Gov4Nano
meeting the needs of nanotechnology

Deliverable Report

Deliverable D5.2	*Initial NRGC operational plan: mission (mandate), operational structure and recruited initial members*
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2.	NMBP-13 projects collaboration core groups	Yes
3.		
4.		
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6.		
7.		

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1 Summary

Establishing a Nanotechnology Risk Governance Council (NRGC) is central to the Gov4Nano project and impacts on all other work tasks and packages. This deliverable report provides:

- A distilled but comprehensive description of the considerations taken and processes involved in developing a Blueprint for the NRGC, and
- A Blueprint that clearly describes the envisaged NRGC and that will be used to guide the further development and implementation of the Council.

As described in this report, key aspects in the process included:

- Gaining global understanding. Critical analysis of the current policy landscape in risk governance of nanotechnologies in order to inform the most appropriate positioning of the NRGC relative to existing systems and structures.
- Co-creation. Establishing a strong collaboration with the other projects – RiskGONE and NANORIGO – that are also addressing risk governance of nanotechnology.
- Engagement. Strong and regular engagement of internal (consortium members) and external stakeholders to facilitate an iterative developmental process including an internal evaluation of the final form of the proposed Council.

The result of this deliverable is the Blueprint for the NRGC. It is a planning document based on the collaborative effort by the three Horizon 2020 projects tasked with improving governance of nanotechnology risk in Europe in close collaboration with stakeholders. It describes all aspects of the Council: the challenges and opportunities the Council should address; the goals it should pursue to address these; the activities required to realise these goals; and the way it should be organised in order to deliver on its purpose.

Given its nature, the Blueprint's suitability can only be properly evaluated as we move towards implementation. However, the internal evaluation of the Blueprint indicated strong support for the implementation of the proposed NRGC from consortium and Joint NMBP-13 members.

2 Description of task

Task 5.1: An International Think Tank for nanotechnologies: setting up the NRGC

Subtask 5.1.2: mandate and operational structure of the NRGC

Lead: IOM

Partners: RIVM, NIA, AIRI, TEMAS, IenW, AIST, BNN, DIALOG, ISS, YIL

The purpose of this task was to clarify and refine the mission and operational structure of the NRGC, starting from inputs gathered in subtask 5.1.1 (creating the International Think Tank (ITT)), and based on a careful analysis of the current policy landscape in risk governance of nanotechnologies (actors, priorities, issues and tensions and controversy), stakeholder input (through WP6), and interaction with other WPs. The NRGC will focus on policy questions. A workshop process was envisioned to be used to define the issues around the mandate and structure. Key aspects foreseen in the task were:

- Clarify the mandate of the NRGC (through stakeholder interaction)
- Define (propose and agree) a structure for the NRGC
- Define (propose and agree) modes and ways of action ("NRGC tools"). Key aspects that will be taken into account as modes of action include: (inbound) collection and evaluation of data, informant and tools; (outbound) dialogue events, reports and white papers, and online presence
- Launch the "prototype" NRGC

Principles of openness, participation, accountability, effectiveness and coherence were key to setting the governance structure and support credibility and trust in the work of the NRGC.

Results will feed into D5.2. Development and testing activities of the NRGC will run throughout all the other tasks of WP5.

3 Description of work & main achievements

3.1 Background of the task

At the beginning of the Gov4Nano project, many aspects of the envisaged NRGC had yet to be decided. For example, there was no clear consensus as to what the status and remit of the Council would be, how it would be structured and financed, or what the foreseen outputs were. The aim of T5.1.2 and D5.2 was therefore to help address these questions; facilitating the formation and positioning of the NRGC as a self-sustaining European council. The task was to clarify and refine the mission and operational structure of the NRGC, starting from inputs gathered in subtask 5.1.1 (creating the International Think Tank (ITT)), and based on a careful analysis of the current policy landscape in risk governance of nanotechnologies (actors, priorities, issues and tensions and controversy), stakeholder input (through WP6), and interaction with other WPs.

The goal was to ensure that decisions on the organisation of the Council were; (i) well-informed; (ii) explainable and defensible; (iii) based on several concise coherent arguments and realistic scenarios; and (iv) supported by all project partners, stakeholders and the European Commission.

The work of D5.2 will be central to the success of the Gov4Nano project, providing the primary output of the project, the Risk Governance Council. It is also central to the work of other tasks and work packages with a clear idea of the NRGC positioning and operational plan against which to position their own outputs.

3.1.1 *Co-creation approach*

Within the NMBP-13-2018 call, three projects were funded to address the risk governance of nanotechnology, namely Gov4Nano, RiskGONE and NANORIGO. Although each of these projects had their own unique approach and objectives, they shared common goals and visions which were strengthened by constructive cooperation. A collaboration process was established between the three projects.

For this to be effective, strong inter-project communication and collaboration was vital. In order to ensure that decisions were made collaboratively and unanimously across the three projects a series of Core Groups were established, with representatives from each of the projects. The *Risk Governance Council & Framework core group* was established specifically for matters related to council design.

An early decision of this group was that a single (Nanotechnology) Risk Governance Council would be developed collaboratively among the three projects. This ensured that a sustainable and equitable framework and council for nanotechnology in Europe is developed; removing any competition or incoherent messaging to the external community and stakeholders.

To facilitate an effective process, a second smaller group was created - the Scenario Task Force (TF) specifically focused on elaborating options and scenarios for the Council and tasked with co-creating a common design (Blueprint) for the Council.

The work of each of these groups is further elaborated below. Tables 1 and 2 indicate the members of the Risk Governance Council & Framework core group and Scenario Task Force. Links to detailed descriptions of the activities of the NMBP-13 Core Group on Risk Governance can be found in Chapter 8.

Table 1. Members of the Council Core Group

Topic	Gov4Nano	NANORIGO	RiskGONE
	Monique Groenewold	*Janeck J. Scott-Fordsmand*	*Maria Dusinska*
I. Risk Governance Council & Framework	Rob Aitken	Arto Säämänen	Panos Isigonis
	Keld Alstrup Jensen	Marie Valentine Florin	Nils Bohmer
	Andrea Porcari	Christina Benighaus	Dalila Antunes
	-	-	Tommaso Serchi
II. Nano Risk Governance Portal: Tools & Instruments	Keld Alstrup Jensen	Isabel Rodriguez	Antreas Afantitis
	Wouter Fransman	Damjana Drobne	Evert Bouman
III. Stakeholder involvement	James Baker	Mark Morrison	Michael Neaves
	Susanne Resch		Tommaso Serchi
IV. Data management	Martine Bakker	Damjana Drobne	Iseult Lynch
		Janeck J Scott-Fordsmand	Egon Willighagen
			Nina Jeliazkova
User committee	Susanne Resch	Arto Säämänen	Dalila Antunes

Table 2. Members of the Scenario Task Force (TF)

Gov4Nano	NANORIGO	RiskGONE
Rob Aitken	Marie Valentine Florin	Panos Isigonis
Andrea Porcari	Arto Säämänen	Dalila Antunes
Monique Groenewold	Janeck J. Scott-Fordsmand	Tommaso Serchi

3.2 Description of the work carried out

This deliverable provides a description of the processes undertaken, an explanation for the decisions made and the outputs of the Council design process.

3.2.1 *Design process*

During the initial months of the project a series of internal workshops were held to draw together common ideas from the whole project consortium about the purpose of the Council and how it could be organised. These included a workshop on "purpose" and a "value-proposition" workshop organised at the KO meeting in The Hague in March 2019 and a "Straw Man" workshop in Gouda in Sept 19 at which various design options were considered. A number of smaller design workshops were also held with representatives from WP5, 6 and 8. The outputs from these together with those from Deliverables D6.2 Force Field Analysis, D5.3 Report on Regulatory Road and Research Map and Value Proposition Workshops from a Regulators Workshop (Dec 2019) were used to shape initial ideas of how the Council could be organised. Other relevant deliverables and milestones from the three projects have also been taken into account (Chapter 8).

However, with the additional complexity and the collaborative work with the other two projects, it became apparent that a robust strategy and process was needed to guide the design of the Council. This was to ensure concrete consideration of all inputs and opinions being generated by the three consortia, as well as valuable inputs from external stakeholders. In addition, this would allow clear justification for the design decisions being made.

Due to these complexities, we engaged with external consultants at 'The Argumentation Factory (De Argumentenfabriek)' to help facilitate this process. With their expertise in "facilitating thinking processes", this allowed information to be visualised and structured in clear and comprehensive overviews to allow informed decisions to be made and to develop a process of co-creation. The initial work was done within the G4N projects and then extended to become the taskforce process across the three projects. An outline of the developed design process is provided in Figure 1.

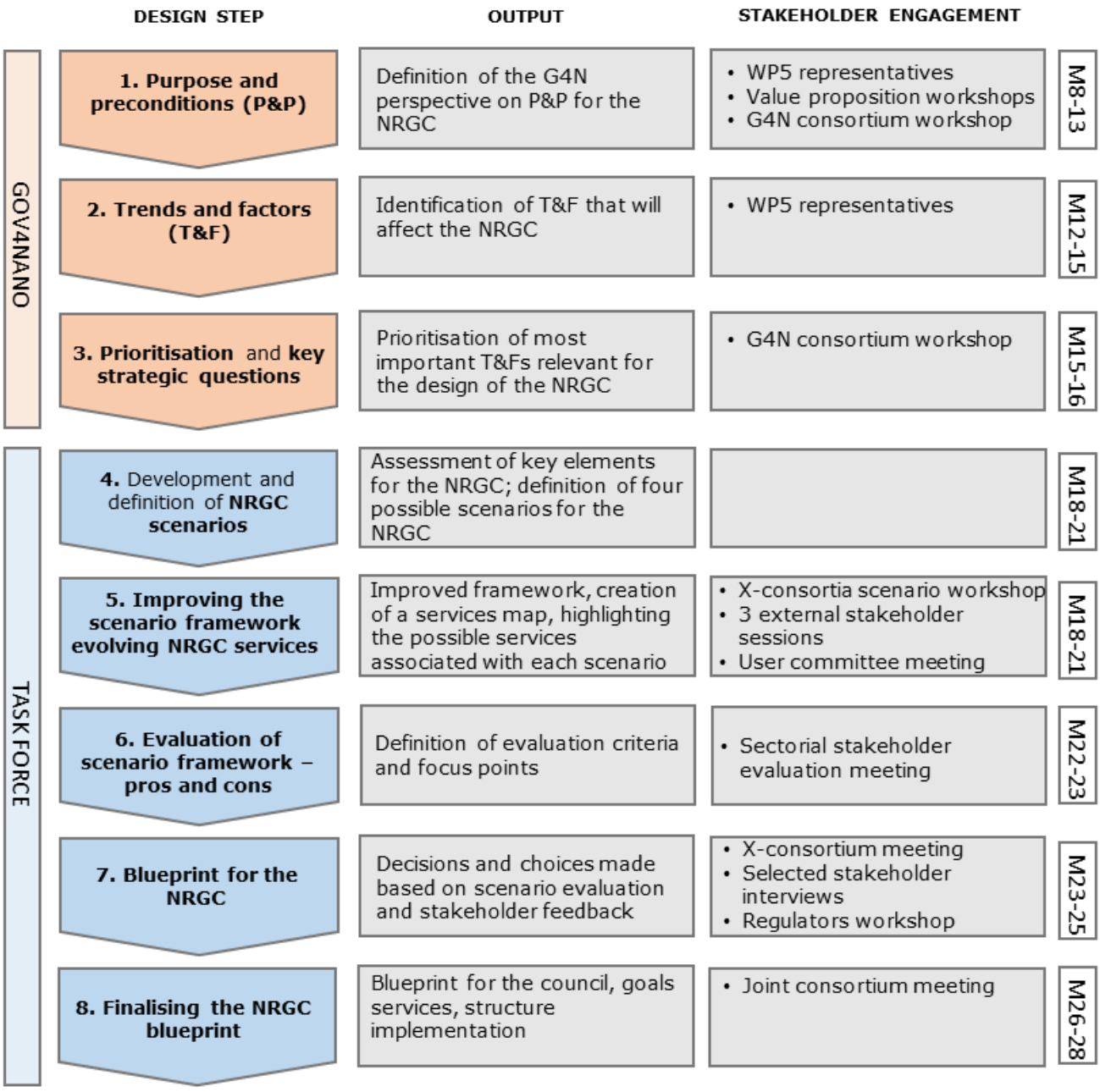

Figure 1. Structured NRGC design process, including stakeholder involvement, outputs and timelines.

The design process was inherently iterative; involving the drafting, developing and refining of ideas and options. The majority of this was done through direct conversations and discussions within the task force, primarily in workshop sessions and across the wider projects and with external stakeholders.

3.2.2 *Stakeholder Engagement*

Stakeholders contribute to risk governance, and this provided a vital source of information for the design, rationale and sustainability of the NRGC. Involving relevant actors at early stages of council design ensured that, to the extent possible, their perspectives, needs and incentives were taken into account. Ultimately, the extent to which the Council was seen as trusted by the external stakeholder community would be an important factor in determining the success of the Council.

Deliverable 6.2 on "Force Field Analysis and Background Analysis of Stakeholders" was an important input in this respect. It focused on understanding the needs and insights of stakeholders regarding the core themes of risk governance, and exploring the key elements (purpose, principles, status, roles and products) to build a risk governance council for nanotechnologies. This included a review of the literature, results from previous and ongoing H2020 projects and outputs from stakeholder activities performed in the Gov4Nano project.

The outputs of D6.2 were highly relevant to the work of this deliverable and were used throughout to support consideration of the purpose, preconditions, trends and factors.

Multiple further stakeholder events were conducted as integral part of the D5.2 process. Table 3 provides a summary of these, including the purpose of the activity and who was engaged.

Table 3. External stakeholder engagement activities

Event	Date	Stakeholders engaged	Purpose
Value proposition workshop	15-Oct-19 5-Dec-19	Academics Regulators	Understanding the needs and insights of stakeholders regarding the core themes of risk governance
Scenario development (3 separate sessions)	12-Sept-20	Civil society Academia Industry Policy makers	To help further develop the four possible scenarios
User Committee meeting	06-Oct-20	Civil society Academia Industry Policy makers	To help further develop the four possible scenarios
Sectorial stakeholder evaluation workshop	03-Dec-20	Civil society Academia Industry Policy makers	Evaluation of the four developed scenarios
Workshops with Regulatory agencies	15-Mar-21 17-Mar-21	Policy makers	Review of the scenarios Review of the Blueprint
1 to 1 interviews with key stakeholders		Civil society Academia Industry Policy makers	Review of the Blueprint

4 Results

The primary focus for this task was the development of a plan "Blueprint" of the Council. This Blueprint is thus the primary result and is discussed at the end of this section. It is also and presented in full as an Appendix to this deliverable. However several of the intermediate steps yielded important and useful output. These are described below. As has already been discussed, these intermediate outcomes were developed iteratively, primarily through discussions, sessions and workshops with various partners and stakeholders.

4.1 Purpose and Preconditions

The first step comprised determination and elaboration of the purpose of the NRGC and what preconditions (or constraints) existed on how it was to be designed. Multiple input documents were considered including the Gov4Nano proposal, Description of Action (DoA), D6.2 ('First Scoping Report on Force Field Analysis and Background Analysis of Stakeholders') and D5.7 (draft 'Report on suitable operational business models for the NRGC').

The main purposes were categorised into the following groups: informative, responsive, regulatory and innovative. Likewise, the preconditions were categorised according to the area of the Council to which they related, including its focus, cooperation, independence, funding, organisation and timeline.

Key purposes and preconditions for the NRGC were summarised in a map (Figure 2) below. The map was developed initially by representatives from WP5 in Gov4Nano, and subsequently refined through the Task Force. Although this map does not appear in the final Blueprint, the contents underpin the final design and as such it represents an important intermediate result.

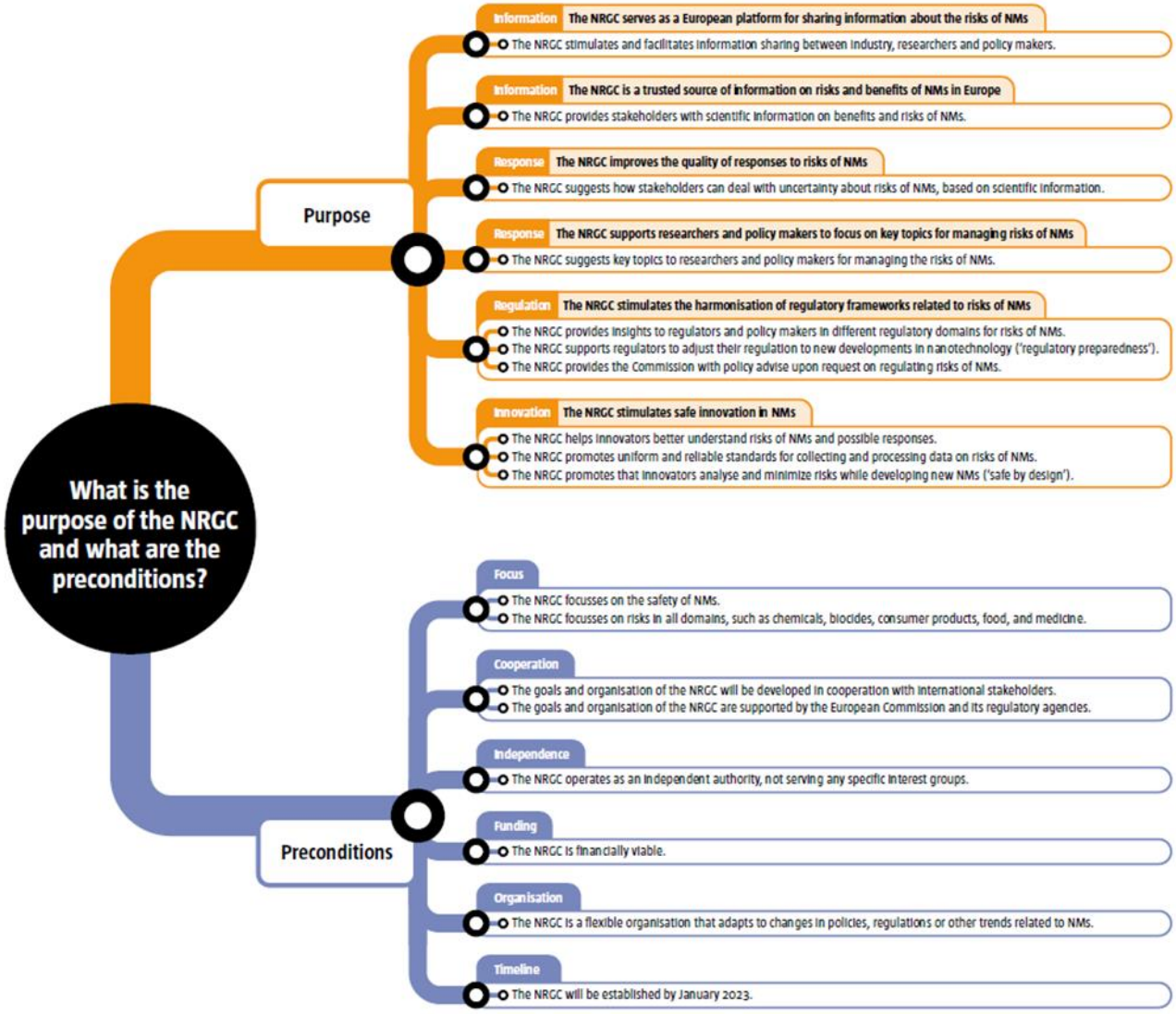

Figure 2. Developed *purpose* and *preconditions* of the NRGC map

4.2 Trends and Factors Analysis

In a similar manner, in this step the relevant trends and factors that could influence how the Council could be formed and operate were elaborated. These included both internal and external factors. The initial map was developed through a set of workshops addressing the question, "What are the important trends and factors that would influence the design of the Council?". The first version of this was developed by representatives from WP5 in Gov4Nano, and was subsequently refined through the task force.

The trends and factors identified are presented in Figure 3 and Figure 4. These trends and factors are split into categories depending on their scope including society, risks, risk management, risk governance, rules and regulations, innovation and research. These trends and factors represent a view of the landscape as interpreted by participants at that time. It is therefore an important snapshot of collected *opinion* rather than thorough critical landscape analysis. The trends and factors were used as part of the design process to develop key questions relating to the Council and subsequently were important in framing the both the challenges and opportunities that the Council would address.

Figure 3. Identified trends and factors: part 1

Figure 4. Identified trends and factors: part 2

4.3 Prioritisation and strategic key questions

In order to prioritise the numerous trends and factors, an interactive session was conducted at the G4N M15 consortium meeting. In this, partners identified the trends and factors they considered most relevant to the design of the Council. From each of the prioritised trends, a strategic question was formulated. These were designed to query the role of or the implications for the Council.

A strategic question was formulated from each of the prioritised trends. These were presented to the consortium to suggest answers or scenarios in which the Council could help address the specific topic. Table 4 presents the eight strategic questions and a first attempt at potential

options, as suggested by the G4N consortium. This acted as a starting point for the development of four realistic options for the NRGC.

