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Executive Summary

The NMBP-13 call launched in 2018 invited consortia to create a Council for Nanotechnology Risk Governance. Further developments in the EU landscape of organisations charged with improving risk assessment and management in the field have indicated that projects should instead focus on describing features of an Organisational Form for Nano Risk Governance. This report provides recommendations for establishing the conditions for it to succeed in support of new developments related to the Chemicals Strategy for Sustainability (CSS). To do this, the three NMBP-13 projects have performed an evaluation of current challenges in the field, done primarily through stakeholder engagement. Outcome of this evaluation has shown that, despite much progress and without discounting the many excellent activities underway by a range of actors, there is a perception that significant challenges remain to be addressed. Yet, any new initiative should be perceived by key stakeholders as being effective and useful in filling outstanding gaps.

There may be a role for a new organisation to primarily provide:

- Priority #1: more connectivity and broader engagement with key stakeholders to collect opinions and concerns and critical expertise that may not be captured in technical hazard and risk assessment alone, and need to be well understood to ensure effective risk management.
- Priority #2: access to multidisciplinary knowledge and expertise, in particular for more systematically integrating social sciences in assessment and decisions.
- Priority #3: better quality data and easier access to data sets along with appropriate tools for risk assessment.

In this context, the design of a possible new organisation has been developed, comprising the building blocks of a supporting organisation (mission, goals, and activities) and how it could be organised.

The report suggests that the overall purpose or mission should be ‘to foster safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe’ (including complex and advanced (nano) materials). A set of organisational goals are suggested, relating to risk governance, cooperation, knowledge, data, innovation and continuity.

Two main options are considered to organise the activities that such an organisation could undertake.

Option A, a "Roundtable", focuses on priority #1

The primary activity in Option A is to organise roundtable meetings where stakeholders of all sorts convene to, inter alia, gather evidence, identify issues they consider relevant, discuss possible conflicting views, and formulate joint positions on these issues (for example, as input for research programs). This provides the possibility of a substantial step forward in enhancing connectivity between stakeholders across the nano-risk governance field. The Roundtable is essentially a 'problem-solving capacity'. It is available to address technical, industrial and societal issues relating to CSS implementation. It can be mobilised upon request from the EC or by autonomous decision of its Governing Board to address particular challenges outside of but in connection with existing institutions.

However, implementing Option A on its own would mean that resources developed by the NMBP-13 projects would not be maintained, and the opportunity to add knowledge resources from future projects would be lost.

Option B, a "House" of Risk Governance, addresses all priorities

The activities in option B (and the resources required to run them) are substantially expanded compared with those in option A. Implementation of Option B substantially improves access to and curation of knowledge and data produced or shared by the current projects, and includes: maintenance of the Risk Governance Framework, maintenance of the Risk Governance Portal, monitoring progress in risk governance, and management of knowledge-based assets. If implemented, Option B would provide the most coherent response. However, it would require substantial investment from a range of actors and regular funding.

In both options, the organisation is described as an independent structure, with Members drawn from the main stakeholder groups, who commit to and support its goals, and an independent Chairperson.

A third option, Option C, is also briefly considered.

Option C involves no new organisation

Instead, one or several existing institutions implement (either of their own volition or at the suggestion of the EC) those elements which each institution considered appropriate so to do. By definition, Option C is not independent. Option C does not address one of the main challenges in the nanotechnology field, namely connection and coherence between the various activities and actors. Splitting the activities across a number of organisations does not improve connectivity.

A comparison between the proposed activities of the options A and B and the CSS actions suggests considerable synergies. The CSS is concerned with chemicals, while the activities proposed in this report are specifically about nanomaterials in Europe' (including complex and

advanced (nano) materials). This indicates that work done under both options can support the work of the CSS for this important subset of materials.

Until February 2023, NMBP-13 project partners will continue engaging with decision-makers to define operational aspects and possible business models for each option. However, it will not be their task to decide whether to implement either or any of these proposed solutions. It is nevertheless their strong opinion that, without some form of central organisation, it would be difficult to capitalize on the progress made, especially around:

- adopting a multidisciplinary and multi-stakeholder Risk Governance Framework suitable to identify, assess, manage and communicate current and future risks and benefits,
- offering a Portal to access databases, instruments, tools and knowledge-based assets that help assess risks to human health and the environment.

NMBP-13 projects are committed to stimulating open-mindedness, creativity and out-of-the-box thinking toward improved risk governance of nanomaterials.

1. Introduction and background

Inefficient risk governance of nanotechnology and more specifically nanomaterials and their applications, undermines the full exploitation of the economic and societal potential of these materials. The three NMBP13 projects (Gov4Nano, NANORIGO and RiskGONE) are working closely together to strengthen the development of more supportive risk governance, support exploitation of the full economic and societal potential of this technology.

It is widely acknowledged (e.g. in the European Green Deal) that the development of advanced materials including nanomaterials[1] and nano-related products play a key enabling role in technological solutions for addressing societal challenges across all sectors. Instead of incremental improvements to existing technologies, nanotechnology offers disruptive, game-changing breakthroughs and innovations that can provide answers and solutions to help our society, environment, and the planet. For example, nanotechnology advances are making differences in energy, environmental protection, resource management and healthcare, through the development of smart materials and connected devices. Further, nanoscience and nanotechnology, as fields, have developed multidisciplinary and multi-stakeholder ecosystems with experience and knowledge sharing. Communication between scientific, engineering, medical, and other communities has also impacted and benefited many related fields.

However, the adequacy and the balancing of these advantages against possible risks from advanced nanomaterials and products remains under debate. Despite much progress in addressing the risks from nanomaterials, issues of uncertainty and ambiguity still complicate and challenge effective risk management of nanomaterials, their production, application and waste handling. These issues pertain not only to environmental, health and safety (EHS) implications, but also to social and ethical concerns regarding emerging nanotechnologies that may cause new risks.

Despite the seeming absence of reported human health or the environment effects to date, (suggesting that the performance of nanotechnology-related risk governance in Europe is effective) there are sufficient uncertainties and concerns about specific nanomaterials and about the validity of test systems, to add doubt to such definitive conclusions. There are certain

[1] Advanced materials, including nanomaterials, are designed with a purpose to have novel or enhanced properties and improve performance over conventional materials in products and processes. https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/key-enabling-technologies/advanced-materials-and-chemicals_en#advanced-materials

nanomaterials applications that are likely to need further investigation, according to the results of some risk assessments and to certain stakeholder views.

In particular, uncertainties about the potential for long-term adverse effects remains an open question and are not well captured in current hazard and risk assessment schemes.

New emerging and more complex advanced multi-component nanomaterials or nanosystems also generate EHS concerns. The implications of developing such materials are particularly complex due to the different properties (e.g. rates of degradation, toxicities) of the separate components, their interactions within the material and interactions among components, and their more complex interactions with biological and environmental systems. These concerns are currently magnified by the lack of fundamental research and regulatory guidance to address the unique properties of advanced materials.

It is important to recognise, though, that these uncertainties and concerns are already discussed by several actors in industry, regulation and research.

All industries whose products may have an adverse impact on the environment, need to pay close attention to safety risks for reasons of legal responsibility, product liability and reputation. Likewise, all industries, and specifically the food and cosmetic industry need to address potential human health issues.

The recent policy and legislative actions in Europe demonstrate a genuine high willingness and ambition to further improve regulation and governance for all chemicals and materials. It represents an acknowledgement that the current state of regulation is not optimum and sets new expectations for considering the high level of health and environmental protection expected in Europe. The European Green Deal policy and its underlying strategies including the EU Chemicals Strategy for Sustainability and the Zero Pollution Action Plan have put higher demands on the development of innovative (advanced nano) materials and, at the same time, have increased the ambitions to address safety and sustainability in terms of ‘toxic free environments’ and ‘zero pollution’. These demands have added complexity to the already existing challenges. It underscores the need to expand/transform the European Nanosafety Community (NSC) into an ecosystem in which scientific insights in identifying and addressing nano-specific issues are connected to policy goals, standardisation processes and application in industry. The EU has placed the bar very high.

The three NMBP-13 projects have worked extensively with a wide range of stakeholders to identify and understand the further difficulties and challenges they face in this complex and changing landscape and to elaborate on possible solutions. As part of this process, they seek ways to increase stakeholder collaboration.

Consultations with different stakeholders have shown the need to promote the safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe, in line with expectations for the circular economy and the green economy. In May 2021, the three NMBP-13 partners delivered a first plan (blueprint) for a possible organisation intended to support the addressing of these concerns[2] [3] . This document was co-created through an extensive process organised jointly by the three projects, including multiple stakeholder engagements. It outlined relevant challenges and opportunities and described the mission and goals, activities and services, and potential organisational arrangements for such an Organisational Form to address these challenges.

In the present deliverable, we re-assess the original blueprint in light of the rapidly changing European policy development landscape and consider how the original plans could be adapted to support the new EU policies. In particular, the report describes two options for an Organisational Form and the conditions of success that could be appropriate to support the EC in implementing the CSS.

[2] NMBP13 JM8 Agreed mode of operation and structure for Risk Governance Council
[3] G4N D5.2 Initial NRGC operational plan: mission (mandate), operational structure and recruited initial members

2. A changing EU Agenda

Beginning in 2019 and with key steps in 2020 and 2021, several EC directorates have achieved significant and promising milestones towards ensuring the safety (and sustainability) of chemicals, including nanomaterials or nano-engineered products and systems: EU Observatory for Nanomaterials (EUON)[4], Green Deal[5], Circularity Action Plan[6], Partnership on the Assessment of Risks of Chemicals (PARC)[7], etc. In particular, the EU Chemicals Strategy for Sustainability (CSS)[8] adopted in October 2020 is one of the critical instruments of the Green Deal that, together with the Circular Economy Action Plan, outlines short- and long-term high-level ambitions towards safe and sustainable chemicals and a non-toxic environment.

Green Deal: At an overarching policy level, the European Green Deal is the EU's central new growth policy to transition the EU economic model to a sustainable model. It is intended to transform the EU into a modern, resource-efficient and competitive economy, eliminating pollution ensuring:

- no net emissions of greenhouse gases by 2050
- economic growth decoupled from resource use
- no person and no place left behind

The goal of the Green Deal is to improve the well-being and heath of citizens through eight main elements: climate action, clean energy, safe and environmentally friendly transport, a healthy food system for people and planet, investing in a green future, a competitive green industrial strategy, protecting the environment, with research and innovation driving transformative change.

The holistic approach of the Green Deal is of particular importance, as it aims to comprehensively improve the health of humans, animals and the environment. The European Green Deal outlines ambitious goals for safe and sustainable chemicals and products and a toxic-free environment, while recognising both opportunities and challenges.

Chemical Strategy for Sustainability (CSS): At an underlying strategy level the CSS addresses chemicals and supports the goals and ambitions of the Green Deal. The strategy recognises that

[4] European Union Observatory for Nanomaterials (EUON) https://euon.echa.europa.eu/.
[5] The European Green Deal https://eur-lex.europa.eu/resource.html?uri=cellar:b828d165-1c22-11ea-8c1f-01aa75ed71a1.0002.02/DOC_1&format=PDF.
[6] Circular Economy Action Plan https://ec.europa.eu/environment/pdf/circular-economy/new_circular_economy_action_plan.pdf.
[7] European Partnership for the Assessment of Risks from Chemicals (PARC) https://www.anses.fr/en/content/european-partnership-assessment-risks-chemicals-parc.
[8] Chemical Strategy for Sustainability, Towards a Toxic-Free Environment https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf.

chemicals are everywhere in our daily life and play a fundamental role in most of our activities, as they form part of virtually every device we use to ensure our well-being, protect our health and security, and meet new challenges through innovation. Chemicals are also the building blocks of low-carbon, zero pollution and energy- and resource-efficient technologies, materials and products. The increased investment and innovative capacity of the chemicals industry to provide safe and sustainable chemicals will be vital to the development of new solutions and support both the green and the digital transitions of the EU economy and society.

At the same time, some chemicals possess hazardous properties that can adversely impact human health and the environment. Certain hazardous chemicals have been shown to cause cancer, affect the immune, respiratory, endocrine, reproductive and cardiovascular systems, weaken human resilience and capacity to respond to vaccines and increase vulnerability to diseases.

Exposure to these harmful chemicals is, therefore, a threat to human health. In addition, chemical pollution is a critical driver that puts the Earth at risk, impacting and amplifying planetary crises such as climate change, degradation of ecosystems and loss of biodiversity. The goal of the CSS is a toxic-free environment. The CSS requires that new chemicals and materials be inherently safe and sustainable, from production to disposal (end of life), while new production processes and technologies must be deployed to allow the chemical industry's transition to climate neutrality. To reach the goal of a toxic-free environment, the CSS advocates a paradigm shift towards "Safe and Sustainable-by-Design (SSbD)" and "One Substance - One Assessment". This has significant consequences for the chemical industry and nanotechnology regarding its products' development, production and disposal.

The CSS has established a High Level Roundtable[9] (an expert group) to support the implementation of the strategy. Its mission is to realise the CSS's objectives and monitor its implementation in dialogue with the stakeholders concerned.

European Partnership for the Assessment of Risks from Chemicals (PARC): The PARC aims to advance research, share knowledge and improve skills in chemical risk assessment including innovative and modern risk assessment methods. In doing so, it will help support the CSS, paving the way for the "zero pollution" ambition announced in the European Green Deal. The partnership encompasses all aspects of chemical risk assessment, aiming in particular to: better anticipate emerging risks, better account for combined risks, and underpin the concrete implementation of

[9] High Level Roundtable on the implementation of the Chemicals Strategy for Sustainability (E03757) https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=3757.

new orientations in European public policies to safeguard health and the environment in response to critical issues for health, the ecology and citizens' expectations

The European Union Observatory for Nanomaterials (EUON): EUON provides information about existing nanomaterials on the EU market. "*Whether you are developing policies in the area, a consumer or representing industry or a green NGO, the information on the EUON offers interesting reading about the safety, innovation, research and uses of nanomaterials".* The EUON is funded by the European Commission. It is hosted and maintained by the European Chemicals Agency (ECHA).

