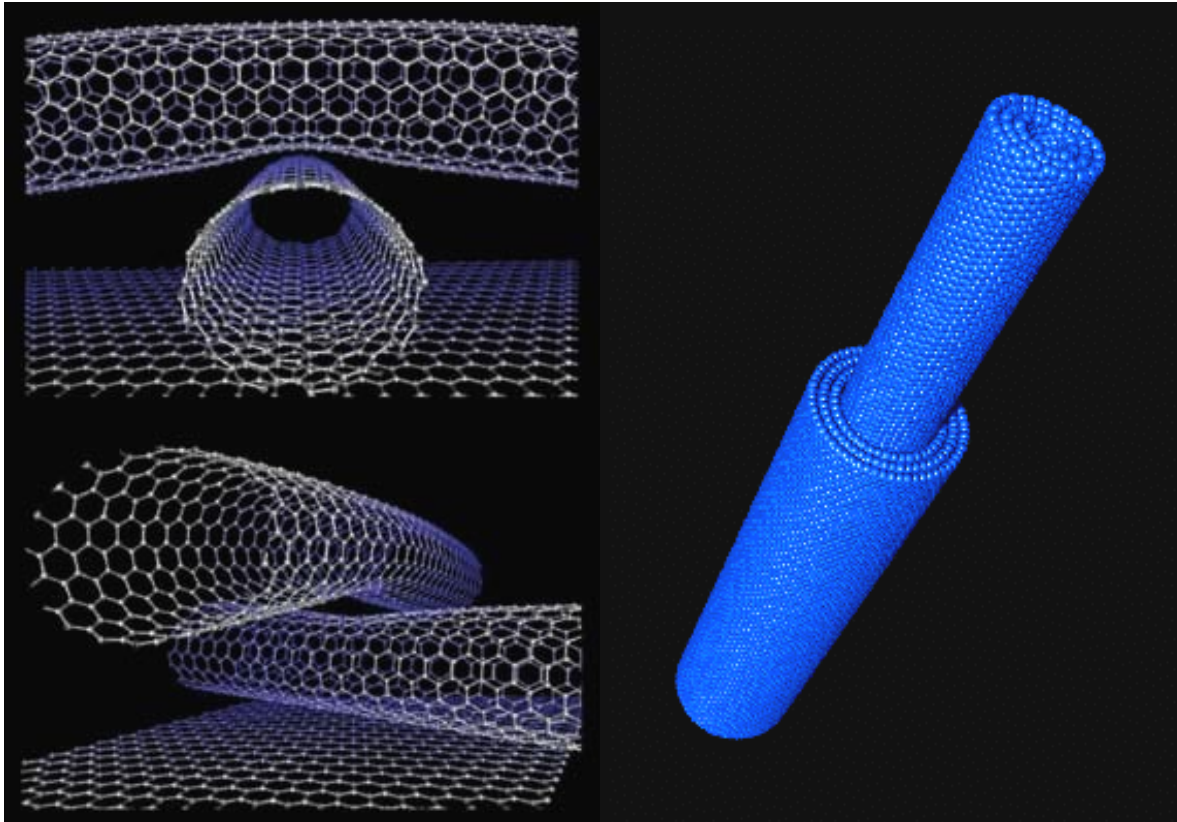


# Nanotechnology & Regulation

A Case Study using the  
Toxic Substance Control Act (TSCA)



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## A Discussion Paper

**Foresight and Governance Project**



Woodrow Wilson  
International  
Center  
for Scholars

*Foresight and Governance Project*

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## Introduction

A recent *Scientific American* article on nanotechnology contains the following observation: “If Einstein were a graduate student today probing for a career path, a doctoral adviser would enjoin him to think small: “Nanotech, Albert, nanotech.” would be the message conveyed.”<sup>1</sup> Nanotechnology seems to be the next big thing, though a couple of years ago, few people had heard of nanotechnology, and even fewer had contemplated its possible economic and societal impacts.

The Los Alamos National Laboratory described nanotechnology as “the creation of functional materials devices and systems, through control of matter on the nanometer (1 to 100nm) length scale and the exploitation of real properties and phenomena developed at that scale.”<sup>2</sup> For reference, a nanometer is about ten times the diameter of an atom, or ten thousand times smaller than the diameter of human hair. There are several reasons for the importance of nano-scale technology and the euphoria of the growing nanotech fanclub. The manipulation of matter on the nano-scale tends to change the properties of chemicals, but not the chemical composition itself. The organization of matter at the nano-scale is key to biological systems, and applications of nanotechnology include medicinal delivery systems. Nano-scale components have high surface areas that aid a variety of physics-based phenomena. In comparison to macro-scale components, the nano-scale provides for harder, less brittle nanomaterials. Even optoelectronics has reasons for supporting nanotechnology, because the wavelength scales begin to converge with the size of nano-scale components. These reasons and many others have scientists and engineers excited about the future for nanotechnology. Examples of nanotechnology applications include commonplace processes like photography, catalysis, and electron tunneling microscopes; however, new nanotechnology applications range from computer hard drives to carbon nanotubes used for handles and frames of tennis rackets or fibers in men’s slacks.<sup>3</sup>

Along with the promise of nanotechnology, a number of cautionary tales have emerged that deal with the technology itself (and potential for self-replication) and the shortcomings of our society and institutions to place proper controls on technological evolution. Those distrustful of the technology have advocated a cautioned approach to its development and deployment. But what exactly does that mean? An outright ban on technological advance is both unrealistic and counterproductive but valid concerns have been raised about our lack of knowledge of the environmental consequences of nanotechnology and, in general, about our inability to anticipate unintended consequences and spillover effects associated with rapid technological change. With real nanotech products already in the marketplace, and a deluge to follow, an urgent set of issues revolve around the adequacy of our existing regulatory system to provide the necessary safeguards and early warnings.

