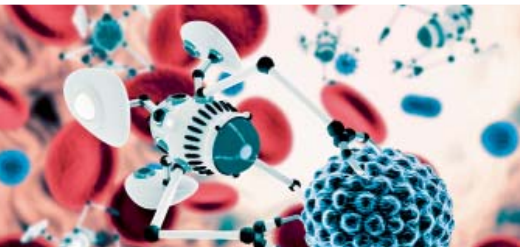
DECEMBER 2012

CASUALTY MATTERS



Handling Nanotechologies With Foresight in the Context of Liability Insurance

by Richard Wieczorek, Gen Re, Cologne

There is no such thing as nanotechnology in the singular. Strictly speaking, we should talk of nanotechnologies in the plural. The term embraces numerous principles from various fields of knowledge, such as science and engineering, quantum physics, materials sciences, electronics and information technology, chemistry, etc. Common to all is the scale on which everything takes place.

Before we tackle nanotechnologies from an underwriting perspective, it is important to explain the dimensions of these technologies:

Experts consider nanotechnologies to be the key technologies of the 21st century. Their diverse manifestations result in a virtually inexhaustible range of applications. Here are some facts that give a rough idea of the scale of these technologies.

- Size

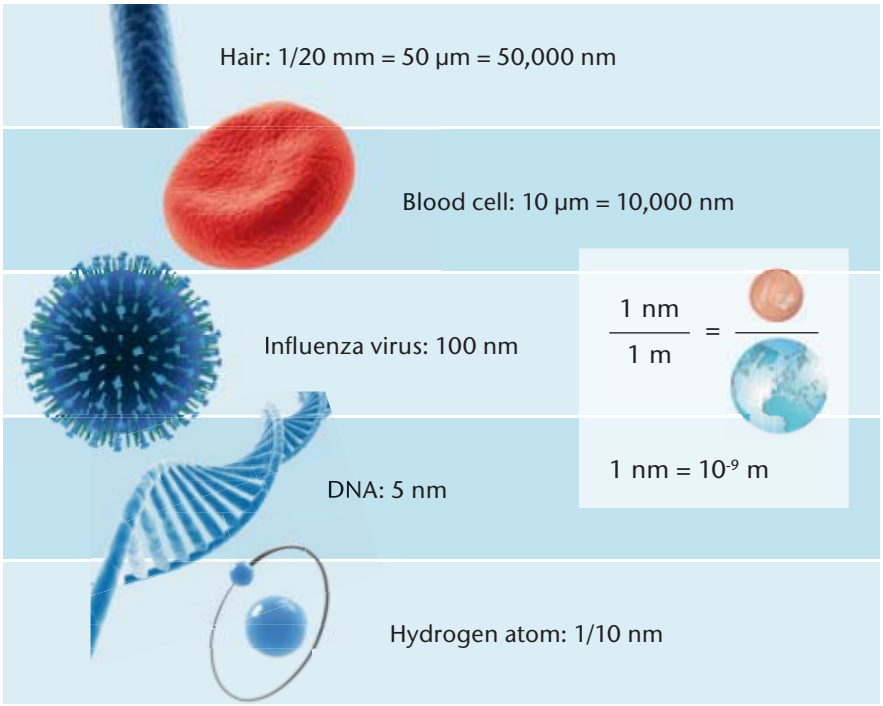
  The European Union published an officially recommended definition of nanomaterial in October 2011. According to this definition, nanomaterials are materials where the main components range in size from 1 nm to 100 nm.[1] The extent to which this definition satisfies practical requirements, particularly when it is a question of linking it with legal consequences, is too complex to be addressed in the context of this article. The definition is intended merely to provide an impression of scale involved (Figure 1).

Contents

About This Newsletter

Gen Re's *Casualty Matters International* reviews new liability developments.

