

25th
ANNIVERSARY

WISE 
Washington Internships for Students of Engineering

Nanotechnology Policy and Environmental Regulatory Issues

Nastassja Lewinski
2005 WISE Intern
Rice University

August 1, 2005

Sponsored By
The American Institute of Chemical Engineers



PREFACE

ABOUT THE AUTHOR

Nastassja Lewinski is a fourth year undergraduate Chemical Engineering student at Rice University. Her interest in nanotechnology stems from her three years of research in Dr. Rebekah Drezek's laboratory at Rice University. This paper was written through her participation in the Washington Internships for Students of Engineering (WISE) program in the summer of 2005. The American Institute of Chemical Engineers (AIChE) sponsored her participation in this program.

THE WISE PROGRAM

For 25 years, the Washington Internships for Students of Engineering (WISE) program has been bringing together various engineering students from universities across the country to study public policy in Washington D.C. This nine-week internship is designed to expose engineering students to the world of public policy and show how engineers can contribute to the legislative process. Participants attend frequent meetings with policy makers, government officials, lobbyists and non-government individuals to learn what influences government decisions on technological issues. At the end of the summer, each student produces and presents a policy paper on a topic of interest to his or her sponsoring society. This multi-society program is supported by the American Association of Engineering Societies. For more information on WISE, see: <http://www.wise-intern.org>.

ACKNOWLEDGEMENTS

I would like to thank everyone involved in the WISE program for making my experience both enriching and enjoyable. Special thanks go to the American Institute of Chemical Engineers for the opportunity to participate in the 2005 WISE program. The advice and guidance of David Gushee, Steve Watkins and Erica Wissolik were greatly appreciated throughout the process of developing this paper. Finally, I would like to thank my fellow WISE interns. Never have I made such fast friends.

PAPER CITATION

Lewinski, Nastassja. "Nanotechnology Policy and Environmental Regulatory Issues." *Journal of Engineering and Public Policy*. Aug. 2005. vol. 9 <<http://www.wise-intern.org>>

ABSTRACT

To date, the United States government has increasingly funded the development of nanotechnology applications. As a result, the growth of the field is outpacing the research on related environmental health and safety (EHS) issues. Depending on whether or not nanomaterials are harmful, exposure to nanomaterials could trigger negative health effects.

Currently, there is no regulation controlling the release of nanomaterials manufactured in the U.S. into the environment. Therefore, the EPA is currently considering how to apply current environmental regulatory laws, in particular the Toxic Substances Control Act (TSCA), to nanotechnology. The main issue concerning TSCA is the interpretation of a “new” chemical. Since many nanomaterials are chemicals already on the TSCA Inventory, they can be considered existing chemicals and enter commerce bypassing EPA review. However, because the unique properties of nanoparticles are a result of their size, considering nanoparticles comparable to their bulk counterparts may be inappropriate. To address this issue, the EPA plans to launch a voluntary program towards the end of 2005 to collect information that will help determine how nanomaterials should be regulated under TSCA.

Five years after the onset of the National Nanotechnology Initiative, environmental issues have finally rose to a major research priority. Government support of environmental implications research should have begun at the same time applications research and development funding started. Therefore, I conclude the government should adopt a horizontal funding or priority approach to future national science and technology research initiatives. This would facilitate all aspects of development since questions concerning applications, safety, utility and commercial viability would be addressed simultaneously instead of one by one.

To address the current concerns with nanotechnology safety, I suggest the EPA (1) make nanotechnology a top research priority, (2) collect exposure, transport, toxicology, and ecological fate information through its voluntary program, (3) become involved in standards development through ANSI and ASTM, (4) consider nanomaterials as “new” or “significant new uses” of chemicals for TSCA and amend the release thresholds.

Chemical engineers should also become more involved with nanotechnology implications research. AIChE should (1) actively participate in the regulatory effort through its Government Relations Committee and (2) bring EHS effects to the attention of the Research and New Technology Committee and the Nanoscale Science and Engineering Forum.

TABLE OF CONTENTS

Preface	2
Abstract	3
Table of Contents	4
1. Introduction	5
2. Background	7
2.1 National Nanotechnology Initiative.....	7
2.2 Defining Nanotechnology.....	7
2.3 Types of nanomaterials and their applications	8
2.4 Benefits of Nanotechnology	9
2.5 Legislative History	10
2.6 21 st Century Nanotechnology Research and Development Act	11
2.7 Nanomanufacturing Investment Act of 2005	11
2.8 Health and Safety Risks of Nanoparticles	11
3. Issues	14
3.1 Toxic Substances Control Act (TSCA) regulated chemicals	14
3.2 TSCA Section 5 and current concerns.....	15
3.3 Possible concerns with TSCA exemptions.....	15
3.4 TSCA Section 4.....	17
3.5 TSCA Section 8.....	17
3.6 Other Applicable EPA-Governed Regulatory Acts.....	18
3.7 Nomenclature and Standards Development	19
3.8 Potential Issues with TSCA's use of CAS numbers	20
3.9 EPA Voluntary Pilot Program	21
3.10 Responsible Development and International Cooperation	22
3.11 FY 2006 Budget.....	23
4. Recommendations	25
4.1 Federal Government Specific	25
4.2 EPA Specific.....	20
4.3 AIChE Specific.....	22
5. References	30
Appendix I: Acronyms and Nanotechnology Websites	35
Appendix II: TSCA Flowchart.....	37

1. INTRODUCTION

Nanotechnology is the “understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications.”¹ Given this definition of nanotechnology, chemical engineers have been dealing with processes involving nanomaterials, such as catalysis and crystallization, for decades. The range of nanotechnology subject areas in which chemical engineers are currently engaged include nanofabrication and nanoscale processing; synthesis, adsorption and transport in carbon nanotubes; nanoscale structure in polymers; synthesis and characterization of nanocatalysts; nanosensors; drug delivery and imaging with nanotechnology; and nanobiotechnology.²

To date, the US government has increasingly supported the development of nanotechnology applications. As a result, the growth of the field is outpacing the research on related environmental health and safety (EHS) issues. With previous emerging technologies, such as genetically engineered foods and genomics, there have been uncertainty and concern about health risks. It is known that nanoparticles can enter the human body after inhalation, dermal exposure, or ingestion. Because nanoparticles have a high bioavailability, they are able to penetrate the bloodstream, digestive tract and even the blood-brain barrier.³ Depending on whether or not nanomaterials are harmful, exposure to nanomaterials could trigger negative health effects. In order to keep the public from questioning the safety of nanotechnology, EHS research should be completed now to facilitate the enforcement of regulations.

Currently, there is no regulation in place controlling the release of nanomaterials manufactured in the U.S. into the environment. While some may argue that nanomaterials have not been developed to the point where significant exposure is occurring, others argue that tons of nanomaterials are being produced annually. Therefore, the issue the EPA is currently facing is how to apply current environmental regulatory laws to nanotechnology. The Toxic Substances Control Act (TSCA) is currently being considered the primary act relevant to environmental implications. However, it remains to be determined whether these particles are new chemicals or not, a key definition needed to apply TSCA rules. Currently, new chemicals are interpreted as chemicals not listed on the TSCA Inventory. Since many nanomaterials are just nanoscaled versions of chemicals already on the list, they can be considered existing chemicals and bypass EPA review and enter commerce. The main issue concerning TSCA is the interpretation of what constitutes a new

chemical. The EPA plans to launch a voluntary program to collect information that will help determine how nanomaterials should be regulated under TSCA.⁴

Whether regulation is necessary at this time is unclear. Ideally, the EPA should uncover all health and environmental implications before nanomaterials become fully commercialized. However, since EHS research has only just become one of the National Nanotechnology Initiative priorities, there are still several roadblocks to regulation the EPA has to overcome. A major impediment is the lack of standard terminology, nomenclature and CAS numbers for nanomaterials. Only recently have standards development organizations, such as American National Standards Institute (ANSI) and American Standards and Technology Management (ASTM) International, created committees to develop guidelines for companies using nanotechnology. Therefore, it will take time before standards are in place to aid in regulation.

Congress is pushing the development of nanotechnology because it anticipates nanotechnology will become a trillion dollar industry over the next 10 years. They are increasing funding and encouraging development not only for this economic aspect but also to ensure the US is the forerunner in this new field. While our competitiveness in nanotechnology is important, it is also important to make provisions to safeguard the people of the US from any detrimental consequences resulting from negligent disposal of nanomaterial waste. If Congress is going to stress the industrialization of nanotechnology, they should also follow that with preventative regulations or more funding for research to keep up with the growth of the technology.