We began this paper with a very simple thought exercise, “How would an existing regulatory framework, the Toxic Substances Control Act (TSCA), administered by the Environmental Protection Agency, apply to nanotechnology?” Also, given the fact that nano-based materials such as carbon nanotubes are already being produced and

commercially marketed, we were interested in whether TSCA had been applied to these substances and, if so, to what effect, and, if not, why? The paper relies on past research on nanotechnology and environmental regulation and draws conclusion based on synthesizing this information. Our overarching conclusions are fourfold:

- **The very nature of nanotechnology – its ability to alter the fundamental properties of substances – is likely to challenge the existing regulatory structure and cause confusion both on the side of industry and the government concerning the role of regulation.**
- **To date, very few people or organizations have addressed the adequacy of our current regulatory system to protect human health and the environment or thought about possible alternatives to existing regulatory regimes (beyond extreme positions such as complete bans on nanotechnology).**
- **A lack of adequate and conclusive research on the health risks of nano-based substances makes the need for a dialogue on regulatory adequacy, inadequacy, or possible alternatives more urgent.**
- **A wrong or ill-conceived approach to regulation could have enormous economic consequences given the revolutionary nature and potential of nanotechnology.**

We begin the paper with an overview of the Toxic Substance Control Act, discuss existing research on the health effects of nanotechnology, examine current recommendations concerning regulation, dive into TSCA in more depth, and provide some tentative observations and conclusions.

## **The Origins of the Toxic Substances Control Act**

Congress passed the Toxic Substances Control Act in 1976 to fill in the gaps of existing chemical substance regulation. The impetus for passing TSCA came from public concern that had grown from recent incidents involving chemical exposures. These included Kepone contamination in the James River and the news of polychlorinated biphenyls' (PCBs) potential harmful effect to the environment. The act gave the EPA Administrator the power to regulate chemicals in commercial use with risk or potential risk to the environment. Consideration was also to be given to the economic and societal effects of government regulation.<sup>4</sup>



TSCA provides a variety of regulatory mechanisms to the EPA. They are:

- inventory of chemical substances,
- new chemical review,
- testing of existing chemicals,
- direct regulation of chemicals,

- reporting/record-keeping requirements, and
- import/export requirements.

The TSCA Chemical Substance Inventory is the list of chemical substances existing in U.S. commerce and it can be accessed at <http://msds.pdc.cornell.edu/tscasrch.asp>. The review of new chemicals occurs under the pre-manufacture notice (PMN) process. The testing of existing chemicals is provided for by test rules outlined by the EPA to industry. The direct regulation of chemicals means that the EPA has the power to prohibit or limit the manufacture of particular chemicals based on risk assessments. Under TSCA, manufacturers must keep records of potential adverse effects of chemicals, and they must report these to the EPA in the required timeframe, especially during the research and development phase. The import/export requirements are under the authorization of the Treasury Department as well as TSCA. With all these methods of regulation, the definitions within TSCA are important to understanding its requirements for industry and potential effects.<sup>5</sup>

Section 3 of TSCA points out key definitions. The most important definition is that of a **chemical substance**. It is defined as “any organic or inorganic substance of a particular molecular identity, including any combination of such substance occurring in whole or in part as a result of a chemical reaction or occurring in nature and any element or uncombined radical.”<sup>6</sup> This definition excludes mixtures, articles, pesticides, tobacco products, nuclear material, food, cosmetics, and drugs. Most of the exclusions are regulated by other agencies of the federal government (see box). A **new chemical**

**substance** is “any chemical substance which is not included in the chemicals substance list compiled and published under section 2607(b) of this title [TSCA Chemical Substance Inventory].”<sup>7</sup> This definition has implications for the international commerce of such chemicals. It is important to keep in mind that foreign companies that produce their chemicals within the U.S. are nonetheless subject to TSCA regulation. These definitions are important to understand for the in-depth discussion of TSCA’s implications on nanotechnology.

#### Product and Corresponding Federal Regulatory Agency

- Cosmetics, food, drugs – Food and Drug Administration
- Nuclear material – Nuclear Regulatory Commission
- Chemicals, Pesticides – EPA, The Office of Prevention, Pesticides, and Toxic Substances

**The Chemical Abstracts Service (CAS)**, which is a division of the American Chemical Society, develops chemical nomenclature and keeps an important database that is crucial to the EPA. This database has significant implications for the emerging nanotechnology industry. The CAS inventories approximately thirty million chemicals that are spotted in technical literature around the world. A majority of these chemicals are not in commercial use, but exist only in labs at universities and research and development divisions of companies. Each chemical is allotted a registry number, or CASRN, plus a corresponding unique chemical name. The relationship between the CAS and TSCA is critical for nanomaterials, as will be discussed later. The TSCA Chemical Substance Inventory is a database of about eighty thousand chemicals in commercial use in the United States today. EPA as a public record

