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Tyre wear nanoparticles as test for a nano risk governance framework

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The Horizon 2020 consortia NanoRigo, Gov4Nano and RiskGONE jointly developed a nano risk governance framework (NRGF), fit for use for the practice of nanomaterials' development and use, understandable and executable for stakeholders involved in manufacturing, using or regulating nanomaterials, or confronted with incidental exposure to generated nanomaterials. The NRGF includes risk management models, tools and approaches relevant to nanomaterials, as well as nano-oriented LCA and grouping, and takes into account socio-economic aspects and risk-benefit assessment. Special attention was paid to operationalizing concern assessment within the framework of the risk governance approach, emphasizing the different nature of quantitative risk assessment and qualitative concern assessment. The usefulness and added value of the NRGF was tested by means of a case study on rubber tyres. This case study performed a "mock-up" risk and concern assessment of the use of manufactured nanomaterials in the rubber tyre tread and the environmental release of tyre wear particles (TWP) from this tread during car driving. With a focus on the release and hazards of nano-TWP, an approach using the NRGF methodology was defined in collaboration with a group of real-life stakeholders. Simultaneously a group of scientific experts assessed the usefulness of the available tools and methods for assessing this nano-TWP release and investigated related broader societal concerns. The exercise concludes that so far, an exclusive risk assessment of nano-TWP is a step too far, due to the lack of nano-specific health- and environmental exposure and hazard data. Moreover, it seems that public concern about nano-sized TWP emissions is still limited, contrary to emerging scientific concerns. The case study underlines the complexity of deriving robust recommendations for "real-life" cases. Many questions remain on how to weigh the available technical and social evidence in nano risk governance.

KEYWORDS

nanomaterials, nanoparticles, nanoplastics, rubber tyre wear, risk governance framework, risk assessment, case study

1 Introduction

For the dynamic development of nanotechnologies and the growing market for manufactured nanomaterials (MNMs) policy makers stated that transdisciplinary risk governance based on a clear understanding of risk, its management practices and the perception of societal risk by all stakeholders is required (Jantunen et al., 2018). While the REACH regulation requires a specific risk assessment for substances in the nanoform (EC 2018; REACH, 2022), the European Commission indicated that there is a need for an understandable and executable risk governance framework applicable for nanomaterials (EC 2017). There are a few important observations that can be gleaned from the Commission's repeated calls for the transdisciplinary risk governance of nanomaterials (Schuurbiers 2020):

- The Commission considers that risk governance includes more than technical assessment of the risk of MNMs;
- It sees risk governance as a transdisciplinary endeavour;
- It recognizes the relevance of the risk perceptions of all stakeholders as an element of risk governance.

The development of an explicit *nano* risk governance framework (NRGF) started under the H2020 research program NMBP13 through the launch of three projects, NanoRigo, Gov4Nano and RiskGONE, which joined forces for this. In addition, the new overarching European Chemicals Strategy for Sustainability (CSS), operationalized as part of the EU's Green Deal zero pollution ambition, sets out concrete actions to make chemicals safe and sustainable by design to ensure that chemicals can deliver benefits without harm (EC, 2020). The nano risk governance framework (NRGF) developed by the NMBP-13 projects can be an instrument serving these ambitions.

The concept of risk governance refers to institutions, rules conventions, processes and mechanisms by which decisions about risks are taken and implemented (Renn et al., 2008; IRGC, 2017; Aven and Renn 2018; Stone et al., 2018). Several risk governance frameworks have been developed (DIN 2013; Subramanian et al., 2016; IRGC 2017; ISO, 2017; Isigonis et al., 2019; Isigonis et al., 2020).

The NRGF, as used in this study, builds on the IRGC governance framework (IRGC, 2017). It comprises six subsequent interlinked elements. It includes risk management models, tools and approaches relevant to nanomaterials, as well as nano-oriented LCA and grouping, and takes into account socio-economic aspects and risk-benefit assessment (Franken et al., 2019; Sørensen et al., 2019; Isigonis et al., 2020; Mullins et al., 2022). (see Figure 1):

To operationalise and support the practical use of the NRGF, a joint web-based risk governance portal is being established by the NMBP-13 projects, providing guidance at every step. It will be launched in early 2023.

Klinke and Renn (2021) state that the main difference between traditional risk assessment and risk governance is inclusion of social aspects of the risk in the form of concern assessment. In traditional risk governance debates there is limited attention to broader societal and ethical considerations. This discrepancy between the attention to environmental health and safety issues and broader ethical and societal issues is also highlighted by Patenaude et al. (2015), emphasizing the need for a reflective stance in order to reveal the complexity of the situation and the inadequacies of our way of coping with ethical issues in regulatory science.

The NRGF therefore combines technical risk assessment with concern assessment. Concern assessment is a social research activity: it draws on expertise from policy studies, anthropology, sociology, economics, innovation studies, communication sciences, ethics and philosophy to identify public perceptions, social concerns and socio-economic impacts of the risk issue at hand. It does this by way of literature review and horizon-scanning, finding out what is already known in terms of public perceptions, social concerns

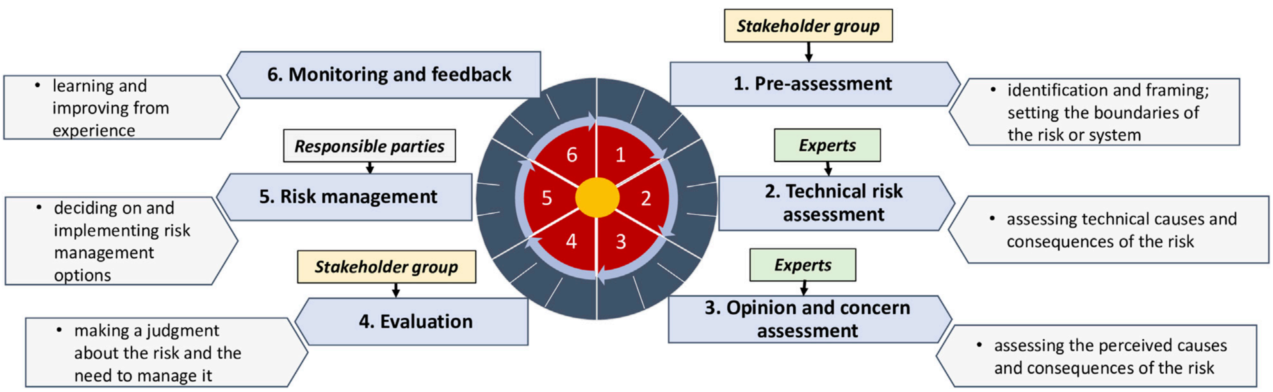

FIGURE 1
Process model of the used Nano Risk Governance Framework and inclusion of interest groups (in the rubber tyre case).

and socio-economic impacts related to the governance issues at hand (Mullins et al., 2022).

The NRGF was tested in several case studies, one of them being the rubber tyre case (RTC), designed to address a hypothetical societal issue, addressing uncertainties and concerns about possible effects of the release of generated nano-sized tyre wear particles from on-road vehicles. The case was hypothetical in the sense that there was hardly to no societal upheaval about possible risks of nanoparticles released by rubber tyres (nor were there societal actors taking up such an issue). Also, from the technical side and within the public debate, at the moment the case study was started, nanoparticle release from rubber tyres was hardly or not seen as a clear additional risk factor to human and environmental exposure to ultrafine particles on and around roads. All in all, in this mock-up rubber tyre case the issue was most of all addressed as a 'what if'-case, and as such typical for uncertain risks that present themselves in early stages of a risk governance cycle.

