Nanotechnology is embedded in the products or processes of nearly every major industry and has become a mainstay of product enhancement. These enhancements will likely generate value and benefit, but may also create new risks and loss scenarios that could directly impact the (re)insurance industry.
Introduction

Nanotechnology is a growing manufacturing technology that is having a tremendous impact on a wide variety of products, enabling new uses of existing products, as well as the development of entirely new and innovative products. Nanotechnology will redefine manufacturing and in the process touch every aspect of society.

Based on some of the reported research, the possibilities for nanotechnology seem endless. These enhanced products will likely generate great value and benefit, but may also generate new risks and loss scenarios that could directly impact the (re)insurance industry. The role of insurance is to help facilitate the positive impacts of new technologies, while also reducing the potential negative impacts by managing the risks, which in the case of nanotechnology, will be challenging.
**Nanotechnology Defined**

The National Nanotechnology Initiative (NNI) is a Presidential research and development initiative, originally proposed by President Clinton in 2000 and supported by Presidents Bush and Obama. The goals of the NNI are: “to advance a world class nanotechnology research and development program; to foster the transfer of new technologies into products for commercial and public benefit; to develop and sustain educational resources, a skilled workforce and the supporting infrastructure and tools to advance nanotechnology; and to support responsible development of nanotechnology.” The NNI defines nanotechnology as the understanding and control of matter at the nanoscale, at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. It encompasses nanoscale science, engineering, and technology. Nanotechnology involves imaging, measuring, modeling and manipulating matter at the nanoscale.

Nanoscale particles and material have been in existence literally since the beginning of time. For example they can occur naturally from volcano eruptions or fire, or vicariously from auto exhaust fumes or cigarette smoke. Only in the last few decades however have scientists been able to intentionally create, design and manipulate a wide variety of nanoscale material to achieve specific objectives.

The development and use of nanoscale material enables the production of objects (both existing products as well as the development of new products and processes) with quality and character beyond prior capability – making things lighter, stronger, more durable, and with greater reactivity, storage capacity, color and conductivity. It can impact everything from consumer products such as clothing, cosmetics, toiletries, food and household cleaning products, to commercial products such as construction material, solar energy batteries and computers. For example, carbon nanotubes can be used to create road paving with unique remote sensing capability; protein nanoparticles may be used to develop improved chemotherapy; and nanotransistors can be used to develop faster computers and Smartphones.

**Nanotechnology Market**

According to BCC Research, the global market for nanotechnology products (nanomaterial used to manufacture finished products) was valued at about US$ 26b in 2014 and is expected to reach about US$ 64.2b by 2019, a compound annual growth rate (CAGR) of 19.8% from 2014 to 2019.

The value of manufactured finished products that will include some aspect of nanotechnology is difficult to determine but various estimates place the number at between US$ 3.0t and US$ 4.4t by 2018, up from about US$ 731b in 2012.

As reported by Reuters, a 2012 study by the law firm of McDermott, Will and Emery looked at which countries are prominent in nanotechnology based on the number of published patent applications and grants. According to their research, U.S. based inventors accounted for 54% of the nanotechnology patent applications and grants reviewed in the study, followed by Asian inventors at about 24%.

Looking at common consumer products that consumers come in contact with every day (e.g. clothing, cosmetics, toothpaste, cleaning material, etc.), a 2013 report issued by the Project on Emerging Nanotechnologies highlights the rapid and steep growth rate of nano-influenced consumer products that are now available, growing from 54 products in 2005 to over 1,300 in 2010, and over 1,600 in 2013. Health and fitness is by far the dominant category led by personal care products (e.g. toothpaste, soaps, etc.), followed by clothing (e.g. wrinkle resistant features), cosmetics, sporting goods and sunscreens.

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**Nano Scale**

Source: nih.gov
Nanotechnology is really a generic term that encompasses a variety of different technologies, techniques and processes used in the investigation, production, processing and use of “nanomaterial” (the specific substances or matter used in the manufacturing process). The value chain of nanotechnology can be summarized as having three major components:

<table>
<thead>
<tr>
<th>Nanomaterials</th>
<th>Nano-intermediates or nanotools</th>
<th>Nano-enabled products or devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>purposefully engineered structures of matter with a dimension of less than 100 nanometers that exhibit size-dependent properties. They have been minimally processed.</td>
<td>intermediate products that are neither raw materials nor goods that represent final consumption that either incorporate nanomaterials or have been constructed with nanoscale features.</td>
<td>finished goods at the end of a value chain that incorporate nanomaterials or nanointermediates.</td>
</tr>
</tbody>
</table>

The bottom line is that nanotechnology is a new industry that impacts many other industries, makes new innovative products possible, and existing products better.

