Volume 1
2017

Allianz Global Corporate & Specialty®

Emerging Liability Risks: Nanotechnology in Food

Risk bulletin

This risk bulletin examines nanotechnology and its applications to the insurance industry, especially to the food and beverage sectors where use of nanotechnology is growing due to its engineered addition into agriculture processes, food ingredients and processing, food packaging and nutritional supplements. It has been prepared by **Allianz Global Corporate & Specialty** and **Praedicat**, a leading think tank for casualty risk analytics.

Executive summary

Nanotechnology is projected to contribute $3tn to the global economy by 2020, and some researchers estimate that around a third of that will be in the "agrifood" industry. Human exposure to nanoparticles is increasing, including via agricultural uses, food ingredients, food packaging and nutritional supplements.

Nanoparticles are routinely incorporated into the entire food processing chain: added to livestock feed and plant fertilizers to improve food taste, coloring and shelf-life; engineered into food packaging to improve biodegradability and heat resistance of food packaging; and introduced into nutritional supplements not normally easily absorbed by the body to enhance their solubility and stability.

The impacts of nanoparticles on human health and the extent of its exposures remain unknown. Cellular and animal evidence on the health effects is underway, but the results and applicability to people is unclear. Scientific understanding on the risks and benefits of nanotechnology in food will increase along with additional research on toxicity, greater regulatory scrutiny and increased public awareness of exposure.

The nanotechnology liability insurance landscape is attempting to keep pace with the technology but it is a challenge. The inherent risks to product recall, food and beverage safety and third party liability are enormous– but improved research and regulations will bring new opportunities for risk mitigation. One of the chief insurance tasks will be to assess the risks across the entire life cycle of nanomaterials and to respond accordingly with new products that ensure risk management criteria and insurability to businesses.

Working closely with clients and brokers, AGCS aims to better understand how companies mitigate the potential risks associated with nanotechnology in order to provide appropriate insurance solutions that protect businesses and their brand. In partnering with Praedicat, scientific analyses and viewpoints are added to ensure academic depth in our underwriting.

The effect of nanotechnology in food, plants and feed is still being researched.

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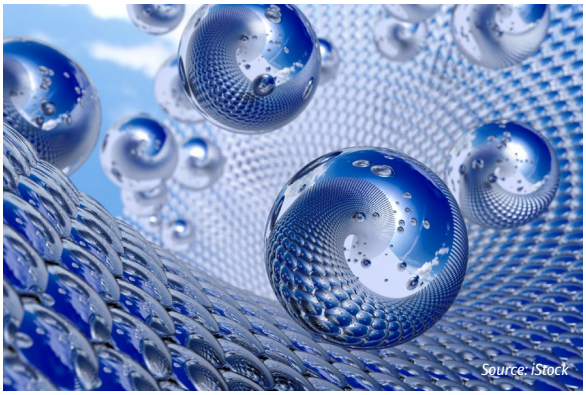
Nanotechnology: What is it?

At times, regulators and researchers have incorrectly used the term "nanotechnology" to describe any technological innovation that is invisible to the naked eye. This definition does not encapsulate the true scale of nanoscience.



Nanotechnology involves the control of matter less than 100nm in size.

A nanometer (nm) is one-billionth of a meter. For comparison, a human hair is approximately 100,000nm wide. Generally, scientists agree that nanotechnology involves the control of matter where at least one dimension is less than 100 nm. At this scale, the physical, chemical and biological properties of particles can differ from those of their larger counterparts. The size of a nanoparticle, therefore, is in the range of 1 to 100nm.

However, the US Food and Drug Administration (FDA), which has no legal definition of nanoparticles, points out that those unique nanoscale properties are sometimes demonstrable in particles as large as a micrometer (1,000nm).

The **US National Nanotechnology Initiative (NNI)** defines nanotechnology as the understanding and control of matter at dimensions between approximately 1 and 100nm, where unique phenomena enable novel applications.

This definition gives some flexibility when particles are outside the 1-100nm size range yet still demonstrate different and unexpected behaviors. Because researchers and manufacturers seek to take advantage of these properties, this framing captures the essence of nanotechnology.

According to the NNI, matter such as gases, liquids, and solids can exhibit unusual physical, chemical, and biological properties at the nanoscale, differing in important ways from the properties of bulk materials and single atoms or molecules, including strength factors, magnetic properties, heat conductivity or light reactivity or reflectivity. These differences are important to manufacturers in understanding the elemental changes to the products they work with.