Figure 1 – Nanotechnology – Dimensional range



- Cross-sectional technology
  Wikipedia offers an appropriate description of cross-section technology in relation to nanotechnology: "Cross-sectional technologies are technologies where the area of application is not restricted to a specific industry, but is found in all industries."[2] The examples in Figure 2 illustrate that nanotechnologies have gained a foothold in a number of industries and that nanomaterials are well-established in many areas.

- Economic significance and development
  Experience shows that assessments of the economic significance and development of nanotechnologies differ wildly. According to international forecasts, nanotechnologies will be a key factor in the value creation of goods, with a market value of up to USD 3 trillion by 2015. Their market potential in 2015 could correspond to approximately 15% of the industrial goods market. This would mean that a large part of global goods production, for example, in the areas of health, information and communication technology, energy and environmental technology would, be based on the application of nanotechnological knowledge. A further indicator of the expected rapid growth is the anticipated public investment volume (Table 1).

According to the German Federal Ministry of Education and Research (BMBF), there were approximately 1,100 nanotechnology companies in Germany in 2011. Around 64,000 jobs involved nanotechnologies either directly or indirectly – a trend that is increasing strongly. In 2011 German nanotechnology companies recorded a total turnover of approximately EUR 14.3 billion.

The databases set up by the BMBF in conjunction with the Association of German Engineers (VDI) Technology Centre and by Friends of the Earth Germany (BUND für Umwelt und Naturschutz Deutschland) provide a current overview of Germany as a nanotechnology location.[3]

With their broad spectrum of options in terms of application, nanotechnologies may also bring potential risks for both people and the environment. There already are signs of these risks.

Risks posed by nanotechnologies

The special feature of potential nanotechnologies' risks is that nanoparticles are so tiny they can be inhaled into lungs and then enter the bloodstream. They can then penetrate any cell in the body and sometimes even breach the blood-brain barrier. There are also possible exposures arising from ingestion and dermal contact. A general assessment of the risks posed by nanomaterials is not possible at this point in time. Current research, however, suggests that some nanomaterials contain a relevant risk potential.

No clear scientific evidence that nanomaterials lead to damage to the environment and health has been available to date – although dozens of studies have found an association between exposure to nanomaterials and adverse health effects. In the case of many nanomaterials, there are still no standardised test methods for comprehensive risk assessment. Consequently, a list of studies on the potential negative impact of nanoparticles on the environment and health is not included in this article.

The lack of clear scientific evidence to date should not be taken as reason for a general all-clear in terms of the risks presented by nanomaterials. The

development of risk research, as will be discussed later, will be promoted on a huge scale over the next few years. Not only countries but associations and companies have recognised that the huge economic potential of nanotechnologies can only be exploited if account is taken of the safety aspect. This will inevitably lead to on-going improvements in technical, medical and scientific quantitative analyses of the potential risks presented by nanotechnologies. Nanomaterials previously classified as harmless could then be identified as damaging to health.

Moreover, numerous other nanomaterials will enter the economic cycle over the next few years as a result of the rapid growth of nanotechnologies. This will at least entail the risk that the number of nanomaterials that are relevant in terms of risk will increase.

Nanotechnologies and risk prevention

Alongside the explosive growth of nanotechnologies, efforts made to prevent the risks presented by these technologies have also been stepped up. In addition to risk research, activities and other issues in the regulatory area have also increased.

Table 1 – Nanotechnologies funding programmes

Country	Funding programmes	Nano-specific?	Period	Value
Brazil	Ministry for Science & Technology	no	Annual estimate	EUR 4.9 million
China	Medium & Long Term Development Plan	yes	2006–2008	EUR 29.1 million
European Union	Framework Programme 7	no	2007–2013	EUR 3.5 billion
France	Nano 2012 Programme	yes	2008–2012	EUR 500 million
Germany	Nano Initiative – Action Plan 2010	yes	2008–2013	EUR 370 million
India	Nano Mission	yes	2007–2012	EUR 144.8 million
Japan	MEXT	no	Annual estimate	EUR 470 million
Russia	Development of nanotechnology infrastructure in the Russian Federation for 2008 – 2011	yes	2008–2011	EUR 693.3 million
UK	Research Councils UK/Technology Strategy Board	no	Annual estimate	EUR 256 million
USA	National Nanotechnology Initiative	yes	2012	EUR 1.6 billion

Source: OECD, Working party on nanotechnology, 16 March 2012, http://www.oecd.org/dataoecd/12/23/49931940.pdf.

