

# Draft guidelines regarding the correct implementation of risk transfer in insurance models.

## DELIVERABLE 3.4

**Due date of Deliverable:** 31.12.2021  
**Actual Submission Date:** 24.12.2021  
**Responsible partner:** TGO, Ireland  
**Report Author(s):** Finbarr Murphy, FM, Martin Mullins MM, Shona Linehan (SL) Evert Bouman, EB  
**Reviewed by:** Khara Grieger (KG), Rolf Packroff (RP), Mark Wiesner (MW))  
**Nature:** R (Document, report)  
**Dissemination Level:** PU = Public

**Call:** H2020-NMBP-13-2018  
**Topic:** Risk Governance of nanotechnology  
**Project Type:** Research & Innovation Action (RIA)  
**Name of Lead Beneficiary:** NILU, Norway  
**Project Start Date:** 1 January 2019  
**Project Duration:** 50-Months



## Document History

<i>Version</i>	<i>Date</i>	<i>Authors/ who took action</i>	<i>Comment</i>	<i>Modifications made by</i>
<i>0.1</i>	02-04-2021	Finbarr Murphy (TGO)	Structure and ancillary details	FM (TGO)
<i>0.2</i>	12-09-2021	Martin Mullins (TGO) and Finbarr Murphy (TGO)	Change in structure and introduction of risk perceptions	FM, MM (TGO)
<i>0.3</i>	11-10-2021	Martin Mullins (TGO) Finbarr Murphy (TGO) Shona Linehan (TGO)	Introduction of Insurance Legal regimes text	FM, MM SL(TGO)
<i>0.4</i>	01-12-2021	Evert Bouman (NILU)	Draft shared NILU	
<i>0.5</i>	07-12-2021	Finbarr Murphy (TGO)	Draft shared with PMB and EAB	
<i>1.0</i>	20-12-2021	Finbarr Murphy (TGO)	Ameliorated based on correct, comments and suggestions by EAB	Suggested modifications by Khara Grieger (NCSU), Mark R. Wiesner (CEINT), Georgios Katalagarianakis (NSC), David Warheit (WS) were implemented by Finbarr Murphy (TGO)
<i>1.1</i>	24-12-2021	PMO (NILU)	Submitted to the EC	



## Abstract

This report contains draft guidelines regarding the correct implementation of risk transfer in insurance models. The document speaks to the wider phenomena of risk perception among the insurance profession and in wider society. The phenomena of social media as a medium in which information and misinformation is propagated is examined. The implications of a real or perceived threat being exacerbated by social media is of significance for insurers and for the Risk Governance Council. The report examines current best practice on the part of insurers around *emerging risk* in general and provide a focused analysis of how the insurance sector deal with nanotechnology related risk. The legal regimes in which insurers operate and the associated court systems are likely to be the forum for contentious claims and therefore an examination of this ecosystem is necessary. This report also outlines the modes of operation of insurers, particularly how insurance is aligned along different risk lines. A detailed interpretation of this mode of business is an important consideration when communicating to the insurance industry. Based on this extensive background research, this report then submits guidelines for risk transfer in insurance models.



## Table of Contents

Document History.....	2
Abstract .....	3
List Of Abbreviations .....	6
1. Aims and Scope.....	7
Aims.....	7
Scope.....	7
2. Introduction .....	8
Insurers Concerns about Nanotechnology.....	8
Insurance and Emerging Risk .....	10
Other Emerging Risks .....	11
Lessons from other Emerging Risk Domains .....	11
GM foods.....	11
Cyber-risk .....	11
Autonomous Vehicles .....	12
Solar storms .....	12
The Operation of Insurance around Emerging Risk.....	12
Emerging risk and the insurance business model .....	14
3. Risk Perception and Insurance .....	15
Risk Perception.....	15
4. Risk Perception of Nanotechnology: Evidence from Twitter .....	18
5. Insurance Related Legal Regimes around Nanomaterial Risk.....	19
Legal Systems in Europe (and globally) .....	19
The Notion of Causation and ENMs .....	20
Causation at common law.....	20
The Example of the Environmental Liability Directive (ELD).....	21
6. Potential Impact of Nano Risk and how the Insurance Responds .....	23
Health/ Life Insurance.....	23
Casualty (Extended Product Liability and Environmental Pollution).....	23
Lines of Business Impacted by Nanomaterial Risk .....	24
Product Liability shall mean:.....	24
Extended Product Liability shall mean: .....	24
(Insured's) Product shall mean:.....	24



Duties of producer shall mean:.....	24
Product Recall shall mean: .....	25
Business (Industry-sector): .....	26
Application: .....	26
Nano-specific Exclusions in Insurance Policies .....	26
Excluding nano-technology related risks .....	26
7. Draft Guidelines .....	29
8. Conclusions .....	32
9. Bibliography .....	34



## List Of Abbreviations

CBA	Cost Benefit Analysis
EFSA	European Food Safety Authority
ELD	Environmental Liability Directive
GM	Genetically modified
GDP	Gross Domestic Product
GTPL	General Third Party Liability
EIL	Environmental Impairment Liability
ENM	Engineered Nanomaterial
IPR	Intellectual property rights
MCA	Multi-criteria analysis
NM	Nanomaterials
NNI	National nanotechnology initiative
PPP	Polluter pays principle
RA	Risk Assessment
RDM	Robust Decision Making
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RG	Risk Governance
RM	Risk Management
SME	Small-medium enterprise
WTP	Willingness To Pay



## 1. Aims and Scope

### Aims

The aim of this task and deliverable is the provision of draft guidelines regarding the correct implementation of risk transfer in insurance models. Currently, insurers use outdated models to assess risk or none at all. If an adverse event occurs, this puts them in a poor position to respond proportionally. This task first covers existing perceptions of NanoRisk by insurers. The potential for a social media storm is assessed. We then examine the legal context. We talk directly to a number of insurers and finally produce the draft guidelines.

### Scope

This report provides the background to the issue of the insurability of the nanotechnologies sector. In doing so it highlights some of the concerns that exist in the underwriting community as to the risks represented by the use of nanomaterials (NM). This report also speaks to how legal regimes intersect with the liability question and how causation remains a key concept in the civil law systems. The report also highlights the paradigm shift implicit in the introduction of the Environmental Liability Directive, the affording of the environment a legal personality and the introduction of strict liability regimes where the balance of risk and responsibilities is profoundly altered.

This deliverable is both useful for insurance stakeholders and the nanotechnology sector itself. In the case of the former it provides some insight as to the state of the art in terms of risk transfer and in the case of the latter it opens a window on how insurance operates and the logics at play in the sector.

This report includes a piece on risk perception around nanotechnology as expressed on Twitter. This builds on previous work by the authors which sought to contextualise risk perception in the insurance sector within wider societal views on nanotechnology.



## 2. Introduction

### Insurers Concerns about Nanotechnology

Risk has been the dominant paradigm in the governance of new technologies for decades. Attitudes to risk denote responsibility and anticipatory ethics with high levels of risk tolerance pointing to a cavalier disposition towards safety. For Gorgoni (2018) responsibility is best understood as operating in two distinct modes and within two temporal dimensions. To follow Gorgoni's argument, there is both an active and passive sense of responsibility. In the case of the passive, it relates to the idea of being *held* responsible in a moral or legal sense and having an obligation of duty to bear to the consequences. The active dimension relates to the *taking of responsibility* and denotes an active and anticipatory set of actions. In temporal terms, we see backward looking elements which relate to notions of accountability and liability. In a forward looking perspective, we see a proactive set of actions aimed at addressing risk. Risk governance structures span these different dimensions and we would add that insurance and ideas around liability occupy a key role in the governance process. With risk comes the potential for injured parties. If risks are to be taken, it is important to understand what part of society and indeed the environment are assuming these risks. These process of assuming risk may lack agency and any detailed understanding of that risk or set of risks. This is one of the problems that relates to emerging technology and nanotechnology is no different in this regard. Hence, we see different groups *exposed* to risk. In the case of nanotechnology, this will include workers involved in the production process, consumers exposed to the products and wider society exposed to risk related to the end of life and disposal. Insurance as a practice ensures that these groups can be compensated if there is an insurable event. Thus, insurance facilitates the taking of responsibility. The paradigm of fault is important here – and corresponds to an ex post judgement on past actions. This function of providing compensation to victims is an important component of any risk governance process as it goes some way to providing justice to those impacted upon. This does not absolve stakeholders from their forward facing responsibilities and the need for precaution – but it does put in place an important social justice mechanism.

In terms of how insurance functions from an overall governance systems perspective, it operates in the ex-post domain and therefore works with actual events and with a degree more precision than the risk assessment piece. The insurance paradigm - at least in its traditional form – relies on adverse events to feed into probability calculations. Precaution is an important instinct within the insurance industry, but it is more about ensuring justice through compensation.