What do these developments mean for risk governance of nanomaterials?

1. Except for EUON, these strategies/initiatives are focussed on chemicals, not nanomaterials. While there are many commonalities between the risk governance of chemicals and nanomaterials, there are differences based on physical form, transformation, persistence, and long-term effects. Whilst the activities foreseen in these strategies do not exclude nanomaterials, they are generally not explicitly designed to address these differences. In addition, many of the lessons learned over the last twenty years of intensive work on nanomaterial risk issues may provide valuable insights to broader chemical risk issues, *provided they are communicated/transferred effectively.*
2. There are many initiatives and many actors involved. Effective communication will be critical to success. Communication bridges could be built around specific topics, e.g. nanomaterial risks.
3. There is no clear channel or process for communication between those tasked with delivering on the strategies and the wider Nano-safety community.
4. These strategies recognise that all stakeholder groups must be involved in the development, production, sale, use and disposal cycle. It requires a dialogical exchange among stakeholders and emphasises the importance of roundtables on different topics.
5. There remains strong interest in developing, manufacturing, and marketing products based on or containing nanomaterials to strengthen safety, recyclability, and sustainability now and in the future. In addition, innovation leads to a renewed development of nanotechnology, yielding promising results in many areas.
6. The safe and sustainable use of nanomaterials requires effective risk governance today and in the future. However, in summary, concerns remain about technical risk assessment, public acceptance, and regulatory effectiveness and coordination, among other issues. This is where the NMBP-13 projects contribute, by creating a more holistic framework and place for improvements on safety and sustainability through risk governance.

7. One of the main challenges to implementing the CSS will be addressing the expectations on sustainability, because assessing and developing sustainability requires different types of scientific expertise and a different approach than those routinely present in the nano/chemical sector. However, this is not the only challenging goal. Determining what a 'toxic-free environment' is and what an 'acceptable level of risk' is, considering constraints posed by 'essentiality', which allows some exemptions, will also be quite challenging.

This deliverable posits that the EC will need more than what it has already established to implement the CSS. Some decisions will not be possible if they are only based on technical science, they will require broader deliberation with society, especially when matters of economic competition with non-EU countries will be involved.

For these reasons, we will need to connect many forces, of various types, to achieve the goals. Critical steps include the establishment of the High Level Roundtable for the Implementation of the CSS and related Technical Expert Working Groups, which follow the important initiatives with EUON and PARC, among others, and collaboration with international organisations like OECD WPNM.

3. Existing and future challenges regarding governing risks associated with nanotechnology and/or related nanomaterials

Despite many hopeful trends, the safe and sustainable development, use and disposal of nanomaterials continues to be hampered by difficulties in the risk governance process. It remains hard to pinpoint specific risks of nanomaterials. Furthermore, innovation may spur new, unforeseen and unregulated risks. Risk governance is made difficult by sometimes limited cooperation between researchers, regulators, industry and citizens. Moreover, regulatory frameworks and risk assessment guidelines and procedures remain fragmented, despite increasing efforts to align them.

Extensive stakeholder consultation has been a key element of the projects, including with industry, academia, NGOs, and government agency representatives. Primarily this has been through workshops and events, usually with the collection of views through platforms such as Menti and Mural, although other approaches, such as one-to-one interviews have also been used. Details of these engagements are reported in several deliverables[10]. Box 1 below represents the authors' summary of the views expressed through these multiple engagements.

Box 1 - Views and opinions about risk governance of nanomaterials, expressed during various NMBP-13 engagements with stakeholders

RISKS
Concerns and disagreements on nanotechnology-related risks remain, although major incidents have not yet occurred
• *Over a decade of intensive work, research has not delivered a clear consensus on nanotechnology-related risks.* • *There have been no recorded major incidents with (products containing) nanomaterials in recent years.* • *Research outcomes often differ in their assessment of the risks of the same nanomaterial.*
Innovation in nanomaterials may create (new) risks
• *Rapid innovation in (advanced) nanomaterials may lead to new, unforeseen and as of (yet) unregulated risks.* • *Nanotechnology is now increasingly combined with other cutting-edge technologies that are outside of the chemical domain.*

[10] This includes events organised by NANORIGO with proceedings in D4.3 Virtual NRGC workshop no.1 and proceedings, D4.5 Virtual NRGC workshop no.2 and proceedings, D4.8 1st. virtual Conference and proceedings, D4.9 NMBP-13 launch event and proceedings, D4.11 Virtual NRGC workshop no.3 and proceedings and D4.12 Virtual NRGC workshop no.4 and proceedings.

- *'Safe-by-design' is an upcoming concept that is not common practice yet in nanotechnologies (however, it is relatively well established in other domains). The concept of 'Sustainable by design' is even less well defined.*
- *Integrating 'Safe-by-design' and 'Sustainable by design' is a challenging task that requires multidisciplinary expertise.*

RISK ASSESSMENT

Risk assessment guidelines and procedures remain fragmented, despite efforts to align them

- *Guidelines, tools and processes for risk-benefit analysis of nanomaterials are not up-to-date or implemented.*
- *There are no common guidelines and standards for reporting and communicating risks and risk response.*
- *The new EC Chemical Strategy puts emphasis on aligned assessment of nanotechnology-related risks across sectors and regulatory domains (one substance-one assessment').*
- *Certain new developments in nanotechnology raise quite challenging issues for risk assessors. Smart nanomaterials and systems will not easily be assessed using standard chemical assessments. The same is true for advanced multi-component hybrid materials.*

COOPERATION

Cooperation between stakeholders involved in risk governance remains limited

- *An increasing number of organisations and initiatives are dealing with improving risk governance.*
- *Limited cooperation between stakeholders on risk governance leads to inefficiencies.*
- *Going forward, there is limited cooperation foreseen between policymakers and researchers on assessing and addressing the risks of nanomaterials and advanced materials.*

The European public's involvement in risk governance is limited

- *Policymakers find it hard to interest European citizens in discussions on nanotechnology-related risks.*
- *Media coverage of nanotechnology-related risks is often sensational and not based on solid facts and evidence.*
- *More factual communication would probably help to interest citizens and build trust.*

Need for transparency, trustworthiness, independence, neutrality

- *There are high expectations in society for each of these principles, which, according to some stakeholders (not all), are not sufficiently applied to improve the safety and sustainability of nanotechnology applications.*
- *Terms are often vaguely defined, or their characterisation varies among stakeholders.*
- *Some clarity is needed about what these terms mean in practice, in order to avoid frustration and disappointment.*

INFORMATION

The information landscape is complex and difficult to navigate

- *There is significant ambiguity in the way risk issues are described and discussed, causing confusion and even potential for conflict of opinions between stakeholders.*
- *There is no clear and comprehensive overview of (actors involved in) nanotechnology risk research, policies and regulation.*
- *Stakeholders find it difficult to access information on risk governance, often due to limited oversight and confidentiality issues.*
- *Civil society actors feel there is a lack of clear information on products containing nanomaterials and their risks.*

- *SMEs, researchers and NGOs often lack access to useful information and data on nanotechnology-related risks.*

DATA

The information landscape is complex and difficult to navigate

- *Regulators and industry do not always trust the validity of data and research results on nanotechnology-related risks.*
- *Researchers often use different methods to assess risks and disagree about what data to use and how to interpret the results of risk assessments.*
- *There is no common standard for data curation on (risks of) nanomaterials or data storage.*
- *The current nanosafety databases do not fully adhere to the FAIR (Findability, Accessibility, Interoperability, and Reusability) principles.*

REGULATION

Nanomaterials are regulated in separate 'domains'

- *Within the EU and the overarching REACH regulation, applications of nanomaterials are still regulated in separate domain-specific frameworks, such as for food, cosmetics or healthcare.*
- *Regulatory frameworks differ in how they define and classify (products containing) nanomaterials, although significant harmonisation is under way.*
- *Frameworks are slow to adjust to new (technological) developments because this demands thorough procedures.*
- *The new EC Chemical Strategy reinforces the ambition to harmonise regulation, based on risk assessment of nanomaterials across domains.*

INNOVATION

Safe and sustainable innovation in nanomaterials is hampered by limited budgets, knowledge and (access to) quality information

- *Nanomaterials have transformative potential: ubiquitousness (they are everywhere), pervasiveness (they spread widely), unknown reach (they are full of potential) and specificity (they are targeted).*
- *Innovators and researchers (public and private) have a limited understanding of 'safe and sustainable by design'.*
- *Industry sometimes lacks information about and tools for addressing risks of (newly developed) nanomaterials.*
- *SMEs often lack the resources, time and expertise required for robust risk management in developing nanomaterials.*
- *The EU Green Deal offers opportunities for developing inherent safe chemicals ('safer-by-design').*
- *Investors are reluctant to invest in innovation in (products containing) nanomaterials because of risk or uncertainty.*

CONTINUITY

Large-scale investment in nanomaterial risk research has built capacity and created many valuable insights and tools, but the impact on risk governance has been limited and is difficult to sustain

- *The time-limited nature of these projects often means that the outputs have limited viability, and thus impact, after the project ends.*
- *Typically, no organisation is responsible for maintaining the resources developed beyond the project's lifetime.*

Most of these challenges cut across sectors and types of nanomaterials. They are common to some extent to chemicals more generally but have specific inferences concerning NM. The same is true of advanced materials. To a great extent, it has become evident since the beginning of the NMBP-13 projects that these challenges and others are already addressed by existing organisations (and it is recognised that significant progress has been made). However, the stakeholders' feedback suggests that, up till this point, these efforts have not been sufficient and that a more inter-disciplinary approach and better inclusion of stakeholders could help make further progress. Currently, initiatives taken by the EU are not focused on addressing these issues specifically for NM.

We suggest that responding to these challenges requires focusing on three priorities, which have been described and for which response strategies have been formulated in various Gov4Nano and NANORIGO deliverables, and will be detailed under 'missions and goals' in section 7:

1) Enhancing communication, connectivity and **broader engagement with key stakeholders** to complement technical hazard and risk assessment.
2) Providing **access to** and developing **multidisciplinary** knowledge, in particular for more systematically integrating social sciences in assessment and decisions.
3) **Improving access to better quality data** along with appropriate tools for risk assessment.

In other deliverables, further approaches for addressing these three priorities have been suggested by the NMBP-13 projects under the headings of 'Risk Governance Framework' and 'Portal'.

In the view of the NMBP-13 projects, establishing an independent organisation and implementing a Risk Governance Framework could play a critical role in building trust and fostering a robust protection of society and the environment, while enabling the benefits of nanotechnologies to be safely exploited.

More precisely, the new challenges of implementing the CSS and the Green Deal raise new interest in an Organisational Form that would help with the CSS implementation. Therefore, Gov4Nano and NANORIGO are considering that a "House for Nanotechnology Risk Governance" or, more generally, a "Structure" for Nano Risk Governance that could address new upcoming questions on safety and sustainability risks related to engineered nanomaterials, would be a valuable and helpful contribution to implementing the CSS. For example, it could have the mission of acting as a sounding board for developing specific frameworks, guidelines, criteria and indicators for safety and sustainability by design.

4. NMBP-13 approach to risk governance

The NMBP-13 projects are developing a new risk governance approach for advanced (nano) materials and related products to align future nanotechnology developments with European ambitions and goals formulated in the European Green Deal and related strategies.

The projects have established and emphasised the importance of proving technical support to and engagement with stakeholders, including society, to facilitate the development of safe and sustainable nanomaterials, products and production processes, whilst aiming for zero pollution and toxic-free environments. The governance approach consists of a series of coordinated recommendations for:

1) A multidisciplinary and multi-stakeholder Risk Governance **Framework** suitable to identify, assess, manage and communicate current and future risks and benefits,
2) Instruments, tools and knowledge-based assets that help assess risks to human health and the environment, frequently grouped under the term '**Portal**', and
3) A new structure or **Organisational Form** that would coordinate (1) and (2) support their uptake by various stakeholders in regulation, industry, research and civil society. A first proposal was made in May 2021 (see 'Blueprint for a Nanotechnology Risk Governance Council", that developed considerations for a 'Council')[11].

The initial **blueprint** produced by the three NMBP-13 projects between January and May 2021 was used by the projects during consultations between June and September 2021. It described possible options for a 'Council' that the projects were designing and planning to establish by the end of 2022 with an outline of the current context (industrial, social and regulatory landscape) of the risk governance of nanotechnology in Europe.

The initial blueprint adopts a position to **support EU policy** guiding principles and concerns, including that

- **Innovation** brings large potentials but also uncertainties;
- **Safety, circularity and sustainability** must be strengthened for the present and for the future, which will require effective risk governance; and
- Some critical concerns remain about **technical risk assessment, public acceptance and regulatory effectiveness**, among other aspects.

[11] G4N D5.2 and "appendix" to the version of this report delivered by NANORIGO

The collaborative consortia of the NMBP-13 projects recognise the importance of taking into account the values of trustworthiness, inclusiveness, co-creation, transdisciplinarity, transparency, data FAIRness and adaptability in order to meet the requirements of a futureproof and broadly accepted risk governance approach, embedded into an Organisational Form that could become the leading voice for these principles in Europe.

The CSS will have a tremendous social impact and has changed the policy context of the NMBP-13 projects by putting more emphasis on safety and sustainability. Providing support to the EC and stakeholders (primarily national regulators and industry) in implementing the CSS could take various forms, complementary to existing initiatives such as with the High Level Roundtable and technical expert working groups.

Challenges (cf section 3) faced in the domain and associated opportunities, include:

- **Uncertainty** related to future developments and risks of new (emerging) nanomaterials and nano-based products and systems;
- The current **fragmentation** of risk assessment and regulation;
- Limited connectivity and **cooperation between stakeholders**, which in some cases leads to ambiguity, diverging risk perception or concerns that information about knowledge, tools and data are insufficiently shared, understood and taken into account.