established it. The latest update is online, available in certain libraries, or can be purchased from the National Technical Information Service (NTIS). Of the eighty thousand chemicals, the EPA has reviewed only fifty thousand, and only five thousand have been subjected to rigorous testing.<sup>8</sup> In order to keep trade secrets, not all chemicals in the Inventory are published online. The EPA does keep some chemicals confidential, but information on these can be sought by a bona fide intent to manufacture request (BFIM) on the part of industry. Companies typically put in a BFIM to assure that their substance is a new chemical substance, in TSCA's terms.<sup>9</sup> Pre-manufacturing notices (PMNs) may also be required under TSCA before business can start production depending on the specific use of chemicals in the United States.<sup>10</sup> It is important to point out that The Toxic Substances Control Act has become a list-based, not risk-based piece of regulatory policy. TSCA provides a heads-up on the existence of particular chemicals in our environment, but does not provide comprehensive risk assessments of all these substances. However, approximately 35,000 chemicals on the Inventory have been assessed as part of the Pre-Manufacturing Notice program. The issue of whether nanotechnology poses significant environmental and health risks remains a large and looming question requiring the focus of government and industry. Exactly what type of data could be put on the table to satisfy EPA, or larger public, concerns about the potential risks posed by nano-based substances? We will review some of the existing research findings in the next section.

## **Does Nanotechnology Pose Health Risks?**

There has not been a great deal of research done on the subject of nanotechnology and health risks. The significant research that has been done is reviewed here. Five studies cover the inhalation and dermatological risks associated with carbon nanotubes and ultra-fine particles. Three of these studies were presented at a recent conference of the American Chemical Society (ACS). The first series of studies that are reviewed have to do with the toxicity of ultra-fine particles.

Dr. Gunter Oberdöster at the University of Rochester has studied the effects of ultra-fine particles (<0.1 micrometers in diameter). Nanoscale particles fall clearly into this realm, so the question arises as to whether research on UFP's may be relevant to understanding the behavior and toxicity of nanoparticles. Oberdöster's research used ultrafine carbon particles and found greater lung penetration than with larger particles. His recent paper raised the possibility of ultrafine particles crossing the blood-brain barrier and impacting the central nervous system. Oberdöster stated, "With the emergence of so many unanswered questions, the health consequences of inhalation of UFP [ultra-fine particles] remain an important area of investigation."<sup>11</sup> Of those questions, the two most important were the impact of inhalation of ultra-fine particles on the central nervous system and the daily exposure to such particles.<sup>12</sup> The rest of the studies reviewed here examine carbon nanotubes specifically.

Dr. Chiu-Wing Lam at Wyle Labs of the NASA Johnson Space Center and Robert Hunter at the University of Texas (Houston) studied the impact of carbon nanotubes on lung tissue by instilling a suspension of nanotubes directly into

the lungs of mice. They found that the nanotubes clumped together into bundles and stimulated an immune response, which left scar tissue in the lungs. Hunter's message was that "People should really take precautions. Nanotubes can be highly toxic."<sup>13</sup>

Dr. David Warheit at Dupont's Haskell Labs performed a slightly different experiment. He instilled single-walled carbon nanotube soot mixture into the trachea of rats. For comparative purposes, he also instilled a group with carbonyl iron and quartz, respectively. Fifteen percent of the rats treated with carbon nanotubes suffocated to death within twenty-four hours due to clumping of the nanotubes that obstructed the bronchial passageways. Granulomas and lesions formed as a reaction to the foreign substance. The quartz-instilled and carbonyl iron-instilled rats had some toxicity and no toxicity, respectively. The main conclusion was that carbon nanotubes might be irrespirable. All three of these researchers recommended inhalation studies as the next step, since these studies involved instillation, not inhalation, into the lungs of animals.<sup>14</sup>

A year and a half ago at the University of Warsaw, two studies released at the same time studied the dermatological and inhalation effects of carbon nanotubes. In the study on dermatological effects, which used rabbits, the researchers "did not [find] any signs of health hazards related to skin irritation and allergic risks."<sup>15</sup> The study recommended no special precautions with respect to carbon nanotubes in the working environment; in fact, the article was titled "Carbon Nanotubes: Experimental Evidence for a Null Risk of Skin Irritation and Allergy". In the next study, "Physiological Testing of Carbon Nanotubes: Are They Asbestos-Like?" the researchers found that carbon nanotubes do not exhibit effects similar to asbestos. "Thus working with soot containing CNTs [carbon nanotubes] is unlikely to be associated with any health risks."<sup>16</sup> The study instilled a carbon nanotube soot mixture into the tracheas of guinea pigs.

Obviously, these five studies show conflicting results concerning the toxicity of carbon nanotubes. They do not deal with the associated issue of exposure. A recent collaborative study done by the National Institute for Occupational Safety and Health (NIOSH), NASA, Rice University, and Carbon Nanotechnologies Inc., indicated that worker exposure to carbon nanotubes would be low at low agitation levels, but urged caution until more is known about toxicity.<sup>17</sup> This obviously points to the important relationship between both toxicity and exposure in determining the overall risk to humans and the environment.

At the very least, one must consider further research to determine the health and environmental effects of these and other types of nanoparticles. The Office of Research and Development at the EPA has requested studies to be done on the environmental effects of nanotechnology. The next round of studies should be independent, inhalation studies. A place to start may be with the workers at industrial factories that produce significant amounts of carbon nanotubes or other nanoscale substances for either research or commercial sale. The lack of conclusive toxicity studies does not mean the government or industry should wait before considering what type of regulations may

impact nano-based substances and the companies that produce them. A broader issue is whether regulations like TSCA can protect the environment and human health if conclusive evidence of toxicity and high exposure potentials are found. We now review some existing recommendations concerning nanotechnology and regulation.

