SCIENCE-BASED RISK GOVERNANCE
OF NANO-TECHNOLOGY

RISK GONE

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

DELIVERABLE 7.3

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Abstract

The aim of this deliverable is to provide a comprehensive analysis of existing bodies operating as part of a larger framework for the governance of innovations, namely nanomaterials. Governance of emerging technologies such as nanomaterials are accompanied by a range of benefits, as well as a range of uncertainties and risks to both human health and the environment.

Risk assessment has long been the tool of choice for regulators and other stakeholders involved in the managing the emergence of this innovation, but risk governance, including risk perception, risk analysis, risk management and 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 H2020 funded project charged with co-developing a European risk Governance Council (RGC), this deliverable will aim 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 will provide operational and strategic recommendations into the development of the risk governance framework under WP2. This contribution best practices to interact with regulators, public bodies and stakeholders as a means of contributing more widely to governance that takes into consideration and balances between early warnings, precaution, scientific uncertainty, hazard and risk assessment and risk management and communication.

To deliver this contribution, this deliverable will develop a range of framing elements for effective risk governance to analyse existing governance bodies to provide a range of recommendations for reinforcing foreseen decision-making tools to be used by the RGC, as well as recommendations for improved risk governance of nanomaterials more broadly.

The analysis of existing operating practices provided a range of insights and recommendations across the priority areas identified within section 3 of the deliverable, with a range of conclusions and ten clear recommendations for the RGC operating practices and the broader Risk Governance framework to considered for adoption by the RGC.

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1. Introduction

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). Ideal conceptualisations of socio-technical systems have been developed by Smith and Stirling (2007)[1] , 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. 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 even more difficult by the fundamentally uncertain nature within uncertain or complex systems as with 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[2]). 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[3]. Fisher *et. al* defined midstream modulation of technology, a process in which scientists and engineers, bring societal considerations to bear on their work[4], just one example of how governance systems can make

[1] 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.

[2] 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.

[3] Latour, B., 2014. *Give me a laboratory and I will raise the world* (pp. 141-70). Paris.

[4] Fisher, E., Mahajan, R.L. and Mitcham, C., 2006. Midstream modulation of technology: governance from within. *Bulletin of Science, Technology & Society*, *26*(6), pp.485-496.

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space (in the midstream R&D and implementation phase) for the introduction of concerns typically considered external to particular elements of a socio-technical system.

It is in the establishment of a suitable governance system, that the channels for these exchanges or modulations, and the processes which they impact are both formed. This process therefore has impact in how risk as one sub-topic is governed, with risk governance defined as the application of governance principles to the identification, assessment, management and communication of risks[5]. The relationship between the overall approach to governance and how risks are treated is clearly demonstrated in this definition, with this analysis aiming to analyse the existing governance operating practices of organisations, including those directly linked to risk, in order to develop a set of recommendations for how the foreseen Risk Governance Council (RGC) should contribute to the governance of nanomaterials overall.

It is therefore important for our methodology to provide an approach of how to appropriately analyse the current nanomaterial governance framework, identifying the key organisations and operating practices to build upon and compliment upon the establishment of the RGC. The conclusions and recommendations will feed into the work of the three NMBP-13 projects RiskGONE, NanoRigo, and Gov4Nano charged with establishing the RGC, supported by the European Commission.

2. Methodology

Summary

In order to help establish a valuable entity to contribute to and support the governance of nanomaterials in Europe, and more broadly as part of the global governance system for nanomaterials, WP7 partners have established a rigorous but also practical methodology for performing the analysis of the existing bodies in terms of their operating practices, with the aim to extract valuable information that will be useful for the RGC development activities in WP2 and WP7.

This analysis covers all levels of governance, from strategic to operational, that characterise a governance system, requiring framing elements through which to conduct the analysis at these different organisational levels.

Four distinctive steps have been followed to implement the methodology:

- *Establishment of preliminary framing elements of RGC creation, management and work delivery of relevance to operating practices, which included explicit values and terms of reference to be elaborated for the RGC.*
- *Identification of relevant bodies for analysis of operating practices for consideration of application to RGC, based on the framing elements of Step 1*
- *Analysis of identified framing elements of shortlisted bodies, based on the framing elements of Step 1.*
- *Drafting, writing, review and delivery of deliverable report, based on the results of Steps 1-3.*

In terms of RiskGone WP7 partner participation, several partners drafted and analysed the framing elements of the RGC, in an effort to ensure harmonised approaches between WPs 2&7, and ultimately guide identification, analysis and reflection within Deliverable 7.3 more clearly. Further on, a long list

[5] https://irgc.org/risk-governance/what-is-risk-governance/

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of relevant bodies for potential analysis has been identified. The list has been discussed and refined further by WP7 partners, for the creation of the final shortlist, and the selection of the bodies to be analysed.

Each involved partner contributed with the analysis of at least one existing body, based on the individual framing elements for consideration of integration into the design of the RGC, as identified in Step 1. A deep and concise analysis of the collected information has been performed for the extraction of significant recommendations for establishing the operating practices of the RGC, as part of the broader creation of the RGC's operating Framework. The collected information has been drafted, reviewed and delivered in the form of the present deliverable report.

Detailed Overview

The first step in our analysis is to establish preliminary framing elements of RGC creation, management and work delivery of relevance to operating practices which includes explicit values and terms of reference to be elaborated for the RGC. This section will therefore provide a non-exhaustive list of key framing elements for our analysis of operating practices.

To inform this analysis at the strategic level, this analysis identifies several high-level ambitions and ideals based on the motivations for the establishment of the RGC. Additionally, the desired approach of the organisation to risk and to the governance of nanomaterials which could possibly be adopted across all three NMBP-13 projects mentioned.

At the operational level, this deliverable analyses operating practices defined as a set of actions that apply a set of ideas, methods and approaches, as defined by the primary functions of an organisation. In this process it is therefore important to consider what the primary function of an organisation is, and what implications this function has for the set of recommendations resulting from this analysis. At this operational level, one objective of the analysis is to help establish approaches and techniques to reinforce the decision-making tools of the RGC and facilitate risk communication to stakeholders which will inform numerous conclusions and recommendations, alongside more strategic recommendations.

Based on the established framing elements as both a target set of explicit values and operating practices; and a lens through which to identify existing risk governance bodies that may hold value both in best practices and lessons learned regarding how to approach risk governance for nanotechnologies. Moreover, the framing elements will be used as a lens to analyse the suitability and strength of existing operating practices.

This lens acts as the frame through which the most prominent and influential organisations operating in the current nanomaterial risk governance framework for nanomaterials have been analysed. The current understanding of this framework is based upon observations and identified needs regarding risk governance of nanomaterials, and includes proposals for RGC creation, management and work delivery of relevance to operating practices in mind in order to be relevant and practical, elements which may include explicit values and terms of reference to be elaborated upon by the RGC.

The lens is operationalised as a paradigm through which to conduct our qualitative content analysis[6] to identify existing risk governance bodies that may hold value both in best practices and lessons

[6] Elo, S. and Kyngäs, H., 2008. The qualitative content analysis process. *Journal of advanced nursing*, *62*(1), pp.107-115.

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learned regarding how to approach risk governance for nanotechnologies. Moreover, the framing elements are used to analyse the suitability and strength of existing operating practices, that in turn are the basis of this deliverable's conclusions and recommendations.

For the process of content analysis there are several key concepts required to ensure value is reaped from the process itself[7]. It is important that the material selected is the most relevant available, therefore the analysis team conducted this analysis on the basis of all available key documentation that represents overarching operational practices, as well as those specific to the topic of risk governance and/or nanomaterials.