Table 4. Strategic questions and potential options for the NRGC

Identified T&F	Strategic questions	Possible solutions
Regulatory frameworks adjust slowly and do not cover the newest technological developments in NMs	What is the role of NRGC in relation to support in adapting regulation to new technologies?	• Develop a foresight activity (through working groups) to identify gaps in regulation, policies and standards • Facilitate stakeholder interaction through meetings, portal discussion groups • Advise the Commission on the allocation of funds (priorities) • **Scenario 1:** NRGC is a recognised authority - Trusted broker bridging research (disciplines) and regulations with possibility to access and analyse all background information for recommendations and SH guidance, enhancing new regulatory approaches. • **Scenario 2:** NRGC is an amorphous body - Trusted broker bridging research (disciplines) and regulations with possibility to access and analyse "available" background information for recommendations and SH guidance.
The EU Green deal offers funding for developing inherent safe chemicals ('safe-by-design').	How can the Council enhance new developments of inherent safe & sustainable chemicals including safe-by-design?	• Provide, evaluate and direct users to tools for SbD (portal) including guidance • Provide infrastructure on methods, tools, guidance, workshops and training on SbD and sustainable NMs • Run an SME contact-point for SBD including recommending, linking to service providers • Provide targeted information packages and workshops to disseminate and train SHs in SbD and sustainable NM development. • Develop a SbD index (similar to the sustainability index) • Define and promote framework and principles for SbD and sustainable NM development. • Motivate regulators in accepting SbD approaches
There are insufficient internationally agreed criteria for evaluating risk acceptability of nanomaterials.	How can the Council support (the development of) internationally agreed criteria for evaluating risk acceptability of NMs?	• Be a champion for cross disciplinary fertilization. • Lead a multinational, transparent and open decision finding process on agreed criteria to evaluate risks related to nano. • Consolidation exercise, not consensus exercise. • Motivating to comply with (above defined) criteria as much as possible • Gather information, organizing dialogue events and promote communication between SH • Harmonise and communicate regulatory needs • Include grouping approaches into regulation strategies
Producers, in particular SMEs, often lack knowledge of risks of NMs used in their products.	What is the role of the Council to improve knowledge & capability of SME on risk of NM?	• Develop an SME portal, a simple channel for knowledge transfer • Identify training needs for SMEs – this should include training on the tools in the portal • Facilitate the training (by connecting providers with those that want training) • Raise awareness of NM risks and tools to assess and manage them (answer depends on "location of the governance issue": at laboratory / factory vs dowsntream vs regulatory compliance) • Pivotal: The SME must be able to identify that they are considering a NM. Hence, stage 1 is to enable them to identify a NM.

		• Develop a RA voucher approach for SME's • Similar solution to Q2.
Governance of risks related to NMs at the European level is ill-structured, costly and time consuming	What is the role of the Council in improving the governance of risks of emerging nanotechnologies?	• Council could have multiple roles but it should add and support roles carried out by existing organisations and help bridge gap between research and policy.

The budget of EU regulatory agencies is cut by five percent annually in the next ten years.	What is role of the Council to ensure funding for research on risks of NM?	• Agenda setting: making it clear why research is important and what goes wrong if research is not performed
		• Creating a funding pool for independent research
		  ○ Facilitating multi-stakeholder gap analysis leading to a research road map (with priorities)
		  ○ Bridge academic and regulatory research
		  ○ Independent research into both risks and functionalities
		• Monitoring progress of research road map
		• Review projects on materials research

Agencies often differ in their assessment of the risks of the same NMs.	What is the role of the NRGC in supporting agencies in harmonizing regulatory frameworks & methodologies on risks of NMs?	• There is no short or medium term role for the NRGC in harmonizing the regulatory frameworks and methodologies
		• A Think Tank for solutions:
		  ○ Give advice & support informed decision-making to regulators
		  ○ Show consequences of frameworks not being harmonised ('consequence scan')
		• Creating a trusted environment for agencies to share their struggle and to support them in exploring solutions to disharmonized regulatory frameworks

Regulators struggle with the increasing amount of complex NMs and how to classify and group these.	How can the NRGC facilitate the dialogue between research and regulation on how to deal effectively with the increasing amount of complex nanomaterials?	• Develop a process and practices to combine efforts
		  ○ Get an overview of technological developments in materials (foresight?)
		  ○ Identify clusters of new materials (new functionalities) and potential issues (risks, applicability of frameworks, test guidelines)
		• Method:
		  1. Bring together experts who could deal with new materials find solutions to cover potential issues
		  2. Systemic consensus finding. Aim is to identify fields of consensus and dissent
		  3. How to deal with diverge opinions (dissent) or contradiction

4.4 Four scenarios for the Council

Using the outputs from the brainstorming session at the M15 G4N consortium meeting, possible scenarios for the NRGC were further developed into four potential, realistic scenarios for how the Council could be built.

The scenarios were constructed around two main axes, as demonstrated in Figure 5. The horizontal axis concerned the role of the Council, with a facilitating/informing role on the left hand side and a more guiding/advisory role on the right end of the axis. The vertical axis concerned the positioning of the Council, with the two scenarios on top of the page being of a governmental nature, and two non-governmental scenarios at the bottom.

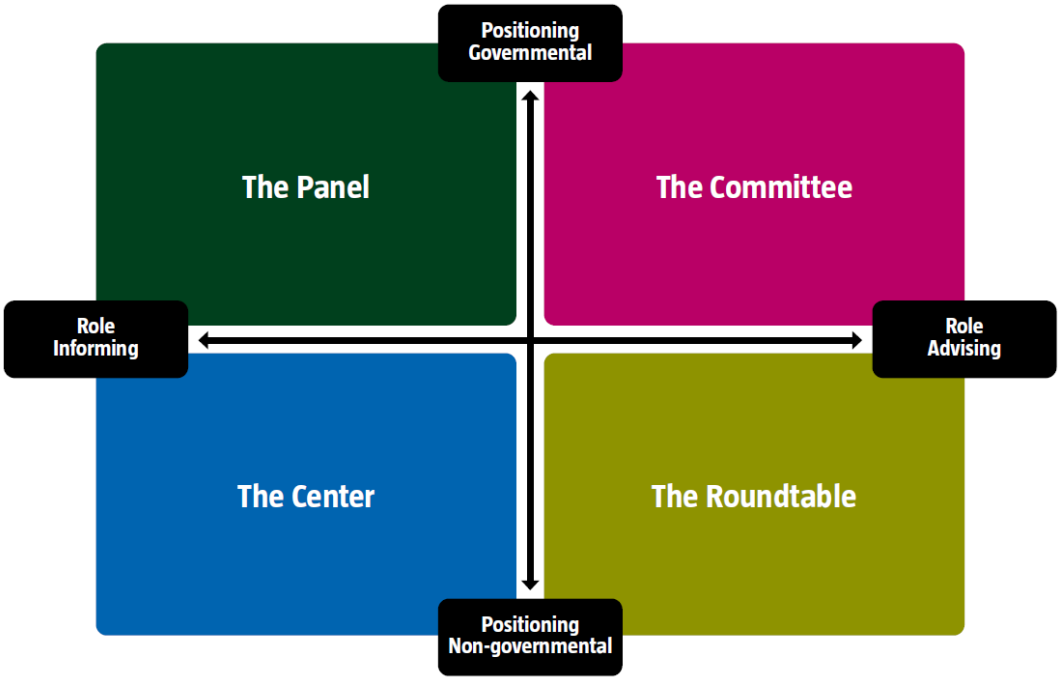

Figure 5. The four scenarios for the NRGC

The Panel is positioned as an EU Intergovernmental organisation with an informing role. It focusses on policy makers and regulators from European governments and the EU. Its members comprise a Board of representatives from European governments and EU-organisations that set the agenda. It is run by experts with a background in public, private and societal organisations. Its Board appoints staff, recruited from all European countries and types of organisations and it is funded by the EC and European governments.

The EU Advisory Committee, similar to the Panel, is positioned as an intergovernmental organisation with comparable focus, staffing and funding arrangements. There is some overlap in the services offered by The Panel and The Committee but The EU Advisory Committee has an advisory role alongside its informing role.

The EU Center is positioned as a non-governmental organisation with an informing role. It focusses on private, public and societal stakeholders within the EU. The Center has a Board with representatives from EU stakeholder groups that set the Agenda. It is staffed by experts working directly for the Center and seconded staff from public, private or non-profit organisations, including nanorisk governance organisations. It is primarily funded from the EU and member states but receives additional funding from public and private research programs and commissioned research. The Center fulfils its informing role by offering EU stakeholders the informational services under it diverse services.

The European Roundtable, positioned as a non-governmental organisations, focusses on informing and advising stakeholders in Europe. It depends on experts seconded from other (nanogovernance) organisations and is funded from member organisations, and additional private and public (research) funds.

4.5 Improving the scenario framework – evolving NRGC services

In the next step, the scenario framework was further elaborated. In addition to defining the Council's role, T5.1.2 aimed to propose and agree modes of action for the Council. This included potential activities related to the collection and evaluation of data, information and tools; dialogue events, reports and white papers, and online presence.

Possible "services" considered were categorised as Mapping, Conducting Analyses, Stimulating Dialogue, Organizing Training; Forming Recommendations and Forming Plans.

These services function as 'building blocks' for the possible NRGC scenarios. Per service, we specify which of the five sub-purposes of the Council it helps to achieve (Table 5):

❶ Helping stakeholders navigate the nanorisk governance landscape within which they operate.

❷ Improving the quality and access to FAIR data on nanomaterials, -risks and -benefits.

❸ Improving the resilience of stakeholders to nanorisks.

❹ Improving quality and harmonisation of regulatory frameworks across domains.

❺ Improving the safety and sustainability of innovation in nanomaterials in Europe.

Table 5. Sub-purposes of the Council achieved per service

Service	Description	Sub-purposes			
Mapping	Providing stakeholders access to information on nanorisk issues and the landscape within they operate.	❶			
	Informing stakeholders on results from private and public research on nanorisk issues.	❶			
	Providing a platform where stakeholders can share information on nanorisk issues.	❶			
Conducting analysis	Identifying emerging nanorisk issues e.g. via foresight studies	❷	❸	❹	❺
	Identifying gaps in research e.g. by engaging researchers in analysis gap analysis.	❷	❸	❹	❺
	Conducting analysis upon request on nanorisk issues.	❷	❸	❹	❺
	Monitoring progress on goals of the Nanorisk Governance Council e.g. with a dashboard on selected indicators	❷	❸	❹	❺
Stimulating dialogue	Engaging stakeholders in dialogue on nanorisk issues, e.g. with stakeholder meetings, conferences and public debates.	❷	❸	❹	❺
Organizing training	Organizing training opportunities for stakeholders, e.g. on safe-by-design or management of risks for data	❷	❸	❺	
	Linking stakeholders to relevant training opportunities	❷	❸	❺	
Forming recommenda-ations	Engaging stakeholders in forming joint positions on nanorisk issues e.g. on research priorities	❷	❸	❹	❺
	Advocating stakeholder positions in other organisations e.g. to decision makers on research programs	❷	❸	❹	❺
	Signalling topics for stakeholders to focus on e.g. suggesting important research topics	❷	❸	❹	❺
	Providing policy makers and regulators with advice upon request on nanorisk issues to support decision making	❷	❸	❹	❺
Forming plans	Engaging stakeholders in forming plans to improve safe and sustainable development, use and disposal of nanomaterials	❷	❸	❹	❺
	Helping stakeholder implement plans e.g. by monitoring progress of implementation	❷	❸	❹	❺

These services and the scenario framework were further evolved through a cross-consortia workshop. External stakeholder input was collected through three external stakeholder sessions and a meeting of the User Committee.

4.6 Evaluation of the scenario framework – pros and cons

Based on the inputs collected descriptions of potential services and elaborations of the four scenarios were developed. These were tested in a stakeholder consultation exercise on 3rd December 2020.

During the stakeholder sessions, input was received on the seventeen potential services the Council could offer, as well as the four more detailed scenarios for the Council.

The stakeholder meeting was an online event in which approximately 31 stakeholders participated (Table 6). Representation of civil society was less than anticipated, and somewhat hampers the representativeness of scores for that group presented in this report.

Table 6. Stakeholder group participation

Stakeholder group	Number of participants
Civil society	4
Academia	9
Industry	10
Policy makers	8

Firstly, participants were informed about the process and the content: the services and the scenarios. Subsequently, they were asked to reflect on the potential services and scenarios in four stakeholder-specific sub-groups. A combination of (quantitative) voting and (qualitative) exploring of arguments in favour or against services and scenarios was used. Based on the stakeholder meeting seven categories of arguments were identified (Table 7).

Table 7. Arguments used during stakeholder sessions on evaluation of the scenario framework

Type of argument	Related question
Demand	What is the added value of this service or scenario?
Supply	Are there other organisations already delivering this service, or better able to do so?
Impact	How impactful is this service or scenario?
Implementation	How complex is the implementation of this service or scenario?
Stakeholder representation	How well does this scenario represent stakeholders?
Independence	How does this services effect the independence of the NRGC?
Funding	How likely is funding for this service or scenario?

A report of that exercise is provided in Chapter 8 (NMBP-13 NRGC scenario taskforce: NRGC stakeholder meeting report). The Taskforce used the input collected to develop a final proposal ('the Blueprint') for the NRGC.

4.7 Blueprint for the Council

All of the input collected from all of the preceding steps was used to develop the "Blueprint for the Council", the *key result* for this task. To get to that result, a draft blueprint was prepared and tested in three engagement processes before the final Blueprint was prepared. These were

1. A cross consortium workshop on 22 March 2021

2. Two workshops with representatives from regulatory agencies

3. A set of 1:1 interviews with selected stakeholders

Based on the output from these a final blueprint was prepared. This is included in full as Annex 1.

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 the 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.

The document is comprised of four maps. These describe

1. Challenges and opportunities

Safe and sustainable exploitation of nanomaterials requires effective risk governance. 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. Key challenges relating to risks, risk assessment, co-operation, information, data and innovation are described

2. Mission and goals

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. Goals relating to risks, risk assessment, co-operation, information, data and innovation are described.

3. Activities

A set of activities (in previous steps called services) are described. These include Maintaining and implementing a multi-disciplinary and multi-stakeholder Risk Governance Framework; Offering stakeholders advice on (emerging) nanotechnology-related risks; Signalling emerging nanotechnology risk issues to stakeholders; Engaging all stakeholders in risk governance via roundtable meetings and; Providing stakeholders (access to) data, information and tools via an online portal. 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.

4. Organisation

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 representation and helps to establish the legitimacy of the Council.

4.8 Council members

No final decisions have been made regarding membership of the Council. Possible members are described in JM6 - Agreed list of invited members for Risk Governance Council.

5 Evaluation and conclusions

5.1 Evaluation of this deliverable

This Blueprint provides elements for a roadmap towards a full-fledged, functioning Nanotechnology Risk Governance Council. The next steps are to move from this Blueprint to implemention. An implementation plan is being developed as a phased approach for testing and implementation over the next 18 months. Key aspects of this include: designing and building prototypes, testing and refining the various elements as well as further engagement to improve the Council, build awareness and seek support (communication strategy). Several elements, for example the Framework and Portal are already well-advanced but others will need to be designed and elaborated. Costing and funding will have to be estimated. In all this is forseen as an iterative process between: (a) NRGC theoretical design (b) examples of possible activities, (c) specific application to real cases, and (d) feedback from regulatory, industry and NGOs.

The main steps are:

1. Testing the Council

- Delivery of case studies illustrating how the Council can add value
    - Case studies on tools
    - Case studies on framework
    - Case studies on materials
- Describing and testing services/activities
- Testing of other elements e.g. portal

2. Refining the Council

- Communication strategy (brought forward from 3) – name, messaging, branding
- Integrating activities of other Core Groups in Council activities
- Stakeholder engagement around the Blueprint
- Monitoring progress
- Mapping the relationship with most important organisations and stakeholders, defining the niche where NRGC would be relevant, useful and add value
- Decision point on narrowing of remit or focus
- Finalisation of the framework
- Finalisation of the portal
- Design of the Council website (incorporating portal)
- Finalising services/activities

3. Stakeholder engagement around the Blueprint

- 1 to 1 interviews with key individuals
- Engagement events:
    - 1st virtual conference and proceedings
    - (Dialogik) workshops
    - Other events
- Identification of "champions" within key organisations (specifically with a view to funding)
- Summarising/finalising multistakeholder dialogue

4. *Sustainability of the Council*

- Refining our value proposition
- Report on suitable operational business models for Council
- Identification of possible (grant) funding models and other support
- Application and securing grants/funding
- Deciding legal status of the Council

5. Launch of the Council

- Agree a launch date
- Development of a detailed plan through to launch
- Agreement of what will be live (infrastructure/activities/portal) at launch
- Launch of Council and Portal
- Launch event and communications

6. Who will be part of the Council and what will be their roles?

- Identification of members
- Identification of executive responsibilities and who will do them
- Finalising TOR and roles
- Appointment of Chair and members

7. Immediate next steps

- Refinement of this "implementation plan"
- Alignment of existing deliverables with these tasks (not just in Council WPs)
- Identification of any gaps and agreement of how to close them
- Timescales to be agreed

5.2 Evaluation of the Blueprint based on consortium feedback

The feedback from participants who took part in the Gov4Nano 5th Consortium Meeting (12-14 April 2021) and the Joint NMBP-13 Conference (14-15 April 2021) was analysed and the results of that analysis used to evaluate the Blueprint as a guide for implementing the Council.

Briefly, the responses to questions posed during Council-focussed sessions and the dialogue that took place during those sessions, were summarised by broad subject area. These were then categorised into distinct themes against which the Blueprint of the NRGC was assessed. The full report on that analysis can be found in Annex 2.

The analysis showed that most of the characteristics of the proposed NRGC deemed valuable by respondents have been covered under the Blueprint for the Council and, notwithstanding the impossibility that the final design would be agreeable to all actors, there is strong support for the Blueprint and keen interest in seeing it employed for the implementation of the Council.

Development of a comprehensive Blueprint for the Council has been an evolutionary and extensive process undertaken by the three projects. It has been truly co-creative, led by the Task Force but involving through multiple engagements, the Core Groups, the wider project Consortia and well as external stakeholders. Inevitably, this has led to compromise in the design and the certainty that not all aspects of the final design are agreeably to all actors, even within the Project Consortium.

Nevertheless, the level to which this exercise has demonstrated widespread support for the final Blueprint across the three consortia is very encouraging. As such, it is concluded that the Blueprint is acceptable as a viable design on which to base implementation of the Council.

Table 8. Alignment of characteristics valued by consortium participants with those of the proposed NRGC

Valued NRGC characteristics and important issues according to participants	Valued characteristics identified under the proposed NRGC's…									
	…Activities					…Organisation				
	Governance framework	Advice	Foresight	Roundtable	Portal	Structure	Members	Staff	Agenda	Funding
	Items covered									
Interaction		✓		✓						
Diversity & inclusivity				✓		✓	✓	✓		
Centralisation and simplicity					✓					
Proactivity		✓	✓	✓						
Exceptionalism					✓					
Support and guidance	✓	✓								
Harmonisation				✓	✓					
Legitimacy through endorsement										✓
Independence and neutrality						✓		✓		✓
Accessibility					✓					
Awareness				✓	✓					
Credibility / Legitimacy								✓		
Translational role: bridging the gap between research and policy				✓						
Interaction/relationship between the Council and other elements	✓									
	Items implicit in the design									
Concern about affront to or clashes with regulators and other important stakeholders										
Training/Education										
Alignment with principles of sustainable development										

Valued NRGC characteristics and important issues according to participants	Valued characteristics identified under the proposed NRGC's…									
	…Activities					…Organisation				
	Governance framework	Advice	Foresight	Roundtable	Portal	Structure	Members	Staff	Agenda	Funding
Legitimisation								✓		
Scope										
Complexity										
Benefits to Regulators										
	Items not explicitly covered									
Mediation										
Clarity, transparency, trust and reliability										
Regulation										
Stakeholder buy in										
Updatable/Flexible										
Equality / Fairness										
Learning from experience										
Unintentional consequences										

6 Deviations from the work plan

6.1 NMBP-13 Collaboration

The decision to create a single council across the three NMBP-13 projects impacted the approach to T5.1.2, as described above in Section 3.1.1. While the outputs remain the same (i.e. clarifying the role, positioning and actions for the Council) the approach was impacted by the unique emphasis of the individual projects and the importance of cross-consortium communication.

6.2 T5.1.1. International Think Tank

Originally, the initial inputs for T5.1.2 was to come from the International Think Tank (ITT), as developed in T5.1.1. However, during the first year of the Gov4Nano project the concept of the ITT in relation to the design of the Council was reconsidered. This decision was also influenced by the activities of the other NMBP-13 projects. A new approach was developed, in which the idea of the ITT remained as a valuable add-on to the NRGC.

Two distinct role became apparent. The NANORIGO User Committee took on the role of monitoring the stepwise establishment of the NRGC; paying particular attention to the trust, integrity and independence of the NRGC. The role of the ITT was directed towards the tasks of the NRGC and how the services of the Council can have impact. More information is available in Deliverable 5.1 'Report describing functioning and members of the ITT'.

As such, at this point no final decisions on membership of the Council have been made. Possible members are discussed in JM6 - Agreed list of invited members for Risk Governance Council.

7 Performance of the partners

IOM led the work package and took principal responsibility for this deliverable. IOM organised all of the regular meetings of WP5 and the all of the Council related sessions at the consortium meetings (at least one at each consortium meeting). Across the three projects, IOM led both the Council Core Group and the Council Design Task Force (TF) and participated in all meetings of these groups. Within this IOM took specific responsibility for organising and leading the two Cross-Consortia meeting as well as the two stakeholder meetings through which the Blueprint was developed. IOM worked closely with De Argumentenfabriek on finalising the content of the Blueprint.

RIVM, was a member of the TF and contributed strongly in all relevant WP, TF and Core group meetings in regards to the development of the NRGC. RIVM commissioned the Argumentation Factory, to guide the process for developing the NRGC and was initially the primary contact with them RIVM also led on the Deliverable 6.2 on "Force Field Analysis and Background Analysis of Stakeholders which provided significant input into this deliverable.

AIRI was co-lead of the WP5 and was a member a member the TF. AIRI contributed strongly to all relevant WP and TF meetings and workshops

IenW led on Deliverable D5.1 Report describing functioning and members of the ITT, and important input to this deliverable. They also contributed via network development ('SPINE' the Safe-by-Design Policy International Network) and opening up their own network to the project.

NIA as Leaders on WP6 provided input and support on stakeholder engagement, organising the workshop in Dec 2020. They also contributed strongly to all relevant WP

BNN: Provided input and support on stakeholder engagement, organising the workshop in Dec 2020. Co-ordinated access to and engagement with the User Group of key stakeholders. Contributed strongly to all relevant WP and consortia meetings and to joint workshops between WP5/6 and 8 on council design.