In terms of commercial/industrial applications of nanotechnology, major areas of use include: construction material such as cement, concrete, steel, and glass (e.g. improve durability and energy efficiency); battery technology that increases capacity and power while reducing size (e.g. hybrid/electric cars, wind/solar power, smartphones, etc); 3D printing technology; autonomous vehicle technology; medical technology devices (e.g. biochips, implants, hearing aids, wound dressings); and healthcare impacting medical protocols for cancer, diabetes and cardiovascular diseases among others.

Looking at a fuller list of the nano–influenced products that are currently on the market today (according to the NNI), there is the breadth and diversity of the products that are influenced by nanotechnology.

- Nanoscale materials in cosmetic products provide greater clarity or coverage, cleansing and/or absorption; personalization in the form of antioxidant, anti-microbial, and other health properties in sunscreens, cleansers, complexion treatments, creams and lotions, shampoos, and specialized makeup.

- Nanoscale additive in polymer composite materials used for sports equipment (baseball bats, tennis rackets, motorcycle helmets), automobile bumpers, luggage, and power tool housings to make them lightweight yet stiff, durable, and resilient.

- Nanoscale additive to material or as surface treatments of fabrics to help make them wrinkle and stain resistive, prevent or limit bacterial growth, and provide lightweight ballistic energy deflection in personal body armor.

- Nanoscale thin films used for surfaces such as eyeglasses, computer and camera displays and windows to make them water-repellent, anti-reflective, self-cleaning, resistant to ultraviolet or infrared light, anti-fog, antimicrobial, scratchresistant, or electrically conductive.

Nanoscale is a billionth of a meter in diameter, or, for comparison:

- The head of a pin is 1 million nanometers across
- A nanometer multiplied by 1000 and 1000 again will get to the size of a raindrop
- A strand of human DNA is 2.5 nanometers in diameter
- A human hair is approximately 80,000-100,000 nanometers wide
- One nanometer is about as long as the amount that a typical man’s beard grows in one second
- There are 25,400,000 nanometers in an inch
- A sheet of newspaper is about 100,000 nanometers thick

Source: National Nanotechnology Initiative (NNI)
Nano-engineered materials in the food industry include nanocomposites in food containers to minimize carbon dioxide leakage out of carbonated beverages, or reduce oxygen inflow, moisture outflow, or the growth of bacteria in order to keep food fresher and safer, longer. Nanosensors built into plastic packaging can warn against spoiled food. Polymer-silicate nanocomposite material has improved thermal, mechanical, and barrier properties and can be used in food and beverage containers, fuel storage tanks for aircraft and automobiles, and in aerospace components.

Nano-engineered materials in automotive products include high-power rechargeable battery systems; thermoelectric materials for temperature control; lower-rolling-resistance tires; high-efficiency/low-cost sensors and electronics; thin film smart solar panels; and fuel additives and improved catalytic converters for cleaner exhaust and extended range.

Nano-engineered materials make superior household products such as degreasers and stain removers; environmental sensors, alert systems, air purifiers and filters; antibacterial cleansers; and specialized paints and sealing products.

Nanostructured ceramic coatings that provide greater toughness than conventional wear-resistant coatings for machine parts and can extend the lifetimes of moving parts in everything from power tools to industrial machinery.

Nanoparticles used increasingly in catalysis to boost chemical reactions. This reduces the quantity of catalytic materials necessary to produce desired results, saving money and reducing pollutants. Two applications are in petroleum refining and automotive categories.

Electronic components – making them faster, smaller, more powerful, more durable, with more capacity, etc.

The insurance industry could directly benefit from nanotechnology as well, through the development of improved safety equipment for workers, improved damage resistive material for cars and buildings and the enhanced ability to contain environmental pollution using nanoparticles to decontaminate chemically contaminated soil or water.

Beyond the broad range of current uses of nanotechnology, ongoing research promises more extensive enhancements and developments in all areas of consumer, commercial and healthcare products, processes and protocols.

### Nanotechnology Risks

As beneficial as nanotechnology can be (and is) for society, there are also risks, as there are with any new technology. That’s where the (re)insurance industry comes into play.

The two major areas of potential insurance related exposures are personal health (workers and consumers – including healthcare related), and environmental risks.