Although an initial set of framing elements acts as basic parameter for analysis, the analysis results in the identification of themes or categories of analysis derived from the available content under review. All the content under review is also only published and communicated by the organisational body concerned in order to maintain reliability and validity of the content under analysis. The subsequent conclusions and recommendations highlight the key insights across each of the framing elements, using them to formulate concrete recommendations for establishing the operating practices of the RGC, as part of the broader creation of the RGC's operating Framework.

Limitations

A major identified limitation of the performed methodology is that for each analysed organisation, within the scope of this activity of WP7, the information listed in this report is provisional and is based on the descriptions of work, structure and information freely accessible on the web. Whether the identified values, inputs and outputs, styles of governance, types of governance, operational practices and relevant information reflect the reality and how they are translated from the theory to practice, remains an open question. This could be addressed in further research into the actual operations and outputs of an organisation with reflection upon this analysis.

3. Identifying Risk Governance Priorities

With the aim of developing recommendations of relevant practices for adoption or adaptation by the RGC to interact with stakeholders (e.g. regulators, public bodies, academia, industry, etc.) it is key therefore to align the framing elements of this analysis with the aims and objectives of the foreseen RGC. This will also enable the RGC to contribute more widely to risk governance, most notably by taking into consideration and balancing elements such as early warnings, precaution, scientific uncertainty, hazard, risk perception, risk assessment, risk management and communication.

Considering this, **risk prevention and precaution** should frame this analysis in order to maximise the efficacy of governance with respect to supporting overarching sustainability considerations that focus on ecological, economical, ethical and social aspects for preventing harm to human health and the environment. In order to achieve this, it has been deemed important to analyse operating practices of organisations from a **global and pan-European** perspective to appropriately understand and take into account the complex system in which nanomaterials are developed. How operating practices take

[7] Mayring, P., 2004. Qualitative content analysis. *A companion to qualitative research*, *1*, pp.159-176.

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these dynamics into account is important in their implementation and efficacy, but this comes with substantial demands in terms of resources and capacity.

In this regard, the RGC once established aims to be self-sustaining both financially and scientifically, in terms of resource capacity and knowledge respectively. It can therefore be assumed that **independence** is a key framing element for our analysis, in that operating practices that support and demonstrate greater independence both economically and scientifically are preferred.

However, it will be important to identify the optimal level of independence and separation from existing institutions and regulatory practices when developing the RGC model with corresponding operational processes. Fundamentally, in all cases, scientific independence and legitimacy is essential.

The RGC is also foreseen to be more multi-disciplinary than organisations that currently undertake elements of nanomaterial risk governance.

Openness and transparency are both values that support a more multi-disciplinary approach and would need to be supported by operating practices that allow for external stakeholders to be as involved as possible, potentially beyond what is already in place. Moreover, in support of this **accessibility** of information for transparency, accessibility of inputs and outputs will also be important in order ensure a wide range of stakeholders are involved.

These elements also apply to digital solutions now increasingly in the field of nanomaterials, such as the cloud-based risk governance framework and set of tools to be developed under RiskGone. Given the potential range of tasks for the RGC to provide support and expert opinions on the EU oversight and policy-making decisions around nanomaterials through several potentially technical tasks, it is important to define how these technical topics are approached.

These potential tasks include:

- *Review the scientific data for* nanomaterials*;*
- *Production of science-based expert opinions about specific RG aspects upon the request of the European Commission;*
- *Review and integration of the Risk Governance Cloud Platform with future developments;*
- *Provide guidance and advice on the development of TGs and SOPs.*

With the aim of carrying out these tasks effectively, a key framing element for our analysis must therefore **scientific robustness** often termed as a ***'sound scientific basis'*** in combination with robust socio-economic and ecological protocols balancing the key elements that the RGC must take into consideration. Acceptability and reliability of the approaches adopted are also key. In addition to this, **efficiency** is important for the sustainability of any organisation, but this should be approached with priority given to **effectiveness** of risk governance across a broad range of criteria.

Sustainability in a holistic sense should also be a framing element when analysing and assessing the existing operating practices currently in place within existing bodies identified in the following section.

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The next section outlines the existing entities involved in the risk governance of nanomaterials, namely the OECD, IRGC, ECHA and associated sub-organisations, as well as EFSA, based on identified priorities as framing elements for the analysis:

- *Governance and Effective Risk Governance*
- *Independence and Trustworthiness*
- *Openness and Transparency*
- *Scientific Robustness*
- *Prevention, Precaution, Wellbeing and Sustainability*

4. Analysis of Existing Operating Practices

4.1 Governance and Effective Risk Governance

The OECD largely acts as a forum for exchange on approaches taken by member countries, with overarching focus on Economic Cooperation and Development, as opposed to the governance of nanomaterials broadly. However, given the organisation's role in sharing approaches and supporting the mutual acceptance of data across member countries, their work can have great impact on governance throughout member countries.

In terms of its operations, the topics and projects that the IRGC decides to take into consideration and provide recommendations on, are analysed by following a specific process as general guidelines that place less emphasis on efficiency and more on themes like good governance and risk:

- *Identifying potential risk issues at the earliest possible stage;*
- *Understanding the issue and the associated risks as well as the institutions and risk governance structures and processes that are currently in place for assessing and managing the risks;*
- *Identifying governance gaps which appear to hinder the efficacy of the existing risk governance structures and processes;*
- *Making recommendations for overcoming these gaps.*

These descriptions show how the IRGC perceives the importance of risk (as a concept) and its inclusion in a systematic analysis, regardless of the sector under analysis.

European organisations including EFSA and ECHA are largely governed top-down by an Executive team or director, supported by a dedicated Management Board. These parts of the organisations largely focus on efficient and effective operations of each organisation, guided by key values and terms of reference. These organisations are fundamentally EU agencies, and therefore have direct impact on EU level governance of technologies including nanomaterials.

On the topic of nanomaterials, ECHA works in close collaboration with Member State competent authorities, the European Commission, stakeholders and international organisations such as the OECD which helps establish a network of trust at EU level and beyond, but its positive impact requires further engagement with stakeholders involved. These stakeholder groups engage and observe ECHA

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processes and meetings, for which ECHA has general approach on their admission and involvement but is often contingent upon the need to work efficiently.

For the NMEG, stakeholder groups include experts from EU Member State Competent Authorities (MSCAs), the EU Commission and relevant Agencies, ECHA and eligible Accredited Stakeholder Organisations (ASOs), with Nominations for participation must be requested through the members of CARACAL. In contrast to ECHA on the other hand, NMEG is an informal ECHA expert group, independent from any of ECHA Committees or any other existing group.

In contrast, efficiency is a key value of ECHA as an organisation in that many of the justifications regarding various operational practices are underpinned by the strongly related goal-orientation, including the need to use public financial resources efficiently and respecting the deadlines and timeframes that the organisation is committed to. It must be noted that ECHA provides the institutional reversal of historic approaches to chemicals management, requiring industry to provide data (evidence) which was previously collected by public authorities, and addresses more than 100,000 chemicals on the market. Efficiency is therefore of prime importance to its management.

These patterns in operational discourse reflect ECHA's role as a chemical regulation organisation geared towards efficient implementation, rather than that of an organisation with the mandate to question. Both its commitment to wellbeing and its terms of reference acknowledge its responsibility as the leading chemicals regulatory authority in Europe.

