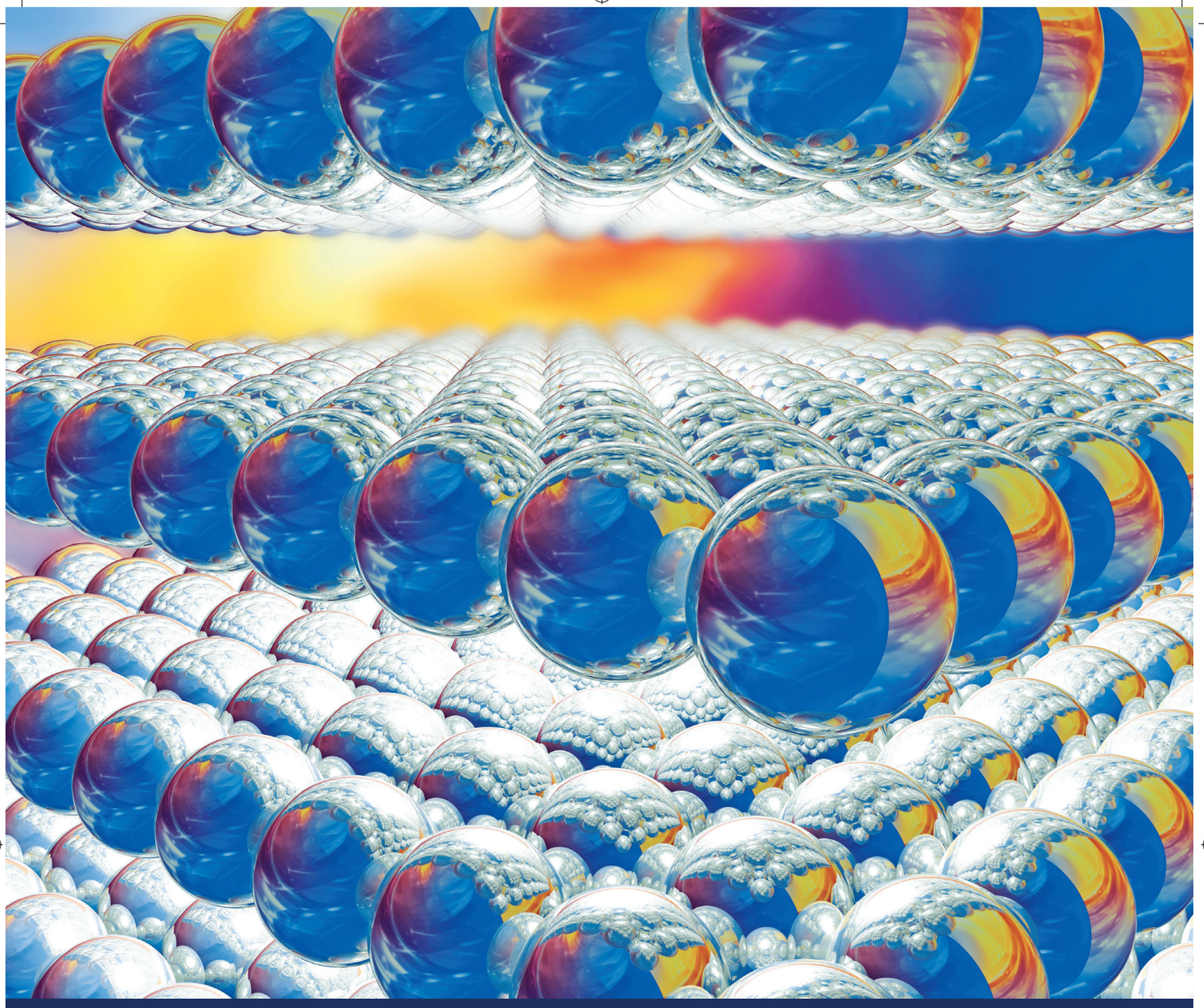


Nanotechnology

CRObriefing

Emerging Risks Initiative – Position Paper

November 2010

CRO FORUM

Executive summary

Nanotechnology is a developing applied science with tremendous potential to create new and innovative consumer and industrial products. It is already used in the production or modification of a wide range of products and significant growth is projected across the industry segments that use these materials.

Nanotechnology presents the insurance and risk management industries with significant challenges and opportunities. Central to these are the relatively unknown environmental, health and safety exposures arising from nanomaterials through their life cycle. Nanomaterials may present different toxicity when compared to their macro counterparts and exposure to hazard may arise in new ways. The toxicity of materials in an unmodified macro state does not necessarily correspond to toxicity in the nanostate, nor can we rely on outdated environmental health and safety regulations or outmoded risk mitigation protocols. This uncertainty has a direct impact on the potential effectiveness of risk management, the availability of insurance risk transfer products, and the ability of insurers to establish suitable reserving practices.

The insurance and risk management industries have an opportunity to collaborate with other nanotechnology stakeholders to close knowledge gaps as quickly as possible in four key areas:

- Nanotechnology risk and safety analysis standards
- Environmental, health and safety (EHS) hazards research
- Regulatory alignment
- Proprietary risk assessment

This paper explores these key areas and the opportunity for collaboration with other stakeholders to pursue the safe and efficient commercial use of nanotechnology.

In summary, the insurance industry seeks to foster opportunity while not ignoring the risks associated with nanotechnology. The insurance industry's primary interest is to achieve a greater understanding of nanotechnology hazards in order to promote risk awareness, risk management and above all, insurability.

Introduction

Identifying and quantifying potentially novel exposures arising from the application of nanotechnology, whether they arise in new or established industries, is a significant challenge for insurers and other stakeholders. Moreover, commercial use of nanotechnology is expanding very rapidly, while management of the accompanying hazards sometimes appears to lag behind. This paper explores the ways in which the insurance industry can respond to this challenge.