2. BACKGROUND

2.1 *National Nanotechnology Initiative*

The National Nanotechnology Initiative (NNI) was established in 2001 to accelerate the discovery, development, and deployment of nanotechnology.¹ Similar to the National Information Technology Research Directive (NITRD) and the US Global Change Research Program (USGCRP), the NNI works to coordinate nanotechnology research and development (R&D) in the 24 associated federal agencies, provide funding to national laboratories and support commercialization efforts by U.S. companies.⁵

In addition, the NNI establishes a national agenda with the main goals being to:

- (1) foster research into developing nanotechnology to its full potential,
- (2) assist with the commercialization of new nanoproducts,
- (3) develop an educated workforce,
- (4) support the understanding of the societal, ethical, health, safety, and environmental dimensions of nanotechnology.⁶

More specifically, the NNI will focus its investment in seven program component areas:

- (1) fundamental nanoscale processes,
- (2) nanomaterials,
- (3) nanoscale devices and systems,
- (4) instrumentation research and standards,
- (5) nanomanufacturing,
- (6) research facilities,
- (7) societal dimensions.⁶

2.2 *Defining Nanotechnology*

Currently, standard terminology for nanotechnology does not exist as the field is still relatively new. Among the various government agencies and laboratories, nanotechnology is defined in different ways. For example, the National Academy of Sciences defines nanotechnology as the “ability to manipulate and characterize matter at the level of single atoms and small groups of atoms”.⁷ Alternatively, the Los Alamos National Laboratory describes nanotechnology as “the creation of functional materials devices and systems, through control of matter on the nanometer (1 to 100 nm) length scale and the exploitation of real properties and phenomena developed at that scale”.⁸ While their definitions are somewhat similar, they still differ in their meaning. As the NNI serves to coordinate the national efforts in nanotechnology, this paper will follow the NNI definition

which states that nanotechnology is the “understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications”.¹

2.3 *Types of Nanomaterials and their applications*

Given the definition of nanotechnology, chemical engineers have been dealing with processes involving nanomaterials, such as catalysis and crystallization, for decades.⁹ The difference now is with the ability to visualize particles at the nanoscale, engineers are able to design materials and processes to take advantage of the enhanced physical, chemical, and biological properties due to their size. There are several classes of nanomaterials currently being developed; five principle nanotechnology platforms will be discussed here. Probably most well known are the two carbon based nanoparticles, fullerenes and carbon nanotubes. Fullerenes, most notably Buckminster fullerenes, Buckyballs or C60 discovered by Professors Robert Curl, Harold Kroto and Richard Smalley in 1985, are spherical cages of carbon.¹⁰ The unique structure of fullerenes gives them potential for uses as superconductors, lubricants, industrial catalysts, and drug-delivery systems. In addition, fullerenes can be elongated resulting in carbon nanotubes, wire-like tubes of carbon that can be single or multi-walled and surface modified. Carbon nanotubes are 100 hundred times stronger than steel, yet one-sixth the weight. Applications include electronics such as computer memory chips, LCD displays, and electrical wires. Nanowires are wires and rods made of one or more semiconductors, such as gallium arsenide or indium phosphide. Possible applications include field-effect transistors, sensors, detectors and light-emitting diodes. Quantum dots are nanometer-scale crystals of semiconductors, such as cadmium selenide. The main application involves medical imaging where the quantum dots are functionalized with an antibody, targeted to specific cells, such as cancer cells, and fluoresced. Of the five, the most patents, 319 as of 2004, were issued for quantum dots.¹¹ Dendrimers are spherical polymers used experimentally for drug delivery and environmental remediation applications.

While currently only nanomaterials have moved towards commercialization, a timeline, as illustrated in Figure 1, for the beginning of nanotechnology commercialization and industrial prototyping has been suggested consisting of four generations of nanotechnology development.

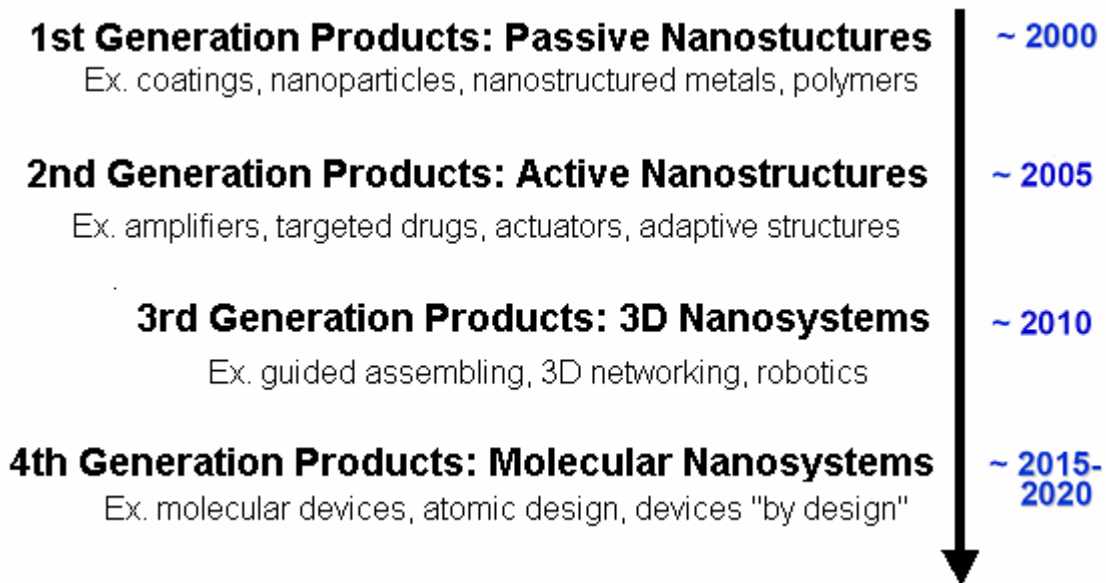


Figure 1 Nanotechnology Development Timeline ¹²

2.4 *Benefits of Nanotechnology*

While nanotechnology is still an emerging field, a number of products are currently being produced utilizing nanomaterials. According to Forbes' Top Ten Nanotech Products Report, these include:

- stain-free fabrics, such as Nano-Care is featured in khaki pants made by Eddie Bauer, Lee Jeans and Old Navy
- sunscreens and cosmetics, such as Revitalift antiwrinkle cream by L'Oréal Paris containing 200 nm “nanosomes of Pro-Retinol A”
- sports equipment, such as Babolat's VS Nanotube Power tennis racket made with carbon nanotubes making the racket five times more rigid than current rackets while packing more power and Wilson Double Core tennis balls, with 20 layers of 1 µm thick clay polymer nanocomposite coating the ball's inner core making it harder for air to escape.
- scratch resistant coatings, such as Nanofilm which consists of 150 nm and 20 µm thick polymer layers giving glass the antireflection and scratch-resistance functionality
- advanced wound dressings for burn victims, such as Acticoat, a wound dressing product is used in more than 100 of the 120 major burn hospitals which utilizes Nanosilver as an antibacterial agent to prevent infection of wounds and burns ¹³

More applications will arise as the technology matures. According to the recently released PCAST review of the NNI, “over 8600 nanotechnology-related patents were issued in 2003, a 217% increase from the year federal funding began in 1996.”¹⁴ These emerging nanotechnologies have the potential to revolutionize industry by improving energy storage, production and conversion; agricultural productivity; water treatment and remediation; disease diagnosis and screening; drug delivery systems; food processing and storage; air pollution and remediation; construction; health monitoring.¹⁵ For example, looking specifically at medical applications, nanotechnology can be utilized to improve gene therapy, surgery techniques, drug delivery, and diagnostic procedures. Surgery can be made less invasive with remote, *in vivo* nanodevices. The therapeutic potential of drug delivery will be enhanced with improved formulations and precise targeting. The ability to manipulate materials at the nanoscale could advance the biocompatibility of artificial tissues and biomaterials.

2.5 *Legislative History*

Some agencies in the federal government have been involved in nanotechnology since the early 1980s, most notably the U.S. Naval Research Laboratory. In November 1996, federal coordination of nanoscale research began with several agencies meeting to discuss their plans and programs in nanotechnology. This informal group was designated in September 1998 as the Interagency Working Group on Nanotechnology (IWGN) under the National Science and Technology Council (NSTC). IGWN completed its first draft of an initiative in nanoscale science and technology in August 1999. The plan went through an approval process involving the President's Council of Advisors on Science and Technology (PCAST) and the Office of Science and Technology Policy (OSTP). Subsequently, in its 2001 budget submission to Congress, the Clinton administration raised nanoscale science and technology to the level of a federal initiative, officially referring to it as the National Nanotechnology Initiative (NNI). Once the NNI had been set up, the IWGN was disbanded and the Nanoscale Science, Engineering and Technology (NSET) Subcommittee was established as a component of the National Science and Technology Council's (NSTC) Committee on Technology.¹⁶

2.6 *21st Century Nanotechnology Research and Development Act*

While the NNI provided a national direction and coordination for the federal agencies involved in nanotechnology research, the 21st Century Nanotechnology Research and Development Act gave greater recognition to the initiative. The bill, which originated in the House of Representatives, was passed in 2003 and formally outlined the authorizations for nanoscale research. In addition, this public law (P.L. 108-153) officially selected the National Science and Technology Council (NSTC), under the President's Office of Science and Technology Policy (OSTP), to create the Nanoscale Science, Engineering and Technology (NSET) subcommittee under the NSTC Committee on Technology. In addition, the National Nanotechnology Coordination Office (NNCO) was established to serve as the secretariat for the NSET and provide technical and administrative support. The NNCO supports the NSET in multi-agency planning and the preparation of budgets and program review documents. It also assists the NSET with the collection and distribution of information on industry, state, and international nanotechnology research, development, and commercialization activities.¹⁷