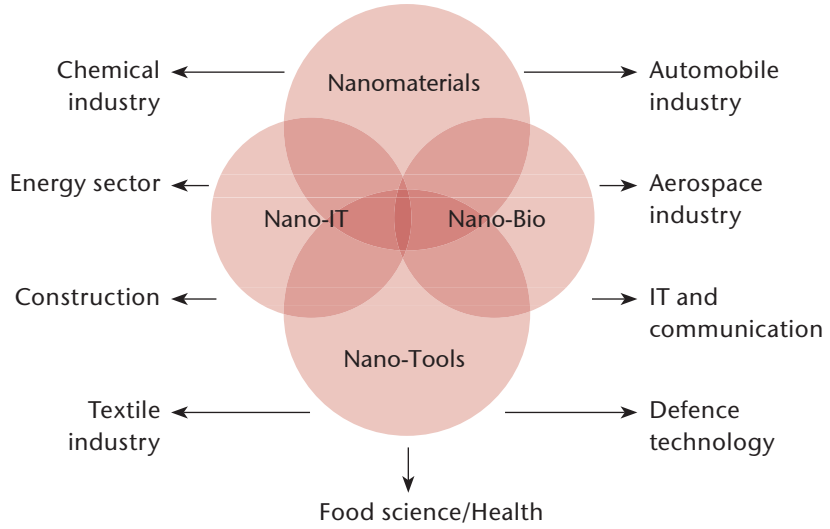
Prevention through risk research

Due to the wide variety of nanomaterials and the outstanding questions to be answered through risk research, the number of research projects on an EU, Federal and state level is rising. Just a few examples of these are discussed below:

- Nanomaterials were researched between 2006 and 2009 as part of the "NanoCare Project" sponsored by the Federal Ministry of Research in order to obtain new findings for science and industry. The environmental and health aspects of carbon nanotubes (CNT) have been examined as part of the Innovation Alliance CNT (Inno.CNT) initiative – specifically: CarboSafe (since 2008) and CarboLifeCycle (since 2010).
- Numerous EU Commission research projects deal with the potential health and safety implications of nanomaterials. Worth noting here is the increase in the budget from the original EUR 2.5 million to EUR 102 million. Currently, 22 projects, such as Nanogenootox, NanoGEM, NanoValid, and NanoRisk, are underway.[4]
- The MARINA project with launched on 1 November 2011, with the aim of developing reference methods for overcoming the risks posed by nanoparticles and nanomaterials.

The efforts made by individual industries and companies to carry out targeted research have also increased:

Figure 2 – Most important nanotechnology user industries



- The TechnoTox project, conducted jointly by science and industry, is investigating the safety of nano-functionalised textiles for people and the environment. A situation-based risk assessment is using data on the behaviour, retention and biological effect of nano-functionalised, fibre-based materials in relation to environmental conditions. Methods are also being developed that have made possible the proof and characterisation of nanoparticles alongside the analysis of their human and ecotoxicological risk potential in relevant environmental media.[5]
- The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the Federal Institute for Occupational Safety and Health (BAuA) and BASF, SE have initiated a joint project examining the potential long-term effects of nanoparticles in the lungs.[6]

Prevention through public dialogue

An open dialogue on nanotechnologies has developed in recent years in Europe and particularly in Germany. An extensive network of stakeholders allows the exchange of knowledge and viewpoints. Numerous information events have also been held to encourage dialogue with the general public. A positive effect of this dialogue is certainly a deeper knowledge of nanotechnologies on a broad scale. However, the emotionalisation and stigmatisation of nanotechnologies could have an adverse effect.