At a working level, ECHA is responsible for numerous processes, no more important than the authorisation process which effectively enables a substance to be legally registered under REACH and used commercially in the EU single market. At the management level, ECHA detail processes relating to management and administration that are constructed in a way that aligns with the Mission and Values of the organisation, these include Management of the Relations with ECHA Stakeholders, Integrated Planning, Monitoring and Reporting and the External communications strategy among others. **The way in which ECHA uses its values as a tool for shaping and characterising its management practices is an important example for the RGC to follow.**

Relative to the various regulatory obligations of ECHA committees, specific rules of procedure exist for the appointment of rapporteurs, opinion development, agreement seeking procedures, accordance checks. For the working procedures for the opinion development under REACH Application for Authorisation there exists a number of required steps for publications of an opinion, which then acts as a recommendation or proposal for agreement. However, in order to provide the required number of opinions, the Committee does not require plenaries for a formal opinion to scrutinise the proposed opinions prior to adoption/approval. **This represents the prioritisation of efficiency and fulfilment of obligations in relation to the REACH framework, which in turn undermines its efficacy as a body for governing risks associated with substances. The capacity to deliver upon the mandate assigned to the RGC must therefore consider the approach and relative workload placed upon the RGC, and how this impacts the ability for the council to provide robust opinions with scope for sufficient scrutiny by all stakeholders.** This will all be dependent on the scope and depth to which the RGC will analyse various substances or groups of substances, or even more broadly how the RGC will analyse or provide opinion on particular issues for governing nanomaterials.

In contrast, restrictions enter a much lengthier process for the approval of corresponding requests, with decisions only made based on plenary agreement. This demonstrates an inherent bias codified

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within the respective working procedures that provides an easier route to substance approval in comparison to restriction.

Receiving its mandate from the Directorate-General for Growth (DG GROW) the SCCS governs its own scientific evaluations. For SCCS Opinions to be approved, the SCCS requires plenary scrutiny of a formal opinion prior to adoption, approval or disapproval, typically following an assessment period of 6 months, but this varies according to the quality of the dossier (i.e. if the industry provided complete data and all required tests following the SCCS Notes of Guidance).

The SCCS has plenary meeting twice a year where all finalised opinions are again discussed and approved prior adaptation. In the form of a clear recommendation, nanomaterials analysed are deemed under certain conditions either safe or in the presence of genotoxicity or reproductive toxicity, unsafe and subsequently a recommendation is given. In the risk characterisation the SCCS also set limits as a margin of safety until which point the test substance is considered safe, which are far lower than the maximum level of concentrations deemed safe. Risk characterisation is followed by risk management and risk communication, which are not in the remit of the SCCS, but of the European Commission. The SCCS is therefore effectively governed in order to provide the outputs expected of the organisation.

However, in terms of governing risk of certain materials, there are many challenges as in establishing margins of safety for example the SCCS only considers nanomaterial in cosmetics and this does not cover other sectors and possible usage conditions given the persistent issues with nanomaterial exposure and fate in the environment. Moreover, the margins of safety are developed to combat but also in the great presence of uncertainty given the lack of data available to support the analysis, an issue that shows the importance of an effective but also harmonious governance framework across different agencies that enables sharing data, agreement of methods and opinions framed by holistic risk governance.

Effective risk governance of nanomaterials under the RGC must take into account these considerations beyond testing and substance characterisation to include realistic use-phase considerations that better reflect the risks and uncertainties of nanomaterial use where concentrations encountered may be higher. Moreover, to be truly effective the RGC should aim 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.

This bias towards authorisation should also be avoided by the RGC in its own operating practices, through a Risk Governance Framework (RGF) that favours a risk prevention and precautionary approach to providing opinion or recommending that substances be allowed on the market.

One challenge faced by ECHA's RAC, is the steadily increasing workload and demand for its oversight in light of greater attention on the need to assess risks related to chemicals including nanomaterials. Regular reviews take place for RAC to continue to guarantee a high-quality of output, such safeguards are recommended for the RGC. Moreover, an anticipatory approach regarding capacity and resources is recommended to keep face with the challenges of increasing innovation in the nanomaterial space.

This may involve some level of prioritisation and consideration of how fundamentally to enable the most-effective form of risk governance given the risks and uncertainties associated with different products. Consideration of how resources are allocated across different substances based on these variables. For example, questioning how resources for intensive analyses are best applied when less

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uncertainty exists, and therefore where the opportunity to provide clear science-based guidance on safe and unsafe application is greater, as opposed to where great uncertainty exists and resources are best used to supporting precautionary recommendations

There may also be a decision to create lighter processes in the pre-assessment phase that enable the RGC to provide clear opinions on a high degree of uncertainty and the perceived risks that therefore requires a greater deal of research and development before a positive opinion can be considered.

These are hypothetical circumstances that demonstrate the need to prioritise issues and how decisions are made coherently with capacity. However, this may be a challenge in the early phases of RGC development.

It will also be important to ensure that the RGC is not only effective upon creation but that it remains so through keeping pace with the state-of-the-art of (risk) governance over time as the discipline and technologies continue to develop and mature. Future generations of nanomaterials, and more broadly advanced materials, will require greater ethical considerations given the complexity and sensitivity of foreseen applications. EFSA has committed to the development of a comprehensive body of good risk assessment practices to guide its Scientific Committee and Panel experts. This helps maintain and build capacity by linking contemporary developments with relevant practitioners within the organisation. **This approach is one example of reflective governance practices[8] that aid organisations engaging with science and technology for reviewing and continuously improving upon its practices with respect to its aims[9], in this case for more sustainable risk governance of nanomaterials.**

The approach to ensuring work practices represent the values of the organisation are largely conducted internally, carried out by internal auditors reporting to senior management, presenting a conflict between quality and openness. EFSA also commissions external evaluations of its work and working practices, with risks more explicitly referred to through internal detailed documents, and not well communicated to non-expert stakeholders.

This in the case of ECHA's RAC and SEAC is due to the need to 'deal' with concrete dossiers, presenting a reluctance to involve any and all stakeholders in technical discussions that impact decisions made by the respective committees, despite a commitment to stakeholder involvement. Even where ASO organisations are admitted as observers, their access in theory only reaches non-confidential documentation. The RAC even includes the restriction regarding disclosure of certain information as a result of its work in the Committee unless otherwise stipulated in European Union or national law, or already publicly available, providing little scope for actually disclosing often important information to a wider group of interested parties, namely civil society and environmental interest groups.

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. What this may look like legally is another matter completely, operational practices can be established that are suitable for this type of framework.

In the case of the SCCS, the organisation engages in nanomaterial risk governance according to a mandate given by the Commission and provides safety evaluation according to 'the Guidance on the

[8] Jørgensen, K.E. ed., 2016. *Reflective approaches to European governance*. Springer.

[9] Stirling, A., 2006. Precaution, foresight and sustainability. Reflection and reflexivity in the governance of science and technology. *Reflexive governance for sustainable development*, p.225.

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Safety Assessment of Nanomaterials in Cosmetics SCCS/1611/19' in conjunction with the general guidance for the submission of safety dossiers of cosmetic ingredients "The SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, 10th Revision, SCCS/1602/18" to assess annex nanomaterial for its use in consumers products.

After the evaluation the opinions are scrutinised prior to adoption/approval. Adopted Opinions are published and opened to public for comments. After commenting period, the SCCS considers and respond formally to each comment.
The opinions of EFSA are used by Commission for communication with industry and serve Commission as decision making tool to permit or ban the nanomaterial for its use in consumers products. EFSA as another public agency also has a limited obligation for making documentation publicly accessible, although limited, this contributes to fulfilling its own obligation to openness and transparency.

Additionally, the EFSA Board (appointed by the Council of the European Union – after consulting the European Parliament – from a shortlist drawn up by the European Commission) governs its meetings in a transparent manner through opening up typically closed meetings to webcast, during which they discuss key priorities, namely ensuring EFSA's priorities are in line with its mandate and key missions. EFSA affirms that the agency is committed to prioritising public and stakeholder involvement in the process of risk assessment but how this prioritisation impacts final decisions is unclear.

EFSA have recognised this in their latest 5-year strategy from 2020 which focuses on building trust in science for safe food, with great emphasis on stakeholder engagement, but this remains largely descriptive.