2.7 *Nanomanufacturing Investment Act of 2005*

Introduced in the House of Representatives on April 6, 2005, the Nanomanufacturing Investment Act of 2005 requests federal funding for pre-commercial nanomanufacturing projects to advance commercialization and increase the commercial application of federally supported research results. In particular, HR 1491 was proposed to address the funding obstacles nanomanufacturers face with the technology transfer of research and development into marketable products.¹⁸ While federal programs such as the Advanced Technology Program are designed to support this transition, funding is not always adequate. Therefore, this nanotechnology specific bill aims to overcome these challenges by investing public money in start up commercialization efforts thus reducing the financial risk on the nanomanufacturing companies.¹⁹

2.8 *Health and Safety Risks of Nanoparticles*

Nanoparticles can enter the human body after inhalation, dermal exposure, or ingestion. Because nanoparticles have a high bioavailability, they are able to penetrate the bloodstream,

digestive tract and blood-brain barrier. Depending on whether or not nanomaterials are toxic, exposure to nanomaterials could trigger negative health effects. Most particle studies have been done on dust from exhaust fumes which normally form clusters and settle spontaneously as deposits within a few days. In contrast, manufactured nanoparticles are usually coated to prevent aggregates from forming and as a result will stay in the air longer which could lead to inhalation problems. Once inhaled, nanoparticles may deposit deep into the respiratory tract, including approximately 20-50% deposition in the lower respiratory tract in humans, which is approximately 2-5 times greater than that of larger particles. Studies in rodents and in cells have shown that ultrafine particles also escape detection and clearance by macrophages to a greater extent than fine particles, and may to a greater degree, travel from alveolar regions to the blood circulation, where they may migrate to other organs.^{3,20} Ultrafine particles can produce greater inflammatory effects via free radical generation. Other contributing factors – such as particle shape, surface charge, coatings and functionality (see Figure 2) – may contribute greatly to particle toxicity; and other factors such as surface reactivity may greatly influence the cytotoxicity of ultrafine particles.²¹

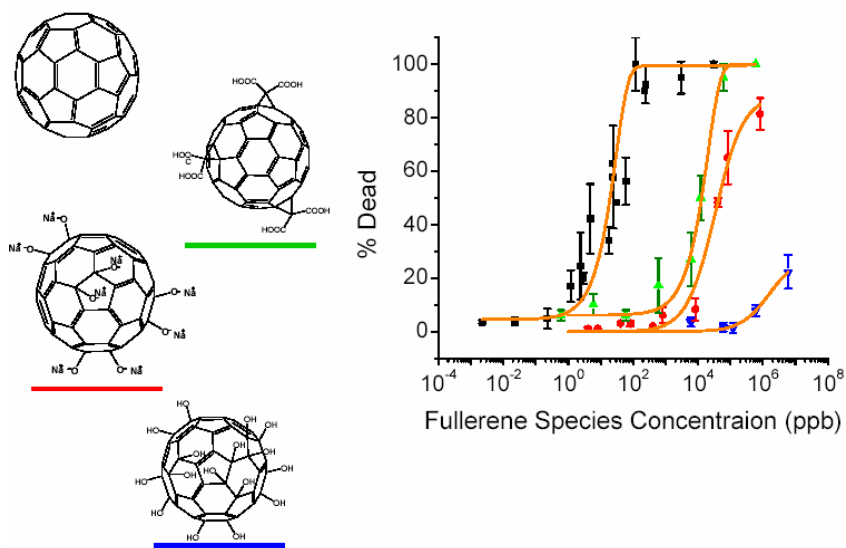


Figure 2 Change in toxicity of buckyballs due to difference in functionality²²

Another significant environmental concern is the potential effects of bioaccumulation due to the high bioavailability of nanomaterials. In a recent study done in collaboration between Rice University and Georgia Institute of Technology, the chemical properties of Buckminster fullerenes

or buckyballs have been found to change when in its aggregate form. Separately, buckyballs have low solubility in polar solvents, but when in contact with water, C60 forms an aggregate that is around 11 orders more soluble. The effect of this increased solubility was also studied by exposing gram-positive and gram-negative bacteria to the C60 aggregate. It was found that low concentrations (0.4 mg/L) the growth of both types of bacteria was inhibited.²³ This study suggests that nanomaterials exhibit different chemical properties from their bulk counterparts, which should be taken into consideration when developing regulation.

Nanoparticles could also facilitate transport of toxins deeper into the soil. Due to their larger surface area, nanoparticles could bond to more pollutants and transport them through the soil causing pollutants to be absorbed faster and deeper than normal. This might mean that ordinarily less mobile pollutants could be transported “piggy-back” style over long distances by the mobile nanoparticles. In addition, since nanoparticles are usually reactive they may catalyze reactions between the pollutants leading to new and possibly toxic compounds.

Although little definitive knowledge is available on how nanomanufactured products behave in the environment, such products are already in use today and more will be launched on the market in the near future. The Frontier Carbon Corporation, a Mitsubishi company, planned to produce 40 tons of nanotubes in 2003 and estimates production of approximately 10 tons of fullerenes per year as C60 by 2007.²³ Therefore, the approach to the opportunities and risks involved must be worked out now.

3. ISSUES

Currently, there is no regulation in place controlling the release of nanomaterials manufactured in the U.S. into the environment. While some may argue that nanomaterials have not been developed to the point where significant exposure is occurring, others, such as Environmental Defense, argue that tons of nanomaterials are being produced annually.²⁴ Evidence of commercialization includes the manufacture of carbon nanotubes that currently can be made by the tons through a CVD method.²⁵ In addition, whether nanomaterial release in the environment poses a significant health risk also remains questionable. Therefore, the issue the EPA is currently facing is how to apply current environmental regulatory laws to nanotechnology. According to Charles Auer, Director of the Office of Pollution Prevention and Toxics at the EPA, TSCA is currently being considered the primary act relevant to environmental implications.²⁶

3.1 *Toxic Substances Control Act (TSCA) regulated chemicals*

The Toxic Substances Control Act was signed into law on October 11, 1976 to address the concern that potentially dangerous chemicals being produced in the U.S. were not being adequately regulated.^{27,28} Through TSCA, the EPA is authorized to screen new and existing chemicals in order to identify potentially dangerous products or uses that should be regulated by the federal government. The most relevant part of the TSCA is Title I dealing with control of toxic substances. The definition of a chemical substance given in Section 3 is:

The term “chemical substance” means any organic or inorganic substance of a particular molecular identity, including:

- (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and
- (ii) any element or uncombined radical.²⁷

Following this definition, nanomaterials apply since they consist of organic (e.g. dendrimers) and inorganic (e.g. gold nanoparticles) substances plus combinations (e.g. nanoshells with gold shells and silica cores). What makes them unique is their nanoscale size, which changes their physical, chemical, and biological properties. For example, with gold nanoparticles, the increase in surface area changes their chemical reactivity making, what is inert in bulk form, a useful imaging agent at the nanoscale. Therefore, the goal of nanotechnology development is to exploit these properties by gaining control of structures at the atomic level and to learn to efficiently

manufacture and use these devices. This makes regulating nanomaterials difficult. A flow chart of the TSCA screening process can be found in Appendix II.

3.2 *TSCA Section 5 and current concerns*

All chemicals manufactured or processed in the United States are listed in the EPA's TSCA Chemical Inventory. Any chemical not on this inventory is, by definition, "new" and subject to the notification provisions of Section 5. The chemical must be added to the inventory if it is to enter commerce. Manufacturers must notify the EPA their intent to manufacture a new chemical 90 days prior to producing the chemical by submitting a Premanufacture Notification (PMN) of New Chemicals or Uses.^{27, 28} In addition, the company must submit any data that might be useful to EPA in evaluating the chemical's potential adverse effects on human health or the environment with the notice. TSCA also requires that manufacturers notify the EPA of plans to produce, process, or use an existing chemical in a way that differs significantly from previously permitted uses. This allows the EPA to determine whether the proposed new use will pose a greater risk of human or environmental effects due to exposure than the former use.

Currently, the issue is whether the difference exhibited between nanoscale chemicals and their bulk counterparts constitutes classifying nanomaterials as new chemicals or existing chemicals under TSCA. With regular chemicals, two molecules with the same chemical formula look and behave similarly. In contrast, two nanoparticles made of the same elements but differing in size can have significantly different chemical and physical properties. Even nanoparticles of the same size and composition can have very different properties, due to differing chemical structure; for example, diamond nanocrystals and buckyballs are both made of pure carbon.²⁹ Therefore, if the EPA decides nanomaterials are significantly different, this will affect nanomanufacturers since "new" and "significant new uses" of chemicals have to undergo TSCA's PMN screening process.

3.3 *Possible concerns with TSCA exemptions*

The altered chemical reactivity of nanoscale materials versus their bulk counterparts also raises questions with regards to TSCA's regulatory exemptions from PMN requirements. These exemptions are outlined in the EPA Code of Federal Regulations (CFR) Title 40 Protection of Environment document and are listed below.³⁰

1. Low Volume Exemption (LVE) – Under Section 723.50, chemical substances imported/manufactured in “low volumes” or quantities of 10,000 kg or less per year are exempt.
2. Low Release and Exposure Exemption (LoRX) – Under Section 723.50(a)(2), chemical substances with low environmental releases and human exposures are exempt provided that the manufacturer/importer meets all outlined criteria.
3. Polymer Exemption – Under Section 723.250, polymers that meet specific exemption requirements are excluded from regulation.
4. Test Market Exemption (TME) – Under Section 720.38, chemical substances for “test marketing purposes” and “proposed test marketing activity” are exempt.
5. Research and Development Exemption (R&D) – Under Section 721.47, the EPA exempts new chemical substances from PMN and SNUR if they are used for R&D, in small quantities and under the direction of a “Qualified Person.”³⁰

Considering size, these TSCA exemptions may not be appropriate given the higher level of activity per unit mass for nanomaterials. For example, the low volume exemption considers 10,000 kg/yr a permissible level. Applying this to nanomaterials, a potentially hazardous amount could be released into the environment.