The term "nanotechnology" refers to technologies that control matter on the atomic and molecular scale of 100 nanometers or less. This is done for the purpose of exploiting properties not found in the macro state (see figure 1). Resulting nano-scale materials have novel characteristics that can be used to create or improve products but may involve new risks (see table 1). For example, the smaller a nanoparticle, the greater its surface area. This leads to increased reactivity with decreasing size. The shape of a nanoparticle also influences its chemical and physical interaction with its environment. The implications of these new properties are not always understood.

Not enough is known about the environmental, health and safety (EHS) implications arising from nanoparticles during their life cycle. We cannot rely on existing knowledge of macro materials or on existing health and safety regulations to deal with risks in the nanostate.

The amount of time and money spent on toxicity research is also limited, being constrained by budget allocation and the availability of dedicated researchers and laboratories. Progress is slow in building knowledge, measurement techniques, standards and nomenclature. Data-sharing that would help participants to understand the risks at hand has also been too limited.

Figure 1: Comparative size chart

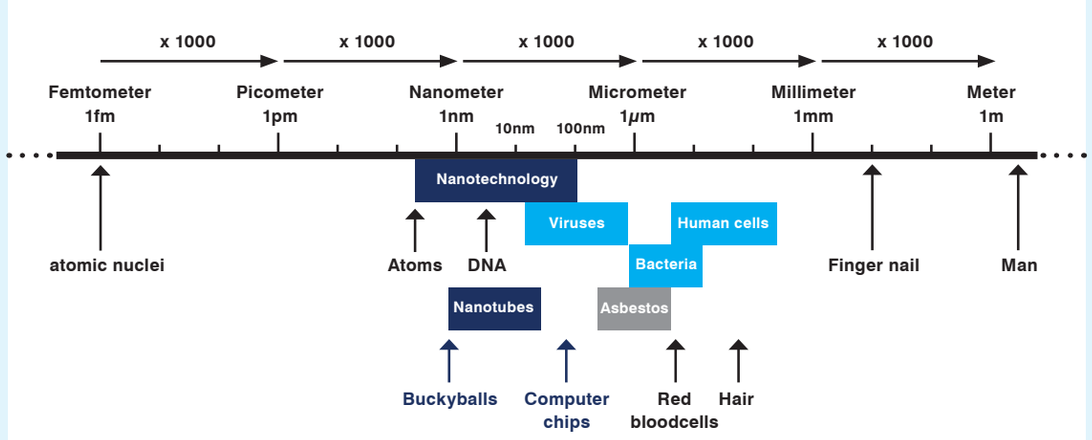


Table 1: Generations of nanotechnology development

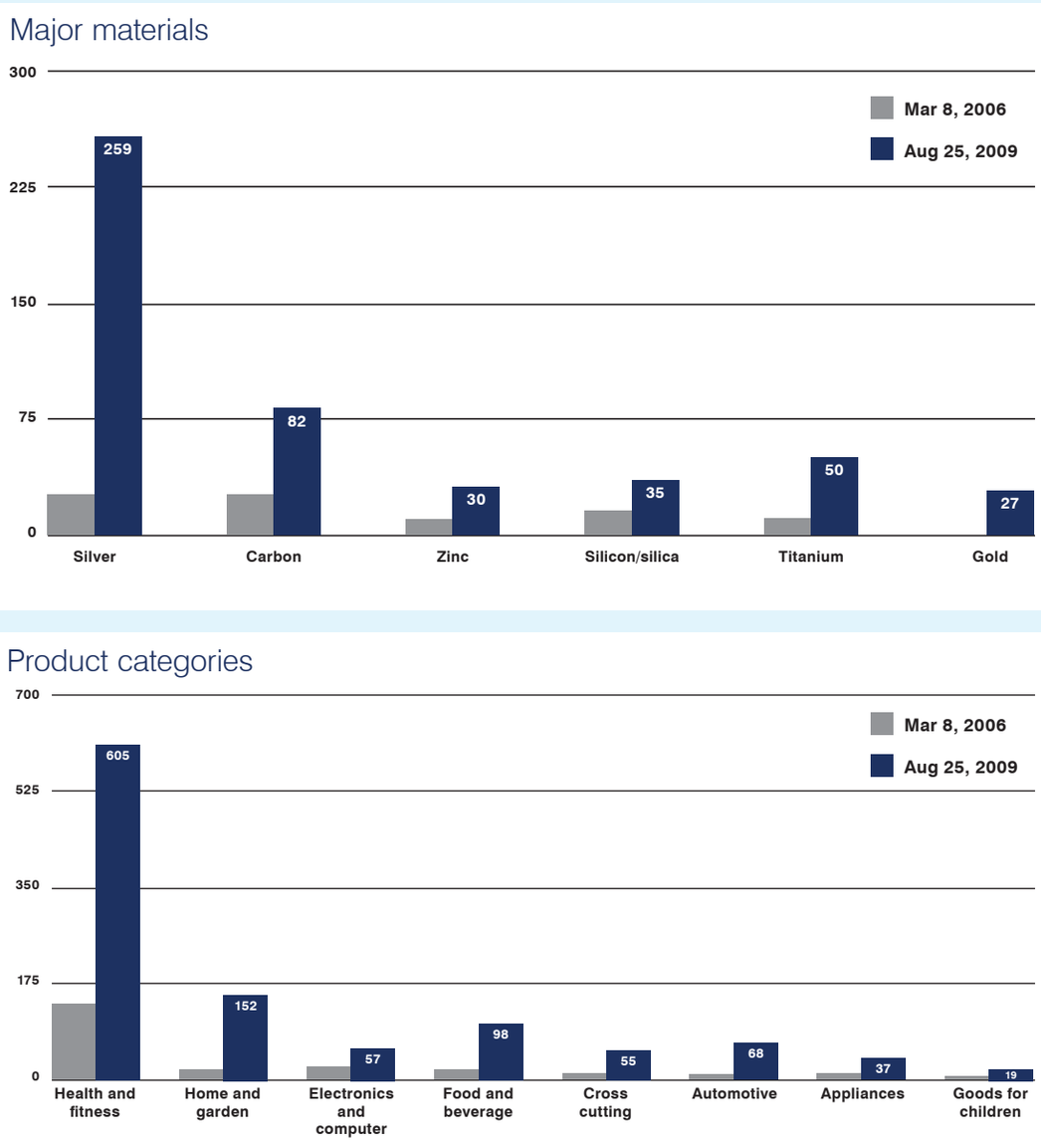
Generation	Generation characteristics
First generation: Passive (steady function) nanostructures e.g. nanostructured coatings and noninvasive nanomaterials; invasive diagnostics for rapid patient monitoring From 2000	**Behavior:** Passive nanostructures are inert or reactive nanostructures that have stable behavior and quasi-constant properties during use. **Use:** Nanoparticles in cosmetics or food. **Risk characteristics:** Often in large-scale production with high exposure rates.
Second generation: Active (evolving function) nanostructures e.g. reactive nanostructured materials and sensors; targeted cancer therapies From 2005	**Behavior:** Active nanostructures whose properties are designed to change during operation. **Use:** Nanobiodevices in the human body; pesticides engineered to react to different conditions. **Risk characteristics:** Behavior is variable and potentially unstable. Successive changes in state may occur that are either intended or as an unforeseen reaction to the external environment with unintended consequences.
Third generation: Integrated nanosystems e.g. artificial organs built from the nanoscale; evolutionary nanobiosystems From 2010	**Behavior:** Passive and/or active nanostructures are integrated into systems using nanoscale synthesis and assembling techniques. **Use:** New applications will develop based on the convergence of nanotechnology, biotechnology, information technology and the cognitive sciences. **Risk characteristics:** The complexity of systems with many components and types of interactions may result in phenomena such as modified viruses and bacteria.
Fourth generation: Heterogenous molecular nanosystems e.g. nanoscale genetic therapies; molecules designed to self-assemble From 2015-2020	**Behavior:** Engineered nanosystems and architectures are created from individual molecules or supramolecular components, each of which has a specific structure and is designed to play a particular role. Fundamentally, new functions and processes begin to emerge with the behavior of applications being based on that of biological systems. **Use:** Genetic therapies, molecular devices 'by design,' atomic design and other emerging functions. **Risk characteristics:** Uses of these applications are not yet clear but potential risks include changes to biosystems and intrusive information systems.