However, with ECHA and EFSA being formally connected with regulation and sensitive information through institutional linkages likely to impact regulatory decisions, they are often hindered by this responsibility in terms of how much information they can legally share. Depending on how the RGC is positioned and what authority it is therefore given, operating practices would ideally step beyond the level of disclosure and transparency that these organisations offer. **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.**

4.2 Independence and Trustworthiness

This section introduces the theme of independence and trustworthiness of the organisations and the manner in which they govern, and asks us to reflect on what the best practices are to ensure that the RGC is established in a manner that represents this continually, and is not subject to undue influence or mistrusted by interested parties which can be a fine balance to maintain.

OECD's work and actions are said to be explicitly driven by objectiveness, guaranteed by the fact that analyses and recommendations are independent and evidence-based, demonstrating what is seen as a direct link between value and procedure.

Making strong links procedurally and communicating these links is therefore key to demonstrate the independent nature of such processes. However, when we question independence of opinion,

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then underpinning this autonomous process with safeguards is key. In addition to independence, OECD goes further in striving to be leader through bold and pioneering actions, relating to an attitude that challenges conventional wisdom and to identify and address emerging and long-term challenges. These values are positive examples of how an organisation can gear its work in a progressive manner and avoid conservatism in the way new challenges are approached. On this approach, the OECD is lacking clear structure and operational practices, although the values are well communicated elsewhere. Despite being an innovative organisation where new methods must be validated in the context of scientific rigour and fit-for-purpose testing, the 'pioneer' value is underrepresented in that currently, greater clear guidance for dealing with nanomaterial innovations is required.

For the RGC to demonstrate an innovative approach that leads the way in risk governance of nanomaterials operational references integrating progressive approaches would be of value for the RGC in supports of aims to lead the way in Europe on the risk governance of a very challenging group of innovations. ECHA's Risk Assessment Committee (RAC) Rules of Procedure specifies independence under Article 9 of its Terms of Reference in relation to regulatory obligations under REACH assigned to the committee.

This largely involves demonstrating that the interests in the work of RAC and background of committee members, advisers and other experts are independent from external influence, although zero susceptibility to external influence can be fully guaranteed, it does impose obligations for external experts or consultants to withdraw from conflictual activities.

This risk can be seen within ECHA's workflow for key processes such as the authorisation procedure in which there is ample opportunity to those with the greatest interest in the authorisation or approval of a dossier, also being the stakeholder, most involved in the process. Similarly in the registration process, ECHA based their registration of a substance on a dossier provided by a company or companies where jointly submitted, which contains *'the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled'*. Evaluation within ECHA also involves the evaluation of information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment. This concerns the Examination of testing proposals submitted by registrants, Compliance check of the dossiers submitted by registrants, and Substance evaluation.

These stipulations give great space to explain away the relevance of risks, demonstrates uncertainty in assessments of risks, and somewhat asserts that there are acceptable levels of risk and that these can be controlled. The commitment to well-being can be said to be undermined by this approach, and that independence is further reduced. Trust in the procedures is essential for the legitimacy of ECHA's work including registration.

These process coupled with concerns for regulatory capture already expressed, establishes 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.

In a similar way to ECHA, EFSA and SCCS also commit to independence from undue external influence and to ensuring that it has the necessary mechanisms in place to achieve this. In support of this, EFSA has procedures in place that authorise the agency to accept or reject proposals for assessment made, this supports its independence, but therefore may limit the scope of proposals to solely scientific

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reasoning due to the scope of assessment criteria. There is also less information on how EFSA works to maintain its independence, illustrating how communication of such measures is valuable in building trust in these processes amongst stakeholders.

In contrast, it is clearly indicated that representatives of food industry and business, farmer organisations, consumer and environment NGOs, distributors, practitioners and academia all have a permanent opportunity to engage with EFSA through the stakeholder forum and bureau established in 2008. The task of the stakeholder bureau to help set the mandate of working groups appears to be particularly influential on the work of EFSA, but the overall depth of engagement does not guarantee a balanced range of opinions are included in the decision-making process itself.

In the case of SCCS there is clear rule for meeting and stakeholder engagements. The SCCS meest every month and each time SCCS members need to declare on each occasion that there is no conflict of interest. Each year members need to answer very long questionnaire about their work and possible private interest, conflict of interest, etc. The members can not directly communicate with industry, only via Commission to ensure independence and mitigate any bias. There are also rules set up and procedures monitored internally, there are also external experts to help to do safety assessment in order to help maintain the balance between openness and independence. There are also safeguards to ensure committee members and external experts to safeguard against the influence of external interests that also cover communications with external parties which contributes to a stringent framework for maintaining independence and transparency.

SCCS has several working groups, including one focusing on methodology where leading experts are invited to share their knowledge to ensure the SCCS keeps pace with nano state-of-the-art. Additionally, the SCCS organises workshops where the approach and methodologies developed are discussed. SCCS guidance documents and opinions are also publicly available to enable better understanding of the approach of the organisation.

It is recommended that the RGC also place great emphasis on establishing rules of procedure and demonstrating how the independence and trustworthiness as that found in the SCCS among other organisations. These organisations safeguard against influence and proactively seek out a broader range of stakeholder opinions could improve current systems for driving stakeholder participation, whilst justifying increased legitimacy and influencing governance of nanomaterials including risk governance.

In doing so, it will be important to maintain the fine balance between independence and openness, and how any aim to influence nanomaterial governance that capture of this process by interested parties does not take place.

In the example of ECHA, external stakeholders are often relied upon to deliver outputs which may sacrifice some degree of independence in their decision-making process, with directly interested parties carrying out analysis as evidence for ECHA opinions.

To structure such processes and try to safeguard against this influence, ECHA and its subsidiary bodies are subject to a range of rules of procedure for stakeholder participation, with implications for how the organisation is governed, and in turn how the issues it deals with are addressed. These procedures cover a range of issues including the involvement of external stakeholders in order to set specific bounds for participation and access to information, such as those for Accredited Stakeholder Organisations (ASO).

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ASO status is granted through provision of an expression of interest statement, with varying implications dependent upon procedure and context of internal process. Specific rules such as these represent a measured approach to remaining independent whilst building trust with a wider range of stakeholders through their involvement. This being said, procedures that erode the independence of an organisation must strive to maintain balance between impartiality and stakeholder participation. Moreover, the balance of stakeholder groups represented is crucial to ensure given the disparity of resources dedicated to such activities, for example by organisations with commercial interests compared to civil society groups.

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 sufficient 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.

4.3 Openness and Transparency

Openness and transparency are key to demonstrating the independent nature of an organisation, and to build trust across a range of interested parties.

At a strategic level, the OECD states that its work and actions are also guided by openness through encouraging debate and a shared understanding of critical global issues, as well as ensuring decisions are ethical in that. Credibility is built on trust, integrity and transparency. This is a commitment to open dialogue but stops before acknowledging that there is a high degree of confidentiality concerning documentation and discussions within its committees and working parties. This is justified by the sensitivity of information discussed with regards to the views of regulators on behalf of their member countries.

Transparency is seen by the OECD to foster cooperation through allowing other stakeholders to access information, yet this provision can also be criticised in that there are great varying permissions depending upon justifications laid out by the organisation. For example, Civil society have access to the Decision Framework for a better understanding of the organisation, which also fosters greater trust in its role. In particular, this is seen to support streams relying upon trust, namely in risk assessment (fit-for-purpose testing) and the Mutual Acceptance of Data (MAD) principle.