## Nanotechnology and Regulation Now

A recent editorial in *Nature* magazine posited that, “There may well be dangers in nanotechnology, as in any emerging area of research. We should certainly look at the potential toxicity of nanoparticles being touted as medical diagnostic tools. But nanotechnology is a diverse field, united only by the factor of scale. So it is not even clear how one would go about regulating nanotech in a manner unique to the discipline.”<sup>18</sup>

Either way this should not stop thinking on nanotechnology and regulation. Two or three papers have explored regulatory opinions, and they are summarized below. The papers reviewed are:

- “Regulating Nanotechnology Development” by David Forrest (1989)
- “Environmental Regulation of Nanotechnology: Some Preliminary Observations” by Glenn Harlan Reynolds (2001)
- “Forward to the Future: Nanotechnology and Regulatory Policy” by Glenn Harlan Reynolds (2002).

The Foresight Institute, a California-based nonprofit educational organization formed to help prepare society for anticipated advanced technologies, sponsored all three of these papers in some way. At the time of Forrest’s paper, nanotechnology was still in its infancy. The significance of this paper is its brief, subtle mention of TSCA. Forrest states:

*“Slightly modifying the language of the Toxic Substances Control Act (TSCA) provides a reasonable starting point... Again, using TSCA as a model, anyone wishing to manufacture a new chemical must give prior notice to the EPA for review under the pre-manufacturing notice requirement. In the face of civil and criminal penalties (as in TSCA) most firms and researchers would comply with the notification requirements.”*<sup>19</sup>

Forrest advocates modest civilian regulation of nanotechnology during its early stage development and envisions a standards-enforcement approach for the field of nanotechnology as it becomes more mature. The major takeaway is his mention of TSCA as a model of future regulation and the advocacy of regulation at some level.<sup>20</sup>

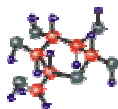
In *Environmental Law Reporter*, Reynolds presents a primer for the upcoming technology and regulation. Nanotechnology is introduced as a promising technology but with potentially dangerous spillover effects. Reynolds makes three conclusions. The first is that a ban on nanotechnology is impossible and harmful. Environmental groups like The Etc Group have advocated this sort of action. The second conclusion is that strict government

*Today, there is no real regulatory policy formulated to deal with nanotechnology. No stakeholder in this arena has taken the initiative to change the status, although some experts believe it is an issue in the immediate future.*

regulation is probably not completely possible, though it may be desirable from a public good standpoint. The third conclusion, and a critical one, is that nanotechnology regulation is a process, not an event.<sup>21</sup> A rush to legislate could be disastrous for a young and rapidly growing industry. About a year later, the Pacific Research Institute released another paper by Reynolds. It examines three possible regulatory futures for nanotechnology: “prohibition, limitation to military applications, and modest regulation with an emphasis on civilian research.”<sup>22</sup> The conclusion is that prohibition is improbable and impossible, exclusive military application might lead to misuse by totalitarian regimes, and modest regulation and civilian research is the best route to the success of nanotechnology.<sup>23</sup>

The thinking in these papers is clouded by the unfortunate tendency to connect nanotechnology (broadly), with molecular nanotechnology (MNT), focused on self-replication, nanobots, and assemblers. A host of regulatory issues will arise long before molecular nanotechnology becomes a reality. Nanotechnology is a body of science and technology, not a specific type. The industry must distinguish between the near and longer-term possibilities of nanotech, or it will suffer a great disadvantage in any dialogue on regulatory schemes. Another assumption affecting the thinking about regulation is the belief that the nano industry is still in its infancy. A few years ago people studying nanotechnology maintained that it would take twenty years for the impact of its industry to be felt on society. The ongoing estimates of the industry’s maturity are continually decreasing. The time to consider regulation and nanotechnology is now, not five years from now.

## **TSCA and Nanotechnology A Guide for the Perplexed**

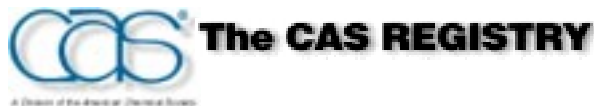


We would now like to take a closer look at TSCA, broken down into its specific steps. We do this from the perspective of a company or someone outside of EPA. To test TSCA’s applicability, we will examine carbon nanotubes, which are already commercialized. According to the NanoBusiness Alliance, thirty-one percent of nanotechnology companies are involved in materials and manufacturing.<sup>24</sup> There are sixteen major producers of carbon nanotubes, and eight of those are in the United States. These companies produce over 2.5 tons of carbon nanotubes per day.<sup>25</sup> Carbon nanotubes are being cited for use in applications for semiconductors and metals to hardened materials. In ten to fifteen years, they could replace silicon in computer microprocessors. In *PC Magazine’s* July 2003 issue, carbon nanotubes were described as one of “20 Hot Technologies to Watch.”<sup>26</sup> Also, in comparison to other nanomaterials, carbon nanotubes have been studied the most. Even though they may not be crucial for this paper, other products from sunscreens to facial creams to clothing use nanomaterials, and each one must be examined individually for its effects on our health or environment.

