

## Executive Summary

### *Risk Governance of Nanomaterials: Analysis of Operating Practices of Existing Bodies*

(RiskGONE Deliverable 7.3)

This deliverable provides a comprehensive analysis of existing bodies operating as part of a larger network for the governance of nanomaterials, as a novel innovation. Risk Governance of novel materials at the nanoscale<sup>1</sup> is accompanied by a range of benefits, as well as a range of uncertainties to both human health and the environment.

Risk assessment (RA) and risk management (RM) processes have long been the choices of reference for regulators and other stakeholders involved in managing the emergence of this innovation, but risk governance, including risk perception, risk assessment and risk communication, is now seen as a superior and more holistic approach to the associated risks and benefits of nanomaterials.

In this context, and as part of the RiskGONE EU H2020 funded project charged with co-developing a European Risk Governance Council (RGC), this deliverable aims to provide a meaningful contribution to both the discussion and implementation of better risk governance of nanomaterials in Europe. In the context of RiskGONE, this analysis will provide operational and strategic recommendations that will be used mainly as input for the design, the development and implementation processes of the Risk Governance Council as well as inform the risk governance framework design under WP2 of the project. This contribution identifies best practices of operation, also in view to interact with regulators, public bodies and stakeholders as a means of contributing more widely to governance. It takes into consideration and balances between early warnings, precaution, scientific uncertainty, hazard and RA and RM and communication.

To deliver this contribution, this deliverable develops a range of framing elements for effective risk governance in order to analyse existing governance bodies. Based on this analysis a range of recommendations for reinforcing foreseen decision-making processes not only decision making tools such as software for technical analysis, but the processes to deliberate and decide upon opinions, to be used by the RGC are provided, as well as recommendations for improved risk governance of nanomaterials more broadly. This is with the aim to reinforce the design of the RGC, to base it on successful principles from other similar bodies, to take the positive and useful elements from these bodies and make sure that we are not missing out while trying to build up the Council, how it should work and possibly frame some decision making processes.

## Overview of Analysis

Governing complex socio-technical systems and their corresponding technologies is a fundamentally indirect, contested, and high-stakes process due to the implications that the crafting and implementation of governing authorities have upon society, the economy, and the environment (Renn 2017)<sup>2</sup>. Ideal conceptualisations of socio-technical systems have been developed by Smith and Stirling (2007)<sup>3</sup>, among others, where governance is framed as (a) the management of complex, incomplete, and potentially contradictory information and incentives, as well as (b) an inherently socio-political activity.

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<sup>1</sup> 1 nm – 100 nm Commission Recommendation on the definition of nanomaterial [Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0696&from=EN>] although nanomaterials are said to technically exist outside of this range.

<sup>2</sup> Renn, O. (2017). Risk governance: coping with uncertainty in a complex world. Routledge.

<sup>3</sup> Smith, A. and Stirling, A., 2007. Moving outside or inside? Objectification and reflexivity in the governance of socio-technical systems. *Journal of Environmental Policy & Planning*, 9(3-4), pp.351-373.

No single ideal permutation of system governance exists that can be applied to all systems or activities, with various actors seeking to influence the development and direction of governing authority in a manner that best addresses their unique interests and perceived needs over a certain period of time (Merad & Trump 2020).

A critical challenge within any socio-technical governing activity is the co-development of shared technical knowledge – a task made all the more difficult by the fundamentally uncertain nature within uncertain and complex systems such as emerging technologies.

Engineered nanomaterials, for example, have novel physiochemical properties whose hazard profile is uncertain and whose consequences are unclear, rendering it impossible to rely solely upon many existing tools of risk assessment to quantitatively and objectively analyse human and environmental health risk (Trump et al., 2018; Linkov et al., 2013<sup>4</sup>). Theoretically, subject matter experts can fill the void created by such physiochemical uncertainty by indicating (a) likely risk concerns that may arise, and (b) opportunities to prevent, mitigate, avoid, or transfer such risks, and effectively balance the benefits of innovation against unacceptable hazards. In practice, however, such knowledge transfer is only one element of broader technology governance, with many stakeholders emphasizing the importance of economic, environmental, and social implications that may not be reflected in typical technology risk discussion.