Health risks arise most prominently in workers and consumers/users of nanomaterial or products. Workers that are engaged in nanotechnology environments where the nanoparticles are in a free form state such as a facility that develops and produces nanoparticles are the most exposed. Less exposed are workers or consumers engaged with nanomaterial that is contained, for example, in a finished product. The degree and nature of exposure varies by the type of nanomaterial and how it is used. Workers maybe exposed not only during the production stage of nonmaterial or products, but also during the disposal, end of life and recycling stages of products as well.

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**Top 10 countries of inventor – nanotechnology patent literature**

<table>
<thead>
<tr>
<th>Country</th>
<th>2012</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>54.0%</td>
<td>45.1%</td>
</tr>
<tr>
<td>South Korea</td>
<td>7.8%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Japan</td>
<td>7.1%</td>
<td>7.1%</td>
</tr>
<tr>
<td>Germany</td>
<td>6.2%</td>
<td>9.2%</td>
</tr>
<tr>
<td>France</td>
<td>4.0%</td>
<td>5.3%</td>
</tr>
<tr>
<td>China</td>
<td>4.9%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Taiwan</td>
<td>4.1%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Canada</td>
<td>2.6%</td>
<td>2.4%</td>
</tr>
<tr>
<td>UK</td>
<td>2.4%</td>
<td>3.1%</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1.4%</td>
<td>2.0%</td>
</tr>
</tbody>
</table>

* Percentages represent the % of total patents having at least one inventor with an address from the designated country. Source: McDermott, Will and Emery, Intellectual Property in the Next Technology Revolution, February, 2013.*
Environmental exposure generally arises in the production stage (both raw material as well as intermediate and finished products) as waste material or industrial emissions. In addition, the environment may also be exposed at the end of a product life stage as the products are either incinerated or disposed of in a landfill. Of course, the nature and degree of environmental exposure could also indirectly effect health risks as well.

To date there have only been a few loss scenarios reported. For example:

- Sparked by research at the University of Wisconsin Superior, initiatives to remove “microbeads” from healthcare products is spreading and has resulted in lawmakers in more than a dozen states taking action to ban the beads that are showing up in waterways as a result of end of life disposal. “Microbeads” are tiny plastic beads from soaps, scrubs and even toothpaste, generally designed to exfoliate skin or help in the cleaning process. While beyond the pure “nanoparticle” size, this is an example of the type of nanotechnology environmental risk the (re)insurance industry could encounter.

- A 2014 Report in the American Journal of Industrial Medicine cited the first reported case of possible nanotechnology exposure causing illness in the U.S. According to the report, a chemist developed various symptoms (throat irritation, nasal congestion, flush face, skin reactions) after starting to work with a powder containing nano-nickel particles used to make ink fluid. As reported, there were no special protective measures used by the chemist and she eventually recovered fully.

- The Japan Airlines 787 Dreamliner fleet was grounded after a fire in one of the planes was reportedly attributed to nanoenhanced lithium cobalt oxide battery technology.

Legal and Regulatory

Litigation

To date there has been minimal nano litigation. One case of note involves a December 21, 2011, lawsuit brought by a coalition of nonprofit consumer safety and environmental groups against the Food and Drug Administration (FDA) in the United States District Court for the Northern District of California. This was an Administrative Procedure Act case seeking declaratory and injunctive relief. The plaintiffs demanded that the FDA respond to a petition these organizations filed with the agency in 2006.

The 2006 petition at the heart of the 2011 suit, documents the groups’ claims of scientific evidence of nanomaterial risks stemming from their unpredictable toxicity and seemingly unlimited mobility. The 2006 petition requested that the FDA take several regulatory actions, including requiring nano-specific product labeling, health and safety testing, and undertaking an analysis of the environmental and health impacts of nanomaterials in products approved by the agency.

Ultimately, the plaintiff groups agreed to drop the lawsuit because the FDA formally responded to their petition, though the agency rejected some of the key proposals.

Even though there has been very little litigation to date, the potential for extensive nanotechnology litigation exists as the potential hazards of certain aspects of nanotechnology have been publicized in the professional literature. Much of this has been more speculative than science based, but the possibility, nonetheless, has been highlighted. As the litigation landscape evolves, regardless of actual liability or the actual validity of the claims, the legal costs in the early stages of litigation will be high in part because of the highly scientific nature of the claims.
Those most directly involved in nanotechnology regulation focus on regulating aspects related to the environment, workers and products. Some examples of regulatory activities include:

**Environment**
- Environmental Protection Agency (EPA) – Based on a 2008 policy position, each carbon nanotube is considered a new chemical (thus requiring restructured chemicals to be reviewed by the EPA). Also, the Federal Insecticide, Fungicide and Rodenticide Act also regulates nano-based pesticides (which often contain silver nanoparticles). In 2010, the Government Accounting Office reaffirmed the EPA’s authority to regulate nanomaterials in the air, water or soil under the Clean Air Act, Clean Water Act, Toxic Substance Control Act and Superfund laws.