In that context, we identified through consultations that a relevant **mission** and role for a new organisation would be: fostering and governing safe and sustainable development, use and disposal of products containing nanomaterials. This mission would place the new organisation in the context of the CSS and actions to implement it.

It was found that conditions of success would include:

- **Independence, transparency and trustworthiness** recognised by a range of stakeholders, which the organisation will engage with and support through dialogue and co-creation; a process that should trigger the ability for the organisation to generate its funding;
- **Ability to bridge** between knowledge generators, users and decision-makers;
- **Agility and adaptability**.

Eventually, a list of possible services or **activities** was proposed. The list was comprehensive enough to accommodate various needs as would be determined by the Governing Board of the organisation and its core stakeholders or funders. It was not prescriptive. Some of the activities could be best organised by existing organisations. Others could be more suitable to or would even need a new organisation conceived as a neutral convening place, access to existing data and

tools and a place for debate and dialogue to advance and safeguard risk governance of nano-based products and systems.

It is recognised that several European organisations are already charged with risk assessment and management of nanomaterials and, furthermore, new initiatives since 2019 (when the NMBP-13 projects started) have been tasked with addressing or working to address some of the remaining challenges, with activities specifically dedicated to filling gaps in the current knowledge assessment, access and transfer, and in the regulatory landscape.

In particular, EUON, the High Level Roundtable and its ten working groups created to implement the CSS and the PARC initiative appear to or could address some of the challenges identified in the NMBP-13 projects. Furthermore, there is significant activity by the industry (e.g. CEFIC[12]) and others such as JRC[13] and EEA[14] to work to implement the CSS.

Under these conditions noted above, and as a consequence, some of the challenges, missions, roles and activities described in the blueprint most probably do not need a new organisation such as the 'Council' requested by the NMBP-13 call launched in 2018, and as described in the contractual description of actions (DoA) of the three projects.

Therefore, NMBP-13 partners have engaged in an active round of consultations with stakeholders in several workshops and interviews organised between November 2021 and January 2022 with national regulators, industry, research representatives, NGOs, as well as various units of the EC.

To develop proposals, they have:

- Tested and validated some overall assumptions, including the extent to which it would be useful to create a new organisation and the relevance and usefulness of different types of activities for various types of stakeholders' needs or concerns. For example, four assumptions regarding the state of nanotechnology risk governance and main needs and expectations were discussed in two workshops on 1st and 2nd December 2021.[15]
- Summarised key features of a possible organisation designed to address outstanding challenges (i.e. those identified from 2019 to mid-2021 *minus* those addressed by new EU initiatives launched in the same period of time).

[12] see CEFIC's position on the CSS and suggestions to implement it: https://cefic.org/policy-matters/chemicals-strategy-for-sustainability-css/. Also: CEFIC's suggestions for 'safe and sustainable by design': https://cefic.org/a-solution-provider-for-sustainability/safe-and-sustainable-by-design/.
[13] see JRC's work on SSbD: Patinha Caldeira, C., Farcal, R., Moretti, C., Mancini, L., Rauscher, H., Rasmussen, K., Riego Sintes, J. and Sala, S., Safe and Sustainable by Design chemicals and materials. Review of safety and sustainability dimensions, aspects, methods, indicators, and tools, doi:10.2760/68587, https://publications.jrc.ec.europa.eu/repository/handle/JRC127109.
[14] see for example work from the EEA on developing criteria for 'safe and sustainable by design'
[15] NR D4.11 Virtual NRGC workshop no.3 and proceedings and D4.12 Virtual NRGC workshop no.4 and proceedings.

If a new organisation is needed, its goal should probably be formulated in a way not to be exclusively linked to the CSS. It should be adaptable to current or future policy issues marked by ambiguity and uncertainty, or that appear to be neglected, ignored or just emerging, and require flexibility and agility for co-creating more collaborative, robust and resilient strategies that can overcome the challenge of regulatory fragmentation.

5. Options for a new Organisational Form

The NMBP-13 projects will not establish a new organisation that might provide competitive services to those of established institutions. Here we focus on outlining the conditions of success of a new Organisational Form to deliver on the goals and tasks broadly described above and in some more details below.

5.1 Major expectations

In broad lines, any new Organisational Form should:

- Support the operationalisation of a risk governance approach appropriate for new challenges faced by the field of nanotechnology, in complement to existing organisations and their mandates.
- Support the implementation of the European Chemicals Strategy for Sustainability for nano-related issues by providing nano-specific information to various actors and working groups.
- Fully embrace new (currently being developed and future) nano-based products and systems, considering a broadening of scope from nanomaterials to new/advanced (nano)materials.
- Support effective exchange of knowledge and knowledge needs to inform scientific and regulatory research and address the challenges faced by stakeholders. This could be done in various ways, including acting as a scientific sounding board.
- Getting the proper knowledge and data in the right place in the most efficient and effective way (e.g., contribute to the sharing, access (transfer) and re-use of information on (nano)-materials, based on FAIR principles).
- Pay particular attention to the challenges that national regulators in the EU Member States face in implementing the CSS and effectively using the best available knowledge for regulatory purposes, including through harmonisation and standardisation (goal: getting the right knowledge and data in the right place in the most efficient and effective way).

5.2 Main features

More than a new organisation, what would be needed is a **generic 'problem-solving capacity'**. This could add value in specific areas such as refinement and implementation of the CSS, and perhaps more particularly on how to design and implement 'safety and sustainability by design' and 'circularity'. This would not necessarily provide 'solutions' directly implementable in regulatory risk assessment or management, for example, but offer a **place and process** where collaborative response strategies can be developed.

Based on a multidisciplinary scientific approach and multi-stakeholder internal organisation and process, the organisation could **engage in co-creation and help bridge** (a) policy issues and industry priorities related to implementing the CSS, and (b) possible response from science and research. It could also organise informal dialogues between the EC, Member States (to better connect them), regulators, industry and civil society organisations (to ensure that all relevant perspectives will be included and communicated).

5.3 Key activities

A new organisation could therefore prioritise the provision of assistance in developing and implementing the CSS and, in particular, the concepts of SSbD, circularity and essentiality, for reaching the goal of a toxic-free environment. To this end, it would ensure:

- The provision of **access to information and expertise** on nanomaterials and their risks and benefits through the Portal (selected databases, including data management and curation, selected tools and toolboxes, DSS, methods and standardisation);
- The maintenance, further development of and support for using the **Nanotechnology Risk Governance Framework**, which provides operating principles and guidance for risk governance (assessing, managing and communicating risks), and access to relevant information. The framework explicitly emphasises the need to engage with stakeholders and to broaden risk assessment to concerns and opinions;
- Recommendations for **engaging with stakeholders**, for improvement of risk assessment, evaluation of risk acceptability, effective risk management and appropriate risk communication. In general, its key activities should prioritise the development of awareness, skills and competencies, and new strategies to address new, neglected or contested challenges.

5.4 Three options

In our opinion, at this stage, there could be three options for a new "Organisational Form", which could be further tested and refined before the projects end in February 2023.

Option A: Roundtable

The first option (A) is a light, yet evolutive, model that can adapt and be upgraded if desirable: a Roundtable. The Roundtable would focus only on the 'problem-solving capacity' and can be mobilised upon request from the EC or by autonomous decision of its Governing Board to address particular challenges outside of but in connection with existing institutions.

In analogy with special taskforces created by the EC in the past few years to collect advice and respond to specific issues[16], the mission of the Roundtable would be to mobilise experts from a broad international network and range of disciplines to rapidly come up with proposals.

- A flexible, responsive Roundtable can stimulate or augment other activities or initiate and encourage reflections and provide opinions, perhaps similar to how the EU Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) operates[17].
- The Governing Board should be representative of various stakeholders and disciplines. Its role would primarily be to mobilise resources from a larger pool of people associated with it, and who can be selected based on the specific issues being addressed.
- Such a Roundtable would be hosted or managed by an established body, which may need to be an organisation of the EU, with participation from Member States, industries and NGOs. The alternative might be a collective of experts that gain mutual benefit through working together, almost like a semi-permanent consortium bidding for EU funding, with the overheads associated with this borne by participating Members.

In this capacity, the Roundtable would be entirely dedicated to being a place for informal and innovative dialogue and experiments with the goal of becoming a force of propositions to address complex challenges.

Option B: House for Risk Governance

The second option (B) is the 'House' model suggested by the NMBP-13 coordination since September 2021. It elaborates from the same basis as Option A, so ***includes* the Roundtable**, but adds responsibility for managing essential resources and infrastructures necessary for organising the activities, providing the services, and ensuring effective outcomes.

The House would have permanent staff and be able to provide some of the services described in the blueprint, which will be prioritised in further consultations.

Although uncertainties would need to be clarified regarding hosting and resources, the **development and maintenance of the Portal (for access to information about data and tools) and the Framework would be key activities** supported by the House, which would be

[16] The EC has some experience creating taskforces, high level expert groups, or platforms with similar goals. Examples include:
- the Platform for Sustainable Finance (https://ec.europa.eu/info/business-economy-euro/banking-and-finance/sustainable-finance/overview-sustainable-finance/platform-sustainable-finance_en) which succeeded a technical expert group on sustainable finance (https://ec.europa.eu/info/publications/sustainable-finance-technical-expert-group_en),
- the High-level expert group on AI https://digital-strategy.ec.europa.eu/en/policies/expert-group-ai, which produced several reports leading to the proposed EU framework regulation on AI.

[17] https://health.ec.europa.eu/scientific-committees/scientific-committee-health-environmental-and-emerging-risks-scheer_en

organised along the principles detailed above (multidisciplinary scientific evidence and multi-stakeholder dialogue in a neutral and independent convening place):

- A major outcome of the NMBP-13 projects, the Portal is designed as a web portal that provides all stakeholders access to the most recent and validated information (data, tools, platforms, frameworks, etc.) from diverse sources and for different purposes.
- The House would support the diffusion and adoption of the comprehensive multidisciplinary and multi-stakeholder Nanotechnology Risk Governance Framework.

Option C: Integrating selected activities into an existing institution

Under Option C, no new Organisational Form would be established. Instead, an existing institution, or several existing institutions, would implement (either of their own volition or at the suggestion of the Commission) those elements developed within the NMBP-13 projects, which each institution considered appropriate. This could range from a full implementation of Option A to just a selected few elements from either option. Whilst no recommendation is made as to which institution may be interested in doing this, there are clear synergies between what has been proposed and existing institutions such as ECHA (and EUON), JRC, EEA, PARC, etc.

The three options are summarised below.

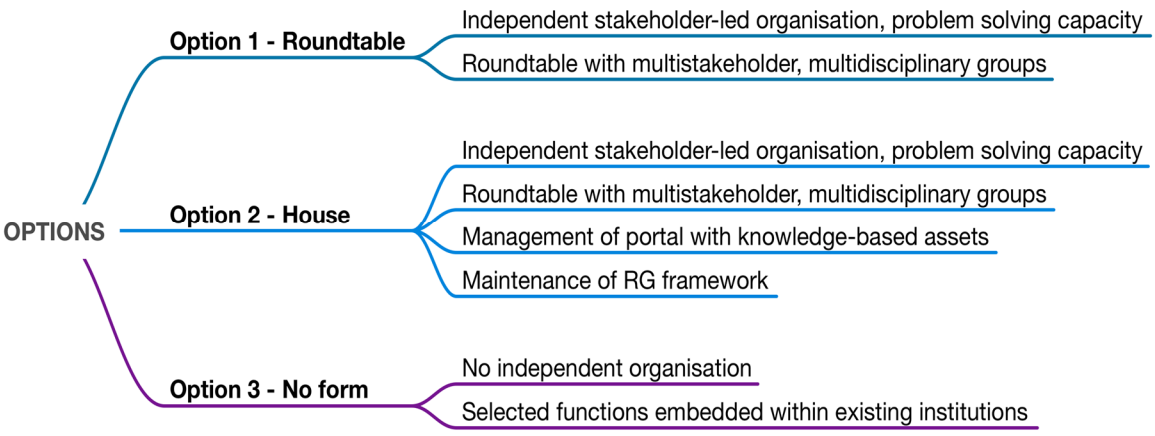

Figure 1 – Summary of the three options

In conclusion, the main difference between the House and the Roundtable results in major differences in investment and resources: higher and permanent in the case of the House, smaller

and more ad-hoc in the case of the Roundtable. These options are further elaborated below (Section 7: design considerations).

6. Conditions of success

Consequently, and even more importantly than creating a structure, and through their work and as a major outcome of the projects, the NMBP-13 partners are listing and describing the conditions of success of a new Organisational Form that would serve to improve the governance of risks and opportunities created by the use of nanomaterials going forward. Conditions of success related to the business plan will be developed in more detail in Nanorigo D7.5. Some conditions of success will depend on specific organisational designs and decision processes, which the leading actors and Governing Board will choose.

The first and most important condition for success is that leading actors perceive the new organisation as **effective in filling the gaps** that remain after the challenges described in sections 2 and 3 are addressed by existing organisations.

Other conditions of success include that:

- The organisation operates with **openness and transparency**, respecting the following organisational and operating principles:
    - Transparent membership and funding structure;
    - Public terms of reference;
    - Public internal processes;
    - Chatham House rules for workshops and internal meetings;
    - Commitment to publish output;
    - Strong and balanced stakeholder engagement.
- As a result of these principles being implemented, stakeholders recognise that the organisation provides a **trusted environment** in which all their views are taken into account: For example, all stakeholders will participate in the identification, prioritisation and framing of the issues that the organisation will be requested to address and in the elaboration of the recommendations made.
- There is a broad agreement among a range of stakeholders from various groups (public policy and regulatory institutions at EC and Member State level, industry, research and NGOs/CSOs) that the new Organisational Form **adds value and is helpful** to them and, therefore, that these representatives of stakeholder groups **commit to participating**, including if necessary, with funding in proportion to their capacity to pay, and with in-kind expertise. In summary, the judgement about whether the organisation is valuable and needed is not made by one actor only, e.g. the EC, but by collective decisions of leading actors in the nanotechnology sector.