The following is an overview of key steps, especially viewed from an industry perspective. This is not meant to be a conclusive guide, so companies and other interested parties should consult directly with EPA concerning steps

specific to their products and concerns. For reference purposes, a flow chart is included at the end of the paper. Here are some of the basic questions that industry, the EPA, and other interested parties need to ask:

### Question 1. Does a CASRN exist for the chemical?



As mentioned earlier, a database maintained by the Chemical Abstracts Service provides the first early warning of the existence of a chemical or substance. Our survey indicates that there are companies producing carbon nanotubes that are not individually classified by the Chemical Abstracts Service. Some examples are: Sigma Aldrich's "Carbon Nanotubes: Single-Walled, Carbole X AP-Grade, 12-15 angstrom diameter", "Carbon Nanotubes: Double-Walled, Carbole X SE-Grade, 12-15 angstrom diameter", and Shenzhen Nanotech Port's "Multi-Wall Carbon Nanotubes, 1-100 nm diameter." Sigma Aldrich produces the carbon nanotubes for the National Renewal Energy Lab (NREL), and NREL's website indicates that these materials have no CASRN.<sup>27</sup> In Shenzhen Nanotech Port's case, even their material safety data sheet (MSDS) has no mention of a CASRN.<sup>28</sup> In the case of carbon nanotubes and nanotechnology more generally, the industry is so new, that neither the CAS nor the industry itself can keep up with new chemical classifications. However, the lack of a CAS registry number does not mean that a new substance does not exist.

What does this mean for TSCA? The EPA would only likely detect chemicals that have a CAS Registry Number, or are found during an agency inspection. In addition, a CASRN is not always required for TSCA compliance, for instance, in the case of confidential substances. Though the CAS registration process is helpful to EPA as an early warning of new chemicals coming into commerce, it may not catch all such substances.

### Question 2. Is the chemical in the TSCA Inventory?

If the chemical has a CASRN, and the chemical is manufactured, imported into, or exported from the United States, then it most likely has to jump through TSCA's hoops. Again, using carbon nanotubes as an example, a number of these substances have been registered with the Chemical Abstract Service, but are not known to TSCA. They are: "carbon buckytubes" (CASRN: 1333-86-4), "fullerenes, tubular" (CASRN: 308068-56-6), and "carbon fibers, nanotubes" (CASRN: 308068-63-0). The last number leads to the trade name of "Hyperion, BN." One can speculate that this is the product of the tonnage-scale facilities at Hyperion Catalysis Corporation located in New England.<sup>29</sup> At this point three options exist:

1. The manufacturer can report under TSCA and apply for one of the exemptions from the regular pre-manufacturing (PMN) reporting.
2. The manufacturer can report under TSCA, not seek an exemption, and enter the Pre-Manufacturing Notification (PMN) process.



3. If the use of the nano-based substance constitutes a significant new use as defined by EPA regulation, then the manufacturer can file a significant new use notification (SNUN).

Let's begin by exploring the various exemptions that may apply to nanotechnology businesses.

### **Question 3. Does the chemical qualify for exemptions that do not require an application?**

There is one exemption applicable to nanotechnology that may exempt a majority of nanochemicals early in the development life cycle. This is the research and development (R&D) exemption. Although this exemption does not require an application, there are record keeping requirements.

#### **The Research and Development Exemption (R&D)**

This exemption is ideal for nanotechnology start-ups, especially those start-ups coming out of university research centers. In reality, many of the nanotechnology companies that are not associated with Fortune 500 companies were originally the research consortiums of university professors. Even though the PMN is not filed with the EPA, there are certain requirements for manufacturers under the R&D exemption. The two most notable are the requirement of record keeping of materials for five years after the substances are developed and the written notification to persons to whom the substance is distributed.<sup>30</sup>

### **Question 4. Does the chemical qualify for exemptions that require an application?**

To qualify for an exemption through the application process, the company normally files a Bona Fide Intent to Manufacture notification (BFIM) with EPA. The BFIM provides credibility of the intent and ability to manufacture the chemical.<sup>31</sup> It allows a company to see if the chemical already exists in the TSCA Inventory. If the chemical still does not exist, there are three exemptions, which with application, can exempt a chemical from TSCA's regular pre-manufacturing notice reporting requirements. They are the Low Volume Exemption (LVE), Low Release and Exposure (LoREx), and the Test-Marketing Exemption (TME).

#### **Important Processes in the Toxic Substances Control Act (TSCA)**

**Pre-Manufacture Notice (PMN)** – A notice sent by the manufacturer to the Environmental Protection Agency 90 days before intending to manufacture a new chemical. If after 90 days there is no response, the manufacturer may proceed with the manufacture of the chemical.

**Significant New Use Rule (SNUR)** – A rule promulgated by the Environmental Protection Agency on a particular chemical or group of related chemicals. It states with specificity the meaning of "new use" for a particular chemical.

**Significant New Use Notification (SNUN)** – A notice sent by the manufacturer to the Environmental Protection Agency 90 days before intending to manufacture a chemical regulated by a SNUR. If after 90 days there is no response, the manufacturer may proceed with the manufacture of the chemical. It is similar to a Pre-Manufacture Notice, but it only pertains to chemicals subject to a Significant New Use Rule.