For these reasons, in very many jurisdictions having the requisite set of insurance covers is compulsory for businesses. These sets of insurance coverages cross different lines of business, from employers liability, to product liability to environmental liability cover. Those engaged in nanotechnology related activities are not different in this regard. If there is no insurance cover available then these activities have to cease. Thus, in terms of the sustainability of the whole nanotechnology sector, access to affordable insurance cover is an essential prerequisite for the continued existence. The principal risk to the NMs sector is that “should an adverse event occur there is a strong possibility that insurance companies will move to write exclusion clauses on nanotechnology-related activities and this will threaten the economic viability and sustainability of nanotechnology-enabled products and, more generally, nanotechnology research and development.”<sup>1</sup> This is true not only in strict legal terms, but other key stakeholders require evidence of insurance in order to deal with the sector. One example

---

<sup>1</sup> See Murphy et al 2017

would be capital providers from banks or venture capital. Overall, then the nanotechnology sector is vulnerable to any withdrawals of insurance cover. We would make the case that in any overall risk governance process this existential risk to the nanotechnology sector needs to be factored in. As argued by Murphy et al (2017), part of the solution lies in improved communication between the scientists engaged in the field and those charged with underwriting the risk within the insurance industry. It may be that the establishment of a risk governance council, which is the driver of the EU funded NMBP-13 family of research consortia, will facilitate this communication.

Given the strategic position occupied by the insurance industry any risk governance structure needs to factor in this key group of stakeholders. This is implicitly recognised and reflected in the public (EU) funding available for nanotechnology research, where research on insurance has been requested as an integral part in projects. Initially the focus was on the worker compensation or employers liability insurance line. This has been broadened out to include other elements of the life cycle. This was the case with SUN for example.<sup>2</sup> There has also been a number of attempts to garner the opinion of this important group and this has been captured in the literature over the past decade or so. In general, insurance respondents have demonstrated a degree of uncertainty over the risk posed by nanotechnology and a desire for a clearer understanding.<sup>3</sup>

---

<sup>2</sup> <http://www.sun-fp7.eu/>

<sup>3</sup> See Malsch, I., Subramanian, V., Semenzin, E., Hristozov, D. and Marcomini, A., 2015. Supporting decision-making for sustainable nanotechnology. *Environment Systems and Decisions*, 35(1), pp.54-75.



## Insurance and Emerging Risk

Emerging risks can have the potential for loss accumulation and/or serial loss. Such risk can impact the business internationally and across different lines of business. Many of these risks are latent but when emerging risks finally do materialize, their effects can be dramatic and may even threaten a company's solvency

Although disappointing, it is not entirely surprising that there remain lacunas in knowledge around the risk assessment of NMs. Estimates vary, but between several hundred million to a billion dollars has been spent on this task.<sup>4</sup> Moreover, it has been 15 years since the first wave of international research programmes designed to address this problem came into being. That said, it took many decades of work to develop strong protocols for the assessment of chemical risk in general and work is still ongoing to develop robust metrics around microbial risk assessments in food. This is the context in which risk engineers and underwriters have to operate hence the importance of risk perception among these communities.

Risk perception around NMs within the insurance sector has been addressed by a number of EU funded projects in the area of NM risk. These have included Sanowork and SUN amongst others. The NMBP-13 family (RiskGONE, Gov4Nano and Nanorigo) of consortium has been charged specifically with establishing a risk governance framework. Insurance opinions have been captured as part of wider surveys of stakeholder views. The position occupied by insurers is somewhat paradoxical in that they are both a key stakeholder and industry professional displaying many of the characteristics of lay people in that their knowledge of the NM sector remains under-developed.

It is valuable to break down the manner in which insurers deal with an emerging risk such as NM production. Across the insurance value chain different sets of calculations take place. Risk engineers (where they exist) are often the first port of call for emerging risks. These are typically specialist teams with bespoke domain knowledge. In one large insurer for example, there are specialists employed to address risks related to medical/pharmaceuticals, automotive, food, and chemicals/materials. New risks are first processed by this group and their findings are fed back to the wider underwriting community - who are charged with accepting or declining business as well as the pricing of the risk.

Also important in this overall process is the position adopted by the reinsurance industry. To afford some context here, a portion of the risks taken on by insurers are passed onto the reinsurance sector. Thus, reinsurers play an important role in assuring the stability of the overall industry. As a corollary of this, reinsurers take an interest in any emerging risk. They have been described as the universities of the overall insurance process in that they are equipped with a research capability. Since 2000, the reinsurance industry has provided a number of reports and posited methods on the insurance of NMs. Reinsurers have an important disciplinary effect on primary insurers and financial risk can end up agglomerating on their books. Therefore in those instances where there is a degree of uncertainty, reinsurers may decline to accept certain types of risk from the primary markets.

In the first decade of the 21st century, there was a degree of concern on NM related risk. This was reflected in the commissioning of reports and also in the 'league tables' of prominent risk. For a number of years NMs occupied a prominent position in these tables. Part of this was driven by reports from toxicologists on the potential hazards associated with NM use and production. It is fair to characterise

---

<sup>4</sup> See Grieger, K., Jones, J.L., Hansen, S.F., Hendren, C.O., Jensen, K.A., Kuzma, J. and Baun, A., 2019. Best practices from nano-risk analysis relevant for other emerging technologies. *Nature nanotechnology*, 14(11), pp.998-1001.

this period as one of confusion on the part of the insurance industry around the risk of NMs. The fact that there was little in the way of consensus among the scientific communities added to the confusion. There was certainly a need for more effective risk communication.

By 2021, the attitude of the insurance industry towards the NM sector is more relaxed. We have two decades without any documented death or injury and this has resulted in the insurance industry deprioritizing NM risk.

## Other Emerging Risks

The insurance industry has had to deal with a number of emerging risks where there is no strong connection to NMs. Nevertheless, these risk areas provide a good illustration of the manner in which insurance companies analyse such risks. The process of identifying risk and arriving at effective risk assessment protocols is both time consuming and expensive. For those operating outside the insurance industry, it is worth bearing in mind that this is a highly competitive environment and where commercial pressures are very much to the fore. It may not be good for business to deny cover for some activities of a large client as this may result in them going elsewhere for insurance coverage. Thus, there is a temptation to leave less well understood risks under the wider umbrella of general liability cover. This would be true until there is evidence (claims or near miss events) that make it prudent to either exclude certain risks or write add-ons to existing policies.

## Lessons from other Emerging Risk Domains

### GM foods

They may have considerable advantages for food producers, but for the insurance industry genetically modified (GM) organisms still represent an emerging risk with a potential for extreme severity. In the area of GM foods, we see firstly some striking divergences between different jurisdictions in terms of risk perceptions and acceptance. Attitudes in the European Union and the United States are remarkably different and regulation around GM foods has continued to sharply diverge. For insurers, it has been important to keep up to date around regulatory regimes - particularly those that pertain to labelling. The complexity of supply chains and content rules around GM foods mean there is exposure to product recall risk for insurers.

### Cyber-risk

Cyber-risk is becoming both a major challenge and opportunity for the insurance industry. It resides very much in the emerging risk category as both the probability of events and the potential consequences are still not well understood. Insurers have entered this area providing cover for the cost associated with crisis management and litigation but there still is some reluctance to cover a more comprehensive set of risks at this juncture.

## Autonomous Vehicles

This emerging technology represents a challenge to insurers as it introduces over time a new paradigm of motor insurance where the locus of liability will migrate from the driver to the vehicle. For insurers, driver risk knowledge has been built up over more than 50 years and the probability of car accidents and their consequences are well understood. Improved driver assistance and automated driving technologies will result in lower aggregate risk, but at a more granular level, risks are less understood. Technology in this sector is changing quickly and this also results in a highly dynamic risk situation where firm risk metrics are difficult to ascertain. The other important element here, is the introduction of more systemic risk and cascading risk effects. The introduction of automated driving will mean that there is much more potential for widespread shut down on the transport network due to phenomena such as cyber-attacks and such events could result in large insurance claims. As in the case with nanotechnology, AV roll-out is likely to see different risk profiles across different lines of business. Product liability and product recall will become more important risk classes over the coming decade.

## Solar storms

Risk around solar storms has many of the characteristics of other emerging risk in that there is an absence of claims data and both the frequency and severity of the risk is hard to metricise. This makes both pricing and reserving for such events problematic for the insurance industry. One of the main lines of insurance business impacted by solar storms is *business interruption*. Given the potential for very large exposure, reinsurance companies have taken the lead in terms of the research around exposure levels. Across emerging risk categories – and this includes NMs, the reinsurance sector is key to understanding risk transfer availability as reinsurance opinion tends to lead and “discipline” the overall insurance market.

## The Operation of Insurance around Emerging Risk

The manner in which insurance companies manage emerging risk varies from insurance entity to insurance entity. From our experience, it is clear that some market participants - even within the primary insurance market expend a lot of resources on this aspect of the business. In such instances, we would see the existence of large risk engineering teams. Such teams are typically constituted by experts from different domains, so for example there may be experts from pharmaceuticals, and automotive as well as a team member with experience in the chemicals industry. These individuals would be qualified up to doctoral level in their respective domains or may have been drafted in from outside the insurance sector from a particular industry. Thus, project teams responsible for managing emerging risk are heterogeneous and interdisciplinary in nature. Also present in this ecosystem is the chief scientific officer who oversees scientific research. In terms of the overall insurance value chain, reinsurance companies due to their levels of exposure are more research intensive than primary insurers and often provide expert advisory services across the wider insurance market. These entities include Swiss Re and Munich Re - both of whom have a well established reputation for expertise across a range of risks. It is fair to say that reinsurers have a closer eye on the actual risk phenomena whilst primary insurers are closer to the actual client base or to use the technical terms, the insured.