- The Governing Board of the new organisation is composed of individual **Members representing various sectors, actors and disciplines**. General criteria for selecting individual Members include representiveness, legitimacy and transnational interest, measured by specific indicators (see, for example, NANORIGO D4.6 Database of NRGC potential members). Selection should be a collective decision.
- In addition to providing services and recommendations considered of high quality and value in broad terms, the new organisation should also be able to challenge the status quo in various ways, for example when the current state of knowledge and institutional approaches to nanotechnology safety and sustainability seem too conservative or protective of particular interest. Furthermore, the organisation should demonstrate an **ability to be agile** (for example with agile governance) and adaptive in its practices as challenges and knowledge evolve. Doing so, a condition of success could be the ability to act as a test bed (experimentation) for innovative ways to ensure safety and sustainability, and to suggest regulations that can adapt to new knowledge and needs.
- In economic terms, **various actors agree to provide funding** to the new organisations to cover the costs of the services that will be delivered. Since it is described as a multi-stakeholder organisation, actors would, in principle, include the EC, Member States (regulators), industry, NGO/CSOs and academia. The assembly of Members can decide financial contributions in proportion to the Members' ability to pay (without compromising the neutrality and independence of the organisation).
- Other conditions of success depend on organising principles (including options for business models and funding) that match requirements and expectations. Further details are provided in the next section.

7. Design considerations for each option

In this section, we consider in more detail what the building blocks of a supporting organisation could be (purpose, mission and goals, activities) and how it could be organised to support the CSS implementation.

7.1 Purpose and mission

What goals should such an organisation pursue to address the challenges and opportunities listed in section 3? An overall purpose or 'mission' is proposed: 'to foster safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe'. The organisation would focus on the whole extent of the production chain, both on nanomaterials themselves and on the products within which they are used. In addition, the organisation should address health, environmental and economic risks and benefits.

7.2 Goals

To achieve the stated mission, a set of organisational goals are suggested. These are intended to address the challenges described in Section 3 and are based on the priority actions identified, namely:

1) **More connectivity and broader engagement with key stakeholders** to collect opinions and concerns and benefit from critical expertise that may not be captured in technical hazard and risk assessment alone, but need to be well understood to ensure effective risk management
2) **Access to multidisciplinary knowledge,** in particular for more systematically integrating social sciences in assessment and decisions, which should rely on the best available knowledge and expertise across a range of disciplines
3) **Better quality data and better access to data sets** along with appropriate tools for risk assessment

The organisation could help improve stakeholders' understanding of (emerging) nanotechnology risk issues by working towards these goals. In doing this, the organisation should promote stakeholder dialogue, especially between industry and regulators, which can help to raise awareness and address regulatory concerns in the early stages of innovation. It could also increase cooperation among stakeholders and help them navigate the risk governance landscape. In addition, it should assist efforts to improve regulation, (access to) quality data and more. Ideally, this can shorten the time for novel nano-based products to reach the market.

Moreover, the organisation will facilitate the transfer of current and future knowledge on the safety and sustainability of advanced nanomaterials to regulatory guidance (e.g., REACH, biocides, consumer products, food and feed, medical technologies) and standard guidelines (i.e. OECD, ISO and CEN). This will contribute toward increasing regulatory preparedness, which refers to the capacity of regulators to anticipate any EHS challenges posed by the emerging materials early enough to take appropriate action, thus ensuring high levels of health and environmental protection.

The goals are summarized in the figure below.

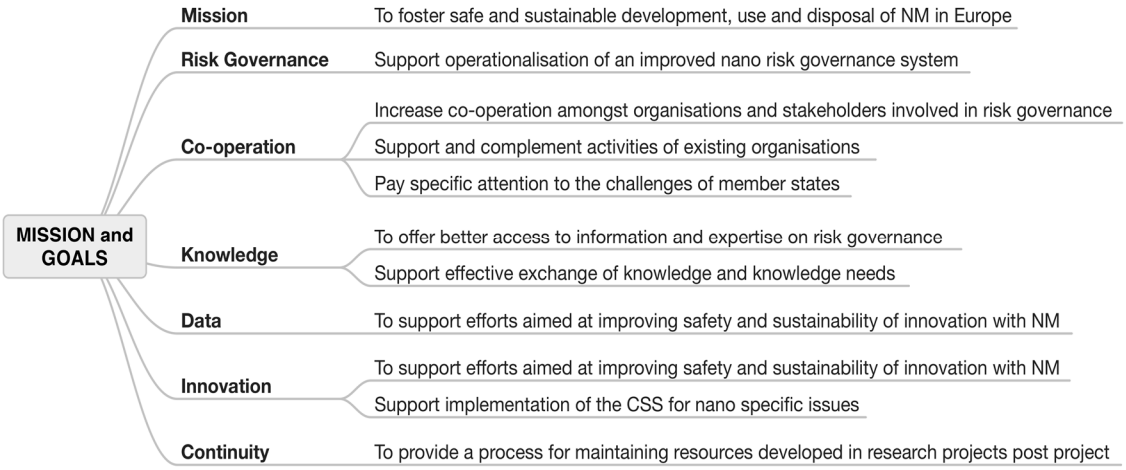

Figure 2 – Mission and goals

7.3 Activities

A set of activities have been defined through which the organisation would achieve its stated goals. In line with the pre-condition mentioned in the previous section, these activities are intended to supplement, complement and support those currently provided by other actors in the field, for example by linking activities and actors across (regulatory) domains. Accordingly, there are substantive differences in the range of activities (and resource needs) between Options A and B.

Option A: Roundtable

The Roundtable option **focuses on Priority 1: *more connectivity and broader engagement with key stakeholders* in risk governance**. The primary activity here is to organise roundtable meetings where stakeholders of all sorts convene to, among other things, gather evidence, identify issues they consider relevant, identify possible conflicting views, and formulate joint positions on these issues (for example, as input for research programs). Roundtable meetings could also be organised to develop joint strategic plans that are both precautionary and innovative to strengthen risk governance in a way that improves innovation, knowledge production, regulation, and risk management.

Roundtables could be set up as "standing" to address a sequence of issues or questions, or they could be set up as one-off workshops (or short series of workshops) to address a specific issue. In either case, typically, the working method would be workshops (either physical or virtual) with some working between events. There would be a need for transparency around membership, process and output with the expectation that the output would be public. A register of Members would also be required to be established. The NMBP-13 projects have established a database of key stakeholders, which could serve as a basis for this register.[18]

Ongoing management and coordination of these groups and the register would be an integral and necessary task to select or accept assignments, maintain the appropriate participation, and ensure efficient working and timely delivery and curation of outputs.

Several stakeholder events have been organised as part of the 3 NMBP projects. These provide a model of how such roundtables may be organised, their working processes and how the outputs could be presented. These include:

- Fair data manager network
    - A group of data managers was established to gather evidence about the level of awareness about FAIR data and to consider the incentives/disincentive relating to the promulgation of FAIR principles. A deliverable report is available[19].
- Nanomaterials risk assessors
    - A group of experts was established and brought together in two workshops to address the question "How to govern risks of particles and nanomaterials in the work environment" The output was presented as a "policy and governance brief",

[18] NMBP13 JM6 -Agreed list of invited members for Risk Governance Council; NMBP13 JM18 -Coordination meetings, stakeholder database, communication activities
[19] G4N D1.2 Report and ready-to –use methods (tools, training sessions) on how to improve data findability and accessibility

a 3-5 page technical document outlining research and policy recommendations, split into four main sessions (background, issues at stake, gaps and roadblocks, way forward: research and policy needs). Further information is available[20].

- Trans-regulatory risk assessors
    - Around 50 participants from various regulatory domains were brought together in two Trans-regulatory Risk Analysis Summits (RRAS 2019, RRAS 2022) to address the lack of trans-disciplinary knowledge on risk assessment of NM. This provided a forum to discuss risk assessment needs and expectations of stakeholders across disciplines and domains and, together, find solutions to address the complexity of risk analysis for nanomaterials[21].
- Network of tools & methods owners and users
    - A network of tools developers and users was established, and an online workshop was held to share information to discuss priorities for tools
- User committees' network
    - The User Committee comprises thirteen experts representing research, industry, regulation and civil society organisations. It was consulted regularly since 2019 and served as a sounding board for testing interim suggestions from the various core groups established by the NMBP-13 coordinators, and providing advice on needs from stakeholder groups and how the NMBP-13 projects could meet their expectations for improving nano risk governance.

The proposed activities foreseen under Option A are summarised in Figure 3.

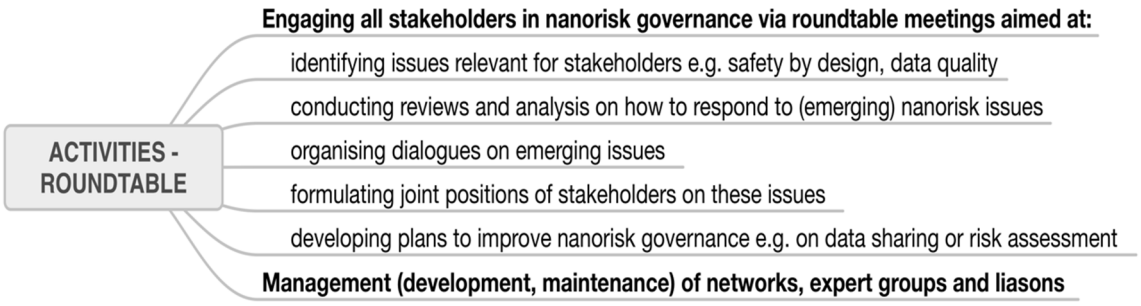

Figure 3 – Activities in Option A (Roundtable)

[20] G4N D5.6: Reports on NRGC case studies (Pending)
[21] G4N D5.3: D5.3: Final Report on Regulatory Road- and Research-Map (Pending)

An illustration of how the Roundtable could be composed and operate, and what kind of decisions it could make, is provided by an analogy with the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). The SCHEER, on request of Commission services, provides scientifically informed 'Opinions' [22] on questions concerning emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other European Union risk assessment bodies. The SCHEER itself can create sub-committees to implement some of its activities. The Roundtable could operate in a similar way.

However, in contrast to the SCHEER, the Roundtable that the NMBP-13 projects recommend should not work only on request from the European Commission. It should have some form of independence in selecting topics that, in the view of its Governing Board (see below), would be relevant to its mission and needed to inform public policy and regulation.

Box 2 below indicates some examples of topics that could be addressed by the Roundtable in an open, flexible and agile manner.

Box 2 - Examples of topics that could be addressed by the Roundtable

The Roundtable could, for example, discuss the following questions or concerns.

- **Appropriate response when (if) signals become visible that a public health or safety crisis is emerging?** This can be in relation to a chemical or biological product involving nanomaterials or advanced materials, because of various and sometimes conflicting views on the safety and sustainability of the products that contain NM (example: rubber tyres).
- **How to develop SSbD for smart nanomaterials across domains?** The concepts of safety and sustainability require very different instruments for their assessment. While the former assesses the properties of a product in a known environment, the latter should focus on assessing long term impact of a product in a future ecosystem. Ongoing work from JRC and EEA addresses this issue. But given the underlying uncertainty and ambiguity around the concept and tools to assess sustainability, more use of social science may be needed that what is currently under way.
- **How to develop Life Cycle Assessment (LCA) methods that account for challenges posed by uncertainties in new nanotechnology development?** The 2022 JRC report about SSbD criteria mentioned above suggests that safety by design could be evaluated using methods for risk assessment, whereas sustainability by design would require LCA. Yet current LCAs are ill-designed for long-term sustainability and in particular for new technology applications and products.
- **What does it mean for consumers (or more generally affected public and society) to move towards a 'toxic-free environment'?** While this concept can make sense to experts, it may be

[22] https://ec.europa.eu/health/scientific-committees/scientific-committee-health-environmental-and-emerging-risks-scheer_en

understood in many different ways by lay-people who may have diverse interpretations or perceptions of toxicity and a toxic-free environment. For the CSS to succeed, there must be a broad societal agreement on this issue, which will only be possible after deliberation with society through multi-stakeholder involvement activities. Are the current organisations charged with implementing the CSS doing this?

- **How should 'essentiality' be defined?** Similarly, the balancing act between removing harmful chemicals and authorising them if they are 'essential' and if no acceptable substitute exists (see concept of 'essentiality' described in the CSS) will result from a definition of what 'essentiality' means and to whom, which will require broad consultations and probably difficult negotiations with important stakeholders from industry and NGOs. Are the current organisations charged with implementing the CSS doing this?
- The CSS reminds that "Global strategic objectives and targets are needed for an ambitious international framework that addresses the current fragmentation and fosters coherent policies and action by all relevant international organisations, governments and stakeholders, including industry." (cf CSS page 22). International collaboration often requires different venues at various levels (governmental, non-governmental) and the Roundtable considered could be one of those, with mission to explore and experiment across regulatory cultures.

Option B: House of Risk Governance

Option B includes all of the Roundtable activities foreseen under Option A but also focuses on **Priority 2:** ***access to multidisciplinary knowledge (and expertise)*** and **Priority 3:** ***better quality data and better access to data***. Hence the activities in this option (and the resources required to run them) are substantially expanded compared with those in Option A. Option B includes four additional activities: maintaining the Risk Governance Framework, maintaining the risk governance Portal, monitoring and management of knowledge-based assets.

Risk Governance Framework: The House develops, maintains and implements a multidisciplinary and multi-stakeholder Risk Governance Framework. This comprehensive and formally structured voluntary system provides stakeholders with clear guidance to govern nanotechnology-related risks effectively. The Framework offers guidelines and recommends processes for assessing, managing and communicating risk. Stakeholders can use the Framework to improve the quality of their processes and decisions. The Risk Governance Framework is one of the key outputs of the three projects. Currently, it is still at a prototype stage, but it is intended to be fully implemented by the end of the NMBP-13 projects. The Framework

has been extensively described in various reports[23]. This is one of the key assets which will be managed and further developed under Option B.