A key example of successful public dialogue is the German government's NanoKommission set up in 2006 as a central national discussion platform. Its task is to promote exchange between social interest groups on the opportunities and risks of nanotechnologies. Over 100 experts in the nanotechnology field have taken part in the often controversial discussions. These have resulted in the NanoKommission's final report "Responsible Use of Nanotechnologies 2011", published in December 2011.[7]

Prevention through regulation

On a national and European level, we are, as before, in a decision-making phase. The definition of nanomaterials published by the EU in October 2011 is a step in the right direction. Alongside European decision making, the international dialogue and coordination process on the subject of nanotechnologies must be intensified – but not just in relation to the definition of nanomaterials.

It is not surprising that in the case of a new technology – where reliable scientific findings are lacking, in particular regarding the relationship between technology and risks – the definition of regulatory standards is extremely divergent. Decision making is therefore dependent on which of the two prevailing currents will ultimately come out on top:

- The current regulatory framework conditions are not sufficient for the exponents of stringent regulation. They consider nanomaterials a completely novel issue and are calling for individual nanotechnology legislation that adheres strictly to the precautionary principle (see below) and takes account of the special features of nanomaterials. The benefit consists in developing maximised regulatory protection for health and the environment against risks in connection with nanomaterials. However, the danger is that the regulatory framework required for this will function like a corset and could suffocate nanotechnology companies and result in the migration of this technology.
- Exponents of moderate regulation essentially consider the existing framework conditions to be sufficient for nanomaterials, but see the need for adjustment to the special features of these technologies. The precautionary

principle also applies here as the basis, with moderate application. The advantage of this solution would be that nanotechnologies would be offered development opportunities in Europe. Many will profit from the positive aspects that nanotechnologies unquestionably have. A danger, however, could arise if substantial risks for health and the environment were only to manifest after a number of years.

The current position of the Federal Government and the EU Commission can be summarised as follows:

- Independent nanotechnology legislation is not currently under consideration.
- Current regulatory standards are essentially also applicable to nanomaterials.
- An adaptation to the special features of nanomaterials or addition to existing regulatory standards is under review.

Current regulatory standards and nanomaterials

A raft of legislation and regulations at the EU level concern the specific areas of application of nanomaterials. These include:

REACH (Registration, evaluation, authorisation and restriction of chemicals)

The REACH regulation, applicable since 1 June 2007, regulates the handling of chemicals used in the EU. Essentially, this regulation covers nanomaterials, but whether it adequately regulates responsible handling of nanomaterials is under review. According to experts, there is a need for adaptation and not simply for practical reasons.

REACH regulates substances produced or imported by a company in quantities of at least one ton per annum. Substance safety assessments and substance safety reports are mandatory for 10 tons or more. Many companies that produce nanomaterials work with smaller quantities; this indicates that a reduction in the tonnage threshold for nanomaterials needs to be considered. The test method used currently in the context of REACH for an appropriate safety assessment is not sufficient in the case of nanomaterials. There is an urgent need for action with regard to the future development of monitoring procedures.

Table 2 – Asbestos: Early warnings and actions

1898	UK Factory Inspector Lucy Deane warns of harmful and "evil" effects of asbestos dust
1906	French factory report of 50 deaths in female asbestos textile workers and recommendation of controls
1911	"Reasonable grounds" for suspicion, from experiments with rats, that asbestos dust is harmful
1911 and 1917	UK Factory Department finds insufficient evidence to justify further actions
1918	U.S. insurers refuse cover to asbestos workers due to assumptions about injurious conditions in the industry
1930	UK Merewether Report finds 66% of long-term workers in Rochdale factory with asbestosis
1931	UK Asbestos Regulations specify dust control in manufacturing only and compensation for asbestosis, but this is poorly implemented
1935–1949	Lung cancer cases reported in asbestos manufacturing workers
1955	Doll establishes high lung cancer risk in Rochdale asbestos workers
1959–1960	Mesothelioma cancer in workers and public identified in South Africa
1962–1964	Mesothelioma cancer identified in asbestos workers, in neighbourhood "bystanders" and in relatives, in the UK and U.S., amongst others
1969	UK Asbestos Regulations improve controls, but ignore users and cancers
1982–1989	UK media, trade union and other pressure provokes tightening of asbestos controls on users and producers, and stimulates substitutes
1998–1999	EU and France ban all forms of asbestos
2000–2001	WTO upholds EU/French bans against Canadian appeal