ECHA, EFSA and SCCS have a much more detailed approach to transparency, making clearer how exactly this is implemented in practice. ECHA's approach to transparency is said to be based on three main pillars: Clear and transparent procedures; Open decision making; and Information Availability. The official policy on this laid out is as follows: *EU citizens and non-EU citizens or enterprises with a registered office in the EU can request access to documents from ECHA under the Regulation regarding public access to European Parliament, Council and Commission documents (Regulation (EC) No 1049/2001).*

In its processes ECHA effects its commitment to transparency and trust with all stakeholders by providing a range of digital tools and repositories of information relating to a range of procedures under each of the respective regulatory frameworks. However, this approach lays out several limitations as to where and how transparency can be applied or maximum transparency, as opposed

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to how to achieve complete transparency. For example, due to foreseen capacity of the organisation, provisions for transparency are restricted at certain points, which may be necessary in some cases.

Nevertheless, it is important to ensure all relevant information reflects the values of openness and transparency. Intellectual property in the various evaluation processes carried out by ECHA also presents a substantial barrier to fulfilling these values. Openness and transparency exist between applicant and agency, but this is where the bounds are set.

The same transparency rules are delegated to the Rules of Procedure for the Risk Assessment Committee (RAC) and Committee for Socio-Economic Analysis (SEAC) respectively. The transparency of work by ECHA across these groups is tiered based on the assigned status and corresponding access to information granted to different interested parties, or stakeholders.

Regarding openness to observers, this status is granted through regular calls for expression of interest in becoming an Accredited Stakeholder Organisation (ASO). This has potential to ensure efficiency but may present a trade-off with transparency due to the limits placed on access to information which offers a codified reflection of discussions and decisions taken within ECHA entities. Decisions on General Application which potentially affect all companies which fulfil certain objective criteria or describe certain ECHA processes , this includes identification and listing of substance of very high concern (SVHC) as those that are carcinogenic, mutagenic, toxic to reproduction, persistent, bioaccumulative and toxic, very persistent and bioaccumulative, or that give rise to a similar level of concern.

Participation is limited to one permanent expert nominated per MSCA, Commission service and relevant EU Agencies. Experts from Industry and Non-Governmental Organisations (NGOs) can also participate in the ECHA-NMEG as Observers, though eligibility criteria for NMEG observers are set. For specific scientific or technical questions additional experts can be invited to the meetings on a case-by-case basis, when such a need is identified, and following suggestions by MSCAs, Commission, relevant EU agencies, ECHA, or ECHA-NMEG Observers from Industry or NGOs.

An open approach is selected as representative for the definition of meeting agendas, as Proposals for agenda items may be submitted by the participating experts, the MSCAs, MSC, RAC and BPC members, ECHA secretariat, EU Commission, EU Agencies and representatives from Industry or NGOs. While NMEG sessions are open, closed sessions are organised case by case, in view of confidentiality issues.

In the SCCS opinion development procedure detailed under the governance category, once opinions published the commenting period starts. This means that everyone, either private person, scientists, industry or NGO, everyone can read the opinion and comment it. After commenting period the SCCS is obliged to take each comment into consideration, to correct the opinion in case SCCS missed some information or explain if it is not clear in the opinion but in each case the SCCS is obliged to respond to each comment by formal letter. After that the Opinion is finalised and send to DG GROW which does risk management – either permit the nanomaterial to be used in the market or not. Each nanomaterial present in consumer product should undergo this procedure.

4.4 Scientific Robustness

A number of key publications by the OECD, namely the Solna Principles (1996) and the Guidance Document on the Validation and International Acceptance of New or Updated Test Methods for

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Hazard Assessment (2005) are where many of the values and terms of reference of the organisation are operationalised through detailed information on study design, validation and test submission and acceptance which then guide other actors in the risk governance of nanomaterials.

The latter of these documents laid out the OECD's guiding principles previously with the intent to afford a systematic and objective system for identifying suitable methods, data sources and technical approaches for the assessment of nanomaterials, even though the applicability is broader.

According to our analysis, OECD implements well its values coherently throughout its communications and test guidelines, especially in the case of scientific rigour where this stands out as a key value to support decision making. The OECD continues to make a coherent link between their values and the work carried out by relevant groups such as the WPMN, with work ongoing to identify appropriate physicochemical parameters and appropriate characterisation of manufactured nanomaterials to continue improving upon the guidance developed and disseminated by the OECD.

However, the delivery of information and test guidelines in a rigorous manner remains under prioritised in terms of how resources are allocated, which has in turn led to initiatives external to the organisation where resources of particular lead nations are focused, in this case the Malta Initiative.

As part of the initiative, interested countries or organisations are welcome to adapt existing OECD TGs or develop new OECD TGs and/or GDs for which OECD lack the required resources from members, demonstrating a disconnect between the governance role of the OECD and the required support in the form of resources provided.

The IRGC is represented entirely by academic and scientific entities, which are involved in the governance of the organisation, setting the priorities, deciding on the activities to be performed and the analysis of the input. In addition, IRGC is an Accredited Organisation by several global and European organisations: UNEP, ECOSOC, Sustainable Development Solutions Network, Europa.eu, Transparency Register. Strong emphasis is therefore placed on pooling highly skilled individuals to address the priorities of the organisation. This also applies to public communications for which IRGC a peer-review process for reviewing any type of information is produced and communicated to the public. **How to best oversee and evaluate outputs of the RGC will be an important consideration and impactful on how different types of insight qualitative and quantitative are favoured or preferred in the outputs of the organisation.**

ECHA for example are obliged to provide outputs that corresponding the REACH technical annexes that cover materials. As of 1 January 2020, additional revised requirements for Annexes I, III, and VI-XII were introduced aiming to significantly clarify REACH registration requirements with regard to nanomaterials. These amendments impacted nano-specific clarifications and new provisions for chemical safety assessment (Annex I), registration information requirements (Annex III and VI-XI) and downstream user obligations (Annex XII)[10]. Therefore, ECHA (including RAC and SEAC) are bound to provide support to fulfilment of these annexes among others to stakeholders including industry and policymakers. **The RGC must also consider where the most valuable contributions could lay with respect to regulatory processes and existing gaps in the evaluation of risks and uncertainties in relation to nanomaterials. This will not only impact the development of framework for risk**

[10] Nanomaterials in REACH and CLP: Revision of REACH Technical Annexes [Accessible at https://ec.europa.eu/environment/chemicals/nanotech/reach-clp/index_en.htm]

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governance but also the positioning of the organisation in the field of chemicals and nanomaterial regulation.

In the case of NMEG, opinions and outputs are based on non-accountability, they are informal and non-binding, and with the group established to give a specialist opinion on nanomaterials without guarantee of scientific robustness or accountability, **serious attention must be given to how authoritative groups are held responsible when providing technical opinions** (Palma-Oliveira et al., 2018)[11]**.**

As stated in section 4.2 on Independence and Trustworthiness, the SCCS tries to safeguard against external influence or bias for favourable opinion for each substance under analysis, but bias exists in many forms, namely bias towards the certainty of scientific methods applied and the calculability it offers. SCCS have also developed series of guidance document and best practices to 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.

Specifically, the SCCS assessment of nanomaterials in cosmetics is specifically covered under the Cosmetic Regulation (EC) No 1223/2009, which provides a definition of a nanomaterial and requires premarket notification, safety evaluation, and labelling of nanomaterials intended for use in cosmetic products. To ensure the quality and consistency in evaluation of nanomaterials the SCCS in 2012 published the Guidance on safety assessment of nanomaterials in cosmetics (SCCS/1484/12). This Guidance was updated in 2019 (SCCS/1611/19) implementing several new developments in the area of nanosafety research. The SCCS in its methodology and nanomaterial working groups addresses several issues and questions regarding the types and quality of the information and data that must form part of the safety dossiers on nanomaterials.