**Workers**
- Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH) – OSHA regulates worker safety on an ongoing real-time basis and NIOSH (part of the Centers for Disease Control) introduced a series of best practices aimed at reducing skin, ingestion and inhalation exposures. An April 2013 NIOSH report recommends limiting worker exposure to nanotitanium dioxide as well as better protective equipment.

**Products**
- Consumer Product Safety Commission (CPSC) – Regulates general safety of consumer products, many of which are now enhanced by nanotechnology.
- National Toxicology Program (NTP) – Part of the Department of Health and Human Services and conducts research into potential human health hazards associated with the use of nanotechnology in the manufacturing process and the resulting products.
- Food and Drug Administration (FDA) – The FDA traditionally regulates product safety on a case by case (product by product) basis. They have traditionally relied heavily on the manufacturer to assure the safety of nano-products and to inform the FDA that the product they are evaluating has been impacted by nanotechnology.

**Regulation**
While nano litigation is yet to fully emerge, the regulatory landscape has started to take shape albeit with some challenges.

First, there is the issue of the decades old question of how much regulation is needed and how much is too much. Too little or the wrong type of regulation may result in harm to the public; too much regulation may undercut a growing economic force and may slow down research leading to the development of potentially lifesaving technology.

Additionally, the science is so new and developing so quickly, that the issue of how to monitor and who is best qualified to monitor nanotechnology is a challenge itself. While there is some state regulatory activity, because of the interstate nature of nanotechnology, this is the type of issue that lends itself more to Federal regulation.

In the 2011 litigation mentioned above, the FDA said it recognizes that nanomaterials may have unusual characteristics compared to their “larger counterparts,” but regulating them as new substances doesn’t conform to the agency’s regulatory authority. Instead, the agency said it will evaluate nanomaterials on a case by case basis consistent with current protocols based on their effects on regulated products, such as foods, drugs and cosmetics. Some types of products will require “pre-market review” before commercialization while others won’t. Labeling all products that contain nanoparticles, as requested by the petitioners, may not be warranted, according to the FDA. None the less, the FDA has taken some initial steps to focus on nanotechnology more broadly by releasing a series of guidance documents for manufacturers aimed at improving safety and quality control of nano-enhanced products.

The FDA advises that additional guidance for the industry will be developed as needed, so the agency appears to be moving gradually towards more robust regulation. However, the FDA continues to rely on existing protocols and laws, leaving it up to individual manufacturers to define whether they are using nano materials and if specific labeling is warranted.

The FDA has not made a “categorical judgment that nanotechnology is inherently safe or harmful.” Some believe that the FDA Guidance is insufficient because it has not set standards that provide real guidance for manufacturers and consumers.
**Risk Management**
Risk management relative to nanotechnology is not in itself unique and typically involves the following fundamental steps:

**Hazard** – Using available scientific/expert analysis, assess the specific engineered nanomaterial and determine the level of risk associated with each to the extent possible.

**Industry** – Determine the specific industries and industry segments (e.g. pharmaceuticals/ cosmetics) that are most exposed to various nanomaterial based on how the nanomaterial is manufactured, processed and used.

**Exposure** – Assess the exposure throughout the entire life cycle of the product. Where is the exposure highest and lowest (e.g. is it manufacturing, consumer use, disposal, etc.)? Emphasis on risk management and safety protocol are the key.

**Insurance impact** – Determine the specific lines of business that may be impacted, the extent to which they will be impacted, and how best to manage the risk and potential losses from an underwriting perspective.

The above applies throughout the entire nanotechnology process depending on the nature of the insured’s operations from raw nanomaterial production through the finished product.

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**Underwriting**
From an underwriting perspective, the insurance industry generally faces challenges with new risks initially because of the lack of data. With nanotechnology, the challenges are tremendous in that regard. There is no credible loss experience, not even a body of judicial activity to examine, and while there are numerous scientific studies, they often produce mixed conclusions.

The lack of data and other definitive loss predictive information means that underwriters need to rely more on qualitative underwriting measures. Some of the broad topics to consider include:

- **Class selection:** Is this a manufacturing risk? If so, is nanotechnology involved and how (e.g. nanomaterial manufacture or user of nanotechnology)?

- **Risk selection and management:** How much of the insured’s business is nanotech related? What risk assessments are in place to address loss control/containment? What are the procedures for disposal, including waste? Are government inspections/certifications performed on the process and products?

