Chapter 6

Technological Evolution

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The preceding chapters introduced you to the nanoscale, the tools scientists use to work in that world, and how each of the classical sciences (physics, chemistry, and biology) can be explored in new ways. So the stage is set: new discoveries can be made, and new inventions developed. But how does the successful lab experiment of today become the superconducting cable or cancer cure of tomorrow?

Chapter 6 explains how the leap from lab to marketplace is made, as well as how nanomaterials are transforming industries and displacing existing products. Whether you are talking about railroads in the 19th century or computers in the 20th century, any new technology can cause very real changes to our society and environment. This chapter explores the problems and opportunities that we face as a result of the emergence of nanotechnology in the 21st century. Business and government have a symbiotic relationship in every industry. As you will learn in this chapter, information, education, and transparency can be vital to establishing and maintaining the public trust necessary for a new technology to flourish.

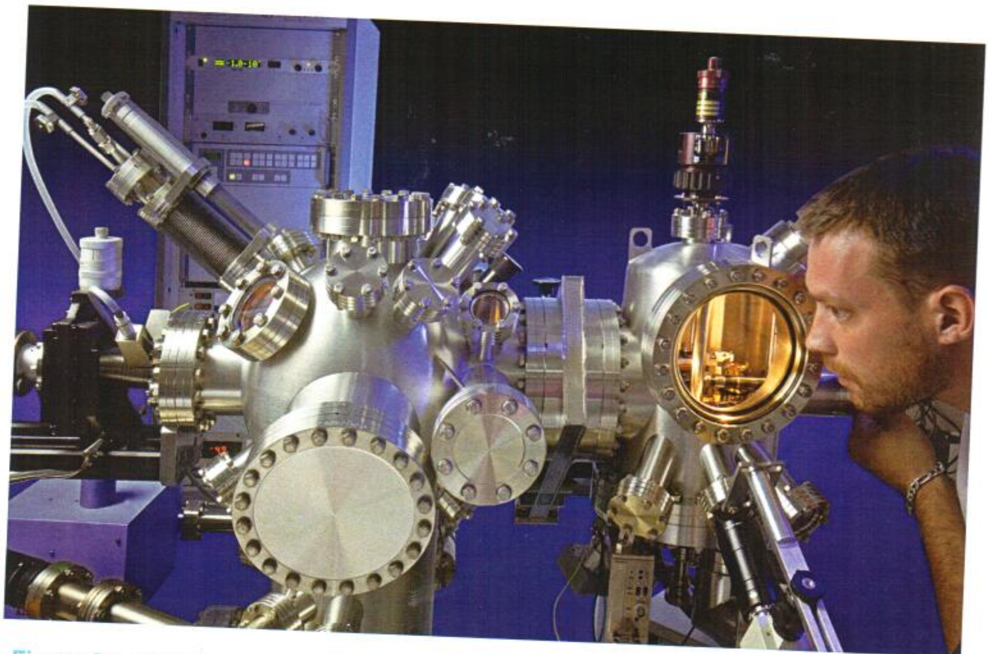


Figure 6.1 Ultra-high vacuum atomic force microscope. *See Figure Credits, p. vi.*

Section 1
The Technology Maturity Model

TAKE-HOME MESSAGES

1. Each phase of the technology maturity model includes many complex processes that drive the development of a safe, effective, and profitable product.
2. Regardless of where a product idea that uses nanomaterials is conceived, most of the initial development work is performed in a laboratory environment.
3. Adherence to a product specification and having a nanomaterial perform as designed are primary goals in product development. Equal to these goals are safety, health, and environmental measures taken to ensure product viability and acceptance.

POINTS TO PONDER

- Some ideas are born out of incidental discoveries, and some are developed from careful, detailed specifications. What are the advantages and disadvantages of how a product idea is born?
- What are some of the areas of product development that are critical to introducing a safe nanomaterial?
- In which phase of the maturity model do you work to resolve defects and establish quality, before full-volume manufacturing?
- What are the names of some of the government agencies that monitor safety, health, and environmental issues?

From bright idea or surprising discovery to the arms of the marketplace, new products travel a similar path despite their diverse origins. We often think of a product idea as beginning with just that—an idea first, then steadily marching down the development path until it reaches its ultimate destination: the market. However, many product ideas first come into focus through the lens of a microscope or through other research performed daily in the laboratories of the world. While pursuing one idea, researchers may find themselves pushed in new directions by unexpected results. Even better ideas or discoveries may lead to the next non-stick surface coating, carbon fiber, or penicillin.

The similar path that nearly all products follow on the way to market is known as a maturity model. Business leaders and scientists work together to nurture an idea or invention through eight phases of development to create a marketable product that is also widely accepted in society. The number of steps a company follows in a technology maturity model may vary somewhat, but all:

- Begin with the creation of a product idea
- Continue with the development of the product
- Introduce the product to the marketplace
- End with the marketing of the product until its end-of-life

In the following pages, we will explore each phase of the technology maturity model from the perspective of nanotechnology.

Phase 0: The Idea: Creation or Discovery

Whether a product idea is a result of discovery or is the result of a planned product idea, the initial focus is identifying what is known about the nanomaterial and learning about what is not known, all of which will determine how the final product can be used. During this phase, researchers and business leaders ask questions about the prospective nanoproduct to help kick-start the research process. At this point, a lot of mystery surrounds the qualities, benefits, and possible dangers of the new material. If it looks promising, a complete and thorough analysis is designed. Some of the initial questions about the nanomaterial may be:

- What is this material?
- What are the properties of the material?
- Can it be created again?
- Is it harmful or lethal?

Actual product-development issues are not considered until more information is available (see Phase 1, etc.).

Figure 6.2 Ideas or discoveries mature into a cohesive concept as the result of team members sharing their thoughts and discoveries. *See Figure Credits, p. vi.*

Phase 1: Defining the Nanomaterial or Process

In this phase of the nanotechnology maturity model, you find that your discovery or idea is worthy of further investigation. By now, many questions have arisen and answers to these questions are needed to help define the material being researched. Not all of your questions will be answered, but the progress made in this phase will set the groundwork for the coming detailed research and product development.

These are just some of the questions that you and your colleagues will ask about the nanomaterial being considered for product development:

- What is the nature of the material: solid, liquid, or gas?
- What are the physical properties of the material: hard/soft, strong/weak, dense, elastic, crystalline, electrically conductive, magnetic, etc., and how are these physical properties affected by the environment?
- Does it exhibit hydrophilic or hydrophobic properties? Under what conditions (for example, temperature and humidity)?
- What are its freezing and melting temperatures?
- Can it be mixed with other materials (preliminary stage)?
- Are any of the properties harmful or lethal? What is the level of toxicity? Does it cause physical symptoms in humans and other organisms: rashes, difficulty in breathing, coughing, or any other adverse effects?
- Are any of its properties harmful or lethal when combined with other materials (organic or inorganic)?

Answering these questions will suggest additional benefits and risks you were not aware of at the beginning of the process. Clearly, the procedure you follow to answer these general questions can vary widely, depending on the nature of the materials with which you are working. For example, nanospheres and biomotors may require completely different tests for safety, toxicity, and effectiveness based on the properties of each, such as their ability to penetrate or interact with cell membranes. The results of these explorations will begin to be revealed in this phase and the next.

Phase 2: Going Deeper into the Assessment of the Nanomaterial or Process

This phase prompts your work as a researcher to delve deeper into the nature and properties of the nanomaterial. By the beginning of this phase, you will know many of the properties and some of the behaviors of the nanomaterial. The focus on the nanomaterial begins to shift from observing just its unique properties to how this material behaves when combined with other materials or when placed in different environments.

Some of the questions that can arise at this phase are:

- Can you reliably recreate the nanomaterial? What is the chemical make-up? What are the environmental restrictions when creating it?
- Do you require additional tools and equipment to complete your research?
- Can your nanomaterial be mixed or combined with other materials? If so, will the properties of your nanomaterial remain stable in a normal environment, or will they begin to break down or cause degradation in the other materials? Does any combination of materials, environment, or time affect the toxicity or stability of your nanomaterial?
- Can the nanomaterial be mixed with both synthetic materials and organic materials, or just one or the other?
- Does adding color to the nanomaterial change the properties? What property in your subject material causes this change?
- What are the effects of time on your nanomaterial, when it is combined or mixed with something?
- How do environmental conditions affect the mixing or combining of your nanomaterial? Did you use different time durations to mix or combine your nanomaterial under the different conditions?

As you can see from these questions, this phase helps you focus on the possible nanomaterial behaviors. Understanding how your nanomaterial behaves (and under what conditions the behavior changes) is a necessary precursor to exploring how it can be used: the next phase.

