship between the extent of exposure (dose) and the resulting changes in health or body function (response)—describes the toxic effect of a substance; and

- exposure—the extent to which humans or the environment are expected to be exposed to the chemical.

EPA is applying this risk assessment paradigm to assess the potential risks from nanomaterials. EPA officials also told us that risk assessment is not the only means of using scientific information to inform decision making. For example, they said that by using green chemistry and life cycle assessment approaches,[4] a material's properties may be modified or exposure controls incorporated to minimize and manage potential risk.

Nanotechnology is an example of a fast-paced technology that poses challenges to agencies' policy development and foresight efforts. We have conducted past work looking at the challenges of exercising foresight when addressing potentially significant but somewhat uncertain trends,[5] including technology-based trends that proceed at a high "clockspeed," that is, a (1) faster pace than trends an agency has dealt with previously or (2) quantitative rate of change that is either exponential or exhibits a pattern of doubling or tripling within 3 or 4 years, possibly on a repeated basis.[6] As our prior work has noted, when an agency responsible for ensuring safety faces a set of potentially significant high-clockspeed technology-based trends, it may successfully exercise foresight by carrying out activities such as

- considering what is known about the safety impact of the trend and deciding how to respond to it;
- reducing uncertainty as needed by developing additional evidence about the safety of the trend; and
- communicating with Congress and others about the trends, agency responses, and policy implications.

Similarly, our 21st Century Challenges report raised concern about whether federal agencies are poised to address fast-paced technology-based challenges.[7] Other foresight literature illustrates the potential future consequences of falling behind a damaging trend that could be countered

[4]Green chemistry, also known as sustainable chemistry, is the design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances. Green chemistry can be applied across the life cycle of a chemical product, including its design, manufacture, and use.

[5]Exercising foresight consists of basing policies on an understanding of forces shaping the future. In this context, a potentially significant trend is one that, although somewhat uncertain, may substantially affect progress toward basic goals across a time horizon more than 5 years forward.

[6]GAO, *Highway Safety: Foresight Issues Challenge DOT's Efforts to Assess and Respond to New Technology-Based Trends*, GAO-09-56 (Washington, D.C.: Oct. 3, 2008).

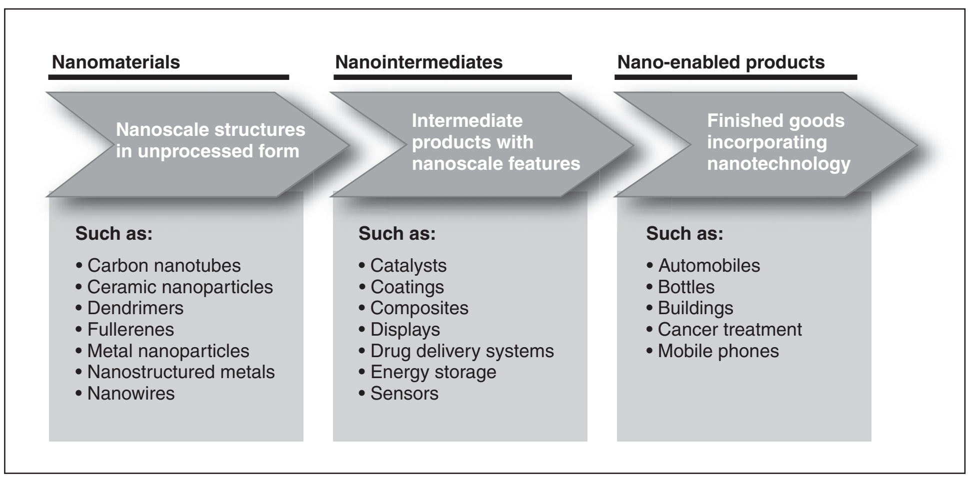
[7]GAO, *21st Century Challenges: Reexamining the Base of the Federal Government*, GAO-05-325SP (Washington, D.C.: February 2005).

by early action. These analyses suggest that unless agencies and Congress can stay abreast of technological changes, such as nanotechnology, they may find themselves "in a constant catch-up position and lose the capacity to shape outcomes."[8]

Nanomaterials Currently Enhance Products across a Number of Industry Sectors, and New Uses Continue to Be Developed

Industries around the world are harnessing the properties of nanomaterials for a variety of products across a number of sectors and are expected to continue to find new uses for these materials. Nanomaterials can enter the marketplace as materials themselves, as intermediates that either have nanoscale features or incorporate nanomaterials, and as final nano-enabled products (see fig. 1). For example, a manufacturer of clay nanoparticles can provide them to a plastic manufacturer, who can use them to enhance a composite material (an intermediate). The plastic manufacturer can then sell the composite material to an automobile manufacturer, who can use the material to mold parts for cars (nano-enabled products).

Figure 1: Examples of Nanomaterials as Raw Materials, Intermediates, and Finished Products



Source: Adapted by GAO from materials produced by Lux Research.

As the uses of nanomaterials continue to evolve, the overall market for them is growing, along with the degree to which they are permeating our

[8]Rejeski, David, and Carly Wobig. 2002. Long-term Goals for Governments. Foresight 4, no. 6:14–22.

everyday lives. In 2009, the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies (Wilson Center) identified a list of more than 1,000 nano-enabled products currently on the market, reflecting a 379 percent increase since this list was first compiled in 2006.[9] The list contains information on products from over 20 countries that can be purchased and used by consumers and provides a baseline for understanding the extent to which nanotechnology is being used. As the Wilson Center has reported, the trend of an increased number of products and applications featuring nanomaterials is also reflected in the number of nanotechnology patents issued by the U.S. Patent and Trademark Office, growing from 125 in 1985 to 4,995 in 2005, which represents a compound annual growth rate of 20 percent. The following is a list of selected industry sectors and some examples of current and potential uses of nanomaterials within each sector that illustrate the ubiquitous nature of these materials in commerce. Because assembling a complete catalog of uses would be difficult in an evolving, dynamic industry, the list is not comprehensive, the examples chosen are simply illustrative, and we have not verified the claims made by the manufacturers of the products used in these examples.

Automotive

From car bodies to exterior coatings to engines on the market today, cars contain numerous enhancements made possible by nanomaterials. In the current marketplace, some bumpers and other auto parts incorporate composite materials containing nanomaterials, such as nanoscale clays, metals, and carbon nanotubes to make these parts stronger, and more fire resistant.[10] Many nano-enabled products in the automotive sector involve the addition of nanoscale ceramic and metal particles to a wide variety of coatings. These nanomaterials provide advantages for coatings over conventional materials, such as the ability to block ultraviolet (UV) light or

[9]The Wilson Center is a nonpartisan research institution established by an act of Congress in 1968 and supported by public and private funds. The products in the Wilson Center's consumer products database are products identified as containing nanomaterials by their manufacturers or another source, which can be readily purchased by consumers, and for which the nanomaterials-based claims for the product appear reasonable. The NanoBusiness Alliance, an industry association representing the nanotechnology business community, estimates that thousands of additional products using nanomaterials are not publicized by their manufacturers. These products would therefore most likely not be counted in databases like the Wilson Center's database.

[10]Carbon nanotubes are basically tubes that consist of rolled-up sheets of graphite. These materials have novel properties, including extraordinary strength and unique electrical conductivity.

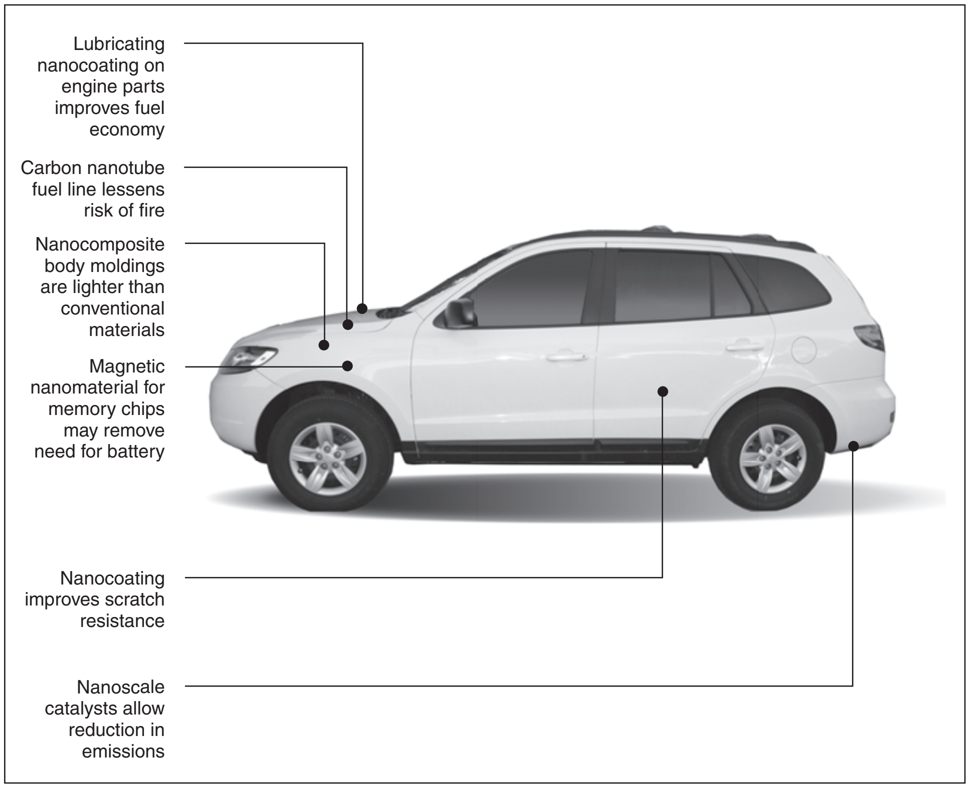
promote self-cleaning without altering the transparency of the coatings. For example, coatings containing nanoparticles are currently dispersed in paints and pigments to make surfaces stronger, smoother, more scratch and stain resistant, waterproof, or some combination of these and other properties. In addition, carbon nanotubes offer an especially high tensile strength—the ability to withstand a stretching force without breaking—of about 100 times greater than that of steel at one-sixth the weight, and their electrical conductivity can be precisely controlled, which helps prevent the build-up of static electricity. As a result, when a manufacturer of fuel lines adds carbon nanotubes to traditional engineering materials, it results in stronger, safer fuel lines.

In the future, nanomaterials could be used to improve the performance of cars, including reducing wear on engine parts and increasing battery power and fuel efficiency. For example, lubricants that contain certain nanomaterials could provide smaller, stronger, and more stable alternatives to oil-based lubricants. In addition, electrodes—electrical conductors that contain movable electric charges—manufactured at the nanoscale could enable higher-performance rechargeable batteries. For example, according to documents we reviewed, one company that is developing a new lithium-ion battery for electric vehicles uses nanoscale metal oxide materials to create crystallized nanoparticles that may enable this nano-enabled battery to deliver 20 percent more power. Moreover, fuel additives with nanoparticles of cerium oxide could increase diesel engine fuel efficiency.[11] One British company has developed such an application for a fuel-based additive that, due to the size-based properties of cerium nanoparticles, creates a greater surface area for catalyzing the combustion reactions between diesel and air.[12] According to this company, the result is a cleaner burn that converts more fuel to carbon dioxide, produces less noxious exhaust, and deposits less carbon on the engine cylinder walls than other fuel additives. Figure 2 shows examples of some current and potential nanotechnology innovations that may be used in automobiles.

[11] Cerium oxide additives are already in use on a large scale in bus fleets in a number of countries including the United Kingdom, but their sale is not currently authorized in the United States.

[12] A catalyst is a substance that increases the rate of a chemical reaction without being consumed by the reaction.

Figure 2: Examples of Current and Potential Nanotechnology Innovations that May Be Used in an Automobile



Source: Adapted by GAO from materials produced by Lux Research.

Note: The photo is illustrative and not intended to imply that this particular vehicle currently utilizes the nanotechnology innovations depicted or will in the future.

Defense and Aerospace

Nanomaterials are beginning to be used in aerospace applications by manufacturers seeking to take advantage of the electrical and mechanical strength advantages they offer and by the Department of Defense, which is seeking ways to enhance the tools available to its soldiers and the effectiveness of its weapons systems. Nanomaterial polymers are currently being used as sensors that detect very small traces of explosives, which indicate the presence of buried landmines, according to Department officials. In addition, according to documents we reviewed, stronger and lighter planes that are better protected against lightning and fire have been made possible by using carbon nanotubes and other nanostructured materials. For example, one company has created a nanolaminated material used for planes that is comprised of layers of metal alloys that are stronger, lighter, and more energy absorbent than steel. In addition, polymers with embedded silver nanoparticles are helping to keep surfaces, including the interiors of aircraft, free of microbes.[13] The polymers contain nanoscale silver particles that, when added to a product's surface, release ions that kill bacteria existing on the surface.[14] Companies are also introducing nanostructured alternatives to standard copper wiring. For example, one company has developed a process to create highly conductive sheets of fabric and lengths of yarn containing carbon nanotubes that can be used to create wiring and cables for airplanes and satellites that weigh much less than traditional copper wire.