Recently in the Wall Street Journal, the affects of low environmental concentrations of industrially manufactured chemicals were scrutinized.³¹ While scientists usually assume that low levels produce a negligible biologic response, some substances have been found to have effects at low concentrations that are not found at high levels of exposure. With the advances in sensory equipment, researchers are now able to study the effect of chemicals at the parts per trillion level. This is much smaller than the concentrations used in the establishment of many environmental laws. In response, the EPA recognized that “additional research is needed to better understand the low-dose hypothesis;” however, they consider “it would be premature to require routine testing of substances for low-dose effects.”³² As the EPA has been urged to “revisit its regulatory procedures to make sure such chemicals are tested in animals at appropriately small doses,” this further suggests the need to evaluate the applicability of the TSCA exemption and permitted release levels for nanomaterials.³¹

3.4 *TSCA Section 4*

If the EPA rules that existing data on a chemical is insufficient to resolve the question of safety, Section 4 of TSCA directs the EPA to require testing on existing chemicals. This mainly occurs when either the manufacture, processing, distribution, use or disposal of a chemical “may present an unreasonable risk” or when the production volume of the chemical is very large where a considerable quantity could be released into the environment causing substantial human exposure.^{27, 28} TSCA is followed under the presumption that testing of new products would take place as the chemical is developed before they become widely used. Therefore, in order for a nanomaterial to be ruled under Section 4, the EPA must recognize a high societal risk associated with the nanomaterial thus warranting investment by the manufacturer to conduct premarket testing. In addition, uniform testing requirements for all new chemicals is not allowed under TSCA since this could stifle innovation in the chemical industry. Therefore, if the EPA plans to require testing of all nanomaterials, it would have to rule on each different type and use. However, individual evaluation is time consuming and costly making this an undesirable option.

3.5 *TSCA Section 8*

Guidelines for reporting and retention of information on chemicals are outlined in Section 8 of TSCA. Under Section 8(a), the types of information the EPA could require manufacturers to submit include trade name, chemical identity, molecular structure, total amount manufactured or processed, description of byproducts, the environmental and health effects, number of individuals exposed, or will be exposed, and the manner or method of its disposal. Sections 8(c), 8(d), and 8(e) deal with reporting information concerning significant adverse reactions, health and safety studies, and substantial risk information on manufactured chemicals respectively. If the EPA identified that they lacked sufficient information on a chemical required in either of these subsections, a ruling on the specific subsection could be made.

From a manufacturer’s perspective, having their chemical ruled under, for example TSCA Sections 8(a) or 8(d), would result in their chemical also being added to the TSCA section 12(b) list of chemicals which requires the company to submit notification to the EPA anytime it plans on exporting their chemical. In addition, if the risks are substantial, then the EPA could recognize that the company failed to report them under Section 8(e). With these rulings in the literature, other

federal agencies such as NIOSH, NIEHS and CPSC could be provoked into determining how their regulatory statutes apply to this flagged chemical. In addition to these consequences, chemical companies do not want their chemicals ruled under TSCA because it compromises the commercial viability of those chemicals. The manufacturer could potentially lose customers due to a ruling on their chemical and thus lose whatever revenue was associated with it. Therefore, regulation has many adverse consequences in the eyes of manufacturers making it possible for the EPA to compel information submission by proposing to rule on a chemical if information is not submitted.

On the other hand, environmental groups, such as Environmental Defense and the ETC group, argue that the purpose of the EPA's screening procedure is to identify potential hazards, and control them before use of a chemical becomes widespread.²⁶ From their perspective, the lack of regulation shows that the EPA is not fulfilling its mission of safeguarding people and the environment. Therefore, potentially toxic nanomaterials are already in commerce unregulated. TSCA also directs the EPA to use the least burdensome option that can reduce risk to a level that is reasonable.²⁸ Since the risk of nanomaterial exposure is still unknown, the least burdensome option is no regulation until new information is acquired.

3.6 *Other Applicable EPA-Governed Regulatory Acts*

In addition to TSCA, the Clean Air Act (CAA), Clean Water Act (CWA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), National Environmental Policy Act (NEPA), and the Resource Conservation and Recovery Act (RCRA) may also have roles in regulating nanotechnologies. The manufacture, use and disposal of nanomaterials have the potential to result in air emissions and water discharges. While the original Clean Air Act only regulates particles greater than 2.5 μm , in 1997 the EPA added National Ambient Air Quality Standards of 15 $\mu\text{g}/\text{m}^3$ annually and 65 $\mu\text{g}/\text{m}^3$ daily for particulates less than 2.5 μm , and these standards could possibly be turned into nanomanufacturing limitations.³³ The Clean Water Act is also a feasible regulatory channel with its rules on effluent limitations for point sources; national pollutant discharge and elimination system permits; new source performance standards; and toxic and pre-treatment effluent standards. According to the Royal Academy of Engineering, the risk of release of nanomaterials would be highest during disposal, destruction or recycling.³⁴ As CERCLA and RCRA regulates hazardous waste disposal, their rules could be modified to capture nanomaterial waste streams. With all the above acts, the EPA would need to specify levels of

acceptable release. Therefore, as the EPA evaluates what levels are appropriate for TSCA, they should ensure the TSCA interpretation of nanomaterials applies to all the applicable acts.

3.7 Nomenclature and Standards Development

Whether regulation is necessary at this time is unclear. Ideally, the EPA should uncover all health and environmental implications before nanomaterials become fully commercialized. However, since EHS research has only just become one of the NNI priorities, there are still several roadblocks to regulation the EPA has to overcome. A major impediment is the lack of standard terminology, nomenclature and CAS numbers for nanomaterials. Recently, two voluntary standards development organizations, the American National Standards Institute (ANSI) and ASTM International, have created committees, the Nanotechnology Standards Panel and the E56 Nanotechnology committee respectively, to develop guidelines for companies using nanotechnology. In addition, the International Standards Organization (ISO) approved a new Technical Committee on Nanotechnology to address nomenclature and management standards pertinent to nanomaterials in May.³⁵ While it will take time for these bodies to approve proposed standards, groups such as the Foresight Institute, have already developed sets of voluntary standards for use by researchers.

The need for standard naming, characterizing and testing methods does not only affect regulation. The patent office has developed their own individual nanotechnology terminology for the purposes of issuing new patents. With the lack of standard classification, it is possible that many patents exist for potentially the same nanomaterial. This will become an issue when commercialization increases and companies begin to enforce their patents. Problems may also arise when companies begin to adopt the emerging ANSI standards, which may differ from the patent office's proposed nanotechnology classifications.

In addition, knowledge is still limited on the impacts of nanomaterial exposure on health and the environment. Environmental Defense has recommended that studies be undertaken to investigate potential risks throughout the entire product lifecycle and take into account worker safety, consumer use, and the ecological effects from product disposal. However, this would require further development and modification of the existing conventional risk assessment methods. For example, the toxicity standards currently used to evaluate environmental and worker exposure are mass or volume based. On the other hand, the toxicity of nanomaterials is more dependent on

the number of particles, surface area, and surface chemistry. Since there are few tools and techniques for measuring these characteristics at the nanoscale, reliable measurement techniques will be needed for effective nanomaterials regulation. The EPA recently shifted its research focus from applications to implications of nanotechnology such as looking into bioaccumulation, bioavailability, and remediation. Yet a method of tracking the movement of nanoparticles in the environment does not exist making the development of standard testing methods even more crucial.

3.8 *Potential Issues with TSCA's use of CAS Numbers*

In order to regulate, the TSCA Inventory currently requires CAS numbers in order for a new chemical to be added to the list. Currently, nanoscale materials of existing chemicals are using the existing CAS numbers. For example, carbon fullerenes and nanotubes list CAS# 7782-42-5 which is originally for graphite dust.³⁶ A CAS Registry Number is a unique numeric identifier designating one substance. While it has no chemical significance, a CAS number serves as a link to information about a specific chemical substance. CAS Registry Numbers are not dependent upon any system of chemical nomenclature. A CAS Registry Number, however, is unique and specific to only one substance regardless of how many other ways the substance can be described. Governmental agencies have found CAS Registry Numbers ideal for keeping track of substances since they are unique, can be validated quickly and reliably, and are internationally recognized.³⁷

Dr. Frederick Klaessig from the Degussa Corporation gave an example of problems with the TSCA inventory due to CAS numbers at the June 23, 2005 EPA meeting. He mentioned that there are six listings for “silica” on the TSCA Inventory. One is listed as “fumes, silica” with CAS# 69012-64-2 and is described as amorphous silicon dioxide particles from the volatilization of furnace feed materials in the manufacture of ferrosilicon and silicon. “Fumed silica” has CAS # 7631-86-9; however, Dr. Klaessig argues that fumed silica is CAS# 112945-52-5, which is described as amorphous fumed silica. He notes that past requests to place CAS# 112945-52-5 officially on the TSCA Inventory were declined for CAS # 7631-86-9. With all this confusion between just silica types, he concluded that the best course is to have EPA-specific definitions for nanomaterials.²⁶

Dr. Vicki Colvin of Rice University argues differently. As the chair of the ASTM International Committee E56 on Nanotechnology, Dr. Colvin urges the EPA to join their nanotechnology standards development process and abandon its plan to create a separate EPA

nomenclature system for nanomaterials.³⁸ Not only would this prevent duplication of efforts, but it would also avoid the costs that would arise from inconsistent usages. However, this will not resolve the CAS number issue. The lack of specific CAS numbers for nanomaterials will support the interpretation that they should be considered existing chemicals under TSCA. Both points brought up by Dr. Klaessig and Dr. Colvin suggest the EPA needs to get actively involved in the nomenclature and standardization process.