As such, the process of technology governance within many countries has evolved into something of a 'give-and-take', with subject-matter experts and a variety of involved stakeholders sharing information regarding technology risks, benefits, and broader implications that then influence the nature and mechanisms of technology governance (Aven & Renn 2010). In turn, a collaborative and collegial governing process can help all parties address the broader picture and implications of technology governance in a manner that is procedurally valid and socially responsive<sup>5</sup>. The analysis therefore took the current state of both existence research literature and current implementation of risk governance frameworks as a departure point for the analysis. Based on a common understanding of these two elements, contributors identified and utilised key framing elements for the development of effective risk governance as parameters for analysis and consolidation of findings to provide conclusions and recommendations. The following conclusions and recommendations are therefore organised by these parameters as pillars of the forthcoming framework, with current practices revealing the implementation gap and how state-of-the-art understanding of risk governance can be better implemented through the RGC. The following conclusions and recommendations are therefore organised by: organisation and effective risk governance; Independence and Trustworthiness; Openness and Transparency; Scientific Robustness; and Integration of Prevention, Precaution, Wellbeing and Sustainability.

## Conclusions and Recommendations

This analysis of existing governance bodies and their operating practises aims to help establish a key entity to contribute to and support the governance of nanomaterials in Europe, and more broadly as part of the global governance system for nanomaterials, taking a leading role in nanomaterial risk governance that has to date remained unfulfilled. Thus, it must cover all levels of governance from strategic to

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<sup>4</sup> Linkov, I., Bates, M. E., Trump, B. D., Seager, T. P., Chappell, M. A., & Keisler, J. M. (2013). For nanotechnology decisions, use decision analysis. *Nano Today*, 8(1), 5-10.

<sup>5</sup> Latour, B., 2014. *Give me a laboratory and I will raise the world* (pp. 141-70). Paris.

operational, that characterise a governance system, requiring framing elements through which to conduct the analysis at these different organisational levels.

Our analysis has shown that there is a range of complex governance dynamics across the different entities analysed, all providing insights and lessons to learn from in establishing the RGC as part of an improved nanomaterial governance system. The following recommendations will therefore aim to highlight the key learnings and recommendations from this analysis to be used when considering governance of nanomaterials, and specifically risk governance of nanomaterials.

### ***Organisation and Effective Governance***

**Risk governance for emerging technologies:** Keeping pace with emerging issues and innovations is another common challenge for the bodies analysed. It is essential to acknowledge that nanotechnology is a dynamic area of innovation that evolves throughout time. Consequently, the initially accorded framework, values and guiding principles should also be able to target corrections and refinement or alterations as research evolves. The operational practices of the forthcoming RGC should therefore include a level of flexibility that allows the organisation to keep pace with the needs of nanomaterial risk governance. Regardless of form, maintaining a consistent set of overarching values to frame the evolution of the RGC will be crucial to characterise any operational changes and ensuring the organisation fulfils its purpose.

**Governance for Social and Environmental Concerns:** These values must ensure consistent consideration of socio-ecological concerns regarding risks from the presence of nanomaterials are consistent across all product areas, especially where there is risk of direct exposure in products such as food or food contact materials, cosmetics and other health related products. A clear set of “Rules of Procedure” for decision making processes should be laid out in order to clearly commit and demonstrate how the RGC plans to ensure fair representation of all interested parties within the risk governance Council.

**Organisation and Operations:** Governing operations across a range of complex topics is a clear challenge for all governance bodies identified, with several different approaches adopted. The organisational set-up of the OECD using numerous specific sub-committees in order to target complex sub-topics in the risk governance of nanomaterials appears to be an effective mean to operationalising values and terms of references of the organisation as a whole in specific socio-technical contexts based on the corresponding topic at hand. Other organisations have established less clear thematic areas, meaning there is often overlapping or competing approaches to an issue or substance. This analysis recommends a similar organisational approach to the OECD that sets clear topics areas based on the perceived topics or issues to be addressed by the RGC, underpinned by appropriate review and verification procedures.