Note: first and second generation technologies are in use now while third generation applications are ready to be launched.

Source: International Risk Governance Council White Paper on Nanotechnology: http://www.irgc.org/IMG/pdf/IRGC_white_paper_2_PDF_final_version-2.pdf

Revenues currently derived from nanotechnology come from relatively few primary nanomaterials[1] (see figure 2). Of more than one thousand nano-enabled products inventoried by the Woodrow Wilson Institute for Scholars up to mid-2009, the small set of materials explicitly referenced are most commonly silver (259 products), carbon (which includes fullerenes) (82), zinc (including zinc oxide) (30), silica (35), titanium (including titanium dioxide) (50), and gold (27). Useful inventories of nanomaterials can be found at www.nanotechproject.org and in the Nanowerk database (http://www.nanowerk.com/nanotechnology/nanomaterial/nanomatmatrix.php).

Figure 2: Commercial uses of nanomaterials and product categories



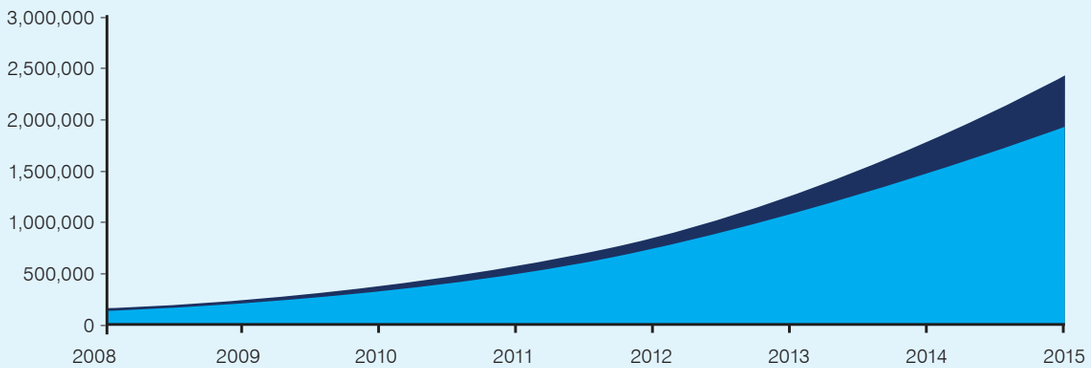
Source: Project on Emerging Technologies http://www.nanotechproject.org/inventories/consumer/

Legend:

- Health and fitness (clothing, cosmetics, filtration, personal care, sporting goods, sunscreen)
- Home and garden (cleaning, construction materials, home furnishings, luxury, paint)
- Electronics and computers (audio, cameras and film, computer hardware, display, mobile devices and communications, television, video)
- Food and beverages (cooking, food, storage, supplements)
- Automotive (exterior, maintenance and accessories)
- Appliances (heating, cooling and air, large kitchen appliances, laundry and clothing care)
- Products for children (toys and games)
- Cross-cutting (coatings)

Revenues generated from nanomaterials, nano-enabled products and nanointermediates may near USD 2.5 trillion by 2015, including computer technology which accounts for roughly 80% of total prospective revenues (see figure 3).

Figure 3: Projected revenues from nano-influenced products



Value chain stage	2008	2009	2010	2011	2012	2013	2014	2015
Nano-enabled products	$145,291	$223,785	$336,062	$519,425	$762,204	$1,081,025	$1,480,928	$1,962,950
Nanointermediates	$18,353	$28,839	$45,592	$75,712	$120,206	$206,823	$322,691	$498,023
Nanomaterials	$812	$1,074	$1,309	$1,540	$1,798	$2,098	$2,462	$2,916
Total	$164,457	$253,699	$382,963	$596,677	$884,208	$1,289,947	$1,806,081	$2,463,890

Source: Lux Research, Inc. : www.luxresearch.com

Legend:

- **Nanomaterials** are purposefully engineered structures of matter with a dimension of less than 100 nanometers that exhibit size-dependent properties and have been minimally processed.
- **Nanointermediates** are intermediate products – neither raw materials nor goods that represent final consumption that either incorporate nanomaterials or have been constructed de novo with nanoscale features.
- **Nano-enabled products** are finished goods at the end of a value chain that incorporate nanomaterials or nanointermediates.