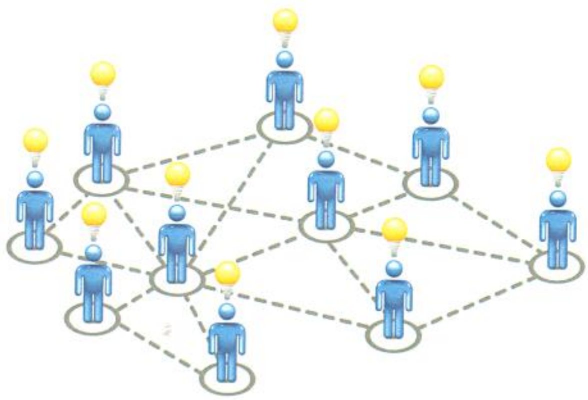


Figure 6.3 As more information is gathered from research, additional team members are added to the project to address the increasing complexity of the project. *See Figure Credits, p. vi.*

Phase 3: Determining the Application and Feasibility of the Nanomaterial

This phase prompts you and your fellow researchers to explore deeper into the unique nature and properties of the nanomaterial you are investigating as a prospective product. Now, you have a better idea of the properties, some of the behaviors, the limitations, and a general idea about how customers might be able to use the nanomaterial and the viability of the nanomaterial as a product.

At this point in the evaluation of the nanomaterial, you should have a pretty good idea as to the toxicity, hazards, and risks, and can begin forming some ideas as to its limitations. As more information about the properties becomes available, the researcher may need to revisit some of the issues that were explored in previous phases in order to create a more complete definition of the properties of the material.

With more information in hand, your research team can now begin thinking more broadly about product development problems and questions:

- Based on the properties, what kinds of products can be produced with this nanomaterial?
- Is there a need for this product? What is it?
- What is the cost and availability of the raw materials required for creating the nanomaterial? Who are the raw material suppliers?
- Are current research, verification, and manufacturing tools sufficient for mass production of the nanomaterial? What modifications are necessary? Is additional research required? How much and for how long?
- What are the limitations to high-volume production? What is the maximum amount of time in a given period that can be spent manufacturing the material while maintaining profitability?
- What is the projected customer base for this product? What production volumes are required to support the customer base? What is the projected return on investment (ROI)? What is the initial investment amount? Are investors available? Will the development of this product be cost effective?
- What are the patent and confidentiality requirements for the development of this nanomaterial, and what are the associated costs?
- What are the health, safety, and regulatory requirements for the manufacturing and marketing of this nanomaterial, and what are the related costs?

With these issues resolved and the financial feasibility approved, the proposed product development is now engaged and various teams such as engineering, marketing, regulatory, and legal can begin collaborating with researchers and lab staff to enable your nanomaterial to progress to the next phase, the resolution of research and manufacturing issues.

Phase 4: Refining the Research and Defining the Manufacturing Methods

With the introduction of key product development issues in Phase 3, the scope of the product investigation expanded to include other departments, such as engineering, marketing, finance, regulatory, and legal for the purpose of assessing the feasibility of the production of the nanomaterial. In Phase 4, you will take an even deeper look at some of the issues addressed earlier.

Figure 6.4 Refining the research and defining the manufacturing methods further verifies all of the information known about the nanomaterial and gathers additional toxicology data. *See Figure Credits, p. vi.*

Risk assessment from an environmental, health, and safety (EHS) perspective is a primary concern in this phase. The research explored in this phase probes deeper into toxicology issues and examines any far-reaching effects not previously explored. Obviously, this is a critical process that must be thoroughly investigated before proceeding to the manufacturing stage.

In some cases, the size and shape of the nanomaterial affects whether it has a toxic effect. Some nanomaterials become toxic when they exceed a certain concentration. During this phase, you may be responsible for coordinating with, reporting to, or following the directives of one or more government agencies for EHS, such as the Environmental Protection Agency (EPA), Food and Drug

Administration (FDA), National Institute of Health (NIH), and the National Institute for Occupational Safety and Health (NIOSH), to name a few. Your reports might include detailed information about the plans for development, control of application, and market introduction of the nanomaterial.

As you explore these issues, you will also bring in the quality assurance department to begin planning and refining manufacturing processes. The quality assurance team may consist of lab researchers, engineers, manufacturing personnel, and any other personnel required to provide feedback on parameters, tolerances, processes, and guidelines as they apply to the manufacturing of the nanomaterial. In this phase, companies will assess their manufacturing processes and equipment to determine production readiness and any equipment and process updates that may be required to accommodate the production of the nanomaterial. During Phase 4 of the technology maturity model, there are numerous interdepartmental dependencies (various schedules, developmental milestone approvals, etc.) to consider—all of them have to be carefully scrutinized and communicated across the various development teams.

In addition, the sales and marketing teams become involved in the planning and shaping of the product and how it will be introduced to the market. Although not as technically-oriented as lab scientists and engineers, the feedback from marketing and sales plays an important role as to how the nanomaterial will be used in the market. It is crucial that scientists and researchers clearly communicate the features, benefits, and risks of a new product to their colleagues in these important departments. They, in turn, are responsible for developing public interest in your new product, resulting in acceptance in the marketplace. In addition, they are responsible for helping customers understand any possible risks in a way that enables them to use the product in a safe and effective manner.

Phase 5: Application Prototype and Product Positioning

In this phase, you firmly establish your customers' product requirements. With that information in hand, you can firmly define the actual product application for your new nanomaterial. The primary activity in Phase 5 is the introduction of the prototype product to focus groups and small regional markets for usability testing and market feedback.

If this Beta testing yields results that fall outside the tolerances and specifications defined in your company's product plan (indicating that the product does not meet manufacturing or marketing requirements), then your teams must perform additional prototyping until you resolve the problems.

Nano Fact

L'Oréal, the largest cosmetics and beauty company in the world, headquartered in the Paris suburb of Clichy, Hauts-de-Seine, France, is the top nanotechnology patent holder in the United States (as of 2010).

While you perform prototype and market testing, the legal, regulatory, and marketing teams continue to work on the patent, safety, environmental, risk assessment, and market aspects. The legal and regulatory teams also work to ensure that your company is in compliance with any governmental regulations that may apply to your new nanomaterial. When your company can demonstrate compliance, communicating the adherence to safety standards and transparency to consumers can also be used as a marketing tool. These qualities can certainly contribute to positive exposure of a new product in an emerging market that few consumers may understand well.

To ensure legal protection for the product, the legal team secures the necessary U.S. and international patents as well as confidentiality agreements with manufacturing vendors, materials suppliers, and various other vendors. Patents, of course, offer your firm some legal recourse should anyone attempt to duplicate your product and sell it as their own. Depending on the specific product uses and whether it will be used internationally, securing international patents provides further protection for your product.

Phase 6: Product Release, Manufacturing Volumes, and Marketing Scope

In Phase 6, the marketing team introduces your new nanomaterial to the market. As with many new products, the first shipments may be on a limited basis to a select group of customers. Sometimes, these first customers are the same test subjects who participated in your focus groups and usability testing during Phase 5.

By this time, patents have been secured or are pending, and all government agency oversight compliances have been satisfied. The marketing has expanded in scope and now your product is being advertised nationally and internationally. Manufacturing volumes are slowly ramping up as the processes become more efficient, and sales orders are beginning to increase. The highest quality is assured, given the careful quality-control practices your company has put into place.

Figure 6.5 With the product release imminent, teams focus on marketing goals and manufacturing scope and prepare for the next phase, product improvements. *See Figure Credits, p. vi.*

Phase 7: Product Recognition and Product Improvements

By the time you reach Phase 7 in the technology maturity model, your nanomaterial has found its place in the marketplace and is recognized and accepted by a growing list of customers. Revenues are increasing, and the sales and marketing teams are refining their goals for better coverage within the available budget.

As a result of quality-assurance practices, the manufacturing process has been streamlined and some materials have been replaced by less expensive materials that perform as well or better than the original materials. Marketing and technical feedback continues to be received by the company. This, in turn, leads to additional product refinements and adjustments. As with the initial product development, all the refinements, streamlining, and technical changes are run through the entire maturity model (Phases 0–7) to ensure adherence to strict product-performance criteria, as well as to all EHS standards.

Section Review

1. After a nanomaterial is discovered or invented, which would be the next phase for exploring its product potential?

2. Toxicity is a primary concern in the potential development of a product. In which phase is this issue resolved? Describe the processes used to ensure the resolution of this issue.

3. What are some of the other major processes that are started in Phase 4 that contribute to the overall progress of the product development? Describe each one.

4. In what phase should you concentrate on resolving critical product defects? In the technology maturity model, what is the process for ensuring that product defects are resolved before moving forward?