In the future, nanomaterials may help enable the development of new applications and products across a wide spectrum in the defense arena, including surveillance devices, explosives and propellants, and uniforms. For example, according to Department of Defense officials and documents we reviewed, nearly "invisible" surveillance may be possible through the incorporation and integration of different nanotechnologies, including radio frequency identification chips; integrated circuits; minute biosensors; and "intelligent" fabrics, films, and surfaces. Miniaturized surveillance techniques under research include using live insects ("spy" bees) tagged with nanomaterials or tiny winged robots that emulate insects to fly into an enemy situation to record data. In addition, more powerful conventional explosives and faster moving missiles may be possible due to the greater amounts of energy provided by nanostructured aluminum. In combination with metal oxides, such as iron oxide, nanostructured aluminum allows many more chemical reactions to occur in a given surface area, increasing the explosive force. Also, nanomaterials such as carbon nanotubes embedded in fabric could allow for lighter uniforms and multifunctional combat suits for soldiers. The uniforms could potentially, for example, change color to match the environment, become rigid casts to protect injuries, or help block bullets and chemical/biological agents. The material could even incorporate sensors that monitor a soldier's condition, or function as drug dispensers activated automatically via radio waves by a remote doctor.

[13] A polymer is a material made of long, chain-like molecules.

[14] An ion is an atom or group of atoms that bears one or more positive or negative electrical charges.

Electronics and Computers

Computers and consumer electronics have also begun to benefit from the advantages nanomaterials offer, including improved display screens and improved electrical conductivity. Carbon nanotubes, quantum dots, [15] and nanoscale layers of polymers can improve the properties of displays. For example, one company has developed an ultra-thin, layered system of polymers that, unlike conventional liquid crystal displays, requires no backlights or filters. The images are brighter and clearer, and the technology could make possible fully bendable plastic displays, according to the company. In addition, since nanomaterials often enhance electrical conductivity, metallic nanoparticles and carbon nanotubes are being used in a growing number of conductive coatings, such as those used for touchscreens and solar cells. According to documents we reviewed, one company sells a transparent conductive coating and a coated film, both incorporating nanowires, which conduct electricity better than traditional materials. The coating and film could eventually replace rare and expensive indium tin oxide, currently the most widely used transparent conductor in the display industry. Moreover, nanomaterials such as lead-free, conductive adhesives could eliminate several steps in manufacturing electronics and could lead eventually to elimination of some or all of the 3,900 tons of toxic, leaded solder used every year by the U.S. electronics industry, according to an EPA document.

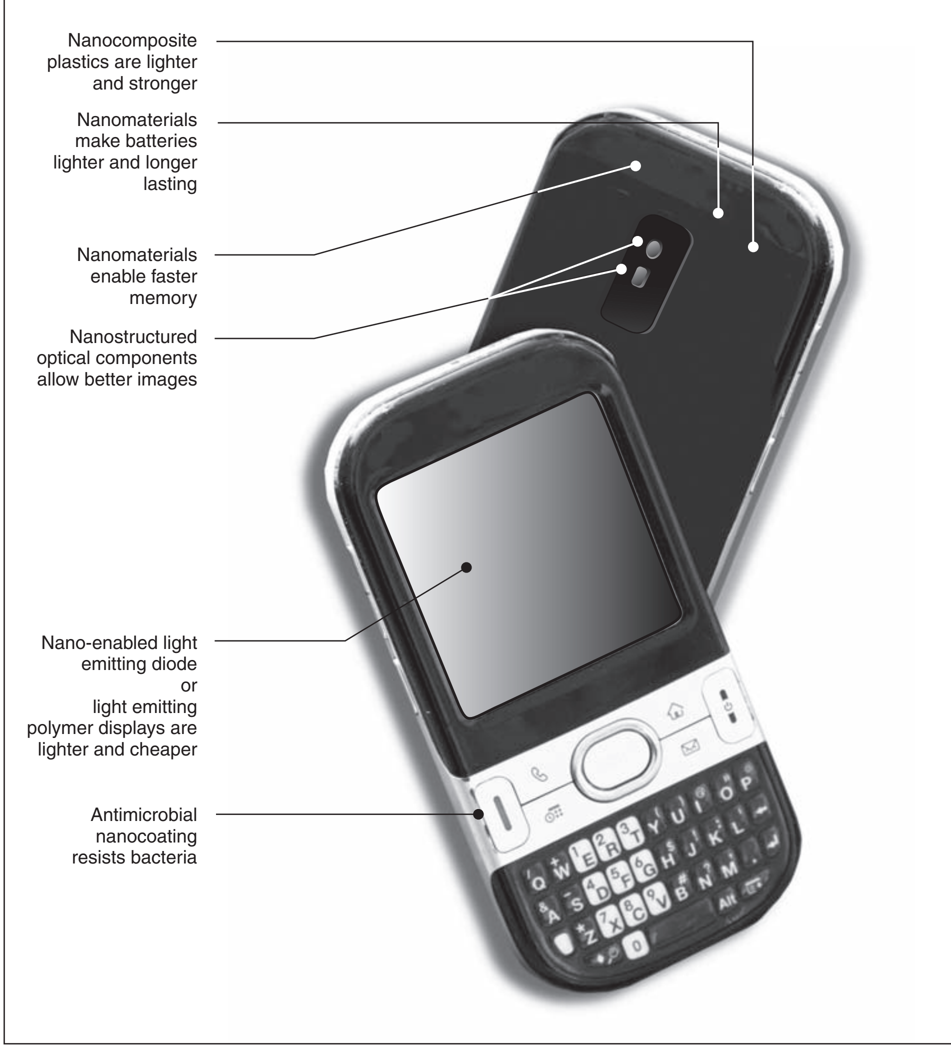
In the future, computers and electronic devices could employ nanomaterials to create more efficient data storage and longer-lasting, rechargeable batteries. Memory storage devices could become more powerful through a variety of nanotechnology applications. New methods of storing information electronically are emerging from a variety of applications aimed at increasing the amount of information that can be stored on a given physical space. For example, one company has demonstrated the potential to create high-density memory devices with an estimated storage capacity of 1 terabyte per square inch—more than 200 times higher than the storage density of a DVD—by storing information mechanically using nanoscale probes to punch nanoscale indentations into a thin plastic film.[16] In addition, companies, research institutions, and government labs are working to develop nano-based technology that could perfect “microbatteries,” which are smaller, cheaper, and more powerful than batteries currently in use. The greater surface area of the nanowires

[15] A quantum dot is a nano-sized crystal that efficiently absorbs light and emits either photons or electrons.

[16] A terabyte is about 1 trillion bytes or about 1,000 gigabytes.

used in these batteries lowers the internal resistance of the battery and therefore allows greater current flow. Figure 3 shows some examples of current and potential nanotechnology innovations that may be used in a mobile phone.

Figure 3: Examples of Current and Potential Nanotechnology Innovations That May Be Used in a Mobile Phone



Source: Adapted by GAO from materials produced by Lux Research.

Note: The photo is illustrative and not intended to imply that this particular phone currently utilizes the nanotechnology innovations depicted or will in the future.

Energy and Environment

Companies are beginning to use nanomaterials to clean up waste, substitute nonrenewable resources with renewable ones, reduce pollution, and increase the efficiency of solar power. Because nanoscale particles can be more chemically reactive than conventionally scaled particles of the same substance due to their large surface area to volume ratio, these materials can be useful for environmental remediation. Specifically, the increased surface area of various types of ceramic or metal nanomaterials can result in the rapid reduction of contaminant concentrations in soil, water, and air, as pollutants or toxins in these media react with the nanomaterials. Similarly, nanoscale iron is being deployed in a growing number of environmental remediation projects with results that are proving successful so far, according to EPA officials. For example, at one remediation project, researchers injected carbon infused with nanoparticles of iron into contaminated soil and found that the nanoparticles made the resulting material more effective at absorbing contaminants than similar materials without the nanoparticles. In addition, nanomaterials are being used to create packaging materials made from waste. For example, one company produces nanoparticle paper coatings made from renewable natural starches that can replace conventional material in paper coatings, which is typically made from nonrenewable petroleum. Nanomaterials are also being used to improve automotive catalytic converters, which feature nano-enabled catalysts that reduce air pollution more efficiently. One company is manufacturing a catalyst consisting of nanostructures with surface areas much higher than traditional materials and that allows catalytic converters to remain effective under prolonged exposure to high temperatures, resulting in more stable, durable, and cost-effective products. In the energy arena, nano-enabled thin-film and photovoltaic technologies are making solar power more efficient. For example, one company has reported gains in the ability of its thin-film solar cell materials to absorb light, because the structure of the nanomaterial is much smaller than the wavelength of light, which allows it to act like an antenna that concentrates, absorbs, and transfers energy with high efficiency.

In the future, nanomaterials could help deliver alternative forms of energy, cleaner water, and more efficient energy transmission. Using nanoscale catalysts, hydrogen—an alternative form of energy—could be produced from water more efficiently. For example, a company has developed a photoelectrode that uses nanoscale material and converts sunlight into hydrogen six times more efficiently than its conventionally scaled equivalent.[17] In addition, nanotechnology-enabled water desalination and filtration systems may offer affordable, scalable, and portable water filtration in the future. Filters, comprised of nanoscale pores which incorporate a wide variety of nanomaterials—including nanoparticles made of aluminum oxide, iron, and gold, and carbon nanotubes—have the potential to allow water molecules to pass through, but screen out larger molecules, such as salt ions and other impurities such as bacteria, viruses, heavy metals, and organic material. In addition, nanoparticles could be used to improve the efficiency of energy transmission by increasing the capacity and durability of insulation for underground electrical cables, allowing cables of smaller diameter to carry the same power as larger cables and to last longer. For example, one company's research shows that cable insulation treated with nanocomposites containing nanosilica have about 100 times longer voltage endurance compared to untreated material. In addition, researchers have demonstrated that carbon nanotube fiber bundles could carry 100 times more electrical current than the leading transmission wires, without as much energy loss. Moreover, one study predicts that if energy transmission losses could be reduced from the current 7 percent using copper wires to 6 percent by using carbon nanotube fibers, the annual energy savings in the United States would be equal to 24 million barrels of oil.

Food and Agriculture

Nanomaterials are currently appearing in food packaging and food supplements.[18] Specifically, nanomaterials are being used in food packaging, where applications such as antimicrobial nanofilms—thin layers of substances meant to hamper the growth of bacteria and fungi—are intended to bolster food safety. Also, composite materials made of nanoclays embedded in nylon can offer strong oxygen and carbon dioxide barriers and have been used in plastic bottles and films for packaging food and beverages. For example, one company produces a nylon and clay nanocomposite used as a flexible, puncture-resistant oxygen barrier for beer and carbonated beverage bottles; in packaging for processed meats and cheeses; and in coatings for paper packaging for juice or dairy products. Moreover, products such as cutting boards and food containers have been infused with nanosilver—which is known for its antimicrobial

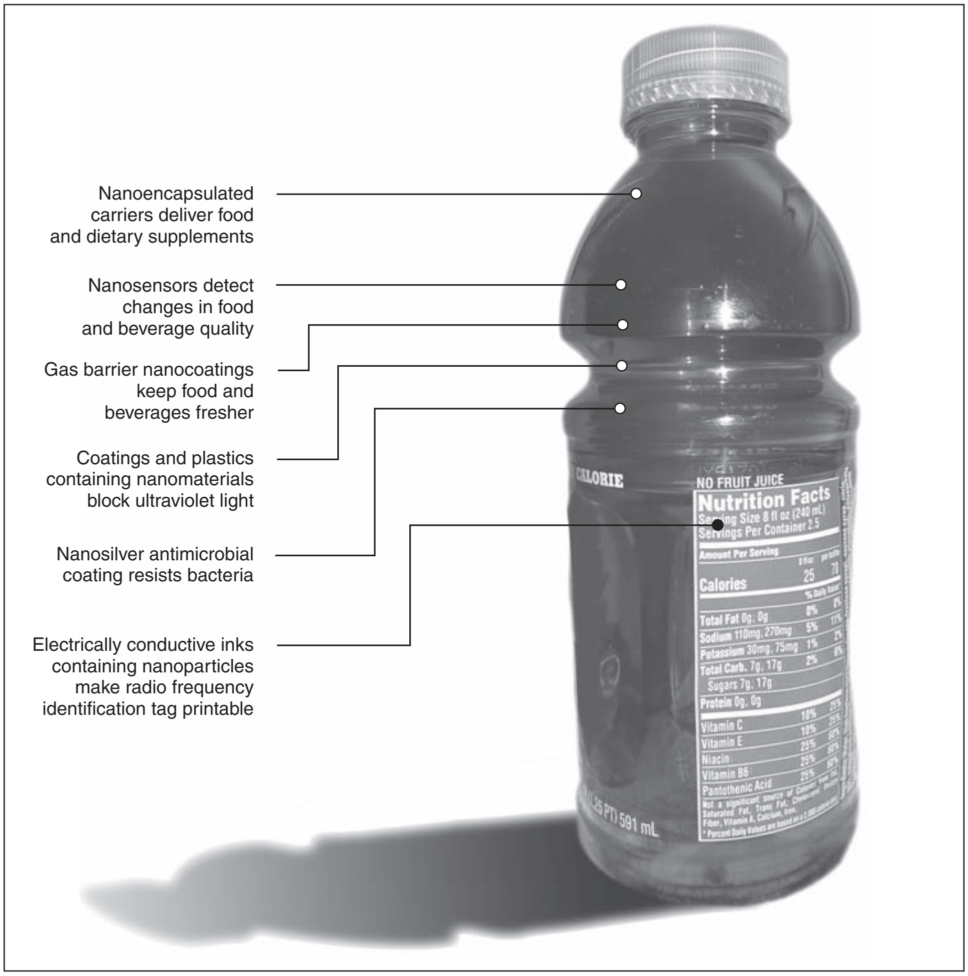
[17] Photoelectrolysis is the splitting of water into hydrogen and oxygen using light energy.