AIST has worked on Task 5.2: Widening the network: transdisciplinary alignment of regulatory questions and needs: a joint Gov4Nano-SAFERA-Workshop was set up and held in Vienna on the 18th and 19th June 2019. The workshop was documented in a meeting report; deliverable D5.4 Initial List of joint calls (M12), which was delivered and accepted in M21 (incl. a public Fact Sheet: G4N Factsheet D5.4 "Report on execution of Regulatory Road and Research Map including joint calls – initial list").

AIST reviews and contributes to deliverable reports of WP5 and have reported the success and progress of the Gov4Nano-SAFERA Projects to a number of external experts.

BAuA participated at the cross-project review meeting for the Nano Risk Governance Council (NRGC). Contributions were made within the plenary session and session B, which was covering the Scientific Committee on Nanomaterials Scenario of the NRGC. BAuA

contributed to the discussion towards the innovation, capabilities and roles of the Scientific Committee as putative model for the NRGC.

EMPA participated in reviewing the deliverable of WP5.

DIALOG: Participated in all relevant WP and consortia meetings

ISS: Participated in all relevant WP and consortia meetings and to the Value proposition workshop held in Bilthoven, The Netherlands, on the 5th December 2019 in the framework of the "Regulatory Risk Analysis Summit 2019".

YIL: Participated in all relevant WP and consortia meetings

TEMAS AG: Participated in all relevant WP and consortia meetings

8 Selected sources of information

NMBP-13 NRGC scenario task force: Proposal for a Nanotechnology Risk Governance Council, consultation draft, March 2021 (Annex 3)

This summary document 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 the three projects tasked with improving governance of nanotechnology-related risks in Europe, in close collaboration with stakeholders.

NMBP-13 NRGC scenario task force: Council Design – Process and progress, WP Discussions, February 2021 (Annex 4)

This document summarises the process and the output of the taskforce, as per 5 February 2021, before a round of consultation with external stakeholders

NMBP-13 NRGC scenario taskforce: NRGC stakeholder meeting report (Annex 5)

This report briefly summarizes the main results from the stakeholder meeting organized on 3 December 2020 by NANORIGO, RiskGONE and Gov4Nano. The session was part of the process led by a Taskforce with 3 representatives from these projects, which has the main task to develop a joint proposal for a Nanotechnology Risk Governance Council (NRGC), with the overarching goal "to stimulate safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe."

Gov4Nano D6.2: First Scoping Report on Force Field Analysis and Background Analysis of Stakeholders

Link to document on Gov4Nano's project site

This deliverable on "Force Field Analysis and Background Analysis of Stakeholders" identifies interests, positions, needs, barriers, and incentives amongst the different stakeholder groups in risk governance of nanotechnologies. The analysis is based on literature review, including results from relevant finalised and on-going H2020 projects, and outputs of stakeholder engagement activities performed by Gov4Nano. Significant inputs have been derived from the EC4SafeNano, caLIBRAte, SUN, NANORIGO, and RiskGONE H2020 projects.

NANORIGO D4.1: Possible mandate, composition, structure of a new Nanotechnology Risk Governance Council (NRGC)

Link to document on NANORIGO's project site

This document outlines aspects to be considered for the design of the NRGC. While a complex network of regulatory institutions already exists, some stakeholders highlight gaps, which the NRGC could help remedy, by unifying and harmonizing the field.

NANORIGO D4.2: Database of potential members of the Nanotechnology Risk Governance Council (NRGC) (Annex 6)

This report provides a preliminary list (database) of potential members of the NRGC, preceded by a brief description of the process followed to develop the list, an outline of possible criteria for selecting members, principles that members may be requested to adhere to, and other open questions that will be addressed in further project work.

NANORIGO D4.3: Virtual NRGC workshop no.1 and proceedings

Link to document on NANORIGO's project site

This document outlines the proceedings of the first virtual workshop to design the NRGC, held on 8 June 2020 online. This first virtual workshop was one of four virtual workshops that NANORIGO will organise, also in collaboration with Gov4Nano and RiskGONE.

NANORIGO D4.4: Mandate, composition, structure of the NRGC

Link to document on NANORIGO's project site

The report summarizes progress achieved so far, without concluding on the optimum design for the Council, which would be premature given the request to produce one unique design across the three projects and the need to test hypotheses before formulating a main recommendation.

NANORIGO D4.5 (MS15): Virtual NRGC workshop no.2 and proceedings

Link to document on NANORIGO's project site

This document outlines the proceedings of the second virtual workshop to design the NRGC, held on 30 September 2020 online. This second virtual workshop was one of four virtual workshops that NANORIGO will organise, also in collaboration with Gov4Nano and RiskGONE.

RiskGONE Questionnaire for interviews (Annex 7)

This document consists of a questionnaire for collecting feedbacks from external stakeholders. It was drafted by the RiskGONE and finalised with Gov4Nano and NANORIGO.

RiskGONE D2.1: Report on Risk Governance needs (Annex 8)

This document summarises discussion related to nanotechnology risk governance (RG), as well as how a 'nanotechnology risk governance council' can provide improved nanotechnology governance leadership for many stakeholder groups within and outside the European Union.

RiskGONE D7.3: Risk Governance of Nanomaterials: Analysis of Operating Practices of Existing Bodies

Link to document on RiskGONE's project site

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

9 List of abbreviations/glossary

D	Deliverable
DoA	Description of Action
EC	European Commission
EU	European Union
ECHA	European Chemicals Agency
EUON	European Union Observatory for Nanomaterials
FAIR	Findable, Accessible, Interoperable, Reusable
ITT	International Think Tank
JM	Joint Milestone
JRC	Joint Research Centre
KO	Kick off
NGO	Non-Governmental Organization
NM	Nanomaterial
NMBP	Nanotechnologies, Advanced Materials, Biotechnology, and Advanced Manufacturing and Processing
NRGC	NRGF Nanotechnology Risk Governance Council
NRGF	Nanotechnology Risk Governance Framework
NSC	EU NanoSafety Cluster
RG	Risk Governance
SbD	Safe by Design
SH	Stakeholder
SME	Small and medium-sized enterprise
TF	Task Force
WP	Work Package

Annexes

Annex 1:

Blueprint for the nanotechnology risk governance council

NMBP-13 Council Task Force

Blueprint for the nanotechnology risk governance council

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meeting the needs of nanotechnology

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NANORIGO

De Argumentenfabriek

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Inhoudsopgave

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).

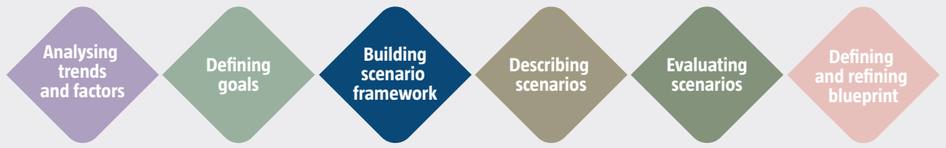
In addition to the maps that describe the building blocks for the NRGC, readers can find additional remarks on the process and visualisations of intermediate results in the appendix.

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

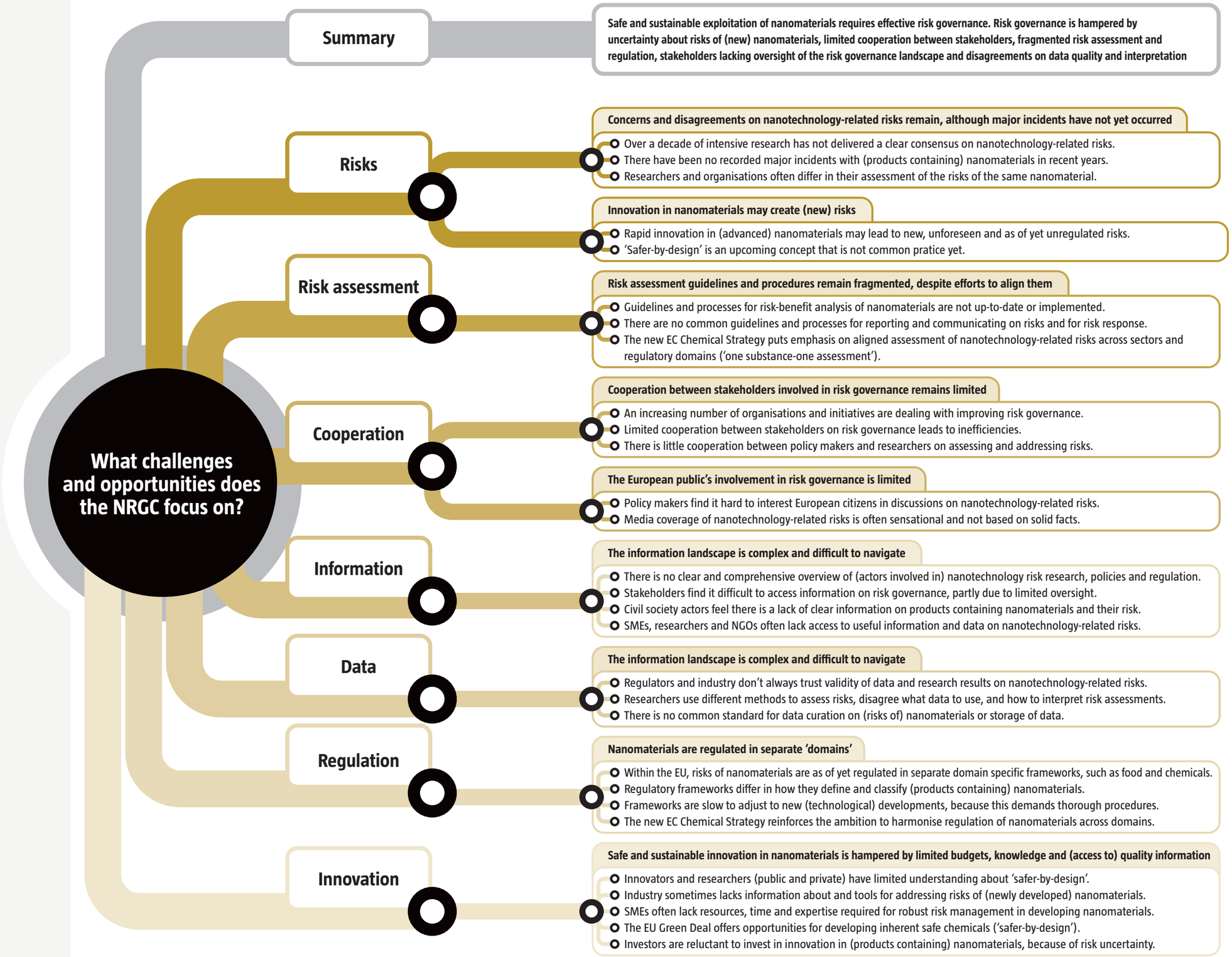
(Innovation in) nanomaterials offers huge potential for economic growth and addressing societal and environmental challenges. Harnessing these opportunities will require effective governance processes - now and in the future. Regulators, policy makers, industry and NGOs are working to identify and assess 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.

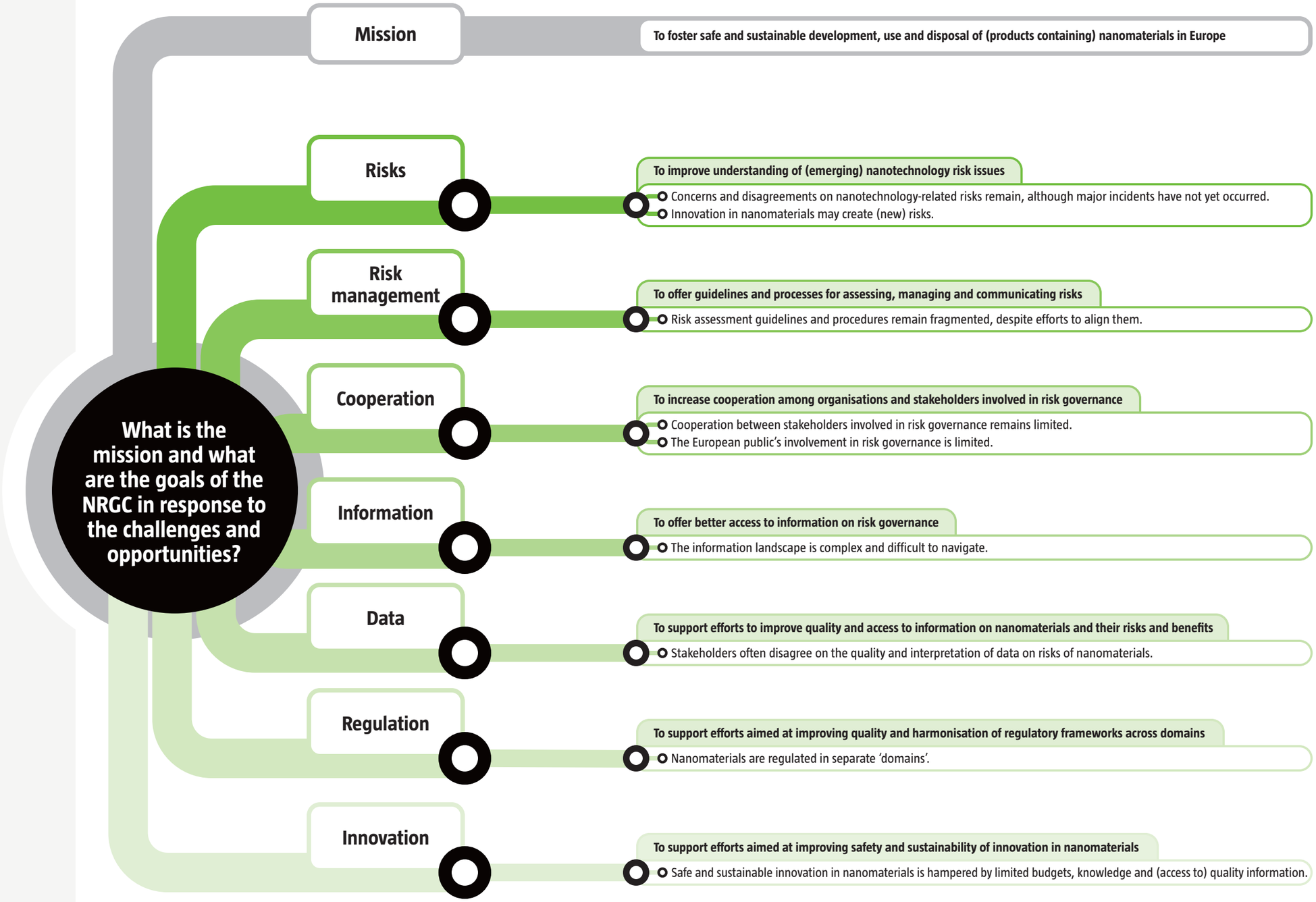
For each challenge or opportunity, a corresponding goal was formulated. First and foremost, the Council could help improve stakeholders' understanding of (emerging) nanotechnology risk issues. It could also increase cooperation among stakeholders and help them navigate the risk governance landscape. 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.

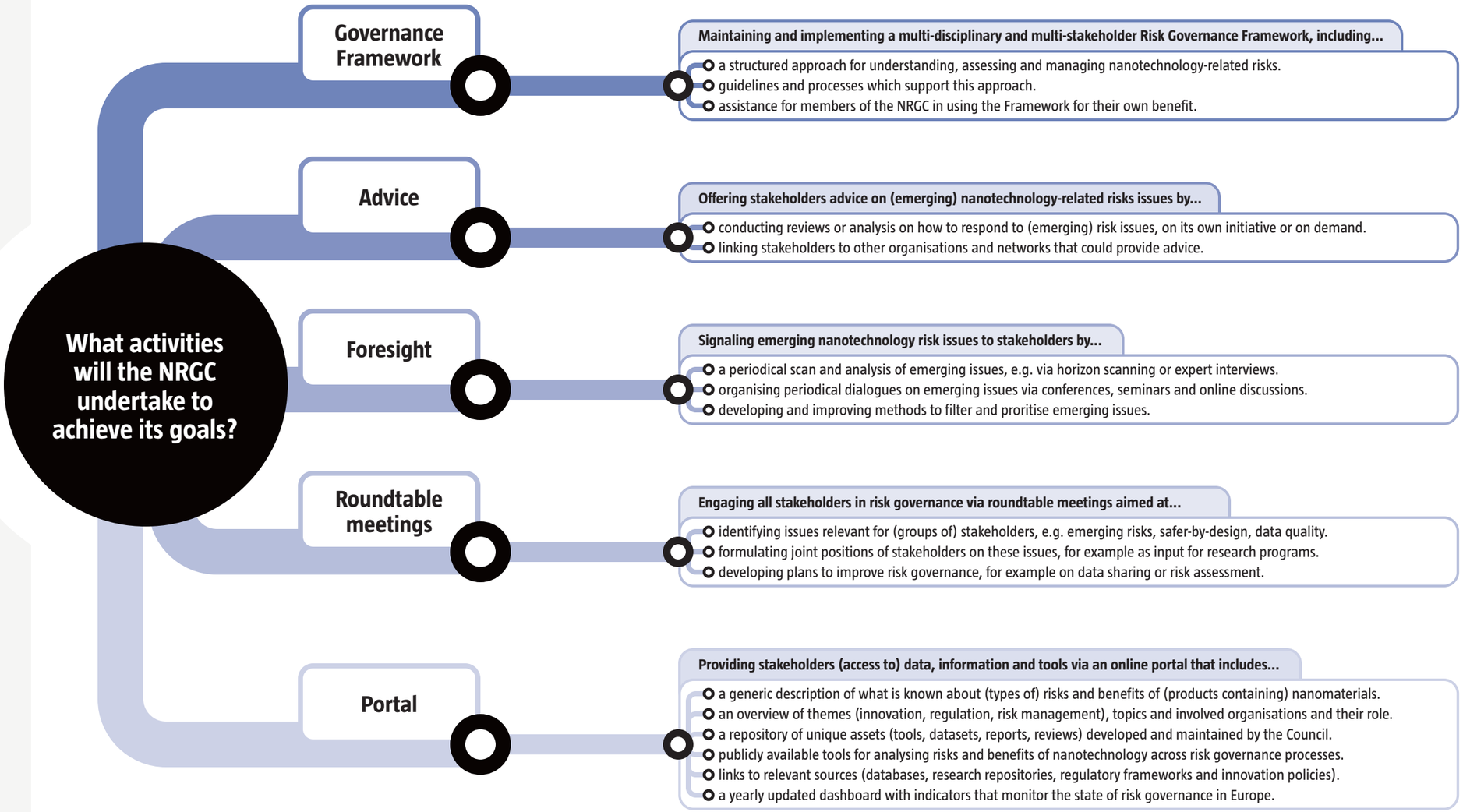
Second, the Council offers advice on (emerging) nanotechnology-related risk issues. It can provide stakeholders, including regulators and policy makers, advice on specific issues in the form of analysis, reviews or case studies. Such advice may be developed following the Council's own agenda setting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

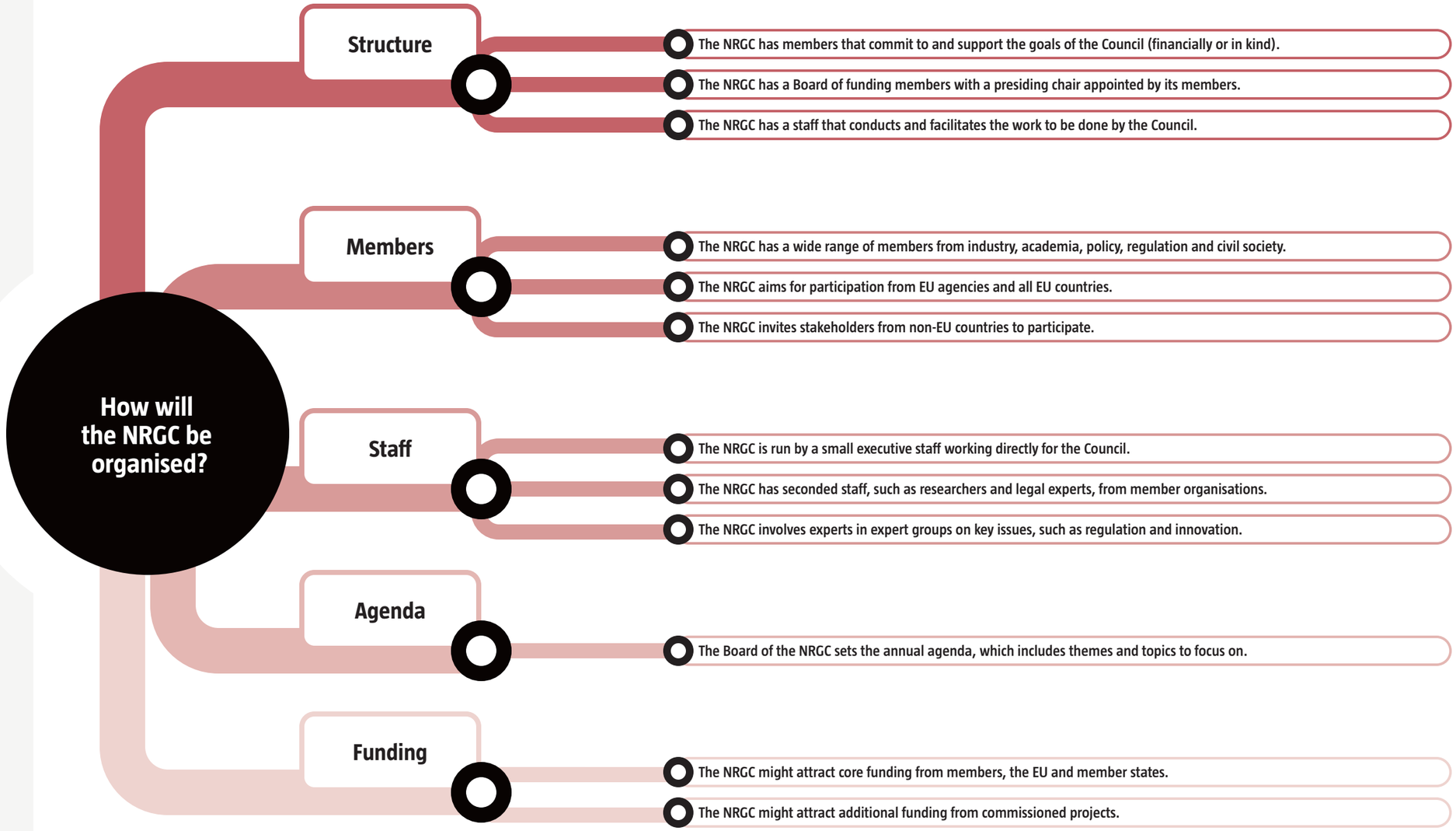
How could the Council deliver these activities? This question can only be answered conclusively once there is a clear consensus on the goals and activities the Council will provide, and who is willing to support the Council.