The relationship between the primary insurer and the insured merits some attention from the perspective of risk governance as a practice. The relationship is developed in such a way that it benefits both parties to reduce levels of risk or exposure. Typically, the insurer will engage with the insured in order to lower levels of overall risk and financial incentives will be built into such an engagement. As risk is reduced so premium costs may fall. Overall then, long term relationships are built up between the client and the insurance company in which there is a symbiotic relationship in which the insured and the insurance carriers share information and learn together how to reduce risk. In such instances, as well as looking at the underlying risk (such as nanotechnology risk) insurance professionals are also very interested in the *risk culture* exhibited by the prospective client. In this phase of the engagement, we may see site visits from the insurer in order to ascertain attitudes towards risk at the “ground level”. For a nanotechnology operator, it would be important to show that there is a strong safety culture across the organisation and training regimes are seen as a good proxy. Geography and culture will play a part at this stage of the engagement. Insurers would be aware that risk toleration and safety culture vary from jurisdiction to jurisdiction and this is factored into the overall set of calculations of whether to insure or not.

Emerging risk is not only seen as a threat to the business, but also as an opportunity. Emerging risk may represent a blue ocean i.e. a brand new market and a new client base. Emerging risks also present an opportunity to roll-out new risk transfer products into the market-place. In more traditional market segments, the market may be very competitive or saturated and hence margins are difficult to attain. Emerging risk may represent a new frontier in terms of selling insurance services. Currently, this is not the case with NM risk as there are very few bespoke NM insurance products and risks are captured alongside general chemical risks. However, if attitudes were to change and an elevated risk perception were to arise, after an initial reluctance, new risk transfer products would come onto the market. In this phase of engagement, insurers would be looking to identify those segments of the market that offer the least amount of risk.

Insurers do not exclusively rely on engagement with clients working in areas defined as emerging risk or indeed on their own internal resources. Consultancies and academics are also active in this ecosystem. Insurance companies rely on these resources to provide risk read outs on certain products and processes. Overall, insurers use a configuration of actors and inputs to make sure they are well informed about their levels of exposure. Part of the rationale here resides with a certain conservatism on the part of the insurance industry, but also on the regulatory requirements the industry has to comply with.

Insurance is one of the most strictly regulated businesses in the economy. Its strategic position in the economic life of each country and the important welfare functions it bears mean this is a politically sensitive industry. As part of the regulation of the insurance industry in the European Union, insurance companies must demonstrate that they have an adequate understanding of their risk exposure. In Europe, this takes place under the auspices of the solvency II set of regulations. Solvency II brings in its wake a requirement that the insurance industry can quantify the risks they are exposed to. In the areas of emerging risk this can be quite challenging.

For Käslin (2008) the following is a list of criteria most often considered in emerging risk assessment.

- Driver of the risk (natural hazards; technological, social, political, or economic developments).
- Type of damage (environmental, personal, assets, financial resources).

- Damage potential (of the individual business units and/or the entire portfolio), cumulative damage potential, serial damage potential.
- Probability of occurrence.
- Latency period of the occurrence.
- Affected lines of business, countries, and insurance classes.
- Demonstrability.
- Coverage aspects.
- Potential to be influenced.
- Awareness of the risk by competitors, customers, and society

### Emerging risk and the insurance business model

The business model of insurance is the collection of premium income in exchange for agreeing in advance to compensate clients in the case of an insurable event. If the probability of this *event* is easy to calculate this model functions quite smoothly, however, in those instances where there is insufficient data to produce accurate risk models a new set of challenges for insurance companies are introduced. In such circumstances, the traditional manner of rate setting cannot be utilised. One particular problem for insurers is that emerging risk may already be covered by existing insurance policies. Important too is the duration of the policy. Insurance policies can span decades and emerging risk can generate sets of events that were unforeseen as the time the insurance policy entered into force. Such exposure is referred to as “long tail” risk. Emerging risks can be relatively trivial in terms of the overall portfolio of risk held by insurers or in some instances they can be global in scope and catastrophic in scale.

In order to protect themselves from such emerging risks, insurers develop practices designed to provide an early warning. Such practices are not formalised and include a variety of internal actors and sources of information. The authors of this report have presented at what is now known as the Emerging Risks Special Interests Group in Lloyds of London.<sup>5</sup> The presentation was on the state of nano-material science and how the risk should be treated by the Lloyds insurance market. This group at Lloyds also examine a number of other emerging risk categories.

In terms of the threat posed to insurance markets by NM, this can happen at various points in the product life cycle, (Mullins et al 2013). This will impact on multiple business lines. In the early stages of nanotechnology, the focus of the insurance industry was on the workers compensation element. In part, this was due to the experience of the insurance market with the asbestosis scandal of the 1990s when most of the claim came from workers exposed to asbestos fibres. However, other lines of business are also impacted. Once nano-enabled product hit the shelves, product liability and product recall are important policies. Both of these types of policy can result in expensive claims on the part of businesses involved in nanotechnology related products. Given the position of NM in a value chain, there is also some potential for business interruption policies to be triggered. Towards the end of the life cycle, there are environmental risk policies that may be triggered if spillages take place. If facilities are based in

---

<sup>5</sup> Based on Baublyte, L., Mullins, M., Murphy, F. and Tofail, S.A., (2014) Insurance Market Perception of Nanotechnology, Geneva Association.

environmentally sensitive areas, this can include policies designed to cater for the requirement of the Environmental Liability Directive, (see Hester et al 2014). The Directive provides a common framework for preventing and remediating certain forms of environmental damage by placing responsibility on operators to take preventative measures if there exists a risk of environmental damage. The Directive aims to ensure that operators also prevent or limit further environmental damage and the adverse effects thereof on human health and to take remedial measures for damage caused. This last clause introduces the notion of metrics for environmental damage generated by a pollution event. Pursuant to the 'polluter pays' principle, which is a keystone of the directive, the cost of remediation is to be borne by operators. By venturing into the highly-sophisticated national, legal, and doctrinal traditions of the Member States, the Directive is an ambitious attempt to create a harmonised legal regime in which the 'polluter pays' principle can operate. It thereby creates a link between a civil law determination of liability and a public law compensation scheme. At all stages of the NM lifecycle, from production of raw materials to the manufacture of products to end of life, there is potential for NM to be released into sewage waste, industrial waste and waste water; and consumer waste into ground water, waste streams, waterways, lakes and coastal waters. They could impact upon the water itself, the land via absorption or diffusion and the biological processes of plant, animal and aquatic life and ultimately under certain circumstances enter the food chain. Dose response assessment studies suggest that toxicity of NM is not necessarily mass dependent. Therefore, it would not be necessary for a paradigmatic catastrophic event such as an oil spillage, chemical spill or nuclear explosion to occur in order for NM to cause environmental damage. Across the different insurance lines actual claims related to third party exposure are not the only potential cost for insurers. Given the nascent state of much of the science around nanotechnology there remains a good deal of uncertainty around chains of causation and biological markers that might be associated with exposure to man-made nanoparticles. This has the potential to lead to expensive litigation and this element is also captured in insurance policies. In many respects this lack of certainty is not surprising given the complexity of the field, but it does raise the prospect of expensive and long drawn out court cases.

### 3. Risk Perception and Insurance

#### Risk Perception

In terms of risk perception or level of concern on the part of the insurance industry, we have seen this decline over the past two decades. This is not surprising given the absence of claims and cases involving nanotechnology. The fact that no one has been killed or seriously injured over the past two decades has led to a more relaxed attitude being adopted on the part of the insurers. In the first few years of the millennium there was a flurry of reports including one commissioned by the Lloyds of London insurance market (Lloyd's 2007). At that time, toxicologists were raising concerns based on a number of *in vitro* experiments which seemed to demonstrate that man-made nano-particles posed a serious threat at the cellular level. There was also some alarm expressed at the prospect of nanoparticles breaching the blood-brain divide interfering with cognitive function. At various junctures, nanotechnology featured with other strategic threats to the industry such as solar storms or GM foods. In the intervening period, nanotechnology has dropped down the *league table*.

The drop in concern has been identified by work carried out in the NMBP-13 project, Gov4Nano and it is fair to say that it has been harder to engage with senior people in the insurance industry more recently. With the tailing away of interest, there has been less focus on tools and methods to measure risk in the insurance industry. Over the past 20 years or so, there had been attempts to develop tools for underwriters to understand nanotechnology risk. Most now seem to have fallen into disuse.

At this juncture, one could characterise the situation as one of *wait and see*. The insurance industry has not settled on a position where they see nanotechnology as not representing a risk. – rather that over time their attention has moved to other sets of concerns. In 2019 for example Hannover Re issued a set of guidelines that alerted the primary insurance market of the potential risks posed and the need for a robust risk management programme to be put in place.

It is worth considering the logic that operates in the insurance market. In essence, what we see is



### The Spectre of Asbestos

In the 1990s the Lloyds insurance markets was devastated by the fall-out from the asbestos affair. This came close to bringing down the whole Lloyds insurance market. In what was a classic example of “long tail” risk, the exposure resided in asbestosis/mesothelioma claims under employers liability/worker compensation policies. The “long tail” or historical element of the claims meant it was difficult to predict the final claims number. Many of the claims dated back to the exposure of asbestos decades previously – and this resulted in claims to insurers from employers. The claims amounted to some €8 billion and resulted in the bankruptcy of many of the financial backers (also known as names) at Lloyds and led to the restructuring of the way the market operated. In the early years of nanotechnology, this traumatic set of losses framed to some extent the manner in which insurers approach nanotechnology related risk.

risks/exposures converted into potential monetary claims and this information is used to calculate premium levels. In many industrial areas, the insurance industry has a long track record of engagement and an extensive dataset of claims. Risks are often well understood and so are calculable within a range of accuracy - in other words, they fit into the paradigm of insurance and their actuaries can with some degree of confidence calculate the exposure. Nanotechnology poses a challenge for two main reasons, it is relatively new and second, it is a dynamic industry that comes up

with new material on a regular basis. Thus, nanotechnology resides in the category of emerging risk where the risk appetite of the business will play a role in determining the underwriting decision.