**Notice of Bona Fide Intent to Manufacture (BFIM)** – A notice sent by the manufacturer to the Environmental Protection Agency to ascertain the existence of a chemical in the TSCA Chemical Substance Inventory. It must establish a credible intent to manufacture the chemical for a commercial purpose. It is helpful in finding chemicals in the confidential part of the

### **A. The Low-Volume Exemption**

The first exemption in this triumvirate and probably most important is the low volume exemption (LVE). It exempts from regular (full) PMN reporting the manufacture of less than 10,000 kilograms per year of a particular chemical. The manufacturer must submit the LVE notice to the EPA and the review process lasts only thirty days.<sup>32</sup> For many nanochemicals, their small production volume predisposes them to meeting this exemption. It is hard to envision a huge plant producing carbon nanotubes like steel plants, though some companies, such as Mitsubishi's Frontier Carbon, are predicting multi-ton production.<sup>33</sup> In this vein, the LVE should be reviewed as it is applied to nanoscopic and microscopic chemicals. Although TSCA was only supposed to review widely used chemicals, the manufacture of nanochemicals is important enough to yield a separate inquiry into the effectiveness of such a policy on nanosized particles.

### **B. Low Release and Exposure Exemption (LoREx)**

The second exemption, and probably the hardest to meet, is the low environmental releases and human exposure exemption (LoREx). It states that the chemical must have no dermal or inhalation exposure to workers and consumers, must meet the low-volume exemption described above, and must not be released to groundwater and landfills. The process is the same as applying for the LVE.<sup>34</sup> It is hard to think of any chemicals that might meet such an exemption, although new nanotechnologies may involve distributing devices in enclosed containers that may involve little or no exposure to humans and/or the environment.

### **C. The Test-Marketing Exemption (TME)**

The third exemption is the test marketing exemption (TME). Test marketing, “involves the distribution of a predetermined limited amount of a chemical substance, or of a mixture or articles containing the chemical substance, to specified number of customers to explore market acceptability before general distribution.”<sup>35</sup> The EPA takes 45 days to make its finding based on considering the fixed quantities that will be available to a fixed number of customers. Within TSCA, this was the effort to make the EPA balance environmental concerns with those of technological innovation. As long as nanotechnology continues to put out new products and chemicals with important potential consumer benefits, the TME is an important tool.

It is important to stress that in the LVE, LoREx, and TME process, the submitter must wait until EPA grants the exemption and the review period is over before proceeding with manufacturing. If the exemption is denied, then a PMN must be filed (below).

### **Question 5. How do I file a pre-manufacture notice (PMN)?**

If chemicals cannot qualify for these exemptions, then manufacturers should submit pre-manufacture notices (PMNs) to the EPA. A pre-manufacture notice is a process begun by a manufacturer that seeks to produce a new chemical substance for a non-exempt commercial purpose. The submission of the notice must begin at least ninety days before production is to take place. The EPA takes this time to determine the safety of the chemical substance prior to its manufacture. This is done through procedures outlined by the EPA. In the PMN process, the burden of proof is on the manufacturer. They must provide the information they possess concerning the chemical's toxicity and other such data. If within ninety days the EPA does not issue a consent order or rule to regulate the substance, the manufacturer may proceed with its plans. The consent order is a binding agreement with the manufacturer that may limit, prohibit, or control the manufacture of the new chemical under the EPA's order.<sup>36</sup>

If the manufacturer has provided the PMN to the EPA, and it completes the review period, then the chemical enters into the TSCA Chemical Substance Inventory when the manufacturer files a notice of commencement of production. As of August 2003, no nano-based substances appear in the TSCA inventory (classified under obvious categories). In searches of the public TSCA Chemical Substance Inventory, nothing comes up under the description, "carbon nanotubes", and similar inquiries were confirmed from regulators at the EPA. A larger issue arises concerning where carbon nanotubes should be classified under the existing categories of graphite, diamond, and unspecified carbon. There may be a possibility that the carbon nanotubes are classified under another broader chemical category. In the case of two manufacturers, Carbon Nanotechnologies and Southwest Nanotechnologies, Material Safety Data Sheets (MSDSs) were found online.<sup>37</sup> The classifications were given as: "fluorinated carbon fullerenes" (CASRN: 11113-63-6), "carbon fullerenes" (CASRN: 7782-42-5), and "synthetic graphite" (CASRN: 7782-42-5). The CASRNs for these chemicals are found under the heading of graphite or fluorinated graphite. This is somewhat puzzling. Does this categorization of nanotubes reflect the lack of an adequate category, and, if so, what changes need to be made to deal with this situation? One can assume that nanotechnologies will continue to challenge existing categorization schemes.