Five key nano trends for the future:

1. Nanoparticles will continue to be integrated into food, food processing and agriculture
2. Consumers will demand transparency about the nanoparticles they are being exposed to
3. Increased consumer transparency will help drive the research agenda
4. More governmental regulations will specifically address nanotechnology
5. Insurance will have an increasingly important role to play in addressing emerging exposures such as environmental impairment liability, liability, product recall and business interruption coverages

A brief history of nanotechnology

Nanoparticle technology dates back to ancient times when it was used for construction materials and glassmaking. Its use encouraged theories and experiments around the properties and synthesis of new nanoparticles, though they were not called nanoparticles at the time. Modern nanotechnology research began in 1959 when Richard Feynman suggested at the annual American Physical Society that a future world would arise where science and computers operated on an atom-sized scale. In 1974, Norio Taniguchi coined the term 'nano-technology' after using it in the title of a conference paper.

In the early 2000s, the US became the first nation to establish a governmental initiative focused on advancing nanoscale-level research – the NNI. Since its establishment, Congress has appropriated over $20bn in funding to the NNI, propelling scientific research. However, concern for worker safety has also grown. Workers and consumers are increasingly exposed to nanoparticles, but there is limited evidence on their safety. Could these particles pose a risk to human health?

Due to their similar dimensions, in 1998 Robert Service writing in *Science* published an editorial asking if carbon nanotubes (CNT) could be the next asbestos. Scientists have responded to his call for more research on the health impacts of nanoparticles. Researchers have only recently discovered biomarkers of fibrosis, or scarring of the lung tissue, in Russian manufacturing workers exposed to multi-walled CNT and determined they were more likely to have abnormal changes in blood cell function.

These papers were the first to demonstrate potential health impacts in human subjects. In response to the publications, the US National Institute of Occupational Health (NIOSH) questioned whether workplace exposure to multi-walled CNTs would result in occupational illness based simply on the findings of a few studies. In the end, the NIOSH called for further research and underscored the importance of precautionary control measures. Moreover, other exposure pathways exist in which people consume nanoparticles in food on a daily basis. Relevant research has been only recently started and many questions remain.

Nanoparticles and food processing

Humans have likely consumed small amounts of nanoparticles from natural and environmental sources for centuries. Today, nanoparticles are accidentally and purposefully engineered and integrated into food at multiple points along the value chain – in agriculture, ingredients and processing, food packaging and even in nutritional supplements. Each step creates possible human exposures.

Relevant research has been only recently started and many questions remain about the effect of nanoparticles in food.

Agriculture

Nanoparticles are commonly integrated into livestock feed and plant fertilizers. Within livestock feed, nanomaterials often act as mineral supplements. Fertilizers also use zinc oxide nanoparticles. These particles can affect plant growth and development. Other areas of research interest include the use of nanotechnology in milk production and the improved delivery of antibiotics to livestock .

Ingredients and processing

The direct addition of nanoparticles to food and food processing, the conversion of raw ingredients into food and other forms by increasing marketability and extending shelf life, likely creates the largest exposure pathway for human nanoparticle consumption. Nanoingredients are primarily used to improve coloring and taste profiles, while some nanoparticles have been used in food processing techniques for decades. Consumption is increasing as technology advances and becomes more widespread. For example, an exposure analysis found the average US adult consumes up to 1mg of titanium per kilogram of body weight per day and much of it is in the form of nano-titanium dioxide.

Food packaging

It appears that the integration of nanotechnology into food packaging may enhance its barrier and heat resistance functions and could also improve biodegradability. Additionally, nanotechnology has been suggested as a material to create "smart packaging" that can change colors to notify consumers of microbial contamination or repair itself if ripped in transport. As of 2012, nanomaterials in food packaging were the most valuable sector of the nanofood industry; estimates are that the sector will be worth between $15bn to $20bn by 2020.

Nutritional supplements

Many nutritional supplements include nanoparticle ingredients, sometimes referred to as nanoceuticals. These products are used to deliver nutritional supplements that normally are not easily absorbed by the body due to limited solubility and stability. There is growing interest around nanoencapsulation, which protects nanoingredients in a lipid or protein-based carrier which the body breaks down during digestion to release the nanoparticles at a delayed or sustained rate. In spite of their availability on the market, the FDA has rarely approved any nanoceutical health claims.