[18] The Food and Drug Administration is generally responsible for overseeing the safety of color additives and foods, including food additives and dietary supplements, as well as for safety of food packaging.

properties. In addition, encapsulation—the process of using one material to deliver another material inside the human body—has been in use for decades but is being improved with nanomaterials. Nanoencapsulated food products and supplements can target nutrients, release drugs on a controlled schedule, and mask tastes. For example, some vitamins can be difficult to deliver in beverages because they degrade and may not be easily absorbed by the body. One company has developed nanoscale structures to deliver the vitamin to the digestive system, making it easier for absorption to occur. Another manufacturer has used nanocapsules to incorporate certain fatty acids that have purported health benefits into bread. The company claims the acids in the nanocapsules bypass the taste buds, emerging only after the nanocapsules reach the stomach, thus avoiding any unpleasant taste.

In the future, manufactured nanomaterials could be used to enhance agriculture; monitor food quality and freshness; improve the ability to track food products from point of origin to retail sale; and modify the taste, texture, and fat content of food. Nanomaterials are being developed to more efficiently and safely administer pesticides, herbicides, and fertilizers by controlling more precisely when and where they are released. In addition, researchers are developing a nanoscale powder that can retain water better than other materials and allows fertilizers to gradually release nutrients for crops or grass, according to the Wilson Center. In addition, researchers have developed nanobiosensors using nanoscale particles for detecting bacteria, such as salmonella, in water and liquid food. Their work could lead to nanosensors that could be used in fields to monitor for bacterial contamination of crops, such as spinach, lettuce, and tomatoes, potentially reducing the spread of food-borne illnesses. In addition, electrically conductive inks containing nanomaterials could be used to print radio-frequency identification tags, which could be integrated into packaging for food products, potentially resulting in improved food security and better inventory tracking and management. Figure 4 shows some examples of current and potential nanotechnology innovations that may be used in a drink bottle.

Figure 4: Examples of Current and Potential Nanotechnology Innovations That May Be Used in a Drink Bottle



Source: Adapted by GAO from materials produced by Lux Research.

Note: The photo is illustrative and not intended to imply that this particular juice bottle currently utilizes the nanotechnology innovations depicted or will in the future.

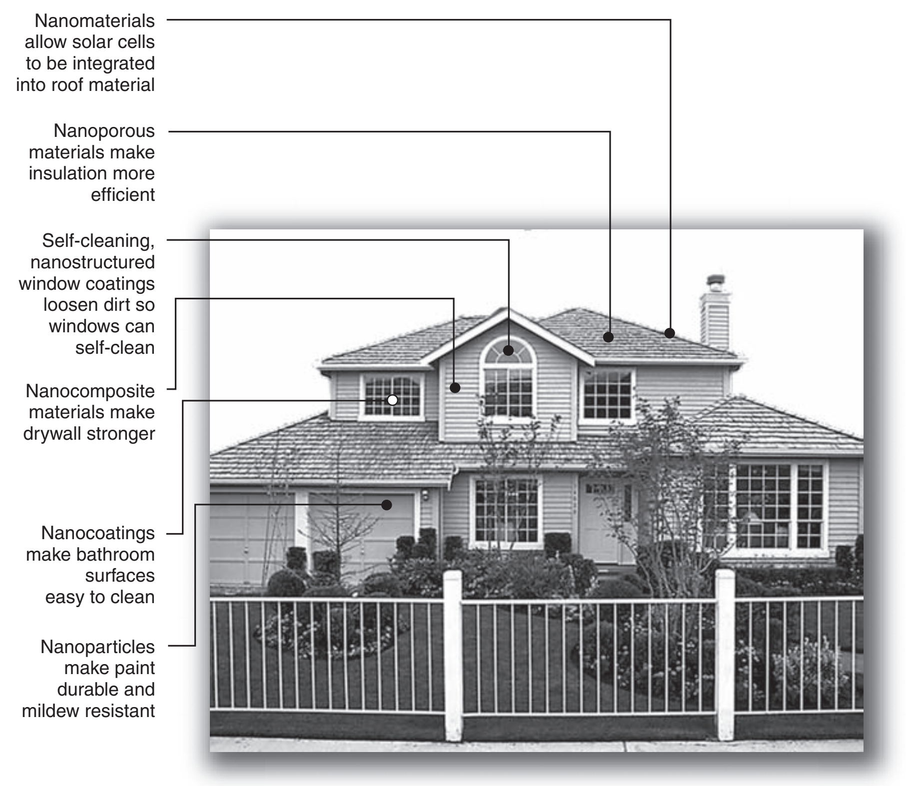
Housing and Construction

Materials and coatings are currently making buildings and homes cleaner and stronger, and in the future will allow them to operate with higher energy efficiency, according to documents we reviewed. Protective coatings and materials that incorporate nanoparticles of titanium dioxide are being used to manage heat and light by blocking UV light from the sun's rays and are taking on self-cleaning properties through a photocatalytic effect.[19] For example, titanium dioxide is being added to paints, cements, windows, tiles, and other products for its sterilizing and deodorizing properties. Additionally, as titanium dioxide is exposed to UV light, it becomes increasingly hydrophilic—attractive to water—and is therefore being used for antifogging coatings or self-cleaning windows. Nanomaterials are also proving beneficial to the construction industry by, for example, making steel tougher and concrete stronger, more durable, and more easily placed. For example, one company has created a structural material with a grain size reduced to the 100 nanometer scale, which it claims has a strength-to-density ratio four times that of the toughest titanium alloys and also resists corrosion. Inside the walls of buildings, insulation made from nanomaterials is providing high thermal performance at minimal weight and thickness. In addition, nanomaterials are being incorporated into some air monitoring technologies, air purification products, and energy-efficient air conditioning systems for residential, commercial, and industrial settings. For example, some air filters that are on the market use nanomaterials to clean air better than conventional materials.

In the future, nanoparticle coatings on windows and buildings could retain energy from the sun for later release. For example, researchers working on phase change materials—materials which absorb and release thermal energy—have found that when graphite nanofibers are blended into these materials the nanofibers improve the material's thermal performance. The result could be cheaper and more efficient uses of these materials for solar energy storage. In addition, nanomaterials may offer approaches that enable materials to "self-heal" by incorporating, for example, nanocontainers of a repair substance (e.g., an epoxy) throughout the material. When a crack or corrosion reaches a nanocontainer, it could be designed to open and release its repair material to fill the gap and seal the crack. Figure 5 shows some examples of current and potential nanotechnology innovations that may be used in a house.

[19]Photocatalysis is the acceleration of a photoreaction in the presence of a photocatalyst.

Figure 5: Examples of Current and Potential Nanotechnology Innovations That May Be Used in a House



Source: Adapted by GAO from materials produced by Lux Research.

Note: The photo is illustrative and not intended to imply that this particular house currently utilizes the nanotechnology innovations depicted or will in the future.

Medical and Pharmaceutical

Nanotechnology is important to the medical and pharmaceutical industry because the extremely small size of nanomaterials makes possible medical interventions that can be directed to individual cell types, allowing for better diagnosis, treatment, and prevention of cancer and other deadly diseases.[20] Current disease detection efforts include the use of nanoscale

[20]The Food and Drug Administration is generally responsible for overseeing the safety and effectiveness of drugs and devices for humans and animals, and of biological products for humans.

sensors to identify biomarkers, such as altered genes, that may provide an early indicator of cancer. Doctors are also using nanomaterials as markers to enhance images from deep inside human tissue, allowing them to track particles to the site of a tumor, resulting in earlier detection of tumors. Certain nanomaterials such as polymer nanoparticles are being used to treat cancer by delivering medication directly to tumors while sparing healthy tissue. In addition, silver nanocrystals are being used in antimicrobial wound dressings, thereby requiring fewer dressing changes and causing patients less pain.

In the future, nanomaterials could be used to help doctors better diagnose and treat disease. In diagnosis, nanomaterials hold promise for showing the presence, location, and contours of cardiovascular and neurological disease, and small tumors. For example, researchers could use metallic and magnetic nanoparticles to enhance imaging, the results of which can be used to guide surgical procedures and to monitor the effectiveness of nonsurgical therapies in reversing the disease or slowing its progression. In the future, sensors implanted or delivered with a drug could allow for continuous and detailed health monitoring so disease might be managed better, turning a drug into a multifunctional tool for diagnosis and treatment. For example, bio-sensors could be attached to targeted drugs and linked to a mechanism that reports the body’s condition. Furthermore, according to the National Institutes of Health, gold nanoshells are being developed to simultaneously image and destroy cancer cells using infrared light. Nanoshells can be designed to absorb light of different frequencies, generating heat. Once the cancer cells take up the nanoshells, scientists apply near-infrared light that is absorbed by the nanoshells, creating an intense heat inside the tumor that selectively kills tumor cells without disturbing neighboring healthy cells. Such a targeted delivery approach could reduce the amount of chemotherapy drug needed to kill cancer cells, potentially reducing the side effects of chemotherapy. Medical researchers are also exploring the use of nanomaterials to deliver molecules and growth factors to promote better healing for burns and wounds that heal without scars. For example, Department of Defense researchers have conducted tests in animals using nanofiber mesh scaffolds to treat bone, nerve, cartilage, and muscle injuries and have reported that preclinical data from the studies indicate improved healing. Other nanofibers are being developed for medical use as mesh barriers to stop the flow of blood and other fluids more quickly and effectively.

Personal Care, Cosmetics, and Other Consumer Products

Nanomaterials are currently being used in a variety of personal care items, cosmetics, and other consumer products.[21] These products include sunscreens that contain nanoscale titanium dioxides and zinc oxides, which act as physical filters that absorb UV light. Because these nanomaterials are smaller than the wavelength of light, they make sunscreens transparent instead of opaque, and they may also adhere better when applied and absorb harmful ultraviolet rays more effectively than conventional sunscreens, according to stakeholders and documents we reviewed. In addition, nanomaterials are being incorporated into cosmetics, such as an anti-aging cream, which allows the active ingredients to penetrate deep into the skin where they can be most effectively administered, according to the manufacturer. Nanomaterials are also being used in a wide range of other consumer products. For example, companies are using carbon nanotubes to reinforce a variety of sporting goods, such as bicycle frames, tennis rackets, baseball bats, and hockey sticks, because they offer greater strength and reduced weight, while retaining, or even increasing, stiffness. Companies are using other nanomaterials to improve the performance of products such as ski wax and tennis balls. For example, a nanomaterial coating decreases the gas permeability in tennis balls and therefore allows the balls to maintain pressure for longer periods of time, according to the company producing the coating. Nanomaterials are also being used in coatings to make fabrics and clothing stain and water resistant. For example, one company embeds nanomaterials on the surface of fabric fibers, creating a cushion of air around them. The fabric allows sweat to pass out, while also causing surface water to bead up and roll off. Another company has developed socks treated with nanosilver for its antimicrobial properties.

In the future, consumers may benefit from advanced applications that could emerge from nanomaterial research occurring in a variety of sectors. For example, developments in the health arena could lead to new, beneficial pharmaceutical therapies designed to treat aging and age-related disease. In addition, according to documents we reviewed, researchers are working to make textiles functional by combining manufactured nanomaterials with materials that react to light to create power-generating clothing and nanosilver could be used in textiles to treat

[21] The Food and Drug Administration is generally responsible for overseeing the safety of cosmetics. In addition, the U.S. Consumer Product Safety Commission is responsible for protecting the public from unreasonable risks of serous injury or death from more than 15,000 types of consumer products, including some that may be manufactured with nanomaterials.

skin conditions. Researchers are also developing nano-enabled textile surfaces that can remove scratches and scuff marks, as well as decolorize red wine spills.

Potential Risks to Human Health and the Environment from Nanomaterials Depend on Toxicity and Exposure, and Current Understanding of the Risks Is Limited

The properties of nanomaterials affect their toxicity and, in turn, their risks to human health and the environment. Furthermore, the risk of nanomaterials also depends on the extent and route of exposure to nanomaterials, but current understanding of nanomaterial toxicity and exposure is limited, according to the studies we reviewed.