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.

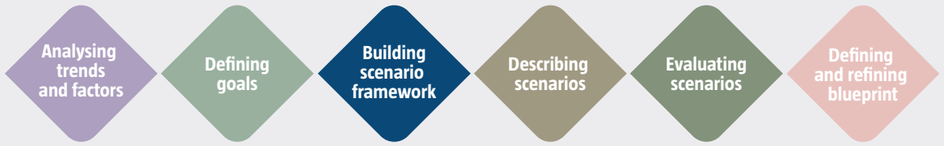
As a first step, the added value that the Council could have was made explicit. Recognising that there are already many organisations out there that deal with risk governance, and in order to get a grip of the most important matters the Council could address, a list of potentially relevant trends and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

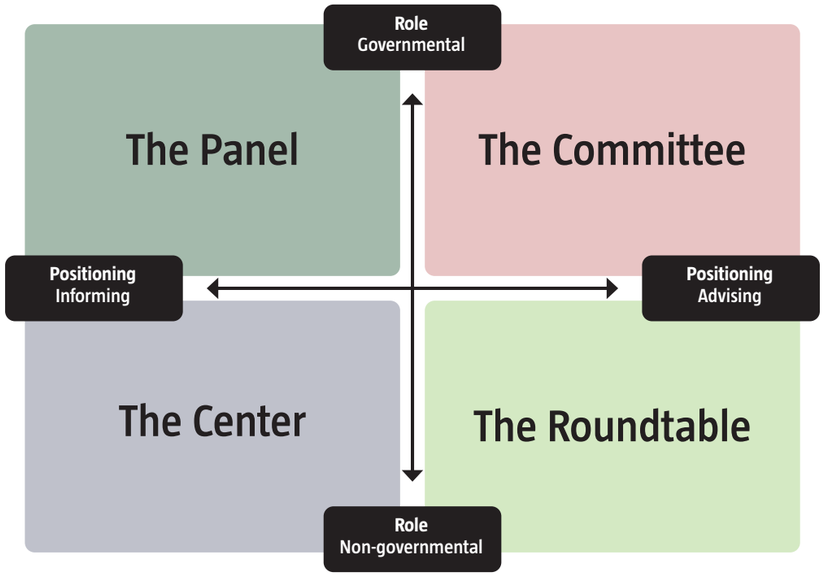
From this longlist of possible developments and factors, those that pose a clear challenge or opportunity that the Council needed to address were distilled. Corresponding to these challenges and opportunities, seven goals were formulated and an overarching mission that illustrate the added value of the 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

Annex 2 - Evaluation of the Blueprint for the NRGC based on Consortium feedback

1 Background

An evaluation of the Blueprint for the Council, based on the expert views and opinions of participants of the Consortium Meeting (12-13 April 2021) and the Joint NMBP-13 Conference (14-15 April 2021), was undertaken.

2 Source data and analysis approach

The responses to questions posed during Council-focussed sessions of the above-named meetings (Table 1), and the dialogue that took place among participants during those sessions, were summarised by broad subject area. These were further categorised into distinct themes that were then compared with the characteristics of the proposed NRGC as defined in the Blueprint.

Table 1. Data sources

Meeting / session	Questions posed or source of information
Gov4Nano/WP5 technical meeting	Are any of these activities not needed or are any activities missing from your perspective?
Joint NMBP-13 Conference – report from coordinators	Q1: Do you consider that the Council as proposed will add value to the risk governance process?
	Q2: What are the most important ways it adds value?
	Q3: How could it be further improved to add more value?
	Q4: Regarding Activities, are any of these not needed or are any activities missing from your perspective?
	Q5a: Do you support moving to implementation of Council based on this
	Q5b If not, how should it be changed so that you can support it?
	Q6: What other implications are there for the Blueprint from your workshop sessions?
Joint NMBP-13 Conference – Joint Core Group Coordination	Dialogue during the Council session

3 Results of analysis

The perceived added value to risk governance of the Council as proposed, and how that value could be improved were investigated by posing Questions 1, 2 and 3:

Q1: Do you consider that the Council as proposed will add value to the risk governance process?
Q2: What are the most important ways it adds value?

Q3: How could it be further improved to add more value?

3.1 Themes

The majority of participants felt that the Council as proposed will add value to the risk governance process (54/59; 92%). One of the 5 who answered 'no', explained that although they thought the Council might add value, too many details were lacking for them to give a proper judgement on this question.

There was considerable overlap in the responses to Questions 2 and 3, indicating that while some respondents thought that the Council as proposed added one or other value; others anticipated that, on the contrary, those values would be needed to improve the Council. For instance, while one respondent thought that the proposed Council would add value as a Mediator, another felt that being a Mediator (as opposed to a facilitator) would *improve* its added value.

In the following sections the themes that arose in response to Questions 2 and 3 are listed and described. Where relevant, sample texts from the answers of participants are given in *italicised* text.

Some themes were based on explicitly expressed ideas and opinions while for others an interpretation of implicit views was required.

3.1.1 Themes around added value of the Council as proposed

Question 2: What are the most important ways it adds value?

Interaction and Mediation

It is believed that the proposed Council will facilitate interaction and stimulate dialogue among stakeholders by providing a common space where stakeholders from across the spectrum with diverse disciplines can interact with each other on an equal footing.

It would mediate between regulators and provide a platform for regulator / stakeholder interaction with such interactions signalling that it is a joint effort towards effective risk governance.

Communication, equality and diversity ('*acceptance of (non-usual) stakeholders')* were important aspects of interaction that surfaced:

- *'sharing, mutual learning across disciplines, sectors (toxicologist, risk managers, innovator, business operators, regulations, professional users)'*

Diversity and inclusivity

Respondents thought that the Council would promote diversity within the nanotech milieu. Sometimes coupled with integration, the key point was that through its inclusivity, it would promote true integration among different stakeholders that may have widely different needs and perspectives.

- *'communication and integration of different approaches and stakeholder needs, inclusiveness, flexibility'*

Clarity, transparency, trust and reliability

Clarity, transparency, trust and reliability were four inter-related themes deduced from responses.

It is thought that the proposed Council would bring clarity to risk governance of nanotech by being explicit about what the purview of risk governance for nanomaterials is. However, a number of respondents thought that the mission of the Council itself was not yet clear and its purposes still needed to be delineated.

Transparency was coupled with clarity. However, as a theme in its own right, it underscores the proposed Council's perceived value as a transparent, reliable and trusted entity.

Centralisation and simplicity

By providing a central source for all risk governance tools, it would simplify all aspects of risk governance.

Proactivity

It would take a proactive approach in dealing with existing risk as well as new and emerging risks.

Exceptionalism

The mention of the '*highlighting of the exceptionalism of nanotech'* as a value the Council would provide, suggests that there is a (risk governance) gap that is best filled by the proposed Council and cannot be managed by entities charged with risk governance of conventional materials.

Support and guidance

It is valued as an entity that would provide support for both tangible and intangible aspects of risk governance.

By tangible it is meant e.g. '*access to state-of-the-art tools for development of NEPS and ENMS.'* Intangible aspects include items such as '*help with decision making';* being a *'signpost to knowledge resources';* or *'support for sustainability and safety of nanotechnology'*

Support might also be in the form of '*providing guidance and data for SMEs'*, and representing all the nano-safety community with regards to new technological and policy developments.

Harmonisation

It would add value by ensuring a consistency of approach across member states (?) e.g. '*overarching national regulations'*

Regulation

Respondents thought that the proposed Council would add value by having some sort of regulatory-related role. A view of what that role would be varied among respondents. It included:

- Facilitating regulatory readiness and acceptance
- Being proactive by steering research ahead of regulation
- Engaging stakeholders (e.g. industry and NGOs) in a process that would lead to better regulation, and
- *'Providing a regulatory role in the absence of a central regulation'*

3.1.2 Themes around how the Council's value could be improved

Question 3: How could it be further improved to add more value?

Some of the themes that emerged in response to Question 2 also appeared in response to Question 3. This may signal that respondents felt that these were absent from the Council in its proposed form, or that they wished to reiterate the importance of these characteristics. These included:

- Interaction
- Clarity and transparency
- Diversity & Inclusivity:
    - '*It can be inclusive and unifying, communicating in a manner that would appeal to different types of user groups.'* In other words, its guidance should be relevant to its range of users.
- Centralisation
- Exceptionalism:
    - '*needs to make clear about how it differs from existing institutions and tools'*
- Mediator:
    - '*Build in a mediating (not facilitating) role'*
- Regulation (Compliance)
    - *'It could also promote compliance to authorities'* That the Council could promote compliance aligns with a possible aforementioned regulatory-related role.

The themes that emerged in response to Question 3 and not previously mentioned included:

Legitimacy through endorsement

It was felt that its value would be improved by endorsement from large influential actors such as governmental institutions and political players.

Independence and neutrality

Neutrality and independence was named as core values encircling other Council activities or previously-mentioned values such as:

'*being a neutral body that connects regulators and other stakeholders*'

or being…

'*…a source of reliable and balanced information, tools and assessment.*'

'Legitimacy through endorsement' and 'Independence and neutrality', especially where the endorsement comes from political or industry players, are at odds with each other. There is the risk that the former might engender distrust and a perceived partiality of the Council making it difficult to be seen as independent and neutral. During implementation of the Council it will be important to weigh which of these is more crucial to the Council's development and future prospects and/or illustrate clearly that the Council is outside the influence of its endorsers.

Stakeholder buy in

Acceptance by stakeholders and their commitment to the Council would improve its value. Hence a stakeholder needs assessment would be valuable.

Accessibility

It could add more value by being '*accessible and user-friendly*'.

This theme of Accessibility, together with other characteristics such as 'Diversity and Inclusivity' indicates what respondents felt the ethos of the Council should be.

Awareness

The Council *'should be aware of where risk communication takes place.'*

An alertness on issues (in this case risk communication) relevant to its purpose needs to be maintained. It is important for the Council to maintain a proactive investigative or observatory mode as part of its basic operations in order to keep on top of issues that may impact it.

Other

Other responses included it should be easily updatable (flexibility) and that a business model should be considered in its functioning.

3.1.3 Themes around superfluity or inadequacy of the Council as proposed

> Question 4: Are any of these activities not needed or are any activities missing from your perspective?

Question 4 was posed in two different forums: the *Gov4nano WP5 technical meeting* and the *Joint NMBP-13 Conference – report from coordinators meeting* so have been processed together. Interestingly, while there was overlap in some of the themes that emerged and likely overlap of respondents in attendance at these two meetings, there were considerable differences in the nature of the responses of the two groups.

Some items in response to Question 4 had already been tabled in response to the Questions 2 and 3 concerning the added value of the Council. These will not be expounded further here but include:

- Interaction

- Mediator
- Clarity
- Proactivity
- Guidance
- Harmonisation
- Regulation
- Independence
- Awareness

Themes in response to Question 4 and not previously mentioned were:

Acceptance/recognition of the need for all of the Council activities indicated

This was one of the top two themes that emerged from the responses to this question. Respondents were clearly supportive of the proposed activities of the Council, appreciative of the work that went into it and noted that all the basic requirements were covered.

It was also noted that the NMBP community was the only one whose members held the breadth of expertise capable of establishing a Council that would be fit for purpose.

Concern about affront to or clashes with regulators and other important stakeholders

A top concern was the possible affront to or clashes with regulators and other important stakeholders and the impact this might have on the Council's effectiveness. They also questioned the reason behind the lack of support from regulators for the NRGC and queried whether a rigorous gap analysis had already been undertaken. They felt that the latter would help determine what niches the NRGC could fill without encroaching on the jurisdictions of regulatory bodies engaged in similar tasks or ending up in a stand-off with them or other stakeholders.

Training/Education

Training was an activity thought to be missing from proposed Council activities. Although how and where this should be implemented varied, including that:

- *'it should be part of the Portal, '*
- *'a helpdesk function on tools/data'*
- *'it should address public at different levels of understanding'*

Alignment with principles of sustainable development

It was felt that clear links to the ethos of sustainability were missing or not clearly apparent among the currently proposed activities of the Council. A possible role for the Council in supporting safe and sustainable development of nano- and advanced materials was mentioned. It was also proposed that the Council should be in alignment with EU activities such as the chemical strategy for sustainability where SSbD is central, as well as to the UN Sustainable Development Goals.

Other

Other items that were mentioned include:

- The relative importance of the Council versus the Portal where the portal is thought to have a more important role than the Council.
- A translational role for the Council where it helps bridge the gap between research and policy.
- The question of whether the Council needs to focus beyond nanomaterials, and
- Its role as an influencer in industry:

- *'nudging in order to raise awareness and shift thinking in industry'*

Question 5a: Do you support moving to implementation of Council based on this?

Question 5b: If not, how should it be changed so that you can support it?

3.1.4 Moving towards implementation

Respondents were unanimously in favour of progressing to implementation of the proposed Council based on the current Blueprint (42/42; 100%). However, it was suggested by one participant that it should '*start small with a round table.'*

Question 6: What other implications are there for the Blueprint from your workshop sessions?

3.1.5 Implications for the Council as proposed

Blueprint finalisation and Blueprint to Council translation

There was keen support for the finalisation of the Blueprint and the subsequent move from the Blueprint to the implementation of the Council. There was a sense that this would help other areas of the overall project to progress and, notwithstanding the uncertainties, *'Learning by doing'* is seen as the best way to proceed.

> *'Portal and tools depend a lot on the blueprint'*
>
> *'Move from this theoretical blueprint to the real world'*

The use of case studies and other types of simulated scenarios was thought to be useful in facilitating the translation from Blueprint to Council. Suggestions included:

> *'Build(ing) use cases to address some well recognised 'problem' '*
>
> *'Link(ing) blueprint activities with the outcomes of different WPs across the project, start using them as testing of the council' and,*
>
> *'If a few work items can be defined, it would help'*

Legitimisation

Once again legitimisation of the Council arose where it was felt that *'Legitimisation by high-level, respected players (is) needed for implementation'*.

Interaction/relationship between the Council and other elements

The relationship between the Council and the other arms of risk governance within this project were mentioned. It is thought that development of the Council and the Framework complement each other – developing '*hand in hand'* so to speak. With respect to the Portal, it was questioned whether the Council would have a follow-up role once this project came to an end.

3.1.6 Joint NMBP-13 Conference – Joint Core Group Coordination – Dialogue analysis

Analysis of the dialogue that took place during the Council-focussed part of the Joint Core Group Coordination revealed themes that were related but not clearly apparent during the analyses of dialogue of the sessions described above.

Scope

The Scope of the Council with respect to what type of material would fall under its remit was discussed.

- *'are we only looking at nanomaterials or also nano-enabled products? or have not decided yet?'*
- *'In principle, both…'*

The context of this was partly around *'securing the right stakeholders'*. However, the theme of scope together with the related themes of clarity and transparency mentioned under 3.1.1, suggests a need for the Council to be explicit about its scope in general. It should detail, among other things, what type of materials it covers and be very clear about what falls under its remit.

Complexity

The issue of scope regarding the type of material, led to reflections around the complexity of risk governance of nanomaterials since the same material could exist in different forms – freely, aggregated or embedded in a matrix – with considerably different risk implications. In general, a life cycle assessment will be useful in determining the risks associated with different production-utilisation- and end-of-life phases of nanomaterial-containing products as this would help identify at what stages risk mitigation is needed. This information would help the development of appropriate legislation and complementary analytical tools to support that legislation.

Credibility / Legitimacy

Once again the importance of credibility emerged with some respondents thinking that an indication of approval from an influential, neutral entity such as the EU could be a measure of credibility, while others felt that trust of the Council would need to be gained slowly. Again we see the idea of 'Legitimacy through endorsement' but there is also a sense that, given how trust is usually engendered, the Council should independently establish itself.

Equality / Fairness

Equality and Fairness are seen as important qualities for the Council to uphold with one respondent querying whether this would be formally included as a basic principle of the Council as it moves towards implementation.

> '*…there needs to safeguards against capture by any specific group to maintain the balance between all stakeholder groups'*

Learning from experience (with specific reference to COVID risk communication)

It was thought that there was much to be gained by drawing from previous experience.

> '*…we should take care of safety of product, safety of process and safety of usage. These are the three major pillars of the work we have done in OECD SIA SBd, and this should be reflected in the NGRC.'*

It was also felt that, notwithstanding the differences in scenarios, there are relevant lessons that could be learnt from the handling of the COVID pandemic with respect to:

'risk perception by the public, actions of regulators and communication, etc.'

Especially with regards to connection between regulators and relevant stakeholders some felt that the poor communication between key players during the pandemic should highlight to the Council the need to have suitable plans for stakeholder communication and risk/benefit communication. Others felt that the difference in communication needs did not allow such comparison while still others saw the usefulness in learning from the COVID approach e.g. to engage young people using social media.

Benefits to Regulators

It was thought that the COVID example should highlight to regulators the Council's value in connecting regulators with stakeholders, assuming that they recognised the Council's benefits in the first place. It is believed that through the Council:

'…Regulators would have a neutral body that connects, gives feed-back and expert advice, etc.'

Unintentional consequences

One respondent expressed the concern that the Council might pose a job threat to consultants; This was considered an unfavourable outcome.

> *'And we should not threaten jobs here, I see consultancy jobs being erased by this council'*

Considering this and other similar concerns, an impact analysis of the Council on existing practices and structures providing similar services, might be prudent and help circumvent or mitigate unintentional (adverse) consequences.

4 Summary and overall conclusion

4.1.1 How well do valued characteristics of the proposed NRGC align with expectations?

Table 2 gives an overview of valued NRGC characteristics and important issues around the NRGC as identified by respondents, and whether these have been taken into account under the proposed Council.

Most of the characteristics that respondents deemed valuable were either covered under the proposed NRGC as part of its proposed activities or how it is organised; or were implicit in the design or ethos of the NRGC. Some of the characteristics that were deemed valuable but not covered under the proposed Council would be difficult to assess prior to implementation of the Council e.g. stakeholder buy in, equality/fairness, unintentional consequences. However, having been highlighted they can be proactively monitored and, where necessary, steps can be taken to ensure they are considered during the implementation stage of the Council.

Table 2. Alignment of characteristics valued by consortium participants with those of the proposed NRGC

Valued NRGC characteristics and important issues according to participants	Valued characteristics identified under the proposed NRGC's…									
	…Activities					…Organisation				
	Governance framework	Advice	Foresight	Roundtable	Portal	Structure	Members	Staff	Agenda	Funding
	Items covered									
Interaction		✓		✓						
Diversity & inclusivity				✓		✓	✓	✓		
Centralisation and simplicity					✓					
Proactivity		✓	✓	✓						
Exceptionalism					✓					
Support and guidance	✓	✓								
Harmonisation				✓	✓					
Legitimacy through endorsement										✓
Independence and neutrality						✓		✓		✓
Accessibility					✓					
Awareness				✓	✓					
Credibility / Legitimacy								✓		
Translational role: bridging the gap between research and policy				✓						
Interaction/relationship between the Council and other elements	✓									
	Items implicit in the design									
Concern about affront to or clashes with regulators and other important stakeholders										
Training/Education										
Alignment with principles of sustainable development										
Legitimisation								✓		
Scope										
Complexity										
Benefits to Regulators										

Valued NRGC characteristics and important issues according to participants	Valued characteristics identified under the proposed NRGC's…									
	…Activities					…Organisation				
	Governance framework	Advice	Foresight	Roundtable	Portal	Structure	Members	Staff	Agenda	Funding
	Items not covered									
Mediation										
Clarity, transparency, trust and reliability										
Regulation										
Stakeholder buy in										
Updatable/Flexible										
Equality / Fairness										
Learning from experience										
Unintentional consequences										

4.1.2 Overall conclusion

Development of a comprehensive Blueprint for the Council has been an evolutionary and extensive process undertaken by the three projects. It has been truly co-creative, led by the Task Force but involving through multiple engagements, the Core Groups, the wider project Consortia and well as external stakeholders. Inevitably, this has led to compromise in the design and the certainty that not all aspects of the final design are agreeably to all actors, even within the Project Consortium.

Nevertheless, the level to which this exercise has demonstrated widespread support for the final Blueprint across the three consortia is very encouraging. As such, it is concluded that the Blueprint is acceptable as a viable design on which to base implementation of the Council.

Annex 3: Proposal for a Nanotechnology Risk Governance Council

Consultation draft

Task Force for the Nanotechnology Risk Governance Council
11 March 2021

Introduction

The European Commission Chemicals Strategy for Sustainability, the Green Deal, and other important initiatives in Europe outline urgent (short-term and 2030-2050) and a high level of 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 nano-based products 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. And yet, very important concerns remain about technical risk assessment, public acceptance and regulatory effectiveness among other aspects. Improvements are needed in how risks to human health and the environment are addressed.

This summary document 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[1] tasked with improving governance of nanorisks in Europe[2], in close collaboration with stakeholders.

The document describes the goal that the Council could aim to, and why, the activities and services it could offer. It also presents some of the organisational elements. The purpose of the document is to engage with key stakeholders in regulation, industry and NGOs to collect their feedback as possible members of the NRGC. This feedback will be used to refine the recommendations for the NRGC, which will be presented in April 2021 to the three projects.