### **Question 6. Is there a significant new use for the chemical or substance?**

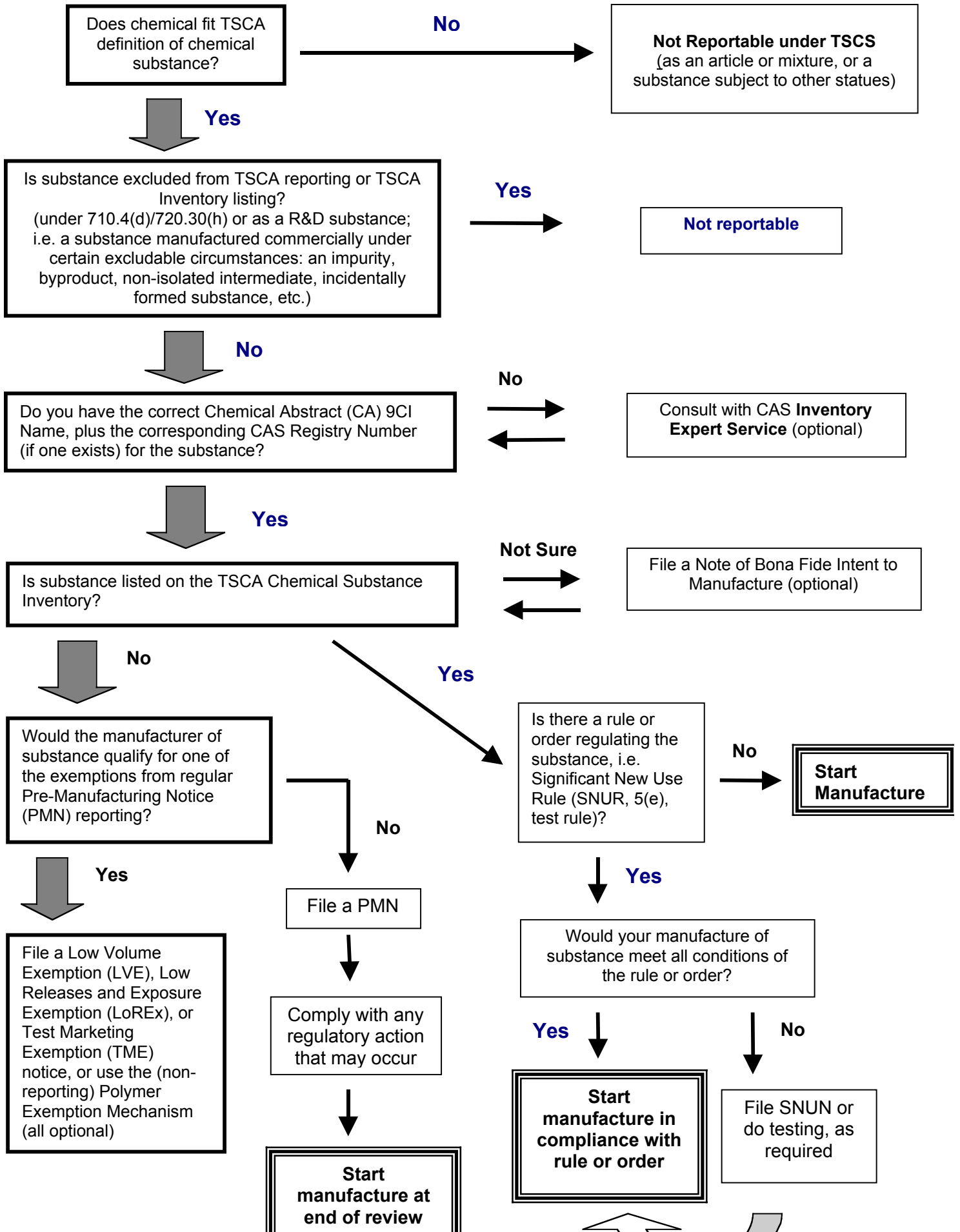
One question nanotech businesses will have to answer in dealing with the TSCA process is whether the application of nano-based substances constitute a "significant new use." This may be a difficult call in many cases given the property changing ability of nanoengineering. In addition, even nano-based substances that are TSCA compliant may find new uses that require that the manufacturer meet extra EPA's requirements in the form of a Significant New Use Rule (SNUR). The Significant New Use Notice (SNUN) is another notice, like the Pre-Manufacturing Notice, that allows the EPA to investigate the effects of the chemical prior to the manufacture of that substance. The filing of the SNUR may not only apply to manufacturers, but the processors or importers of chemicals as well.<sup>38</sup> In

general, the EPA will require up-front testing. In most cases, the new use will be accepted without limitations or prohibitions in manufacturing. From 1976 to 2000, the EPA issued about 1200 SNURs and 750 consent orders.<sup>39</sup> In the case of carbon nanotubes, and nanotechnology in general, the SNUR process is a possibility. A foreseeable problem is establishing a “new use.” If we get past this difficulty, the issuance of SNURs to nanochemicals is good for both sides. In cases where a Significant New Use Rule has been established, it is relatively easy to determine what does or does not constitute a new use on a case-by-case basis for future chemicals or substances.

## **Observations**

The steps outlined above do not constitute an exhaustive trip through the TSCA process, but are designed to highlight some of the major intersections and decision points. This brief exploration raises further questions that will need to be addressed by industry, the government, and other interested parties. It is not clear that TSCA, in its existing form, can address the challenges posed by the burgeoning nanotechnology industry. For instance, in classifying new substances, TSCA does not address differences in the macro- and nano-scale behavior of substances. In the case of nanotechnology, chemical compositions may stay the same, but the fundamental properties change. In addition, issues may arise around what constitutes a significant new use. For example, carbon nanotubes may be used in dozens of different applications, but who knows, under existing guidance, whether each one constitutes a significant new use. This means that a Significant New Use Rule may have to be developed to deal with any aspect of use, manufacturing, and processing that EPA is potentially concerned about.

Issues such as the ones mentioned can be addressed but they need to be tackled sooner, rather than later, before significant numbers of businesses are affected and significant amounts of these materials are produced and distributed into the environment. Clearly, an industry and government dialogue would be helpful at this point in the development of the nanotechnology sector.