The Toxicity of Individual Nanomaterials May Vary According to Their Properties and Affects Their Risks

The toxicity of each nanomaterial may vary according to a combination of the individual properties of these materials—including size, shape, surface area, and ability to react with other chemicals—and these properties affect the potential risks posed by nanomaterials, according to some of the studies we reviewed. The properties of a nanomaterial may differ from the properties of conventionally scaled material of the same composition. For example, the properties of conventionally scaled gold have been well characterized: gold is metallic yellow in color and does not readily react with other chemicals. As a nanoparticle, however, gold can vary in color from red to black and become highly reactive. The following are examples of how toxicity may be affected by the properties of nanomaterials as compared with their conventionally scaled counterparts:

- *Size.* Research assessing the role of particle size on toxicity has generally found that some nanoscale (<100 nanometers) particles are more toxic and can cause more inflammation than conventionally scaled particles of the same composition. Specifically, some research indicates that the toxicity of certain nanomaterials, such as some forms of carbon nanotubes and nanoscale titanium dioxide, may pose a risk to human health because these materials, as a result of their small size, may be able to penetrate cell walls, causing cell inflammation and potentially leading to certain diseases. For example, the small size of these nanomaterials may allow them to penetrate deeper into lung tissue, potentially causing more damage, according to some of the studies we reviewed. In addition, some nanomaterials may disperse differently into the environment than conventionally scaled materials of the same composition because of their size. However, according to EPA, the small particle size may also cause the nanomaterials to agglomerate, which may make it more difficult for them to penetrate deep lung tissue.

- *Shape.* Nanomaterials may be produced in a wide variety of shapes, including spheres, tubes, threads, and sheets, as well as more ornate forms, such as dumb-bells. The shape of nanomaterials may be connected to the type of health risks they may pose. For example, some carbon nanotubes resemble asbestos fibers. When inhaled by people, asbestos fibers are known to cause mesothelioma—which is a disease associated with asbestos exposure. The similarity of these carbon nanotubes to asbestos fibers has caused researchers to question if exposure to such nanomaterials may lead to a similar disease. Furthermore, a study has shown that exposing the abdominal cavity of mice to certain long carbon nanotubes may be linked with inflammation of the abdominal wall. The abdominal cavity in mice is often used as a surrogate for understanding how the mesothelial lining of the human chest cavity will react to substances.

- *Surface area and reactivity.* Nanomaterials may also be more reactive with other chemicals than similar conventionally scaled materials because nanomaterials have a higher surface area-to-mass ratio, providing more area by weight for chemical reactions to occur. Some studies have found that because of this increased reactivity, some nanoscale particles may be potentially explosive and/or photoactive—that is, sunlight triggers a chemical reaction in them. For example, some nanomaterials—such as nanoscale titanium dioxide and silicon dioxide—may explode if finely dispersed in the air and they come into contact with a sufficiently strong ignition source. However, in general, the extent to which such nanoscale dusts may be more explosive than larger size dusts of the same composition is not fully known, according to the National Institute for Occupational Safety and Health. Other research has shown that particle surface area is a better predictor of toxic response to inhaled particles than is particle mass. For example, research into nanoscale titanium dioxide in mice and rats has shown that particle surface area seems to be a more appropriate measure for comparing the effects of different-sized particles, provided they are of the same chemical structure.

Risk of Nanomaterials Is Also Affected by the Route and Extent of Exposure

In addition to toxicity, the risk that nanomaterials pose to humans and the environment is also affected by the route and extent of exposure to such materials. Nanomaterials can enter the human body through three primary routes: inhalation, ingestion, and dermal penetration.[22]

- Inhalation is the most common route of exposure to airborne nanoparticles, according to the National Institute of Occupational Health and Safety. For example, workers may inhale nanomaterials while producing them if the appropriate safety devices are not used, while consumers may inhale nanomaterials when using products containing nanomaterials, such as spray versions of sunscreens containing nanoscale titanium dioxide. According to officials at the National Institutes of Health, although the vast majority of inhaled particles enter the pulmonary tract, evidence from studies on laboratory animals suggest that some inhaled nanomaterials may travel via the nasal nerves to the brain and gain access to the blood, nervous system, and other organs, according to studies we reviewed.

- Ingestion of nanomaterials may occur from unintentional hand-to-mouth transfer of nanomaterials or from the intentional ingestion of nanomaterials.[23] Ingestion may also accompany inhalation exposure because particles that are cleared from the respiratory tract can be swallowed. A large fraction of nanoparticles, after ingestion, rapidly pass out of the body; however, according to some of the studies we reviewed, a small amount may be taken up by the body and then migrate into organs. The effect of these small amounts of ingested nanomaterials is currently unknown, but concerns have arisen from a growing body of evidence which indicates that certain types of nanoparticles may cross cellular barriers.

- Nanomaterials may also be absorbed through the skin. For example, one laboratory study has shown that certain nanomaterials have penetrated layers of pig skin within 24 hours of exposure. In addition, some cosmetics and sunscreens—among the first commercial products to incorporate nanomaterials—contain nanoscale titanium dioxide to increase the ultraviolet light-blocking power of the product. The nano titanium dioxide

[22]The routes of exposure listed are generally for incidental or consumer exposures to nanomaterials. For medical applications, the primary route of exposure is intravenous.

[23]Some consumer products containing edible nanomaterials are available. Consumers may now purchase food containing nanomaterials such as prepared milkshakes containing nanoscale vitamins used to fortify the shakes.

is believed to be less toxic than other chemicals that have been used to provide ultraviolet protection in sunscreens. However, according to some of the studies we reviewed, concerns have been raised that nanomaterials in sunscreens could penetrate damaged skin. In contrast, according to officials at the National Institutes of Health, there are several studies that have found little dermal penetration from nanomaterials when applied to undamaged skin. According to some stakeholders we spoke to, given the known hazards of sun exposure, sunscreens containing nanomaterials may be reasonable choices for the protection that they provide to consumers from sun exposure.

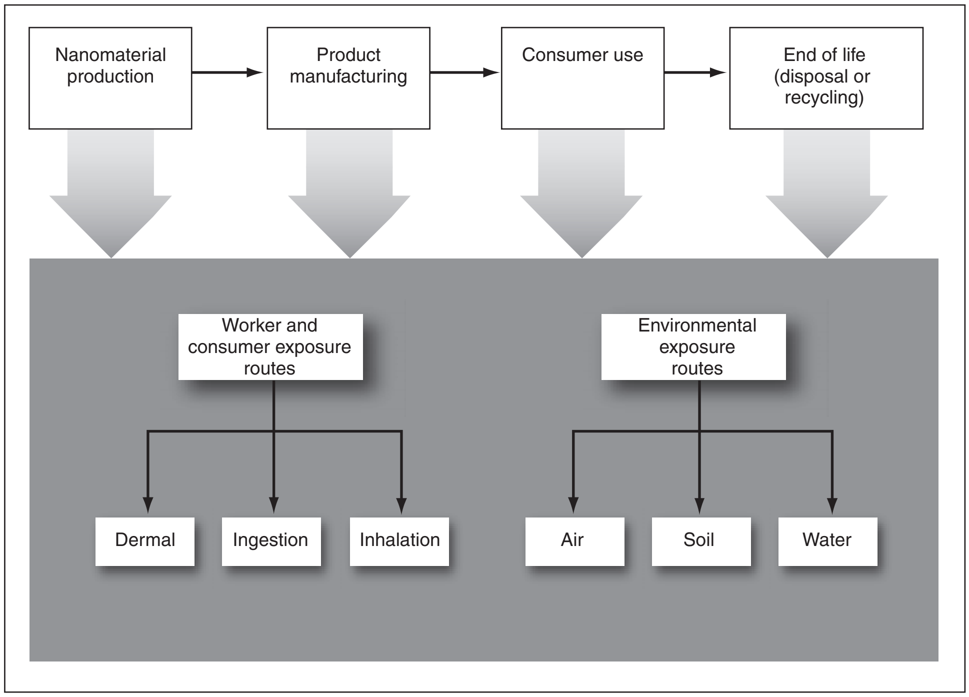
In addition to the route of exposure, the extent of exposure—that is the frequency and magnitude—to consumers and workers also affects the risks posed by nanomaterials. Workers may be accidentally exposed to nanomaterials during the production of nanomaterials or products containing them, as well as during use, disposal or recycling of these products. At present, there is insufficient information on the number of workers exposed to nanomaterials in the work place or the effects on human health of such exposure, according to the European Agency for Safety and Health at Work. In addition, because nanomaterials have applications in many consumer products and the use of such materials in products is increasing, consumers have an increasing chance of exposure to these materials. For example, consumers may now purchase appliances such as washing machines coated with silver nanomaterials purported to kill bacteria. When consumers purchase such a machine, their clothing will be exposed to the silver nanomaterials, thus increasing their exposure to nanomaterials. Similarly, consumers may now purchase socks containing nanosilver, which exposes them to this nanomaterial. According to EPA officials, occupational exposure is a particular concern and warrants attention because the exposure and risk to workers is potentially greater than the risk to consumers.[24]

In addition to humans, the environment may also be exposed to nanomaterials through releases into the water, air, and soil, during the manufacture, use, or disposal of these materials. For example, nanomaterials could enter water through discharges from production facilities. In addition, when nanomaterials are used in pharmaceuticals, cosmetics, and sunscreens, the nanomaterials could enter water via the

[24]The Occupation Safety and Health Administration is responsible for ensuring the safety and health of workers by setting and enforcing standards and encouraging continual improvement in workplace safety and health.

sewage system during washing, showering, or swimming after having been applied to the skin and may eventually end up in a waste water treatment plant. These nanomaterials, if antibacterial in nature and if released in sufficient amounts, could potentially interfere with beneficial bacteria in sewage and waste water treatment plants and could also contaminate water intended for re-use, according to some of the studies that we reviewed. Moreover, some researchers have raised serious concerns that antibacterial nanomaterials will pose toxicity risks to human health and to environmental systems into which waste products are released. In addition, according to research, unused cosmetics are most likely to be disposed of in household waste, which may be incinerated, potentially putting nanomaterials into the air, or put in a landfill, potentially leaching out of the landfill into the water. In addition, nanomaterials that are currently being used to treat polluted water will result in releases of the materials into water and soil. For example, iron nanoparticles are being used to treat polluted water. According to EPA officials, although little is known about how these particles move through the environment, they are expected to react with contaminants or with naturally occurring substances in water and become iron oxides. Figure 6 shows the potential exposures to humans and the environment throughout the lifecycle of nanomaterials.

Figure 6: Potential Exposure Routes throughout the Life Cycle of Nanomaterials



Source: Adapted by GAO from materials produced for the European Parliament's Committee on the Environment, Public Health and Food Safety.

Currently, it is difficult to assess the risk of nanomaterials that are released into the environment because these materials are so varied and it is difficult to make generalizations about how they will behave once they are released, according to EPA officials. Specifically, it is unclear whether the nanomaterials will (1) stay suspended, (2) aggregate or cluster together to form larger particles, (3) dissolve or further break down, or (4) react with natural materials found in the environment. For example, the release of carbon nanotubes, nanoparticles of iron and titanium dioxide, or fullerenes—which are nanoscale spheres of carbon—into water may result in their aggregation, according to some of the studies we reviewed. These larger aggregates may have different toxicological properties when compared to those exhibited by the original nanomaterials. The risk posed by some nanomaterials is presumed to decrease if they aggregate because the nanomaterials may grow to the size of conventionally scaled substances, according to some of the studies we reviewed. However, the extent of aggregation may be limited because many nanomaterials receive coatings to decrease the aggregation of these materials. In addition, some nanomaterials may react with the environment and eventually build up in the environment, according to some of the studies we reviewed. Specifically, some nanomaterials may become attached to and continue to build up in the soil, depending on the nanomaterial characteristics and the characteristics of the soil. Some nanomaterials may also bioaccumulate in organisms, according to EPA.

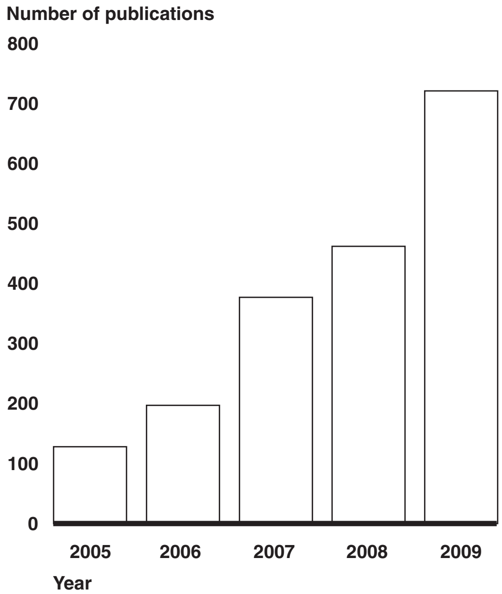
Understanding of the Risks Posed by Nanomaterials Is Limited by Several Factors

Current understanding of the risks that nanomaterials may pose is limited by several factors, including the limited amount of research that has been conducted to date and a lack of tools and methods needed to conduct additional research. As a result, predicting and assessing the potential hazards, exposures, and resulting risks from nanomaterials is difficult. Although the number of studies that have focused on assessing the risks of nanomaterials has increased over the past 5 years (see fig. 7), the studies completed to date have yielded limited risk information, according to EPA officials and other stakeholders that we spoke with, and our review of these studies. Some of these limitations include the following:

- The findings from completed toxicity studies of a nanomaterial constructed in one manner may not be applicable to understanding the risks posed by the same nanomaterial constructed in a different manner and, therefore, studies of similar nanomaterials may not be comparable. For example, carbon nanotubes may be produced in several ways, each with its own potential level of toxicity so that the results of a study for one type of carbon nanotube may not be comparable to the results of a study of a different type of carbon nanotube. Similarly, some early studies of carbon nanotubes did not specify the length of the nanotubes being studied, making it difficult to compare the results of those studies with subsequent carbon nanotube studies, according to stakeholders. This is important because researchers now know that different nanotube lengths may pose different risks.