[1] The European Commission, through the Horizon 2020 NMBP-13 call has funded three projects Gov4Nano, NANORIGO and RiskGONE, and tasked to work together to improve the governance of nanorisks in Europe. A central element to this work is the establishment of a Nanotechnology Risk Governance Council.

[2] Governance refers to the actions, processes, traditions and institutions by which authority is exercised and decisions are taken and implemented. Risk governance applies the principles of good governance to the identification, assessment, management and communication of risks.

Process
In order to make a well-informed proposal for the goals, services and organisation of the Council, a scenario-building exercise was conducted:
- Identification of potential trends and factors relevant for the Council.
- Distillation of the challenges the Council aims to address and key questions to answer.
- Selection of two axes; fleshing out of four detailed scenarios.
- Evaluation round to pinpoint weak and strong points of the scenarios
- Based on these arguments: formulated of the proposal presented in this document

Main goals of the Council

The Council will **work to stimulate safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe**. This overarching goal covers the whole extent of the production chain, and focuses both on nanomaterials as materials and on the products within which they are used. The Council will address physical, economic and environmental risks and benefits.

Supporting conditions for meeting the goal:

- The NRGC will address the needs of four stakeholder groups: civil society, industry, policy makers/regulators and academia. It will involve all groups in its work and help all groups to participate in nanorisk governance, giving them a voice in existing processes.
- Recognizing that there are many organisations out there doing good work already - from research and regulatory bodies to industry associations and NGOs, the NRGC will be designed in a way not to duplicate or interfere with existing efforts. Rather it will provide clear added value through efficient improved co-ordination and linking of existing activities and generate transdisciplinary efforts by bringing together stakeholders to align to common goals.

Keeping these preconditions in mind, and considering existing challenges and untapped opportunities described in box 1 below, five specific goals are proposed:

1. **Increasing cooperation** and **helping stakeholders navigate** the nanorisk governance landscape. On the one hand, the Council will help bring together current actors, activities and organisations in the field of nanorisk governance and increase synergies. On the other hand, the Council will inform stakeholders on organisations, actors and activities.
2. Supporting efforts to **improve the quality and harmonisation of regulatory frameworks** across domains.
3. Assisting in identifying, developing and implementing **effective guidelines and processes for assessing, managing and communicating on nanorisks, with a framework for nanotechnology risk governance-e**.
4. Supporting efforts to improve **quality and access to data and information** on nanomaterials, -risks and -benefits.
5. **Improving the safety and sustainability of innovation** in nanomaterials in Europe.

Box 1

Challenges which the NRGC will work to remedy; untapped opportunities.

Processes for the governance of risks related to nanomaterials in Europe are already established. Regulators, policy makers, industry and NGOs are working to assess risks and benefits, collect and share data, improve regulation and provide the basis for market entry and safe use of nanomaterials, yet many questions, challenges and 'untapped' opportunities remain. (Innovation in) nanomaterials offers huge potential for economic growth and addressing societal and environmental challenges. But harnessing these opportunities will require effective governance processes - now and in the future.
The establishment of a Council, and with that the implementation of a Risk Governance Framework (see below), can play a critical role in building trust and fostering a robust protection of society and our environment, whilst enabling the benefits of these technologies to be safely exploited. Five challenges and opportunities have been identified for the Council to consider addressing:

1. **To increase the efficiency of the current risk governance process, a more transparent and connected landscape is needed**

An increasing number of initiatives and organisations have needs and responsibilities on improving nanorisk governance. Dimensions include from safe and sustainable by-design thinking to initiatives in mapping (risks of) nanomaterials to regulation of (new) nanomaterials. At the same time, cooperation or alignment of activities between these organisations is often limited. This can lead to inefficiencies, for example through lack of a shared view on needs, methods and data requirements or through duplication of activities. Due to increased stimulation of innovation, e.g., by the Green Deal, organisations are faced with a complexity of processes and actors with limited nano risk governance guidance.

2. **Efforts must intensify to improve quality and harmonisation of regulatory frameworks across domains**

Within the EU, risks of nanomaterials are regulated in separate frameworks, such as food and chemicals. These frameworks often differ in how they define nanomaterials, how they classify products as containing such materials, what guidance they offer and in what requirements they place on applicants. This poses challenges to regulators and industry alike. In addition, adapting regulatory frameworks to the newest technological developments or development from other regulatory domains proves difficult and too slow in practice.

3. **Common procedures and methods for assessing and addressing risks need to be developed for more efficient risk governance**

As of yet, there are no internationally agreed procedures and methods for performing risk (safety) and benefit (functionality and cost) analysis, for reporting and communicating these risks, and for risk response.

4. **Stakeholders need access to trusted quality data and information**

Related to the previous challenge: stakeholders sometimes lack access to quality data on risks of nanomaterials. Lack of common standards and methods for data curation and risk assessment make it difficult to consistently and precisely assess risks and create interoperable datasets. Trusted data and information are needed both to develop sound regulations and sound assessment of risks

5. **Innovation in safe and sustainable nanomaterials offers huge potential but suffers from bottlenecks**

There is an increasing number of ideas, tools, processes and budgets available for improving innovation leading to safer and more sustainable nanomaterials. Yet, there is still a lack of validated common methods and tools for assessing and managing risks. This forms a bottleneck for companies planning to invest in innovation of nanomaterials. In addition, although ideas such as safe-by-design are gaining traction as an important concept, knowledge and application of this concept in innovation processes remains limited. Finally, it seems that some SMEs lack resources, time and expertise required for robust risk management.

Activities and services

The Council will deliver on these five goals through a set of activities and services. In line with the precondition mentioned in the previous paragraph, the Council will supplement, complement and support activities currently provided by other actors in the field. It will be designed in a way to provide added value for existing organisations by offering services in support of their work, and by linking activities, actors, organisations and (regulatory) domains, thus creating synergies.

An **online portal/platform** will be central to the provision of these services, as a single, trusted point of access for users and stakeholders. The portal/platform will help stakeholders facilitate access to information, data and tools (both developed by the Council itself and by others) and provide support to how 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. In addition, the portal/platform will include a yearly updated dashboard with indicators that portray the state of nanorisk governance in Europe.

The Council will develop, maintain and implement a **Nanorisk Governance Framework**, a comprehensive and formally structured system to provide stakeholders with a clear way to effectively govern nanorisks. The framework provides context and points to guidelines and processes for assessing, managing and communicating nanorisks and benefits. Stakeholders can use this framework to improve the quality of processes and decisions.

The Council will also help stakeholders **identify and address emerging issues**. It will evaluate and report on emerging issues through foresight, horizon-scanning and through organizing periodical dialogues on (emerging) issues via conferences, seminars and online discussions.

The Council will also **engage stakeholders in (regular) roundtable meetings,** to identify issues they consider relevant, and to formulate joint positions of stakeholders on these issues (for example as input for research programs). On behalf of stakeholder groups, the Council could give voice to these joint positions in other organisations. Roundtable meetings could be organised to develop joint-plans to improve nanorisk governance, innovation, regulation, data and/or risk management.

Finally, the Council will provide stakeholders, including regulators and policy-makers, **advice or briefings on specific nanorisk issues**. This may take the form of analysis, reviews or case studies and may be developed through the Council's own agenda setting process or may be on demand or on request from particular members or stakeholder groups.

Organisation

How will the Council organise its activities? This question will be answered conclusively after the consultation process, including on indication of interest to support it, which will be done in the next few months. In the meantime, the following considerations will guide the thinking going forward:

The Council is intended to be a collaborative organisation, one which values openness, clarity of purpose and of execution. It will have clear terms of reference and clear accountabilities.

At this stage, the Council is envisaged as an independent organisation. Members will be drawn from the main stakeholder groups, and commit to and support the goals of the Council (financially or in kind). EU agencies and members states will be invited to participate. Representation from non-EU countries will be encouraged. The extent to which the Council is a governmental or non-governmental organisation remains an open question at this stage.

The Council will comprise a Board of members, whose chairman will be appointed by rotation. The Board will decide on the annual Agenda, which will include themes and topics to focus on.

The Council will be managed by an executive committee, supported by seconded staff of member organisations, who work on projects from the Council. In addition, the Council will involve experts in 'expert groups' on key issues, such as regulation, innovation, etc.

Options for funding are under discussion. One option is that the Council would rely on core funding from members and the EU (member states). Additionally, the Council would attract supplementary funding from commissioned projects.

Next steps

The Council must be trusted by all the key actors and important stakeholders, to add value to the risk governance landscape. Hence the process for designing the Council is as open and collaborative as possible, for example through co-creation process to design plans with the help of the stakeholder community, through engagement in a series of workshops, and through one-to-one guided interviews with open-ended questionnaires.

To finalise this document, a further round of consultations is organised with our target audience in various stakeholders groups, which will be invited to reflect and advise on how these plans could be further improved and used to build a viable Council. This document is intended to support this engagement activity.

Following this engagement, the description of the Council will be finalised and then presented to the three projects mid-April 2021 as a proposal for their approval and agreement to implement the Council.

In the next phase, plans for implementation of the Council will be made and shared. A phased approach is envisaged, in which the various elements (activities and services, organisational structure, members, staff and expert groups) will be brought on stream over an 18-month period. Development of several of these elements, for example the Framework and Portal are already well-advanced within the projects. As in the previous steps, a design-led process will be used for designing and building prototypes, testing and refining the elements, working towards a full launch in 2022.

During that period, the engagement process will be stepped up further to improve the Council, build awareness and seek support.

The Council development taskforce looks forward to engaging with you in these next steps.

List of Task Force members

Rob Aitken
Marie-Valentine Florin
Panagiotis Isigonis
Dalila Antunes
Monique Groenewold
Andrea Porcari
Arto Saamanen
Janeck James Scott-Fordsmand
Tommaso Serchi

Annex 4

Council Design – Process and progress WP Discussions

8 Feb 2021

Rob Aitken, IOM

Expected outcome

- The main purpose of the Council is:

  to stimulate the safe and sustainable development and use of nanomaterials in Europe
- Overarching, independent, trustworthy body
- Self-sustained
- Bridge between knowledge generators and decision makers
- Work with and support existing actors
- Services for all stakeholders

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement 814401

Our approach

- Joint activity of the three projects. We are committed to develop a single council.

- Goals
  - We want to make a well informed decision on the organisation of the council
    - Explainable and defensible
    - Based on several concise coherent arguments and realistic scenarios
    - Supported by all project partners, stakeholders and the Commission

- Approach
  - A ***co-creating*** approach for developing the NRGC scenarios, deciding organisational structure
    - Scenario task force (TF) approach, suggested 3 from each project
    - Structured facilitated workshop sessions,
    - Regularly consult with, project partners, stakeholders, Commission to strengthen scenarios and build support
    - Design led thinking

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement 814401

Taskforce

RiskGone	NanoRigo	Gov4Nano
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Dalila Antunes dalilaantunes@factorsocial.pt	Janeck James Scott-Fordsmand jsf@bios.au.dk	Monique Groenewold Monique.groenewold@rivm.nl

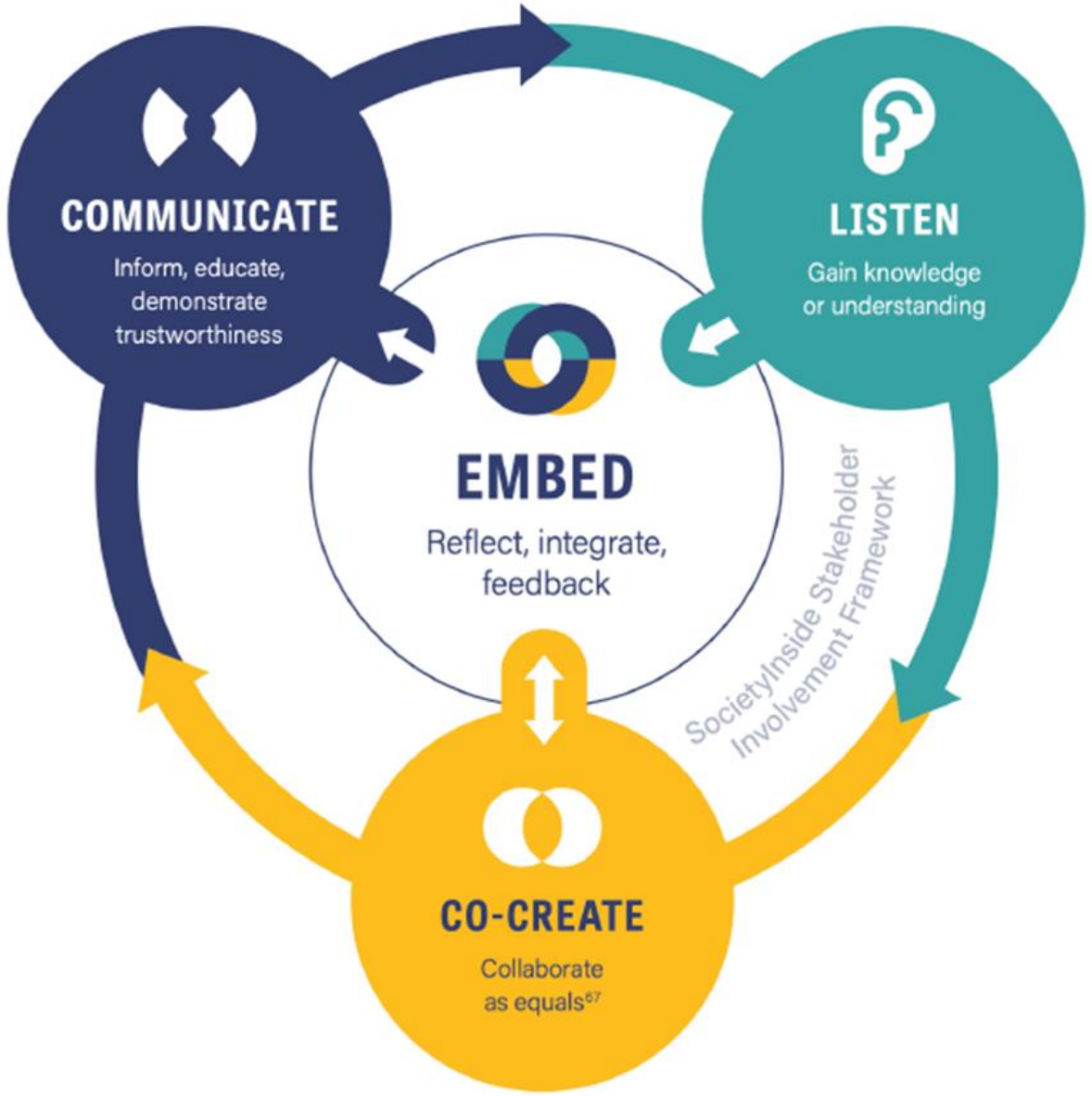
Keld sometimes deputises for Andrea
Supported by the 3 Co-ordinators, Janeck, Monique, Maria
Facilitated by Maarten Gehem and Thomas Bakker from Argument Factory
Additional support with stakeholders James, Susanne

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement 814401

Task force process – co-creation

- **Inputs**
  - First 15 months, collecting input through workshops, engagements, reviews etc
- **Analysis**
  - Analysis of trends and factors leading to purpose and preconditions
- **Design**
  - First design of scenario framework – 4 possible scenarios
- **Evolution**
  - Evolved Scenario framework – Refining the Goals, Elaborating "services", Improving of 4 scenarios
- **Evaluation**
  - Blueprint for the council – Goals, services, proposed structure and organisation
- **Blueprint**
  - Blueprint for the council final – Goals, services, structure, implementation

JM8 — Agreed mode of operation for Risk Governance Council



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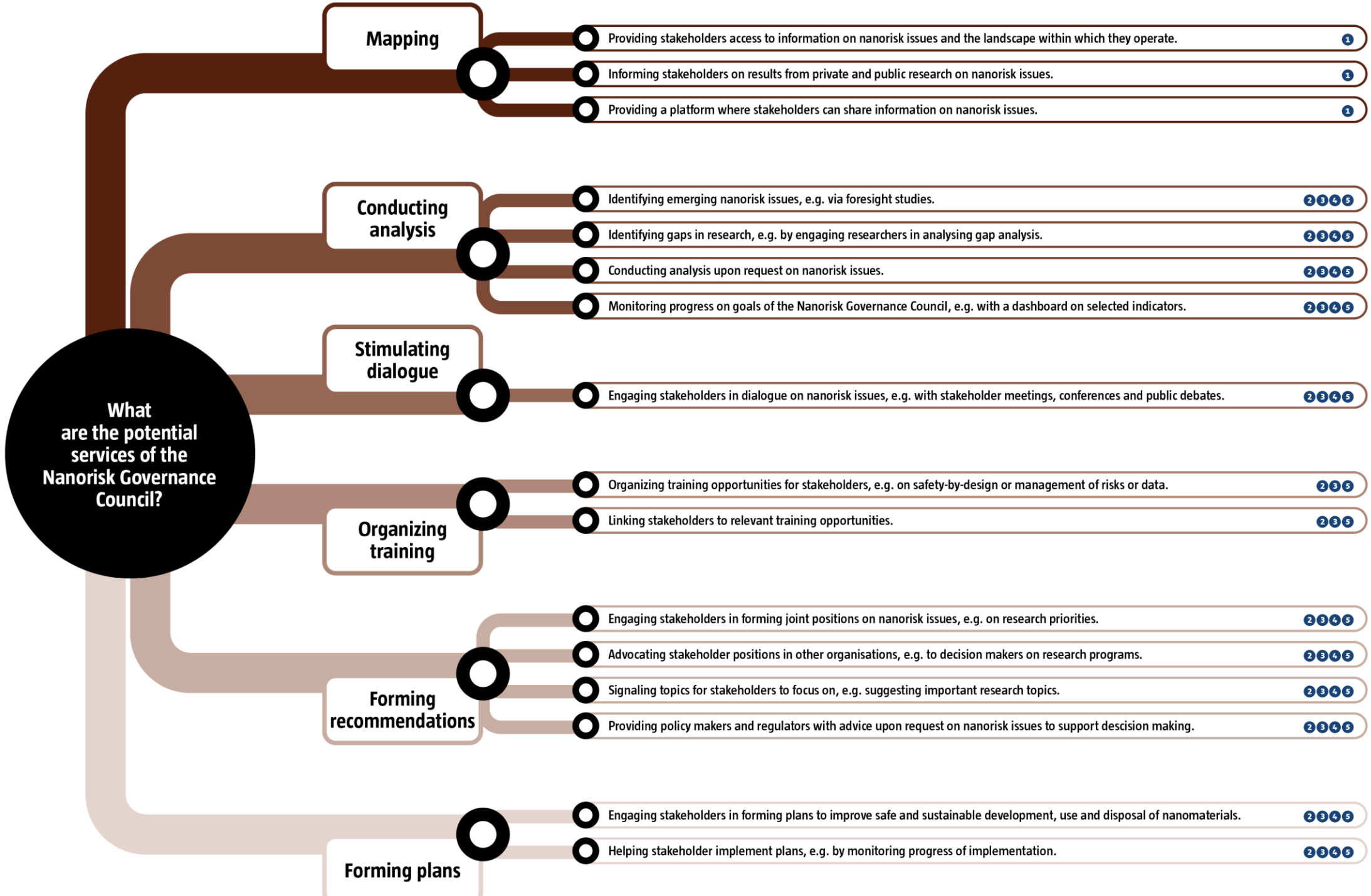
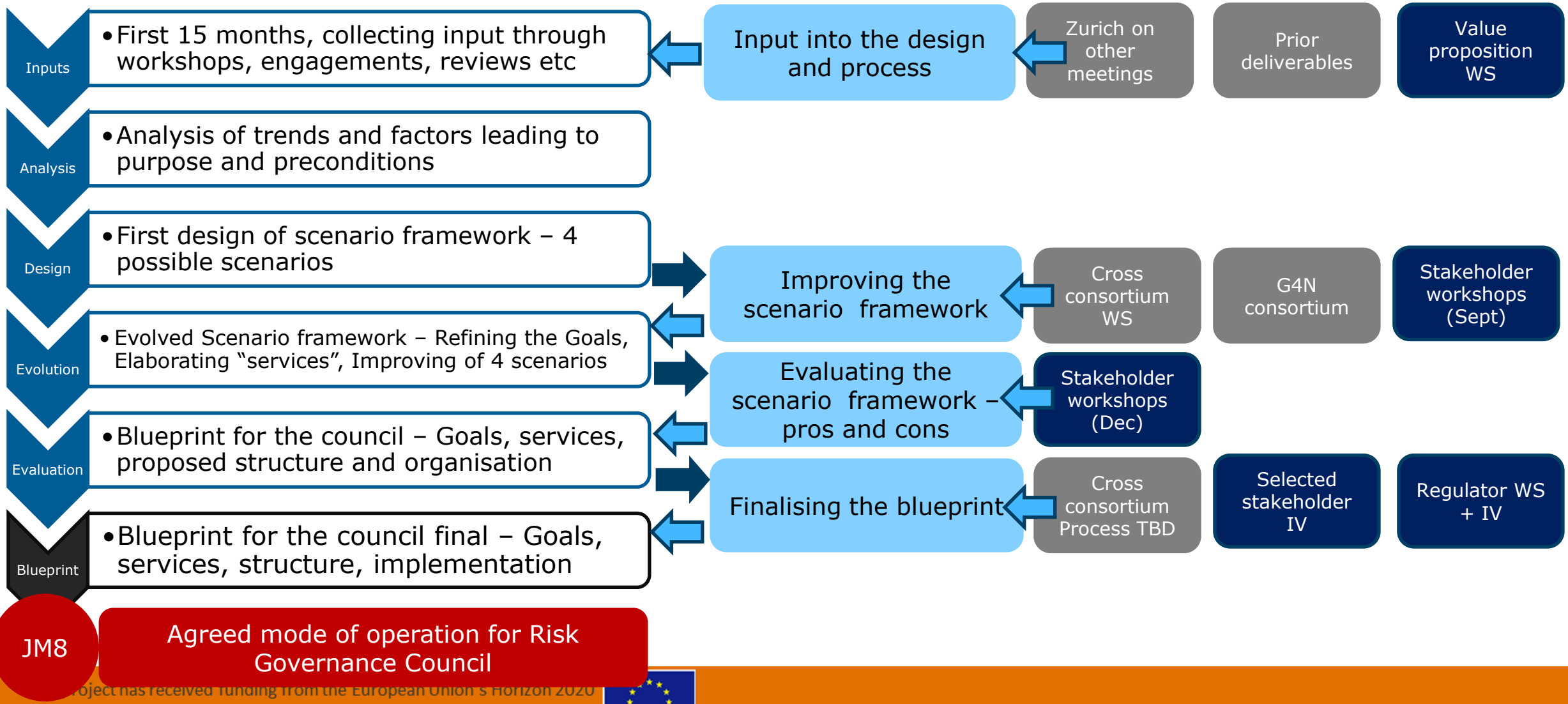