3.9 *EPA Voluntary Pilot Program*

On June 23, 2005, the EPA held a public meeting to discuss the potential launch of a nanoscale materials voluntary pilot program and to determine the scope and purpose of the program including what information it should collect. How can the definitions for new and existing chemicals become more transparent for identifying nanoscale materials on the TSCA Inventory? Is the current regulatory structure adequate? If not, where should EPA focus its attention for regulating nanotechnology? The public meeting served to get answers to these questions from other parties such as environmental groups, industry and academia. When launched, the voluntary program will mainly focus on collecting information that will help determine how the EPA should regulate nanomaterials under the Toxic Substances Control Act (TSCA). As mentioned, nanoscale materials have different molecular organizations and properties than their bulk chemical counterparts. Whether or not this results in differing interactions from their bulk chemical counterparts is still unknown. The lack of EHS data is preventing the EPA from initiating TSCA regulation of emerging nanotechnologies. However, the EPA is taking a proactive approach with its plan to create a voluntary pilot program to oversee the voluntary submission of EHS data from manufactures on nanomaterials.

Several people argue that it is too early to regulate. For example, Jim Von Ehr, founder, President and Chief Executive Officer of Zyvex Corporation, the first nanotechnology development company, believes regulation is only necessary when there is a market failure, and since nanotechnology is just coming out on the market, it is too early to regulate. He argues that premature regulation of nanotechnology will shut down innovation towards the development of the next industrial revolution.³⁹ Dr. Mark Wiesner, Professor and Director of the Environmental and Energy Systems Institute at Rice University, also agrees. Understanding the effects of nanotechnology on human health and the ecosystem is critical to avoid potential problems.

Therefore, he believes because the research to inform regulatory policy is currently insufficient, it is too early to regulate.⁴⁰

On the other hand, Dave Rejeski from the Woodrow Wilson Institute contends that a reactive regulatory approach will become unsustainable as the pace of scientific progress increases. Instead, he believes regulators need to be proactively involved in assessing the environmental ramifications of products as they are being designed. This will enable agencies such as the EPA to intervene at an early stage to avoid irreversible damages.⁴¹ While the EPA's nanoscale material voluntary program does not interfere with nanotechnology innovation, whether it will be sufficient in safeguarding the public from the potential hazards of nanomaterials increasingly entering commerce is yet to be determined.

3.10 Responsible Development and International Cooperation

Throughout the NNI reports, “responsible development of nanotechnology” is a recurring priority of the nanotechnology research effort.^{1, 6, 14, 17, 42} Responsible development requires the Government to address the various societal dimensions of this new technology, including concerns regarding possible health or environmental effects. Collaboration with the international scientific community on areas of nanotechnology research and its societal dimensions that are of mutual interest can facilitate this goal. The President's Council of Advisors on Science and Technology (PCAST) recently concluded that “governments around the world must take a proactive stance to ensure that environmental, health, and safety concerns are addressed as nanotechnology research and development moves forward in order to assure the public that nanotechnology will be safe.”¹⁴

Whether international collaboration should be promoted on issues of global concern, such as public health and the environment, risk assessment, regulatory approaches, metrology, and nomenclature is now in question. An effort was initiated at an international workshop sponsored by the NSF, which resulted in a joint declaration by participants from 25 countries and the European Union supporting responsible development of nanotechnology.⁴² Arrangements between the European Commission and the NSF or cooperation through groups like the U.S. Civilian Research & Development Foundation (CRDF) and the Organization for Economic Cooperation and Development (OECD) could accelerate the acquisition of knowledge and also maximize efficiency. International collaboration is already occurring through the ISO's nanotechnology committee.

3.11 FY 2006 NNI Budget

The fiscal year 2006 budget requests \$1.05 billion for the NNI program.⁴³ Of this, \$82 million is allocated for the societal dimensions of nanotechnology. This amount is further split with \$39 million for programs that are directed primarily at environmental, health, and safety R&D and \$43 million for education-related activities and research on the broad implications of nanotechnology for society, including economic, workforce, educational, ethical, and legal implications. According to the NNI Supplement to the FY 2006 Budget, “research and development on the environmental, health, and safety implications of nanotechnology includes efforts whose primary purpose is to understand and address potential risks to health and to the environment posed by this technology. Potential risks encompass those resulting from human, animal, or environmental exposure to nanoproducts – here defined as engineered nanoscale materials, nanostructured materials, or nanotechnology-based devices, and their byproducts.”⁶ Therefore, only \$39 million, or 3.7%, of the total \$1.05 billion designated for nanotechnology research will be appropriated towards understanding how nanomaterials interact with people and the environment.

Table 1. Fiscal Year 2006 Planned NNI Agency Investments within Societal Dimensions: EHS R&D and Societal Implications/Education (in \$ millions)⁶

Agency	EHS R&D	Societal Implications/ Education
NSF	24.0	35.5
DOD	1.0	1.0
DOE	0.5	0.6
NASA	0	0
HHS-NIH	3.0	5.0
HHS-NIOSH	3.1	0
DOC	0.9	0
USDA	0.5	0.5
EPA	4.0	0
DOJ	1.5	0
DHS	0	0
TOTAL	38.5	42.6

Some groups argue that there is not enough federal government money allocated to environmental implications research in comparison to R&D investments. At this rate, nanotechnology applications will exponentially increase and commercialization of many nanomaterials will become more pronounced while the potential consequences of unregulated production remain unknown. How can the government expect knowledge on the environmental and health effects to keep up with the development of the technology and industry if there is not adequate funding? The Environmental Defense group suggests that the government allocate more money, increasing the yearly amount to \$100 million or roughly 10% of the entire NNI budget, towards this cause.²⁴ In comparison, Dr. Colvin testified to the House Science Committee in 2003 that a good start for EHS research funding would be to follow the 3 to 5% rule used by the Department of Energy in the Human Genome Project.⁴⁴ In 2004, \$5.3 million and \$3.2 million were spent collectively on environmental and health implications respectively. Together, this constituted less than 1% of the total \$1,094 million budget. This amount was nearly tripled to \$22.6 million or around 2% of the total \$1,231 million estimated for this year's budget.⁴⁵ Finally, for the 2006 budget an amount in the 3-5% suggested range has been proposed. With research into the environmental effects already lagging behind, allocating more money will draw more attention to this concern and consequently quicken the understanding of the EHS effects of nanotechnology.

Looking at the EPA specifically, \$4 million are being allocated for nanotechnology EHS R&D. This constitutes only 6% of the total \$65 million anticipated for the STAR program and less than 1% of the \$536 million for EPA's total Science and Technology R&D.^{46, 47} With the overarching applications of nanotechnology and its increasing presence in commerce, understanding how nanomaterials will interact with the environment should be one of the EPA's top priorities in order to fulfill its mission to protect and safeguard human health and the environment.

Congress is pushing the development of nanotechnology because it anticipates nanotechnology will become a trillion dollar industry over the next 10 years.¹² Therefore, they are funding and encouraging development not only for this economic aspect but also to ensure the US is the forerunner in this new field. While our competitiveness in nanotechnology is important, it is also important to make provisions to safeguard the people of the US from any detrimental consequences resulting from negligent disposal of nanomaterial waste. If Congress is going to stress the industrialization of nanotechnology, they should also follow that with preventative regulations or more funding for research to keep up with the growth of the technology.

4. RECOMMENDATIONS

4.1 *Government Specific Recommendations*

Overall, I suggest that the government adopt a horizontal funding or priority approach to future national initiatives concerning research into new agents/biological matter/chemicals/devices/materials. Implication research should be made a top priority at the onset of new technology research instead of following the vertical chain of development. This would facilitate all aspects of development since questions concerning applications, safety, utility and commercial viability would be addressed simultaneously instead of one by one.