The issue of "generated nanoparticles from wear of rubber tyres of cars" was deliberately chosen for its inherently diffuse character (realistic or not), in terms of:

- Physical-chemical properties and risks, as tyre wear particles (TWP) form an associated heterogeneous mix with road wear particles (TRWP) of different shape, size, surface area and chemical composition with mostly undetermined risk characteristics),
- "*What goes in is not what comes out*" (i.e., MNMs in the tread rubber are not released as MNMs, but as embedded in abraded micro and nano rubber particles containing the constituent as well as chemically transformed components, including nucleation particles) (Mitrano et al., 2015; van Broekhuizen, 2017; EC-FAQ, 2022; Wagner et al., 2022),
- Different exposure characteristics (as airborne TWP release potentially affecting people, nature, and the environment and after deposition directly on and in the vicinity of roads, as well as after transport in more distant and remote terrestrial and aquatic areas),
- Divergent roles, responsibilities, and ownership (stakeholders range from car, rubber and tyre producers to transporters, and drivers, from road workers and their employers to road authorities, from different local, national, and supra-national governments to industry and civil society; between them, not all roles and responsibilities regarding this issue are clearly and/or legally defined),
- Complementing risk governance strategy options (ranging from innovative technical approaches to improve tyre performance, to road design and maintenance, and to social-economic approaches influencing the driving behaviour (avoiding TWP-generating stressed driving), speed limits, the purchasing of heavy cars (SUVs).

As such, the case study was intended to challenge basic assumptions within the NRGF design including the key elements of the risk governance such as methods and tools. The basic questions for the case study were:

- What is the added value of the developed NRGF and its identified and developed risk management tools for a real-life case as wear particles from rubber tyre?
- How can issues such as concern assessment and divergent risk perceptions be assigned a more structural position within the risk governance process?
- Who should be initiating such a decision-making risk governance process?

For risk governance it is important to carefully distinguish TWP and TRWP, but for real-life sampling this can be complex. The term TWP (tyre wear particles) is used for particles not contaminated with road wear, which is the most likely form to be generated in laboratory experiments (e.g., a road simulator). The term TWP is also used when the release of tyre wear is discussed in general. The term TRWP (tyre and road wear particles) is used for associates (agglomerates or aggregates) of TWP with road wear particles, i.e., the most likely form for environmental sampling and for risk assessment in practice (Halle et al., 2020). T(R)WP is used when both forms are likely.

TWP are also classified under the general definition of microplastics. To define "nanoplastics", publications refer to upper size limits of either 100 nm or 1,000 nm (Mitrano et al., 2021). In analogy with the EC definition for nanomaterials (EC 2022), this study uses an upper limit of 100 nm for the qualification of nanoplastics. Pragmatically, this upper limit is used as well for nano-TWP.

2 Materials and methods

2.1 Set up and organisation

In this mock-up case study, the first four risk governance steps were exercised: namely pre-assessment, technical risk assessment, concern assessment and risk evaluation (see Figure 1). An overview of the activities performed within these steps is presented in Figure 2.

In this experiment, the involved stakeholders and the project partners were assigned separate tasks. Within the NanoRigo project, the stakeholders were involved in steps 1 and 4 - the pre-assessment and the evaluation. The risk and concern assessment experts from all NMBP-13 projects (NanoRigo, RiskGONE and Gov4Nano) were engaged to carry out step 2 and 3 - technical risk assessment and the opinion and concern assessment (see Figure 1).

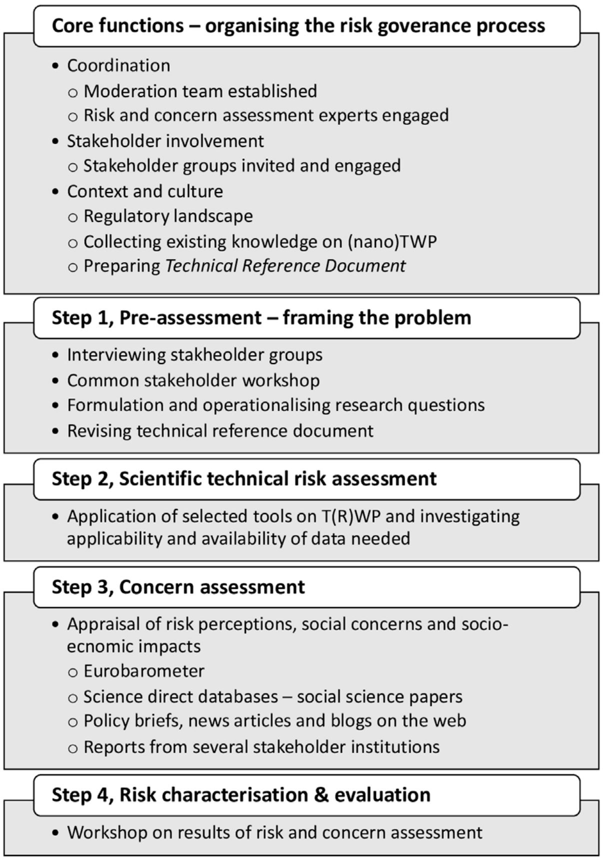

FIGURE 2
Overview of the actions taken in the mock-up tyre wear case study.

2.2 Organizing the risk governance process

The risk governance exercise was led by a small team of social and natural scientists. It started with compiling a technical reference document (for internal use) to understand the current situation regarding potential human and environmental impact and risk governance initiatives related to the use of rubber tyres, as published in public sources and collected according to conventional literature search methodologies (van Broekhuizen, 2022). To avoid influencing the participating stakeholders, the technical reference document was not exchanged with them before the pre-assessment phase.

A heterogeneous, Dutch-speaking stakeholder group of 11 persons was formed with representation from: tyre and rubber manufacturers associations, tyre recyclers association, tyre manufacturers, road authorities, trade unions and citizens living in the vicinity of (contested) highways.

Experts were recruited from the three EU projects: NanoRigo, Gov4Nano and RiskGONE with backgrounds in chemical, environmental, occupational hygiene, social and ethical sciences.

2.3 Pre-assessment

The aim of the pre-assessment phase (step 1) with the stakeholders was to agree on a jointly shared definition of the issues “at stake”, to capture their current perspectives on opportunities and risks, and to identify possible strategies to address them. It was carried out in two steps. First, semi-structured interviews were arranged separate face to face with each of the stakeholder groups. The topics addressed in the interviews are shown in Box 1:

BOX 1 Topics addressed in the questionnaire for stakeholders in the pre-assessment phase

- The nature of the issue (reasons to deal with TWP, and whether it is perceived to be a (nano)problem?)
- Demarcation of the issue (prioritizing the most relevant aspects)
- Risk and challenges in this issue (which issues are at stake, such as: health, environmental, safety, justice, economy etc.)?
- Positioning of the respective organization in these issues (Did your organization identify the issue as a problem? Does it get attention? What would be a reason for further action? When would a threshold be exceeded to force action? And conversely, when is no further action needed?
- Identification of other relevant stakeholders (brainstorm, control, responsibilities)
- Available knowledge and existing gaps in knowledge
- Expectations from this nano risk governance approach

Subsequently, based on the results of these interviews, a round-table workshop with the stakeholders was organized. A report based on the results of the pre-assessment was produced. The overall question, put forward to the stakeholders was:

- According to you, does the nano-sized TWP emission (next and in addition to the other emissions and exhausts from road traffic) necessitate (more, additional, other) risk management activities?