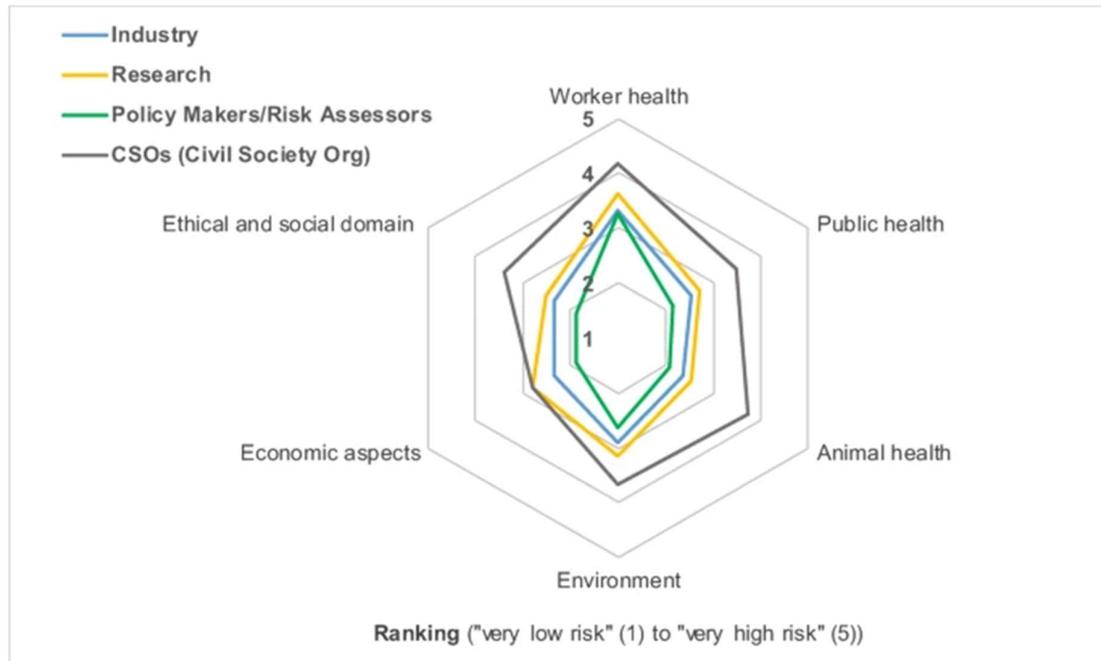


Figure (i) from Porcari, A., Borsella, E., Benighaus, C., Grieger, K., Isigonis, P., Chakravarty, S., Kines, P. and Jensen, K.A., 2019. From risk perception to risk governance in nanotechnology: a multi-stakeholder study. *Journal of Nanoparticle Research*, 21(11), pp.1-19.

Baublyte et al 2014 found that the insurance community occupy an intermediate area between expert and lay groups. Both qualitative and quantitative data analysis showed that insurers are relatively well aware of the characteristics of nanotechnology. That said, interview data did suggest that there was a lot of knowledge gaps. Porcari et al (2019), capture “risk assessors” alongside policymaker (Figure (i)) and similarly, Baublyte et al find that insurers have a more benign attitude towards NM related activity than lay opinion. This study asked participants to express opinion of the risk posed to worker, consumers, the public, animal health as well as the environment with the rationale being these are corresponding to the main perils insurers cover under general commercial liability insurance.

## 4. Risk Perception of Nanotechnology: Evidence from Twitter

Murphy, F., Alavi A., Mullins, M., Furxhi, I., Kia, A. and Kingston, M (2022) Risk Perception of Nanotechnology: Evidence from Twitter. Working Paper

This section is largely taken from a paper that has been submitted to a peer review publication for evaluation. The paper, when published, will be open access to the public. The following subsection details the abstract. In the meantime, any further queries should be directed to [Finbarr.Murphy@transgero.eu](mailto:Finbarr.Murphy@transgero.eu)

Nanotechnology governance, particularly in relation to human and environmental concerns, remains a contested domain. In recent years, the creation of both a risk governance framework and council has been actively pursued. Part of the function of a governance framework is the communication to external stakeholders. Existing descriptions on the public perceptions of nanotechnology are generally positive with the attendant economic and societal benefits being forefront in that thinking. Debates on NMs' risk tend to be dominated by expert groupings while the general public is largely unaware of the potential hazards. Communicating via social media has become an integral part of everyday life facilitating public connectedness around specific topics that was not feasible in the pre-digital age. When civilian passive stakeholders become active their frustration can quickly coalesce into a campaign of resistance, and once an issue starts to develop into a campaign it is difficult to ease the momentum. Simmering discussions with moderate local attention can gain international exposure resulting in pressure and it can, in some cases, quickly precipitate legislative action and/or economic consequences. This paper highlights the potential of such a runaway, *twitterstorm*. We conducted a sentiment analysis of tweets since 2006 focusing on silver, titanium and carbon-based NMs. We further examined the sentiment expressed following the decision by the European Food Safety Authority (EFSA) to phase out the food additive titanium dioxide (E 171). Our analysis shows an engaged, attentive public, alert to announcements from industry and regulatory bodies. We demonstrate that risk governance frameworks, particularly the communication aspect of those structures must include a social media blueprint to counter misinformation and alleviate the potential impact of a social media induced regulatory and economic reaction.

---



## 5. Insurance Related Legal Regimes around Nanomaterial Risk

It is important to understand that many of the decisions that impact the sustainability of the nanotechnology will take place in the legal arena. Given its status as an emerging technology and current state of the science around NM risk it is probable that causation chains around any adverse event will be contested. These contests will play out in legal courtrooms around the world. Of course regulations inform civil liability claims but there are other inputs to such cases. If culpability is established pay outs can be sufficiently large to bankrupt economic entities operating in this field. It is not only the actual pay outs that need to be considered, mounting a legal defence in contested scientific space is very expensive in and of itself.

Thus, the nano-toxicological research and the potential for the causation of harm to workers has given rise to fears of latent civil liability claims and parallels have been drawn with the potential for claims on the scale and magnitude of the asbestos litigation. To date there have not been any reported employers' liability claims arising from exposure to engineered NMs (ENMs). The risk governance literature has acknowledged the inevitability of latent civil liability claims and the uncertainty of the specific dynamics of this future litigation. But it has not gone beyond that to systematically address legal liability risk. It is not only claims relating to employees that are a source of concern, we also need to consider other potential claims arising across the life cycle including those related to consumers and the environment.

Understanding the legal risks around ENMs exposure is essential for effective risk governance because it informs legal risk assessment which in turn informs decision making in relation to the design and implementation of risk management strategies. Understanding legal liability risk in the ENMs context is also important for decision support for liability risk insurance providers.

The ability to transfer risk must be a central element of any robust decision making process within the nanotechnology industry. It also informs any cost benefit analysis as expenses accrued through improvement in risk management procedures may be offset by the savings in insurance/risk transfer cost. Currently, there exists a great deal of ambiguity within insurance policies in relation to nanotechnologies, insurance companies lack the tools to evaluate risk. Although several data integration methods and tools have been proposed to guide risk management in the face of heterogeneous information and uncertainty they have not been used in regulatory or industrial contexts. Information is the fundamental decision support tool and it is a crucial prerequisite to the business of insurance. But ENMs risks "remain largely beyond the bounds of prevailing actuarial calculations and underwriting standards of the insurance industry" (Hester 2017). The potential liability exposures and uncertainties for insurers are a problem. Many of them fear that the unknown risks could result in long tail risks similar to asbestos.

### Legal Systems in Europe (and globally)

Courts across Europe are the products of different historical trajectories and constitutional settlements. However, while there are differences in the European legal systems, those differences should not be overestimated. Tort law is mainly case law. This implies that the power of developing this area of law has been with the courts rather than with the legislator in response to the requirement for pragmatic solutions which best serve societal needs. From a policy point of view, English tort law which primarily concerns corrective justice and distributive justice has historically played and continues to play an increasingly important role. Continental European tort law systems are more designed to provide distributive justice. The approach is underpinned by the rationale that whereas in modern society,

everyone takes more or less advantage of increased welfare, the materialisation of risks is highly arbitrary: disadvantages only affect a small number of individuals.

Differences in structure will linger but interesting and complex issues concern the substance of the law. As Lord Bingham said: “In a shrinking world there must be some virtue in uniformity of outcome whatever the diversity of approach in reaching that outcome”.<sup>6</sup> He considered the way other jurisdictions had dealt with personal injury claims arising from exposure to asbestos.

Development of the law in an individual count cannot depend on a simple metric of decisions and codes adopted in other countries around the world, often against a background of different rules and traditions. The law must be developed coherently, in accordance with principle, so as to serve, even-handedly, the ends of justice. If, however, a decision is given in a country which offends one’s basic sense of justice, and if consideration of international sources suggests that a different and more acceptable decision would be given in most other jurisdictions, whatever their legal tradition, this must prompt anxious review of the decision in question. Therefore, the operation of other legal systems can have an impact on decision making in say the Irish courts.