Section 2
Global Impact of Nanotechnology

TAKE-HOME MESSAGES

1. Nanotechnology is advancing rapidly—some say faster than information technology/IT—and will continue this pace as long as the benefits continue to prove their value and the risks are managed effectively.
2. Nanotechnology products and applications currently affect almost all areas of our society and the industrialized countries around the world.
3. Nanotechnology is outrunning oversight and regulatory readiness.

POINTS TO PONDER

- Name five industries that use nanotechnology products.
- Nanosilver is used in a variety of products. What are some products that use nanosilver?
- Nanotechnology is already affecting our lives through the products we use. What are some benefits and risks associated with using nanotechnology products?

With the accelerating pace of nanoscience discoveries in recent years, an abundance of nanomaterials have been integrated into a range of products that may be surprising to you and most consumers. The abundance of newly engineered nanomaterials is growing into an impressive list and is now being used in consumer products such as cosmetics, sports equipment, clothing, textiles, and building materials, as well as in agriculture, food, and medicine. While companies that produce products using nanomaterials advocate the benefits, the public has expressed a concern about whether these benefits are worth the risks to health, safety, and the environment. Clear, open communications by all who work in nanotechnology will help to provide customers with the information they need to understand the science and determine for themselves their position on nanotechnology products and issues.

Just as biotechnology and DNA fingerprinting were new to the '90s generation, nanotechnology is still quite unknown to a large portion of the public today. However, many companies, government agencies, and universities all over the world are becoming more vocal in promoting the new products and promise of nanotechnology. News articles, popular books, corporate marketing, and even the label on a new sweater will help raise awareness of the average consumer.

The Current Nanotechnology World

Plato said, "Necessity is the mother of invention." However, seemingly unrelated discoveries in science have also driven the emergence of new technologies, as is often the case in the world of nanoscience. With the advancement of microscopy and imaging methods, scientists and researchers are able to peer more clearly into the nanoscale world, which now enables manipulating matter in ways that were previously impossible. These observations at the nanoscale have yielded discoveries that have provided valuable information about the size and properties of carbon nanotubes, nanospheres, and other nanomaterials. Scientists have discovered that many materials often exhibit a different behavior at the nanoscale than at the macroscale due to the unique properties that exist at the nanoscale. The discovery of these unique properties has led to new methods in which researchers use nanomaterials; these developments have resulted in new applications and products around the world.

Nanoproducts

The number of new products on the market that use nanomaterials is impressive and growing rapidly. These products span numerous industries, markets, and applications such as consumer products, agriculture and food, building materials, energy-related applications, and medicine. For example, nanosilver, which has antibacterial properties, is commonly used in particle sizes that range under 50 nanometers (nm) in diameter. Today, nanosilver is found in a diverse range of products, including some of the products shown in the following tables.

Food
Food containers
Cutting boards
Milk bottles (for babies)
Emulsifiers in foods (to prolong shelf life)

Health
Colloidal silver for internal ingestion (antibacterial and supplements)
Disinfectants
Air filters
Swimming pool algaecides
Nasal sprays
Bandages for wounds
Topical wound treatments (liquids, gels)
Medical equipment (knee braces, slings, braces, sleeves)
Hair and scalp treatments
Toothpastes
Coatings for medical equipment
Shampoos and conditioners
Soaps and hand sanitizers
Water treatment

Consumer Products
Fabric softeners
Sheets and bedding
Bath and sports towels
Clothing (shirts, pants, underwear, socks, hats)
Babies pacifiers and chew toys
Kitchenware (glasses, cups, dishes, utensils)
Appliances (refrigerators, washing machines, vacuum cleaners)
Cosmetics (face creams, hair gels, hairsprays)
Scent-elimination for hunters
Hair-styling equipment (hair dryers, curling irons, brushes)
Plastic surfaces manufactured with nanosilver (computer keyboard, mouse, mobile phone)
Home-cleaning tools
Handrails (staircases, elevators)
Detergents
Plastic storage bags

Figure 6.6 Some nanoproducts currently on the market.

Medical Nanomaterials and Processes

The healthcare profession has been using nanomaterials and related processes for a few years, and like other industries, the number of medical applications using nanomaterials is expanding. Some of the applications in which nanomaterials are used and being developed include appetite control, bone replacement, cancer and disease diagnostics, chemical substitutes, cholesterol diagnostics, diagnostic tests, drug development, hormone therapy, imaging, immunosuppressants, and medical tools.

Nanoparticle-based drug-delivery systems are being researched for the potential treatments of cancer and other diseases and are utilizing the unique properties of nanospheres, nanoshells, and other nanostructures. These drug-delivery methods often use nanostructures, usually with a biologically inert gold coating, covered with a drug material that is activated or released when illuminated by a specified frequency of light. Sometimes just the particle itself is used to fight disease. A similar method using nanostructures of gold and other materials is also used for diagnostic purposes using fluorescent dyes and a light source to track the nanostructure in an organism.

Figure 6.7 A scanning electron microscope (SEM) image of a silver nanoparticle wound dressing made of nylon fabric (white) and an activated charcoal cloth impregnated with silver (black).
See Figure Credits, p. vi.

Food and Agriculture

Food, one the basic components required to sustain human life, is a subject that elicits interest in almost everyone, from perspectives of food as a basic for survival to the luxury of gourmet cuisine. Regardless of how various cross-sections of societies obtain and prepare food, most of us rely on the processes of agriculture, food-processing and shipping, and markets to obtain the food we eat every day. The influences of nanotechnology on these areas are becoming more prominent and will accelerate and become more prolific as research and manufacturing advance. Because of the importance of food, food and agribusiness concerns are at the forefront of commercializing nanotechnology innovations, and their successes or failures could affect future commercialization of nanotechnology products in all industries.

While the current uses of nanotechnology in foods and agriculture are still quite small, we have learned from the introduction of biotechnology and the creation of genetically modified organisms (GMOs) that the discoveries made in bioscience have led to a rapid expansion of applications used in agriculture and food production. However, in addition to the many benefits promised by the companies promoting biotechnology, these advances have also presented concerns about health, safety, and the environment, which are similar to the concerns with nanotechnology and will be discussed later in this section.

One of the less controversial applications being considered is the use of extremely sensitive devices that can monitor how water flows through farmlands. Further developments from this research could provide ways to stop runoff from crops or to prevent livestock from polluting nearby water systems. The prospect of using nanomaterials to convert leftover crop materials (leaves, stalks, corncobs) into ethanol for fuel is an idea that could be a model for considering other bio-applications for energy-related uses. Corn stalks and other agricultural refuse are also being used to create polymer fibers for pillow and bed linens that do not require oil products.

Nano Fact

Representatives of the Project on Emerging Nanotechnologies in the U.S. stated that when focus groups are asked the question, "How can the public be reassured about the development of nanotechnolgies?", they always responded with "transparency" as the most important factor.

Nano Fact

According to the Project on Emerging Nanotechnologies (PEN), in March, 2009, health and fitness items continued to dominate the PEN inventory of nano-based products, representing 60 percent of those listed. More products are based on nanoscale silver—used for its antimicrobial properties—than any other nanomaterial; 259 products (26 percent of the inventory) use silver nanoparticles. The updated inventory represents products from over 24 countries, including the U.S., China, Canada, and Germany.

Improving Life: The Benefits of Nanotechnology

Aside from the very promising potential of the development of nanotechnology applications in medicine, food, and agriculture, nanoscience research has generated many other applications in other industries. The table in Figure 6.6 shows a broad scope of nanotechnology applications and clearly illustrates the large number of uses of nanosilver across a wide variety of industries. The important common characteristic among the various uses of nanosilver is its antibacterial property. The efficacy and reliability of this nanomaterial is, in part, responsible for its broad uses and applications.

Water Purification

Potential applications for restoring the environment are actively being researched, and a fascinating array of products is already in use. Without question, water purity is key to human survival. As shocking as it sounds, in many developing countries it is common for arsenic to be found in drinking water. The short-term effects of arsenic exposure from drinking water can cause thickening and discoloration of the skin, stomach pain, nausea, and diarrhea, and long-term exposure can lead to cancer of the lungs, skin, kidney, liver, and prostate. However, by using magnetic nanorust, arsenic can be removed from drinking water at a cost that is affordable for the poorest communities. The large surface area of nanorust enables it to collect 100 times more arsenic than microscale and macroscale counterparts.

Nanofiltration is another area of water purification currently being investigated. Researchers are developing new nanomaterials for filtration with improved permeability restrictions that are more effective than conventional filters in how they are able to limit the passage of smaller sizes of particles. These new filtration membranes have proven to be effective in producing safe drinking water from brackish groundwater. Another water-purification method combines reverse osmosis with a uniquely cross-linked matrix of polymers and engineered nanoparticles that attract water ions but repel nearly all contaminants. The new membranes are structured in such a way as to create molecular tunnels through which water flows more easily than the contaminants (see Chapter 3, Section 2: A Closer Look at Fluidics). This requires less energy to pump water through the membranes, and because of the nanofluidic properties of the membrane, contaminant particles are repelled, resulting in a slower fouling of the membrane and in less maintenance and longer use.