Portal: Central to the provision of these services will be an online portal or 'platform' providing a single, trusted point of access for users and stakeholders. The primary purpose of the Portal is to help stakeholders navigate the risk governance landscape and improve access to nano risk-relevant information and data. It combines several functions. It offers stakeholders easy access to data, information and tools (developed by the new Organisation itself and others) and support to use them. This includes descriptions of what is known about (types of) risks and benefits, key themes and actors, available tools for analysing risks and benefits, and links to relevant sources such as databases, research repositories, regulatory frameworks and innovation policies. The three projects have jointly developed the risk governance Portal as one of the key outputs of the consortia. A major aspect of the Portal is the facility to incorporate new information or outputs of future risk governance projects (e.g. those funded under (NMBP14/15). Currently, the Portal is still at the prototype stage, but it is intended to be fully implemented by the end of the projects. The Portal has been extensively described in other reports[24]. This is the second key assets that will be managed and further developed under Option B.

Monitoring Scheme: In addition, the Portal includes a dashboard with indicators to monitor the current state of risk governance in Europe. Indicators developed are based on six broad areas of activity: standardisation, fair data and data quality, innovation and governance, funding and value of the investment, SSbD and communication. All indicators are quantifiable and are intended to be updated regularly (annually). The scheme is based on a balanced scorecard approach and combines the indicators to provide an overall picture of risk governance in Europe relative to a baseline. It is a unique resource developed as part of the projects[25].

Management and further development of knowledge-based assets: The three projects have jointly developed several essential knowledge-based assets. These assets will be managed and further developed under this Option. In almost all cases, these will be made available through the Portal, but the work to promote and curate these is the responsibility of the House. They include:

- Portal – described above.
- Framework – described above.
- Risk governance monitoring scheme – described above.

[23] NMBP13 JM1 -Shared working document on Nano Risk Governance Framework & Portal; NMBP 13 JM17 -Final version of the Risk Governance Framework (pending).
[24] JM1 -Shared working document on Nano Risk Governance Framework & Portal; JM14 -Final decision on potential merging portal, cloud platform, and web tool (pending).
[25] G4N D7.4 Monitoring Scheme for Risk Governance (pending).

- Portfolio of “policy and governance briefs”. These are short technical documents outlining research and policy recommendations, split into four main sections (background, issues at stake, gaps and roadblocks, and way forward: research and policy needs). At the time of writing this report, a number of these are under development.
- Multiple project deliverables: These include reports on stakeholder engagements and workshops, among which: methodologies and protocols used and outcomes, design considerations, recommendations on FAIR data quality evaluation, research recommendations etc.
- OECD test guidelines: A set of OECD test guidelines has been developed (and validated) as part of the project activities. The publication route for these is through OECD, but the availability of draft guidelines on the Portal will raise awareness within the community as they are developed.

These activities are summarised in Figure 4 below.

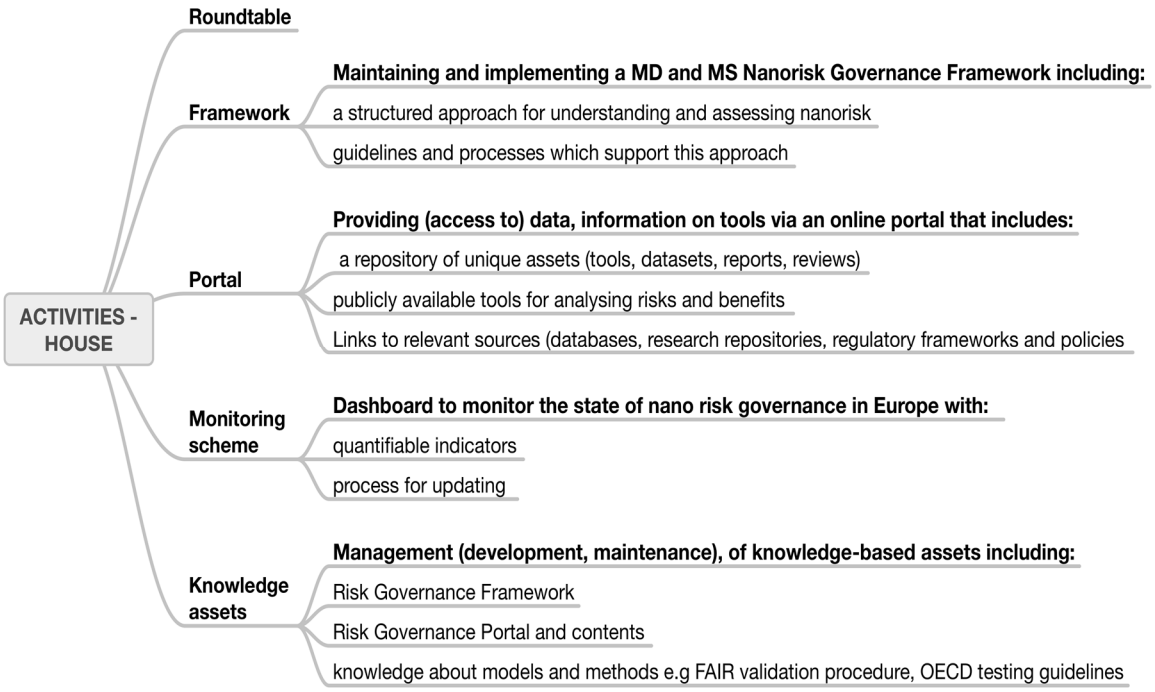

Figure 4 – Activities in Option B (House)

Option C: No new Organisational Form

The activities for Option C would be set by the adopting institutions. They could choose whichever subset of the activities suggested for Option A or B would add value to their existing activities,

subject to appropriate agreements concerning Intellectual Property (IP) or other ownership or licencing issues.

7.4 Organising principles (including options for business models and funding needs)

Under Options A and B, the Organisational Form is, at this stage, described as an independent structure, with Members drawn from the main stakeholder groups, who commit to and support its goals (financially or in-kind). Participation from EU agencies, EU countries and invited stakeholders from non-EU countries establishes broad representativeness and helps establish the Organisational Form's legitimacy and acceptance.

Under both options, the Organisation would comprise a Governing Board (Board of Members) with a chairperson that can be appointed by its Members. The Governing Board would set the strategic agenda, which would include themes and topics to focus on. In addition, the Organisation would involve experts in 'expert groups' on key issues, such as regulation, innovation, etc. Several different funding options could be considered, but all likely require an element of grant funding.

Under Option A, a light organisational arrangement is envisaged. Without the requirement to maintain the Portal, Framework and other knowledge-based assets, requirement for executive staff (and associated cost) would be substantially lower, and possibly not even a necessity. As a minimum though some level of secretariat support would be necessary. However, it should be considered that if these aspects are not supported, then unless alternative hosting agreements can be made with other institutions, then this option will not continue. In any case though, the appointment of an independent Chairperson, along with a Governing Board is considered to be highly desirable so as to maintain the independence of the organisation.

As described above, the closest example of this type of organisation is the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), a scientific committee created by the EU to provide advice on public health. The Roundtable could operate with a similar mission but focusing on nano-related issues. However, there are notable differences: SCHEER is funded by the Commission, which also provides the secretariat. SCHEER only provides opinions upon request from Commission services, whereas this report proposes that the Roundtable could set its own agenda. SCHEER members are appointed by the Commission, whereas our proposal is based on a broader stakeholder membership selection.

Under option B, executive and research staff would be necessary to manage the additional activities and assets, which would require significant funding.

Figure 5 below summarises the main organisational aspects. Many membership and public organisations have a similar type of structure.

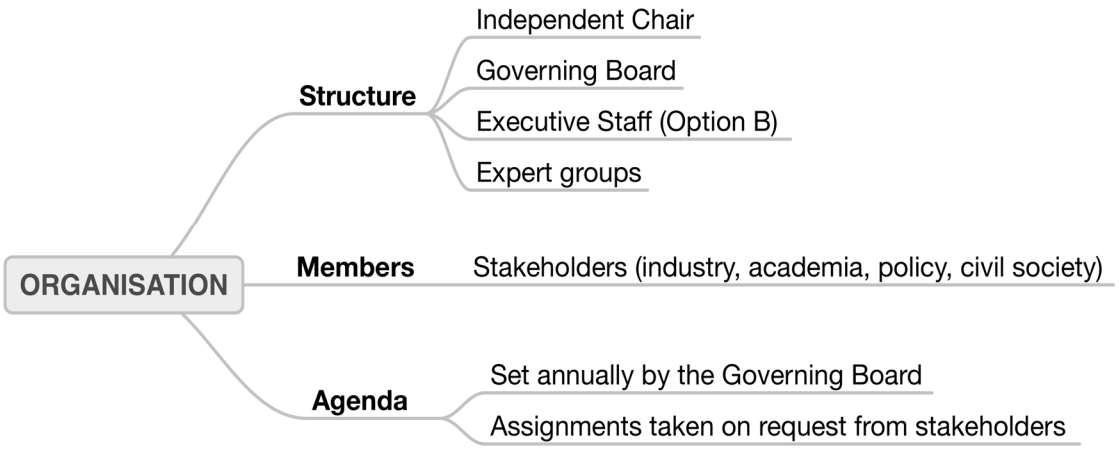

Figure 5 – Organisation

Option C

The organisational model for Option C would be set by the adopting institution. It is unlikely that this would include an independent Chair or Governing Board, which may limit the perception of its independence.

7.5 Supporting CSS and other policy initiatives

In all options, the Organisational Form will provide contributions to support the CSS through the activities proposed. This is summarised in Box 3 below (including results already produced).

Box 3 - Alignment of activities with CSS actions

Activities proposed	Relevant CSS action
Roundtable (Option A, B)	
The Roundtable offers the infrastructure for stakeholder engagement, interaction and collaboration.	• Establish an EU-wide safe and sustainable-by-design support network to promote cooperation and sharing of information across sectors and the value chain and provide technical expertise on alternatives • Engage with stakeholders to increase the EU's strategic foresight on chemicals • Promote interregional collaboration along sustainable chemicals value chains, through smart specialisation, in order to accelerate the development of joint investment project
Several networks are established: a) Advanced Nano Implementation Network for FAIR data b) EU risk assessors via the organised summits c) Access to national representatives of Authorities d) International nano network (ISISS[26]) Stakeholder network	• Establish an EU-wide safe and sustainable-by-design support network to promote cooperation and sharing of information across sectors and the value chain and provide technical expertise on alternatives
The research needs (regulatory roadmap), as a result of the EU risk assessors' summits, the stakeholder interactions, etc. Establish and update available tools, develop novel tools and identify current gaps	• Establish and update a research and innovation agenda for chemicals, driven by an EU-level Coordination Group that would also promote the regulatory uptake of research findings
Framework (Option B)	
Promotion of sound risk assessment and management of nanomaterials internationally.	• Promote the sound management of chemicals through international cooperation and partnerships, in bilateral, regional and multilateral fora, including through cooperation with Africa, as well as cooperation with neighbouring countries and other partners to support their capacity to assess and manage chemicals in a sound manner
Portal (Option B)	
The risk governance portal facilitates information and knowledge sharing and offers a platform for networks. The Portal and platform give access to various	• Establish an EU-wide safe and sustainable-by-design support network to promote cooperation and sharing of information across sectors and the value chain and provide technical expertise on alternatives

[26] Islamic State of Iraq and Syria.

platforms hosting data (FAIR), methodologies and models, educational material and tools	• Map and address safe and sustainable-by-design skills mismatches and competence gaps, and ensure adequate skills at all levels - including in vocational and tertiary education, research, industry and among regulators • Develop methodologies for chemical risk assessment that take into account the whole life cycle of substances, materials and products • Develop a common open data platform on chemicals to facilitate the sharing, access and re-use of information on chemicals coming from all sources • Establish tools and practices to ensure that relevant academic data is easily and readily accessible for safety assessments and is suitable for regulatory purposes • Foster multidisciplinary research and digital innovations for advanced tools, methods and models, and data analysis capacities to also move away from animal testing
Expertise with FAIR data development and the establishment of an Advanced Nano Implementation Network for FAIR data a) workflows for FAIRer and quality-checked nanosafety data b) enhanced re-use of nano-related data c) extended database interoperability (Nanosafety Data Interface/eNanomapper database)	• Ensure availability of information on chemical content and safe use, by introducing information requirements in the context of the Sustainable Product Policy Initiative, and tracking the presence of substances of concern through the life cycle of materials and products • Develop a common open data platform on chemicals to facilitate the sharing, access and re-use of information on chemicals coming from all sources • Remove legislative obstacles for the re-use of data and better streamline the flow of chemical data between EU and national authorities
Risk Governance Monitoring Scheme (Option B)	
Risk Governance monitoring system – dashboard of indicators	• Establish, in close cooperation with stakeholders, Key Performance Indicators to measure the industrial transition toward the production of safe and sustainable chemicals • Develop a framework of indicators to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of relevant legislation. (Develop an EU early warning and action system for chemicals to ensure that EU policies address emerging chemical risks as soon as identified by monitoring and research)
Knowledge assets (Option B)	
Contribute to the standardisation and validation process by: evaluating, optimising and pre-validating SOPs, producing nano-specific guidelines (TGs) and guidance documents, and integrating them into a risk governance framework. Contribution to AOP and IATA. Several new SPSFs on the characterisation of human and environmental hazards will be submitted to OECD.	• Promote the development of common standards and innovative risk assessment tools internationally, notably with the OECD, and promote their use under international frameworks, inter alia to shift further away from animal testing.