Nanoparticles and food consumption

Consumers ingest numerous types of nanoparticles that migrate to foods or are directly and indirectly added into them. The Organization for Economic Cooperation and Development (OECD) frequently comments on the safety of common nanoparticles. In 2010, for example, they released a list on nanoparticles that should be prioritized for testing due to concerns around human and environmental safety. Of the 13 OECD prioritized nanomaterials, the four most commonly found in foods are silicon dioxide, silver, titanium dioxide, and zinc oxide.

Silicon dioxide

Silicon dioxide food-grade silica has been used for decades as a food additive under the code E551. The FDA permits the use of E551 as an anti-caking food additive and coloring agent. It is also approved by the European Food Safety Authority.

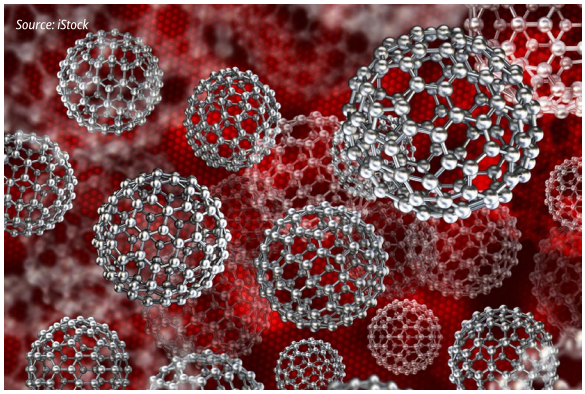
There has been some disagreement among certain entities of the safety of silicon dioxide nanosilica particles with some saying that if enough of the E551 particles are present they agglomerate to larger molecules. Once in aggregate, the silica would no longer be considered nanoparticles.

In spite of its long history in the food industry, relatively little information is available on direct human exposure to E551. Estimates have shown that the amount of nanosilica in 27 food products demonstrate that the worst case consumption scenario would result in an intake of 1.8mg per kilogram of bodyweight per day for an average-sized adult, which would be seen to be a harmless level.

The consensus suggests that a suitable dose of silica nanoparticles is safe while being used as a food additive. However, more attention should be paid to the possible toxicity of long-term and low-dose exposure to silica nanoparticles which will happen, particularly if silica nanoparticles are abused in food without strict regulatory control.

Silver

Silver nanoparticles have antibacterial properties that are of commercial interest especially in food storage containers and plastic storage bags. Other products use silver nanoparticles as a biocide, although many have not been registered with the EPA and it has been estimated that over 100 pesticide products contain nanosilver.



Silver nanoparticles have been shown to interfere with the digestive process in humans.

Colloidal silver is also sold as a dietary supplement and homeopathic remedy, although the FDA does not generally recognize it as safe. Estimates about daily silver consumption, based on intake alone, range between 20 to 80µg (micrograms) per day in both nanoparticle and non-nanoparticle forms.

The most direct evidence on the health impacts of silver comes from studies examining people who willingly ingest colloidal silver as a homeopathic remedy. Colloidal silver contains some nanoparticles, but large silver particles constitute the bulk of these products. People who ingest large amounts of colloidal silver can have a skin reaction known as argyria, which is largely irreversible. Colloidal silver ingestion has been linked to renal and neurological impairment.

While it remains unclear whether nanosilver can have the same systemic impact as larger silver particles, researchers have examined its impacts on cellular function and animal health. Interference with the digestive process has also been found.

Titanium Dioxide

Both the FDA and European Union (EU) permit the use of food grade titanium dioxide, or E171, as a food additive. Primarily, E171 adds color to make foods appear brighter. It also functions as an anti-caking agent used in candies, gum, toothpastes, dairy products, and dietary supplements. In the US, the FDA mandates that titanium dioxide must not exceed 1% by weight. Similar to food grade silica, the exact amount of nanotitanium dioxide within E171 is unknown, but it has been shown that over 93% of titanium dioxide in chewing gum was in nanoparticle form.

Despite its widespread use in food products, little research on human exposure to nanotitanium dioxide via ingestion currently exists. Most risk assessments of titanium dioxide examine transdermal exposure since it is a common sunscreen ingredient. The International Program on Chemical Safety states that most ingested titanium dioxide is excreted with urine and poses little risk to humans given limited evidence of toxicity. Other studies have shown a microinflammation of the colon, which could be the first step in identifying a potential link between nanotitanium dioxide and colon cancer.