Energy: The Influence of Nanotechnology

Currently, coal, oil, and natural gas are the mainstays of production and consumption in the world energy markets. The well-established infrastructures of these technologies and the seeming abundance of these fuels make it profitable to supply these fuels to the public. This energy system is still our primary choice for energy usage. However, these variables and world conditions are changing rapidly, thereby causing an urgency to find new methods and sources that will provide clean, reliable, and affordable energy to an expanding population with ever-expanding energy needs.

Nanotechnology, in its infancy, has already shown great promise with many of the products and applications recently developed in the energy related industries and in current research. With the growing understanding of carbon nanotubes, research is leading to applications in which the reduction in weight and increased structural strength of materials are rapidly being improved. These improvements enable reduced fuel consumption while ensuring structural improvements that result in maintaining operational safety. Some of these properties are being explored in new airplane designs and other material uses that require lighter weight and increased strength. These improvements to existing materials and systems are the initial steps that will eventually lead to larger and more dynamic shifts in energy production and usage as the legacy infrastructures of our current energy systems begin to evolve at an accelerated pace. The awareness of the dependence on fossil fuels, the negative environmental effects of using them, and the fact that the supply of these fossil fuels is limited are accelerating the quest for alternative energy sources and better use of available energy.

A report published a few years ago from a London research group made the following assertions about how nanotechnologies can contribute to sustainable energy markets:

- A major near-future benefit from nanotechnology will occur as a result from weight-reduction in materials used in the auto and aerospace industries.
- Nanomaterials will make better use of existing energy resources instead of simply generating new forms of renewable energy.

Current applications of nanotechnologies could result in a global annual saving of approximately one million tons of carbon dioxide by 2014. As other sources of energy such as wind, solar, and geothermal are being explored and refined, advances in nanotechnologies are also providing improvements to these non-fossil fuel energy sources. For solar energy systems, researchers and engineers are creating improvements to solar panel materials and manufacturing that result in increased efficiencies in both cost and energy production. One of the primary problems with solar cells is related to the high cost of materials such as crystalline silicon, the best performing material in photovoltaic (PV) cells today. The use of nanowires and other nanomaterials combined with streamlined manufacturing processes for creating less expensive solar cells is being explored. The first versions of these new solar cells are not as efficient as the silicon-based versions, but the low cost of materials and manufacturing offset this disadvantage. With refinements to these nanomaterials and manufacturing processes and advances being made with other possible nanomaterials, solar cell use is expected to increase rapidly.

The widespread use of batteries across many applications presents another way nanotechnology can improve the way we use energy. Storage capacity, lifespan, weight, and safety are a few of the properties that are improved by current advances in nanotechnology. Nanoporous materials can facilitate increased speed in the discharge of battery electrodes, carbon nanotubes can improve the conductivity, and ceramic nanoparticles can improve the possible operating temperatures, thereby improving safety and reliability. The property of increased surface area provided by nanomaterials is enabling batteries to supply energy for longer periods using the same amount of electrode material. Hand-held applications

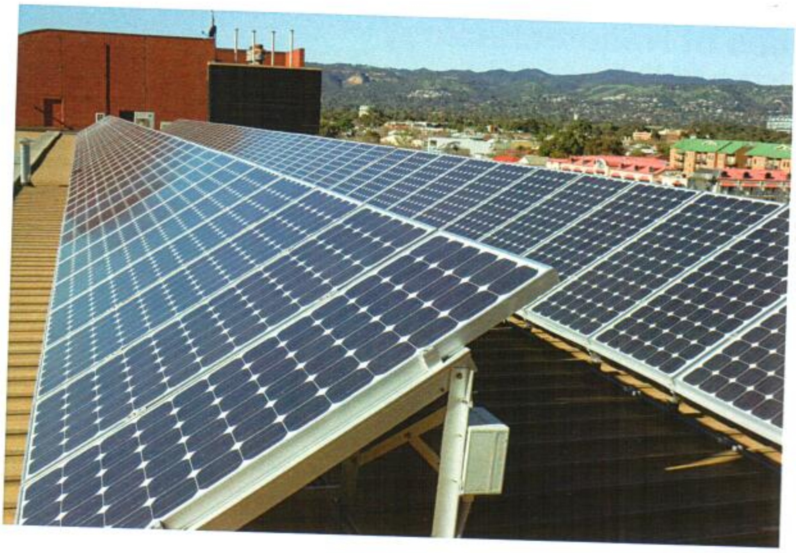


Figure 6.8 Advances in the construction and materials of solar cells are resulting in efficiencies in the sunlight-to-energy conversion process. *See Figure Credits, p. vi.*

using batteries such as cell phones, MP3 players, and power tools are continuously being updated with longer-lasting battery life, while continuing to become smaller. Safety (overheating and possible explosions) has been the primary factor limiting the use of lithium-ion batteries as an application for powering electric vehicles. Now though, a battery company working with a leading university has developed low-impedance electrode technology using lithium iron phosphate nanoparticles to create battery components that yield higher voltage and extended battery life, thereby increasing the travel range of a car while providing a safer battery.

Information Technology

The ongoing progression of miniaturization of electronic components has been the trend in the electronics industry since the 1960s, when Gordon Moore (co-founder of Intel) predicted the rate at which the number of transistors placed on an integrated circuit would double approximately every two years. Since about the year 2000, feature sizes in microchips have dropped below 100 nm, and the future of information technology is highly dependent on our ability to fabricate and integrate components at scales well below 100 nm. In order for Moore's law to be sustainable, novel approaches to nanofabrication must be continuously developed for industrial applications. The resulting increase in our ability to store, process, and communicate information at increasing levels of complexity continues to provide new challenges and opportunities in nearly all aspects of life.

The Possibilities of Nanotechnology

With a myriad of nanoproducts entering the marketplace and nanoscience research continuing to gain momentum, discoveries of new nanomaterials and new applications of known nanomaterials are sure to perpetuate the emerging technologies of nanoscale-based products. At the backbone of this movement is the research community making contributions from universities, corporations, and government agencies around the world.

Research: Tools and Practices

In addition to research providing an environment for new discoveries, many believe more research is needed to make refinements to current nanoproducts and nanomaterials and to initiate studies for understanding the long-term toxicology effects of nanomaterials in health and the environment. However, the potential for research advances is highly dependent on continued advances in metrology, microscopy, and imaging tools.

Figure 6.9 An atomic force microscope (AFM) probes the surface of a material to create a three-dimensional image down to the scale of an atom. *See Figure Credits, p. vi.*

Scientific research continues to be a driving force in the development of better imaging tools, as well as measurement devices and methods. One of the fundamental approaches that researchers use to establish the results of their studies is to apply some straightforward logic to the systems being studied. The basic approach to any measurement or test system is comprised of three segments:

- What is initially present in the system (the input or existing energy and materials)?
- What is being added to the system (the sample or entity to be tested)?
- What is the result in the system (the output or resulting data)?

Figure 6.10 The relationship between three segments of research data: input, output, and the sample. If you know, with a high degree of accuracy, the information in two of the segments, a lot can be determined about the third.

Typically, when researchers know enough about two out of three of these segments, they can infer a lot of information about the third segment. For example, with a well-known sample and accurate test results, researchers can determine a fair amount of information about the input or initial conditions of the system. Consider this scenario: a team of geologists with a sample of rock and output measurements. By knowing a lot of information about the sample rock and having a considerable amount of test results for the rock, they can carefully assess these two segments of information and can infer what some of the initial conditions must have been, such as pressure, age, and weathering.

Alternatively, if a significant amount of information is known about the input and the output is accurately measured, then a considerable amount of information about the sample (which may be previously unknown) can be determined. This is often the case with nanoscale research. Nanoscale tools are used to determine, as accurately as possible, the input conditions and the output results or measurements. Then, the unknown sample can be characterized. New nanotechnology devices may utilize this methodology. Devices or sensors with a known initial state and expected resulting states could quickly characterize a sample.

Much of the complexity of nanoscience research is due to the need for extremely accurate measurement tools and technology. Smaller, finer, and more accurate measurement tools for research and testing will continue to be a direct application of nanotechnology.