Future use of nanotechnology will be diverse as applications are found for an ever-growing range of products and processes, from lengthening the lifespan of rechargeable batteries to creating better treatments for Parkinson's disease.

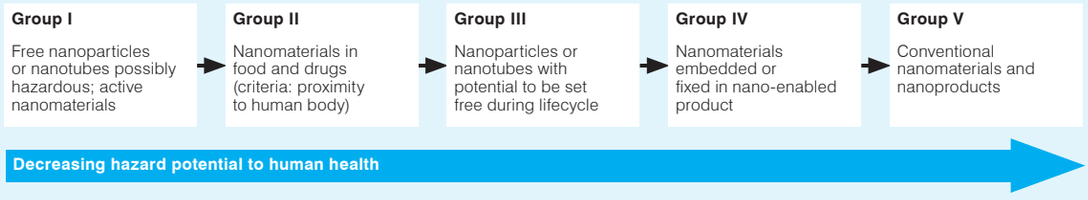
Nanotechnology and insurance: key areas

For insurers, nanotechnology remains largely beyond the bounds of prevailing actuarial calculations and underwriting standards. Yet every day, knowingly or unknowingly, insurers assume risks associated with nanotechnology and extend a considerable amount of capital in terms of policy limits, defense obligations and/or other commitments (see Box A and Box B).

From the insurer's perspective, negative effects that manifest themselves quickly can be identified and contained before they escalate into widespread harm and major losses. Determining whether a nanomaterial holds some latent hazard that may have a significant but delayed impact is a much more difficult task and a key concern for insurers.

A classification approach may assist understanding and there are several ways of segmenting the risks of nanostructures, materials and products. Figure 4 exemplifies a possible classification according to the hazard potential of nanoparticles to human health, mainly based on the risk of inhalation or swallowing. This figure applies to first generation (so-called "passive") nanoproducts only.

Figure 4: Risk segmentation proposed for passive* nanomaterials and nanoproducts
(*active nanoproducts are not considered, as they are not yet marketed)



Given nanotechnology's broad and growing reach, insurers need to be well informed about developments in this market and work with all stakeholders to close knowledge gaps as swiftly as possible.

Progress is required in four key areas:

- Nanotechnology risk and safety analysis standards
- Environmental, health and safety (EHS) hazards research
- Regulatory alignment
- Proprietary risk assessment

Developments in each of these areas may have a direct impact on the availability of insurance risk transfer products, the effectiveness of risk management/mitigation services and the ability to establish adequate reserving practices. This will, in turn, support the safe and efficient commercial use of nanotechnology.

Box A: Nanotechnology – opportunities

Damage-resistant building materials

Nanocomposites, which combine nanomaterials with traditional materials such as steel, concrete, glass and plastics will dramatically improve the performance, durability, and strength-to-weight ratio of the resulting composite material. Nanocomposites promise to reduce the costs of property damage and business interruption associated with natural disasters, such as hurricanes and floods. On the other hand, loss patterns arising from use of new materials may be unfamiliar, and consequently loss adjustment will be more difficult.

Wireless monitoring

Wireless, nano-enabled sensors can be embedded in bridges and other structures to report defects and changes in structural integrity, allowing intervention prior to failure and catastrophic loss. Hermetically sealed wireless sensors powered by bridge vibration can remain on the bridge without maintenance for decades, providing continuous monitoring of such parameters as ice conditions, traffic flows and the integrity of the structure itself. These nano-enabled sensors will reduce the potential of catastrophic loss events, such as collapsed bridges and dams, and ensuing property, business interruption and liability losses.

Pollution cleanup and prevention

Nanoremediation has the potential to reduce both the cost and time required to clean up large-scale contamination sites, and to eliminate the need for treatment and disposal of contaminated dredged soil. Nanoremediation may reduce some contaminant concentrations dramatically and can be done *in situ*. These methods entail the application of reactive nanomaterials for transformation and detoxification of pollutants *in situ* or below ground. No groundwater is pumped out for above-ground treatment and no soil is transported to other places for treatment and disposal, in contrast to slow and costly pump-and-treat remedies. The unique properties and characteristics of nanomaterials also lend themselves to being used to prevent pollution by reducing the release or emission of industrial hazardous waste and other pollutants.[2]

Nanomedicine

Several procedures are currently undergoing trials to exploit the possibilities of nanotherapy in cancer treatment. Some are based on the use of metallic nanoparticles whose surfaces have been modified to target tumor cells specifically. After insertion, the patient is put in a rapidly alternating electromagnetic field. This causes the metal particles to oscillate, generating heat and destroying the cancerous cells locally. Such treatments should become available in the near future.

Nanotechnology is also being used to develop transport systems to deliver drugs (with active ingredients) directly to diseased organs in order to avoid the unwanted side effects of traditional full-body treatment. Nanoscale vesicles (i.e. nano-sized lipid droplets such as micelles or liposomes) are well suited as vessels to pack and transport conventional medicines with aggressive pharmaceutical properties. This is already a billion dollar market. Alternatively, the active ingredients may be coupled to nanoparticles that will then go directly to the targeted organ.

Of course, as encouraging as these developments are, nanomedicine presents more than a simple, unmixed picture of benefit for insurers. The following points about nanomedicine need to be kept in mind:

- Some pharmaceutical products using these new delivery systems have already received FDA approval in the United States; others are in various stages of clinical testing or are already on the market.
- After an elevated risk phase, exposures will fall. During the introductory phase, the risks are greater that the transport systems themselves will cause unexpected negative effects or that the calibration of a dose will be wrong. Once these problems are mastered, the benefits of targeted or individualized medicines will be realized, meaning lower exposures.