Zinc Oxide

The FDA lists zinc oxide as "generally recognized as safe". It has been used to fortify processed foods, as well as in nutritional supplements, food packaging, and plant fertilizers. The average amount of zinc oxide ingested is difficult to calculate due to its popularity in supplements.

Although generally considered safe for human consumption, studies have shown there could be potential health impacts.

Initial evidence demonstrates that zinc oxide nanoparticles can penetrate intestinal cells and induce cell damage and cytotoxicity (dangerous to cell health). Animal evidence on the health impacts of zinc oxide is limited. When orally administered to mice, researchers found the zinc oxide particles distributed to the spleen and thymus, suggesting that human consumption could lead to health impacts via disruption of homeostasis of trace elements.

Nanoparticles and the impact on human health

Upon ingestion, nanoparticles face a single layer of mucous cells that line the digestive tract. At present, the foundation for understanding the potential human health impacts of nanoparticle ingestion consist of a few experiments that have suggested they may cause immuno-deficiencies in the intestines and even the growth of lesions. Little other direct evidence exists.

More broadly, researchers are also linking nanoparticles to colitis, obesity, colon cancer, food allergies, diabetes, proper food digestion and immune dysfunction. Despite the lack of risk-related evidence, researchers looking at nanotechnology and risk perception recently found that consumers perceived nanomaterials in food as the biggest health risk across multiple product categories including cosmetics, medicines and pesticides.

Impact of regulation

Despite growing human exposures, regulatory agencies have been slow to enact rules specific to nanotechnology. Several expert bodies have requested additional assessments of the potential risk including the EU scientific committees and agencies, the International Organization for Standardization (ISO), OECD and the FDA. Under existing authority, the FDA has issued guidance on the use of nanomaterials in animal feed, manufacturing processes of food ingredients and food contact substances and dietary supplements. These guidance documents are not legally enforceable.

> Legislative action is hampered by the lack of a consensus definition of nanoparticles which still vary across pieces of EU legislation that specifically cover nanomaterials .

These include regulations on contact materials, biocide products, and how information reaches consumers. The EU also mandates that all engineered nanoingredients in food or biocidal products be clearly labeled.

Governments of other developed countries, like Canada, Japan and Australia, have demonstrated an interest in nanotechnology regulation. However none, with the exception of the EU, have adopted legally binding provisions.

While other jurisdictions have taken steps to regulate the use of nanotechnology, the US has avoided regulation in favor of voluntary, non-binding guidelines. Worker safety and public and environmental health, however, should be protected by maintaining a focus on critical risk research and immediate action plans to mitigate potential exposures until proven safe. In the view of the industry, regulations should require labelling of nanomaterials from which consumers can be exposed.

Emerging nanotechnology trends

The nanotechnology landscape will continue to advance and change. Several general trends are likely to emerge:

Continued use in food, food processing and agriculture

Nanotechnology is projected to contribute $3tn to the global economy by 2020, and some researchers estimate that around a third of that will be in the "agrifood" industry. Many of the potential products, like those used in food packaging and agriculture, are still under development and represent additional potential growth points in the market. The overall growth across the agricultural and food sector means that more products will integrate nanotechnology and consumers will become increasingly exposed.

Consumer demand for transparency

Consumers are increasingly savvy about ingredients and personal exposures. Mandated labelling in the EU has also increased awareness. When it comes to nanotechnology, both the risks and benefits remain unclear. Therefore, public acceptance is likely to hinge on the initial toxicity research and any emerging evidence on human exposures and health outcomes.

Increased nanotechnology research

Consumer ingestion of nanoparticles will likely lead to significantly less exposure than occupational inhalation. Researchers are eager to understand the health risks around human exposure, but causal research directly linking ingestion to human harm probably will not emerge within the next few years because human research takes time. Overall, the state of the science indicates that more in vitro and in vivo evidence is forthcoming.

Researchers are eager to understand the health impacts of nanotechnology, but more work needs to be done.

Increased governmental regulation

As public awareness and scientific evidence around the risks and benefits of nanoparticles increases, more regulation is likely. It is difficult to foresee how nanoproducts will be finally regulated, but it is generally agreed that guidance is needed to provide clarity and legal certainty to manufacturers, policy makers, health-care providers, enforcement authorities, and the consumer.

Future outlook and insurance challenges

Initial scientific evidence demonstrates that ingestion of certain nanoparticles has the ability to impact cell function and animal health, but the results of these studies are often mixed. No human evidence on bodily injury regarding ingestion is available, and causal research is unlikely to emerge in short order.