- The studies that have been conducted have focused more extensively on some nanomaterials than others. For example, certain silica nanoparticles and carbon black are among the best studied nanomaterials, according to EPA. In contrast, less is known about nanomaterials such as nanoscale aluminum oxide and nanoclays. Therefore, little or no information is known about the risks of these types of nanomaterials.

Figure 7: The Increase in Environment and Human Safety Research Relating to Nanomaterials since 2005



Source: GAO analysis of International Council on Nanotechnology data.

Additional efforts to study the risks from nanomaterials will also be hampered because certain tools necessary to conduct these studies are lacking. Specifically, according to studies we reviewed, research on nanomaterials depends on the availability of tools, such as models or measurement technologies, to characterize or describe the nanomaterials' main qualities. However, although some tools are available, the scientific community does not currently possess all the needed tools to do so, and it will require extensive research to develop these tools. Additionally, lack of data and appropriate models also limits our ability to study the risks posed by nanomaterials, according to some of the studies we reviewed and stakeholders that we spoke with. While researchers have developed models for conventionally scaled chemicals that predict their characteristics based on the characteristics of similar, or analogous, chemicals, no such models exist yet for nanomaterials. For example, as mentioned earlier, free nanoparticles may aggregate in the natural environment, forming larger structures that may have different toxicological properties to those exhibited by the original nanoform, but researchers lack models to accurately predict how, when, and with which nanomaterials this aggregation will occur. Moreover, according to stakeholders we spoke to, small changes in the characteristics of some nanomaterials, such as a 10 percent change in their size, may alter the toxicity of the nanomaterials. The effect of such a small change compounds the difficulty in creating predictive models of nanomaterial toxicity.

EPA Has Taken a Multipronged Approach to Managing the Potential Risks of Nanomaterials but Faces Various Challenges in Regulating These Materials

EPA has taken a variety of actions to better understand and regulate the risks of nanomaterials, including conducting research and asking companies to voluntarily provide information about the nanomaterials that they produce or use. Although EPA has taken some regulatory action under its existing statutory framework with regard to nanomaterials, its authority to do so varies depending on the statute that it is using to regulate specific nanomaterials.[25] Moreover, the agency faces additional technical and informational challenges that may impact its ability to regulate nanomaterials effectively.

EPA Has Ongoing Research Efforts Related to Nanomaterials

In June 2009, EPA issued its Nanomaterial Research Strategy, which lays out the agency's plans for research to understand the potential human health and environmental impacts from exposure to nanomaterials, as well as how certain nanomaterials can be used in environmental protection applications, such as remediating contaminated waste. The strategy builds upon a body of research already conducted by EPA in areas such as ultrafine particulate exposure and toxicity, fate and transport modeling, life cycle assessment, and green chemistry.[26] EPA's strategy states that the agency's research efforts will advance two key objectives: (1) develop

[25]We selected six key statutes administered by EPA—TSCA, FIFRA, the Clean Air Act, the Clean Water Act, RCRA, and CERCLA—for the purpose of assessing actions EPA has taken to better understand and regulate the risks posed by nanomaterials as well as its authorities to do so. Also, as noted previously, EPA is one of four agencies that administers laws that regulate manufactured nanomaterials depending on how they are used. We did not review the other three agencies' regulatory authorities as part of this report, although we did identify nanomaterial uses that may be regulated by them.

[26]EPA has been conducting research in ultrafine particulate matter, particularly in the air. In this research, EPA defines ultrafine particles as those less than 100 nanometers, making them nanoscaled.

approaches for identifying and addressing any hazardous properties, while maintaining beneficial properties, before a nanomaterial enters the environment and (2) identify whether, once a nanomaterial enters the environment, it presents environmental risks. EPA stated that it plans to pursue these objectives from a life cycle perspective—from the production of a nanomaterial, through its use in products, and as it is disposed of or recycled. Ultimately, EPA plans to develop models and other tools to enable it to predict the risks posed by various types of nanomaterials. According to the strategy, EPA's research efforts will be coordinated with those of other federal agencies. For example, EPA's laboratories are collaborating with the National Institutes of Health to conduct research on, among other things, the health effects of carbon nanotubes. According to EPA, its research builds on and is consistent with the scientific needs identified by the NNI's Nanotechnology Environmental and Health Implications working group and in EPA's 2007 Nanotechnology White Paper.

EPA is also coordinating with international organizations, such as the Organisation for Economic Co-operation and Development (OECD) and the International Organization for Standardization (ISO),[27] on nanomaterials research. Specifically, the OECD established the Working Party on Manufactured Nanomaterials in September 2006, with EPA as a member and the initial chair of the working party. This working party is engaged in a variety of projects to further the understanding of the properties and risks of nanoscale materials and how to mitigate exposures and potential risks. For example, one project involves a program for testing the safety of a set of 14 nanomaterials. Specifically, member countries have agreed to develop certain data for a group of 14 nanomaterials selected by the OECD working party, in part, because they are in commerce or close to commercial use.[28] As part of this effort, EPA has the lead for the testing of fullerenes, single-walled carbon nanotubes, multiwalled carbon nanotubes, silver nanoparticles, and nano cerium oxide, among others. In addition, EPA is participating in several ISO working groups for nanomaterials. ISO has established a technical

[27]The OECD is a forum for the governments of 30 developed countries to work together to address economic, social, and environmental issues.

[28]The 14 nanomaterials that the OECD has selected for further review are aluminum oxide, carbon black, cerium oxide, dendrimers, fullerenes, iron nanoparticles, multiwalled carbon nanotubes, nanoclays, polystyrene, silicon dioxide, silver nanoparticles, single-walled carbon nanotubes, titanium dioxide, and zinc oxide.

committee to develop international standards for, among other things, nanotechnology terminology, specifications for reference materials, and test methodologies.

Under TSCA, EPA Has Regulated Some Nanomaterials as New Chemicals or New Uses, but Some Nanomaterials May Be Entering the Market without EPA Review

Over the last 3 years, EPA's approach for regulating nanomaterials under TSCA has been evolving as more information has become available on the potential risks. In January 2008, EPA launched a voluntary program called the Nanoscale Material Stewardship Program. Under this program, EPA posted a notice in the *Federal Register* asking manufacturers and processors of nanomaterials to submit existing information on the nanomaterials they produce or use to help EPA better understand the human health and environmental risks from these substances. Thirty-one companies voluntarily provided information on 132 nanomaterials, according to EPA officials. In its interim report on this program, issued in January 2009, EPA noted that although the program provided useful information regarding certain nanomaterials in commerce, a significant number of environmental health and safety data gaps remain. For example, as part of the voluntary program, EPA estimated that companies provided information on only about 10 percent of the nanomaterials that are likely to be commercially available. In addition, EPA reported that its review of data submitted through the program revealed instances in which the details of the manufacturing, processing, and use of the nanomaterials, as well as exposure and toxicity data, were not provided. This further reduced the usefulness of the information received because exposure and toxicity data are two of the major categories of information that EPA had identified as being needed to better inform its risk assessments of nanomaterials. EPA concluded from the low response rate that most companies were not inclined to voluntarily supply information on their nanomaterials.

In January 2008, EPA released a document entitled *TSCA Inventory Status of Nanoscale Substances—General Approach*, which addressed whether nanomaterials constituted new chemicals for the purpose of regulation under TSCA. TSCA provides EPA with different authorities for regulating new chemicals and existing chemicals. New chemicals are those that are not already listed on the TSCA inventory, which is a list of chemical substances manufactured or processed in the United States. Existing chemicals are those already in commerce, including about 62,000 which were already in commerce when EPA began reviewing chemicals in 1979. In general, existing chemicals can be manufactured or processed without any notification to EPA. By contrast, companies intending to manufacture a new chemical must generally submit a notice to EPA before manufacturing or producing the chemical. In its 2008 document, EPA stated that a nanomaterial is a new chemical for purposes of regulation under TSCA only if it does not have the same “molecular identity” as a chemical already on the inventory. Under TSCA, a chemical is defined in terms of its particular molecular identity. Although molecular identity is not defined in the statute, EPA considers chemicals to have different molecular identities when, for example, they represent different allotropes—a variant of a substance consisting of only one type of atom—or isotopes. [29] According to EPA officials, EPA generally does not consider the properties—such as size, shape, and reactivity—of a chemical in establishing its molecular identity. Thus, because titanium dioxide is already listed on the TSCA inventory, nanoscale versions of titanium dioxide, which have the same molecular formula, would not be considered a new chemical under TSCA, despite having a different size or shape, different physical and chemical properties, and potentially different risks. However, fullerenes—a class of nanomaterials made of spheres of carbon—would be considered a new chemical because they represent a different allotrope, or molecular arrangement of carbon atoms, than those chemicals already listed on the inventory.

If EPA makes certain findings, on the basis of information presented in a premanufacture notice, it may control the manufacture, processing, distribution in commerce, use, and disposal of the chemical. The agency sometimes issues a consent order to the company that places conditions on the use of the chemical or requires the company to generate more information on the chemical’s health and environmental effects. Since 2005, the agency has received over 90 premanufacture notices for nanomaterials under TSCA, according to EPA officials. EPA officials also told us that about 20 of these notices were requests to be exempt from the full new chemical review process based on regulatory exemptions for substances that met specific low release and exposure criteria or which were produced at low volumes.

TSCA also authorizes EPA to issue rules addressing new uses of certain materials—known as Significant New Use Rules (SNUR). These rules identify new uses of existing chemicals that could affect the nature of

[29] Allotropes are different forms of the same element in which the atoms are arranged differently. For example, graphite and diamond are allotropes of carbon. Isotopes are different forms of the same element that have different atomic weights because they have different numbers of neutrons. For example, helium-3, which has two protons and one neutron in its nucleus, is an isotope of helium.

human and environmental exposure to the substance. If a company wants to use a chemical in a way that has been designated as a significant new use, it must submit a Significant New Use Notice to EPA. For example, if EPA determines that manufacturing a chemical in a powder form instead of a liquid form would be a significant new use of that chemical, the company planning on manufacturing the chemical in a powder form would have to notify EPA. Upon receipt of a notice, EPA has 90 days to evaluate the intended use and, if warranted, to prohibit or limit it before it occurs. In 2008, EPA issued two such rules for nanomaterials. Specifically, having received premanufacture notices for nanoscale versions of siloxane-modified silica and alumina particles, EPA determined that certain uses of these chemicals, including use without employing personal protective equipment, as a powder, and uses different from those described in the premanufacture notices, were significant new uses.

In 2008, EPA entered into consent orders with a manufacturer of a specific type of carbon nanotubes that placed conditions on the use of that manufacturer's carbon nanotubes. EPA was unable to determine the potential for human health effects of these nanomaterials based on the information available in the premanufacture notices and determined that the uncontrolled manufacture, import, processing, distribution, use, or disposal of these nanomaterials may present an unreasonable risk to human health. Accordingly, EPA imposed exposure and release controls on the manufacture of these nanomaterials in addition to certain testing requirements. Subsequently, in November 2009, EPA proposed SNURs for these nanomaterials, making the limitations articulated in the consent orders applicable to all companies that might seek to manufacture them, and in January extended the comment period until February 2010.[30] As of March 2010, no final rule had been issued, but according to EPA, the agency is in the process of issuing the final SNURs after considering public comment. Until the SNURs are finalized, carbon nanotubes produced by manufacturers other than those bound by the consent orders may be entering the market without EPA review of available information on their potential risk. However, according to EPA, no manufacturer or importer has been able to demonstrate that their carbon nanotubes are chemically identical to another manufacturer's carbon nanotubes; hence the agency

[30]The SNURs were originally issued as direct final rules—that is, they would go into effect without formal consideration of public comment after a certain period if EPA did not receive any adverse comments. Because EPA received a notice of intent to submit adverse comments, however, EPA withdrew the SNURs. When EPA proposed these rules again in November, it provided for a public comment period.

has treated all carbon nanotubes as unique chemical substances for the purpose of listing them on the TSCA chemical inventory.

In the fall of 2009, EPA announced it would reconsider the policy described in its January 2008 document, *TSCA Inventory Status of Nanoscale Substances—General Approach*, and subsequently announced it planned to develop a SNUR to regulate nanoscale versions of conventionally scaled chemicals that are already on the TSCA inventory as a significant new use of that chemical. The agency intends to propose this rule in December 2010. EPA stated the agency would determine the existing uses of nanomaterials by using information submitted through the voluntary Nanoscale Materials Stewardship Program and other sources. EPA officials told us that issuing a SNUR would allow the agency to regulate nano versions of chemicals already on the TSCA inventory the same way it would regulate a new chemical. One problem that EPA may face in issuing such a SNUR is that many uses of nanomaterials are no longer new because nanomaterials are rapidly entering the market, according to stakeholders we spoke with.