Box B: Nanotechnology – threats

Health risks

Nanostructures can enter the body via lungs, mouth and skin absorption, yet the degree to which individual nanostructures expose the human body to adverse health risks is not fully understood. Some nanoparticles (like copolymer particles, cerium oxide particles, quantum dots, and carbon nanotubes) have been found to induce various stress reactions in animal cells. We do not yet know enough about related health consequences to draw clear conclusions. As with any developing body of research, published studies are often followed by contrary results, opinions, even new directions for enquiry. Toxicity research is not merely a brake on commercial use; in fact, it can stimulate it.

Environmental risks

Free-form nanostructures can be released into the air or water during production or as waste byproducts, ultimately accumulating in soil, water or vegetation. It is not yet known if any nanostructures will constitute a new class of non-biodegradable pollutant, but if so, such pollutants could be extremely difficult to remove from air or water, in particular if they are free and not aggregated or agglomerated among themselves.

Financial

The expansion of nanotechnology development and investment is creating an environment that risks securities claims and claims for financial losses, including those that could result from a collapse of stock prices. False and misleading statements about the promises of nanotechnology prompted three securities class action suits against a company that uses nanocrystalline materials in a variety of products, including flooring and sunscreens. A subsequent settlement was reported to have been covered by professional liability policies.

Defense obligations

In some jurisdictions, such as the USA, insurance customers may be entitled to legal defense if the underlying complaint alleges that liability for damages is potentially covered under their policy. Furthermore, the carrier has an affirmative duty to investigate the claims and look beyond the complaint to determine whether there is any potential liability for covered damages. The expense of the defense obligation often comes in addition to the limits of liability on the policy. As an emerging technology, nanotechnology may present previously untested loss scenarios, prompting claimants to advance novel legal theories and interpretations of policy language.

Fear of disease

At least three U.S. courts have addressed the issue of whether cell damage, without any associated symptoms or disability, is covered as “bodily injury” under standard liability policies. In the early stages of nanotechnology development, the lack of definitive scientific knowledge may increase the potential for claims alleging a ”fear of future disease.” Although decisions to date have been mixed, a significant number of U.S. courts may someday rule that such claims are both legally viable and covered by some policies.

Nanotechnology risk and safety analysis standards

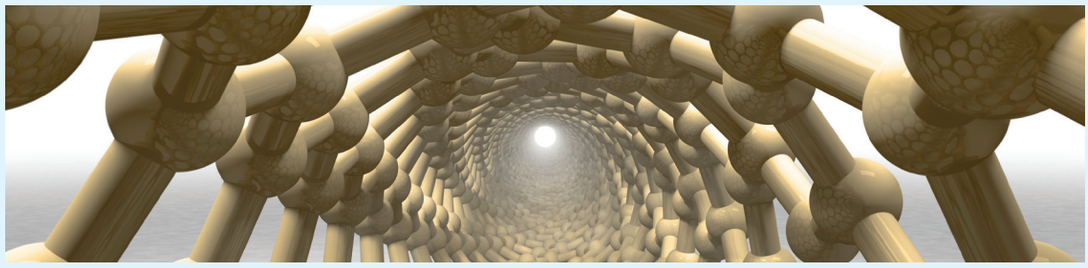
Stakeholders have a common interest in developing a terminology for nanotechnology that is comprehensive, coherent and globally consistent.

There is also a need to develop protocols for toxicity testing, life cycle and environmental impact analysis and measurement including use of certified reference materials for calibration. The current lack of standardization undermines the ability to interpret results from many environmental, health and safety (EHS) research studies.

Efforts are underway to address the need for science-based safety analysis standards in nanotechnology[3] but progress has quite often lagged behind the pace of commercial exploitation.

Environmental, health and safety standards and derived best practice and guidance will eventually form the foundation for regulation. This may increase the long-term insurability of nanotechnology risks. Development of global standards may also support the advancement of trade in nanotechnology.

Box C: Well-known nanoparticles and their potential risks



Carbon nanotubes (CNTs) are among the most well known nanomaterials, with an estimated market of USD 49m in 2006, projected to grow to USD 460m in 2011. CNTs have about one hundred times the tensile strength of steel at one-sixth of its weight. Other properties vary depending on a CNT's particular structure: some demonstrate metallic or semi-conducting properties; some are elastic and can be bent and twisted without breaking. These extraordinary properties make CNTs potentially useful in electronics (e.g., rechargeable batteries, memory chips and sensors), optics (e.g., TV displays, computer monitors and military imaging) and other fields of materials science (e.g., composite materials for sports, automobiles or aerospace). However, additional findings on toxicity may limit their use and economic significance. Some studies have suggested that particular CNTs may potentially have asbestos-like effects. These two factors have put CNTs at the center of discussion over the risk implications of nanotechnology.

Titanium dioxide (TiO_2) nanoparticles are smaller than the wavelength of visible light and thus appear transparent, in contrast to the brilliant white appearance of their macroparticle counterparts. They are, however, opaque to ultraviolet light, making them ideal as invisible filters in sun creams. They also form free radicals and thus possess antibacterial qualities. In addition, TiO_2 nanoparticles can be processed to form an extremely hard, ultrathin layer, suggesting possible use in self-cleaning surfaces. Nanoscale TiO_2 is used in the cosmetics industry (sunscreen, toothpaste) and in OTC drugs. It is used in textiles and added to paints to produce scratch-resistant, soil-resistant coatings for glass and metal surfaces and flooring. Applications are steadily expanding to include household products, sports equipment, medical devices, and more. The safety of sunscreen creams containing nanomaterials has been intensely debated. Intact skin seems to be an effective barrier to nanoparticles; nonetheless, some NGOs have demanded a moratorium on their use. Currently the risk management focus is on workplace safety.