Job Markets and Nanotechnology

As of 2010, a website that exclusively advertises jobs in the nanotechnology field listed jobs under the following categories: dendrimers, fullerenes, MEMS, microarrays, microfabrication, microfluidics, nanobelts, nanobiotechnology, nanocapsules, nanocoatings, nanocrystalline materials, nanodevices, nanoelectronics, nanofabrication, nanofibers, nanofluidic systems, nanomagnetics, nanooptics, nanopackaging, nanoparticles, nanophotonics, nanoporous materials, nanosprings, nanotools and instruments, nanotubes and related structures, nanowires, NEMs, quantum dots, and spintronics. This listing is just the nanotechnology job categories from one website among many from the private sector. When government funding increases to meet the required support for oversight and regulatory management, nanotechnology employment opportunities may increase to meet these needs, causing the private sector to respond to this signal, further increasing the product development momentum. By the year 2015, an estimated 2 million

Nano Fact

In the Consumer Products Inventory (in the database of the Project for Emerging Nanotechnologies) there are currently 1015 products, produced by 485 companies, located in 24 countries.

workers from around the world will be needed in nanotechnology industries. As some traditional jobs may disappear as the result of emerging nano applications, jobs directly related to nanotechnology industries may compensate with new job fields and positions.

Section Review

1. What are the three logic components commonly used in a basic measurement or test system that enable the researcher to infer information when only two components are available? Give an example.

2. Name an application in the energy field that can be used now to reduce energy consumption.

3. Name five areas of nanotechnology in which job markets are expanding.

Section 3
Social Issues and Opportunities

TAKE-HOME MESSAGES

1. Technological advances can profoundly change society.
2. Public awareness and involvement in emerging technologies can have a positive effect on their development and acceptance.
3. Many of the properties and characteristics of nanoparticles are still unknown; so it is challenging to determine whether they are hazardous.

POINTS TO PONDER

- What's the difference between hazard and risk?
- What would be adequate labeling for products that include nanomaterials?
- How could nanoparticles help to remove toxins from our environment?

Nanotechnology will undoubtedly change our lives; it is already influencing what we study, what we buy, and the work we do. Indeed, the most significant advances in technology bring about change on a societal level. The amount of government funding for education, and research and development in nanotechnology reflects its current and potential impact on the economy, in the U.S. and globally. If we strive for sustainable development, development that meets our current needs as well as secures the ability of future generations to meet their needs, we must consider the intersection between the socio-economic and environmental impacts of nanotechnology.

With all the extraordinary properties and possible applications of nanomaterials comes the challenge of understanding all the effects they may have on our bodies and our environment. There is still a lot to learn about nanoscale interactions and nanomaterials; more research is needed. The potential benefits of nanotechnology bring with them yet-unknown risks. Each unique material in each unique application poses its own set of risks as well as benefits. As with most areas of technology at the nanoscale, new methods must be developed in the area of toxicology in order to be successful in accurately determining and mitigating the risks of nanotechnology.

Public Awareness

Public awareness is a fundamental aspect of the evolution of technology, because public perception determines to some extent the acceptance or rejection of that technology. It also influences regulation and funding for research and development. Despite the ever increasing number of dollars spent on research (currently in the billions) and nanoproducts on the market (three to four new products every week), a national survey among adults reports that only 31% say they have some awareness of nanotechnology, while 37% say they have not heard anything at all about it.

> There have been only minor shifts in awareness of nanotechnology over the past four years. Today, three in ten Americans say they have heard a lot or some about nanotechnology—the same proportion measured in 2006. (Hart Research Associates for Project on Emerging Nanotechnology, 2009)

Technology that develops and becomes prevalent without public awareness can cause social upset and potentially the rejection of that technology. When consumers find out that technological advancements have been applied in areas that impact human and environmental health and safety without their knowledge, they feel tricked (such as with Genetically Modified Organism, or GMO, foods). People like to know what they are buying so they can make informed decisions. There is a need for companies developing new technologies to build the public's trust. People want companies to be honest about what they know and to be committed to finding out more. Polls reveal that people want disclosure and transparency from the nanotechnology industry as well as premarket testing by third-party labs.

Figure 6.11 How much do you know about nanotechnology? In 2009, only 3% of adults surveyed said they know a lot about nanotechnology. *See Figure Credits, p. vi.*

> Nothing seems to be more prominent about human life than its wanting to understand all and put everything together. (Buckminster Fuller, 1969)

Some experts argue that to avoid public suspicion and the perception of a threat, the public must be engaged in decisions that affect their environment. They believe scientists should bring research out into the open, communicate their findings, and have the support of the government and their peers. People may not realize that much of the nanotechnology research is actually publicly available in peer-reviewed journals.

There are always sectors of the public who care to know only a little bit about new technology, and who will often adopt the technology despite having no interest or understanding little about it. With so many U.S. tax dollars going to nanoscience and nanotechnology programs (education, research and development, and oversight), it stands to reason that the taxpayers should be informed about nanotechnology, if for no other reason than to be effective in guiding how their tax dollars are spent. With all the complexities and unknowns at the nanoscale, consider how much a member of the public might need to understand about nanoscience and nanotechnology to be a discerning voter. The complexity of nanoscience should be understood, yet remains a challenge for many. There is a need for reliable information to reach the public.

How does someone find out about nanotechnology? Certainly the media is one place to start. Many universities and research institutions working in nanotechnology also have public outreach programs in their communities. In addition, various organizations and agencies are making nanotechnology information, educational materials, and news available to the public via their websites:

- The National Nanotechnology Initiative (NNI) has FAQs and brochures with basic information about nanotechnology for the general public. They also have the Nanotechnology Public Engagement and Communication (NPEC) Working Group, which is actively involved with the public. (www.nano.gov)
- The U.S. Food and Drug Administration has information on the products they regulate as well as their Nanotechnology Task Force. (www.fda.gov)
- The National Science Foundation (NSF) funds the National Science Digital Library (NSDL) and the National Center for Learning and Teaching (NCLT) in nanoscale science and engineering. (www.nsdl.org and www.nclt.us)
- The Project on Emerging Nanotechnologies (PEN) created and maintains an online inventory of manufacturer-identified nanotechnology-based products that are currently on the market. (www.nanotechproject.org)
- The Center for Biological and Environmental Nanotechnology (CBEN) has an educational outreach program that works with high school teachers and students. (www.cben.rice.edu)

Quick Activity

Share a Nano Fact

1. Nanotechnology is such a vast subject; we still have a lot to learn. Go to one of the online resources listed on the previous page and discover something new about nanotechnology that has not already been discussed in this course.

2. Notice how much time it takes you to find this "Nano Fact." Share your Nano Fact with your class, your group, or your instructor. Tell them why you find this new information interesting and how you found it.

3. Spread the word; take this Nano Fact home and share it with your family and friends.

Education

Government funding for education in nanoscale science, engineering, and technology continues to expand in hopes of cultivating the next generation of technicians, researchers, and inventors in the field. In 2009, the NSF contributed approximately $28.8 million dollars to nano-specific educational programs. Next-generation contributors will need a solid foundational education as well as specialized skills in nanotechnology. They will depend also on state-of-the-art research and development facilities and equipment for their work.

> Educational programs continue to be developed with NNI support for all levels, including K-12 schools, community colleges, vocational schools, and major research universities. Building on this foundation, additional measures are needed to develop and maintain a skilled nanotechnology workforce. (National Nanotechnology Initiative, 2009)

Although changes to the education system happen slowly, education reform continues to be necessary for the U.S. to maintain its leadership status in the international arena of science, technology, and engineering. Again, nanotechnology brings additional complexities, as it is often necessary to be knowledgeable in multiple disciplines, such as physics, chemistry, and biology, to be successful in nanotechnology. Multidisciplinary teams are emerging around nanoscience research and development, which requires greater cooperation and sharing between specialists. Such teams are forming in the education system as well, where specialized teachers are working together to develop and teach new nanoscience curricula. Having begun at the university level, nanoscience education is expanding quickly to more schools and younger students.

Risk Assessment

Everyone faces risks; many common activities (eating, driving, working, and playing) inherently have some possibility of harm or danger to our lives. As we learn more about ourselves and our world, we recognize that some things pose a greater chance of injury or death, and we naturally make choices to avoid these situations. At the same time, we become comfortable with a certain amount of risk when we find great benefit, an improved quality of life, in the way we choose to live, work, and play. As we strive to understand the potential payoffs and dangers of nanotechnology, we look to those with a greater understanding of the technology, the experts, to guide us in reaping benefits while avoiding potentially hazardous situations.

The benefits of nanotechnology are often easy for us to grasp as nanoparticles are applied as solutions to a myriad of problems. Section 2 of this chapter discusses wide-reaching examples of beneficial nano-applications, such as locating and destroying cancer cells with nanogold, targeted drug delivery, stronger and lighter materials requiring fewer resources, and more efficient solar panels.