### The Notion of Causation and ENMs

Parallels have been drawn between the effects of NMs and asbestos fibres on biological processes. This has been particularly the case with carbon nanotubes which are thought to have some similar properties to asbestos. In the absence of reported ENMs exposure claims on which to base the assessment of legal liability risk, we can use the precedents which have been established by the English law of negligence in the asbestos litigation to model liability risk. It is important to alert ENMs employers and their insurers about how ENMs related claims could play out. Scientific uncertainty presented challenges in the determination of asbestos related claims. These challenges were overcome by the adaptation of the standard test of causation based on precedents set in earlier, non-asbestos related claims.

### Causation at common law

In the common law system based on the traditional regime of liability and compensation, the basic rule is that the causal relationship between the damaging agent and the resulting injury, which is known as causation, must be proven on the balance of probabilities by the person who is making the claim i.e. the plaintiff. The focus of enquiry in *toxic* tort cases is typically on proof of causation. The primary focus is on causation because the scientific uncertainty which still surrounds the hazards of exposure to ENMs and the absence of reported claims present challenges for proof of causation. Without both, it is difficult to know what the liability risk will be.

“Fortunate is he who can understand the cause of things”.

The mere fact that a defendant has breached a duty of care owed to the plaintiff does not automatically lead to an award of compensation in favour of the plaintiff. The establishment of the existence of the duty of care and breach is just a step on the long road from obligation to compensation. While there may be no doubt that the defendant was negligent or in breach of duty, the basic rule is that the causal relationship between the damaging agent and the resulting injury – causation - must be proven on the

---

<sup>6</sup> See Hester 2017 b pp 275.

balance of probabilities by the person who is making the claim - the plaintiff. Causation is the most difficult legal and evidentiary hurdle which the plaintiff must overcome in a tort case. In toxic tort cases, it is even more problematic because in these cases, typically categorised as evidentiary gap/probabilistic causation cases, the plaintiff cannot prove causation based on the traditional test of causation. It has been said that “[h]ere the law is in a mess”. John Fleming describes the difficulties which causation poses in the law of torts:

There is perhaps nothing in the entire field of law which has called forth more disagreement, or upon which the opinions are in such a welter of confusion. Nor despite the manifold attempts which have been made to clarify the subject, is there yet any general agreement as to the proper approach. Much of this confusion is due to the fact that no one problem is involved, but a number of different problems, which are not distinguished clearly and that language appropriate to a discussion of one is carried over to cast a shadow upon the others...[causation] has plagued courts and scholars more than any other ... in the law of torts.<sup>7</sup>

It is a well-established principle of tort law that the plaintiff must have suffered damage/injury. Establishing clear lines of causation is complex even in long established scientific domains. Consider, a lung disease of a worker living in an urban area, they would be exposed to a variety of risk factors over the course of their life. Within the legal system, success for the plaintiff means it must be shown that the defendant wrongfully caused that damage/injury. This means that at the outset it must be satisfactorily established that on the balance of probabilities the defendant wrongfully caused the damage to the plaintiff. The defendant’s act must be linked in a factual or scientific way to the plaintiff’s injury. The negative formulation of the standard causation rule is helpful. If there is no factual causal link between the defendant’s conduct and the plaintiff’s injury, then the defendant cannot be liable.

### The Example of the Environmental Liability Directive (ELD)

The ELD entered into force on the 30th April 2004 and has been subject to review and fine tuning in terms of implication ever since. In 2020, a new study was undertaken by the Commission focusing on the improvement of the implementation of the directive. The ELD introduced a new type of regime for a number of industries including the chemicals sector that pose a risk for environmental damage. The ELD is the first environmental framework directive to recognise the need for the environment itself to have recourse in the event that it suffers from the actions of an economic operator. The environment, in the context of the ELD, deals specifically with damage to water, land and biodiversity (flora and fauna).

While the prevention and remediation of environmental damage are the primary objectives, the protection of human health against damage as a result of damage to the environment is a more discreet but equally important objective of the directive. There are a significant number of references to the threat of damage to human health arising from environmental damage in the directive.<sup>8</sup> In fact, the directive is specifically intended to apply strict liability provisions “as far as environmental damage is concerned, to occupational activities which present a risk for human health or the environment”.<sup>9</sup> 13The rationale for the ELD is based on the preventative principle 14 and the polluter pays principle (PPP) but its conceptual significance is more far reaching. One of the most interesting facets of this directive is its civil liability

<sup>7</sup> Fleming, J (1998), *The Law of Torts 9<sup>th</sup> ed.* North Ryde LBC Information Services.

<sup>8</sup> ELD, Preamble paras. 1, 7, 8, Art. 2; Annex 1 criteria for determination of “significant damage”; Annex II para. 1; Annex II paras. 1.3.1, 1.3.3; Annex II, para. 2.

<sup>9</sup> LD, Preamble, para. 8.

regime in that the directive adopts a strict liability approach where causation does not necessarily have to be established. As a civil liability regime, it speaks directly to the competing theories of tort law. A mixed theory of tort law and distributive justice underpins the rationale of the directive. The first theory understands tort liability as an instrument aimed at the goal of prevention explained. Overall, ELD can be said to adopt an eco-centric rather than an anthropocentric approach whereby the rationale for the preservation of the environment is not merely instrumental but rather that the environment itself has an intrinsic value and is worthy of preservation.

This is all relevant to NM sector. Paragraph 7(a) and (b) of Annex III provide that the manufacture, use, storage, processing, filing, release into the environment and onsite transport of dangerous substances and dangerous preparations respectively can constitute environmental damage.

Thus, NM falls within the ambit of both regulations, hence the substances regulated thereunder are relevant “activities” pursuant to Annex III of the directive. Important too is the fact that unlike the provisions of the REACH regulation, there is no volume threshold to trigger application under the directive, hence “significant” damage caused by substances even in negligible quantities such as NM will bring the activities within the scope of the directive. Under a strict liability regime there is no need to prove the subjective element, meaning that liability is established without proof of intention, recklessness or negligence. The rationale for a strict liability regime is that the operator is carrying out a high-risk activity and accordingly should be held responsible for the damage which that activity causes. This framing makes the legal regime potentially more onerous on economic actors.

Within the EU, there is a realisation that the ELD needed to be supported by adequate insurance offerings in order to underpin the remediation piece. This is a complex area and in turn this risk transfer element needs to be supported by technical work and economic valuation in order to facilitate any underwriting processes. In terms of the awareness of the directive and its provision, it has been something of a mixed picture, that said;

“Operators aware of their environmental liabilities have tended to cover the resulting risks through a mix of environmental insurances such as General Third Party Liability- GTPL, Environmental Impairment Liability- EIL or other stand-alone insurance products. Operators were using to a much lesser extent other financial security, such as captives, bank guarantees, guarantees and funds.”<sup>10</sup>

This process of putting in place an adequate suite of financial security products remains a work in progress. Suffice to say here, it is important that the NM sector is aware of the implications of this directive and indeed insurers are cognisant of the opportunities it offers them.

---

<sup>10</sup> See <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52010DC0581>

## 6. Potential Impact of Nano Risk and how the Insurance Responds<sup>11</sup>

In the following sections, we describe different types insurance, and how liability may influence different parts of the NM value chain. Further, one section is devoted to a discussion and exemplification on exclusions, as exclusions specific to nanotechnology have potentially large effects on nanotechnology manufacturers.

The coupling of asbestos risk and nanotechnology risk is an uncomfortable association. Asbestos did provide enormous benefits and could continue in this regard but the association with cancer is overwhelming. Early confidence in asbestos led to complacency and this was replaced by an outright prohibition. There is an argument that NMs have equally entered into a period of complacency on behalf of regulators and insurers.

One potential solution would be to better couple insurers and regulators with the science and industry of NMs to get a better, more nuanced, understanding of the risks. This approach would be in contrast to the current approach which is based on risk appetite or, in other words, the commercial viability of the risk to the insurer which is a Simmelian approach. That said, it is difficult to project how this couple could be implemented in practice.

### Health/ Life Insurance

Nanotechnology can reduce death and disability rates through its use in medicine. At the same time there may be risk of an increase in the cases of death and illness due to the potentially harmful properties of some nanoparticles. One major area of concern is likely to be the chemical industry, where the production and/or processing of NMs is a potential risk for employees.

### Casualty (Extended Product Liability and Environmental Pollution)

Nanotechnology can have different impacts in terms of Casualty Insurances: for environmental pollution, the transport of NMs can lead to environmental pollution and liability damage in the event of an accident. For product liability, the agriculture and the food industry are of concern as fertilizers, veterinary medicine and subsequently, the produced food contains harmful nanoparticles. The widespread use of nanoparticles with new properties in food without adequate testing represents a significant liability risk in the medium and long-term time frame.

Hence, the main line of business to be affected is (Extended) Product Liability as it covers the bodily injury, property damage and consequential financial loss caused by the insured's products. Characteristics of a product liability claim (combination of one or more of the following):

- In tort-negligence
- a breach of contract
- negligence of fault and/or

- strict liability (e.g. for a defective product under the Product Liability Directive in the EU)

Other insurers such as health insurers can conduct subrogation claims in accordance if the provisions of product liability are fulfilled (see Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products).