Consumer exposure to nanoparticles continues to increase as more agricultural processes incorporate nanoparticles and new nanoingredients come to market. Because consumers have grown increasingly aware of food ingredients, they will likely demand to know more about their exposures to nanoparticles and the risks of their ingestion. The EU has mandated that nanoingredients be listed on food labels and biocides, increasing consumer awareness, but other regions have been slow to enact legislation, particularly in the US.

The nanotechnology industry will continue to grow and manufacturers can be mindful and proactive of the potential risks and benefits of nanotechnology since consumer trust will be necessary to the success of their products. Nanotechnology has tremendous potential to create new and innovative products which in turn presents the insurance industry with significant challenges and opportunities.

Nanoparticle risks

Why are nanoparticles risky?

- They are relatively cheap and can be manufactured in large quantities
- They are broadly used in consumer products
- They may present a different toxicity in comparison to other ingredients with similar functionality and may therefore develop new hazards
- They can be highly reactive
- They often have unknown toxicity or it may be difficult to quantify, as further scientific understanding is needed
- They can disperse easily in air or water if not controlled by a robust structure

Impact for risk management and insurance

Nanotechnology offers the opportunity of risk reduction in many industries. For example, imagine a food packaging wrapper that is impregnated with nanoparticles so it can change color in the presence of contaminants like *Listeria*. This would reduce the risk of illness or death from consumption and will reduce the financial burden of Listeria outbreaks, which results in over two billion dollars in illness costs in the United States, annually.

> One of the tasks for the insurance industry will be to assess the risks spanning across the life cycle of nanomaterials.

But nanotechnology does present risk, especially in the product recall sector and in particular for the food and beverage industries, as personal injury exposures are most imminent.

The vast use of nanotechnology and nanoparticles needs to be regarded as part of modern technology with further significant growth expected across various industries. Insurers need to understand the developments in the use of the technology and materials and the scientific discussion and evolution surrounding those developments.

Possible insurance scenarios*

Should nanoparticles prove to be harmful, the following possible scenarios may already have insurance solutions with insurers such as AGCS.

- Pollution spill from a nanoparticle production facility
  - Environment impairment liability (EIL) insurance policies would at least cover the clean-up costs
- Employees at a nanoparticle manufacturing facility develop chronic illnesses
  - This scenario could give rise to potential costs paid under liability policies
- Nanoparticles leach from products to accumulate in human bodies or in the environment
  - There may be costs associated with medical treatment of affected persons and/or remediation of environmental conditions; touches both EIL and liability policies
- Product recall due to research findings indicating that a product is a hazard
  - Insurance policies may cover the costs of recalling products, the interruption to the business and the detrimental impact to the companies brand, among other things

* Bulleted scenarios, although not specifically food & beverage related, refer to possible nanotechnology issues as highlighted by Lloyd's. The sub-bullets are AGCS specific insurance solutions to those issues.

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Further information

About Allianz Global Corporate & Specialty

Allianz Global Corporate & Specialty (AGCS) is the Allianz Group's dedicated carrier for corporate and specialty insurance business. AGCS provides insurance and risk consultancy across the whole spectrum of specialty, alternative risk transfer and corporate business: Marine, Aviation (incl. Space), Energy, Engineering, Entertainment, Financial Lines (incl. D&O), Liability, Mid-Corporate and Property insurance (incl. International Insurance Programs).

Worldwide, AGCS operates in 32 countries with own units and in more than 160 countries through the Allianz Group network and partners. In 2016, it employed more than 5,000 people and provided insurance solutions to more than half of the Fortune Global 500 companies, writing a total of €7.6 billion gross premium worldwide annually.

For more information please visit **www.agcs.allianz.com**.

About Praedicat

Praedicat is a science-based data analytics company that works with (re)insurers and corporates to manage liability exposure and capture opportunity for better risk management and product stewardship.

It uses science-driven risk analytics to help companies evaluate the current state of the science around emerging risk and look ahead to determine how science might evolve.

Praedicat was formed in 2012 by RAND Corporation and Risk Management Solutions, Inc. when the need to improve identification and prioritization of emerging risks collided with the availability of cutting edge knowledge engineering and modeling technology. Praedicat has been named by CIO Review as one of the top 20 most promising insurance technology solution providers. Clients include corporations in the insurance, reinsurance, and global industrial and chemical markets.

For more information please visit **www.praedicat.com**.

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