Like the ionized bulk silver (Ag^+) that has been used for millennia, **nanosilver** is a potent killer of bacteria that is also effective against fungi, algae and some viruses. Nanoscale silver particles produce a much greater effect than the silver in jewelry or coins due to their greater surface area. Nanosilver particles, being several nm in diameter, consist of thousands of silver atoms that are released, one after the other, as silver ions (Ag^+) – and it is these which are the actual antimicrobial agents. The most common application of nanosilver is as an antimicrobial agent for wound dressings, disinfectant sprays, textiles, refrigerators, food storage containers and more. There are also around 200 consumer products available today that contain nanosilver but the qualities that make nanosilver useful could boomerang during disposal: nanosilver has been found to be toxic to important soil bacteria at very low concentrations (0.14 μg/ml). It is unrealistic to think that nanoparticles can be recovered once they are broadly distributed in the environment.

Environmental, health and safety (EHS) research

The insurance industry's primary interest in achieving a greater understanding of nanotechnology hazards is not to promote risk avoidance, but rather to promote risk awareness, risk management and above all, insurability.

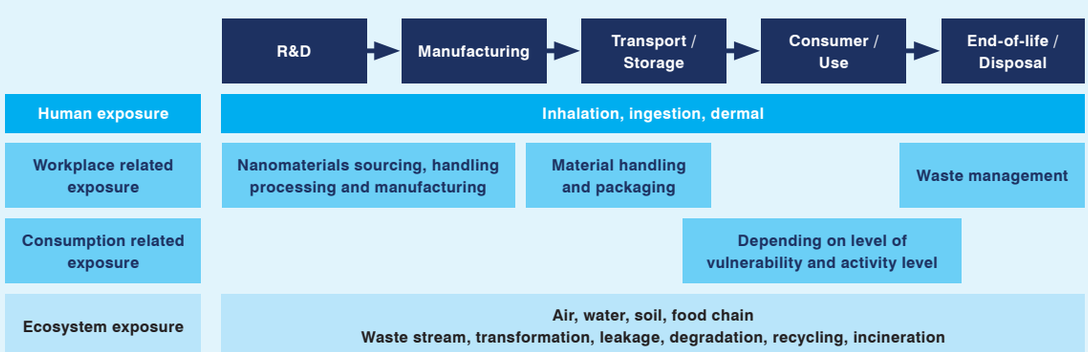
Known risks are potentially insurable. Unknown risks are less so. As a rule, unknown hazards and exposures present a much greater potential risk for insurers and their customers than known high hazard exposures that are properly managed. Known hazards can be identified, mitigated, eliminated and addressed by various risk transfer options.

EHS research must take into account the fact that a particular nano particle does not necessarily present a static potential exposure during its product life cycle. Indeed, nano exposures present varying levels of human and ecosystem risk depending on use, lifecycle stage and the affected industry segment.

Figure 5 is a generic representation of a nanotechnology commercial value chain/life cycle and related exposures that may arise at various stages.

Figure 5: Nano life cycle

Nanotechnology commercial value chain / life cycle and related exposure



By way of emphasis, figure 6 illustrates the complexity of potential exposures throughout the life cycle of a specific nanostructure – carbon nanotubes – as modified by application, industry and life stage.

A low exposure potential arising from carbon nanotubes used in memory chips in the IT industry contrasts with the medium exposure potential of carbon nanotubes used for therapeutics within the pharmaceutical industry.

A more detailed description of carbon nanotube exposures is discussed in the CRO ERI briefing "Carbon Nanotubes (CNT)."[4]

Figure 6: Carbon nanotube life cycle potential exposures

CNT application	Industry affected	Manufacturing	Customer	End-of-life
Coating	Automotive, consumer electronics, textiles, packaging			
Composite	Automotive, aerospace, cons. goods, construction, textiles, packages			
Catalysts	Energy, automotive			
Display	Consumer electronics			
Drug delivery	Pharma			
Energy storage	Consumer electronics, automotive			
Memory	IT			
Solar cells	Energy			
Sensors	IT, pharma			
Therapeutics	Pharma			

High exposure **Medium exposure** **Low exposure**

Improving knowledge of the interaction of these variables through EHS research will support the development of risk mitigation techniques and insurability.

A comprehensive EHS management should encompass among other things;

- Standardized reference materials at nanoscale
- Standardized instruments and detection methods to measure nanomaterial exposure (in air, water, soil)
- Standardized toxicological and environmental measurement methods so that comparisons can be made
- Complete knowledge of exposure levels and exposure pathways during the nanomaterial life cycle
- An emphasis on small and medium sized enterprises regarding workplace safety and loss prevention, as funding for protection measures may be less available than they are for larger enterprises

Table 2 sets out some high level risk management recommendations.

Table 2: Risk management recommendations

Hazard recommendations	Exposure recommendations	Risk recommendations
Testing strategies and metrics for assessing (eco-) toxicity	Exposure monitoring methodologies	Risk assessment methodologies
Nomenclature which includes novel attributes, such as surface area	Methods for reducing exposure and protective equipment	International guidelines and best practices
Pre-market testing and full lifecycle assessment (incl. secondary risks)	Estimation of exposure for events with great uncertainties	Evaluation of probability and severity of risks, including loss of benefits
Disposal and dispersion methods for nano-engineered materials		Balanced knowledge-based communication of EHS methods
Identifying hazards using scenarios		Developing capacity to address uncertain/unknown and ambiguous developments at national and global levels
Matrix for assessing the identified hazards		Identifying and analyzing controversial developments

Source: International Risk Governance Council White Paper on Nanotechnology: http://www.irgc.org/IMG/pdf/IRGC_white_paper_2_PDF_final_version-2.pdf

Research funding

Generally speaking, global funding for research has been increasing. Global government funding of nanotechnologies in 2009 were estimated at USD 9.75 billion[5] and, according to many estimates, private industry is investing at least as much as governments worldwide.

Looking at the U.S. data[6], the proposed 2011 fiscal year budget for federal nanotechnology research and development coordinated by the National Nanotechnology Initiative is USD 1.76 billion, with USD 116.9 million allocated to environmental, health and safety (EHS) research. This is an increase from USD 87 million for EHS research in 2009 and more than triple the USD 35 million figure of 2005.