What are the potential services of the Nanorisk Governance Council?
Mapping
Providing stakeholders access to information on nanorisk issues and the landscape within which they operate. 1
Informing stakeholders on results from private and public research on nanorisk issues. 1
Providing a platform where stakeholders can share information on nanorisk issues. 1
Conducting analysis
Identifying emerging nanorisk issues, e.g. via foresight studies. 2 3 4 5
Identifying gaps in research, e.g. by engaging researchers in analysing gap analysis. 2 3 4 5
Conducting analysis upon request on nanorisk issues. 2 3 4 5
Monitoring progress on goals of the Nanorisk Governance Council, e.g. with a dashboard on selected indicators. 2 3 4 5
Stimulating dialogue
Engaging stakeholders in dialogue on nanorisk issues, e.g. with stakeholder meetings, conferences and public debates. 2 3 4 5
Organizing training
Organizing training opportunities for stakeholders, e.g. on safety-by-design or management of risks or data. 2 3 5
Linking stakeholders to relevant training opportunities. 2 3 5
Forming recommendations
Engaging stakeholders in forming joint positions on nanorisk issues, e.g. on research priorities. 2 3 4 5
Advocating stakeholder positions in other organisations, e.g. to decision makers on research programs. 2 3 4 5
Signaling topics for stakeholders to focus on, e.g. suggesting important research topics. 2 3 4 5
Providing policy makers and regulators with advice upon request on nanorisk issues to support descision making. 2 3 4 5
Forming plans
Engaging stakeholders in forming plans to improve safe and sustainable development, use and disposal of nanomaterials. 2 3 4 5
Helping stakeholder implement plans, e.g. by monitoring progress of implementation. 2 3 4 5

Summary Map
Nanorisk Governance Council

4 Possible Scenarios to build the Council

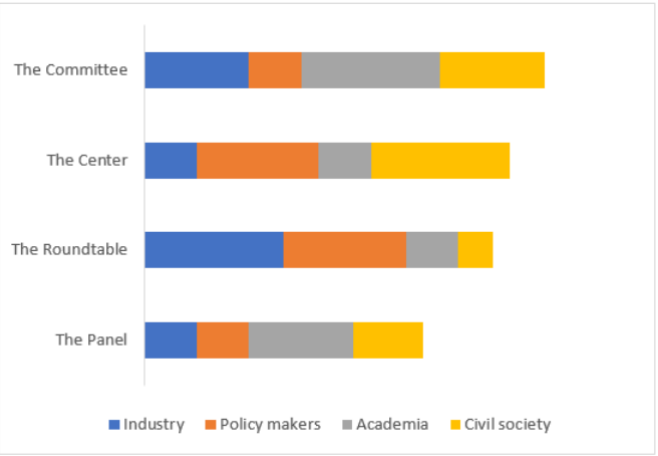
This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement 814401

Our Design led process – co-creation

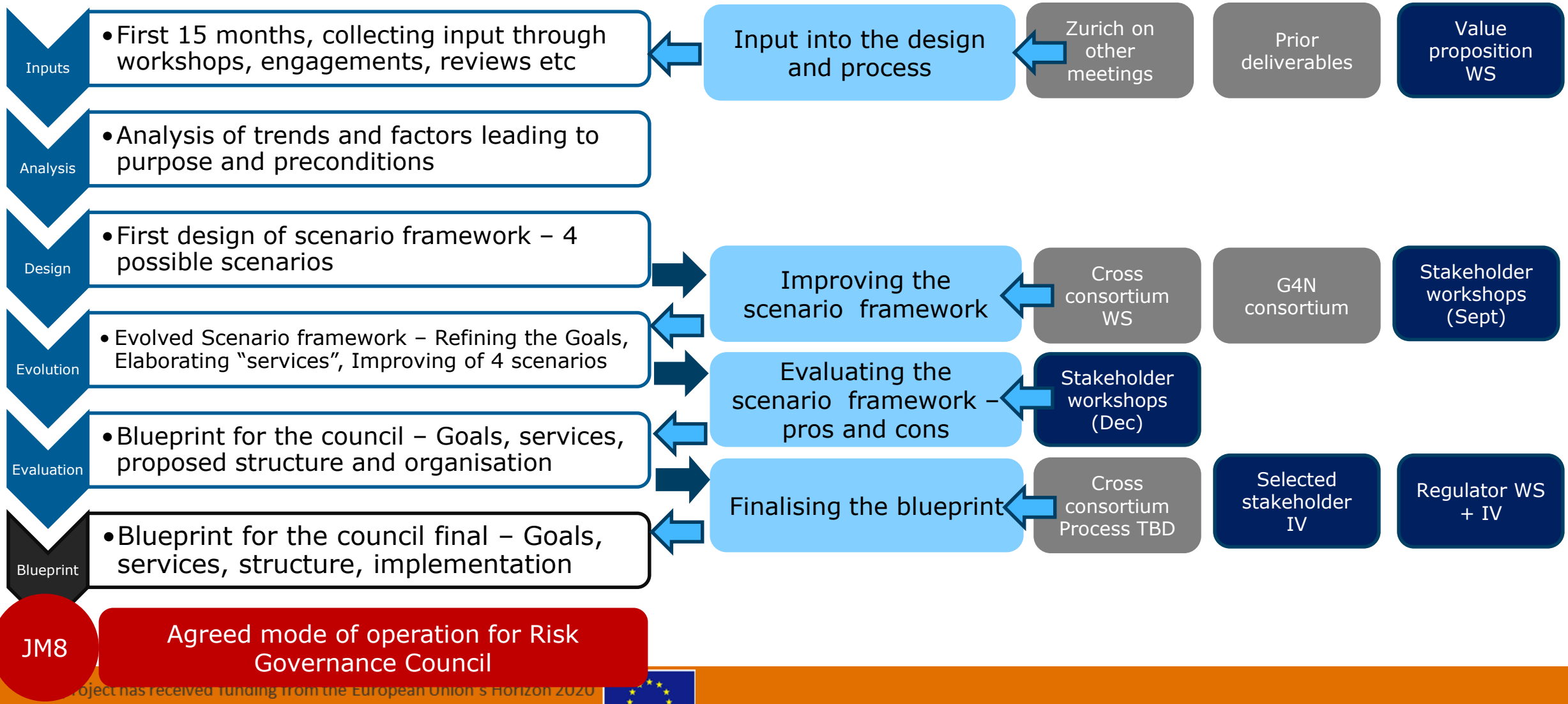


oject has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement 814401

Intermediate outputs

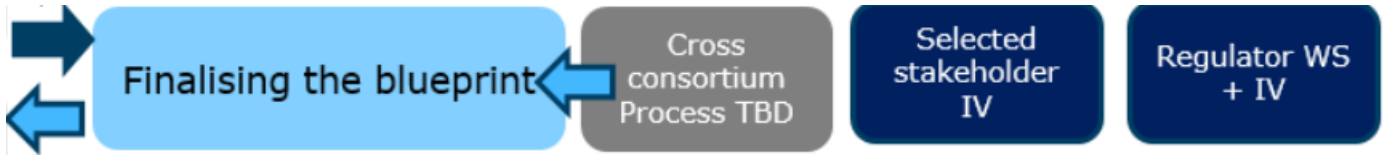


Our Design led process – co-creation



oject has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement 814401

Finalising the blueprint



- Cross Consortium process
  - Draft blueprint and other materials, 3 pager
  - Workshop
  - Key questions
  - Output used to refine the blue print
- Stakeholder process
  - Selected interviews with "target audience" (users and funders)
  - Structured interview with key questions
  - Opportunity to engage with European Environmental Bureau (EEB)
  - Qualitative video/telephone interviews with different experts working in the field of consumer or crisis communication (Task 3.1)

How can we make best use of these opportunities to build trust and support?

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement 814401

Towards implementation

- Joint Milestone and G4N deliverable
  - Description of the process
  - Purpose and preconditions
  - Services an overlap with existing organisation
  - 4 scenarios for the council
  - Blueprint for the council
- Status
  - A recommendation of the task force
  - **A decision of the 3 projects is required**
- A plan for implementation
  - Joint Consortium meeting (April)
  - How do the other WPs in the 3 project contribute towards building the council

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement 814401

Implementation plan

1. Elements to be included?
    1. Eg communication strategy, building the services, funding, budget, testing
2. How can this WP contribute?

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Annex 5

NRGC-STAKEHOLDER MEETING REPORT (SUMMARY)

NRGC-Stakeholder meeting, December 3, 2020

THE TASKFORCE FOR THE NANORISK GOVERNANCE COUNCIL

Introduction

This report briefly summarizes the main results from the stakeholder meeting organized on the 3d of December by three Horizon 2020 projects NANORIGO, RiskGONE and Gov4Nano. The session is part of a process led by a Taskforce with 3 representatives from these projects, which has the main task to develop a joint proposal for a NanoRisk Governance Council (NRGC), with the overarching goal "to stimulates safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe."

During the stakeholder sessions, we received input on the seventeen potential services the Council could offer, and four more detailed scenario's for the Council that the taskforce developed in previous months (see summary attached). The Taskforce will use the input to develop a final proposal ('the blueprint') for the NRGC. The session and the larger taskforce trajectory is assisted by The Argumentation Factory.

Method

The stakeholder meeting was an online event in which in approximately 31 stakeholders participated.

Stakeholder group	Number of participants
Civil society	4
Academia	9
Industry	10
Policy makers	8

First, we informed participants on the process and the content: the services and the scenario's. Subsequently, we reflected on the potential services and scenarios in four stakeholder-specific sub-groups. We used a combination of (quantative) voting and (qualitative) exploring arguments in favour or against services and scenarios.

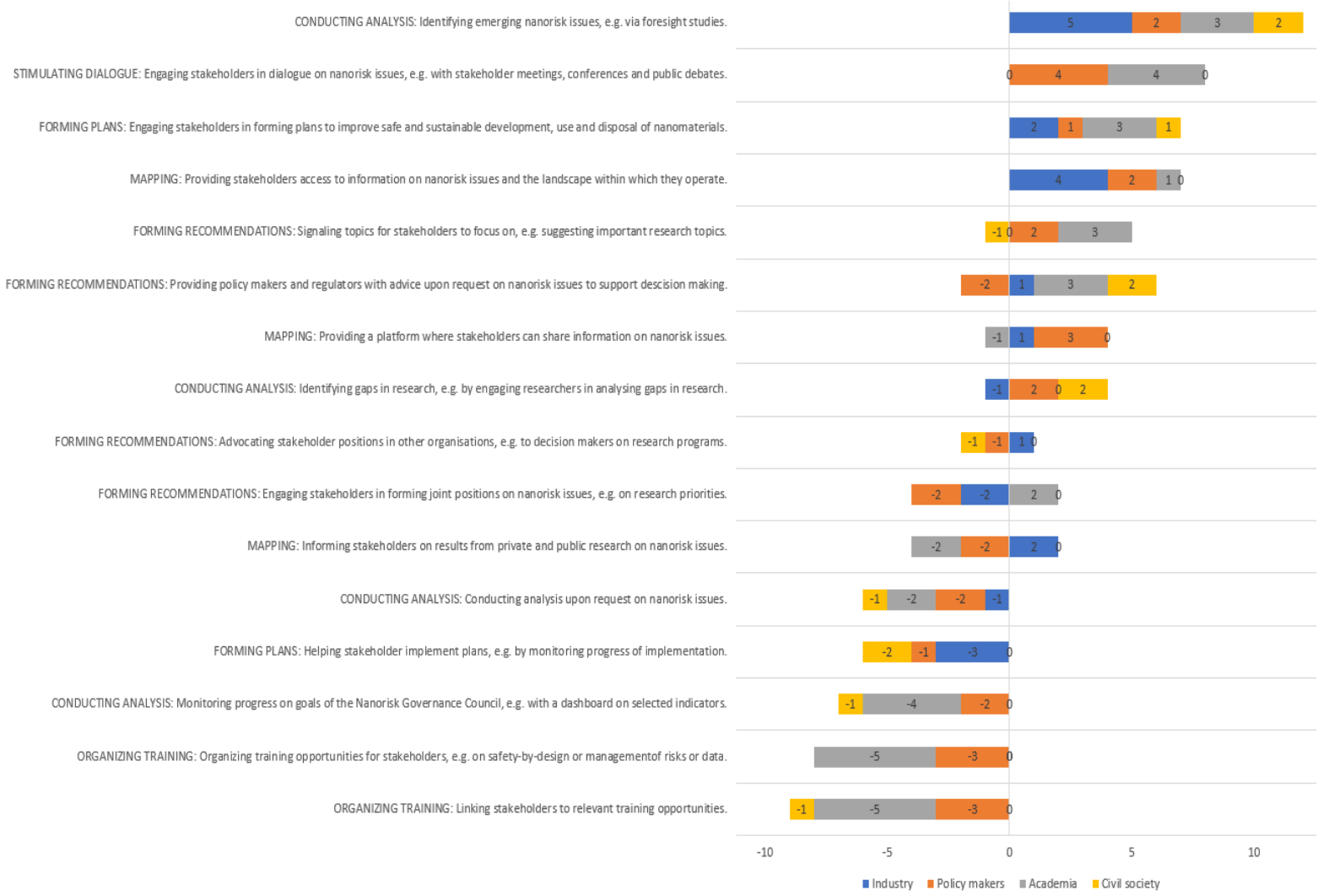
Based on the stakeholder meeting we have identified seven categories of arguments.

Type of argument	Related question
Demand	What is the added value of this service or scenario?
Supply	Are there other organisations already delivering this service, or better able to do so?
Impact	How impactful is this service or scenario?
Implementation	How complex is the implementation of this service or scenario?
Stakeholder representation	How well does this scenario represent stakeholders?
Independence	How does this services effect the independence of the NRGC?
Funding	How likely is funding for this service or scenario?

The main quantitative results are highlighted below.

Stakeholder's reflection on services of the NRGC

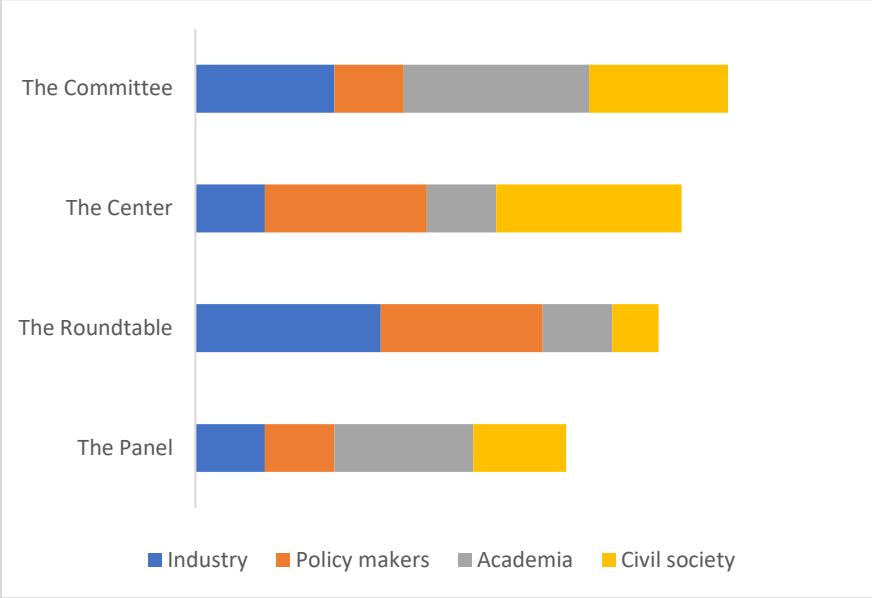
What are the most important services for the NGRC according to stakeholders? Below, we show the aggregated scores of services across all stakeholder groups. Negative scores indicate that stakeholders voted a service as unfavourable. Positive scores mean that stakeholders selected a service as favourable.



Stakeholder reflection on the scenario's for the NRGC

What do stakeholders think of the four scenario's we developed for the Council? We asked participants to rank the four scenario's (see below for the aggregated scores).

How do stakeholders rank the four scenario for the NRGC? [1]



Follow-up

The Taskforce will use this stakeholder input along with other inputs to build the blueprint for the NRGC in January 2021. In the following month, the Taskforce organizes a final consultation on this blueprint with stakeholders, the European Commission and representatives from the project partners (from NANORIGO, RiskGONE and Gov4Nano). After this consultation round the Taskforce will adjust the blueprint present the NGRC report in March 2021

[1] This ranking is based on the sum of the outcomes per stakeholder group. Each stakeholder group has equal impact on this ranking, irrespective the number of participants.

Annex 6

Date: 30-06-2020

DELIVERABLE No.	**D 4.2**
DELIVERABLE TITLE	**Database of potential members of the Nanotechnology Risk Governance Council (NRGC)**
RESPONSIBLE AUTHOR	**Christina Benighaus (DIALOGIK)**

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement n°814530 This document reflects only the author's view and the Commission is not responsible for any use that may be made of the information it contains.

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LEAD CONTRACTOR	**DIALOGIK**
AUTHOR(S)	**Christina Benighaus** **Marie-Valentine Florin** **Nils Bohmer** **Martin Mullins** **Mark Morisson** **Rudolf Reuther** **Daan Schuurbiers** **Janeck Scott-Fordsmand** **Anca Rusu**
REVIEWED BY	**NANORIGO Steering Board**
PLANNED DELIVERY DATE	**M18**
ACTUAL DELIVERY DATE	**M18**
DISSEMINATION LEVEL	**Confidential**

Table of Contents

Executive Summary

This report provides tentative suggestions for potential members of the Nanotechnology Risk Governance Council (NRGC) by way of a list of candidate organisations. It begins with a brief description of the process to develop the list, followed by an outline of possible criteria for selecting members and principles that members may be requested to adhere to. The development of the NRGC is a core task of the NANORIGO project, in collaboration with the other two NMBP-13 projects (Gov4Nano and RiskGone). Therefore, this report is a working document that will be refined in further collaborative project work, in view of producing a more final list in D4.6.

1. Introduction – NANORIGO principles regarding NRGC membership

This report provides a preliminary list (database) of potential members of the European Nanotechnology Risk Governance Council (NRGC) for engineered nanomaterials (section 6), preceded by a brief description of the process followed to develop the list (section 2), an outline of possible criteria for selecting members (section 3), principles that members may be requested to adhere to (section 4), and other open questions that will be addressed in further project work (section 5). The development of the NRGC is a core task of the NANORIGO project. Collaboration with the other two NMBP13 projects (Gov4Nano and RiskGone) is particularly important for this task, intending to move together towards the design of a common Council.

Preliminary information from the project design (description of action) includes four aspects that will be taken into consideration for the selection of possible members:

1. At the core of the project is the observation that the transfer of knowledge regarding the safety of nanomaterials and the use of this knowledge in regulation needs a strengthened '... risk governance based on a clear understanding of risk and of societal risk perception by all stakeholders' due to the high level of complexity and uncertainty of nanomaterials resulting from the rapid development of advanced materials and the convergence with other technologies.

2. The suggested NRGC is expected to be a transparent, self-sustained and science-based body for addressing the highly important issues related to the risk governance of engineered nanomaterials and nano-based products with a mandate to deal with uncertain and ambiguous risks, or emerging issues. Therefore, transparency, sustainability and scientific legitimacy will be critical criteria for recommendations regarding the Council.

3. The NRGC will address risks from

- manufacturing chemical industry
- food industry and the various additives in food processes
- agricultural industry and various pesticides
- medical applications
- medicines
- new emerging products (batteries, electronics, tyres, water recycling).

Therefore, membership will represent the broad diversity of application domains in which engineered nanomaterials are produced and can be used this includes workers, consumers and hosting communities.

4. NANORIGO D4.1 describes the possible mandate, composition and structure of a new NRGC and contains various elements that this report (D4.2) elaborates upon. D4.1 will be refined in D4.4, after which this report (D4.2) will be refined in D4.6. Therefore, this report should be read as a working document.

2. Process for building a database of potential NRGC members

In addition to taking into account the 'aspects to consider for the design of the NRGC' presented in section 1 of D4.1 as well as 'statutes and operating rules', 'code of conduct for members' and 'membership rules' presented in section 2 of D4.1, the process that NANORIGO follows for building the database of NRGC members results from:

1. **WP4's series of workshops** (virtual and in-person) with potential members, that will progressively refine matters around types and number of members, membership rules and other aspects. The first workshop was held on 8 June and discussed a range of issues regarding the vision and mission of the NRGC as well as other open questions. Proceedings of the workshop are available in D4.3. Matters of membership were discussed at the 8 June workshop very briefly, because such discussion would have been premature, given the advancement of the project.

2. Contributions provided by the NMBP-13 **User Committee (UC).** In its past meetings, and particularly in its 3 June meeting, the UC expressed its strong interest for being involved in the design of the NRGC ('needs, for whom, issues of possibly duplicating tasks with existing institutions, remits, the timing of actions, intervening power'). This report does not integrate their suggestions regarding NRGC membership but further revision in D4.6 will be made in October 2020.