When scientific research or new discoveries produce new nanomaterials that are considered potential products, continued research is usually inspired by the potential benefits that the market-ready nanomaterial may provide, as well as the ability to compete in the marketplace and eventually yield profits (see Chapter 6, Section 1, The Technology Maturity Model). Equally important in the early phases of new nanomaterial analysis, research, and product planning is the awareness of the potential risks that the nanomaterial may present to health, environment, and overall safety. In other words, what are the known and unknown nanomaterial properties that could pose a problem to consumers and the environment? Some questions being asked are:

- Which physicochemical characteristics of nanoparticles are associated with adverse effects? Some of these characteristics are size, chemistry, crystallinity, biopersistence (ability of a material to remain in the body despite the physiological clearance mechanisms to eliminate the material), surface coating, porosity, and charge.
- Is cellular uptake (process by which a material enters a cell) involved? If so, what are the uptake and translocation (transport within an organism, especially across a cell membrane) mechanisms?
- What should be considered when designing biocompatible nanosized materials? What would make a toxic nanoparticle biocompatible?

There are still many questions about the risk involved with the pervasive use of nanomaterials. According to experts, there is no risk without exposure. Risk is a combination of how hazardous or toxic something is and the degree to which people are (or a system is) exposed to it. So in risk assessment there are always two considerations:

- To determine if something is hazardous
- To determine the source and extent of potential exposure

It is widely agreed that much more research is needed to determine the key physical and chemical characteristics of nanoparticles and accurately assess if they are hazardous or toxic. The possible modes of exposure (air/breath, water/skin, and soil/ingestion) and the quantities to which a biological system is exposed are key factors in determining the potential toxicity of a nanoparticle. Risk assessment of nanomaterials is dominated by complexity, as well as uncertainty and ambiguity in current scientific knowledge.

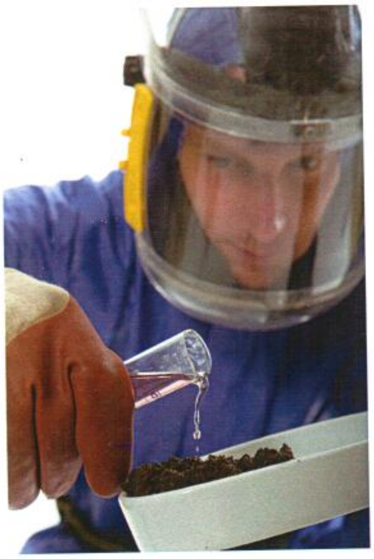
Many toxicologists believe that the same special, beneficial properties of nanomaterials also enhance risk concerns. For example, higher surface area to volume ratio makes nanoparticles more reactive and can vastly improve the performance of solar cells, but could also be potentially harmful to your body or to fish or microorganisms.

Public Health and Safety

The health and safety of people is of utmost concern. We can easily identify two main categories of people who have the most exposure to nanomaterials: workers in nanotechnology industries and consumers of nanoproducts.

Workers

Since 2005, the U.S. National Institute for Occupational Safety and Health (NIOSH) has offered recommendations for the safe handling of nanomaterials in the workplace. NIOSH identifies several potential health concerns for workers in nanotechnology, including the potential for nanomaterials to enter the body via the respiratory system, the skin, or by ingestion. As with any potentially hazardous material, safety precautions can and should be taken to prevent such exposure.



There are currently no national or international consensus standards on measurement techniques for nanomaterials in the workplace. (NIOSH, 2009)

Manufacturing processes will require additional scrutiny when they include ultrafine and engineered nanoparticles, because of the challenges in detecting and measuring nanomaterials. It is impossible to predict all the workplace scenarios in which workers could be

Figure 6.12 Workers in nanotechnology environments wear protective gear to reduce the yet-unknown risk of exposure to nanoparticles. *See Figure Credits, p. vi.*

exposed to nanomaterials, but authorities at NIOSH have identified job-related factors with increased potential for exposure, including:

- Working with nanomaterials in liquid media without adequate protection (gloves) or during operations including pouring, mixing, and a high degree of agitation
- Handling (weighing, blending, spraying) powders of nanostructure materials
- Cleaning up spills or waste material
- Cleaning dust-collection systems used to collect nanoparticles
- Machining, sanding, drilling of nanomaterials or processes that lead to nanoparticles being dispersed as an aerosol

Risk-management programs can help minimize the potential for workers to be exposed to nanoparticles. While the implementation of such programs will vary greatly across industries, risk management is based on common objectives, such as:

- Using available data to evaluate the hazards posed by nanomaterials
- Determining the potential for exposure for individual job tasks
- Providing workers with safety training for nanomaterials
- Installing and evaluating engineering controls (such as exhaust ventilation) where exposure to nanomaterials might occur
- Determining the need for and providing personal protective gear (clothing, gloves, respirators)
- Evaluating that control measures are working properly

Many people believe that the amount of National Nanotechnology Initiative (NNI) funding spent on health and safety is both inadequate and grossly disproportionate to the amount spent on developing the applications of nanotechnology. Nevertheless, government and industry are striving to research and address the safety concerns of manufacturers and handlers. There is a real need for new materials safety data sheets (MSDS) to be written for nanoscale materials; however, that is again dependent on our ability to accurately identify the unique properties and characteristics of these materials.

Consumers

Consumers of nanoproducts also have an increased exposure to nanomaterials. The Project on Emerging Nanotechnology (PEN) maintains the most comprehensive public inventory of manufacturer-identified nanoproducts on the market. The list has nearly doubled in size since it was created in 2006, and now exceeds one thousand nano-based consumer products. However, not all manufacturers choose to identify or label their nanotechnology products as such, and the actual number of nanoproducts on the market is probably much larger.

As discussed earlier in this chapter, the antibacterial property of nanosilver has resulted in a rapid and widespread adaptation of this nanomaterial, and it is used in a very diverse range of applications that are now integrated into our society. Depending on the nanomaterial and intended use, many new nanomaterials are not tested prior to the introduction of a product into consumer markets or industries. For example, currently, cosmetics are not required to participate in any required oversight safety reviews. In contrast, drugs are required to participate in a comprehensive safety review, and other nanoproducts fall in between these two extremes.

Nanoproducts containing silver can be in the form of silver ions, silver colloid solutions, or silver nanoparticles. Nanosilver is available in different shapes, can have different electrical charges, can be combined with other materials, and can be coated in different ways. Each of these factors, as well as others, affects toxicity and environmental behavior. A property of a nanoparticle that appears as a benefit could also be a hazard. For example, the ability of some nanoparticles to cross the blood-brain barrier is advantageous for delivering drugs to the brain (an organ that is difficult to access), but this same ability also illuminates the possibilities of toxicity concerns in situations where this effect is not wanted.

Nano Fact

Nearly one third of nanosilver products on the market in September, 2007 had the potential to disperse silver or silver nanoparticles into the environment. Few methodologies exist for routine environmental surveillance of nanomaterials, including nanosilver. As of 2007, there were no examples of adverse effects from nanosilver technologies occurring in the environment. Because of the rapid growth of products containing silver nanoparticles, environmental surveillance is critical to future risk-management strategies.

Because the use of nanosilver is relatively new and is part of an emerging technology, very few comprehensive studies have been completed, and an in-depth knowledge of the effects of the properties and possible impacts to health, environment, and safety is lacking. However, the broad presence of nanosilver in the marketplace and the lack of monitoring, oversight, and regulatory participation are not unique when looking at the introduction of other nanomaterials, with nanoparticle drugs being the exception. Clearly, oversight and regulation are some of the most important challenges facing nanotechnology, along with acceptance in the consumer marketplace and across industries.

There are currently no laws or regulations that require manufacturers to tell consumers if their products contain nanomaterials. Companies may be reluctant to disclose the presence of or claim the benefits of nanomaterials in their products due to regulatory uncertainty or potential fines (if beneficial claims are unsubstantiated). Some experts suggest consumer product labeling should be required for nanoproducts. While so many questions remain as to the potential risks of nanomaterials, it may be prudent to inform consumers when products contain nanomaterials. However, there are also many questions as to how to create meaningful consumer labels that will not have a negative impact.

Environmental Health and Safety

Around the world, scientists and engineers are working to find ways to use nanotechnology to improve our quality of life and ease our impact on the planet. They are developing and researching nanomaterials that could provide safe and cost-effective methods of harnessing renewable energy and removing pollutants and toxins from our air, water, and soil. At the same time, other researchers are working to determine if existing nanomaterials, in various forms, are toxic to the environment. Some research has found that exposure to certain nanomaterials has harmful effects to animals and vital microbes in our ecosystems.