**Measuring Effective Governance:** Greater consideration must be given to what effective governance means, as opposed to efficiency orientated governance that can prevail. Effective risk governance must go beyond a quantitative analysis of outputs, and focus on the influence of the organisation on the governance of risks, namely the prevention of risks to humans and the wider environment, and ensuring substances are used in a limited and safe manner where necessary (Linkov et al., 2018)<sup>6</sup>. The model for a sustainable RGC should therefore not rely upon targets for risk analysis and decision-making alone, but a broader range of governance indicators which represent the RGC’s impact on risk governance of

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<sup>6</sup> Linkov, I., Trump, B. D., Anklam, E., Berube, D., Boisseau, P., Cummings, C., ... & Jensen, K. A. (2018). Comparative, collaborative, and integrative risk governance for emerging technologies. *Environment Systems and Decisions*, 38(2), 170-176.

nanomaterials in Europe. The operating practices of the RGC should prioritise quality over quantity concerning formal opinions or recommendations relating to nanomaterials, supported by a framework that sufficiently balances efficiency with the fundamental need for robust scrutiny, supported by protocols that suitably frame the risk assessment process.

**Review:** Additionally, regular reviews take place across some organisations to continue to guarantee a high-quality output. Such safeguards are recommended for the RGC. Moreover, an anticipatory approach to risk governance capacity is recommended to keep pace with the challenges of increasing innovation in the NM space. Effective Governance and Risk Governance for the RGC may involve some level of prioritisation of how to most efficiently address various uncertainties and different types of risks posed by different existing and emerging substances.

**Resource Allocation:** Consideration of how resources are distributed on this basis could be crucial. There is a need to consider whether to continue with the current approach that invests great resources where the most uncertainty exists, or validate the low-hanging substances of the nano world and consider higher-risk substances on the basis of uncertainty alongside data. For example, in some cases resources intensive analyses may be better implemented where less uncertainty for a substance exists, and therefore the opportunity to provide clear guidance on safe and unsafe application is greater.

**Risk Governance Processes:** There may also be a need to create lighter processes in the pre-assessment phase that enable the RGC to provide clear opinions even in light of a high degree of uncertainty and risk. Such instances may therefore require a greater deal of research and development before a clear opinion can be offered. There may also be a roadmap developed for reaching a level of definition that allows an opinion to be given, which could include a level of minimum required data.

When developing the risk governance framework for the RGC and the subsequent processes that the RGC will carry out, it is important to evaluate how these processes and obligations will impact the freedom for the organisation to fulfil commitments to openness and transparency. This also applies to internal procedures such as internal review and management procedures carried out by responsible entities within the organisation, or alternatively by external parties. Legitimacy through independence and trust in the governance framework and corresponding processes is crucial for impact.

### ***Independence and Trustworthiness***

ECHA's RAC, EFSA as well as Scientific Committee on Consumer Safety (SCCS) Rules of Procedure specify independence and involve demonstrating that the interests in the work and background of committee members, advisers and other experts are independent from external influence. Although zero susceptibility to external influence cannot be fully guaranteed, it does impose obligations for external experts or consultants to withdraw from conflictual activities.

These processes coupled with concerns for regulatory capture already expressed, establish a firm basis for creating an operational framework that separates the decision-making process from purely economic interests in order to maintain and fully implement an independent assessment of a chemical or nanomaterial, which in turn impacts the perceived associated risks. Openness and transparency can help visibly demonstrate independence and reinforce legitimacy as well as trust in the RGC.

### ***Openness and Transparency***

A robust policy for independent procedure including decision-making must be established and underpinned by appropriate safeguards and verification procedures for the RGC to create and maintain enough trust and legitimacy in its contribution to nanomaterial risk governance. Nevertheless, these

procedures must be based upon and favourable to scientifically robust and transparent processes that inform the various foreseen outputs of the RGC.