In view of this, the SCCS published a memorandum (SCCS/1524/13 Revision of 27 March 2014) to highlight the importance of relevance, adequacy and quality of the data provided in a safety dossier on nanomaterials. The SCCS thus requires use of OECD test guidelines performed under Good Laboratory Practice (GLP). This means that for the safety assessment of cosmetics, the necessary safety data can only be drawn from validated tests. Another challenge is that the safety assessment of cosmetic products and ingrediencies can be performed only with alternative non animal tests to fully implement testing and marketing bans on animal testing under the European Cosmetic Regulation. In view of these challenges and high uncertainty the SCCS in its Methodology and Nanomaterial Working Groups discuss the key issues and invites top scientists to increase the quality of their work and implement the latest knowledge into risk assessment of nanomaterials in consumers products.

[11] Palma-Oliveira, J. M., Trump, B. D., Wood, M. D., & Linkov, I. (2018). Community-driven hypothesis testing: A solution for the tragedy of the anticommons. *Risk Analysis*, *38*(3), 620-634.

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The SCCS acknowledges where required that insufficient data or information exists to clearly provide an opinion through the plenary process outlined in section 4.1 of this document, and in acknowledging shortcoming of supporting data for the implementation of the methodologies used, the organisation accounts for the need for truly robust analysis, but falls short of in fact providing no quantifiable opinion in the face of great levels of uncertainty. This is a difficult judgement to make in the nanomaterial sphere but would provide more effective protection of civil society to the risks of nanomaterials, and help the field strive for improved harmonised techniques to meet highly set scientific requirements.

The quality of data and analysis is also a clearly identified value that EFSA are committed to, with a specific ISO 9001:2015 accredited Quality Management System (QMS) in place to ensure that scientific processes are developed consistently and continuously improved. This therefore directly integrates the values of the organisation into their operational practices as per the ISO standard, although verification of this is dependent upon requirements of the standards itself which is determined externally.

In terms of analysis and decision making, EFSA largely rely upon their Scientific Panels and Committees largely comprised of only scientific experts recruited through an open call, and experts are renewed every three years.

Driven by the work of these groups, EFSA place knowledge, experience and decision-making of its scientific experts at the heart of their work, and therefore a largely analytical perspective characterises the recommendations, opinions and other outputs produced by EFSA panels. However, question marks remain regarding how overall aims for the governance of nanomaterials are taken into account as part of decision-making processes.

EFSA follows a workflow know as their 'Scientific Process' of request, assessment and adoption, underpinned by scientifically accepted methodologies and supporting tools that are commonly used by assessment bodies across the globe. Interestingly, the request for scientific advice that initiates the assessment and adoption phase subsequently must be requested by an EU or National body dealing with food safety. Additionally, EFSA have the authority to accept or reject proposals for assessment made, this supports its independence but therefore may limit the scope of proposals to solely scientific reasoning.

This in turn limits the direct impact that other stakeholder groups may have in calling for assessments of nanomaterials used in foods, even in the presence of clear social pressure. The operational practices in place to assess risk therefore rely on political reactivity to health or environmental concerns raised by interested parties including civil society groups or individuals. An independent agenda that focuses on key socio-technical issues including scientific gaps for example, will be key to ensuring a clear and robust work programme is developed addressing all crucial issues.

EFSA also develops their own approaches to meet the specific needs of its EU food safety remit. It can therefore 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 food could be a specific target area for the forthcoming RGC to address or support EFSA in addressing**.

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4.5 Prevention of Risk, Precaution, Wellbeing and Sustainability

The activities of IRGC are largely related to the improvement of the understanding and management of risks. Clearly its mission features risk as "*the development of concepts of risk governance, anticipating major risk issues, and providing risk governance policy advice for key decision-makers*".

This aims to be translated into opportunities by providing insight into systemic risks (for human health and safety, the environment, the economy and the society) and to draw upon scientific knowledge and expertise to develop fact-based risk governance recommendations for policymakers. This demonstrates clear emphasis on addressing risk directly, and offering recommendations based on facts beyond scientific analysis of a substance in isolation.

However, the IRGC does also emphasise risk governance as a tool for avoiding stifling of innovation through the following scheme:

- *Make sense of emerging technological opportunities that the public sector can benefit from and should support*
- *Identify and analyse existing and emerging risks that both industry and public authorities should be aware of, in order to assess and make decisions about these risks. Risks can be:*
    - *Technical, e.g. potential negative consequences of new technology*
    - *Perceived, e.g. a ambiguous attitude towards a technology*
- *Be a neutral platform for dialogue on opportunities and risks related to science and technologies, with the aim of providing recommendations for their governance.*

This appears to shift the overall mission and focus of the organisation's work on risk in favour of innovation rather than the prevention of risks. The former holistic approach is strongly recommended for the RGC to better account for sustainability issues alongside innovation in a more balanced manner.

ECHA acknowledges that it is a key enabler of safe and sustainable chemical use, positioning itself as a gatekeeper in this field. Although framed as an enabler for chemical use, the inclusion of safety in this value however does allude to a sense of risk perception and assessment. Mentions of risk in the values and terms of refences of organisations analysed vary, reflecting the differing perceptions of risk and how explicitly or implicitly risk should be communicated, in part due to the multi-faceted nature of many of the organisations that impact the risk governance landscape. Even for NMEG, as a specialist entity within ECHA, concerns regarding scientific rigour within the organisation, prevention and precaution concerning risk is not specifically highlighted within the available mandate beyond what is already mentioned at ECHA level. The focus on *'informal advice on scientific and technical issues'* includes "*Risk management dossiers for substances with nanoform*", whereas a broad description of issues related to nanomaterials is provided for setting the sectors of interest for the organisation activities.

Again the informal nature of this group as part of an influential and regulatory responsible body is a concern regarding this priority area. The creation of a dedicated organisation focused on this space with a clear mandate to ensuring prevention, precaution, wellbeing and sustainability to guide the organisation will be key to improving upon the current framework.

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Within ECHA, their commitment is recognition of the risks associated with the substances addressed by ECHA's commitment to wellbeing, with safety being a key part of this commitment. However, risk and accompanying uncertainties are more explicitly referred to within more detailed operational documents. For example, as per the latest organigramme presenting ECHA Risk Management and Hazard Assessment entities are also used as the categories by which to organise ECHA itself, with dedicated directorates having been respectively established.

The organisation and structuring of the organisation with clear missions focused on risk therefore legitimise such activities, but within an organisation largely focused on governance of nanomaterials and risk governance, it will be important to establish a culture throughout the organisation using all structural tools to drive impact.

Under the ECHA Workplan on Nanomaterials 2016 – 2018, there is great mention of the uncertainties and risks of nanomaterials, reflecting a lack of provisions for nanomaterials in REACH and CLP Regulations at the time of creation at the time of writing. ECHA positions itself as a contributing and reactive organisation that will work to utilise the growing evidence base on nanomaterials to make the necessary evaluations and process nanomaterials under the regulations nevertheless. Implicitly this does demonstrate a proactive approach with a clear concern for well-being, but this is contrasted by the framing of ECHA as a largely procedure based organisation that relies upon regulatory action, even considering to take no action until Regulation is updated despite the acknowledged uncertainties of nano-scale particles. They conclude to place burden-of-proof of safety solely on registrants which demonstrates reliance in such processes, relying on those with potential to benefit from positive results, to supply the results which question the legitimacy of such a process, especially in light of the acknowledged uncertainties. Risks concerning the acceptance of data, on substances whose variability in terms of environmental fate, is not acknowledged.

As a neutral agency ECHA places trust into the regulation and industry stakeholders. In terms of transparency, again, a great deal of the information used in evaluation processes is not disclosed.