8. Implementation

At the time of writing (October 2022), outstanding questions include:

- Status of the organisation and its governing bodies;
- Link to the EC, Member States and private stakeholders;
- Funding and ability to draw funding from those who benefit from a new organisation;
- Ability of the organisation to continue some outcomes of the NMBP-13 projects, namely the Portal and the Risk Governance Framework.

Nevertheless, the projects have created a set of unique and valuable assets that support improved risk governance for enhancing engineered nanomaterials' safety and sustainability throughout their life cycle. Without an organisation to curate these going forward, it is difficult to see how these could be maintained or efficiently utilised.

It is not the role of these projects to implement any of these options. However, it is useful to consider how the options could be implemented and over what timescales. Each option presents different needs in terms of funding to support activities. Full implementation of Option B would be the most expensive option. Funding requirements will be detailed in subsequent deliverables[27] [28].

Funding models (for both options) may include:

- Grant funding from the Commission. Possible instruments include Horizon Europe.
- Grant funding from Member States. Possible instruments include national funding agencies.
- Grant funding from other organisations, such as philanthropic foundations.
- Direct funding from the Commission. This would be similar to how SCHEER is funded, for example.
- Funding provided by stakeholders/Members. In this model, Member organisations must pay a "membership fee" to cover some of the running costs. Fees could be set at different levels for different types of stakeholders according to their capacity to contribute.
- In-kind contribution from stakeholders/Members. In this approach, Member organisations could commit to funding specific assets or activities from their own resources, for example by hosting the Portal or maintaining one of the networks. With the right levels of commitment, this could be established relatively quickly. While this model would not likely be sustainable in the longer term, it could provide a way to provide continuity to (some)

[27] G4N D5.7 Report on suitable operational business models for the structure of Nano Risk Governance.
[28] NR D7.5 Final business plan for NRGC.

of the initiatives developed in the project to gain experience, build further support and act as a bridge until a more sustainable form of funding could be established.

A prior deliverable[29] has proposed that, before the Organisational Form is built, it should be tested within an experimental setting to explore the feasibility. A literature search identified four different experimental settings that might be useful for testing the proposed Organisational Form. These are:

- Innovation test bed;
- Innovation hub;
- Innovation or regulatory sandbox;
- Business incubator.

An innovation (or regulatory) sandbox is an environment and toolset that enables large groups of stakeholders to act autonomously and without hierarchy in building innovative concepts and solutions. The main purpose of an innovation sandbox is to allow individuals to collaborate in real-time in the act of problem-solving, opportunity identification and concept building. An innovation sandbox offers the ideal environment for testing an organisational form for risk governance. In conclusion, a sandbox, specifically an innovation sandbox, seems the most appropriate experimental setting to test either the Roundtable or House of Nanorisk Governance.

[29] Gov4Nano 5.8/NANORIGO 3.5 Inventory of organisational forms in support of the CSS.

9. Summary

The activities and organisation of the three options are summarised in Box 4 below.

Box 4 - Summary of activities in each option

	Option A	Option B	Option C
Activities			
Roundtable	•	•	
Framework		•	?
Portal		•	?
Monitoring scheme		•	?
Knowledge assets		•	?
Organisation			
Independent Chair	•	•	
Governing Board	•	•	
Executive staff		•	
Secretariat	•	•	•
Expert groups	•	•	?

10. Conclusion

The NMBP-13 projects will neither establish nor implement a sustainable organisation extending beyond the project ending in February 2023.

This deliverable is primarily concerned with describing features of and establishing the conditions for an organisation for Nano Risk Governance to succeed, in support of new developments related to the Chemicals Strategy for Sustainability.

To do this has required an assessment of current challenges in the field, done primarily through stakeholder engagement. It is clear that there is a perception that significant challenges remain. This is not to discount the many excellent activities underway by a range of actors. Indeed the first and most important condition for success is that key stakeholders perceive the new organisation as **effective** in **filling the gaps that remain** after existing organisations address the challenges described.

However, this assessment does suggest that there may be a role for a new organisation to primarily provide:

1) **more connectivity and broader engagement with key stakeholders** to collect opinions and concerns and critical expertise that may not be captured in technical hazard and risk assessment alone, and need to be well understood to ensure effective risk management.
2) **access to multidisciplinary knowledge** and expertise, in particular for more systematically integrating social sciences in assessment and decisions.
3) **better quality data and easier access to data sets** along with appropriate tools for risk assessment.

In this context, a design for a possible new organisation has been developed. This design comprises the building blocks of a supporting organisation (Purpose, Mission, Goals, and Activities) and how it could be organised. The overall purpose or 'mission' is 'to foster safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe'. A set of organisational goals are suggested. These are intended to address the challenges described in Section 3 and are based on the priority actions identified above. Goals relate to: risk governance, cooperation, knowledge, data, innovation and continuity.

Two main options are considered to organise the activities that such an organisation could undertake. Option A, the Roundtable, focuses on Priority 1 (more connectivity and broader engagement with key stakeholders in risk governance). The primary activity here is to organise roundtable meetings where stakeholders of all sorts convene to, *inter alia,* gather evidence,

identify issues they consider relevant, identify possible conflicting views, and formulate joint positions on these issues (for example, as input for research programs). The Roundtable focuses only on the 'problem-solving capacity' and can be mobilised upon request from the EC or by autonomous decision of its Governing Board to address particular challenges outside of but in connection with existing institutions.

Option B, the House of Risk Governance, includes all of the Roundtable activities foreseen under Option A and, in addition, addresses Priority 2 (access to multidisciplinary knowledge and expertise) and Priority 3 (better quality data and easier access to data). Hence the activities in option B (and the resources required to run them) are substantially expanded compared with those in option A. Option B includes four additional activities: maintenance of the Risk Governance Framework, maintenance of the Risk Governance Portal, monitoring progress in risk governance, and management of knowledge-based assets. In both options, the organisation is described as an independent structure, with Members drawn from the main stakeholder groups, who commit to and support its goals and an independent Chairperson.

A third option, Option C, has also been briefly considered. In this option, no new Organisational Form is established. Instead, an existing institution, or several existing institutions, implements (either of their own volition or at the suggestion of the Commission) those elements which each institution considered appropriate so to do. By definition, Option C is not independent.

A comparison between the proposed activities of the two options and the CSS actions suggests considerable synergies. The CSS is concerned with chemicals, while the activities proposed in this report are specifically about nanomaterials (and potentially advanced materials). This indicates that work done under both options can support the work of the CSS for this important subset of materials.

Implementation of Option A would provide the possibility of a substantial step forward in enhancing connectivity between stakeholders across the nano-risk governance field. In addition, the unique (in terms of nanomaterials) problem-solving capacity would be available to address technical, industrial and societal issues relating to CSS implementation. The independent status of the Roundtable would provide additional value to the outputs generated. However, implementing Option A on its own would mean that resources developed by the projects would not be maintained, and the opportunity to add knowledge resources from future projects would be lost.

Implementation of Option B would substantially improve access to and curation of knowledge and data arising from and curated by the current projects. It would also provide a solution to the longstanding problem of maintaining access to and sustainability of outputs from future projects. Ultimately Option B would provide the most coherent response.

Option C has two immediate disadvantages when compared with Options A or B. Firstly, as one of the main challenges in the nanotechnology field are connection and coherence between the various activities and actors, splitting the activities across a number of organisations would not improve connectivity. Instead, the situation would likely be made worse. Secondly, as stated, the organisation of the activities would not be independent. Although it could, in principle, be possible to appoint an independent Chair, it would be much more challenging to demonstrate openness and transparency in the operations and more difficult to achieve a trusted environment.

Ultimately it is for others than partners of NMBP-13 projects to decide whether to implement either or any of these proposed solutions or any other type of support. However, without some form of central organisation, it is difficult to see how the progress made in these three projects and future risk governance projects can be maintained and used effectively towards improved risk governance.

In the meantime, the NMBP-13 projects will continue to strive to stimulate open-mindedness, creativity and out-of-the-box thinking toward improved risk governance of nanomaterials.

Appendix: Blueprint for the nanotechnology risk governance council

Blueprint for the nanotechnology risk governance council

NMBP-13 Council Task Force

Blueprint for the nanotechnology risk governance council

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Preface

The European Commission Chemicals Strategy for Sustainability, the Green Deal, and other important initiatives in Europe outline urgent (short-term and 2030-2050) and high level ambitions towards safe and sustainable chemicals/products and a non-toxic environment.

Innovation brings huge potential for economic growth, helps address societal and environmental challenges but also brings uncertainty. This signals a new interest for developing, producing and commercialising products based on or including nanomaterials in a way that strengthens safety, circularity and sustainability, now and in the future. Innovation is leading to a renewed development of nanotechnology, with promising outcome in many domains. Safe and sustainable exploitation of nanomaterials requires effective risk governance. And yet, very important concerns remain about technical risk assessment, public acceptance and regulatory effectiveness among other aspects.

Risk governance is hampered by uncertainty about risks of (new) nanomaterials, limited cooperation between stakeholders, fragmented risk assessment and regulation, stakeholders lacking oversight of the risk governance landscape and disagreements on data quality and interpretation.

Improvements are needed in how risks to human health and the environment are addressed.

This Blueprint is a planning document which presents a possible design and role for a new organisation that would be tasked with governing risks from nano-based products, a Nanotechnology Risk Governance Council (NRGC). It is the result of a collaborative effort by three Horizon 2020 projects tasked with improving governance of nanotechnology risks in Europe, in close collaboration with stakeholders.

The document describes the goals that the Council could aim to, and why, the activities and services it could offer. It has been developed in a co-creation approach with key stakeholders and represents the current view of how such a council could be organised.

The purpose of this document is to provide a framework to test elements of the council design and further engage with key stakeholders in regulation, industry and NGOs to collect their feedback as possible members of the NRGC. This process will be used to refine the design of the NRGC prior to a possible launch in 2022.

Introduction

What can be the added value of a Nanotechnology Risk Governance Council (NRGC)?[1] What challenges and opportunities should it address? What should its mission be and what goals should it pursue? What activities should it conduct, and how should the Council be organised? The answers to these questions form the building blocks of the 'Blueprint' described in the pages below.

The Blueprint is the result of a collaborative effort by three Horizon 2020 projects tasked with improving governance of nanotechnology-related risks in Europe.[2] Specifically, the risks addressed relate to the development, use and disposal of nanomaterials and products containing them. These three projects set up a task force, which over the last year developed the Blueprint through a co-creation approach facilitated by The Argumentation Factory.

As part of this process, the task force consulted widely within the projects and with external stakeholders through workshops, interviews and questionnaires, sharing and evolving aspects of the Blueprint. This report can be seen as the best possible answer by the task force to the question what the NRGC should look like.

Process and content

To make a well-informed proposal for what the NRGC should look like, a scenario-building exercise[3] was conducted (see figure below).

Recognising that there are already many organisations in Europe involved in risk assessment and management of nanomaterials, and in order to focus on the most important issues the Council should address, a list of trends and factors was compiled. From this list, key challenges and opportunities were selected that were currently not (sufficiently) addressed and that the Council should aim to improve or expand upon (see the map on page 10-11). This yielded a corresponding list of seven goals, described in the map on page 14-15.

In the next step a scenario framework was developed comprising two main 'axes' that reflect some of the most defining choices for the Council: will it be a governmental of non-governmental organisation? And will it be an organisation focused on informing stakeholders, or on providing them with advice? In addition, potential activities the Council could following undertake: were listed.

In step four, the logical set of activities were described for each of the four scenarios and answered several organisational questions, for example on potential members or funding. In step five, the scenarios were evaluated and, in step six, this overview of strong and weak points was used to formulate a draft-Blueprint for the Council that reflects 'the best of four worlds'. Using feedback from stakeholders the activities the Council should undertake were then further refined and the way it should be organised (see the maps on page 18-19 and 22-23).

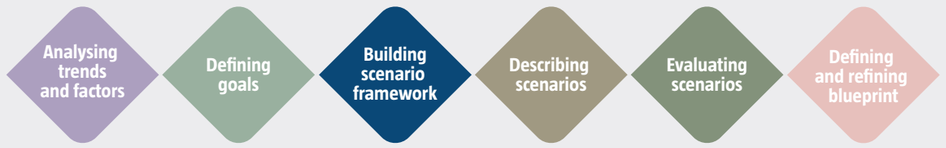
In addition to the maps that describe the building blocks for the NRGC, readers can find additional remarks on the process and visualisations of intermediate results in the appendix.

The road ahead

This Blueprint provides elements for a roadmap towards a full-fledged, functioning Nanotechnology Risk Governance Council. To all those who have participated in the co-creation process so far: a heartfelt thank you for your input, ideas and energy. All readers are invited to reflect on the suggestions for the NRGC and share their thought with the task force.

The NMBP-13 Council task force

What were the main steps of the scenario-building exercise?



What terms and abbreviations do we use in this report and what do they mean?

Nanomaterials refers to materials on a nanoscale, between 1 and 100 nanometres, at all stages of its lifecycle - from development, production and use to disposal.
Nanotechnology risks refers to risks to people and society related to the development, use and disposal of nanomaterials and products containing them. Such nanotechnology-related risks can have wide ranging (first and second order) effects on our safety, but also on the environment and the economy.
Governance refers to the actions, processes, traditions and institutions by which authority is exercised and decisions are taken and implemented.
Risk governance concerns the identification, assessment, management and communication of risks.
Stakeholders refers to policy makers and regulators, researchers, industry, NGOs and citizens.

EC	European Commission
EU	European Union
NGO	Non-governmental organisation
SME	Small and medium-sized enterprise

[1] In this report, the terms Council and NRGC are used intermittently.
[2] The European Commission, through the Horizon 2020 Nanotechnologies, Advanced Materials, Biotechnology, and Advanced Manufacturing and Processing ('NMBP')-13 call has funded three projects NANORIGO, RiskGONE and Gov4Nano, and tasked to work together to improve the governance of nanotechnology risks in Europe. A central element to this work is the establishment of a Nanotechnology Risk Governance Council.
[3] More details on this process can be found in the Appendix.