TSCA also gives EPA authority to issue rules requiring companies to submit certain information about chemicals. EPA plans to issue one such rule for nanomaterials that would require manufacturers to provide information on production volume, methods of manufacture and processing, and exposure and release, as well as available health and safety studies.[31] Evaluation of this information will provide EPA with an opportunity to consider appropriate action under TSCA to reduce unreasonable risks to human health or the environment, according to EPA. This rule may also help them collect information on nanomaterials not covered by the SNUR discussed above. EPA intends to propose this rule in December 2010. This, however, raises the concern that, in the meantime, nanomaterials may be entering the market without the scrutiny these materials may merit. Furthermore, stakeholders and EPA officials point out that the completeness of information collected under a reporting rule may be limited because the current definition of small manufacturers and processors may exempt numerous manufacturers and processors of nanomaterials from such rules. Some stakeholders told us this exemption may be particularly limiting in the case of nanomaterials because much nanomaterial development is being done by small startup companies.

[31]EPA plans to propose this rule under section 8(a) of TSCA.

Moreover, the reporting rule that EPA intends to propose will not require periodic updates of the material reported.

EPA also collects data on chemicals through its Inventory Update Rule. Under this rule, EPA requires companies to regularly report certain information, including production volume and use information for chemicals they produce in quantities over 25,000 pounds.[32] This reporting threshold is intended to capture information on chemicals that account for most of the total U.S. production volume covered by TSCA. EPA has not adjusted this threshold to capture the production of nanomaterials, and thus EPA may be missing the opportunity to collect important information on nanomaterials under this rule.

Under TSCA, EPA can also issue rules that require chemical companies to test chemicals for their health and environmental effects. To require testing, EPA must find that a chemical (1) may present an unreasonable risk of injury to human health or the environment or (2) currently is or will be produced in substantial quantities and that either (a) there is or may be significant or substantial human exposure to the chemical or (b) the chemical enters or may reasonably be anticipated to enter the environment in substantial quantities. EPA must also determine that there are insufficient data to reasonably determine or predict the effects of the chemical on health or the environment and that testing is necessary to develop such data. EPA officials told us they intend to propose a rule in December 2010 that would require companies to generate test data on the health effects of 15 to 20 different nanomaterials, including carbon nanotubes, nanoclays, and nano aluminum, and also on nanomaterials used in aerosol-applied products.[33] This information will help EPA correlate the properties of these materials with specific health effects, manage or minimize risk and exposure, and help EPA determine the need for additional testing of these nanomaterials, according to EPA. EPA officials told us they will be working with the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission on this effort. However, as we have noted in a prior report, EPA has had difficulty

[32]Every 5 years, companies must report certain information on the production volume for chemicals they produced over 25,000 pounds at one location during that year. Companies must also report additional use information on chemicals that they produce over 300,000 pounds at one location.

[33]EPA plans to propose this rule under section 4 of TSCA.

in promulgating test rules in the past because, as described above, it must demonstrate that chemicals may pose certain health or environmental risks or meet volume and exposure thresholds before it can require companies to establish such risks through testing.[34] Because relatively little is currently known about the potential risks of nanomaterials and many of them have low production volumes, EPA may have similar difficulties in making the types of determinations necessary to promulgate a test rule for nanomaterials.

EPA Has Not Developed a Clear Process under FIFRA for Regulating Pesticides Containing Nanomaterials

FIFRA requires companies to obtain a registration in order to distribute or sell a pesticide. According to EPA, this authority extends to pesticides containing nanomaterials. EPA must register a pesticide if it determines, among other things, the pesticide will perform its intended function without unreasonable adverse effects on the environment.[35] Under FIFRA, EPA is authorized to require companies to submit or generate data that EPA needs to assess the risks of the pesticide. EPA may publish and periodically revise both data requirements and guidelines identifying the types of information it generally requires to assess pesticides for registration and the methods by which such data may be generated. According to EPA, the agency may, on a case-by-case basis, modify data requirements and guidelines for specific pesticides. In making its registration decision, EPA can allow the pesticide to be distributed and sold; allow it to be distributed and sold under certain conditions, such as the need to develop further information; or prohibit its distribution and sale altogether. However, according to the agency, EPA's current guidelines do not require companies to specify whether their pesticides contain nanoscale materials.

Officials told us that since 2007 they have received a few applications for registration of various nanosilver pesticide preparations. EPA officials told us that some of the companies that have submitted registration

[34]GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005).

[35]The phrase "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard for tolerance under the Federal Food, Drug, and Cosmetic Act. 7 U.S.C. § 136(bb) (2006).

applications for nanopesticides have told EPA that the pesticide includes nanomaterials, while in other cases EPA told us they were able to determine the pesticide contained nanomaterials from the manufacturing processes. However, EPA officials told us they registered at least one pesticide since 2007 without being aware that it contained nanomaterials. A group of environmental and consumer organizations has identified 260 products currently on the market that claim to contain nanosilver. This group contends these products should be regulated as pesticides due to the antimicrobial effects of nanosilver, but that these products are not registered with EPA under FIFRA.[36] Because applicants do not have to identify whether their pesticidal product contains nanomaterials, EPA may not know that certain pesticides contain nanomaterials, and these pesticides may be entering the market without EPA specifically considering the potential risks their nanomaterials may pose.

EPA officials told us that if a company replaces a conventionally sized active ingredient in a pesticide with a nanoscale version of that ingredient, it is mandatory for the company to amend its registration. Officials also noted, however, that the agency's position on this point needs to be made explicit to the regulated community and such a clarification could be made in EPA guidance. According to stakeholders, manufacturers of nanopesticides are required to obtain an amended registration in such a circumstance even without new EPA guidance explicitly requiring it since the registration requirement is based not only on questions of chemical identity, but also on claims made about the pesticide; its composition; and its chemistry, toxicology, and other information. However, until EPA makes the requirement to obtain an amended registration for pesticides that substitute a nanoscale ingredient for a conventionally sized ingredient clear, such pesticides may be re-engineered to include nanomaterials without EPA's knowledge and review.

[36]In November 2008, a group of environmental and consumer organizations filed a petition asking EPA to regulate products containing nanosilver as pesticides. Petitioners included the International Center for Technology Assessment, the Center for Food Safety, Friends of the Earth, Greenpeace, the Center for the Study of Responsive Law, and the Consumers Union.

EPA Believes It Has the Authority to Regulate Nanomaterials under Air, Water, and Waste Statutes but Technology-related Limitations and Volume-based Regulatory Thresholds Present Regulatory Challenges

According to EPA officials and stakeholders, the agency can regulate nanomaterials as it regulates other pollutants and waste under the Clean Air Act, Clean Water Act, and RCRA, as well as undertake cleanups of nanomaterials under CERCLA. Nanomaterials do not pose the same definitional difficulties under the air, water, and waste statutes as they do under TSCA and FIFRA because pollutants and wastes are defined by their effects on humans and the environment rather than by their composition. For example, EPA can list a nanomaterial as a hazardous air pollutant if the agency can establish that the nanomaterial may present a threat of adverse human health effects.[37] Similarly, EPA can list a nanomaterial as a toxic water pollutant if exposure to the nanomaterial causes death, disease, and genetic mutations, among other effects. Similarly under RCRA, a material is characterized as a hazardous waste if it is specifically listed as hazardous waste by EPA or it demonstrates any of four hazardous characteristics—ignitability, corrosivity, reactivity, or toxicity—based on testing or the knowledge of the manufacturer or processor that generated the waste. Finally, under CERCLA, a material is characterized as a hazardous substance if it is deemed hazardous under CERCLA, RCRA, the Clean Water Act, the Clean Air Act, or TSCA. EPA can designate additional substances as hazardous under CERCLA if their release may present substantial danger to the public health or welfare or the environment.

According to EPA officials and stakeholders, the agency faces technical challenges to enforcing certain statutory provisions for nanomaterials in air, water, and waste. For example, some stakeholders told us that because fine particulates (particulates under 2.5 micrometers in diameter) are already defined as a conventional air pollutant under the Clean Air Act,[38] EPA could apply this conventional air pollutant standard to nanomaterials. However, EPA officials told us that while they could regulate nanomaterials under this standard, they do not yet have the technology needed to monitor particles of this size to enforce the

[37]EPA may promulgate a rule designating a given material as a hazardous air pollutant if the material presents, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects (including carcinogenicity, mutagenicity, neurotoxicity, reproductive dysfunction, or acute or chronic toxicity) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise. 42 U.S.C. § 7412(b)(2) (2006).

[38]A conventional air pollutant is one that causes or contributes to air pollution that may reasonably be anticipated to endanger public health or welfare. There are five other conventional air pollutants in addition to particulates: they are ground-level ozone, carbon monoxide, sulfur oxides, nitrogen oxides, and lead.

standard. According to EPA and stakeholders, the agency may need to reassess how it measures pollutants under the Clean Air Act with respect to nanomaterials. This is because given the relatively small weight associated with nanomaterials, EPA may need to count particles or measure their surface area rather than weigh them, as the current air pollutant standard calls for.

Similarly, according to some stakeholders, in order to enforce any technology-based effluent limitations for nanomaterials established under the Clean Water Act in the future, EPA would need to identify technology that can reliably and economically measure these materials in effluents, which it does not currently have.[39] Similarly, EPA may face challenges in regulating nanomaterials in waste under RCRA because the tests used to establish the hazards of waste in general may be inadequate to characterize the hazards of nanomaterials. For example, according to some stakeholders, to the extent that nanoparticles behave in significantly different ways than larger-scale particles in soil, groundwater, and drinking water, EPA's assumptions under current testing procedures may not fully assess how toxic wastes containing nanomaterials might affect groundwater.

In regulating nanomaterials, EPA also faces challenges attributable to volume-based thresholds and special conditions, such as waste coming from households, that trigger application of air, water, and waste laws and regulations. For example, EPA exempts household waste from RCRA hazardous waste regulation because it is impractical to regulate individual households. Moreover, EPA officials told us that landfill liners, as described in EPA's criteria for municipal solid waste landfills under RCRA, are sufficient to handle the small amounts of hazardous waste that end up in municipal landfills as a result of the household hazardous waste exemption. However, some stakeholders argue that until the risks of nanomaterials are better understood, it will not be known whether the landfill liners are sufficient to address the potential risks of nanomaterials that might be present in household waste. An example of a volume-based threshold issue arises under the Emergency Planning and Community

[39] An effluent limitation is a restriction on the discharge of pollutants from, for example, a factory, into the waters of the United States.

Right to Know Act.[40] EPA has set thresholds in the regulations implementing hazardous chemical inventory reporting requirements under these provisions that may not establish a threshold that is appropriate for nanomaterials. For example, the regulations include a default inventory reporting threshold for releases of 500 pounds for extremely hazardous substances and releases of 10,000 pounds for other hazardous chemicals. Stakeholders question whether these thresholds may be too high in the context of nanomaterials. EPA can set the thresholds lower than the defaults and has, for example, reduced the default threshold for some specific extremely hazardous substances to 1 pound. However, it has not yet done so for any nanomaterials.

In addition to the challenges that EPA faces in regulating nanomaterials under air, water, and waste statutes, the agency may also be missing certain opportunities for gathering information on nanomaterials under the Clean Water Act. For example, EPA may not be collecting all available data on nanomaterials discharged into water. EPA has authority under the Clean Water Act to require owners or operators of facilities discharging pollutants to keep records, report information, monitor and sample discharges, and provide other information that EPA may reasonably require to carry out the act. The act also gives EPA the authority to inspect facilities and review records.[41] According to stakeholders, at least one court has interpreted this authority broadly, upholding as reasonable an EPA permit requirement directing an applicant to disclose all toxic pollutants used or produced in the facility.[42] Thus, stakeholders pointed out that EPA was able to obtain information not only on toxic pollutants that were in fact being discharged from a facility, but on those that had the potential to be discharged as well. Stakeholders concluded that even if EPA cannot currently measure nanomaterial discharges or cannot impose monitoring requirements on facilities, the agency has the ability to obtain information on the potential for nanomaterial discharge by a facility.

[40]Under this act, covered facilities must submit an emergency and hazardous chemical inventory form to (a) the appropriate local emergency planning committee; (b) the state emergency response commission; and (c) the fire department with jurisdiction over the facility. 42 U.S.C. § 11022(a) (2006).

[41]33 U.S.C. § 1318 (2006).

[42]*NRDC v. EPA*, 822 F.2d 104, 119 (D.C. Cir. 1987).