### Lines of Business Impacted by Nanomaterial Risk

Figure (ii) The life cycle of products containing nanomaterials and the type of insurance products that can be impacted



Figure (ii) is from Baublyte et al 2014

#### Product Liability shall mean:

The legal liability of the Insured to pay damages and/or compensation to any party, other than the Insured or Employees, in respect of Bodily Injury and/or Property Damage arising out of or from the Insured's Products anywhere within the Territorial Limits, but excluding liability arising out of or from Pollution or for Financial Loss.

#### Extended Product Liability shall mean:

Extended insurance cover against the liability risk arising from losses out of the processing of the insured's products at the final producer's site/plant and/ or damage or defect of the final product.

#### (Insured's) Product shall mean:

Any goods or product manufactured, installed, repaired, serviced, treated, sold, supplied or distributed by the Insured (including packaging and containers) in connection with the Business in or from the Territorial Limits after it has ceased to be the property of or in the custody or legal control of the Insured.

#### Duties of producer shall mean:

To design the product according to the state of technical and scientific knowledge at the time the product was put into circulation

To organise the manufacturing and quality control process in a manner that precludes or eliminates the risk of harm to the extent possible

To provide instructions for use and to warn of dangers in such a way that the user is informed of such dangers

To monitor and observe the product on a continual basis once it has been put into circulation

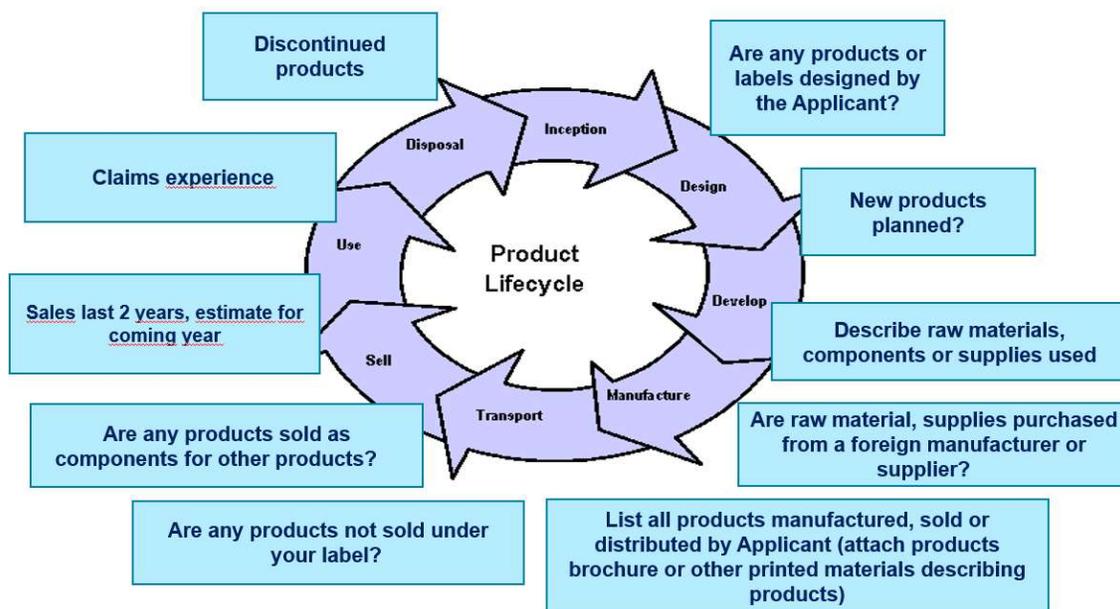
**Product Recall shall mean:**

Insurance to cover risks associated with the recall of a product and/or a public warning about the product,

Recall is basically not a liability cover but a cost cover and is divided into first party (i.e. the recall costs of the insured) and third-party (i.e. the recall costs of the client of the insured (suppliers))

As NMs are only a partial risk under Extended Product Liability, the overall risk assessment lies mainly in the type of business to be covered:

**Products Exposures – What do we need to know?**



### Business (Industry-sector):

- Pricing on turnover
- Production / activity / delivery program
- Other aspects as per attached questionnaire

### Application:

- Identification of high-risk areas in which the product is directly in contact with human beings
- **Chemicals & Cosmetics:** defective NMs in for example cosmetics for personal hygiene may be targeted for consumer lawsuits should they injure someone. In these claims, the plaintiff must provide evidence that the manufacturer or vendor had prior knowledge or should have been aware of these products.
- **Food & Agricultural Products:** All mass-produced food, beverages and agricultural products may be subject to product liability lawsuits if they are contaminated and cause food poisoning or other illnesses possibly caused by NMs. If the claimant can establish that a law was broken, it can be proven that the defendant exercised some level of negligence.
- **Pharmaceutical Products:** Drug manufacturers must conform to the authorization regulations of the respective country regarding the fabrication, promotion and sale of a product. However, if a drug is defective, this will override the fact that the company followed all of the domestic guidelines. It is the responsibility of the drug manufacturer to alert consumers and doctors of all potential side effects.
- **Medical equipment:** Use of faulty machinery and tools can result in serious injury. If this damage was caused by a product defect or failure to provide sufficient notice about a risk in the product, the manufacturer or vendor could be held accountable. Defendants involved in these cases are also required to inform consumers of the potential dangers that coincide with misuse of their product if they could reasonably have predicted that the products could be used inappropriately.
- **Automotive products:** absence of warranted characteristics can result in bodily injuries. Manufacturers and vendors have the responsibility to carefully inspect their products for safety issues and warn the public about possible risks.

### Nano-specific Exclusions in Insurance Policies

#### Excluding nano-technology related risks

According to International Risk Management Institute in the realm of insurance an *exclusion* is defined as a provision of an insurance policy or bond referring to hazards, perils, circumstances, or property not covered by the policy. Exclusions are usually contained in the coverage form or causes of loss form used to construct the insurance policy.<sup>12</sup> Over the last decade or so several insurance companies have incorporated nano-specific underwriting questions into applications. At the same time, there has been

---

<sup>12</sup> See <https://www.irmi.com/term/insurance-definitions/exclusion>

some debate in insurance circles on the acceptability of risks created by on-going exposure to an ever increasing number of ENMs.

**Sample 1: Nanotechnology Exclusion**

[R]★★★★

XXX preferred for Liability

It is hereby understood and agreed that this contract shall not apply to and does not cover any actual or alleged liability whatsoever for any claim or claims in respect of loss or losses directly or indirectly arising out of, resulting from or in consequence of products and/or manufacturing processes involving Nanotechnology.

Nanotechnology is defined as National nanotechnology Initiative (NNI 2007):

Involves all of the following:

1. Research and technology development at the atomic, molecular, or macromolecular levels, in the length scale of approximately 1-100 nm range in any direction;
2. Creating and using structures, devices, and systems that have novel properties and functions as a result of their small and/or intermediate size; and
3. Ability to control or manipulate on the atomic scale.

Comments<sup>13</sup>

*The definition stems from the US. NNI stands for national nanotechnology initiative (US government programme).*

*Nanotechnology is considered as an emerging risk. Similar to other emerging risks it is a widespread and rather recent technology. Numerous studies have been carried out (and are being carried out) but with no conclusions yet.*

*NMs (see below definition from the EU in remarks) which are of particular suspect are nanocarbon particles due to their similar shape to asbestos fibres and therefore the risk of developing mesothelioma.*

*However potential risks are much more widespread, inclusive environmental issues.*

**Sample 2: Nanotechnology Exclusion**

[R]★★★★

It is hereby understood and agreed that this contract shall not apply to and does not cover any actual or alleged liability whatsoever for any claim or claims in respect of loss or losses directly or indirectly arising out of, resulting from or in consequence of products and/or manufacturing processes involving Nanotechnology.

However, this exclusion shall not apply to policies

<sup>13</sup> The comments are from a professional working in the reinsurance sector.

- issued on claims-made basis
- which provide defense costs within all limits in the policy
- which provide coverage for diminution of value of property that do not also require, for such coverage, visible physical damage
- excluding occupational-disease

Nanotechnology is defined as (NNI 2007):

Involves all of the following:

1. Research and technology development at the atomic, molecular, or macromolecular levels, in the length scale of approximately 1-100 nanometer (nm) range in any direction;
2. Creating and using structures, devices, and systems that have novel properties and functions as a result of their small and/or intermediate size; and
3. Ability to control or manipulate on the atomic scale.

#### Comments<sup>14</sup>

*This clause is recommendable as it limits the latency risk connected with emerging risks through claims-made and exclusion of occupational disease. It does as well reflect the risk of heavy defence costs burden, i.e. it does limit it. Pure financial losses are excluded to safeguard against possible allegation of negative effects of nanotechnology and thus leading to reduction of values of exposed objects.*

*When using this clause specific care should be taken if the cedant is active in the following industries: food, chemical, pharmaceutical, medical, automotive.*

*The clause favours the reinsurer and is recommendable.*

---

<sup>14</sup> The comments are from a professional working in the reinsurance sector.

## 7. Draft Guidelines

In order to generate draft guidelines for risk transfer, this report first covers important and necessary groundwork. In the main, this requires an understanding of the insurance industry and the factors that influence that industry. Furthermore, an understanding of contemporary insurance concerns and business processes are required in order for the risk governance council and associated stakeholders to communicate effectively and efficiently with the insurance sector.

To that end, in this report we commenced with an historical overview of the concerns of the insurance sector. Asbestos remains a significant and influential moment for insurers. The scale and long tail effects of asbestos continue to influence the underwriting community and that influence extends to how they view NMs today. To that end we looked at lessons from other emerging risk domains including GM foods, cyber risk and autonomous vehicles.