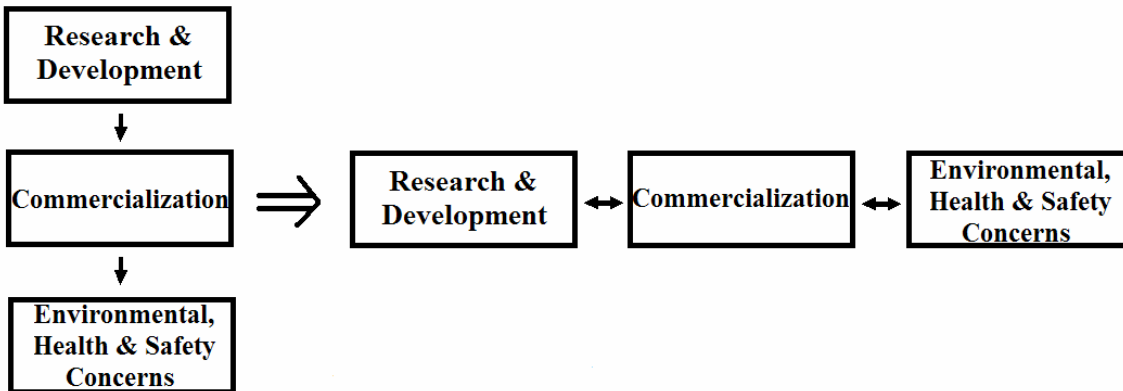


Figure 3 Vertical versus Horizontal Methods of Development

4.2 *EPA Specific Recommendations*

- 1) Through the proposed voluntary pilot program on nanotechnology, the EPA should:
 - a. Require companies to submit research findings concerning exposure, toxicology, and ecological fate and transport of their manufactured nanomaterials.
 - b. Ensure communication of the submitted data within the agency to facilitate clarifying regulatory concerns.

- c. Establish a database of all nanomaterials being studied under the program. This could be modeled after the EPA's High Production Volume (HPV) Challenge Program* that assesses the hazards of HPV chemicals.
 - 2) The EPA should get more involved in the standard development process by joining the ANSI Nanotechnology Standards Panel and the ASTM E56 Committee on Nanotechnology Standards. Since ANSI is involved with the ISO, this would also be an international effort on the part of the EPA.
 - a. In my opinion, the EPA's failure to rule whether nanomaterials should be considered new or existing chemicals for the purposes of TSCA regulation is due to the lack of unique CAS numbers. A challenge for research is determining a systematic way of differentiating nanomaterials. It would be unreasonable to test only a select few nanoparticles and generalize the findings for the remainder. However, developing material safety data sheets (MSDS) for all nanomaterials would be a costly endeavor. Therefore, the EPA should work towards finding a way to assess the risk of nanomaterials in an effective manner, and getting involved in the standards development process could accomplish this.
 - 3) The EPA should regulate nanomaterials under TSCA.
 - a. The EPA should consider nanomaterials as "new chemicals" for TSCA. I believe, with the right interpretation of the language used in TSCA, considering nanomaterials as "new chemicals" or "significant new uses" of existing chemicals will encourage companies to conduct more research into the EHS implications and therefore make companies understand the properties of their product. As Professor Berube said at the June 23, 2005 EPA public meeting, "Companies involved in production must be given an economic reason to divert funding into R&D of toxicological studies."

* The HPV Challenge Voluntary Program, created in cooperation with industry, environmental groups, and other interested parties, was designed to assemble basic screening level test data on the potential hazards of HPV chemicals while avoiding unnecessary or duplicative testing. Data collected and developed under the HPV Initiative provided basic information about the environmental fate and potential hazards associated with HPV chemicals which, when combined with information about exposure and uses, allowing the EPA to evaluate and prioritize potential health and environmental effects and take appropriate actions.

- b. The EPA should amend the TSCA's release limitations taking this into consideration the benefits of nanotechnology are based on the fact that small amounts of nano-sized chemicals are more reactive than their bulk counterpart. Current metrics used in TSCA are not adequate for nanomaterials; the volume exemption and mass metric are inappropriate. New limitations should be particle based or surface area/composition based since these properties are more indicative of the toxicity of nanomaterials.
- 4) EPA needs to lead implications research by making it also a focus of their National Health and Environmental Effects Research Laboratory (NHEERL).
 - 5) EPA should facilitate communication of environmental implications and toxicity research findings through the establishment of an online database. This could be done by commissioning a university center to establish a database or through collaborating/contributing to existing databases such as Impart-Nanotox, a European commission website to establish an online database of environmental implications and toxicity of nanotechnology.
 - 6) Nanomaterials that are currently out in commerce, such as carbon nanotubes, should be added as candidate chemicals for inclusion on a list that the Interagency Testing Committee (ITC)^{*} recommends to EPA for development and standardization of test rules. This committee's work could further aid the EPA research the environmental implications of nanomaterials.
 - 7) The EPA should utilize its National Pollution Prevention and Toxics Advisory Committee (NPPTAC).^{**}
 - 8) The EPA should communicate with other federal agencies such as the FDA or FIFRA, which regulate some nanoscale chemicals already commercialized.

^{*} TSCA requires the ITC to consider (1) quantity of the substance to be manufactured, (2) quantity of the chemical in environmental releases, (3) number of people who will be exposed occupationally and the duration of exposure, (4) extent of non-occupational human exposure, (5) similarity of the chemical to any other chemical known to present an unreasonable risk, (6) existence of data concerning environmental or health effects of the chemical, (7) the quantity of information to be gained by testing, and (8) the availability of facilities and personnel for performing testing.

^{**} NPPTAC provides advice, information and recommendations on the overall policy and operation of programs managed by the Office of Pollution Prevention and Toxics (OPPT), in performing its duties and responsibilities under the TSCA and the Pollution Prevention Act (PPA). The objectives of the Committee are to provide policy advice and recommendations in areas such as assessment and management of chemical risk, pollution prevention and toxic chemicals, risk communication, and opportunities for coordination.

4.3 *AICHE Specific Recommendations*

The chemical engineering discipline deals with the production and processing of chemicals and materials through a fundamental understanding of transport, thermodynamics, kinetics and unit operations. With this in mind, chemical engineers have been pursuing nanotechnology research for the many years. For example, fuel production has benefited from improved catalysts in which their pore structure is controlled with nanoscale precision, and polymer properties have been improved by controlling the polymer structure at the nanometer scale. Chemical engineering will continue to make important contributions to nanotechnology, and will play a critical role in the transition from basic science and engineering research to commercial applications. In addition, chemical engineers should actively participate in the nanotechnology policymaking process.

- 1) AIChE should make nanotechnology regulatory policy a topic of interest for the Government Relations Committee.* Concerning nanotechnology, AIChE has supported the National Nanotechnology Initiative and continues to foster research through its technical programs, publications and basic research. Beyond that, AIChE has not significantly contributed in the development of nanotechnology legislation.
- 2) AIChE does not traditionally act as a standards developing group; however, AIChE is involved in providing guidelines through its Center for Chemical Process Safety (CCPS). While I believe as a society AIChE should strive to become more involved in the technology developing process, such as standards development, I suggest that AIChE make nanotechnology terminology and production standardization a subject for one of the Center for Chemical Process Safety Reports. They therefore can produce their own set of guidelines, for example standard nanocatalyst surface area quantification.

* The AIChE Government Relations Committee is a volunteer based group that works to inform policy makers on technical issues concerning chemical engineers by providing technical educational pieces to Congress. It has also worked in developing language to insert into bills to benefit the interests of chemical engineers. In addition, AIChE's government relations programs work to (1) enhance AIChE's reputation among government officials and the public as a credible source of assistance and information on policy issues that impact chemical engineers, (2) develop sound technical information and provide professional assistance to government policy-makers on pending legislative and regulatory matters that impact chemical engineers, (3) formulate and advocate positions on policy issues affecting chemical engineers, create awareness among AIChE members about policy issues of importance to the profession, (4) stimulate members to interact with government officials and provide their expertise in policy debates, and (5) strengthen the Institute's impact on public policy through collaboration with other professional organizations.

- 3) AIChE should make environmental implications research a topic of discussion for the Nanoscale Science and Engineering Forum (NSEF)*.
- 4) AIChE should make one of its Annual Meeting Topical Conferences dedicated to Environmental Implications of Nanotechnology.
- 5) EHS effects should be brought to the attention of the Research and New Technology Committee since this committee identifies and prioritizes opportunities for research in chemical engineering and the emerging fields of technology that may employ chemical engineering skills.

* This forum was established in 2003 as a new division of AIChE to promote nanotechnology efforts in chemical engineering. Currently, the objectives of the NSEF are to (1) provide a forum for communication and networking among those with an interest in nanoscale sciences and engineering, (2) coordinate, sponsor, co-sponsor, and advertise relevant programming, including crosscutting and special-initiative technical sessions and conferences, (3) promote interchange of ideas, concepts, know-how, and experiences in nanotechnology, (4) encourage educators at all levels, particularly in chemical engineering, to integrate concepts of nanoscale sciences and engineering, (5) advocate curricula that prepare students for career use of nanotechnology, (6) promote lifetime learning through workshops and short courses, (7) provide centralized links to technical publications and databases related to nanotechnology as it relates to chemical engineering sciences.