Challenges and opportunities

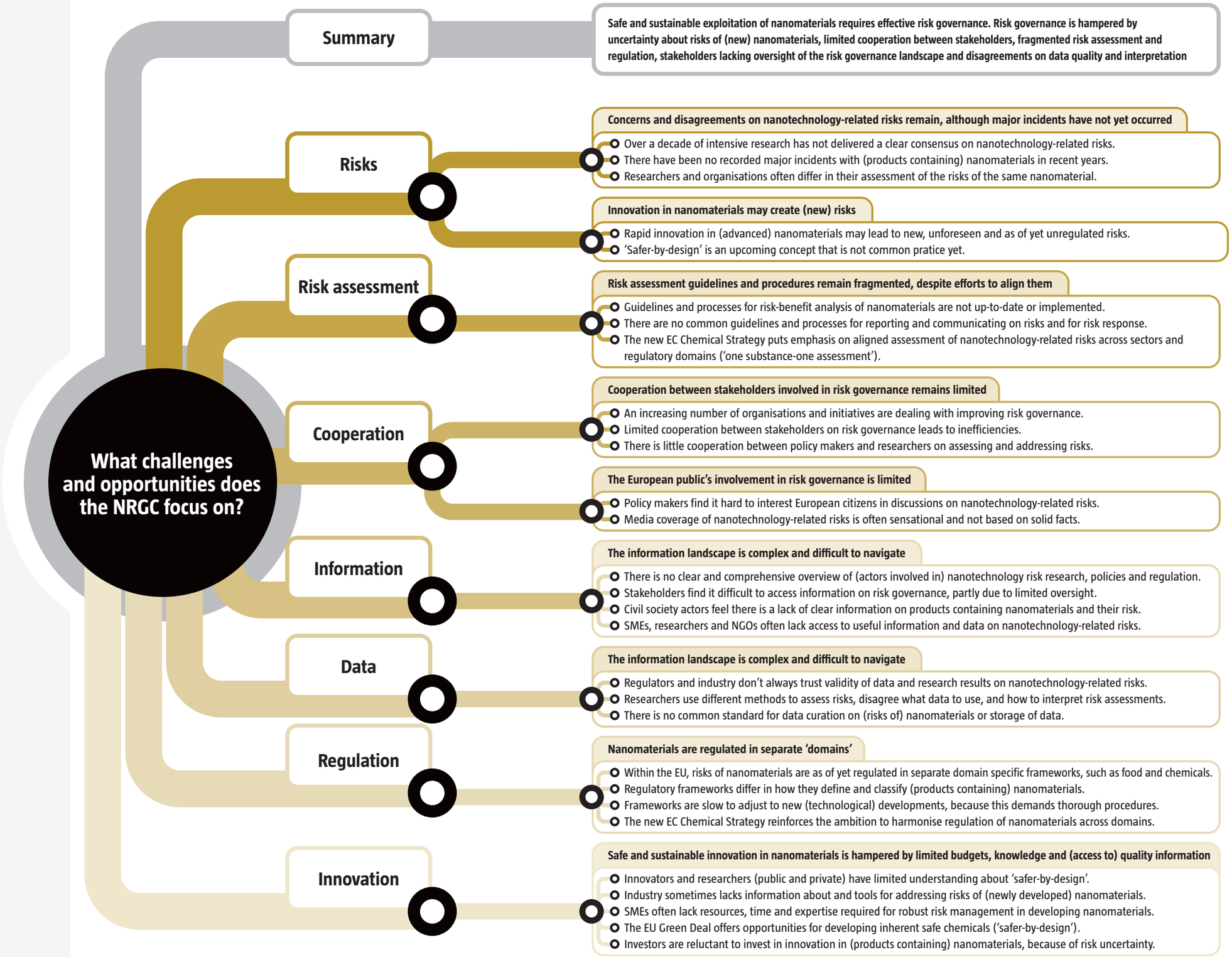
(Innovation in) nanomaterials offers huge potential for economic growth and addressing societal and environmental challenges. Harnessing these opportunities will require effective governance processes - now and in the future. Regulators, policy makers, industry and NGOs are working to identify and assess risks and benefits, collect and share data, aim to improve regulation, provide the basis for market entry and safe use and recycling of nanomaterials, and so on.

Despite many hopeful trends, the safe and sustainable development, use and disposal of nanomaterials is hampered by difficulties in the risk governance process. Although no major incidents have occurred, it remains hard to pinpoint precise risks of nanomaterials. Furthermore, innovation may spur new, unforeseen and unregulated risks. Risk governance is made difficult by sometimes limited cooperation between researchers, regulators, industry and citizens. And regulatory frameworks and risk assessment guidelines and procedures remain fragmented, despite increasing efforts to align them.

In the view of the task force, the establishment of a Council - and with that the implementation of a Risk Governance Framework (see next section) - can play a critical role in building trust and fostering a robust protection of society and the environment, while enabling the benefits of these technologies to be safely exploited.

The map on the next page describes the seven challenges and opportunities the Council should address.

Challenges and opportunities map



Mission and goals

What goals should the Council pursue in order to address the challenges and opportunities listed in the previous map? The overall goal, or 'mission' of the Council is 'to foster safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe'. The Council thus focuses on the whole extent of the production chain, and both on nanomaterials itself, and on the products within which they are used. In addition, the Council should address both physical, economic and environmental risks and benefits.

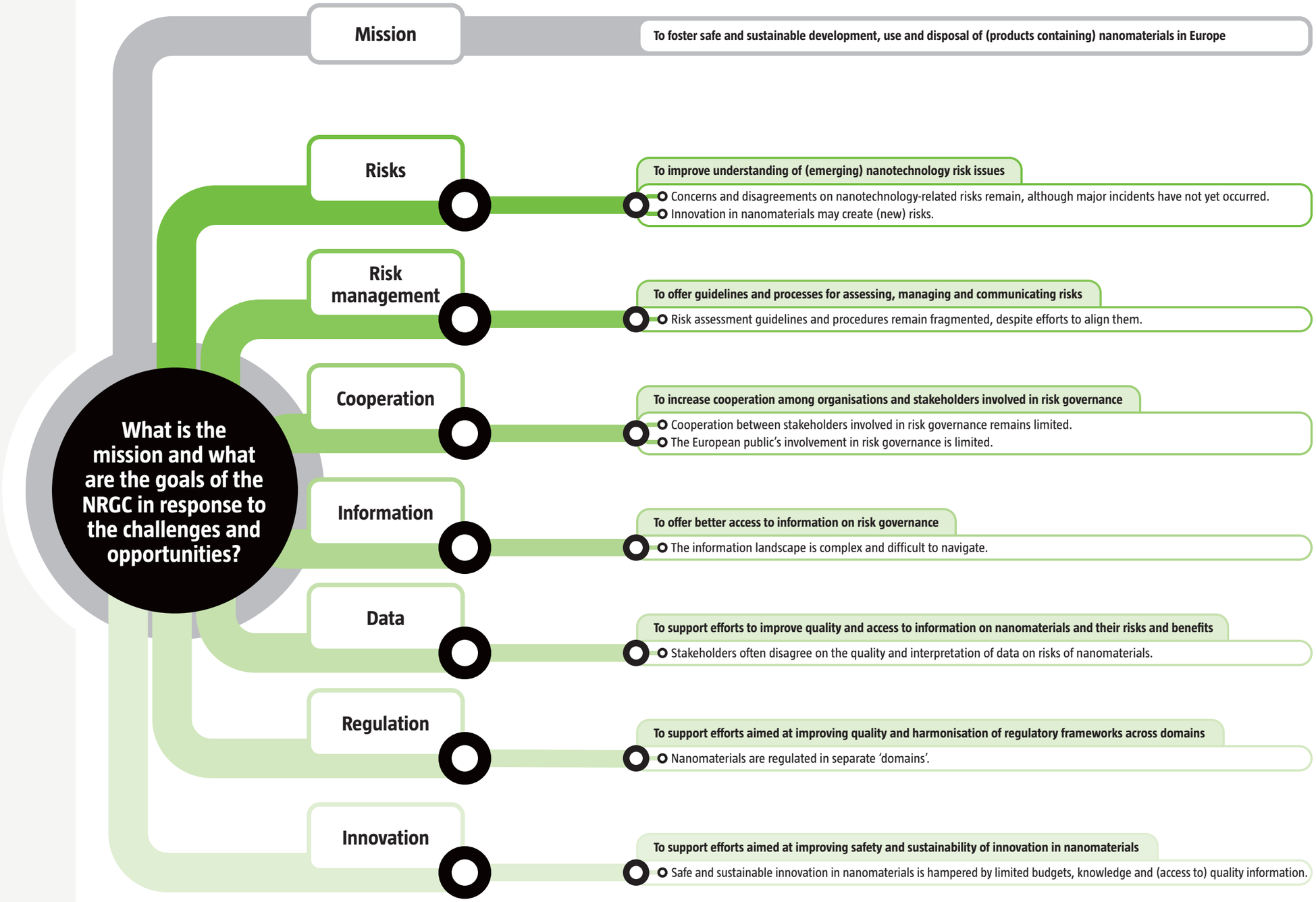
For each challenge or opportunity, a corresponding goal was formulated. First and foremost, the Council could help improve stakeholders' understanding of (emerging) nanotechnology risk issues. It could also increase cooperation among stakeholders and help them navigate the risk governance landscape. In addition, it should assist efforts to improve regulation, (access to) quality data and more safe and sustainable innovation processes.

Preconditions

In addition to the goals mentioned above, two preconditions were set for the NRGC. First, it should target a wide range of stakeholder groups: policy makers and regulators, researchers, industry, NGOs and citizens. The Council should play a key role in involving all stakeholders in risk governance and giving them a voice in existing processes.

Second, the Council should not duplicate or interfere with existing efforts and should add clear value. Indeed, there are many organisations in Europe that provide essential contribution towards ensuring safety of nanomaterials - from research and regulatory bodies, to industry associations and NGOs.

Mission and goals map



Activities

The task force formulated a set of activities to realise the goals of the Council. In line with the precondition mentioned in the previous section, these activities are intended to supplement, complement and support those currently provided by other actors in the field. Activities are intended to support their work, for example by linking activities, actors, organisations and (regulatory) domains.

First, the Council develops, maintains and implements a multi-disciplinary and multi-stakeholder Risk Governance Framework. This is a comprehensive and formally structured voluntary system to provide stakeholders with a clear way to effectively govern nanotechnology-related risks. The framework offers guidelines and stipulates processes for assessing, managing and communicating on. Stakeholders can use this framework to improve the quality of processes and decisions.

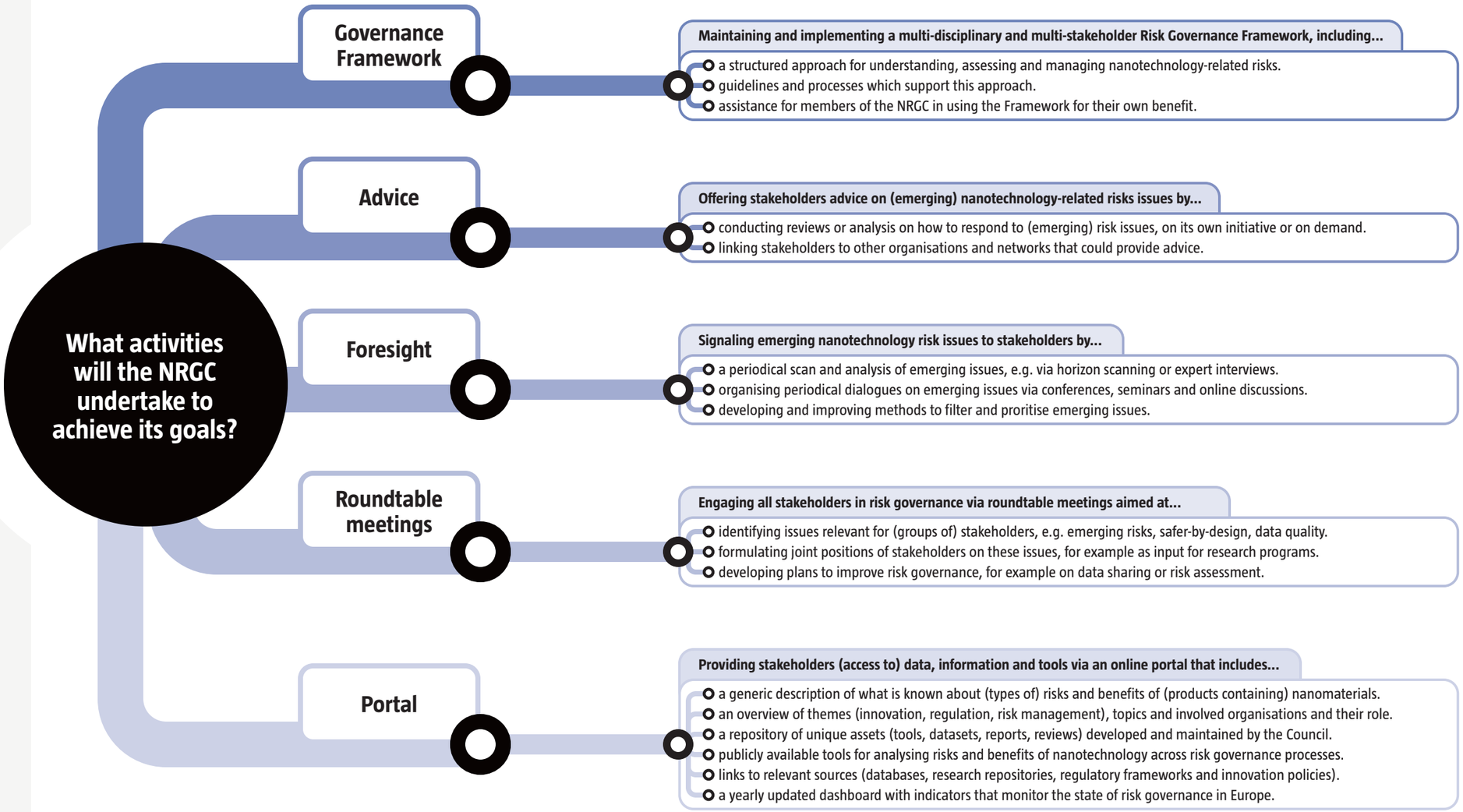
Second, the Council offers advice on (emerging) nanotechnology-related risk issues. It can provide stakeholders, including regulators and policy makers, advice on specific issues in the form of analysis, reviews or case studies. Such advice may be developed following the Council's own agenda setting process or may be on request from particular members or stakeholder groups.