Figure 6.13 Nanoscale metrology has a crucial role in characterizing nanoparticles with the highest degree of accuracy and reliability. *See Figure Credits, p. vi.*

Clearly defining the properties and characteristics of nanoscale materials is a primary challenge for nanotechnology scientists. We also need to become much better at detecting and measuring nanomaterials. How can we determine if something is toxic, if the fundamental properties of it are unknown to us? Does it behave vastly differently from the materials that we are familiar with? Can we accurately detect how much of it is present in a system? In addition to improved metrology methods, much more toxicology research is needed in order to understand whether nanoparticles are hazardous.

Current research shows that the specific configurations of nanoparticles matter a great deal in how they behave in a system. The size, shape, surface chemistry, composition, coating, and concentration of nanoparticles affect whether they are toxic. Furthermore, their effects on systems vary greatly depending on the system (microbe, worm, fish, rat), the method of exposure (inhaled from air, ingested or absorbed through the skin via water or soil), and the amount of exposure. Research indicates that there is often a threshold amount of exposure to nanoparticles that, once exceeded, has a toxic effect.

As nanoproducts are developed, it is necessary to consider the entire manufacturing process as well as the life cycle of the product to begin to assess the potential environmental impact. For example, nanosilver can kill bacteria in socks, but eventually the nanoparticles may get into soil or the water supply and kill helpful bacteria.

There is concern that not enough money is being spent on Environmental Health and Safety (EHS) research. Approximately 5% of National Nanotechnology Initiative (NNI) 2010 funding in nanotechnology is budgeted for EHS research. Some experts argue that no amount of money spent on EHS research would be enough to address all the innovations. They suggest that a global plan should be conceived and implemented to coordinate international research efforts in order to use all the resources that are dedicated to EHS in the most efficient way possible. Furthermore, since good research strategies are based on the foundational knowledge of a science, strategies in nanotechnology research must be continuously revised as new knowledge is acquired.

Nano Fact

The total NNI EHS budget planned for 2010 is \$87.7 million, or 5% of the total NNI budget of \$1.6 billion. This is an increase of approximately 23% from 2009 and more than double the \$35 million dedicated to EHS research in 2005.

Section Review

1. Why is public awareness important to technological evolution?
2. What two factors are essential to risk assessment?
3. What two segments of the population have the most exposure to nanomaterials?
4. Name three elements of a risk management system.
5. Name three characteristics of nanoparticles that impact whether they are safe or toxic to a system.
6. What nanomaterial is used across a wide spectrum of applications and industries, and what is the property that enables it to be used so diversely? Name five different industries in which these applications are marketed, and name an application for each industry.

Section 4
Nanobusiness Regulation

TAKE-HOME MESSAGES

1. Most of the nanoproducts on the market today are considered to be passive types of products.
2. Registered patents are one way that companies can protect their intellectual property.
3. The government regulatory agencies that oversee nanotechnology products, substances, and wastes are the CPSC, FDA, and EPA.

POINTS TO PONDER

- What nanoproducts or product ideas are classified as passive, active, or hybrid?
- How could manufacturers share important information about their nanoproducts without giving away company secrets to competitors?
- How might the current regulatory system be changed to better address the challenges presented by nanotechnology?

With more than a thousand nanoproducts already on the market around the world, the business of nanotechnology is thriving. In years to come, many experts predict the industry will have unprecedented growth due to its far-reaching applications. Nanobusiness companies range from established technology firms that are adapting current products with nanotechnology innovations to start-ups forging new territory.

The nanotechnology foundations, institutes, and agencies formed by the government serve a variety of functions. Some of these include funding, promoting, and encouraging the economic development of and serving as a watchdog or monitor for this emerging technology. These organizations play a pivotal role in the introduction and growth of nanotechnology applications in society as well as the future. Many factors come together to make the oversight of nanoproducts and nanotechnology a real challenge for existing agencies. The emergence of nanotechnology may force the government to not only increase agency budgets, but change the entire system of regulation.

Nanobusinesses of Today and Tomorrow

All over the U.S., 30–40% of all large and mid-size companies are manufacturing nanomaterials. Many of these are established companies that are successfully incorporating nanotechnology innovations into their existing products. For example, HP has successfully engineered nanoparticles for their toner, which increases the efficiency and accuracy of their printing equipment. There are also many start-up companies in the arena of nanotechnology. These new companies are often founded by innovators who see an opportunity to create something radically new from an emerging technology or who hope to fulfill a need and assist in the emergence of the technology.

Manufacturers' products include:

- Semiconductors, nanowires, lithography and print materials
- Nanostructured particulates and nanotubes
- Coatings, paints, thin films, and nanoparticles
- Precision materials, manipulation tools and devices for enhanced manufactured goods
- Equipment and sub-components such as defense and protection gear
- Telecommunications, displays, and optoelectronics
- Nanobiotechnology and nanomedicine applications, and energy products

Successful companies point to collaboration as essential to their success, which is not surprising given the multidisciplinary nature of nanotechnology. A survey by the National Center for Manufacturing Sciences (NCMS) reveals that more than 75% of companies engage outside collaboration with the goal of gaining access to global markets, new technology, and capital equipment.

Business analysts are advising companies to grow their base of support with the public and the government funders by focusing on nanotechnology applications aligned with national concerns, such as improved information technologies, energy resources, environmental protection, and pharmaceuticals.

Generations of Products

Experts point to future developments and uses of nanotechnology that are increasingly sophisticated and lead to materials and products that behave in different ways according to how they are used. Many experts discuss the types of current and emerging nanoproducts in terms of generations or phases of technological development. Most experts agree on three generations, or developmental types, of nanoproducts: passive, active, and hybrid. Of course, people have different names for these types and some break them into smaller categories, but these are the basics. While third-generation hybrids are somewhat dependent on the fruition of passive and active types, scientists are striving toward all three types of nanoproducts. Often it is in the pursuit of the most complex advancements that the necessary primary structures are created, discovered, or innovated.

Almost all of the current applications and uses of nanotechnology belong to the first generation, passive nanomaterials. In this category, nanomaterials with unchanging behaviors are combined with some other material to add functionality or value. Examples of passive nanoproducts are CNT-fortified tennis rackets and nanosilver socks. It can be said too that our current societal framework (the scientific, industrial, consumer, and regulatory communities as well as existing infrastructure) best supports passive products.

The second generation, active nanostructures, includes nanoscale structures that have the capacity to change their behavior in response to stimulus. Research from the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies (PEN) suggests that the following categories of active nanostructures are emerging from current research: remotely activated, environmentally responsive, miniaturized, uncommon combinations, and transforming. Researchers at PEN note that active nanostructure prototypes often fall into more than one of these categories, which makes more complex and dynamic innovations.

The third generation, hybrid technologies, will introduce complex and innovative nanosystems that are predicted to be the result of merging nanotechnology with other technologies, such as biotechnology, information technology, and robotics.

Business Considerations

Among the issues that companies need to consider when manufacturing nanoproducts is the question of how much information to share about their work and how much to keep under lock and key. Companies need to introduce and market their nanoproducts much the same way they do all their products, but with this emerging technology they must also determine how much product information will satisfy both consumers and regulators.

Intellectual Property and Patents

Individuals and companies can legally own their new creative ideas; this is called intellectual property (IP). New ideas and inventions can be legally protected by registration with the government as patents, trademarks, or copyrights. In business, it is wise to protect your new ideas and keep them secret so that you have time to develop and profit from them. Without protection, competitors may be able to capitalize on your ideas by developing them faster or cheaper.

As nanotechnology companies garner government grants and private investment funding for research and development, it is important that they take appropriate steps to protect their IP interests. Non-compete and non-disclosure agreements between collaborators can prevent trade secrets from being divulged and start the process of documenting the ownership of new ideas.

There are more than 5,500 registered nanotechnology patents in the U.S. Patent and Trademark Office. While the majority of these patents are held by U.S. companies, nearly 25% are held by companies in other countries such as Japan, Germany, and South Korea. In the U.S., companies have obtained the most nanotechnology patents in California (with 807), New York, Massachusetts, and Texas. The number of nanotechnology patents continues to grow each year.

Figure 6.14 Patents are one way that companies can protect their intellectual property. See Figure Credits, p. vi.

Secrecy vs. Open Source

While it is acknowledged that companies need to protect their IP, there is also growing debate over whether companies should be revealing more information to the public and regulators about the nanomaterials in their products. Some businesses choose not to declare that their products contain nanomaterials to avoid the potential stigma and regulations that may come with using nanomaterials.

Berkeley, California, was the first city in the world to pass a nanotech ordinance that requires companies to disclose what nanomaterials they are working with and give risk data to the local government. Imagine the diversity of regulations within the U.S. and the considerations nanobusinesses may have to weigh before introducing new products, without regulation at the state or federal level.