More generally, the recessionary cycle and mounting public debt may impact availability of research funds in the immediate future. It is imperative that funding allocated to EHS research is maintained or better still, expanded.

Insurers and their customers have an opportunity to support public and private EHS research, the benefits of which are key to nanotechnology insurability.

Regulatory alignment

To allow the nanotechnology industry to achieve its full potential, regulations should protect consumers and the environment while not hampering business development or safe consumption. Consistent regulation across agencies and international boundaries supports free trade, as well as consistent and practical risk management. The degree to which these goals of regulatory efficiency and consistency are met will have a direct impact on insurers, their customers and consumers.

Self-imposed regulation by nanotechnology industries is one way of demonstrating a standard of care that safeguards against EHS damage and counters allegations of negligence. To that end, several organizations have developed codes of conduct or framework documents for the safe handling of nanomaterials. All such efforts should focus on the three most important phases in a nanoparticle's life cycle:

- minimizing workplace exposure during manufacture;
- increasing product labeling and warnings directed to end users; and
- promoting proper methods for environmentally safe disposal.

Regulators are challenged by how to discharge their duties with respect to nanotechnology. At present, most industrialized countries deal with nanotechnology risks within existing regulatory frameworks by making minor adjustments where gaps are identified or new uncertainties emerge. Box D gives a comparative overview on existing regulation of chemicals, cosmetics and food[7].

Box D: The current situation in the U.S.[8] and European Union:

Chemicals regulations: The key legal instruments for regulating chemicals are TSCA (Toxic Substances Control Act, USA) and REACH (Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals, EU). They are complemented by additional regulatory frameworks such as the FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act, U.S.) and the CLP (Regulation on Classification, Labeling and Packaging, EU). These regulatory frameworks are broadly applicable and thus also address nanomaterials in principle. TSCA and REACH are similar in that they require manufacturers to check prior to marketing whether a chemical is subject to regulatory requirements. However, the standards and processes that trigger regulatory requirements, in particular with regard to nanoscale chemicals, differ substantially in these two jurisdictions.

Cosmetics regulations: The FDCA (U.S. Federal Food, Drug and Cosmetic Act) does not explicitly address nanomaterials, while the reframing of the EU Cosmetics Directive is going to create substantial differences and deviations from common practices in the two jurisdictions in that amendments to this EU Directive include specific references to nanomaterials. These amendments have created the first legal definition of "nanomaterials" while it is also noted that this term needs to evolve in accordance with scientific developments. Materials that meet this definition will require submission of additional information and labeling.

Food regulations: The U.S. and EU take a similar approach to food safety in that they differentiate between product categories and require different levels of safety. They also use similar instruments for enforcement, ranging from pre-market review to labeling. Again, food containing nanoproducts or food made with nanotechnology is addressed by existing regulation. Existing regulatory processes and assessment schemes in these jurisdictions contain case-by-case nano-specific safeguards. Apart from these general similarities, specific regulatory elements and implementation regarding nanoproducts differ: generally, EU rules require pre-market safety assessment and mandatory labeling (amendments of novel foods regulation), while the U.S. prefers to base regulation on a case-by-case approach until more generally applicable evidence emerges.

continued

Continued

Noteworthy developments:

U.S.: In 2008, the Environmental Protection Agency implemented a voluntary Nanoscale Materials Stewardship Program (NMSP) to help provide a scientific basis for regulatory decisions. The program was intended to encourage manufacturers, importers, processors, and users of nanoscale materials to submit information on nanoscale materials to the EPA. The EPA is developing a new Significant New Use Rule (SNUR) rule[9] to ensure that nanoscale materials receive appropriate regulatory review. The SNUR would require persons who intend to manufacture, import, or process new nanoscale materials based on chemical substances listed on the Toxic Substances Control Act (TSCA) inventory to notify the EPA at least 90 days before commencing that activity. This information will help the EPA evaluate the intended uses of nanoscale materials and to take action to prohibit or limit activities that may present an unreasonable risk to human health or the environment.

EU: Further consumer protection regulation may be expected.

Technological progress and the question of how an appropriate level of safety can be achieved by regulation is an ongoing process that requires a reliable framework, one that is both flexible and adaptable. The insurance industry can bring its unique perspective to these issues directly through trade associations, and indirectly through influencing their nanotechnology customers.

The goal is reasonable and practical regulations that align across jurisdictions. Coordination will also be essential to build a common language among regulators and between regulators and the regulated. The objective of this coordination is to improve the consistency of decision-making and to communicate clearly with those being regulated (see Box E).

Box E: Public-private coordination

Recently, the U.S. administration and some individual states – e.g., California, New York, and Massachusetts – as well as Canada, the UK, France and the EU – have either announced or signaled that they are considering compulsory data call-ins on nanomaterials under their respective chemical control laws. This marks a shift from enforcement of existing regulations and voluntary reporting to addressing nanomaterials explicitly. Their goal is to develop specific ways of identifying nanomaterials that may be out of compliance under current regulatory standards and definitions. This comes after several voluntary data reporting schemes have been established by public authorities (e.g. DEFRA[10] in the UK). Response was poor, in part because the underlying intention was unclear and because no feedback procedure was established between the regulator and the data providers. Consequently, voluntary data call-in has shifted to a compulsory regime.

Proprietary risk assessment

Nanotechnology, in its immense diversity, is developing rapidly. Just as one set of questions on its potential risks is answered, new ones emerge (see Box F).

The potential exposures arising from nanotechnology may impact various lines of business, including general liability, products liability, products recall, workers' compensation, directors and officer's liability and/or environmental impairment liability. With nanotechnology already in commercial use many insurers may not want to wait for EHS research to mature or regulations to be implemented before developing strategies that address risks and opportunities.