Source: David Gee, Morris Greenberg, Asbestos: from 'magic' to malevolent mineral, in: Late lessons from early warnings: the precautionary principle 1896 – 2000, EEA Environmental Issue Report Nr. 22/2001, http://www.eea.europa.eu/publications/environmental_issue_report_2001_22.

The precautionary principle as a legal basis for orientation in terms of nanotechnology

Experts agree that action on the part of legislative bodies in relation to regulatory measures on nanotechnologies will be hallmarked now and in the future by the so-called precautionary principle. The precautionary principle is established as a general legal principle and acts as legal orientation for the EU, in the area of the environment, for example. The precautionary principle, according to the concept, would apply if a need for legal action were to arise on account of potential risk to health and the environment, even though existing scientific findings were lacking or not enough to justify causality between nanotechnologies and the risks with sufficient probability.

Precautions taken without well-founded scientific evidence must be avoided at all cost. In extreme cases this could result in regulatory standards, which although they effect maximum protection (active defence) for health and the environment, also lead to nanotechnologies becoming financially unattractive (stringent provisions for operations, stringent liability standards – strict liability) and no longer used at least in those areas where these standards apply. In order that this does not happen at least in theory, the precautionary principle complies with certain mechanisms:

The first step is to determine the so-called reason for caution and cohether precautionary measures can be taken. An abstract potential for concern is sufficient as the reason for caution; therefore a theoretical (as opposed to pure speculation, but, supported by reasons of scientific plausibility) initial suspicion, which is, however, as yet empirically incoherent or must be provable.[8]

The firm establishment of the reason for caution takes place in two stages:

- When analysing risk, an attempt is made through research measures to determine the risk potential of nanotechnologies.
- Based on the results of the risk analysis, the reason for caution then needs to be established using normative risk assessment and identifying which risk potential can be tolerated or whether appropriate regulatory measures must be taken as matter of course.

In summary, clear determination of the reason for caution concerning nanotechnologies is not currently possible on a broad basis; however, attention to risk research, and thus the financial resources for such research, have increased significantly (see main article). Due to a lack of standardised test methods to date, it remains difficult to combine nanomaterials in classes, including substances with similar effects. At present, recourse has to be made to complex and therefore costly individual testing. The huge innovative strength of nanotechnologies makes matters worse. The extent to which risk research can keep pace here is questionable.

If the reason for caution cannot be determined in this context, the precautionary principle keeps a shifting of the burden of proof open. In this case, the risk initiator must disprove the assumption of risk made.

Cosmetic products regulation

European Regulation (EC) No 1223/2009 on cosmetic products entered into force in March 2009. It stipulates that only safe products may be placed on the market. It is the first piece of European legislation to treat nanomaterials expressly as an individual group of substances. Mandatory identification of nanomaterials and mandatory safety testing for specific nanomaterials will be introduced in 2013.

A need for adjustment is also seen here. The definition of nanomaterials used is extremely narrow. Soluble materials or materials with size-specific properties above 100 nm are not covered. Authorisation is only mandatory for nanomaterials, that are used as colourants, UV protection or preservatives. Fullerene anti-ageing creams are not included. Safety assessments will then only need to be made by the European Commission if the EU is in doubt about the safety of nanomaterials.