Other National Authorities Are Collecting Information on Nanomaterials and Are Evaluating Their Legislation to Ascertain if Changes Are Needed

Australia and the United Kingdom have undertaken a voluntary approach to collecting information on nanomaterials while Canada plans to require companies to submit certain data. In contrast, the European Union collects data on all chemicals being produced at a certain volume as required by its basic chemicals legislation, which also includes nanomaterials. All of these entities are reviewing their existing legislation to determine the need for additional regulatory authority to specifically address nanomaterials.[43]

Australia Has Asked Companies to Voluntarily Provide Information on Nanomaterials and Is Currently Reviewing Comments on Proposed Legislative and Regulatory Changes

Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS)—the government's regulatory body for chemicals—has issued two requests for companies to voluntarily provide information on nanomaterials but, like the U.S. experience, these requests have produced limited results. In February 2006, NICNAS issued a voluntary request for information from industry on the uses and quantities of nanomaterials being manufactured or imported into the country. Nanomaterials used exclusively in certain products, such as sunscreens and food additives, among others, do not fall within the scope of NICNAS and were consequently outside the request for information. Data requested included chemical and trade name, molecular formula, and estimates of total quantity imported or manufactured, and NICNAS did not request data on nanomaterial toxicity. Companies supplied information on 21 types of nanomaterials, 17 of which were available for commercial use. The largest group of nanomaterials reported was metal oxides, which are used in surface coatings, water treatment, cosmetics, and catalysts. In October 2008, Australia expanded the information requested in 2006 when it initiated a second request for information that targeted all manufacturers or importers of nanomaterials or products containing nanomaterials for commercial or research and development purposes. The second request was for companies to identify what data they have on their nanomaterials' toxicological properties, while not requiring the data be provided to NICNAS. The request also stipulated that no new data needed to be

[43] We selected a judgmental sample of four national authorities for our review, based on criteria such as countries that have recently taken action with regard to nanomaterials.

generated. Although information was due to NICNAS by the end of January 2009, the results of this request have not yet been made public.

In addition to collecting information, NICNAS announced in fall 2009 that it is reviewing Australia's legislative framework and administrative practices to ensure that any potential risks from nanomaterials are adequately identified and appropriately managed. A 2008 review by an Australian university determined that Australia's regulatory frameworks should be reviewed to ensure that the risks posed by nanotechnology are better managed.[44] The following are areas, among others, that were identified for review by the report.

- *Classification of nanomaterials as new or existing.* Uncertainty exists as to whether the nano-form of a chemical is considered new or an existing chemical under current legislation. The NICNAS new chemicals program—for chemicals not listed on the national inventory—currently applies to nanomaterials and allows for them to be assessed before commercial use. However, nanoscale versions of existing chemicals—chemicals already on the national inventory—can legally be introduced and used without notification to NICNAS.
- *Weight or volume.* Some Australian regulatory requirements are currently triggered by weight or volume. For nanomaterials, weight or volume thresholds may not be meaningful because current production levels of nanomaterials are too low to trigger the threshold and not enough is known about the appropriate threshold levels.
- *Risk assessment protocols.* It is uncertain whether risk assessment methods currently being employed by various regulatory agencies are suitable for goods that contain nanomaterials. Such uncertainties reduce confidence in the results of assessments.

To address these areas of concern, Australia's NICNAS has proposed a range of reforms, including removing nanomaterials from certain exemptions and potentially requiring nanomaterials based on conventionally scaled existing chemicals to go through the new chemicals review program. Public comment on these proposals closed on February 12, 2010, but the results of these comments have not yet been made public.

[44] Monash University, *Review of the Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks* (May 2008).

The United Kingdom Has Asked Companies to Voluntarily Report Certain Data on Nanomaterials and Is Currently Reviewing Whether Legislative Changes Are Needed

The United Kingdom launched a voluntary reporting scheme for nanomaterials in 2006 that targeted manufacturers, importers, and users and that also resulted in the collection of limited information. This effort focused on free nanomaterials—nanomaterials not enclosed in other materials—because they were identified as having greater potential for environmental exposure. Information requested included chemical identity; dimensions and shape; size range; predictions of surface area; uses; available toxicological data; and certain physical and chemical characteristics, such as water solubility, stability, and flammability. As of July 2007, the United Kingdom had only received nine responses to its voluntary reporting scheme.

Regarding legislation, the United Kingdom commissioned reviews of the adequacy of existing legislation for each of its key regulatory departments to assess whether current regulatory frameworks are adequate to address the potential risks posed by nanomaterials. In general, these reviews concluded that the current regulatory framework, while broadly sufficient, has the potential for nanomaterials to fall outside of regulatory controls in certain circumstances, such as regulations with production volume or mass thresholds developed in the context of macroscale materials. The review also found that certain consumer products containing nanomaterials may be found safe for consumer use, but that risk assessments may not consider the full product life cycle, including its disposal. Consequently, in June 2009, the United Kingdom recognized that there may be a need to adjust existing systems to create a more integrated approach to address risks from nanomaterials. The United Kingdom is currently considering these issues as it develops its strategy on nanotechnologies.

Canada Is Drafting a Requirement That Companies Provide Information on Nanomaterials and Plans to Review the Data Collected before Proposing Any Regulatory Changes

Canadian officials have proposed but have not implemented a one-time requirement for companies to provide information on nanomaterials produced in or imported into Canada. Canadian importers and manufacturers would be required to report their use of nanomaterials produced or imported in excess of 1 kilogram. In 2009, Canadian officials reported to the OECD that information required would include chemical and trade name; molecular formula; and any available information on the shape, size range, structure, quantity imported or manufactured, and known or predicted uses. Also required would be any available information on the nanomaterial's physical and chemical properties—such as solubility in water and toxicological data, among others. Under the proposal, companies could claim information as confidential, but regulators would publish a summary of information provided. Canada plans to use this information to help develop a regulatory framework for nanomaterials and to determine which information requirements would be useful for subsequent risk assessments. Canadian officials stated they originally hoped to issue this requirement in the spring of 2009 but could not predict when it would be implemented.

With regard to current law, a report prepared for the government of Canada in 2008 stated that Canada has no specific requirements for nanomaterials and is considering whether they are needed. However, Health Canada and Environment Canada—two agencies responsible for health and the environment—have taken the first steps in recognizing the potentially unique aspects of nanomaterials. These regulatory agencies are currently relying on existing authority delegated to them through legislation, such as the Canadian Environmental Protection Act, to address nanomaterials. Specifically, in June 2007, Environment Canada released a new substances program advisory announcing that nanomaterials will be regulated under the act's new substances notification regulations. Per this advisory, any nanomaterial not listed on Canada's chemical inventory—the Domestic Substances List—or with "unique structures or molecular arrangements" compared to their non-nano counterparts, requires a risk assessment. A review panel of the Canadian Academies found that, while it is not necessary to create new regulatory mechanisms to address the unique challenges presented by nanomaterials, the existing regulatory mechanisms could and should be strengthened in a variety of ways, such as by creating a specific classification for nanomaterials and by reviewing the regulatory triggers that prompt review of the health and environmental effects.

The European Union Is Considering Revising Its Chemicals Legislation to Better Address Nanomaterials, and Is Requiring Labeling of Nanomaterials in Certain Products

The European Union passed its chemical legislation in 2007, known as Regulation, Evaluation and Authorization of Chemicals (REACH),[45] under which the European Union generally collects information on all chemicals. However because REACH requirements apply to chemicals with a production volume of greater than 1 metric ton per year, some stakeholders have expressed concern that the provisions of REACH will not identify the risks of most nanomaterials because companies do not produce these materials at this level or volume. Because of this concern, the European Union is reviewing whether the provisions of REACH need to be modified to take into consideration the unique properties of

[45]REACH's requirements are being phased in and will not be in full force until 2018.

nanomaterials by, for example, adjusting the volume-based thresholds. This review is ongoing, according to official EU reports, and is not scheduled for completion until 2012.

In addition to efforts under REACH, the European Union has developed a regulation to require labeling on certain types of products containing nanomaterials. For example, a European Union Cosmetics Regulation will require cosmetic products that contain nanoscale ingredients to be labeled as such. The regulation would also require the manufacturers of new cosmetic products containing nanomaterials to notify regulators and provide them with certain safety information. Manufacturers of products containing nanoscale ingredients already being sold in the European Union also would have to notify regulators and submit certain safety information. In addition, the regulation requires all nanomaterial ingredients be clearly indicated in the list of ingredients and the names of such ingredients shall be followed by the word “nano” in brackets. The regulation also calls for the European Commission to compile a publicly available catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV filters, and preservatives. Although this regulation was published in November 2009, its provisions are not scheduled to go into effect until July 2013.

In addition to the Cosmetics Regulation, the European Union has also begun to regulate nanomaterials in food. Specifically, in January 2010, revised regulations on food additives went into effect. The regulations clarify that when there is a change in the particle size of a previously approved food additive, a new approval is required before the additive goes to market. The European Union is also considering an update to its regulations on novel foods—foods or ingredients not widely consumed by people prior to 1997—that includes measures to regulate manufactured nanomaterials in food. Specifically, the proposed update would require that all foods containing manufactured nanomaterials undergo premarket authorization.

Some State and Local Governments Have Begun to Address the Risks of Nanomaterials

Some U.S. states and localities have begun to address the potential risks from nanomaterials by, for example, issuing requests for information. Specifically, in January 2009, California required companies that manufacture or import carbon nanotubes into the state submit certain readily available data on these materials to the California Department of Toxic Substances Control by January 22, 2010. California officials told us that carbon nanotubes are an important category of emerging nanomaterials for which data on toxicity, physiochemical properties, and environmental fate and transport are largely unavailable. California posted the 22 responses it received on its Web site, as well as the names of companies that failed to respond. In addition, California environmental officials said they are now considering whether to conduct additional information requests on nanoscale forms of metal oxides, including nano aluminum oxide, nano silicon dioxide, nano titanium dioxide, and zinc oxide, as well as nanosilver, nano zerovalent iron, and nano cerium oxide. According to stakeholders we spoke with, environmental officials in other states have also considered similar information requests. For example, in 2009, some Wisconsin state legislators called for a study on the feasibility of creating a nanotechnology registry and the development of subsequent legislation.

In addition to states, some municipalities have considered collecting information on nanomaterials. For example, in December 2006, the City of Berkeley, California, issued a hazardous materials ordinance that requires companies to report the manufacture or use of nanomaterials. According to stakeholders we spoke with, this was the first time a U.S. city took such an approach. Berkeley's ordinance requires that facilities that manufacture or use nanoparticles submit a separate written disclosure of the material's known toxicology and how the facility will safely handle, monitor, contain, dispose, track, and mitigate the risks of such materials. Cambridge, Massachusetts, also considered implementing a similar ordinance but has not done so yet.

Several state environmental officials told us they have considered whether their states' current regulations provide enough authority to address the risks of nanomaterials. For example, environmental officials in California told us they planned to review the data gathered under their requests for information to determine if additional action is needed. According to a report issued by the Environmental Council of the States, [46] other states are taking some preliminary actions with regard to nanomaterials. Specifically,

- Maine officials developed an Air Toxics Priority List in July 2007 that includes particulate matter from nanotechnology,

[46] The Environmental Council of the States is the national non-profit, non-partisan association of state and territorial environmental agency leaders.

- the Massachusetts Department of Environmental Protection identified nanomaterials as an emerging contaminant of concern and established an Interagency Nanotechnology Committee,
- the Washington State Department of Ecology considers nanomaterials to be an emerging contaminant of concern and has revised its manual for hazardous waste inspectors to include specific information on nanomaterials, and
- Pennsylvania and South Carolina have identified nanoparticles as contaminants of concern.

The report identified nanomaterials, among other substances, as emerging contaminants of concern.[47] The report specifically requested that federal agencies consider nanomaterials as a special class of emerging contaminants due to properties that may make them behave in ways that conventional-scale contaminants do not. In addition, the report identified a number of states that are taking some preliminary actions with regard to nanomaterials.

Conclusions

The use of nanomaterials in products is growing faster than our understanding of the risks these materials pose to human health and the environment. While EPA has taken steps to improve our understanding of these risks, such as by asking companies to voluntarily provide information on the nanomaterials they produce, the information gathered through these efforts has been limited and does not provide a strong foundation for understanding the increasing potential for exposure to these materials as their uses become more prevalent. EPA has taken some regulatory action with regard to nanomaterials under TSCA and has developed plans to take further action with regard to information collection and testing of nanomaterials. However, these changes have not yet gone into effect and products may be entering the market without EPA review of available information on their potential risk. Moreover, although EPA requires chemical companies to periodically provide certain information on many of the chemicals currently in commerce, EPA has not extended this requirement to nanomaterials. Thus, EPA may be missing the opportunity to gather some additional information on nanomaterials from the regulated community. Furthermore, although EPA is taking steps

[47]Environmental Council of the States. *State Experiences with Emerging Contaminants: Recommendations for Federal Action*, January 2010.

to regulate pesticides containing nanomaterials, it has not clearly stated this to manufacturers, and the current data requirements do not require companies to specify whether any materials in their pesticides are nanoscaled.

EPA also may be missing the opportunity to gather some additional information on potential discharges of nanomaterials from the regulated community. We acknowledge that EPA faces technical challenges in its research and regulatory efforts caused in part by a lack of tools and models to help generate information on the potential risks; however, better use of existing environmental statutes, such as the Clean Water Act, may enable EPA to collect useful information on nanomaterials.

Recommendations for Executive Action

We recommend that the Administrator of EPA, take the following three actions:

- Complete its plan to issue a Significant New Use rule for nanomaterials.
- Modify FIFRA pesticide registration guidelines to require applicants to identify nanomaterial ingredients in pesticides.
- Complete its plan to clarify that nanoscale ingredients in already registered pesticides, as well as in those products for which registration is being sought, are to be reported to EPA and that EPA will consider nanoscale ingredients to be new.