Insurers are ready to work with their customers to support a precautionary approach to the production, use and disposal of nanotechnology products. Prudent workplace safety measures are appropriate even in the absence of a concrete knowledge of a hazard. Such actions can limit subsequent adverse impact to human health and the environment. They can also reduce uncertainty about risk and enable risk transfer.

If insurers are to underwrite nanotechnology exposures effectively, they may want to position themselves by building underwriting and risk management tools to address exposures, just as insurers have done for other materials such as the chemicals used in the pharmaceutical, food and beverage industries.

As an example, the assessment of nanotechnology exposure may include the following or similar steps for nanomaterials, nano-intermediates and nano-products:

- **Hazard description – risk assessment of engineered nanomaterials**
  Inherent hazards are identified and valued by scientific research or expert judgment of their material properties in the context of human and ecosystem exposures
- **Identification and assessment of exposed industry sectors and segments**
  Distinguish industry-specific and application-specific exposures
- **Exposure assessment of the entire product life cycle (R&D, manufacturing, transport/storage, consumer/use and end of life/disposal)**
  List exposures along the product life cycle by industry segment
- **Lines of Business impact assessment**

Box F: Nanotechnology and food

There are only a few nanoscale food additives on the market. One which has been used in large amounts for decades is silicon dioxide (SiO_2, also known as amorphous silica). Added to spices, for example, it prevents clumping so that the spices can be shaken out. Amorphous silica is a fine powder containing nanoparticles of varying sizes that, simply stated, resemble very fine sand. This substance has been tested and approved, and is declared on product labels under the code E551. Other nanoparticles are used to give frozen foods a more uniform mix, so that they thaw uniformly.

A possible case of food-related exposure, however, could come from nano-enhanced packaging. Little has been done to answer the question of whether and under what conditions nanoparticles can free themselves from the surface of the packaging. It would be undesirable for antimicrobial particles of nanosilver, for example, to be transferred from the packaging to the food. PET bottles are commonly coated with a layer of nanomaterials to prevent the penetration of oxygen. The risk that this nanoscale protective layer will detach is lowest when it is sandwiched into the composite with a layer of PET on both sides.

In their individual ways, insurers can build a solid risk assessment approach similar to the one mentioned here, with the existing body of research at its core – research from credible sources that has undergone appropriate peer review. Such a core allows continuous improvement to reflect technological developments and research results.

One of the most difficult tasks in assessing nanotechnology exposures is to translate technical research studies into useful benchmarks that are relevant to insurance underwriting. Insurers may develop such skills internally or seek independent consultation.

An underwriting protocol usually supports the individual account-level underwriting decision and allows portfolio and accumulation management of nanotechnology. Just as insurers manage the accumulation of insured property values in hurricane prone regions, the insurer may need to manage diversification of insured nanomaterials.

Whatever the proprietary and competitive position an individual insurer may take, there is common interest in taking proactive steps to address potential nanotechnology hazards in underwriting and risk assessment strategies.

Conclusion

The rapid commercial exploitation of nanotechnology challenges the insurance industry to react swiftly regarding environmental, health and safety exposures.

The insurance and risk management industries have an opportunity, in collaboratation with other stakeholders, to encourage and participate in four areas of development that will support the safe and efficient commercial use of nanotechnology:

- nanotechnology risk and safety analysis standards;
- environmental, health and safety (EHS) hazards research;
- regulatory alignment;
- and proprietary risk assessment.

Positive developments in each of these four areas will have a direct impact on the availability of sustainable insurance products, the effectiveness of risk management / mitigation services and the ability to establish adequate reserving practices.

Credits and endnotes

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Endnotes

[1] These include titanium dioxide (TiO2); zinc oxide (ZnO); silica (silicon dioxide, SiO2); iron (Fe) and its oxides; silver (Ag) and silver ions (Ag+); and carbon nanotubes (CNT). Applications include use in sunscreen products (TiO2 and ZnO), textiles and bandages (Ag+), waste disposal (Fe), and modern rechargeable batteries (CNT).

[2] U.S. Environmental Protection Agency "Science in Action" Using Nanotechnology to Detect, Clean Up and Prevent Environmental Pollution, July 2009

[3] Some key players involved in harmonization of standards include international organizations, such as the International Standards Organization (ISO), the Organization for Economic Co-operation and Development (OECD) and the American Society for Testing Materials (ASTM); as well as national standards bodies such as the American National Standards Institute in the U.S. (ANSI) and the British Standards Institute in UK (BSI).

[4] CRO Forum Emerging Risk Initiative CRO briefing on Carbon Nanotubes (CNTs) http://www.croforum.org/assets/files/publications/Carbon_nano%20_tubes_FINAL.pdf

[5] Nanotechnology Takes a Deep Breath…and Prepares to Save the World!" April 2009, Cientifica, Ltd.

[6] In 2004, the EU, Japan and the United States together made up 85% of global R&D spending. By 2009 that was reduced to 58% of global spending. That proportion is predicted to shrink still further (though not in dollar terms) as China and Russia emerge as major nanotechnology players.

[7] For an overview including further readings and references for Box D see "Securing the Promises of nanotechnologies – Towards Transatlantic regulatory Cooperation" by Linda Breggin et al., Chatham House, September 2009 (http://www.lse.ac.uk/nanoregulation)

[8] EPA "Control of Nanoscale Materials under the Toxic Substances Control Act" http://www.epa.gov/oppt/nano/

[9] section 5(a)(2) of TSCA

[10] DEFRA: the UK's Department for Environment, Food and Rural Affairs, http://www.defra.gov.uk

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The Emerging Risks Initiative (ERI) was launched in 2005 to raise awareness of major emerging risks relevant to society and the (re)insurance industry. The initiative is currently chaired by Zurich Financial Services Group and consists of nine members representing AIG, Allianz, AXA, Generali, Hannover Re, Munich Re, RSA, Swiss Re and Zurich Financial Services Group. This initiative pursues the following goals:

– Raising awareness and promoting stakeholder dialogue.

– Developing best practice solutions.

– Standardizing disclosure and sharing knowledge of key emerging risks.

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