5. REFERENCES

- 1) Small Wonders, Endless Frontiers: A Review of the National Nanotechnology Initiative. National Research Council/National Academy of Sciences. 2002.
- 2) Wong, Michael; Lee, Gil. "Selected papers from the Fourth Topical Conference on Nanoscale Science and Engineering of the American Institute of Chemical Engineers." Nanotechnology. July 2005, **16**(7).
- 3) Oberdörster, Günter; Oberdörster, Eva; Oberdörster, Jan. "Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles." March 2005.
<http://www.infonano.de/media/document/34_2494reviewnanotoxicologyoberdorsteretal.pdf>
- 4) Chow, Flora. "Nanoscale Materials; Notice of Public Meeting." Federal Register. 10 May 2005. **70**(89); 24574-6.
- 5) Richard Russell, OSTP (July 14, 2005) and Barbara Karn, EPA (July 19, 2005)
- 6) National Science and Technology Council (NSTC). Nanoscale Science, Engineering and Technology Subcommittee (NSET). 2005a. The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry. Supplement to the President's FY 2006 Budget. Washington, D.C.: the Council, <http://www.nano.gov/NNI_06Budget.pdf>
- 7) Los Alamos National Laboratory, "What is Nanotechnology?" Nanotechnology at Los Alamos National Laboratory, 25 June 2002, <<http://www.lanl.gov/mst/nano/definition.html>> (8 June 2005).
- 8) Roco, Mihail; Bainbridge, William. "Societal Implications of Nanoscience and Nanotechnology." NSET Workshop Report. National Science Foundation. March 2001. <<http://www.wtec.org/loyola/nano/NSET.Societal.Implications/nanosi.pdf>> (8 June 2005).
- 9) Catherine Brahic. "Big development role for tiny technology, says study." Science and Development Network April 12, 2005. <<http://www.scidev.net/quickguides/index.cfm?fuseaction=qguideReadItem&type=1&itemid=2042&language=1&qguideid=5>>
- 10) "The Nobel Prize in Chemistry in 1996." The Nobel Foundation, 14 April 2005, <<http://nobelprize.org/chemistry/laureates/1996/>> (8 June 2005).
- 11) Moore, Samuel. "The Nanotech Patent Trap." IEEE Spectrum. July 2005; 18.
- 12) Roco, Mihail. "Nanoscale Science and Engineering: Unifying and Transforming Tools." AICHe Journal. May 2004; 50(5); 890-897.

- 13) Paull, Robert. "The Top Ten Nanotech Products Of 2003." Forbes. 29 Dec. 2003.
<http://www.forbes.com/home/2003/12/29/cz_jw_1229soapbox.html> (19 July 2005).
- 14) President's Council of Advisors on Science and Technology (PCAST). 2005. The National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel. Washington, D.C.: The Council.
<http://www.nano.gov/FINAL_PCAST_NANO_REPORT.pdf>
- 15) Salamanca-Buentello, Fabio; et. Al. "Nanotechnology and the Developing World." PLoS Medicine. April 2005, 2(4), 300-3.
<http://www.utoronto.ca/jcb/home/documents/PLoS_nanotech.pdf> (19 July 2005).
- 16) Lane, Neal; Kalil, Thomas. "The National Nanotechnology Initiative: Present at the Creation." Issues In Science and Technology. Summer 2005.
<<http://bob.nap.edu/issues/21.4/lane.html>> (19 July 2005).
- 17) U.S. Congress. Public Law 108-153. 2003. 21st Century Nanotechnology Research and Development Act. 15 USC 7501. 108 Cong., 3 December 2003.
- 18) Nanomanufacturing Investment Act of 2005 H.R. 1491 109th Congress. April 2005.
- 19) Staunton, Jay. "Honda Nanotechnology Bill Bridges Gap for New Products." 6 April 2005
<<http://www.honda.house.gov/latestnews.asp?ARTICLE3753=5674>> (8 June 2005).
- 20) Chiu-Wing Lam, John James, Richard McCluskey, Robert Hunter. "Pulmonary Toxicity of Single-Wall Carbon Nanotubes in Mice 7 and 90 Days after Intratracheal Instillation." Toxicological Sciences. 2004; 77(1); 126-134.
- 21) Warheit, D.B., *et al.*. "Comparative pulmonary toxicity assessment of single wall carbon nanotubes in rats." Toxicological Sciences January 2003 77:117-125.
- 22) Colvin, Vicki. "The potential environmental impact of engineered nanomaterials." Nature Biotechnology. 21(2003), 1166-1170.
- 23) Fortner, J. D.; Lyon, D. Y.; Sayes, C. M.; Boyd, A. M.; Falkner, J. C.; Hotze, E. M.; Alemany, L. B.; Tao, Y. J.; Guo, W.; Ausman, K. D.; Colvin, V. L.; Hughes, J. B. "C₆₀ in Water: Nanocrystal Formation and Microbial Response." Environ. Sci. Technol.; 2005; 39(11); 4307-4316.
- 24) Denison, Richard. "A proposal to increase federal funding of nanotechnology risk research to at least \$100 million annually." Environmental Defense. April 2005.
- 25) Wolfgang Luther. "Industrial Application of Nanomaterials – Chances and Risks." German Association of Engineers. 2004
<<http://nano.uts.edu.au/nanohouse/nanomaterials%20risks.pdf>> (8 June 2005).
- 26) Notes from EPA Public Meeting held on June 23, 2005.

- 27) "Toxic Substances Control Act." Title 15 U.S. Code, Sec. 3. 1976 ed.
- 28) Schierow, Linda-Jo. "The Toxic Substances Control Act : A Summary of the Act and Its Major Requirements." CRS Report for Congress. 1 Dec. 2004.
- 29) Service, Robert. "EPA Ponders Voluntary Nanotechnology Regulations." Science. 1 July 2005 309, p. 36.
- 30) "Protection of Environment." Title 40 C.F.R. Sec. 723. 1995 ed.
- 31) Waldman, Peter. "Common Industrial Chemicals In Tiny Doses Raise Health Issue: Advanced Tests Often Detect Subtle Biological Effects; Are Standards Too Lax?" The Wall Street Journal. 25 July 2005. **246**(20), p.1.
- 32) EPA Statement. "Endocrine Disruptor Low-Dose Hypothesis." 26 March 2002. <<http://www.epa.gov/scipoly/ospendo/docs/edmvs/lowdosepolicy.pdf>>
- 33) Bergeson, Lynn. "Nanotechnology Trend Draws Attention of Federal Regulators." Manufacturing Today. March/Apr. 2004.
- 34) "Nanoscience and nanotechnologies: opportunities and uncertainties" The Royal Academy of Engineering. 29 July 2004. <<http://www.nanotec.org.uk/finalReport.htm>> (8 June 2005).
- 35) Shindo, Hideo. "Nanotechnology Standardization in Japan." ASTM Standardization News. July 2005. <http://www.astm.org/SNEWS/JULY_2005/shindo_jul05.html> (19 July 2005).
- 36) "MSDS Raw Single Walled Carbon Nanotubes." Nanoledge. 9 Oct. 2003. <http://www.nanoledge.com/userdocs/MSDS-RW-SWNT_Nanoledge.pdf> (19 July 2005).
- 37) "Frequently Asked Questions." CAS Registry Website. <<http://www.cas.org/EO/regsys.html>> (19 July 2005).
- 38) Colvin, Vicki. "Comments of ASTM International Committee E56 on Nanotechnology Concerning EPA's Potential Voluntary Pilot Program For Certain Nanoscale Materials." 22 June 2005. Courtesy David Karmol of ANSI.
- 39) Miller, Sonia. "Measuring Nanotechnology's Effect on the Law." New York Law Journal. 4 Feb. 2005. <<http://www.law.com/jsp/article.jsp?id=1107178539454>> (19 July 2005).
- 40) EurekaAlert's on-line chat on the environmental impacts of nanotechnology.
- 41) Kellyn Betts. "Will EPA shape the future?" Environ. Sci. Technol. A-Pages; 2003; 37(13); 247A-247A.
- 42) National Science and Technology Council (NSTC). Nanoscale Science, Engineering and Technology Subcommittee (NSET). 2004. The National Nanotechnology Initiative: Strategic Plan. Washington, D.C.: the Council, <http://www.nano.gov/NNI_Strategic_Plan_2004.pdf>

- 43) Roco, Mihail. National Nanotechnology Investment in the FY 2006 Budget Request. AAAS Report XXX: Research and Development FY 2006. <www.aaas.org/spp/rd/06pch24.htm> (19 July 2005)
- 44) Dr. Vicki L. Colvin. "Nanotechnology Research and Development Act of 2003" U.S. House of Representatives Committee on Science. April 9, 2003.
- 45) "An Overview Of The Federal R&D Budget For Fiscal Year 2005." Hearing Before The Committee On Science House Of Representatives 108th Congress. February 11, 2004. <http://commdocs.house.gov/committees/science/hsy91690.000/hsy91690_0.HTM>
- 46) "EPA Boosts Homeland Security Research, Proposes Modest Increases for R&D Programs." AAAS Report XXX: Research and Development FY 2006. 2 March 2005. <<http://www.aaas.org/spp/rd/epa06.htm>> (19 July 2005).
- 47) Dr. John H. Marburger, III. "FY 2006 Budget Hearing on the National Science Foundation, the Office of Science and Technology Policy, and the National Science Board." U.S. Senate Committee on Appropriations Subcommittee on Veterans Affairs and Housing and Urban Development, and Independent Agencies. February 17, 2005. <<http://appropriations.senate.gov/hearings/record.cfm?id=232168>>

Additional Resources

- 48) ANSI-NSP Priority Recommendations Related to Nanotechnology Standardization Needs. November 15, 2004.
- 49) "Nanotechnology Hearing." Committee on Commerce, Science and Transportation. Subcommittee on Science, Technology and Space. 107th Congress. Sept. 2002.
- 50) The National Nanotechnology Initiative: Review and Outlook. Hearing Charter. U.S. House of Representatives Committee on Science Subcommittee on Research. May 18, 2005.
- 51) Ahson Wardak. "Nanotechnology & Regulation: A Case Study using the Toxic Substance Control Act (TSCA) A Discussion Paper." Woodrow Wilson International Center for Scholars. Foresight and Governance Project. Sept. 2003.
- 52) Bailey, Melissa; Lattimore, Rachel. "Nanotechnology: Now is the Time to Assess Risks." Occupational Hazards. Sept. 22, 2004.
- 53) Bergeson, Lynn; Auerbach, Bethami. "The Environmental Regulatory Implications of Nanotechnology." Environmental Quality Management. 14 April 2004. <http://www.lawbc.com/other_pdfs/The%20Environmental%20Regulatory%20Implications%20of%20Nanotechnology.pdf> (26 June 2005).
- 54) Bergeson, Lynn; Campbell, Lisa; Rothenberg, Lisa. "TSCA and the Future of Chemical Regulation." EPA Administrative Law Reporter. 15(4) 2000: 1-23.