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## References

- <sup>1</sup> Gary Stix, "Little Big Science," Scientific American, September 2001, 32.
- <sup>2</sup> 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 August 2003).
- <sup>3</sup> Los Alamos National Laboratory.
- <sup>4</sup> Lynn L. Bergeson, Lisa M. Campbell & Lisa Rothenberg, "TSCA and the Future of Chemical Regulation," EPA Administrative Law Reporter 15, no. 4 (2000): 4, 19; Chan B. Thanawalla, Complying with TSCA Inventory Requirements, (New York: John Wiley and Sons, 2002), 4.
- <sup>5</sup> The Environmental Law Institute and Latham & Watkins, TSCA Deskbook, (Washington, D.C.: Environmental Law Institute, 1999), 7-8.
- <sup>6</sup> 15 U.S.C. § Sec. 2602 (2)(a).
- <sup>7</sup> 15 U.S.C. § Sec. 2602 (9).
- <sup>8</sup> Bergeson et al., 5.
- <sup>9</sup> The Environmental Law Institute et al., 14; Thanawalla, 33.
- <sup>10</sup> Thanawalla, 29.
- <sup>11</sup> Günter Oberdöster and Mark J. Utell, "Ultrafine Particles in the Urban Air: To the Respiratory Tract and Beyond?" Environmental Health Perspectives 110, no. 8 (August 2002): A440.
- <sup>12</sup> Oberdöster and Utell, A440-A441.
- <sup>13</sup> Dagani, 30.
- <sup>14</sup> Dagani, 30.
- <sup>15</sup> A. Huczko and H. Lange, "Carbon Nanotubes: Experimental Evidence for a Null Risk of Skin Irritation and Allergy," Fullerene Science and Technology 9, no. 2 (2001): 247.
- <sup>16</sup> A. Huczko et al., "Physiological Testing of Carbon Nanotubes: Are They Asbestos Like?" Fullerene Science and Technology 9, no. 2 (2001): 253.
- <sup>17</sup> Baron, Paul; Maynard, Andrew; Foley, Michael (2003): "Evaluation of Aerosol Release During the Handling of Unrefined Single Walled Carbon Nanotube Material," NIOSH DART-02-191, April.
- <sup>18</sup> "Nanotech is Not So Scary," Nature, 421 (2003): 299.
- <sup>19</sup> David Forrest, "Regulating Nanotechnology Development," 23 March 1989, <<http://www.foresight.org/NanoRev/Forrest1989.html>> (20 June 2003).
- <sup>20</sup> Forrest.

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- <sup>21</sup> Glenn Harlan Reynolds, "Environmental Regulation of Nanotechnology: Some Preliminary Observations," Environmental Law Reporter, 31 (2001): 10685.
- <sup>22</sup> Glenn Harlan Reynolds, "Forward to the Future: Nanotechnology and Regulatory Policy," (San Francisco: Pacific Research Institute, November 2002), 1.
- <sup>23</sup> Reynolds, "Forward ...", 12-14; William G. Schulz, "Nanotechnology Under the Scope," Chemical & Engineering News, 9 December 2002, 24.
- <sup>24</sup> Ann M. Thayer, "Nanotech Offers Some There, There," Chemical & Engineering News, 26 November 2001, 14.
- <sup>25</sup> Kurt Kleiner and Jenny Hogan, "How Safe is Nanotech?" New Scientist, 29 March 2003, 15.
- <sup>26</sup> Cade Metz, "Carbon Nanotubes: Silicon's Likely Successor, and Much More," PC Magazine, July 2003, 83.
- <sup>27</sup> National Renewable Energy Laboratory, "MSDS List C," ES&H Reference and Support Materials: Chemical Safety, 1 November 2001, <<http://www.nrel.gov/esh/reference/chemsafe/msds197c.shtml>> (16 July 2003).
- <sup>28</sup> Shenzhen Nanotech Port Co., Ltd., "Material Safety Data Sheet: MWCNTs," Shenzhen Nanotech Port Co, 2003, <<http://seasunnano.com/MSDS1.pdf>> (16 July 2003).
- <sup>29</sup> Kent Anapolle, <[Anapolle.Kent@epa.gov](mailto:Anapolle.Kent@epa.gov)> "Re: CAS Numbers for Carbon Nanotubes," 18 July 2003, personal e-mail (18 July 2003).
- <sup>30</sup> Thanawalla, 13.
- <sup>31</sup> Bergeson et al., 19.
- <sup>32</sup> Thanawalla, 18-19.
- <sup>33</sup> See: "Fullerenes by the Ton," Chemical and Engineering News, August 11, 2003.
- <sup>34</sup> Thanawalla, 21-22.
- <sup>35</sup> Thanawalla, "PMN and TOC Instruction Manual," 162.
- <sup>36</sup> Thanawalla, 10-11.
- <sup>37</sup> Carbon Nanotechnologies, Inc., "Buckytube MSDS," 25 April 2002, <[http://cnanotech.com/download\\_files/MSDS%20for%20CNI%20SWNT.pdf](http://cnanotech.com/download_files/MSDS%20for%20CNI%20SWNT.pdf)> (16 July 2003); Carbon Nanotechnologies, Inc., "Buckytube MSDS," 25 April 2002, <[http://cnanotech.com/download\\_files/BuckyPlusTM%20Fluorinated%20MSDS.pdf](http://cnanotech.com/download_files/BuckyPlusTM%20Fluorinated%20MSDS.pdf)> (16 July 2003); Southwest Nanotechnologies, "Single Wall Carbon Nanotubes MSDS," (1 March 2003) <<http://www.swnano.com/Website/Product%20Info/MSDS%20-%20SWeNT%20Carbon%20Nanotubes%204.1.03.pdf>>
- <sup>38</sup> Thanawalla, 10-11.
- <sup>39</sup> Bergeson et al., 6.