2.4 Technical risk assessment

The aim of the technical risk assessment (step 2) is to provide information about the hazards, exposure and vulnerability of the affected populations and systems and to indicate the likelihood and severity of the potential effects. The tests for the risk assessment were limited to an assessment of the risks to humans and the environment caused by the release of (nano-sized) TWP during the tyre

TABLE 1 List of tools and approaches for risk assessment integrated into the web based governance portal, and tested by NMBP13 experts, for potential useful contribution to nano risk governance of TWP.

Tool	Tool aim	References
S(S)bS	Safe (and Sustainable) by Design approach	Kraegeloh et al. (2018)
Licara Nanoscan	Assessment of benefits and risks of new and existing nanoproducts	Harmelen et al. (2016)
SUNDs	Nano-product sustainability assessment. Decision Support System	Subramanian et al. (2016)
		https://www.sunds.gd/
		Pizzol et al. (2019)
SSWD-SSDs	Species sensitivity distributions (SSDs) and species sensitivity weighted distribution (SSWDs)	Semezin et al. (2015)
GUID Enano	Tool for risk assessment and mitigation for specific products	Fernández-Cruz et al. (2018)
SEG4 Nano	Simple Ecotoxicological Grouping System for nano. Tool for aquatic and terrestrial toxicity	Kühnel et al. (2019)
Nano Risk Cat	Tool to identify, categorize, rank and communicate eventual risk associated with the specific application(s) of a given nanomaterial	Hansen et al. (2013)
Swiss Precautionary matrix for synthetic NMs	Method to assess nano-specific health and environmental risks of nanoproducts	FOPH (2018)
MCDA	Multi Criteria Decision Analysis, screening the benefit of NMs	Giese (2022)
PERST	Prospective Early Risk Screening Tool	Gottschalk et al. (2022)
Risk Assessment	Risk Assessment of NMs, Reflection on challenges and data needs	Jensen (2022)
Insurance companies	Their role and positioning towards TWP release	Mullins (2021)

use phase. The information requirements for the characterisation of the TWP exposure consists of the MNM-specific data, as well as transformation and ageing-specific physical-chemical properties, matrix conditions (free or embedded), size-distribution, exposure levels and release rate. Hazard characteristics include limit values, epidemiology, test data on effects, read-across and information on predictive possibilities (micro→nano).

The experts were selected for their knowledge or their contribution to the development of specific tools for risk or concern assessment within the NMBP-13 governance projects. They received the results of the stakeholders' round-table workshop and their formulation and framing of the "problems-at-stake". The experts were also provided with the technical reference document, so that they did not have to perform data searches themselves. Subsequently, they were asked to judge whether the specific tool or governance approach they assessed could contribute to the risk governance process of rubber tyre wear. The models and tools for risk assessment that were assessed by the experts are shown in Table 1. The positioning of the insurers as a stakeholder with regard to tyre wear risks was highlighted as part of the experts' input.

The expert input, their findings and ideas, was discussed with them in an online meeting (due to corona-limitations), with a focus on data-needs for the tools, data-gaps, usefulness of tools for this real-life rubber tyre case.

2.5 Concern assessment

The concern assessment (step 3) aimed to assess what is known about the concerns and attitudes of stakeholders in relation to nano wear of rubber tyres, available evidence in the literature on the different stakeholders' opinions, concerns and values related to the identified risks and any evidence of societal reactions to perceived risk associated with TWP. In addition, the preliminary results from the pre-assessment interviews and workshop were used as a starting point for the concern assessment.

The approach used in this study for the assessment of opinions and concerns was based on a (preliminary) review of scientific and grey literature, focusing on each of the three constituent elements of the concern assessment (i.e., risk perceptions, social concerns and socio-economic impacts), including:

- A review of public opinion surveys and perceptions studies from major survey organisations like the Eurobarometer and on Science Direct;
- Analysis of concerns on the TWP through social science papers, policy briefs from civil society organisations, news articles and blogs on the web, and reports of citizens and multi-stakeholder events such as roundtables, consensus conferences and focus groups;
- A review of socio-economic impact assessments by research institutes, advisory bodies, NGOs and trade organisations.

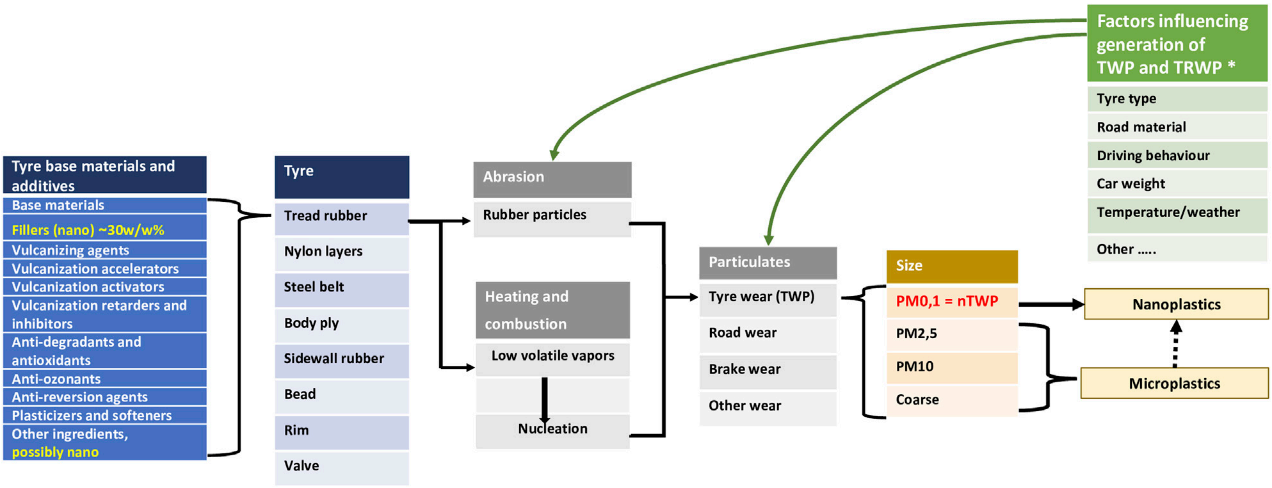

FIGURE 3
Schematic representation of the formation of tyre wear nanoparticles and factors influencing it. * TWP, Tyre Wear Particles; TRWP, Tyre and Road Wear Particles; PM, Particulate Matter.

2.6 Evaluation

In step 4, the results of the risk and concern assessments were communicated in a round table session with stakeholders and experts. Due to COVID-19 this round table was organised as a hybrid event, where most of the stakeholders attended in person and most experts presented and discussed their findings on-line. The evaluation, was operationalised by means of a small questionnaire to the stakeholders, focusing on the step-by-step governance approach, the round-table stakeholders' approach and the focus on nanomaterials.