Relative to other key values of the organisation, well-being is largely underrepresented with little or no mention of human and environmental health, as well as general public engagement and involvement in a meaningful way. The largely scientific and technical processes are predominantly inaccessible in terms of content to the public, and these processes are restricted to assessing known risks for limited applications, and there is little stakeholder engagement on general concerns they may have prior to or beyond any scientific assessment process. Moreover, transparency and communication into ECHA processes and full disclosure as to what is and is not known is not visible. Independence is also not well represented in that there is a constant exchange with stakeholders whose activities are regulated under REACH or CLP for example, all of which is overseen by the other EU institutions with little freedom for the agency to develop its role in better regulating chemicals in Europe.

As described with regards to the independence of ECHA, operational practices in meetings and provisions for conflict of interest management, transparency, trust, and possibly a strong commitment to well-being are all underrepresented when managing the involvement of external parties in important conversations regarding substances in which they may have a vested interest.

Within the OECD test guidelines previously cited, risk is largely framed a quantifiable element that relates to uncertainty concerning the assessment or characterisation of a nanomaterial. The guidelines do not exceed guidance for testing of physicochemical properties or physicochemical characterisation

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by framing the overall use of the appropriate testing approaches as part of a wider approach to risk governance. This reflects the limitations/boundaries of the work carried out by the OECD which does not encroach upon OECD member economic or environmental strategies.

5. Conclusions

The conclusions and recommendations of this deliverable are designed to be considered and adopted under RiskGone WP2 for the development of the RGC's Risk Governance Framework, as well as by other Work Packages and NMBP-13 projects developing operational guidance and/or tools for adoption by the RGC.

As outlined in our introduction, this analysis of existing governance bodies and their operating practise aims to help establish a valuable entity to contribute to and support the governance of nanomaterials in Europe, and more broadly as part of the global governance system for nanomaterials, this analysis must cover all levels of governance from strategic to 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 are 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.

Effective Governance and Risk Governance

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 and will change 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 agility that allows the organisation to keep pace with the evolving 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.

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 procedure for decision making procedures could 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 framework.**

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Moreover, such decision making procedures in the context of effective risk governance of nanomaterials 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., and not only exposure under purely controlled conditions found within the laboratory or the conception of product use alone. Moreover, to be truly effective the RGC should aim 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.

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 are recommended.

Greater consideration must be given to what effective governance means, as opposed to efficiency orientated organisations that currently exist. Effective risk governance must go beyond a quantitative analysis of outputs, but in fact the influence of an 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)[12].

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 activities which represent the foreseen RGC's impact on risk governance in Europe.

Additionally, regular reviews take place across some organisations to continue to guarantee a high-quality of output, such safeguards are recommended for the RGC. Moreover, an anticipatory approach to risk governance capacity is recommended to keep face with the challenges of increasing innovation in the nanomaterial space.

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.

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 substances. Consideration of how resource intensive analyses are better applied when less uncertainty exists, and therefore the opportunity to provide clear guidance on safe and unsafe

[12] Linkov, I., Trump, B. D., Anklam, E., Berube, D., Boisseasu, P., Cummings, C., ... & Jensen, K. A. (2018). Comparative, collaborative, and integrative risk governance for emerging technologies. *Environment Systems and Decisions*, *38*(2), 170-176.

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application is greater. **There may also be a decision to create lighter processes in the pre-assessment phase that enable the RGC to provide clear opinions with a high degree of uncertainty and the perceived risks that therefore requires a greater deal of research and development before a positive opinion can be considered.**

The RGC must also consider where the most valuable contributions could lay with respect to regulatory processes and existing gaps in the evaluation of risks and uncertainties in relation to nanomaterials. This will not only impact the development of framework for risk governance but also the positioning of the organisation in the field of chemicals and nanomaterial regulation.

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.

Independence and Trustworthiness

ECHA's RAC, EFSA and SCCS Rules of Procedure specify independence and involve demonstrating that the interests in the work of RAC 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 process coupled with concerns for regulatory capture already expressed, establishes 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

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 would have to be accompanied by the required regulatory and procedural obligations in order to force industry stakeholders to agree to such disclosures. A clear case for justifying disclosure may therefore be required.

Scientific Robustness

The SCCS acknowledges where required that insufficient data or information exists to clearly provide an opinion through the plenary process outlined in section 4.1 of this document, and in acknowledging shortcoming of supporting data for the implementation of the methodologies used, the organisation accounts for the need for truly robust analysis, but falls short of in fact providing no quantifiable

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opinion in the face of great levels of uncertainty. The RGC should use this example of scientific reflection and ensuring a robust process, whilst also going beyond to better reflect both the overall state-of-the-art in substance evaluation, as well as real-world conditions that cannot be accounted for in a laboratory environment.

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 RGC areas of operation. 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 including scientific gaps for example, will be key to ensuring a clear and robust work programme is developed addressing all crucial issues to ensure scientific robustness is not undermined by competing agendas in the field of nanomaterials.

Prevention, Precaution, Wellbeing and Sustainability

As already stated, the RGC must ensure consistent considerations of risks to humans and the wider environment, and ensuring substances are used in a limited and safe manner where necessary. 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 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 must take a holistic approach to addressing risk directly, and by developing outputs based on facts beyond scientific analysis of a substance in isolation.

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6. RGC Risk Governance Recommendations

- *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;*

- *The RGC risk governance framework must be future-proof and agile to keep pace with nanomaterial innovations and evolving regulatory needs;*

- *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;*

- *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;*

- *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;*

- *The RGC Risk Govnernance 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 are recommended;*

- *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;*

- *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;*

- *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;*

- *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.*

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Annex I – Identification of Existing Nanomaterial Risk Governance Bodies

This section provides an overview of existing organisations, including their scope both in terms of geographical coverage and reach, but also their powers and corresponding approach to risk governance. This overview is organised from global to European level to also highlight the links and differences between the global and European landscapes for nano risk governance.

OECD

In the context of nanomaterial risk governance, the OECD is an intergovernmental organisation with representatives of 36 industrialized countries from across the world and is therefore influential in developing technical guidance developed by its numerous committees and working parties, thereafter, adopted by member countries and other nations globally. Governance of the OECD itself is largely administered by the Secretariat which relies upon the input and support of OECD member countries. Member countries are also charged with driving stakeholder engagement at national level, which is then taken into account at OECD level meetings where relevant. In the case of stakeholder engagement of the Working Party on Manufactured Nanomaterials (WPMN) as a WP of the Chemicals Committee, NGOs and BIAC (Business at OECD) are also able to attend meetings, with the latter being a permanent industry focused stakeholder organisation. The organisation focuses on building better policies leading to better lives, such as shaping policies that foster prosperity, equality, opportunity and well-being. Although the OECD covers several relevant topics, the work of the Chemicals Committee is most relevant, that of subsidiary bodies set-up to manage/engage with specific issues including risk and hazard assessments. Such groups include the WPNM already mentioned and and the Working Parties on Exposure & Hazard Assessment (WPEA and WPHA), all of which are grouped under the organisation's Environment, Health and Safety (EHS) Programme.

Influencing all of these activities the OECD has several guiding principles including relevance, adequacy, reliability and objectivity, all of which are underpinned by purpose as defined below:

OECD Guiding Principles[13]		
Principle	**Definition**	**Applications**
Purpose	*A clear description of the need and intended use of the data with defined domain of applicability. For example, measurement of particle size distribution for the assessment of substance identity or for the assessment of environmental fate. Purposes with associated physico-chemical endpoints/parameters are defined in the Decision Framework.*	• Method evaluation/selection • Reporting guidance • Non-guideline method improvement • Data usability
Relevance	A measure of the degree of alignment of the overall methods and/or data with regards to the intended purpose. Methodology capable of	

[13] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2019)13&doclanguage=en

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	identifying key mechanism should be prioritised, if possible.	
Adequacy	A measure of the repeatability, reproducibility, trueness (accuracy) and suitability of the reported data and applied methodologies with respect to necessary degree of resolution as specified by the intended purpose.	
Reliability	A measure of the completeness of the methodological description and reported data with respect to the intended purpose.	
Objectivity	A measure of the extent of bias due to sampling, estimations and systematic effects based on the overall methods employed and study design with respect to the intended purpose.	