In addition, the Administrator of EPA should make greater use of the agency's authorities to gather information under existing environmental statutes. Specifically, EPA should

- complete its plan to use data gathering and testing authorities under TSCA to gather information on nanomaterials, including production volumes, methods of manufacture and processing, exposure and release, as well as available health and safety studies; and
- use information-gathering provisions of the Clean Water Act to collect information about potential discharges containing nanomaterials.

Finally, the Administrator of EPA should consider revising the Inventory Update Rule under TSCA so that it will capture information on the production and use of nanomaterials and so that the agency will receive periodic updates on this material.

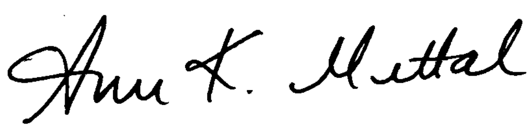
Agency Comments

We provided EPA a draft of this report for review and comment. EPA concurred with the report's recommendations and stated that the recommendations are consistent with the agency's approach to effectively managing nanoscale materials. EPA's comments are reproduced in appendix II. In addition, EPA provided technical comments, which we incorporated into the report as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Administrator of EPA, and other interested parties. The report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or mittala@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

Sincerely yours,



Anu K. Mittal
Director, Natural Resources
and Environment

Appendix I: Objectives, Scope, and Methodology

Our objectives for this review were to (1) identify examples of current and potential uses of nanomaterials, (2) determine what is known about the potential human health and environmental risks from nanomaterials, (3) specifically assess actions the Environmental Protection Agency (EPA) has taken to better understand and regulate nanomaterials as well as its authorities to do so, and (4) identify approaches that selected national authorities have taken to address the risks associated with nanomaterials. In addition, you asked us to identify any U.S. states and localities that may have begun to address risks from nanomaterials.

To identify examples of current and potential uses of manufactured nanomaterials, we analyzed documents and reports created by stakeholders, including synthesis studies, databases of nanotechnology-related products, and Web sites that compiled and analyzed nanotechnology-related products from various sources. We identified the documents and reports (1) through interviews with knowledgeable stakeholders, (2) through open source research, and (3) from a literature search. Because of the dynamic nature of nanotechnology, we used only documents published since 2005. We also sought reports that sorted the current and potential uses of nanomaterials into broad categories, so that our report would not exclude any major industry sectors. We analyzed the information, compared the sets of industry sectors used in various reports to each other, and created a list of eight industry sectors that in our estimation reflected the breadth and depth of the commercial market for products enabled by nanomaterials. We selected specific examples within each sector for further analysis. Because assembling a comprehensive catalog of uses would be difficult in an evolving, dynamic industry, our list of examples is not comprehensive but rather was selected in a manner that allowed us to convey the wide spectrum of materials in current use, or which could be in use in the future, across a large range of products. In addition, we interviewed cognizant agency officials from the top six agencies conducting nanotechnology-related research. These six agencies accounted for over 95 percent of federal nanotechnology research reported in fiscal year 2009.[1] We also interviewed knowledgeable stakeholders, including officials from the National Nanotechnology Initiative, the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies, Lux Research—an independent research

[1]These agencies are the Department of Defense, the Department of Energy, EPA, the Department of Health and Human Services' National Institutes of Health, the Department of Commerce's National Institute of Standards and Technology, and the National Science Foundation.

firm that conducts market analysis of nanotechnology, among other things—and the NanoBusiness Alliance—a nanotechnology related business association. To identify knowledgeable stakeholders, we used an iterative process, often referred to as "snowball sampling," in which we asked our initial interviewees to identify others we should talk to, and we selected for interviews those who would provide us with a broad range of perspectives on the current and potential uses of nanomaterials.

To determine what is known about the potential human health and environmental risks of nanomaterials, we reviewed documents that had been published by peer-reviewed journals, government agencies, and international nonprofit organizations. In conducting this review, we searched databases, asked knowledgeable stakeholders to identify relevant studies, and reviewed studies from article bibliographies to identify additional sources of information on the potential risks. Because of the importance of using the most current risk-related research, the team used only documents published since 2005. Of the over 700 documents we identified published between 2005 and 2010, we narrowed our review to 140. Of these, we selected 20 for more detailed analysis. We selected these documents in large part because they provided a synthesis of available research related to nanomaterials risks and they covered a variety of nanomaterials. To assess the credibility, reliability, and methodological soundness of these publications, a senior GAO technology analyst reviewed each of the publications and considered such factors as the bibliographies of evidence cited and the location of where the articles were published. We did not examine the references cited by these studies as part of our analysis. We concluded that all 20 reviews were sufficiently reliable for the purposes of this report. For the purposes of this review, all the documents, studies, and syntheses we reviewed will be referred to in our report as "studies." We also spoke with a variety of knowledgeable stakeholders representing government, industry, academia, nongovernmental organizations, and the regulatory community. These knowledgeable stakeholders were also selected using a snowball sampling method.

To assess actions EPA has taken to better understand and regulate nanomaterials and its authorities to do so, we analyzed selected laws and regulations, including the Toxic Substances Control Act of 1976; the Federal Insecticide, Fungicide, and Rodenticide Act; the Clean Air Act; the Clean Water Act; the Resource Conservation and Recovery Act; and the Comprehensive Environmental Response, Compensation, and Liability Act. We also reviewed data and reports on EPA's Nanoscale Materials Stewardship Program, which EPA developed to encourage companies to voluntarily develop and submit information to EPA on the characteristics of nanomaterials. We interviewed and obtained documentation from agency officials responsible for implementing these laws in EPA's Office of Air and Radiation, Office of Pollution Prevention and Toxic Substances, Office of Pesticide Programs, Office of Solid Waste and Emergency Response, and Office of Water. We also interviewed and obtained documentation from staff in EPA's Office of Research and Development. Furthermore, we consulted with knowledgeable stakeholders and legal experts to obtain their perspectives on EPA's available authorities to regulate nanomaterials.

To determine which national authorities had recently addressed nanomaterials, we interviewed knowledgeable stakeholders, including EPA officials who participated in working groups within the Organisation for Economic Co-operation and Development to identify candidate national authorities. We selected a judgmental sample of four countries for our review based on the following criteria: (1) EPA officials agreed that these countries have robust environmental regulations that were comparable to US regulations and (2) the countries had recently taken action with regard to nanomaterials, including considering to regulate nanomaterials. Based on this, we selected Australia, Canada, the United Kingdom, and the European Union. To identify the approaches these national authorities have used to address the potential risks associated with nanomaterials, we analyzed these authorities' laws and regulations that would be applicable to regulating nanomaterials, reviewed reports that other organizations had conduced of these countries' laws as they pertain to nanotechnology, and supplemented our understanding with interviews with knowledgeable stakeholders and legal experts.

To identify any states or local governments that may be taking action with regard to nanomaterials, we interviewed with knowledgeable stakeholders including EPA officials, representatives from environmental organizations, and the Environmental Council of States—a nonpartisan association of state environmental officials. We collected and analyzed documentation on these activities and supplemented our analysis with interviews with selected state officials.

Appendix II: Comments from the Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 04 2010

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Anu Mittal, Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, NW, Room HQ 2T31
Washington, D.C. 20548

Dear Ms. Mittal:

Thank you for the opportunity to review the U.S. Government Accountability Office's (GAO's) draft report entitled *Nanotechnology: Nanomaterials Are Widely Used in Commerce, but EPA Faces Challenges in Regulating Risk* (GAO-10-549). We appreciate and concur with GAO's recommendations, which are consistent with the Agency's approach to effectively managing nanoscale materials.

We note GAO's acknowledgement that there are unanswered questions about the potential risks of nanoscale materials to human health and the environment. The same special properties that make nanoscale materials useful are also properties that may cause some nanoscale materials to pose potential risks to humans and the environment. At this point, not enough information exists to fully assess these risks. EPA will need a sound scientific basis for assessing and managing any unforeseen future impacts resulting from the introduction of nanoscale materials into the environment, as well as informing material design and use decisions that avoid or reduce risk. A challenge for environmental protection is to help fully realize the societal benefits of nanotechnology while identifying and minimizing any adverse impacts to humans or ecosystems from exposure to nanoscale materials. The growing diversity and complexity of the types and uses of nanoscale materials available and being developed presents challenges in evaluating risks associated with the manufacture and use of these materials.

As noted in the GAO report, this understanding will come from environmental research and development activities. EPA is heavily involved in efforts to understand the potential risks to humans, wildlife, and ecosystems from exposure to nanomaterials. Through innovation and discovery, scientists are studying the unique properties of nanomaterials, determining their potential impacts, and developing approaches to evaluate and prevent any risks. They are also exploring how nanomaterials can be used effectively to clean up contaminants released into the environment. With the use of nanotechnology in the consumer and industrial sectors expected to increase significantly in the future, nanotechnology offers society the promise of major benefits. The challenge for environmental protection is to ensure that, as nanomaterials are developed and used, unintended consequences of exposures to humans and ecosystems are prevented or minimized.

The recommendations contained in the GAO draft report are consistent with the Agency's approach to effectively managing nanoscale materials and we accept them. Below are comments on each of the recommendations found in the draft report.

EPA Response to GAO's Recommendations for Executive Action

We recommend the Administrator, EPA, take the following actions:

- Complete its plan to issue a Significant New Use Rule for nanomaterials.

  EPA agrees. EPA will continue to issue SNURs for nanoscale materials that are new chemical substances on a case-by-case basis, as appropriate, and intends to propose a SNUR for nanoscale materials that are existing chemical substances by December 2010.

- Modify FIFRA pesticide registration guidelines to require applicants to identify nanomaterial ingredients in pesticides.

  EPA agrees and intends to clarify that, as part of the application for registration, applicants for pesticide registrations which contain nanomaterial ingredients need to specifically identify those ingredients.

- Complete its plan to clarify the FIFRA guidelines to make clear that already registered pesticides that have been reengineered to include nanomaterials need to obtain an amended registration.

  EPA agrees and is working on clarification of registrant's responsibilities under FIFRA with respect to nanomaterials.

In addition, GAO recommends the EPA Administrator should make greater use of its authorities to gather information under existing environmental statutes. Specifically, GAO recommends EPA should:

- Complete its plan to use data gathering authorities under the Toxic Substances Control Act (TSCA) to gather information on nanomaterials, including production volumes, methods of manufacture and processing, exposure and release, as well as available health and safety studies.

  EPA agrees and intends to propose a section 8(a) information gathering rule as described in the recommendation and also intends to propose a section 4 test rule.

- Use information gathering provisions of the Clean Water Act to collect information about potential discharges containing nanomaterials.

  The Agency agrees that collecting information about discharges is a critical component of understanding potential environmental risks. EPA's Office of Research and Development, and others, is conducting research to determine whether nanomaterials

2

may enter the water in forms and levels of concern, as well as how to detect and monitor nanomaterials in effluents and aquatic systems. Once we have these capabilities, EPA will consider whether new reporting requirements should be applied to companies who may be discharging nanomaterials into the environment, including under the Clean Water Act.

- Finally, the EPA Administrator should consider revising the Inventory Update Rule under TSCA so that it will capture information on the production and use of nanomaterials and so that the Agency will receive periodic updates on this material.

  EPA agrees and will consider proposing periodic reporting under the Inventory Update Rule for nanoscale materials.

Again, we appreciate the opportunity to review and comment on this draft report. Should you have any questions or concerns regarding this response, please contact Bob Trent, EPA's GAO Liaison Team Lead, at 202-566-0983.

Sincerely,

Stephen A. Owens
Assistant Administrator

3

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Anu Mittal, 202-512-3841 or mittala@gao.gov

Staff Acknolwedgments

In addition to the contact person named above, Elizabeth Erdmann (Assistant Director), David Bennett, Antoinette Capaccio, Nancy Crothers, Cindy Gilbert, Gary Guggolz, Nicole Harkin, Kim Raheb, and Hai Tran made key contributions to this report.

Related GAO Reports

Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS). GAO-10-246. Washington, D.C.: February 3, 2010.

Chemical Regulation: Observations on Improving the Toxic Substances Control Act. GAO-10-292T. Washington, D.C.: December 2, 2009.

High-Risk Series: An Update. GAO-09-271. Washington, D.C.: January 22, 2009.

Federal Research: Opportunities Exist to Improve the Management and Oversight of Federally Funded Research and Development Centers. GAO-09-15. Washington D.C.: October 8, 2008.

Highway Safety: Foresight Issues Challenge DOT's Efforts to Assess and Respond to New Technology-Based Trends. GAO-09-56. Washington, D.C.: October 3, 2008.

Nanotechnology: Accuracy of Data on Federally Funded Environmental, Health, and Safety Research Could Be Improved. GAO-08-709T. Washington, D.C.: April 24, 2008

Nanotechnology: Better Guidance Is Needed to Ensure Accurate Reporting of Federal Research Focused on Environmental, Health, and Safety Risks. GAO-08-402. Washington, D.C.: March 31, 2008.

Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals. GAO-07-825. Washington, D.C.: August 17, 2007.

21st Century Challenges: Reexamining the Base of the Federal Government. GAO-05-325SP. Washington, D.C.: February 2005.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday afternoon, GAO posts on its Web site newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to www.gao.gov and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's Web site, http://www.gao.gov/ordering.htm.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Ralph Dawn, Managing Director, dawnr@gao.gov, (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548