3 Results

3.1 NRGF step 1—Pre-assessment, framing the issue and raising questions

In the pre-assessment phase stakeholders defined and framed the risk governance problem for the RTC, being the issues of nano-TWP, TRWP and traffic emissions (see Figure 3) and their environmental release to air, soil and water, for which the contribution to fresh waters and the oceans of microplastics should be taken into account as well. Also, the issue of risks of further environmental degradation of micro-into nanoparticles was brought forward. Food, as potential exposure route was mentioned as well to be considered. Furthermore, stakeholders asked for insight in the options for nano-technical innovation to optimize the tyre design.

A schematic representation of the formation of nano-TWP and the influencing factors was drawn (see Figure 3).

A major issue for framing the risk governance problem is the distinction between occupational and environmental exposure, that could possibly lead to different approaches being utilised. Each exposure scenario requires a different level of availability of data and different tools that should be utilised in the next steps of the NRGF for assessing the risks, estimating possible management measures and communicating/monitoring the risks.

3.2 Uncertainties

Different levels of uncertainty exist between different stakeholders. Obviously, these relate to knowledge on tread rubber composition and (nano)particles' release. Some of the societal stakeholders have no idea about their composition nor on potential effects. Still, there are concerns among them about the TWP release, about the routes of exposure to TRWP, about environmental impacts, and especially whether TWP release is a potential nano-problem and whether filters in cars can control exposure. The question on whether the MNMs in or released from tyres could be a (health or environmental) problem is also a concern among manufacturers, although their focus on the release of microplastics is pushing the potential nano-problem more into the background for now. Manufacturers stress that if there is a problem, it is instead TRWP to which humans and the environment are exposed. Both reflect the high need to more thoroughly quantifying the nanoTWP release, to qualify the potential adverse effects and to relate these with other traffic-related exhaust and non-exhaust emissions, as well as with accepted occupational exposure levels and air quality limit values and requirements. It is recognized that there are still large gaps in knowledge relating to these issues.

TABLE 2 Summarized questions as formulated by stakeholders in the pre-assessment phase.

Questions from stakeholders	Operationalized questions
Scientific and technical questions about nano wear of rubber tyres • Release, hazard, effects, prevention, measurement	• What are the risks of nanoparticles (NPs) released during the use of rubber tyres?
Questions about access to, translation, interpretation and validation of the available evidence • Access to data and knowledge, conditions for trust	• How to integrate concern assessment and risk perception, and to contribute to building trust?
Questions about innovation governance • Early warning, holistic approach	• And if there are risks, how could these be controlled?

The issue of trust is also prominent among societal stakeholders, with particular emphasis on the independence of the information provided. For example, the answers as provided by manufacturers, through the Tyre Industry Project (TIP, 2005), should at least be complemented by independent scientific research.

The questions and uncertainties as discussed were summarised for the further RTC activities in three operationalised questions (see Table 2).

3.3 The technical reference document

A summary of the technical reference document (TRD) is available in the Supplementary Material. The full TRD is available at ResearchGate (van Broekhuizen, 2022). However, a nano-specific summary of the document is presented here.

There is little nanospecific information and measurements available in open literature sources. The main focus of tyre wear research and exploring risk management initiatives is on the release of microplastics (van Broekhuizen, 2022), for which an increasing contribution to ambient particulate matter is expected OECD (2020). Although also in this area large data gaps are identified (Andersson-Sköld et al., 2020; Mennekes and Nowack, 2022).

MNMs used in tread rubber are carbon black, amorphous silica and nanoclay (Ullmann 2011; OECD 2020). It is not clear whether new MNMs are actually used, as the exact rubber receipts remain confidential and tyre manufacturers state that most promising innovative MNMs are still in the laboratory phase of development. Ideas for innovative MNMs to further improve tyres' performance are published (Felix and SivaKumar 2014; OECD, 2014; Evonik 2018; INSCX, 2022).

The used MNMs are generally not released from the tyre tread as 'pristine' nanomaterials. In contrast, high stress driving generates a mix of coarse, micro and nanoparticles consisting of tread rubber particles and heating and combustion products, together referred to as TWP (see Figure 3). This TWP readily associates with road wear to form TRWP (Waquier et al., 2020). Mild braking at 90 km/h can generate more than twice as much TRWP as heavy braking at 50 km/h (Beji et al. (2020). It is estimated that the TWP mass makes up approximately 50% of the total TRWP. Nano-TWP only constitute a limited contribution to the total mass (Järlskog et al., 2020). The majority of the TRWP-mass is reported to be in the micrometer range (5–220 μm) (Kreider et al., 2010; Simons 2016; Sommer et al., 2018). Nevertheless, in particle numbers, the release of the smallest nano-sized TRWP fraction (between 10 and 100 nm) contributes up to 92% of the total number of particles in the PM10-fraction (Beji et al., 2020; Emissions Analytics 2022). The average release of non-exhaust (nano) particles numbers per vehicle is estimated to vary around 10^{11} #/km (Dahl et al., 2006; Mathissen et al., 2011). Exposure measurements of a road inspector (43% of his worktime in the car) showed an average exposure (8 h-TWA) of 70.000 #/cm^3, concerning a mix of exhaust-derived (nano)particles and non-exhaust (nano)particles (TRWP) (Wander and Verbist, 2016). For this, the employer established a 'company-OEL' of 60.000 #/cm^3. So far, no nano-specific health or environmental hazards of TRWP have been established. A (non-nano specific) NOAEC of 55 μg/m^3 was derived for coarse TRWP (Kreider et al., 2019).

3.4 Testing the fitness of the NRGF and tools for the real-life rubber tyres case

3.4.1 NRGF step 2–risk assessment

In this step, the selected tools and models (described in Table 1) together with the data collected in the TRD were applied by the group of selected experts (see Figure 2) to assess the risks of nano-TWP. Overall, the experts stated that the main challenge was to differentiate between two potential scopes of assessment: the nano-TWP as released debris, or the used nano-additives in the tyre tread and its release simultaneously with the abrasive wear. Most tools address the latter case, and foresee a case-by-case assessment (i.e., for each different type of nanoparticle applied). None of the tools is designed to address complex mixtures of material debris, while for T(R)WP heterogeneous mixtures of nanoparticles, other fillers, additives and chemicals need to be considered. (Hund-Rinke & Kühnel 2021). Process-generated emissions can be assessed by some tools, but requires information on release rate and limit values of the (nano-)TWP mixture considered as one exposure. I.e. toxicological tests on the T(R)WP is needed similar to how the risk of MNM in sanding dust has been addressed (Saber et al., 2012a, b).

Several tools can be used as well for the Safe by Design (SbD) of tyres to estimate hazard and exposure of workers to nanomaterials. Nevertheless, limitations are similar as in risk assessment because the supporting tools are the same. The safe innovations approach (Soeteman-Hernandez Lya 2019) provides guidance on 'how to do' SbD, but requires improved interaction between innovators and regulatory authorities throughout the whole innovation process. (Suarez-Merino, 2022). In this respect as well the role of other stakeholders should be mentioned (see Section 4).