Risk perception by the public of materials irrespective of actual risk is acutely understood and appreciated by insurers. The reason for this is that risk perception will find an outlet in the form of a class action against a manufacturer, for example. This is particularly so in the USA where the jury system can be particularly sympathetic to individual cases against corporations. For this reason we took a significant detour to look at how social media can exacerbate and exaggerate risk perceptions. We specifically looked at Twitter and examined how localized events can come to global attention in the form of a twitterstorm. These citizen led campaigns, however organic, can lead to regulatory action. They can also precipitate an insurance reaction. This may take the form of an exclusion policy or indeed a full withdrawal of insurance coverage of a particular sector. Therefore the influence of social media on the public perception of NMs has a direct and proportional effect on the perception by the insurance sector of NMs.

This report also gave considerable attention to legal frameworks and jurisdictions. The legal framework in which insurers operate is particularly influential in determining insurers risk appetite and the cost of risk for industry.

Finally, in order to lay the foundations for appropriate guidelines, this report detailed how the insurance industry is organized as a business. In this report we detailed health and life insurance and other lines of insurance business. The main insurance lines that the risk governance council needs to be cognizant of include product liability, employer's liability, product recall and environmental liability. Again, an appreciation of how the insurance sector is organized is important in determining how risk is communicated from the scientific community to the business sector.

The primary insurer has direct access to the risk information for the business to be covered. Based on the underlying risk, the primary insurer can use the following items to mitigate the risk:

### Monetary items

- ✓ Retention/ Deductible/ Franchise
- ✓ Sub-limits
- ✓ Annual (Aggregate) Limits

### Non-monetary items

- ✓ Policies to be written on claims made basis



- ✓ Claims series clause/ batch
- ✓ Vendors endorsement
- ✓ Territorial scope (Non-US vs. US)
- ✓ Exclusions: punitive damages, intellectual property rights (IPR), certain materials (e.g. asbestos), future sales exclusion
- ✓ “fairly” exclusion of nanotechnology (see examples)

The reinsurer does not have direct access to the risk information for the business to be covered (except for facultative business). This is because the reinsurer provides coverage for a whole portfolio and not for one specific risk per se. Therefore, an effective risk control is quite complicated as the reinsurer is bound to the underwriting decisions made by the primary insurer (referred as “underwriting risk”). Besides limiting the risk exposure with the above mentioned monetary and non-monetary items, the reinsurers can mitigate the risk due to the nature of reinsurance contracts. For example, using a proportional quota-share, an alignment of interest can be ensured as both parties share, in the same proportion, the premiums and losses for the risks in question.

A number of reports have emanated from the industry and risk consultancies on the risk posed by NMs and provide some guidance for insurers on potential loss scenarios. The use of NMs in food production has led to heightened levels of interest in NM risk due to the potential for widespread exposure. One such is a 2017 report by Allianz and Praedicat which highlight a number of possible insurance scenarios, with potential insurance solutions.<sup>15</sup>

■ **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

In the food industry as elsewhere, nanotechnology is not only a risk but also can function as a risk management tool. Here we have the example of the opportunity for risk management if nano-enabled food packaging can signal if there is a health threat.

---

<sup>15</sup> See AGCS-Praedicat-Emerging-Risks-Nanotechnology.pdf

Nanomaterial	Use in Food	Potential Risk
Silicon Dioxide	Anti-caking and colouring agent	Possible toxicity associated with long terms low exposure use
Silver	Antibacterial agent used for food storage	Ingestion of large amount of colloidal silver linked to renal and neurological problems
Titanium Dioxide	Anti-caking and colouring agent	Uncertainty around long term effects persist
Zinc Oxide	Fortify processed foods	Some evidence of risk of cell damage in intestinal track

Overall, through the vector of food, we are seeing much greater levels of exposure to nanoparticles on the part of European consumers. This has led to increased calls for more transparency on the part of consumer groups with much of the debate focused on the labelling of food products.

## 8. Conclusions

In the view of Transgero and RiskGONE (and this same view is reflected among the industry stakeholders consulted over the duration of this project) one of the main risks to the NM sector resides with the unpredictability of the reaction of insurers to an adverse event related to NMs. Given the status of insurance professionals as lying between lay people and scientists in terms of their knowledge of NM related risk, there is a possibility that the insurance industry could react abruptly and decisively and move to limit any exposure to NM risk. Given the structure and make up of the NM industry it would be left in a vulnerable position if such a course of action was taken. Previous work by Carrol et al (2016) identified that the NM sector is made up of a high proportion of SMEs who do not have the scale or the necessary financial resources to either self-insure or manage a captive insurer. Without the requisite insurance provided by the insurance industry, particularly the compulsory insurance such as employers liability, this component of the NM industry would be left in an unsustainable position.

Risk perception plays an outsized role in determining both insurers and regulators reactions. This report shows how social media could propagate real or fake information causing significant disruption. This report suggests that a risk governance council or any agency that provides risk information should be familiar with tools to counteract social media misinformation storms. In this way, risk governance has an obligation to scan the internet for potential twitter storms and have a response plan in place.

It is incumbent on the insurance sector to participate in the risk governance functions. This might be possible at an industry group level such as Lloyds Market but, in the experience of the authors, a higher level group with a more global voice would be necessary.

In order to mitigate the risks to the sector it is important that underwriters are able to distinguish between high and low risk activities. Control banding techniques as suggested by Mullins et al (2013) may offer a way forward in this regard. This methodology may allow for any exclusion clauses to focus on the high risk areas. Similarly, the use of bow-tie risk management strategies would allow for insurers to engage with the nanotechnology sector to both try and mitigate risk and manage claims volumes. The most acute set of risks to be managed are those related to bodily injury claims as these may have a “long tail” component. One strategy the insurance industry has to lessen its exposure in this regard is the use of “claims made” policies. That is to say that insurance policies operate in a narrow temporal window and therefore reduce latent or tail risk. However, this would leave the industry in a vulnerable state with a great deal of exposure related to past usage. This would be the case around the risk related to workers, consumers and the environment. Here it is worthy of note that with the increasing ubiquity of NM in products the risk profile rises. Of particular concern are food and pharmaceuticals as they are ingested by millions of consumers.

Given the status of ENM as key enabling technologies and their importance in a high number of value chains, there is a need for some contingency planning on the part of the EU and national governments. At this juncture, NMs are viewed as low risk, however if risk perceptions around NM were to change there may be a need for hybrid insurance structures to be put in place to support the industry in the short term. This could include public-private partnerships where risk sharing mechanisms were put in place in the short and medium term whilst the insurance industry came to a more granular understanding of the risks around nanotechnologies across different sectors of the economy.

Overall, the insurance industry is a key stakeholder in the continued sustainability of this important sector. In many respects, insurance is a proxy regulator. This is especially the case around emerging technology where the so-called “pacing problem” (that is the delay in legal and regulatory regimes

around new technologies) remains a structural issue. Both the proposed risk governance framework and the risk governance council could assist in keeping open the line of communication and mitigating the risk of any abrupt change in how NMs are perceived by insurance professionals.



## 9. Bibliography

Ajasa, O. (2014). Ebola: Nigerians blast US FDA for calling its experimental drug, pesticide. Vanguard.

Akingbule, G. and H. Vogt (2014). Ebola Virus: Nigerian Patients to Be Given Experimental Drug. The Wall Street Journal. Online.

Alamoodi, A. H., et al. (2021). "Sentiment analysis and its applications in fighting COVID-19 and infectious diseases: A systematic review." Expert Systems with Applications **167**: 114155.

Ansell, C., et al. (2020). "Understanding inclusion in collaborative governance: a mixed methods approach." Policy and Society **39**(4): 570-591.

Baublyte, L., et al. (2014). "Insurance market perception of nanotechnology and nanomaterials risks." The Geneva Association **54**.

Blaznik, U., et al. (2021). "Use of Food Additive Titanium Dioxide (E171) Before the Introduction of Regulatory Restriction Due to Concern for Genotoxicity."

Bourdieu, P. (2007). Outline of a Theory of Practice, Duke University Press.

Burri, R. V. and S. Bellucci (2008). "Public perception of nanotechnology." Journal of Nanoparticle Research **10**(3): 387-391.

Carroll, A., Mullins, M., Murphy, F., McAlea, E.M. and Hester, K., 2016. Nanomaterial and Nanotechnology Firms: A Typology. In *Managing Risk in Nanotechnology* (pp. 9-28). Springer, Cham.

Commission, E. (2018). Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances. 2018/1881. E. Commission.

Dransfield, G. (2000). "Inorganic sunscreens." Radiation protection dosimetry **91**(1-3): 271-273.

ECHA (2017). "Titanium dioxide proposed to be classified as suspected of causing cancer when inhaled." from <https://echa.europa.eu/-/titanium-dioxide-proposed-to-be-classified-as-suspected-of-causing-cancer-when-inhaled>.

EFSA (2021). "Titanium dioxide: E171 no longer considered safe when used as a food additive." Retrieved 18/11/2021, 2021, from <https://www.efsa.europa.eu/en/news/titanium-dioxide-e171-no-longer-considered-safe-when-used-food-additive>.

Felt, U., et al. (2014). "Technology of imagination: a card-based public engagement method for debating emerging technologies." *Qualitative Research* **14**(2): 233-251.