3. Input from the **NMBP-13 stakeholder database**, which is a database of relevant stakeholders. In a similar way to item 2 above, the planned WP7 activities to engage stakeholders will include discussion on NRGC membership, which will be fed into WP4 as appropriate.

4. Contribution from partners in

- Other NANORIGO tasks and deliverables such as D4.1 that describes a potential mandate, composition and structure for the NRGC, and NANORIGO working documents about the nanotechnology risk governance framework
- Other **NMBP-13 projects**, in particular (but not exclusively), authors of Gov4Nano D6.2 that explores the key elements (purpose, principles, status, roles and products) to build a risk governance council, performs an inventory and evaluates the possible roles of the various stakeholders and their potential contributions to the tasks of defining and setting up the Nano Risk Governance Council; and of RiskGone D7.3 that analyses the operating practices of four bodies involved in nanotechnology risk governance and provides hints for possible membership criteria.
- Other EU projects such as GoNano's D5.1 that provides an overview of current policy context in three domains: food, health and energy.

5. Other **collaboration activities with NMBP-13 projects**, and in particular the **'Scenario taskforce'** organised by Gov4Nano in May-July 2020 that adopts a systematic and rigorous scenario development process to progressively refine four types of Councils. As of 30 June 2019, the task force has met three times and produced a description of (a) purpose and conditions for the NRGC, (b) trends and factors that work towards the design of the NRGC should take into account, (c) two main axis that could determine four types of scenarios (see Figure 1: Axis 1: the NRGC could result from a governmental versus a non-governmental initiative / be a

governmental versus a non-governmental institution. Axis 2: it could have a role to facilitate versus to recommend/prescribe).

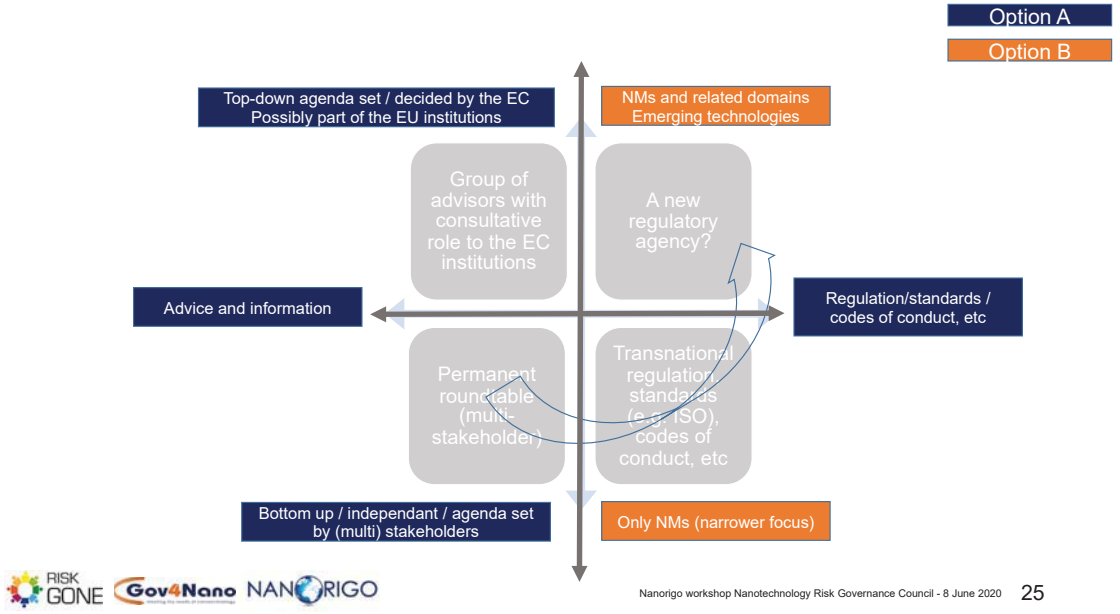

Figure 1 - **Four possible scenarios of the Council** – as presented in a workshop with potential members (cf D.4.3)

3. Tentative criteria for NRGC membership

This section suggests a tentative list of criteria for membership. D4.1 introduces the concept of **'statutes'** that, in addition to establishing the vision, mission and main principles for the NRGC, will 'specify matters such as relationships with other nanotechnology-related entities, how stakeholder/members will work collaboratively, how decisions will be made, how the Council will be sustainable (funded)' (cf. section 2). D4.1 also introduces the concept of **'membership rules'** suggesting that 'details of membership will be specified in a separate document, that the Council's management will be able to revise as necessary'.
The criteria for membership shall thus be established most probably in these 'statutes' and 'membership rules'. These criteria will be applied to determine if a possible member is admissible, i.e. matches the membership criteria or profile. Therefore before a new member is appointed, or signs up, or joins the Council (depending on the design of the NRGC).

The following criteria are tentative and should be seen as options, until the final design of the Council is determined.

1) Criteria 'Multi-stakeholder representativity of the NRGC'

The members of the Council will be representative of the five pillars shown in figure 1 below, introduced in D4.1.

Figure 2 - Multi-stakeholder representativity of the NRGC

Membership of the Council is open to delegates from different stakeholder groups, who are legitimate and credible actors in the domain of engineered nanomaterials. They should have scientific knowledge on the topics, nano expertise from the networks or interest in safety and sustainability is beneficial, but not mandatory to support a holistic perspective of members (D4.3).' They could be organised into the following categories (the list and description of the categories are still in discussion among NANORIGO partners):

- **Scientific, research and academic institutions**, with no other mandate than providing education and doing research to improve scientific knowledge and understanding of properties and characteristics of nanomaterials, and of risk for human and environmental health
- **Industry** (production and manufacturing) and **industry associations** (with role to represent industry members in various fora)
- **Regulatory bodies and policymakers** (at national, European or international level), with role to design public and private regulation, including standards or codes of conducts, and design public policies and strategies
- **NGOs representing organised civil society** (citizens / CSOs) **and end-users** (consumers), and in particular environmental and societal non-governmental organisations with the mission to protect environmental and human health
- **Other stakeholders**, including innovation agencies, technology platforms, and other business actors such as finance and insurance

2) International or European focus

The scope of action (national, European or international) could be a second criterion. The NRGC is primarily European, but collaboration with non-EU organisations (e.g. recognized national regulatory institution, foreign industry) and international institutions (e.g. OECD, UN) will be necessary, so some place could also be given to representatives of non-EU organisations when close cooperation is as needed.

3) Focus on safety and long-term sustainability

The Council has been described in D4.1 as possibly in charge of pursuing a vision of balancing innovation and precaution towards the future. If this option is chosen, then members should be selected for their expertise in safety and/or long-term sustainability.

4) Financial sustainability

The NRGC will be financially sustainable and sustainable model(s) of the Council shall be developed and proposed. So, it may be that members will have to contribute financially 'in relation to their capability. For examples, if financial sustainability relies on membership fees, one should expect that large companies will pay higher membership fees than NGOs. ' (D4.1, section 2, page 21).
If the funding through members is only partly possible, leading institutions (e.g. founders or the EU itself) will be expected to secure the necessary funding to support the NRGC activities, including staff and operating expenses, although this might impair independence.

5) **Other criteria**

for membership may be defined after the principles of membership will be established

4. Code of conduct for members

D4.1 (section 2, page 21) suggests that 'a "code of conduct" for members' will be established, and more specifically that 'each member will publicly commit to certain rules of behaviour, within the Council and outside of the Council, to demonstrate its commitment to vision and goal. The code of conduct shall be public'.

The tentative principles that members would be expected to commit to should be developed, described and confirmed by the founding council members themselves when the Council is constituted.
Possible basic principles could include that members should:

- Strive to be science-based
- Express transparency, openness and responsibility
- Respect basic principles for good governance
- Adhere to the European Code of Conduct for Research Integrity
- Adopt the highest standards in terms of norms of good and ethical behaviour
- Support other members
- Respect the principles of democracy and legitimacy

5. Definition of role, responsibility and competence of members

While defining the role and specific competencies of the members will be critical, it is too early to do it at this stage. This will be work of the NMBP-13 projects during the development process. Here is a list of options that could be considered:

- Membership or appointment (by election, nomination, or as representative/delegate of an entity) to the Council can be for a fixed period of xx years, renewable at certain conditions, or not.
- When members are appointed, they are expected to:
    - attend and take an active part, e.g., in Council Board meetings and activities
    - take position and decide independently of their affiliation, or decide as the entity that they represent requests them to do
    - respect all operational rules for a good internal functioning of the Council
    - etc.

- Members may have differentiated rights and obligations depending on the stakeholder group that they belong to. For example, those who represent science may have different responsibilities and duties than those that represent industry, and within the group of industry representatives, large industry and SMEs may have different levels of contribution. In essence, each member will have roles and responsibilities in relation to its capabilities and competences.
- Members' roles, competences, rights and obligations may to some extent be self-determined by Council members themselves (for example in the Council executive committee or in a General Assembly of members). These specific questions will be addressed once the mission and purpose of the Council are determined (in D4.4).

6. Examples of possible members (public and private organisations)

In this section, we suggest some organisations that could be members of the NRGC, for illustrative purposes. Further refinement will be made through collaboration with other NMBP-13 projects. The underlying hypothesis in this section, **which is not confirmed yet,** is that members are not individuals, but organisations. Organisations would be represented by an individual person, i.e. a member of staff appointed by his/her organisation to represent them). Such organisations may be public institutions or private entities.
The term 'organisation' is used to describe any type of public institution (national or EU agency, regulator, etc.) or private company (industry), or association (e.g. for NGOs, civil society organisations -CSOs).

Further work on the design of the Council may deliberate that instead or in addition to organisations, members may be individual appointed for their own expertise, independently from any affiliation. This latter option is not pursued in this section but may be considered later on.

In addition to being grouped under the five broad stakeholder types listed above (science and academia, industry, regulatory and policy institutions, NGOs, and others), members will be grouped according to the level at which they are active: European, international, or national. For example, CSOs or NGOs may represent and reach out to citizens and consumers at the European, international or national level. The EU or International focus will be prioritized, but the connection with the national level is essential. But this separations isn´t done in the list of examples yet, they are ordered aphetically only.

Possible member organisations, for illustrative purposes

Allocation to stakeholder group is tentative and may be revised

The list could but does not include here 'generic' national institutions such as Ministries, Environment Agencies or Innovation Agencies, which all could be interested in joining the Council

SCIENCE	INDUSTRY	POLICY AND REGULATION	NGOs	OTHERS
Scientific, academic and research institutions	Production and manufacturing, Industry associations	Regulatory and public policy institutions, Standard setting organisations, Governmental Institutions	Civil Society Organisations & other Non-Governmental Organisations – with focus on human and environmental health	Innovation agencies, Technology platforms, Finance and Insurance,
• CEA-Leti (Technology research institute) • CEREGE (Centre Européen de Recherche et d´enseignements des Géoscience de l´environnement) • CSIC (Spanish Council of Scientific Research) • Demos (think tank UK) • Fraunhofer (Nanotechnology Alliance) • Gaiac (Research Institute for Ecosystem Analysis and Assessment) • IASS (Institute For Advanced Sustainability Studies e.V.)	• Arkema (French chemical company) • BASF (German chemical company) • BioBasque (cluster of life science) • CEFIC (European Chemical Industry Council) • Clariant (Swiss chemicals company) • Dechema (DECHEMA Gesellschaft für Chemische Technik und Biotechnologie e.V.) • Dow Dow Chemical Company • DuPont de Nemours	• BauA (Federal Institute for Occupational Health and Safety) • BfR (Bundesinstitut für Risikobewertung) • ECHA (European Chemical Agency) • EFSA (European Food Safety Agency) • EMA (European Medicine Agency) • EUON (European Union Observatory for Nanomaterials • IPChem Platform (Information Platform for. Chemical Monitoring) • ISO (International Organization for Standardization)	• ANEC (European Association for the Co-ordination of Consumer Representation in Standardisation) • Avicenn (Association for surveillance and information on nanosciences and nanotechnologies) • BEUC (Bureau Européen des Unions de Consommateurs) • ChemSec (international chemical sekretariat) • CEO (Corperate Europe Observatory)	• AEGON (Duch life insurance company) • Ageas Holding (Belgian insurance company) •AIDA (Association Internationale de Droit des Assurances) • Allianz (German financial services company) • Assicurazioni Generali (Italian insurance company,) • AXA XL (American insurance and reinsurance company) • Chubb (Swiss insurance company) • CNP Assurances (French insurance company)

SCIENCE	INDUSTRY	POLICY AND REGULATION	NGOs	OTHERS
• INERIS (Institut National de l'Environnement Industriel et des Risques) • IEEP (Institute for European Environmental Policy) • ILSI (International Life Sciences Institute, European Branch) • IMEC (Interuniversity Microelectronics Centre) • ICN2 (Institut Català de Nanociència i Nanotecnologia) • IEEP (Institute for European Environmental Policy) • Institute of Bioengineering and Nanotechnology • ILSI (International Life Sciences Institute) • IMEC (Interuniversity Microelectronics Centre) • INL (International Iberian Nanotechnology Laboratory) • IUTA (Institute of Energy and Environmental Technology e.V. • KIT (Karlsruher Institute for Technology) • NCS University	• EBN (European Business and Innovation Centre Network) • ERF (European Risk Forum) • Evonik Industries AG • FDE (Food Drink Europe) • ICCA (International Council of Chemical Associations) • INTRA (INTRASOFT International) • KRONOS International • LANXESS (German chemicals company) • Nanogate (German nanotechnology company) • Nanologica (Swedish nanotechnology company • Nanotech Europe • NIA (Nanotechnology Industries Association) • Rathenau Instituut • Responsible Care • SABIC (Saudi Arabia) • SmartMembranes GmbH	• JRC (Joint Research Centre) • OECD (Organisation for Economic Co-operation and Development) • PARC (Partnership on Assessment of Risk of Chemicals) • SCENHIR (Scientific Committee on Emerging and Newly Identified Health Risks) • UNEP (United Nations Environment Programme)	• Ciel (Center for International Environmental Law) • CODATA (Committee on Data for Science and Technology) • ECOS (European Citizen's Organization for Standardization) • EEB (European Environmental Bureau) • EFBWW (European Federation of Building and Wood Workers) • EDF (Environment Defense Fund) • ETUI (trade unions) • EuroFIR (European Food Information Resource) • Friends of the Earth • IndustriAll (IndustriAll European Trade Union) • MIO-ECSDE (Mediterranean Information Office) • WECF (Women Engage for a Common Future	• ETPN (European Technology Platform Nanomedicine) • Fotonica21 (The Spanish Technology Platform for Photonics) • Innovate UK (United Kingdom's innovation agency) • Mapfre (Spanish insurance company) • Munich Re (German Insurance company) • NN Group (Dutch insurance company) • SCOR (French reinsurance company) • Swiss RE (Swiss reinsurance company) • Talanx (German insurance company) • Unipol (Italian financial services company) • Zurich Insurance Group (Swiss insurance company)

SCIENCE	INDUSTRY	POLICY AND REGULATION	NGOs	OTHERS
• ÖAW (Austrian Academy of Sciences) • Sciensano (Belgian research institute) • CSIC (Spanish Council of Scientific Research) • UBP (Politehnica University of Bucharest) • UC (scientific representatives) • VITO NV (Flemish Institute for Technological Research) • VTT (Technical Research Centre of Finland Ltd)	• SocietyInside and TIGTech • Solvay Engineered Polymers GmbH • temicon GmbH • UCN (UC Nano Technologies Inc., China)			

NANORIGO

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Annex 7

Interview with regulatory agencies

The consortia of three H2020 funded projects are collaborating extensively to address a call of the European Commission to design and form a European Nanotechnology Risk Governance Council (NRGC) for engineered nanomaterials. The background of this call is the observation that the transfer of knowledge regarding the safety of nanomaterials and the use of this knowledge in regulation needs a strengthened " *… risk governance based on a clear understanding of risk and of societal risk perception by all stakeholders*".

The suggested NRGC should be a transparent, self-sustained and science-based body for addressing the highly important issues related to risk governance of engineered nanomaterials and nano-based products. In this context, the options for determining the purpose and objectives of the NRGC are explored, together with the gathering of information and opinions on the possible mandate, foreseen activities, relevance to EU agencies, membership and where it could be positioned/hosted. Your expertise and opinion on these issues are of critical importance to us, for the design and implementation of the NRG Council.

Section A: Purpose and objectives of the H2020 NMBP-13 call

- Q1. Do you share the observation that there are gaps in the current governance (institutions, processes) for dealing with nano-related risks?
  Examples:
  - A common knowledge base for regulatory risk assessment is missing (Chemicals, Food, Cosmetics etc.)
  - A common/shared regulatory research road map (for all regulatory frameworks) is missing
  - Other, please specify: ……
- Q2. What is, from your perspective, missing and what is needed to improve the current governance?
  For example (prompt if needed)
  - (uncertain) risks of nanomaterials
  - are there gaps in clearing and making available good quality data?
  - are there gaps in sharing good methodology for risk assessment and management, and guaranteeing the quality of certain methods and decision-making tools?
  - address emerging, future issues and new technological innovations?

Section B: Role, positioning and design of the NRG Council

- Q3. What could the role of the Council or such an organisation be? (activities)
  For example (prompt if needed):
  - organise multi-stakeholder dialogues, with the goal of informing the policy or regulation process?
  - organise data and knowledge sharing?
  - work to improve risk awareness and communication with the public?

- Q4. Do you think the Council should have a clear and official mandate or should it work as a fully independent body with complete freedom to determine its mandate as its members see needed?
    - Should the RGC have a mandate, what would you consider relevant and suggest?
    - In the latter case, issues and activities would be determined 'bottom-up', as in a membership organisation?
- Q5. In your opinion, who should the delegates or members be?
    - Organisations or individuals?
    - Should it be a multi-stakeholder organisation, with representatives of the various stakeholder groups?
    - Who do you think should sit in the Council?
- Q6. Who would appoint the delegates or members?
    - Should the Council members be appointed by (and thus represent) EU member states?
    - Should the members be appointed by the institution that will host the Council? What do you think of these options? Would you consider or prefer other options?
- Q7. How would the Council interact with ECHA or with other important EU institutions in charge of risk assessment and/or management of nano-related risks? How does ECHA (other agency we address) see the role of a future Risk Governance Council?
- Q8. Where should the Council be positioned (hosted)?
    - in an independent structure (e.g. RTO, University)?
    - in an official environment (e.g. a relevant European agency, such as ECHA, SCCS)?
    - Should it be placed in an EU agency, which one do you think would be the most relevant location?
- Q9. Would you be in favour of having the member states supporting the delegates?
- Q10. One central point is to ensure the financial sustainability of the Council. How do you think this could be achieved?
  For example (prompt if needed):
    - Should the EU member states financially support the delegates? Or should they provide financial contribution to the Council?
    - Should there be contributions from industry or other stakeholders?
    - If the Council is a multi-stakeholder organisation, how would each member contribute financially?

Section C: Other aspects

- Q11. Should the international dimension be integrated in the design of the Council? If so, in which way?
  For example (prompt if needed):
    - Would there be delegates from non-EU countries and international organisations?
- Q12. Which other aspects, not yet addressed in the questions above, do you see as relevant for the design of the NRCG?
- Q13. Would you be interested in being involved in the development of the NRCG? If so, in which way?

Annex 8

Project co-funded by the Horizon 2020

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Science-based RISK GOvernance of Nano-tEchnology

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

DELIVERABLE D2.1:
Report on Risk Governance needs

Due date of Deliverable:	30.09.2019
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Responsible partner:	FS- portugal
Report Author(s):	Dalila Antunes/FS, Benjamin Trump/FS, Joana Dias/FS, Igor Linkov/FS; Finbarr Murphy/TGO; Ineke Malsh/MALSH; Michael Neaves/ECOS; Mihaela Cimpan/UIB; Panagiotis Isisgonis/UNIVE; David Warheit, Mark Wiesner, Qasim Chaudhry, Rolf Packroff, Sabina Halappanavar,Stefan Pfuhler (AB members)
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DELIVERABLE D2.1: Report on Risk Governance needs

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1.0	02-10-2019	Project management office (NILU)	Submitted to Commission	

Contents

1. ABSTRACT

This document summarises discussion related to nanotechnology risk governance (RG), as well as how a 'nanotechnology risk governance council' can provide improved nanotechnology governance leadership for many stakeholder groups within and outside the European Union.

Below, numbered sections include an overall background on nanotechnology risk governance, the need for a risk governance council (RGC), insights from recent questionnaires answered by RiskGONE Advisory Board (AB) members regarding RGC needs/challenges/requirements, additional insight from published and grey literature, and further reading recommendations. This document is intended to provide RiskGONE as a project with the knowledge of what to prioritise with the construction and implementation of a RGC, as well as the role the RGC should assume, and how to remain relevant and useful in guiding nanotechnology stakeholders.

2. TECHNICAL AND SCIENTIFIC PROGRESS

2.1. Background – Nanotechnology Risk Governance

In the field of nanotechnology, there is a growing interest in the practice of risk governance. Academically, scholars tend to agree that risk governance is the nexus of risk perception, analysis, management, and communication. In practice, however, risk governance of emerging materials is often conflated with ideas of risk assessment, which focuses upon hazard and exposure assessments to a given receptor, representing a limited view of the analysis stage of risk governance alone.

A review of nanotechnology literature and recent developments in the field of nanotechnology indicates a growing yet still limited interest in risk governance (Trump et al., 2018), while risk governance frameworks for nanomaterials, which could formalise and support the risk governance process, despite not being universally unified so far, present significant similarities and overlaps (Isigonis et al., 2019). The challenge of nanomaterial governance surpasses the capabilities of risk assessors to characterise hazard and assess exposure, where instead a broader effort of risk perception, analysis, management, and communication is necessary to inform technology development and material safety (Renn & Roco 2006). Such discussions are a helpful approach to argue why risk governance is needed, but generally remains conceptual, stopping short of who can execute it as well as how it can realistically be accomplished. Experience from other fields can provide examples of the institutional and intellectual arrangements that are required to execute nanomaterial risk governance through a scientifically-informed and socially responsive Risk Governance Council.