An LCA approach can support the evaluation of the impacts of tyre use, by quantifying the impacts of nano-TWP release during the use phase, and by obtaining a global and comparative assessment along the full tyre life cycle. This will allow quantifying and balancing impacts of modifications of the tyre composition along the tyre life cycle. Guidelines for performing an LCA, as developed by the RiskGONE project (Igos et al., 2020), have been examined for application in the RTC. However, the amount of data needed to perform such an assessment is very high, and not fully covered by the data collected in the technical reference document. Data are required on material and energy consumption during production, and on the emissions to air, water and soil. Also, the assessment of the health and environmental impacts of nanoforms requires modelling in terms of DALYs (disability-adjusted life years) and affected species, but here again gaps exist with regard to physical-chemical and (eco)toxicological data on the various emitted nanoforms, whereby transformation products must also be taken into account. In this context, an LCA of rubber tyres would require strong commitment and demand of effort, as well as information available (Hund-Rinke & Kühnel 2021).

As such, pre-assessment using the LICARA nanoSCAN is in principle possible for comparing the environmental, economic and societal benefits as well as human health risks with a reference. Data are often available for assessing human health risks in tyre manufacturing, but due to missing precise data regarding emissions and human exposure it is considered to be less suitable for assessing TWP exposures in the use phase.

Data gaps can hinder the use of the SUNDs, SSWD-SSDs and GUIDEnano tools as well, for which health and environmental data such as the PEC, PNEC, DNEL and NOAEL for TWP or TRWP should be available. Relevant data are also missing to apply the SEG4nano tool for aquatic and terrestrial hazards but there are indications that there might be hazard from TRWP due to released substances of unknown identity. Consequently, these tools are considered not to be applicable with the data available (Hund-Rinke & Kühnel 2021).

The NanoRiskCat tool (Hansen et al., 2013) faces the problem of assessing the TWP as *process-generated* nanoparticle mixtures with largely unidentified compositions as well. The tool aims to identify, categorize, rank and communicate any eventual risk associated with the application(s) of a given nanomaterial within the context of a product or application. This complicates the assessment of multi-nanoparticle products, as no mixture assessment is foreseen, and would require a NPs' case-by-case approach for the risk assessment. Also, a general problem occurring is the required dose metric as demanded by the tool (mass-based, number-base, % of . . .) for which complex data conversion would be necessary. Regarding the exposure end-point, NanoRiskCat would categorize NPs in tyres and T(R)WP as matrix embedded and with low direct nano-exposure potential. As such, the tool is just categorizing risks and not applicable for assessment of the potential nano-TWP itself (Hund-Rinke & Kühnel 2021).

The Swiss precautionary matrix for synthetic nanomaterials (FOPH, 2018), operationalising the *precautionary principle* (von Schomberg 2006), allows for dealing with nanomaterials with limited health and environmental data, by applying a worst-case approach in case of data-gaps (see also Box 2). TRWP, as undefined process-generated particles, is not directly suitable for assessment, but using available inputs and assuming low a-cellular reactivity, moderate induction of mediators of inflammation in cellular systems (Kreider et al., 2010) and high biopersistence in the human body and the environment, the Swiss Matrix advises that consumers should take precautions when exposed to TRWP.

The first tier of the staged "screening" MCDA is in principle applicable for rubber tyre design with a benchmark and a limited amount of data. The tool is developed to support further product development by early screening for the benefits of using a specific (nano) material. It examines the possible impact of the life cycle phases of a material on the environment, society and the economy. LCA-related and socio-economic aspects are assessed. The MCDA does not take into account environmental and health risks (exposure x hazard) caused by the material directly, as this tool was developed to be combined with the PERST, which already covers direct risks. The focus of the MCDA test for tyres can be on a single additive (Nanoprene, silica, graphene or CNT) as well as on a mixture of components even including the (synthetic) rubber matrix as long as input information for the mixture as a single composite material according to the criteria of the respective tier are available.

It is possible to use the screening MCDA for tyres to evaluate the environmental and socio-economic impacts of single nanomaterials or even the effects of heterogeneous TWP mixtures (Giese 2022). The tests show that single nano-sized additives nanoprene and premium silica perform as good as the benchmark (a common tyre without any of the new additives) in terms of LCA criteria. Screening MCDA evaluates the use of graphene and CNT in tyre rubber as potentially negative with regard to the environmental impact, mainly because of end-of-life concerns. The first-tier approach limits further nuancing due to the limited number of data and criteria used. Further nuancing would need a higher tier of the MCDA, but inevitably leads to a higher data need.

The prospective early risk screening tool (PERST) is a prototype developed in the NANORIGO project (Gottschalk et al., 2022). It is applicable as a tool within the risk assessment process of real-life generated TWP. It integrates predictive computations for human and environmental risks based on various questions concerning exposure and vulnerability by combining the environmental load of potential pollutants with (eco)toxicological considerations and data. Some product data, life cycle data and estimated release data are needed. PERST was applied to two different tyre brands. Based on the available scientific and public data and databases (especially on carbon black), an early risk screening was carried out and aspects such as material (load) monitoring in economic circulation, in the technosphere, in nature, in bioaccumulation, risk profiles at critical concentrations and risk predictions were evaluated over a long time period (100 years). For both tyre brands we see a middle risk probability score, which is again strongly dominated by the possible deposition of TRWP in sediments, which, assuming non-degradable material and long-lasting deposition, poses risks for all organisms.

As a general remark regarding risk assessment, Jensen (2022) concludes that if exposure levels or hazards are not known or if essential elements for these are missing, there is a high data demand to predict risks. A comprehensive risk assessment should include both direct roadside exposure as well as exposure to the general public (air-pollution dispersion modelling). If exposure fractions can be determined, estimating a relative risk is likely to be possible by linking epidemiological risk data with ambient air-pollution levels (scale of potential effect).

3.4.2 NRGF step 3—concern assessment

The horizon-scan of constituent elements of concern assessment (i.e., risk perceptions, social concerns and socio-economic impacts) reveals that most of these activities are "informal" in that they do not constitute an explicit part of regulatory frameworks (Schuurbiers 2021). This goes especially for the analysis of risk perceptions and social concerns: they often have a "research" character and serve to inform policy more generally. The same goes for the majority of the socio-economic impact assessments, although there are some examples where socio-economic impact assessments are mandated by laws and regulations (the Socio-Economic Analysis of REACH for Substances of Very High Concern (SVHC) being a notable example).

The idea of identifying public perceptions of (nano)TWP by exploring databases of scientific literature and sources such as Eurobarometer (2017) generates only a limited number of publications on rubber tyres in the social sciences and humanities domain, but with no useful information. The main interests seem to concern tyre-road noise and workplace hazards or general worries about impacts of micro- and nanoplastics.

Using news, blogs and reports on the Internet to identify societal concerns shows a predominant focus on the TWP microplastics problem, as well as a broader interest in the scientific research into the toxic effects of 6PPD on Coho salmon. The majority of hits address the problem of end-of-life tyres and the different reuse and recycling possibilities for tyre waste.

Alongside environmental concerns from researchers and NGOs, an online search for "concern" also led to reports on positive expectations from research and industry. Nano-innovation may contribute positively to tyre characteristics such as fuel efficiency and wear resistance, especially by replacing carbon black by silica, although most nano-innovations still seem to be at the lab-phase (OECD 2014). While noting the possibilities of nano-innovations, the OECD (2014) also mentions environmental health and safety as: "*a main and continuous concern for the development of new nanomaterials in tyre production, even for those closest to market*" and a Safe-by-Design approach is advocated.