Foodstuffs legislation

A review of the regulations concerning novel foodstuffs, which entered into force in 1997 (Novel Food Regulation, EC No. 258/97), explicitly envisaged the inclusion of nanomaterials. Their use would thus have become liable to registration. Furthermore, the intention was to introduce the mandatory identification of nanomaterials. The review was, however, not completed and consequently the previous 1997 regulation remains in force. Experience shows that a new legislative procedure would take several years.

Biocide products and pesticides

The European Council announced the adoption of a regulation on the use of biocide products, such as insect poison, disinfectants and repellents. Drugs and pesticides are not included. This regulation, which will enter into force on 1 September 2013, incorporates the definition of nanomaterials recommended by the EU. The recommendation demands that manufacturers using nanomaterials in products assess the risk for the environment and health separately. Moreover, all nanomaterials contained in the products must be identified on labels using the word "nano" in brackets.

Voluntary agreements on the part of institutions and companies

Regulation in the form of a legal framework for nanomaterials, is only just emerging. This process will still take many years, not in the least due to the generally known, long implementation phases of regulatory standards.

Institutions and companies see an opportunity to exercise a positive influence on this process in the context of voluntary agreements. Moreover, they should demonstrate to the public that they are dealing with nanomaterials responsibly. Here, too, we are certainly at the beginning of a long road, and according to environmental and consumer organisations, voluntary agreements that are already in place do not go far enough. Voluntary agreements cannot, of course, replace legal obligation. Nevertheless, they represent an additional way of developing the handling of nanomaterials that is as safe as possible.

Some examples of voluntary agreements prove that adequate moves have been made in this regard:

- The BASF code of conduct defines four principles for responsible handling of nanomaterials. Here are a few extracts:

  "The protection of humans and the environment is one of our company's basic principles."

  "Financial interests have no priority over safety and protection of health and the environment."

  "We will notify the authorities and the general public of any new findings immediately."

  "Where applicable legislation and guidelines do not as yet take account of nanotechnology, BASF is making a constructive contribution to the development of legal provisions. It is our aim to define appropriate and robust standards in terms of risk and to support the corresponding legislation."[9]

- Evonik Industries nano guidelines[10]
- Guidelines for activities involving nanomaterials in workplaces in the chemical industry in collaboration with the Federal Institute for Occupational Safety and Health (BAUA)[11]
- NanoBioNet code of conduct[12]
- Guidelines of the Association of the German Paint and Printing Ink Industry for handling nano-objects in the workplace[13]

Public perception of nanotechnologies and acceptance

Nanotechnologies have entered public consciousness more strongly in the last three years. Two significant streams can be identified:

Like many other states, the European Union is engaged in predominantly positive public relations work. In addition to the huge financial potential, there is the intentionally and extremely transparent reporting on the potential risks and precautions and direct dialogue with the general public. Moreover, the voluntary agreements exemplified by the institutions and companies already mentioned positively contribute to further often application-related transparency.

In the media, however, the previously positive reporting on nanotechnologies has changed.[14] The risks have increasingly become the focus of reporting since 2008. At the present moment, it can't be determined whether or not this focus can be justified on the basis of scientific facts because, as already indicated, risk research is not at this point yet.

Up to now the attitude of the general public towards nanotechnologies has been largely positive. However, this may change and public perception may revert to its negative tendency, not only as a result of the realisation of risks from

nanomaterials and the transparency that has been deliberately called for, but also as a result of increasingly negative reporting in the media. This would increase the pressure on the legislative bodies to develop precautionary measures of various kinds that are designed to contribute towards reducing or completely preventing risks to the environment and health posed by nanotechnologies. A strengthening of liability legislation based on the precautionary principle would inevitably be the result.

We will now look at nanotechnologies from an underwriting perspective and apply our discussion of current technological developments, precautionary measures and public perception.

Potential loss exposure in liability lines of business

Our discussion of developments in nanotechnologies shows the potential risks and liability exposure. Because of the global presence of nanomaterials in numerous products and industries, many people could be harmed by them – a scenario which would make the liability insurance industry vulnerable to an enormous potential loss exposure.