Ferri, L., et al. (2021). "How risk perception influences CEOs' technological decisions: extending the technology acceptance model to small and medium-sized enterprises' technology decision makers." *European Journal of Innovation Management* **24**(3): 777-798.

Flynn, R. (2007). Risk and the Public Acceptance of New Technologies. *Risk and the Public Acceptance of New Technologies*. R. Flynn and P. Bellaby. London, Palgrave Macmillan UK: 1-23.

Folayan, M., et al. (2014). "Compassionate use of experimental drugs in the Ebola outbreak." *The Lancet* **384**(9957): 1843-1844.

Gorgoni, G. (2018). Responsible Research and Innovation and the governance of human enhancement. *Nano Ethics*, **12**(3), pp. 257–267.

Grieger, K., Jones, J.L., Hansen, S.F., Hendren, C.O., Jensen, K.A., Kuzma, J. and Baun, A., 2019. Best practices from nano-risk analysis relevant for other emerging technologies. *Nature nanotechnology*, **14**(11), pp.998-1001.

Gupta, N., et al. (2015). "Ethics, risk and benefits associated with different applications of nanotechnology: a comparison of expert and consumer perceptions of drivers of societal acceptance." *NanoEthics* **9**(2): 93-108.

Hellsten, I., et al. (2019). "Active and passive stakeholders in issue arenas: A communication network approach to the bird flu debate on Twitter." *Public Relations Review* **45**(1): 35-48.

Hester, K., Mullins, M., Robert, F.O.R.D. and Murphy, F., 2017. The ELD: Applicability to Nanotechnology Risk and the Liability Implications of Environmental Damage. *European Journal of Risk Regulation*, **8**(1), pp.140-157.

Hester, K, 2017 (b) Engineered Nanomaterials: Employers Liability Risk, REACH & Governance, PhD Thesis [ulir.ul.ie](http://ulir.ul.ie)



Hilbeck, A., et al. (2020). "GMO regulations and their interpretation: how EFSA's guidance on risk assessments of GMOs is bound to fail." Environmental Sciences Europe **32**(1): 54.

Hutto, C. and E. Gilbert (2014). Vader: A parsimonious rule-based model for sentiment analysis of social media text. Proceedings of the International AAAI Conference on Web and Social Media.

Isigonis, P., et al. (2020). "Risk governance of emerging technologies demonstrated in terms of its applicability to nanomaterials." Small **16**(36): 2003303.

Isigonis, P., et al. (2019). "Risk governance of nanomaterials: review of criteria and tools for risk communication, evaluation, and mitigation." Nanomaterials **9**(5): 696.

Jagiello, R. D. and T. T. Hills (2018). "Bad news has wings: Dread risk mediates social amplification in risk communication." Risk analysis **38**(10): 2193-2207.

Jun, I., et al. (2020). Understanding Perceptions and Attitudes toward Genetically Modified Organisms on Twitter. International Conference on Social Media and Society.

Kaeslin, B., 2008. Early detection and management of emerging risks in the financial services industry: lessons from insurance businesses.

Kasperson, R. E., et al. (1988). "The social amplification of risk: A conceptual framework." Risk analysis **8**(2): 177-187.

Klinke, A. and O. Renn (2021). "The Coming of Age of Risk Governance." Risk Analysis **41**(3): 544-557.

Knowles, K. A. and B. O. Olatunji (2021). "Anxiety and safety behavior usage during the COVID-19 pandemic: The prospective role of contamination fear." Journal of Anxiety Disorders **77**: 102323.

Krech, R. and M.-P. Kiény (2014). The 2014 Ebola outbreak: ethical use of unregistered interventions, SciELO Public Health.

Kyle, R. and S. Dodds (2009). "Avoiding Empty Rhetoric: Engaging Publics in Debates About Nanotechnologies." Science and Engineering Ethics **15**(1): 81-96.



Lee, C.-J., et al. (2005). "Public Attitudes toward Emerging Technologies: Examining the Interactive Effects of Cognitions and Affect on Public Attitudes toward Nanotechnology." Science Communication **27**(2): 240-267.

Liu, Z. and J. Z. Yang (2021). "In the Wake of Scandals: How Media Use and Social Trust Influence Risk Perception and Vaccination Intention among Chinese Parents." Health Communication **36**(10): 1188-1199.

Lloyd's of London, 2007, "Nanotechnology: Recent Developments, Risks and Opportunities."

Maduka, O. and O. Odia (2015). "Ethical challenges of containing Ebola: the Nigerian experience." Journal of medical ethics **41**(11): 917-919.

Malsch, I., Subramanian, V., Semenzin, E., Hristozov, D. and Marcomini, A., 2015. Supporting decision-making for sustainable nanotechnology. *Environment Systems and Decisions*, **35**(1), pp.54-75.

Malsch, I., et al. (2017). "Comparing mental models of prospective users of the sustainable nanotechnology decision support system." Environment Systems and Decisions **37**(4): 465-483.

Murphy, F., et al. (2017). "Insuring nanotech requires effective risk communication." Nature Nanotechnology **12**(8): 717-719.

Mullins, M., Murphy, F., Baublyte, L., McAlea, E.M. and Tofail, S.A., 2013. The insurability of nanomaterial production risk. *Nature Nanotechnology*, **8**(4), pp.222-224.

Murthy, D. (2012). "Towards a sociological understanding of social media: Theorizing Twitter." Sociology **46**(6): 1059-1073.

Park, A. (2014). FDA Cracks Down on Unproven Ebola Cures.

Pimbert, M. P. and B. Barry (2021). "Let the people decide: citizen deliberation on the role of GMOs in Mali's agriculture." Agriculture and Human Values **38**(4): 1097-1122.



Porcari, A., Borsella, E., Benighaus, C., Grieger, K., Isigonis, P., Chakravarty, S., Kines, P. and Jensen, K.A., 2019. From risk perception to risk governance in nanotechnology: a multi-stakeholder study. *Journal of Nanoparticle Research*, 21(11), pp.1-19.

Prakash, D., et al. (2011). "Risks and Precautions of Genetically Modified Organisms." *ISRN Ecology* 2011: 369573.

Romanach, L., et al. (2015). "Societal acceptance of an emerging energy technology: How is geothermal energy portrayed in Australian media?" *Renewable and Sustainable Energy Reviews* 42: 1143-1150.

Runge, K. K., et al. (2013). "Tweeting nano: how public discourses about nanotechnology develop in social media environments." *Journal of Nanoparticle Research* 15(1): 1381.

Ruz, G. A., et al. (2020). "Sentiment analysis of Twitter data during critical events through Bayesian networks classifiers." *Future Generation Computer Systems* 106: 92-104.

Schweizer, P.-J. (2021). "Systemic risks – concepts and challenges for risk governance." *Journal of Risk Research* 24(1): 78-93.

Singh, P., et al. (2018). "Social media buzz created by #nanotechnology: insights from Twitter analytics." *Nanotechnology Reviews* 7: 521 - 528.

Slovic, P., et al. (1982). "Why study risk perception?" *Risk analysis* 2(2): 83-93.

Smijs, T. G. and S. Pavel (2011). "Titanium dioxide and zinc oxide nanoparticles in sunscreens: focus on their safety and effectiveness." *Nanotechnology, science and applications* 4: 95.

Song, H., et al. (2021). "The Role of Fairness in Early Characterization of New Technologies: Effects on Selective Exposure and Risk Perception." *Risk Analysis* 41(9): 1614-1629.

Stieglitz, S., et al. (2018). "Social media analytics—Challenges in topic discovery, data collection, and data preparation." *International journal of information management* 39: 156-168.

Stilgoe, J., et al. (2014). "Why should we promote public engagement with science?" *Public understanding of science* 23(1): 4-15.

Subramanian, V., et al. (2016). Integrating the social impacts into risk governance of nanotechnology. Managing risk in nanotechnology, Springer: 51-70.

Tufekci, Z. (2017). Twitter and tear gas, Yale University Press.

Turnbull, C., et al. (2021). "Global Regulation of Genetically Modified Crops Amid the Gene Edited Crop Boom – A Review." Frontiers in Plant Science **12**(258).

Ulnicane, I., et al. (2021). "Framing governance for a contested emerging technology: insights from AI policy." Policy and Society **40**(2): 158-177.

Veltri, G. A. (2013). "Microblogging and nanotweets: Nanotechnology on Twitter." Public understanding of science **22**(7): 832-849.

Westervelt, A. (2015). Dunkin' Donuts to remove titanium dioxide from donuts. The Guardian. Online.

WHO (2014). "Statement on the 1st meeting of the IHR Emergency Committee on the 2014 Ebola outbreak in West Africa." Retrieved 16/11/2021, 2021, from <https://www.who.int/news/item/08-08-2014-statement-on-the-1st-meeting-of-the-ihc-emergency-committee-on-the-2014-ebola-outbreak-in-west-africa>.

Willis, R. D. (2021). "Exploring the relationship between global Twitter campaigns and domestic law: methodological challenges and solutions." Information & Communications Technology Law **30**(1): 3-16.

Zhang, Y., et al. (2014). "Fighting Ebola with ZMapp: spotlight on plant-made antibody." Science China. Life sciences **57**(10): 987.





[www.riskgone.eu](http://www.riskgone.eu) | [riskgone@nilu.no](mailto:riskgone@nilu.no)

LIMERICK, 24 12 2021

*The publication reflects only the author's view and the European Commission is not responsible for any use that may be made of the information it contains*