The OECD (2014) socio-economic impact assessment expects, overall, net benefits of rubber tyre innovation. As fuel impacts dominate life cycle impacts, improved fuel efficiency may lead to net positive effects, although the assessment did indicate that there are uncertainties around the assessment of environmental impacts. There are as well publications on the role of tyres in a circular economy and on cost-benefit analysis. These papers point to general environmental concerns about the use of rubber tyres (and mostly about end-of-life tyre recycling approaches), not to social concerns or specific nano-concerns, (e.g., Araujo-Morera et al., 2021). Even the designation 'stakeholder perspective', as used by Hu et al. (2021) refers to stakeholders in the 'narrow' or traditional sense of the word (i.e., researchers/innovators, producers and policy makers). Campbell-Johnston et al. (2020) specifically call for increased collaboration and multi-stakeholder governance to enable circular approaches in tyre production and recycling. They review the extended producer responsibility system for rubber tyres in the Netherland and state: "The existing EPR (Extended Producer Responsibility) system lacks effective connection and collaboration between tyre producers and recyclers. This inhibits product innovation concerning the application of reclaimed rubber. The EPR system for tyres in the Netherlands could hence be improved by further integrating recyclers, disposers and processors members with the waste management company of the Dutch tyre association. This would reinforce collaboration across the whole value chain and ensure that the EPR system does not just incentivize low-cost recovery options."

Ethical impacts of the use of nanomaterials in rubber tyres have been explored by Malsch et al. (2022) through an ethical impact assessment tool. Authors report possible ethical risks and benefits, through self-assessment of available literature, but a more thorough assessment should be performed for assessing possible ethical impacts from TWP.

Guidelines for assessing social impacts and macro-economic risks and benefits, developed in the RiskGONE project was hampered though by the complexity of the topic of TWP, various uncertainties and data gaps.

Insurers play a specific role within establishing liabilities for health consequences of tyre use and release of TWP (Mullins, 2021). There are a great many questions around where liability might reside even if a clear causal link can be made between the said particles and health injury. The tyre manufactures, the vehicle owners, original equipment manufacturers, road operators and authorities are all part of a configuration of actors operating in this space—all of whom might be perceived to have some responsibility. In that regard, insurers do carry risk related to tyres - but this relates to safety performance. Insurers provide cover for manufacturers risk related to product liability and product recall. If tyres are found to have played a role in an accident because of a fault to the tyre or related to their fitting this can result in insurance claims. Hence, insurance companies do have an interest in tyre performance—but this is solely around the safety issue during the use phase. The issues around the role that nano-particles embedded in tyres play in health-related risks are complex and multifaceted. Traffic-related exposures are diverse and establishing causation and liability within an insurance paradigm is difficult. In terms of the insurance industry as a stakeholder, there is no evidence at present that they share any particular concerns around the release of nano-particles from tyre use. Moreover, it appears that the insurance industry does not believe that it faces any exposure from this type of risk. This may be because the scientific debate around the impact of the release of tyre (nano) particles from wear and tear is still, relatively speaking, in its infancy. Yet, the perception of this risk may change if the focus was set on TWP as micro- and nanoplastics.

3.4.3 NRGF step 4—evaluation

The evaluation of the collected information in the previous steps is complex, especially because it requires combining the "hard" quantitative data of the risk assessment with the "soft" qualitative data of the concern assessment. Due to their complex, contested and inherently qualitative nature, broader ethical and societal considerations do not lend themselves to integration in decision support tools which require accessible, quantifiable, reproducible and more or less uncontested indicators as input (Schuurbiers 2021). As such, a sort of balancing act with the incomparable quantitative and qualitative 'natures' of risk and concern is required, which generates overarching (and politically vulnerable) questions like: "what priorities should be set?", "who does the weighing?", "what's in and what's out?". Essential questions that should lead to input for the risk management in step 5 of the NRGF. Besides emphasizing the need for a deliberative setting for discussing and solving these questions, currently the NRGF does not provide an advice for the preferred methodology (Schuurbiers 2021).

Practically, the RTC did not aim to organise a real-life risk governance activity ending with the NRGF step 5 (and 6) for Risk Management (see Figure 1). Nevertheless, the organization of steps 2 and 3 for risk and concern assessment was very time consuming at a high expert level and, as mentioned, was hampered by the many data gaps, which did not provide useful quantitative risk data for the release of nano-TWP, nor into usable data that could be used to substantiate concern for this. Typically, a risk governance exercise is a collaborative activity of all stakeholders performed by or with close involvement of the risk owner; in this case the tyre industry. The sharp division of tasks between the stakeholder group (step 1 and 4) and the experts (step 2 and 3) was experienced as a missed opportunity. This held especially for the exclusion of the stakeholder group from the expert activities in risk and concern assessment, but on the other hand this would have needed a huge time investment from all of them, and was therefore deemed unfeasible. Indeed, a closer involvement was warranted by the car tyre manufacturers and could have ensured the technical background much faster. As Grieger et al. (2019) indicated it may help prepare and align stakeholder expectations early on if they have realistic estimates of the time, costs and degrees of complexities involved to derive concrete conclusions regarding risks.

4 Discussion

4.1 The pre-assessment

What do the results of this mock-up assessment say about the usability of the NRGF and assessed tools and models? The aim of the exercise was of course not to perform a full risk governance procedure of TWP but rather to explore to what extent the NRGF is or is not helpful to govern complex risks 'in the real world'. One way in which the NRGF did prove helpful is that it renders the salient governance issues in all their complexity: risk governance entails the implementation of risk management options on the basis of both risk *and* concern assessment. This implies that risk governance is by definition a multi-stakeholder process, including producers, researchers (with technical and social expertise), regulators and users. This is why the pre-assessment phase (step 1 in the NRGF) is an essential start-up phase of the risk governance process (Renn et al., 2008). It frames the governance process and determines the topics for deliberation and the results that can be achieved (Renn 2015; IRGC 2017; Grieger et al., 2019). To be able to test the tools and models of the NRGF on a practical level, the RTC had to dive rather deep into the problem along with the stakeholders' group, while avoiding building any illusions that this setting could (or should) solve whatever part of the (nano)TWP problem. This emphasizes the need to thoroughly align the expectations (Grieger et al., 2019). The RTC saw for example wide disparities in (technical) knowledge related to TWP within the stakeholders' group and consequently expectations. The manufacturers and their associations worked already intensively on the issue for decades (OECD 2014), while the others in fact delved into it for the first time and were confronted as well with the trust-question: who to believe?

4.2 Initiating of the RG process

Nevertheless, playing a game cannot be done without reality in the background, and the information gathered about TWP and TRWP, especially the framing of the nano-issue with its information gaps, illustrates the real-life situation clearly (see also van Broekhuizen, 2022)). It also raises questions on '*who should initiate and lead the (nano) risk governance process, aiming at making clear, broadly supported governance agreements?*'. Amongst the many stakeholders there are at least the tyre and rubber manufacturers, the car manufacturers and distributors (developing increasingly heavy vehicles), the road authorities responsible for the maintenance of the roads and regulators while facing climate change deciding to promote (heavier) electric cars which wear out tyres more rapidly. Moreover, of course, there is the single consumer whose driving behaviour, its tyre purchases (e.g., ADAC 2021) and preference of many towards bigger and heavier vehicles contributes to the generation of the TRWP. In fact, there is not one owner of the problem, nor one to solve this extremely broad and multi-faceted health and environment topic that reaches from transport and maximum speed decisions, *via* road design and maintenance issues towards individual behavioural decisions. All of them have a stake in contributing to their part of identified mitigation measures (Verschoor et al., 2016; OECD 2021; ADAC 2021, Supplementary Material) all of which require input and commitment from different stakeholder groups. The question remains whether civil society organizations could take an initiative to start a true risk governance process, as well as on who should take the lead in such an endeavour and how the NRGF can support. According to ISO 21505:2017 risk governance should be run by a manager or a board that can act on behalf of the organization and has decisive power.