- <http://www.occupationalhazards.com/safety_zones/47/article.php?id=12403> (8 June 2005).
- 55) Kalpin, Mark; Hoffer, Melissa. "Nanotechnology and the Environment: Will Emerging Environmental Regulations Stifle the Promise?"
- 56) Roco, Mihail. "Responsible Development of Nanotechnology." Environmental Science & Technology. March 1, 2005.
- 57) "Nanotech News in Living Colour: An Update on White Papers, Red Flags, Green Goo, Grey Goo (and Red Herrings)." Communique. May/June 2004.
<<http://www.etcgroup.org/documents/livingcolorfinal.pdf>>

APPENDIX I – ACRONYMS AND NANOTECHNOLOGY WEBSITES

Federal Agencies with budgets dedicated to NNI

- DOD – Department of Defense (www.defenselink.mil)
- DOE – Department of Energy (www.science.doe.gov/bes/NNI.htm)
- DHS – Department of Homeland Security (www.dhs.gov/dhspublic)
- DOJ – Department of Justice (www.usdoj.gov)
- EPA – Environmental Protection Agency (<http://es.epa.gov/ncer/nano/>)
- NASA – National Aeronautics and Space Administration (www.ipt.arc.nasa.gov/index.html)
- NIST – National Institute of Standards and Technology
(http://nvl.nist.gov/nvl2.cfm?dynamic=res_subj&subjectid=17)
- NIOSH – National Institute for Occupational Safety and Health
(www.cdc.gov/niosh/topics/nanotech)
- NIH – National Institute of Health (www.becon.nih.gov/nano.htm)
- NSF – National Science Foundation (www.nsf.gov/crssprgm/nano)
- USDA – Department of Agriculture (www.csrees.usda.gov/ProgView.cfm?prnum=4235)

Participating Agencies without specific NNI budgets

- BIS – Bureau of Industry and Security (www.bxa.doc.gov)
- CPSC – Consumer Product Safety Commission (www.cpsc.gov)
- DOS – Department of State
- DOT – Department of Transportation (www.dot.gov)
- FDA – Food and Drug Administration (www.fda.gov/nanotechnology)
- ITC – International Trade Commission (www.usitc.gov)
- IC – Intelligence Community (www.intelligence.gov)
- NRC – Nuclear Regulatory Commission (www.nrc.gov)
- TA – Technology Administration (www.technology.gov)
- USPTO – U.S. Patent and Trademark Office (www.uspto.gov/)

Agencies under the EPA

- NCER – National Center for Environmental Research (<http://es.epa.gov/ncer>)
- OPPT – Office of Pollution Prevention and Toxics (www.epa.gov/oppt)
- ORD – Office of Research and Development (www.epa.gov/ord)
- SBIR – Small Business Innovation Research
- STAR – Science To Achieve Results

Additional Relevant Agencies

- AAAS – American Association for the Advancement of Science (www.aaas.org)
- ANSI – American National Standards Institute
(www.ansi.org/standards_activities/standards_boards_panels/nsp/overview.aspx?menuid=3)
- ASTM – American Standards and Technology Management
(www.astm.org/COMMIT/COMMITTEE/E56.htm)
- NIEHS – National Institute of Environmental Health Sciences (<http://www.niehs.nih.gov>)
- NSTC – National Science and Technology Council (www.ostp.gov/nstc/html/nstc.html)
- NTIS – National Technical Information Service (www.ntis.gov/nanotech)
- OECD – Organization of Economic Cooperation and Development (www.oecd.org)
- OSTP – Office of Science and Technology Policy (www.ostp.gov)

Policies and Advisory Committees

- IWGN – Interagency Working Group on Nanotechnology (www.wtec.org/loyola/nano)
- NNAP – National Nanotechnology Advisory Panel
- NNI – National Nanotechnology Initiative (www.nano.gov)
- NSET – National Science, Engineering and Technology
- NTP – National Toxicology Program
(<http://ntp-server.niehs.nih.gov/index.cfm?objectid=3E9BB311-F1F6-975E-7EE52F8B5367E815>)
- PCAST – President’s Council of Advisors on Science and Technology
(<http://www.ostp.gov/pcast/pcast.html>)
- TSCA – Toxic Substances Control Act (www.access.gpo.gov/uscode/title15/chapter53_.html)

Organizations

- ED – Environmental Defense (www.environmentaldefense.org)
- ETC – Action Group on Erosion, Technology and Concentration (www.etcgroup.org)
- CBEN – Center for Biological and Environmental Nanotechnology (<http://cben.rice.edu>)
Center for Responsible Development (www.crnano.org)
Foresight Nanotech Institute (www.foresight.org)
- ICON – International Council on Nanotechnology (<http://icon.rice.edu>)
International Association of Nanotechnology (www.ianano.org)
Meridian Institute (www.nanoandthepoor.org/)
- NNIN – National Nanotechnology Infrastructure Network (www.nnin.org)
- NSTI – Nano Science and Technology Institute (www.nsti.org)
Nanotechnolgy Special Interest Group (www.nanosig.org)
Woodrow Wilson International Center for Scholars (www.wilsoncenter.org)

APPENDIX II – TSCA FLOWCHART

This is a visual representation of the overall regulatory process under TSCA. By following this flow of questions a company would determine if any preliminary reporting is necessary before manufacturing a chemical.

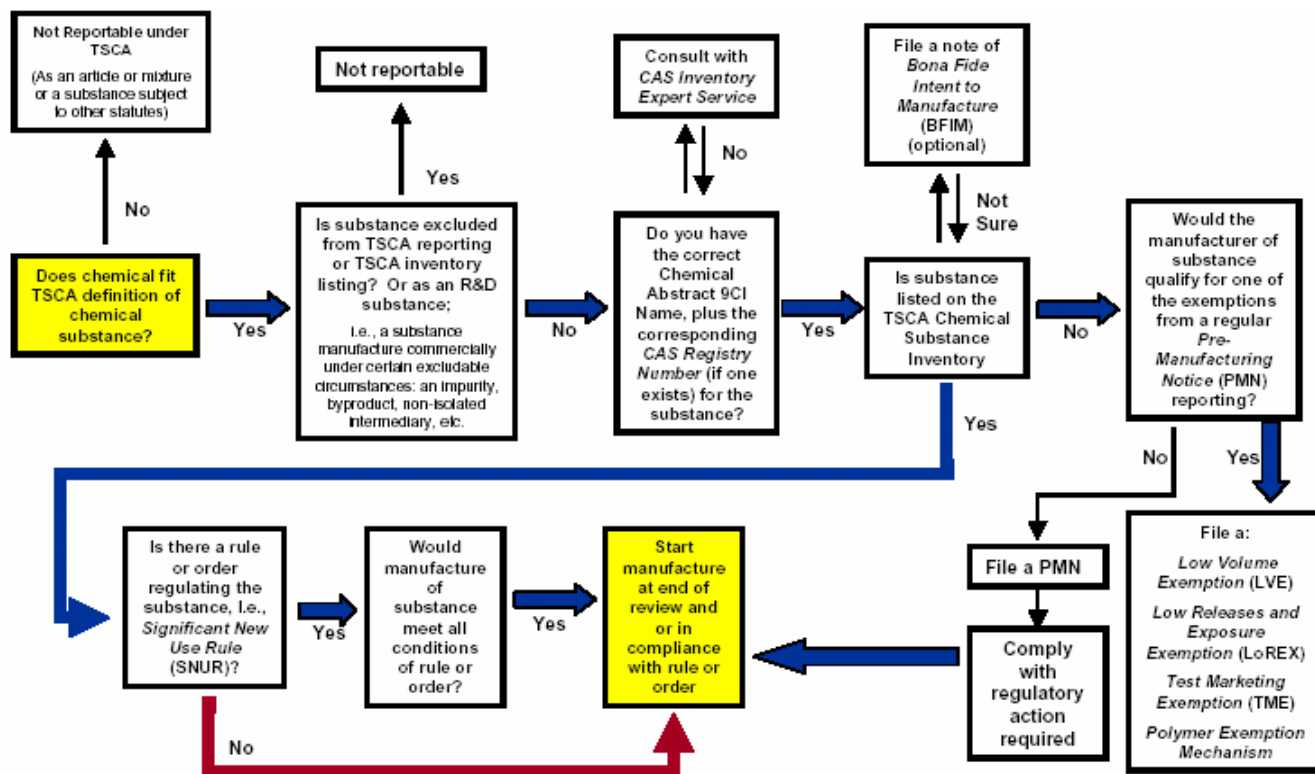


Figure 4 TSCA Chemical Screening Process Flow Chart