Next, the NRGC will identify and report emerging issues. Either through foresight studies or through organising periodical dialogues on (emerging) issues via conferences, seminars and online discussions. It will also reflect on how to improve methods to filter and prioritise emerging issues.

A fourth subset of activities focusses on engaging stakeholders in risk governance. The key route here is to organise roundtable meetings where stakeholders of all sorts convene to identify issues they consider relevant and formulate joint positions on these issues (for example as input for research programs). And roundtable meetings could be organised to develop joint plans to improve risk governance, innovation, regulation, data and/or risk management.

Central to the provision of these services will be an online portal or 'platform' providing a single, trusted point of access for users and stakeholders. The portal is primarily aimed at helping stakeholders navigate the landscape and improving access to information and data. It combines several functions. It offers stakeholders access to data, information and tools (both developed by the Council itself and by others) and support in how these can be used. This includes descriptions of what is known about (types of) risks and benefits, key themes and actors; available tools for analysing risks and benefits; and links to relevant sources, such as databases, research repositories, regulatory frameworks and innovation policies. In addition, the portal includes a yearly updated dashboard with indicators that monitor the state of risk governance in Europe.

Activities map



Organisation

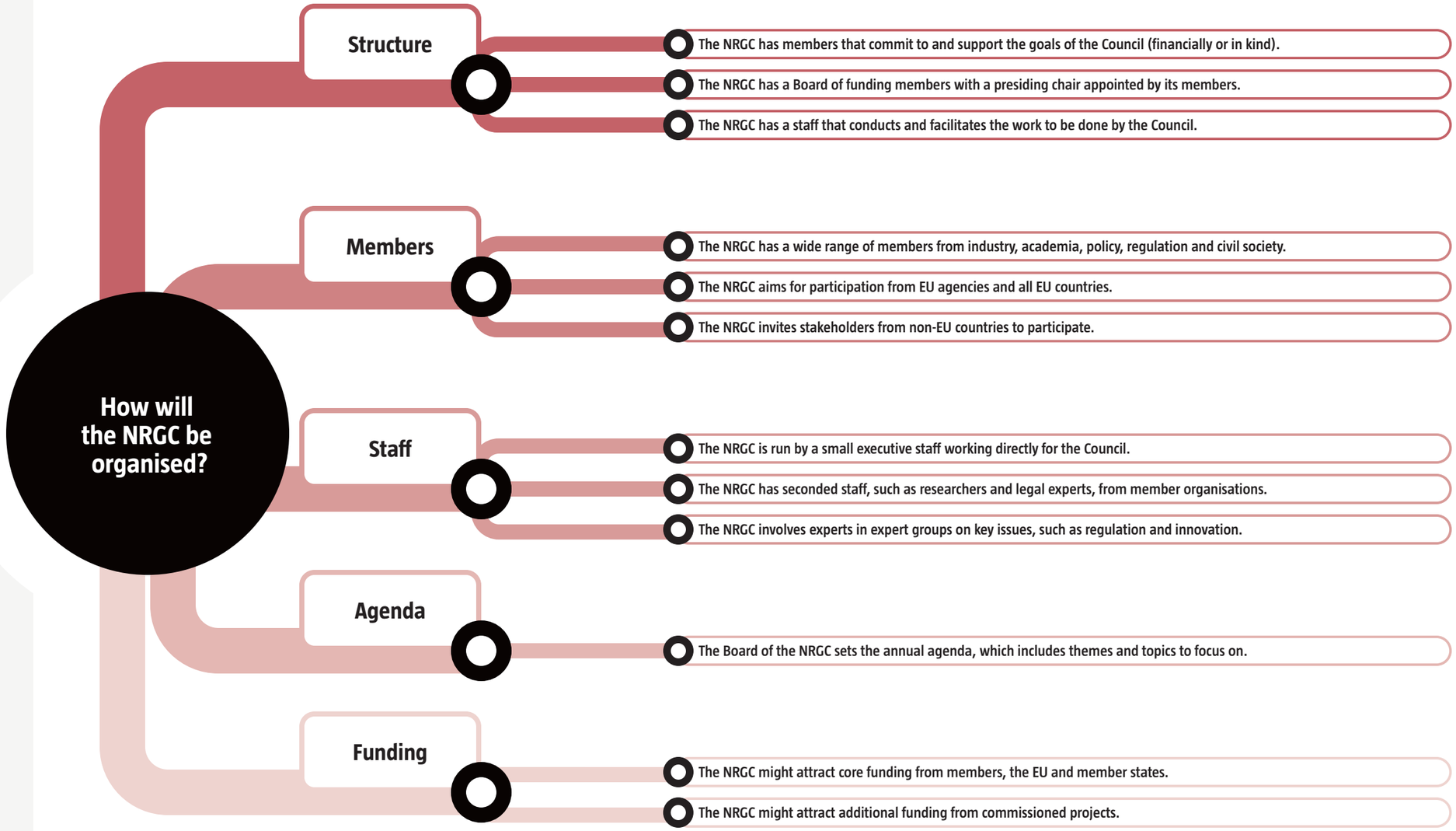
How could the Council deliver these activities? This question can only be answered conclusively once there is a clear consensus on the goals and activities the Council will provide, and who is willing to support the Council.

At this stage, the Council is described as an independent organisation, with members drawn from the main stakeholder groups, who commit to and support its goals (financially or in kind). Participation from EU agencies and all EU countries and invited stakeholders from non-EU countries establishes broad representativity and helps to establish the legitimacy of the Council.

The Council comprises a Board of funding members with a chairman appointed by rotation. The Board of the NRGC sets the Agenda, which includes themes and topics to focus on. The organisation is run by an executive group, supported by seconded staff of member organisations, who work on projects from the Council. In addition, the Council involves experts in 'expert groups' on key issues, such as regulation, innovation, etc.

Options for funding are under discussion.
The Council would benefit from attracting core funding from EU organisations and member states and other stakeholders. It could also raise additional funding from commissioned projects.

Organisation map



Acknowledgement

The task force would like to thank all participants in this process. First and foremost, all partners in NANORIGO, RiskGONE and Gov4Nano, who took part in this co-creation effort. Next, the advisory boards of the three projects. And last but not least, all external stakeholders who participated in the workshops, ‘user group meetings’ and interviews.

Appendix

The Blueprint described in this report is the result of an extensive consultation process. The task force used a six-step scenario building exercise which we describe in some more detail below.

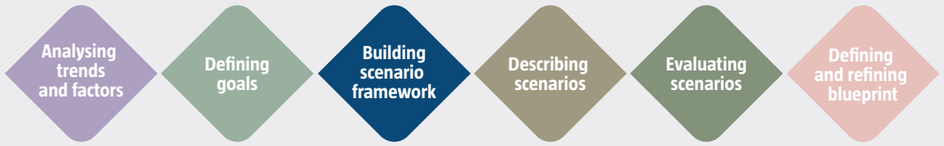
As a first step, the added value that the Council could have was made explicit. Recognising that there are already many organisations out there that deal with risk governance, and in order to get a grip of the most important matters the Council could address, a list of potentially relevant trends and factors was first compiled.

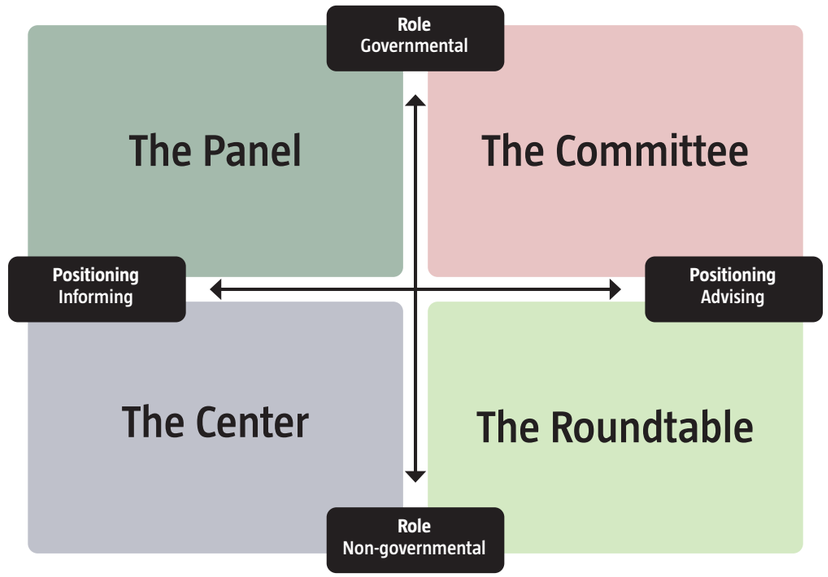
From this longlist of possible developments and factors, those that pose a clear challenge or opportunity that the Council needed to address were distilled. Corresponding to these challenges and opportunities, seven goals were formulated and an overarching mission that illustrate the added value of the Council. These goals and mission functioned as reference point in the process towards building the Blueprint.

In addition to these goals, two preconditions were set for the NRGC. First, it should target a wide range of stakeholder groups: policy makers and regulators, researchers, industry, NGOs and citizens. The Council should play a key role in involving all stakeholders in risk governance and giving them a voice in existing processes.

Second, the Council should not duplicate or interfere with existing efforts and should add clear value. Indeed, there are many organisations in Europe that provide essential contribution towards ensuring safety of nanomaterials - from research and regulatory bodies, to industry associations and NGOs.

What were the main steps of the scenario-building exercise?





In step three, a scenario framework was devised with two main axes, reflecting fundamental choices to be made in the Blueprint: its positioning (will the Council be a governmental or non-governmental organisation?) and its role (will the Council primarily serve as a body informing other stakeholders, or will it also provide advice and recommendations?). This yielded four scenarios (one for each quadrant), visualised on the next page.
A list of 17 potential services with which the Council could meet these challenges and realise these goals were also created - such as conducting foresight studies, informing stakeholders on the main issues and actors, and organising roundtable sessions aimed at improving risk governance.

In step four, four scenarios for the Council were described. In discussions with members of the three NMBP-13 projects and in close consultation with stakeholders, the task force built four logical sets of services and answered several organisational questions per scenario, for example on potential members or funding (for a summary of the four scenarios, see the maps on page 28-31).

Next, the strong and weak points of the four scenarios were evaluated, by hosting a range of ‘argumentation sessions’ with stakeholders. From the collected arguments in favour and against services and scenarios, a draft-Blueprint for the Council was then constructed. Based on the feed-back from stakeholders the final version of the Blueprint described in this reporrt was then refined and defined .

Scenario map

The Panel | The Committee

The Center | The Roundtable

What are the most characteristic elements in the four scenarios for the NRGC?

The EU Advisory Committee

The Committee is an intergovernmental organisation...

- focussed on policy makers and regulators from the EU and member states. — **Target audience**
- with a staff of experts working directly for the Committee. — **Members**
- with funding from the European Commission and member states. — **Funding**

The Committee has an informing and advising role by offering EU policy makers and regulators...

- information on selected risk issues and research results. — **Mapping**
- insights in trends in nanotechnology-related risk issues. — **Analysis**
- a platform for engaging in stakeholder dialogues on topics relevant to them. — **Dialogue**
- providing advice upon request to support decision making. — **Recommendations**

The European Roundtable

The Roundtable is a non-governmental organisation...

- informing and advising stakeholders in Europe. — **Target audience**
- with a seconded staff of experts from other (nanogovernance) organisations. — **Members**
- with funding from member organisations, and additional private and public (research) funds. — **Funding**

The Roundtable has an informing and advising role by offering European stakeholders...

- an online portal with access to information on risk issues, research results and information sharing. — **Mapping**
- insights in trends in nanotechnology-related risk issues. — **Analysis**
- a platform for stimulating debate and engaging in dialogues on topics relevant to them. — **Dialogue**
- a platform for forming and advocating positions and signaling topics to focus on. — **Recommendations**
- a platform for forming and implementing plans to improve risk governance. — **Plans**

The Panel | The Committee
The Center | The Roundtable

What are the most characteristic elements in the four scenarios for the NRGC?

The European Intergovernmental Panel

The Panel is an intergovernmental organisation...

- focussed on policy makers and regulators. — **Target audience**
- with a staff of experts working directly for the Panel. — **Members**
- with funding from the European Commission and member states. — **Funding**

The Panel has an informing role by offering European policy makers and regulators...

- information on selected risk issues and research results. — **Mapping**
- insights in trends in nanotechnology-related risk issues, analysis upon request and monitoring progress on goals of the Center. — **Analysis**
- a platform for engaging in stakeholder dialogues on topics relevant to them. — **Dialogue**

The EU Center

The Center is non-governmental orgnisation...

- focussed on stakeholders in the EU. — **Target audience**
- with a staff of experts working directly for the Center and seconded staff from other organisations. — **Members**
- with funding from the EC and member states, research programs and commisioned research. — **Funding**

The Center has an informing role by offering EU stakeholders...

- an online portal with access to informatie on risk issues, research results and information sharing. — **Mapping**
- insights in trends in nanotechnology-related risk issues, research gaps, and monitoring progress on goals of the Center. — **Analysis**
- a platform for stimulating debate and engaging in dialogues on topics of societal relevance. — **Dialogue**
- organising and reffering to training opportunities. — **Training**


De ArgumentenFabriek