4.3 Qualitative and qualitative data

The risk governance process encompasses both quantitative and qualitative data. Ideally, the decision-making process and the choice of control measures are taken on the basis of an integrated judgment incorporating both types of data. In chemical risk assessment (including nanoparticles), the demand for quantifiable results dominates. Quantitative risk data may be either experimental, field data and epidemiological, or predicted by tools. Within the context of risk governance, the word 'tool' usually refers to digital applications, based on a simplified computational model for risk assessment. Often, they embody the promise that risk assessment can also be done by non-experts, for as long they have the right input data. Not only does this drive the demand for quantifiable results; these tools also leave non-experts empty-handed in cases where not all data are readily available. The 'tool-testing'-nature of the rubber tyre case may thus lead to premature conclusions about lacking data and overly complex situations. At the same time, it enabled us to improve the guidance issues on the web-based risk governance platform by improving the explanation of each tool's scope, output and limits, suggesting how to deal with data gaps and uncertainties and to emphasize the need to allow for more flexibility for example through a read across approach, the use of default or worst case/best case values. In addition, there may still be plenty of conventional scientific methods that can be employed to deal with these complex situations.

The demand for quantifiable results means a need for physically measurable outcomes and a well-established reference framework with health limits and environmental quality values. The real-life tyre wear problem with a focus on "nano", shows that this demand encounters major barriers, insufficient hazard and exposure data, a too limited legal reference framework and incomplete nano-specific regulations, such as OELs, air quality guidance values and nano-specific measurement demands (Miller and Wickson, 2015). The sampling of nano-sized TWP and TRWP is more complex than sampling of microscale exhaust and non-exhaust emissions. Therefore, nano-TWP and nano-TRWP in real-life situations has only been investigated to a limited extent. Contrary, hazard assessment of the released process-generated nano-TWP is hampered by a great lack of hazard data. This lack relates to the complex heterogeneous mixture of particulates with different physicochemical characteristics, association behaviour, degradation, ageing and other phenomena, which are not covered well by any data or the tested tools and models. It also has to do with the predominant use of the mass-based measurement approach and regulation (setting mass-based limits) and as such ignores the share of nanoparticles in the risks. There are also uncertainties about acceptable environmental, health and safety levels of nano-sized T(R)WP and ambiguities relating to the interpretation of observations. As a result, many of the tools selected for risk assessments within this NRGF test highlight this lack of data and are hitherto unsuitable for direct use. Table 3 summarizes the main data gaps that have been identified through the case study and their potential severity in hampering the risk governance processes.

This rubber tyres mock-up exercise indicates a poor institutional embedding of the used nano risk governance model and despite the clear step-by-step process, the application can easily create overestimated expectations that an instrumental collection of tools and methods would guide the user to solve the identified problems. In practice, risk governance is a deliberative social process, taking place within the frame of existing rules, regulations and

TABLE 3 Main identified data gaps and their potential severity in hampering the risk governance processes.

Identified data gaps	Importance/Severity
Exposure data	High
Hazard data	Medium
Realistic concentrations	High
Ecotox and occupational scenarios	High
Estimation/Separation of particles types and related concentrations in the TWP and TRWP matrix (nanoparticles from tyre wear, break wear, road wear, exhaust, microplastics, nanoplastics, other types of particles)	High

procedures and with institutions and stakeholders participating with their expertise, interests, values and concerns that may play a role, and should be considered simultaneously in other steps as well. Just imagine the case in which there are real indications of an increase in cancer prevalence of people working and living in the vicinity of highways, and that an association with TWP is suspected. In those cases, actual institutions (environmental and health authorities, research institutes, workers associations, municipalities, industry, political parties, the press) would all engage in a serious societal debate (and possibly in power play) about the problem definition, the assessment of the actual risks and their origins, about who is responsible and liable, et cetera. Such risk governance in practice is steered just as much by logical-scientific rationale as by institutional rules, shifting power balances and perceptions. In this sense, the rubber tyre case study only has a very faint resemblance to a real-life case.

The qualitative nature of the outcomes of concern assessment makes them difficult to combine and weigh against the quantitative outcomes of risk assessment. While integration is essential for risk management and frequently advocated, balanced integration often fails (e.g., Miller and Wickson, 2015; Patenaude et al., 2015). Indeed, an earlier review of existing governance frameworks suggested that despite a long-standing interest in integrating stakeholder concerns in risk governance, agreement on how to implement such accommodating mechanisms has thus far proved elusive (Mullins et al., 2022). This is in part due to the incommensurability of ‘hard’ scientific risk assessment data with ‘soft’ qualitative data from concern assessment (Mullins et al., 2022). This was also the case in this case study. The challenge was to create a more ‘socially robust’ governance process that includes a capacity to anticipate and respond to broader ethical and societal concerns.

4.4 Public concern

Still, attempts to include stakeholders’ societal risk perceptions and concerns and to find out the implications, revealed the mentioned scarcity of rigorous methods and tools for concern assessment, but it was interesting to identify the absence of concerns about the MNMs’ use amongst societal stakeholders, while process-generated nanoparticles (nano-TWP) was a slight concern amongst them (Schuurbiers 2021). Previous stakeholder surveys have also shown low to moderate public concerns in regards to most products with nanomaterials, except when direct contact or intake of MNM was likely (Porcari et al., 2019). Most of these concerns are expressed in scientific publications, and some of these have been picked up by the media and in blogs. Generally, they are not identified specifically as “nano”-concerns. The tyre wear-related microplastics issue and hazardous leaching, safe driving issues and noise disturbance ranked high as concern, including worries about rumours of the use of carbon nanotubes in the rubber tread. Nano-related concerns on liability issues seem not to play role either (Mullins, 2021).

In contrast, in a comparable line as a follow-up on news publications, there are high expectations among all stakeholders about the assumed benefits of the nano-innovations for improving driving safety and fuel economy, showing a positive attitude towards nano-applications.

4.5 Reflection on the seriousness for concern

As a general reflection it can be stated that concern assessment does not offer clear findings, but it suggests ‘hunches’ that:

- there may be a problem with the effect of TRWP that wash into streams on aquatic life
- there are signs that car tyres contribute to microplastics in the oceans
- there may be a problem with the contribution of TWP to ultrafine-dust in the air

But how concerned should we be? How certain do we need to be about the specific causes to warrant preventive measures? What are legitimate sources of evidence for “concern”? When is a concern “in”, and when is it “out”? (This underlines the importance of defining criteria in the pre-assessment phase).