Regarding transparency and the disclosure of essential information, the RGC must establish a more suitable set of rules that constitute an improvement to existing intellectual property regimes that better support openness and transparency.

For this to be implemented, this may have to be accompanied by the required regulatory and procedural obligations in order to force industry stakeholders to agree to such disclosures. A clear mandate from the EU institutions to mandate or incentivise these disclosures may therefore be warranted.

### ***Scientific Robustness***

SCCS give scientific advice to the Commission based on mandates from DG GROW. The committee provides risk assessment of nanomaterial according to Guidance on the Safety Assessment of Nanomaterials in Cosmetics SCCS/1611/19. The opinions of the Scientific Committee present the views of the independent scientists who are members of the committee. These opinions are published by the European Commission.

EFSA also develops its own approaches to meet the specific needs of our EU food safety remit. It can be said that socio-political considerations, including risk perception, are seemingly external to EFSA decision making processes. Greater inclusion of these considerations concerning risk governance for nanomaterials in areas of particular concern could be a means to focusing operational areas for the RGC.

Where particular groups or entities within the RGC are given power to provide scientific input or opinion on a topic if that is to be the case, even when from external organisations, **serious attention must be given to how authoritative groups are held responsible when providing technical opinions.**

In terms of organising a range of topics and activities, **this analysis recommends that an independent agenda that focuses on key socio-technical issues (e.g. scientific gaps).** These recommendations **will be key to ensuring a clear and robust work programme is developed** to address all crucial issues to ensure scientific robustness is not undermined by competing agendas in the field of nanomaterials.

### ***Integration of Prevention, Precaution, Wellbeing and Sustainability***

As already stated, the RGC must ensure consistent considerations of risks to humans and the wider environment, and safeguard that substances are used in a limited and safe manner where necessary. The model for a sustainable risk governance council should therefore not rely upon targets for risk analysis and decision-making alone, but a broader range of governance activities which represent the foreseen RGC's impact on risk governance in Europe.

Like the approach of the IRGC, the governance and operations of the RGC should take a holistic approach to addressing risk directly, and by developing outputs based on facts beyond scientific analysis of a substance in isolation.

## **RGC Risk Governance Recommendations**

1. The RGC must establish and define overarching values in the priority areas identified (Governance and Effective Risk Governance; Independence and Trustworthiness; Openness and Transparency; Scientific Robustness; Prevention, Precaution, Wellbeing and Sustainability) that directly influence the implementation of the RGC's mission;
2. The RGC risk governance framework must be future-proof and agile to keep pace with nanomaterial innovations and evolving regulatory needs;
3. The RGC risk governance framework must clearly commit and establish procedures that demonstrate how the RGC plans to ensure fair representation of all interested parties within the risk governance framework;
4. RGC decision making procedures must enable the RGC to take into account considerations beyond substance characterisation to include realistic use-phase considerations that accurately reflect the risks and uncertainties of nanomaterial use where concentrations encountered may be higher;
5. The RGC risk governance framework should aim to enable the RGC to provide an overarching opinion across all substances rather than limited to certain areas of application to account for the range of exposure pathways possible in realistic conditions;
6. The RGC Risk Governance Framework should also establish a clear mandate and set of topics areas based on the perceived crucial issues to be addressed by the RGC, underpinned by appropriate review and verification procedures;
7. In establishing the RGC risk governance framework, the concept of effective risk governance must go beyond quantitative analysis of outputs, and strive for the prevention of risks to humans and the wider environment, and ensuring substances are used in a limited and safe manner where necessary, as a means to effective risk governance contributions;
8. The operating practices of the RGC should prioritise quality over quantity concerning formal opinions or recommendations relating to nanomaterials. This should be supported by a framework that sufficiently balances efficiency with the fundamental need for robust scrutiny, supported by protocols that suitably frame the risk assessment process;
9. The RGC must take a holistic approach to addressing risk directly, and by developing outputs based on facts and conditions beyond scientific analysis of a substance in isolation.
10. The RGC must establish a more suitable set of rules that constitute an improvement to existing intellectual property regimes that better support openness and transparency;