In that view, the impact would be felt by virtually all liability lines of business:

- CGL (Comprehensive General Liability) insurance
- Product liability insurance
- Environmental liability insurance
- Product recall
- Workers Compensation

A distinction would certainly need to be made between exposures in the workplace and the (private) use of products. It is definitely easier to demonstrate causation in the workplace than in the use of products.

Another important aspect is the unlimited passive legal protection for consumers offered by liability insurance policies. And yet another consideration is the complexity of nanotechnologies, which would create the need for an elaborate defence at considerable cost, and the number of compensation claims for damages caused by nanomaterials that could increase within a few years.

A forward-looking approach to nanotechnologies within the scope of liability insurance

Considering the complexity of nanotechnologies, the insurance industry is well advised to address in detail the main risk issues, including its own risk provisioning, and to develop actuarial mechanisms that positively support nanotechnologies. At present, however, nanotechnologies are only occasionally approached at the necessary level of detail from an insurance perspective – a situation that is not limited to Germany. In the insurance industry we call this “a waiting period”.

When looking at the harmful effects to people and the environment, a comparison between nanomaterials and asbestos is premature and has not been validated by scientific research. Nevertheless, recognition of the effects of exposure to asbestos fibers, from initial warnings to international precautions (see Table 2), should be a warning.

Nanotechnologies should be taken into account when underwriting now. It is essential to initiate a process that systematically deals with these technologies and their potential risks from an insurance perspective.

A first step should be to create transparency in the insured portfolio. How many policyholders and what kind of nanomaterials are involved? (Risk assessment). For Germany the databases of BMBF[15] and Friends of the Earth Germany[16] can provide a quick overview. An efficient risk assessment can also be made by means of risk questionnaires on nanotechnologies.

Liability insurers with no or insignificant exposure in their portfolios do not need to take any action at this moment in time. Regular monitoring, however, is a reasonable precaution.

Liability insurers with portfolios where a significant number of insureds are in contact with nanotechnologies should take the next step and implement a risk monitoring and analysis process. This means monitoring and analysing developments in research, regulation and public perception that concern areas of nanotechnology risk relevant to their insureds. Ultimately it means getting to the bottom of the issue of where risks

can be expected to arise with a high degree of probability and/or where they already exist. However, the implementation of such a process is time-consuming and costly due to the demanding requirements and complexity.

Process requirements

- Systematic worldwide registration of sources with risk-relevant content
- Continuous observation of these sources
- Identification of potential "negative" trends
- Analysis of potential "negative" trends

Such an instrument for risk monitoring and analysis is, for example, "360 degree risk radar for insurance companies", developed by the Innovation Society, St. Gallen, for insurance and reinsurance companies.[17]

Several insurers and reinsurers could collaborate in processing an analysis, which could also be reasonably supplemented with questionnaires that address risk exposure.

Bringing about increased transparency in insured liability portfolios, with regard to insureds working with nanotechnologies, as well as the identification and analysis of potential risks from these technologies, will be a key underwriting task over the next few years.

In summary it must be noted that our goal as an insurance industry should support highly profitable nanotechnologies from an underwriting perspective, but without losing sight of the considerable risk potential. This can only be achieved through risk identification, risk monitoring and risk analysis. Simply waiting until risk materialises could have significant consequences for the insurance industry.

Moreover, we should be thinking now about how we can align both of those goals – support for nanotechnologies and justifiable limitation of the potential financial risks for the insurance industry. A step in the right direction could be to contain the problem of late claims, which are inherent with these technologies, by employing the claims made principle.

Endnotes

1 Recommendation of the European Commission of 18 October 2011 on the definition of nanomaterials (2011/696/EU); http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:DE:PDF.

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16 www.bund.net/themen_und_projekte/nanotechnologie/nanoproduktdatenbank/.

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