4.6 Applicability of the NRGF

The aim of this study was to test the applicability of the established NRGF and the tools with the mock-up RTC focusing on the possible risks of the released nano-TWP. The format of the generic NRGF used, in particular the pre-assessment phase, proved suitable as guidance for the stakeholder platform to jointly develop, formulate and frame the questions for the intended risk governance process. For the RTC these focused on the effects of release of nano-TWP. The complexity and abundant uncertainties in this area emphasized the need for real-life risk governance to fully integrate concern assessment in the process and not to view this as a separate step besides risk assessment. Hence, the expert assessment of risks and concerns has to be followed up by a process of “sense-making” involving a wider group of stakeholders, where both qualitative and quantitative data are weighed to come to proportionate risk management measures. The dual approach of the RTC, i.e., the mock-up stakeholders’ risk governance activity in the pre-assessment and evaluation phases and the experts’ activities of testing of the tools for risk and concern assessment phases, was complicated and confusing and might have led to too high expectations amongst the involved stakeholders, but it was unavoidable for proper testing the NRGF and the tools.

Although no “real-life” risk governance process was carried out, the applied dual approach with an emphasis on the experts’ input, allowed to identify some major drawbacks in the (in) applicability and/or immaturity of the currently available technical risk assessment tools. The tools were not suited for the real-life complex debris of the released nano-TWP and the data gaps prevented use of most of them. Besides the direct release, physiochemical and hazard data requirement, questions also arise on metrology within the area of regulation, which currently adhere to mass metrics. As indicated in the technical reference document (van Broekhuizen, 2022) the lack of specific legal requirements for measuring and assessing (nano) TWP, may lead to the (possible) health and environmental risks of nano-TWP being overlooked and consequently on not recognizing the urgency for starting a real-life risk governance process on this issue. It points to the importance of the operationalization of the SbD initiatives and possibly as well to the need to consider some form of a precautionary approach.

4.7 A precautionary approach

The overall question, whether the NRGF and its tools may help to guide a nano risk governance process for nano-TWP, and the preceding question, whether such a nano risk governance approach for nano-TWP is needed or desirable, cannot be answered unambiguously. At the same time however, there is enough information about the significant contribution of TWP to the terrestrial microplastics load, making it likely that nanoplastics may contribute as well, with so far unknown effects. Existing knowledge on adverse effects of nanoplastics is at least reason for (scientific) concern that nano-TWP might have effects as well. This brings for this case a discussion about a precautionary approach to the foreground. As von Schomberg (2006) formulated clearly as policy definition for the precautionary principle (Box 2):

BOX 2 Policy definition for the precautionary principle (von Schomberg 2006)

“Where, following an assessment of available scientific information, there are reasonable grounds for concern for the possibility of adverse effects but scientific uncertainty persists, provisional risk management measures based on a broad cost/benefit analysis whereby priority will be given to human health and the environment, necessary to ensure the chosen high level of protection in the Community and proportionate to this level of protection, may be adopted, pending further scientific information for a more comprehensive risk assessment, without having to wait until the reality and seriousness of those adverse effects become fully apparent.”

The various uncertainties identified while compiling the technical reference document, and the large deficiencies in required hazard and release data justify a recommendation to undertake a *systematic review* (EFSA 2010) for the issue of nano-TWP. The focus should be at least on identifying sufficient data for performing assessment on occupational as well as environmental exposure limits, and estimating realistic exposure scenarios and related concentrations for this variable and heterogeneous source. It is possibly as well a vital step in the full risk governance process.

5 Conclusion

Exploring the usability and added value of NRGF for nano-TWP in a mock-up RTC approach was an intensive, time-consuming and knowledge-intensive process. This was the case on both the expert and the stakeholder level, even though it was ‘just’ an activity without the aim of carrying out a real-life risk governance process resulting in the formulation of risk management options for further risk mitigation. The findings illustrate the enormous complexity of operationalizing a governance process for this (nano)product, the rubber tyre, that is used by almost all citizens, all with their own stakes and interests. It is a (nano)product with MNMs going in and other nanoparticles coming out, with insufficient health and environmental hazard and exposure data form risk assessment. However, the results gave important input for the practical operationalisation of the NRGF as a web-based nano risk governance portal, the way the user is guided through the risk governance process and the application of related tools and models. It also emphasised the need for a risk communication platform providing an open and trustful room for dialog among stakeholders.

An appropriate legal reference framework for assessing the risks of the nano-sized TWP is missing and consequently lack of a general public awareness of the potential (but not yet unequivocally determined) risks. In addition, without clear indications of major social concerns specifically related to the nano-TWP. On the other hand, there are concerns over the contribution of TRWP to the environmental microplastics load and effects as well as the tyres' end-of-life, issues that are regularly discussed in public media.

The RTC underlines the importance of a deliberative platform where stakeholders can jointly form an opinion about the economic and social costs and benefits of the application of new technologies (such as the development of new nanomaterials for rubber tyres). The platform should allow a robust deliberative approach to come to a reasoned, collective judgement on the level of risks (related to nanomaterials) that the stakeholders are willing to take for the sake of innovation - one that has formal standing and a real impact on governance decisions. It emphasizes as well that mutual *trust* is an essential element for this deliberation. It is possible to recognize a broad variety of societal forces in terms of stakeholders putting pressure on decisions, through the media, lobby, social protest, stakeholder participation, etc. - but this positioning does not happen in a formal, transparent way. It would help to build trust with the governance approach if that process were more transparent, robust and reasoned: to provide insight into which (whose) societal considerations are actually based on governance decisions.

Existing knowledge on the TWP issue (van Broekhuizen, 2022) illustrates that today's TWP research is mainly mass-based, focused on the identification and characterization of micro- and larger-sized particles. Existing health and environmental measurement conventions and legal requirements for assessing release and exposure limit themselves to a mass-based approach and do not demand for particle number-assessment. As a consequence, the nano-TWP release remains largely poorly investigated. Consequently, it does not readily generate a reason for concern, at least not amongst many societal stakeholders. In a broader sense, the RTC (and other studies) shows that there is a need to perform standard wearing tests on finished products and the possible release of (nano)particles, and not just to limit to the REACH suggested tests on the MNMs used for manufacturing (Nielsen et al., 2021).

So far, the questions as put forward by the stakeholder's group, "whether the fraction of nanoparticles (nanoplastics) generated by road traffic TWP, whether or not associated as TRWP pose a significant environmental or health issue? And if this is the case, how big is this problem? Do nanoplastics, besides the strong increasing attention for microplastics, require an added, specific approach to complement a balanced risk assessment?" cannot be answered unequivocally, although there are clear indications that they are generated.

While the NRGF and its tools and models offer a refreshing and more 'socially robust' perspective on these important governance questions (highlighting the need to combine quantitative and qualitative data), much work remains to be done for such a new governance framework to be practically applicable. Apart from the framework giving clear guidance on issues to be considered, the dominating data gaps relating to heterogenous process-generated and environmentally transformed nano-sized mixtures, largely undefined and variable in composition, lead to the conclusion that the data are insufficient for quantitative assessment and the tools are not directly applicable for assessing risks of nano-TWP. Only tools with a higher generic and prospective character, which can use indications or general indicators, can provide a general indicative answer (such as 'interesting' or 'potential risks'), but generally require more detailed data for better substantiation.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Author contributions

PvB wrote and edited the paper and co-organised the case-study with KLB. AS contributed to the discussion, conclusions and editing. DS was responsible for the input on the concern assessment. PI organised the input from the RiskGONE project. KAJ organised the input from the Gov4Nano project and the input on risk assessment. DK was responsible for input on environmental risk assessment and the communication platform. KLB organised the input from the case study. All authors reviewed and revised the manuscript in its final form.

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Conflict of interest

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fenvs.2022.1045246/full#supplementary-material

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