Current Regulation

The U.S. and Europe have created governmental oversight and regulation of new technologies in order to foster public acceptance and the proper functioning of commercial markets. U.S. federal government participation in nanotechnology began formally in 2000 when the NNI was formed with a funding mandate from the White House and the Office of Scientific Technology Policy (OSTP). Although federal agencies are in place to protect and educate the public, it seems impossible for them to keep up with the rapid development of nanomaterials and the commercialization of nanoproducts, many of which make it to market without safety testing.

Currently, one of the major challenges to the governmental and regulatory agencies is acquiring the funding and support necessary to begin setting up the required oversight and monitoring systems. These should ensure that new nanomaterial products enter the marketplace only after their properties and uses are fully understood and risk assessments have been determined. However, nanoscience discoveries and the resulting rapid nanotechnology product expansion are growing faster than the pace of the emerging oversight infrastructures. The real risk to this emerging technology lies in the possibility of a major mishap occurring before the correct oversight infrastructures are in place. This in turn could potentially lead to unrealistic public fear and broad consumer resistance to the development of other beneficial nanotechnology products.

One solution proposed to avoid the potential for consumer fear and resistance may be requiring manufacturers to do third-party testing of their nanoproducts for health and environmental effects. Because of the unique properties of nanomaterials, oversight agencies will need to redefine assessment methods that were based on technologies prior to the emergence of nanotechnology. Additionally, transparent, clear communication is needed between the developers of new nanomaterials and the current oversight government agencies and consumers. You need to be included in the communication of nanoproduct information so you can make informed choices regarding your purchases of nanoproducts. In addition, consumers, manufacturers, and oversight agencies will need to work together to address the end-of-life recycling of products containing nanomaterials, to ensure that potentially polluting nanomaterials are captured and not introduced into the environment.

Current regulatory agencies engaged in the oversight of nanotechnology products, substances, and wastes include:

- The Consumer Product Safety Commission (CPSC)
- The Food and Drug Administration (FDA)
- The Environmental Protection Agency (EPA)

Despite the presence of these agencies created to protect consumers and the environment, many experts point to problems with the current regulation of nanomaterials. There are thousands of nanoproducts on the market already without a well-coordinated plan for how to evaluate and regulate them. The CPSC does not have adequate resources to study and assess these products. The FDA developed its policy in 2007, but the EPA is still struggling with whether to consider nanoparticles or nanomaterials new materials under the Toxic Substances Control Act. Meanwhile, some experts are concerned that nanomaterials are being released and the waste is accumulating in the environment. People are using cosmetics and other over-the-counter products with nanomaterials, and, while they may be perfectly safe, federal regulatory scrutiny of these products is lower than for medicines.

In terms of international regulation, there are a few multinational organizations that the FDA and EPA participate in, such as the Organization for Economic Co-operation and Development (OECD), ASTM International, and the International Organization for Standardization (ISO). These organizations are discussing the potential for cooperative efforts on nanotechnology regulation. The FDA plans to share perspectives and information on regulation of nanotechnology with foreign regulatory agencies, and the EPA is working with OECD to standardize regulations internationally as much as possible.

Consumer Product Safety Commission

More than half of the nanoproducts on the PEN Consumer Product Inventory fall under the jurisdiction of the U.S. Consumer Product Safety Commission (CPSC). The CPSC was created in 1972 to protect the public "against unreasonable risks of injuries associated with consumer products." They oversee a multitude of products such as clothing, hazardous household cleaners and substances, electronic devices, appliances, furnishings, building materials, toys and other juvenile products. Some types of products that are not regulated by the CPSC are regulated by the FDA, such as cosmetics, drugs, devices, and veterinary products.

CPSC has the authority, under the Federal Hazardous Substances Act, to require warning labels on products that contain hazardous substances. However, a product must be deemed toxic before such a label can be required. Given the current state of toxicity research, it is not likely that labeling will be required any time soon.

In areas of commercial industry where the U.S. government is not regulating the materials, it is up to the company to perform due diligence to determine whether their products are safe. Manufacturers are motivated to perform the necessary research, because when people are harmed due to negligence, businesses experience a backlash in which this breach of trust often leads to consumer rejection and a failed product. If enough evidence is collected, products or the use of specific substances can be banned by the CPSC.

Food and Drug Administration

The types of products the Food and Drug Administration (FDA) regulates are: foods, dietary supplements, color additives, drugs, biological products (vaccines, blood products, and tissues), cosmetics, devices, and radiation-emitting electronic products. While the FDA states that it is "aware of several FDA regulated products that employ nanotechnology," it is manufacturers who must claim the use of nanotechnology in their products in order to initiate the FDA's current regulatory processes.

Many private companies are developing nanoproducts that are not within regulated areas of business, so the FDA does not require much from these companies. Instead they are left to regulate themselves, in a sense, performing what they think is adequate testing and disclosure with the incentive that doing so may protect them from lawsuits in the future.

With medical products, such as pharmaceuticals, the regulation process of the FDA is well established and includes extensive pre-market safety testing and informed consent of participants in pre-market clinical trials in the approval process. However, cosmetics do not get the same scrutiny from regulators. Experts suggest that the cosmetics industry is one area that is under-regulated by the FDA and is left unchecked, without independent safety testing on its products.

Figure 6.15 Cosmetics containing nanoparticles may not be getting the safety research and regulatory scrutiny they deserve. *See Figure Credits, p. vi.*

The FDA defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance." Many people use personal care lotions, powders, sprays, shampoos, and make-up every day. While cosmetics companies are using nanoparticles in their products to deliver active ingredients deeper into the skin or hair shafts, the risks of physical application or inhalation of nanomaterials are yet unknown.

While the FDA is "currently not aware of any safety concerns" with cosmetics and sunscreens that claim to contain nanoparticles, it is "planning additional studies to examine the effects of select nanoparticles on skin penetration."

According to the FDA, their experts believe that nanotechnology products present challenges similar to those of other emerging technologies. They recognize, however, that product safety and effectiveness can change as size goes up or down within the nanoscale, which adds a level of complexity to their review process. The agency anticipates that nanotechnology will have many areas of application, such as foods, drugs, cosmetics, and medical devices.

The FDA also expects that many nanoproducts will be what it calls combination products, spanning the regulatory boundaries between drugs, medical devices, and biologics.

The Environmental Protection Agency

Companies importing or manufacturing nanoparticles need to be aware of how nanoparticles are regulated by the Environmental Protection Agency (EPA) under the authority of the Toxic Substances Control Act (TSCA). Manufacturers may face additional difficulties as they navigate EPA regulations due to the challenges of classifying nanoparticles.

The EPA has recently determined that seven material types may require safety decisions under its regulatory programs: single-walled carbon nanotubes, multi-walled carbon nanotubes, fullerenes, cerium oxide, silver, titanium dioxide, and zero-valent iron. A proactive research strategy involves focusing on these types in the near-term and later extending to other types of nanomaterials. Testing the variations of nanomaterials is too big a task to be accomplished in the near term. Many researchers share the goal of developing predictive methodologies to enable efficient testing across material types.

Future Nanotech Regulation

In the U.S., the regulatory system is currently focused on risk assessments and cost-benefit analysis. While nanotechnology does not necessarily pose new regulatory policy issues, it seems to highlight the existing weaknesses in regulations and our ability to deal with emerging technologies. The combination of challenges with nanotechnology regulation, such as unique properties, low public awareness, and secrecy about and protection of intellectual property, is putting pressure on the existing system to respond and adapt.

> The federal regulatory agencies already suffer from underfunding and bureaucratic ossification... New thinking, new laws, and new organizational forms are necessary. Many of these changes will take a decade or more to accomplish, but there is an urgent need to start thinking about them now. (Bryan Wilson, 2009)

Experts in nanotechnology are suggesting that in the future the system should look beyond these utilitarian concerns and take a multi-criteria approach. This new approach has the potential to open up the evaluation of a regulatory or oversight system to opportunities for transparency, public input, and minimized conflicts of interest, as well as recognition of health and safety impacts.

Policymakers often rely on the input of the scientific community and research findings when formulating new regulations. In the area of nanotechnology, public opinion is also being given consideration. In January, 2009, the Obama administration issued a new federal register notice for regulatory review, which asks for comments on a new executive order related to nanotechnology. The notice asked for comments on topics such as public engagement, the consideration of social and ethical issues, transparency, and the effects on future generations.

Section Review

1. What are the attributes of an active nanoproduct?
2. Which state holds the most nanotechnology patents in the U.S.?
3. What regulatory agencies oversee nanotechnology products, substances, and wastes?
4. What beneficial properties do nanoparticles offer cosmetic products?
5. Which government agency regulates cosmetics?
6. What opportunities are present for changes in the oversight of nanomaterials?