- **Coverage (for nanotechnology exposed risks based on the above):** Trigger - claims made? All risk (standard CGL) or named peril? Sub-limits? Defense unlimited or contained? Extent of environmental impairment liability coverage or exclusion? Intellectual property, D&O, product recall, etc.?

Looking at some of the possible coverage scenarios, losses could emerge from several sources as mentioned above. Coverages that could be affected the most are workers compensation, environmental liability, and products liability, followed by premises/operations, D&O, cyber/internet, medical malpractice and life/health, which are less significantly, but still exposed.

The most challenging nanotechnology coverage aspect is the standard industry general liability coverage (CGL), for several reasons:

- **Trigger** – It has a broad occurrence trigger that is open to a variety of court interpretations – exposure, manifestation, injury in fact, triple trigger. The latent nature of possible health effects of nanomaterial, particularly for products that involve multiple occurrences (e.g. cosmetics used daily) will be challenging.

- **Unlimited defense** – The newness, uniqueness, rapid evolution, and uncertainty of the potential impact of nanotechnology will make it very expensive to litigate.

- **Perils covered** – Coverage is an “all risk” rather than a named peril form. It covers everything that’s not clearly excluded. With a rapidly evolving scientific, commercial and legal landscape for nanotechnology, the all-risk nature of the CGL policy makes it a challenge because exclusions in many ways define the scope of coverage.
In the absence of an exclusion, the industry is likely already covering nanotechnology exposure under the standard CGL policy, perhaps unknowingly. There are several problems with applying a broad nanotechnology exclusion, however. Nanotechnology itself is a process, not a product or a thing. This makes excluding nanotechnology itself very difficult. Furthermore, nanotechnology is a process that is applied to and/or embedded in thousands of other products. Other than a risk that actually manufactures or distributes nanomaterial, nanotechnology has no function other than to enhance or create other products. This makes it virtually impossible to exclude just nanotechnology without excluding the product that it is embedded in, meaning that an insurer is better off excluding products liability for designated products if they have concern about the manufacturers’ use of nanotechnology.

**Conclusion**

The future for nanotechnology is expansive and robust. The field is rapidly growing and already a major part of the manufacturing landscape, impacting a myriad of consumer, industrial and health related products. The potential benefits are enormous both economically and socially. But with the benefits come risk, perhaps significant risk. Understanding and managing that risk is one of challenges of the insurance industry.

Broadly speaking, the role of insurers and reinsurers is to enable advancements like nanotechnology to succeed in delivering value to society by helping to manage the related risk and mitigating the impact of potential economic losses that might arise from those risks.

Nanotechnology, at this stage in its evolution, is challenging for the (re)insurance industry for several reasons. First, in most cases, the underwriter is not insuring the initial phase of the nanotechnology process (the actual manufacture of the nonmaterial), insuring instead the manufacture of a finished product. Underwriters may not be aware that nanomaterial is being used to manufacture that finished product unless they specifically inquire. Here “underwriter inquisitiveness” takes on critical importance. Secondly, reported loss activity directly tied to nanotechnology has not been material enough to generate broad industry concerns. A lack of known incidents may be giving underwriters a false sense of security.

The potential latent exposure present in nanotechnology, even if it is relatively remote, is perhaps the greatest nanotechnology related risk for (re)insurers, particularly with respects to bodily injury. The (re)insurance industry would be well served to actively monitor nanotechnology developments and underwrite manufacturing operations with nanotechnology in mind.

**Exposure Checklist**

The following are examples of some information that underwriters should explore, particularly with respect to manufacturing or processing operations involving nanotechnology:

- Does the insured’s production activities involve nanomaterial?
- What nanotechnologies/materials are used, including those supplied and created?
- How is nanotechnology used in the insured’s operations or products?
- Has an analysis of the product's entire lifecycle been performed, including disposal? What is the outcome?
  - What are the identified hazards?
  - What are the results of OSHA, NIOSH, FDA or other governmental agency or other inspections?
  - Toxic effects? Environmental effects?
  - Are there guiding principles at the board or senior management level for managing nanotechnology risks?
  - Is nanotechnology risk management part of the organization’s enterprise risk management efforts?
- Workers – How are worker hazards managed? Is the workplace monitored for nanoparticles exposure? What safeguards are taken to protect employees? Do employees wear proper respiratory and other protective equipment?
- Customers – Does the company inform customers about nanotechnologies it uses or sells?
- Environment – How does the company manage pollution risk – waste or otherwise?
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