Table 1: OECD Guiding Principles

IRGC

Another international organisation in this space is the International RGC (IRGC) which is an independent non-profit foundation with activities widely spread on global topics related to risk governance of emerging technologies. The IRGC *aims to help improve the understanding and management of risks and opportunities by providing insight into systemic risks that have impacts on human health and safety, on the environment, on the economy and on society at large.*

IRGC is run by its Foundation Board. The foundation board is IRGC's main strategic, oversight and decision-making organ. Board members hold honorary office on an individual basis. EPFL (École Polytechnique Fédérale de Lausanne) provides the IRGC with a secretariat and resources for establishing the activity. Close collaboration with EPFL centres is required and specifically since 2016 IRGC collaborates with EPFL International Risk Governance Centre. In the first phase of the organisation (2003-2012) had a founding director and financial support from the State Secretariat of Switzerland.

In addition to the Board, IRGC has a Scientific and Technical Council and a Director. The activities and responsibilities within each of these roles are not clearly described in the related documentation. A decentralised structure facilitating a network of academic and scientific institutions is the main working body of IRGC (9 locations, US, Portugal, UK, Germany, India, China and Switzerland). Every network member is an active contributor to IRGC's work, whether via the provision of funding, expertise, and research work, or a combination of these. IRGC is a non-profit foundation that relies entirely upon funding and research contributions from its network members and grant-making institutions, both private and public. This comes in accordance to the independent and collaborative core values of the organisation.

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Like the OECD, the activities of the IRGC is also based on a set of core values, in this case Openness, Accountability, Collaboration, Independence.

IRGC Core Values	
Value	**Definition**
Open	*Project outcome are shared freely.*
Accountable	*Science-based project work and scrutinised recommendations, via peer review before publication.*
Collaborative	*At the heart of the IRGC approach and vital integrated working methods.*
Independent	*Free choice of subjects to focus on, selection of experts and partner organisations for collaboration, and design of appropriate governance recommendations to deal with the risks addressed.*

Table 2: IRGC Core Values

On the basis of these values, key outputs for IRGC are considered the development of concepts of risk governance, anticipating major risk issues, and provision of risk governance policy advice for key decision-makers, all possible outputs for the RGC to consider developing specifically at the European level.

ECHA and related organisations

The European Chemicals Agency, commonly known as ECHA, is one of the most influential bodies in Europe, where it operates at the centre of EU Chemicals Legislation, covering all EU Member States.

ECHA deals with a number of important regulations including: REACH (Registration Evaluation, Authorisation and Restriction of Chemicals) which aims to improve the protection of human health and the environment from the risks that can be posed by chemicals; CLP (Classification, Labelling and Packaging) focusing on hazards of chemicals are clearly communicated; BPR (Biocidal Products Regulation) and several others[14].

Across these areas ECHA aims to help companies to comply with the legislation, advance the safe use of chemicals, address chemicals of concern, and provide information on chemicals to all stakeholders including civil society. The obligations of ECHA to implement certain processes and corresponding operational practices is largely driven by legislative changes within the frameworks. For example, relevant annexes of the REACH regulation were recently amended to increase requirement of businesses using nanomaterials already and those planning to do so.

[14] https://echa.europa.eu/legislation

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The requirements added through these amendments largely contain obligations to provide data and information, which ECHA must now oversee, placing ECHA at the heart of getting a grip on nanomaterial use in Europe.

Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC) are two key committees in ECHA's assessment focused approach to risk governance of chemicals including nanomaterials. On nanomaterials specifically ECHA also oversee the NMEG (Nanomaterials Expert Group) [15], and previously oversaw the now disbanded GAARN (Group assessing already registered nanomaterials).

These groups represent a large portion of the risk governance actors with expertise on chemical substances that often inform the approach of sector specific bodies to nanomaterials. For nanomaterials as a horizontal topic the NMEG has a mandate defined as the provision of non-binding scientific advice on questions related to nanomaterials under REACH, CLP or BPR, while it is clearly stated that none of these activities will interfere with formal regulatory processes.

The content addressed within NMEG could be used as a preamble for discussions within the Member State Committee (MSC), Risk Assessment Committee (RAC) or Biocidal Products Committee (BPC) level.

EFSA

In the case of food and food contact materials, the Europe Food Safety Agency – EFSA, is the responsible institution for providing opinion and policy recommendations for the use of chemicals and nanomaterials in relevant products.

To fulfil this role's responsibilities, EFSA employs Scientific Panels and Scientific Committees to provide scientific advice and recommendations to EU and Member State policy makers, for example scientific opinions on the presence of nanoscale Titanium Dioxide are provided to the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) made up of Member State representatives, guided by the European Commission. EFSA staff may also produce scientific outputs on behalf of the agency, such as peer reviews of the assessment of active substances in pesticides, or responses to urgent requests for advice. EFSA staff also monitor and analyse information and data on biological hazards, chemical contaminants, food consumption and emerging risks.

SCCS and SCHEER

In addition to specialist EU government agencies, SCCS (Scientific Committee on Consumer Safety) and SCHEER (Scientific Committee on Health, Environmental and Emerging Risks two key European Commission committees focused on public health are also influential in this space through their provision of expert opinions and associated oversight on important decisions at the axis of public health and nanomaterials.

Two independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat. These committees are: the Scientific

[15] https://echa.europa.eu/regulations/nanomaterials/nanomaterials-expert-group

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Committee on Consumer Safety (SCCS) and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and are made up of scientists appointed in their personal capacity.

The SCCS Committee provides Opinions on questions concerning all types of health and safety risks (notably chemical including nanomaterials, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).
The opinions of the Scientific Committees present the views of the independent scientists who are members of the committees. They do not necessarily reflect the views of the European Commission. The opinions are published by the European Commission and are publicaly available for commenting.

Summary of Organisation Analysis Scope

In terms of the scope of existing organisations at global and European level, the main difference lies in regulatory authority that each organisation possesses, and therefore how their organisation is structured, including the impact of outputs produced. At global level, especially in the case of the OECD, the structure and approach of global organisations focus on establishing greater transboundary harmonisation and increasing standards of practice both in terms of risk assessment but also to aid innovation and support nanomaterial development. The OECD has power to establish OECD approved guidelines and adopted documents with the consent of members, but member countries and their respective governments are responsible for legal adoption and implementation, or alternatively implementation through alternative legal instruments. The IRGC work on a more informal basis, as a foundation that issues various publications to try and influence regulatory actions and scientific approaches.

In Europe, existing risk governance are predominantly linked with regulatory frameworks not specific to nanotechnologies but impactful, nevertheless. Despite the addition of specific requirements under the REACH framework for which ECHA are the main enforcement body, there exists a gap for a holistic risk governance body to carry out or assist in the work of ECHA, and other relevant authorities in Europe. This is a key motivation for the establishment of an independent RGC that could help support the adoption or dissemination of best practices for risk governance at European level. Moreover, the RGC must also consider how to best structure the organisation and development of outputs with regards to the involvement of member organisations, and any potential aims for EU and Member State adoption. The IRGC scope also provides a useful example for structuring an impartial organisation focused on risk governance.

The recommendations of this analysis and corresponding recommended practices of the RGC must represent the type of influence the RGC wishes to have, and at what scale the RGC will aim to influence the risk governance landscape, be that at EU level or at global level. Furthermore, it is important to analyse how each organisation views effective governance, whether this is judged upon fulfilling regulatory obligations or providing valuable contributions on certain specialty topics for example.

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