Nanotechnology challenge regulators and developers to ensure that no unacceptable risks are permitted to gain exposure to humans, animals, or the environment (Maynard et al., 2006). There are still uncertainties regarding both nanomaterials properties and behaviour regarding different uses/applications. This challenge is typically addressed through risk assessment, where hazards are analyzed and exposure pathways are characterised in an objective and data-driven manner. However, specific nanotechnology products and their use often lack physical, chemical, or

biological characterisation and interactive behaviour that make risk assessment difficult or even impossible because the existing testing protocols and indicators may not account for the various environmental health and safety risks that such novel technologies pose (Rycroft et al., 2018). Further, such uncertainty may even extend to the governing process that applies to the given technology, where it may be unclear who holds regulatory approval or governing authority within the process of technology development and commodification. Under such circumstances, scholars and policymakers have turned to risk governance (Justo-Hanani & Dayan 2015). Formally, risk governance is a more holistic approach that includes various processes of the perception, analysis, management, and communication of risks posed by an activity or technology within an environment of considerable uncertainty and systemic complexity (IRGC 2005).

Risk governance strategies have been discussed within academic and applied settings, such as the European Union's Horizon 2020 Programme related to the risk governance of engineered nanomaterials (ENMs). The theoretical framing of risk governance in such contexts, including a clear differentiation of risk governance from the more simplified term "governance of risk" is helpful, but does not necessarily provide a guide to operationalise such risk governance in a meaningful way. Instead, risk governance needs to be framed as an actionable objective that systematically addresses any lingering data gaps and potential risks to environmental health and safety as well as to provide clear policy recommendations in the form of best practices, codes of conduct, or statutory requirements. At present, only limited guidance is available to operationalise risk governance activity in a manner that accounts for the various processes, skills, and stakeholders that a risk governance body should include to be successful (Sargent 2016).

2.2 What is a Risk Governance Council (RGC)?

Effective risk governance for nanotechnology requires an involved and transdisciplinary leadership body that is holistically and representatively drawn from various nanotechnology stakeholders. While much of nanotechnology's best practices can arrive from governmental discourse, much of the risk governance process and the priorities for technology governance arrive at the confluence of government, industry, academia, and representatives of civil society. A council serves as one medium to gather such diverse perspectives, as well as to carry out various risk governance activities, including the identification, analysis, perception, management, and communication of nanotechnology risks relative to the process and products of their development.

Councils meet regularly, at pre-defined times, and possess established rules regarding decorum, quorum, public communication, and overall activities that take place within council meetings as well as which activities/research are funded and prioritised to stimulate council discussion. Such activities and discourse are intended to form best practices, operating procedures, and codes of conduct that are informed by a mixture of hard and soft law, and are in compliance with pre-existing national and international norms, regulatory requirements, and cultural/industry expectations.

Hence it should be preferred that a Risk Governance Council is somehow accepted and integrated in the comitology. Still, if it is not the case, the council should position itself strategically in a way to develop its network of influence to inform decision-making and thrive on seeking to be integrated in the process.

2.3 RiskGONE Approach to Risk Governance and the RGC

RiskGONE has set ambitious, but realistic objectives, to adopt and tailor a clear and harmonised framework for RG of ENMs, building on the existing efforts to develop frameworks for RG of ENMs. The overarching aim and most ambitious goal of the project is to establish an international and pan-European body for the RG of EMNs.

This body will bring together key actors from varying backgrounds of relevance to the RG of nanotechnology. It will be constituted by a transparent, self-sustained and science-based RGC, that will have the main function to provide support and expert opinions on the EU oversight and policy-making decisions around ENMs. Preferably it shall be nested within relevant European agencies (e.g., ECHA). As part of this approach under T2.1 a questionnaire was implemented to gather feedback from Advisory Board Members, which would in turn inform the conclusions of this report on Risk Governance needs for the Risk Governance Council.

2.4. How Should a RGC Function?: Insight from Questionnaires on Nanotechnology Risk Governance Council Motivations, Challenges, and Requirements

This section details a synthesis of feedback from the RiskGONE Advisory Board members, subject-matter experts, related to (a) the purpose of a RGC, (b) its activities, (c) its operating requirements, and (d) overall needs and challenges moving forward. Each section below details collective comments from all questionnaires.

The questions aimed on gathering input on the following topics/in the following areas:

- Specific principles under which the RGC should operate. Specifically, respondents were asked to describe such ideas and explain why they consider them important/relevant;
- How Advisory Board members believe they should participate, organise themselves, and set operating procedures to (a) make the RGC functional in its initial meeting, and (b) capable of achieving self-sustaining behavior beyond the duration of the project;
- The scope of activities that RGC members would work within in order to derive and synthesise judgment related to engineered nanomaterial production, commodification, and disposal, among other concerns pertinent to technology risk governance; and
- The resources and contributing factors that are seen important to determine a council's success in developing and maintaining guidance over nanotechnology risk governance.

1) What are your expectations for the RGC, how do you consider it will be operationalised (implemented and run)?

Regarding the expectations of RGC's members on how they consider it will be operationalised, implemented and run, it seems to be unclear to most members that have answered the questionnaire. However, two members reported they expect the RGC to:

i. offer informed opinions and recommendations on the governance of advanced materials that are supported by all relevant social groups and to close the gap between the scientific bodies (e.g. RAC, SEAC…) and the regulatory bodies;

ii. and similarly that the RGC will present itself as an active international leader, globally-recognised, that provides high-quality opinions and guidance for nano risk assessment, risk management, and risk communication. These opinions and guidance will be provided in the form of expert advice, standardised frameworks, valid/validated methods, risk assessment tools, material specifications, etc. The RGC should include representatives of EU and other international bodies, and work to ensure collaboration with such institutions to prevent silos or inconsistencies.

iii. work on the basis of the scientific knowledge gained in the meantime that nanomaterials and other advanced materials pose no statutorily or socially unacceptable hazards and risks with regard to the protection of humans and the environment in comparison to other material innovations, the focus should be broadened

iv. focus on nanomaterials and other advanced materials supported by EU research funding, e.g. Horizon 2020 and Horizon Europe

v. need to adapt testing, measurement and evaluation methods with the aim of regulating safety for humans and the environment while keeping pace with innovation

When it comes to the principles under which the RGC should operate, there appeared to be some consensus between RGC members. Virtually all members mentioned that 1) all members should be solicited for input and that 2) members should come at a consensus when taking decisions or positions. One person has mentioned that where consensus among the RGC is not possible, the feedback mechanism should allow for all points of view to be recorded. Several members also have emphasised that there should be an effort to ensure discussion face-to-face between RGC members to discuss the various datasets, conclusions, and interpretations of the data as this contributes more effectively to a more informed and better decision-making than simple gathering and collating individual answers from different members. One member said that these decisions should be integrated into the procedures of the regulation.

A majority of members have likewise addressed the issue of transparency as a guiding principle of the RGC. Two things should be transparent:

i the code of conduct of the RGC, i.e., the rules of procedure and criteria to come to a conclusion;

ii. the actions taken in response to the RGC recommendations.

Relative to the recommendation given by the RGC, performance of implemented actions should be evaluated according to established criteria. The evaluation should be a dynamic process and allow refinement of the principles and/or policies of the RGC, based on new evidence.

The RGC should guarantee that both science and social groups are equally represented. In addition, independent experts, as well as small and medium-sized enterprises should be adequately involved, as they are important drivers of innovation.

One final principle is mentioned, namely that the RGC should be established in a way that it becomes a financially self-sustaining entity either within or at the end of the current project. This may be determined by a number of fundraising activities, such as (a) funding through EU or international government sources, which will ensure a foundational level of activities that a RGC would be required to carry out, or (b) voluntary and/or dues-based contributions by participating organizations. Funding should, at a minimum, be able to cover stipends for RGC members that execute work in their position, funding for communication efforts with the public (websites, professional documents, town hall meetings), potential funding for the commission of independent experts and scientists for a given meeting/subject, etc. EU or other government funding will ensure that core activities are able to be met in a transparent manner.

In addition, two members mentioned that the RGC should:

i. accept and communicate scientific findings that refute earlier assumptions and perceptions of risk; and that

ii. a technical agreement should inform political and association interests.

2) What are your expectations about the role of the members of the Risk Governance Council?

Some respondents mentioned that they expected members to meet on a regular basis and to contribute to the ongoing discussion, being necessary for them to be familiar with the topics of the RGC.

The majority of members responded that they were expected to provide timely and useful feedback on both positive aspects and on more contentious interpretations, reaching compromises as members of an advisory body (as opposed to collection of individual opinions). As mentioned by one member, this feedback might be to reviewing and evaluating current data, be it legal, scientific texts or regulation.

Moreover, one member has highlighted how each member of the RGC must be recognised in their field (preferably at the global level), and how they should be able to exert a major influence on driving forward the global debate on nano risk governance issues.

Last but not least, one person has responded they expected members to provide some expertise as to the needs, safeguards and requirements to ensure that the RGC is operational, balanced and effective.

3) What activities will members carry out in the Risk Governance Council?

As aforementioned, a great part of members mentioned as an expected activity, regular face-to-face discussions to strive towards consensus feedback on behalf of the RGC (although this consensus is not necessarily required – face-to-face discussions are the crucial component and may yield opinions that are in conflict with one-another).

In regard to the actual activities being performed, the majority of respondents answered they expected to review and evaluate current data (be it legal, scientific texts or regulation), materials, reports, proposed activities and progress made.

One other person has added that they expect to have to assess the state of the art in science with regard to the transition from precautionary to evidence-based risk management, and also to have to relate scientific knowledge and options of governance in order to find appropriate and comprehensible solutions for EU citizens. In line with this, one member has said that they should be capable of seeing through the current barriers and gaps in the nano field and be able to contribute towards resolving them.

4) What is needed in order to implement that vision?

a. Human resources

The great majority of members have mentioned staff support as a human resource necessity. The type of staff support mentioned varies from staff that is expected to aid in materials presented for review and preparing the RGC report, as well as being facilitators for meetings, to being scientist who can communicate appropriately with the representatives, management with support at a high professional level, or even professionally qualified representatives of social groups. During RiskGONE project these needs will be fulfilled by RiskGONE partners.

b. Material resources

In regard to the material resources, two members responded that it is necessary to have access to the Head of various working groups, while two other members mentioned how access to research leadership is a requisite. Finally, one member referred the need to have a common shared website/database.

c. Financial resources

There was high consensus in regard to the financial resources, specifically the need for mobility funds for RGC meeting. One member called for financial incentives for representatives of small and medium-sized enterprises.

d. Decision-Support tools

Nanoparticle governance and risk management decisions involve value trade-offs and a high level of complexity and uncertainty. In such complex decision environments, it is especially difficult for both laypersons and experts to make informed decisions. When multiple lines of quantitative and qualitative information (such as modelling and monitoring, risk analysis, cost-benefit analysis, and stakeholder preferences) must be considered, they are often combined in a subjective and unstructured manner. Making decisions on an ad hoc basis ignores factors that could be crucial to the program's success in meeting promulgated goals and will almost surely lead to a suboptimal and regretted allocation of resources. In general, decision analytic methods may include various tools, programs, and heuristics to guide stakeholders in a rigorous fashion to reach a particular solution.

Pertaining to the decision-support tools necessary, the most mentioned was tools for preparing documents, for example for preparing reports or for preparing documents for a comprehensive review (e.g. in presenting trade-off curves). One other member has highlighted the need of support tools for accessing current scientific reviews, toolboxes for governance, overviews of the current regulation, and for having test, measurement and evaluation methods.

Proponents of most decision models for engineered nanomaterials acknowledge the need to transform and make use of qualitative information derived from subject expert opinion. Additionally, decision analysts also often advocate for the integration of other methodological theories and approaches with existing decision methods such as with Shatkin (2008), Linkov et al (2011), Subramanian et al (2014) and Renn and Roco (2006). Specifically, Shatkin (2008) and Mohan et al (2012) are but a small subset of scholarly works and method proposals which advocate for the linking of life cycle and adaptive management thinking in the utilization of multi-criteria decision analysis, while other such as Linkov et al (2011) call for the more refined use of adaptive thinking and cost-benefit utilization principles to inform nanomaterial decision models.

One example of an engineered nanomaterial decision analytical tool includes that proposed by Tervonen et al (2009), who proposed an environmental and health-based classification of targeted engineered nanomaterials through the use of stochastic multi-criteria acceptability analysis (SMAA-TRI) (Tervonen et al 2009). Such a model was designed to be useful for a variety of

stakeholders with differing perspectives and opinions on engineered nanomaterials, its risks, and associated benefits. This multi-attribute acceptability analysis also seeks to review and compare measurements of material toxicity and physiochemical characteristics alongside considerations of environmental impacts upon release. Tervonen et al (2009) derived a series of test cases via fullerenes, multi-walled carbon nanotubes, aluminum, silver, and cadmium-selenium quantum dots. Using data derived from a combination of expert elicitation and literature discussion, this SMAA-TRI model allows users to evaluate risk and benefit to identify the most optimal and efficient decision alternative available for engineered nanomaterial development.

Collectively, decision analytical methods and support systems bridge the gap of engineered nanomaterial uncertainty and knowledge gaps by integrating available data and expert assessment to produce risk and hazard guidance. As shown by the examples above, this exercise may be conducted for one or several targets (environmental, occupational, and consumer health and safety), and may be intended for use by one or more stakeholders (regulators, industrial producers, etc). While such methods do generally require some training and are not as immediately intuitive as less methods-driven approaches noted above, decision analytical tools can be particularly helpful to assess a variety of generally incongruent criteria and decision alternatives under uncertainty. Additionally, the integration of other approaches such as exposure assessment and life cycle thinking will help such methods improve and focus their efforts at elucidating risk, hazard, and exposure information for individual engineered nanomaterials across myriad contexts.

Search for tools will be extended during the RiskGONE project and a specific risk governance decision support tool will be developed (WP2, T2.4).

e. Other

Lastly, one member has added some other points to consider, namely that it is necessary to ensure that:

i. The RGC will be networked with relevant institutions, projects, and other government and industry initiatives within the EU and internationally;

ii. There is close liaison with the regulatory and standards bodies (e.g. ECHA, EFSA, SCCS, OECD, etc.), as well as with industry led initiatives in this area;

iii. There is a wider stakeholder engagement in all aspects of the RGC work.

3. CORE NEEDS FOR A NANOTECHNOLOGY RISK GOVERNANCE COUNCIL: INTEGRATING IDEAS FROM QUESTIONNAIRES AND LITERATURE

A risk governance body or council is formed to analyze and interpret various signals and metrics associated with human and environmental health hazards as well as various economic, social, and political technology drivers.

To integrate and interpret such inputs in a holistic and responsive manner, a risk governance council must possess explicit characteristics and operating procedures in order to be effective (Roig 2018). Such characteristics include the skills, stakeholders, and processes that allow the council's membership to deliver scientifically and socially informed judgment regarding the necessary statutory requirements (hard law) or voluntary codes of conduct (soft law) that can improve technology governance moving forward (Figure 1).

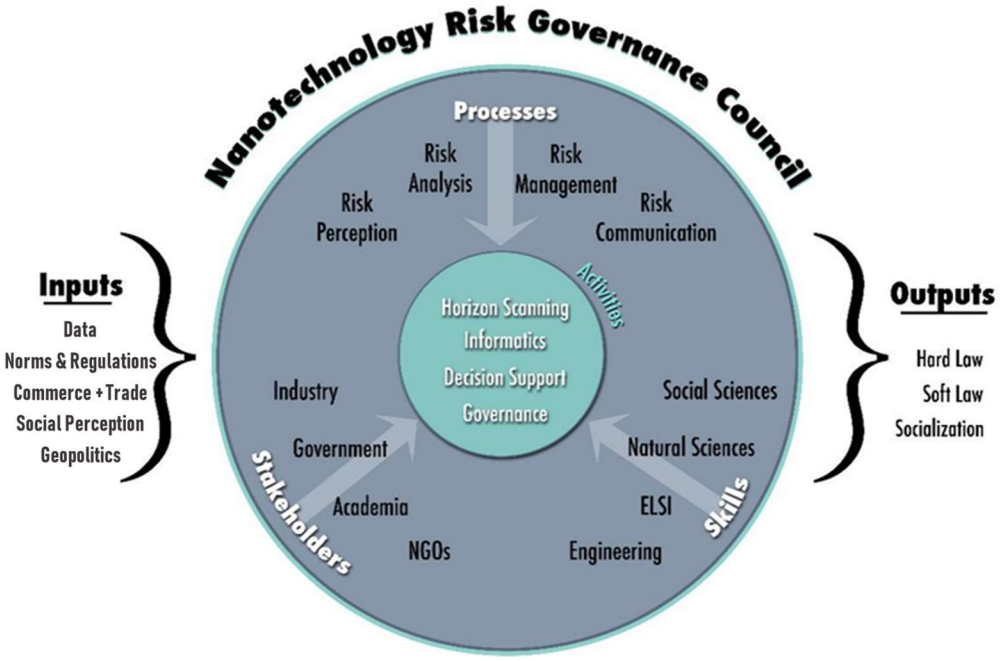

Figure 1. The Inputs, Outputs, and Core Functions/Characteristics of Nanotechnology Risk Governance Council

For starters, nanotechnology risk governance council must have the capacity to execute core risk governance functions as established by the International Risk Governance Council (2005). Namely, this includes a holistic start-to-finish review of risk, including considerations of the perception, analysis, management, and communication of technology hazard and exposure concerns (Linkov et al., 2017). Such actions should be consistent with local regulatory norms and requirements (i.e., United States organizations executing environmental risk assessment requirements as mandated by the Toxic Substances Control Act). For highly uncertain technologies like nanotechnology, operating with a healthy dose of precaution is the norm in many jurisdictions, including Europe, may also be a foundational requirement of all actors within a nanotechnology risk governance council, yet may not be consistent with the practices and legal requirements of other regions with a more permissive risk environment. Further, this will allow the RGC to incorporate updates to the geopolitical situation regarding international nanomaterial and advanced material development and commodification, whereby insight into the risk-based and governance practices of such materials by other countries can be understood and accounted for relevant to an EU-based RGC.

Second, effective risk governance requires a diversity of opinions and perspectives to inform optimal judgment and action for technology governance (Marchant & Wallach 2015). This requires the inclusion of various disciplinary backgrounds (i.e., social sciences, natural sciences, engineers, ethicists, etc.) as well as representatives from various positions in government, academia, industry, and civil society (Linkov et al., 2018). As often occurs in real-world instances, an overemphasis upon one disciplinary area, or the lack of inclusion of a certain perspective of industry or civil society can occur, will inevitably affect the risk governance council's perceived legitimacy by certain stakeholders in technology development and governance. Such legitimacy

is a core requirement for the crafting and implementation of any hard or soft law to improve the technology's governance. A fundamental requirement for such inclusiveness and an integration of a strong network of participants also includes representatives of EU and other international governing authorities.

Third, normatively effective risk governance should be informed by a variety of data gathering approaches and analytical tools. Proactive (i.e., horizon scanning) and reactive approaches (i.e., informatics) are a necessity, as they collectively improve a risk assessor's knowledge of a hazard or exposure pathway of a given nanomaterial (Karinen & Guston 2009). Similarly, such efforts help to identify capability gaps and research priorities related to nanotechnology assessment. Such data points should ultimately be integrated into a scientifically informed and transparent decision support tool that, through multiple iterations and opportunities for improvement, can indicate the best available course of regulatory or stakeholder action given the best available science and social discourse related to engineered nanomaterials within a given industry or product area (Stone et al., 2018).

Risk governance of controversial or even wicked problems related to emerging technologies is no easy task – it requires substantial political and financial resources to develop and execute in a manner that will be respected by all relevant stakeholders (Marchant et al., 2012). With emerging calls for risk governance of emerging technologies like nanotechnology or synthetic biology rising from various parts of the globe, it is essential for such efforts to be grounded in a holistic and effective process (Fiorino 2011; Van Oudheusden 2014). Ultimately, this requires risk governance councils to include actors that can represent critical requirements of process, discipline, and vocational background, and ensure that data and signals related to the technology's potential risks and benefits are framed in a balanced and responsive manner.

4. NEXT STEPS FOR ESTABLISHING THE RISK GOVERNANCE COUNCIL

In order to establish and operationalise an active RGC, RiskGONE partners and AB members will analyse, select and test procedures for implementation of the RGC.

Steps to establish RGC	RiskGONE activities to support RGC operationalization
1) Identify Core Managers/Initial Leaders of RGC a. Draw from multiple disciplines/stakeholder groups b. Establish clear roles and expectations during, and after project for RGC operations	• AB members are the selected initial group which will test and evaluate information and methods developed by the RiskGONE project. • During RiskGONE the AB members will analyse information gathered by the project and the methods to collect such information to check if the information provided is useful for discussion on nanomaterials to inform decision making and policy making on one hand, and to provide feedback on how to enhance the methods and the quality of information, on another hand. • Their main role will include: o The RGC should consider scientific data Production of science-based expert opinions about

	specific RG aspects (e.g., RA, RM) on request of the EC. ○ Review and integration of the RG Cloud Platform with future developments. ○ Guidance and advice on the development of TGs/SOPs. ○ Review and suggestions on the improvements of RG frameworks, based on future Innovation Management and prevention-based RG needs. ○ Communicate to citizens regarding any findings or guidance • Based on this experience AB members will also support the development of RGC role and internal regulations
2) Identify specific risk governance activities that the RGC will operate/utilise a. Risk perception i. What tools? Methods? Horizon scanning/forecasting? Internal and external to EU? b. Risk assessment i. Statutory process-based testing requirements? Product-based requirements? Internal production vs. importation? c. Risk management i. Tools, methods, processes? ii. Multi-method to more holistically assess nanomaterial risk iii. Steps for gathering further evidence for conflicting/unclear risks d. Risk communication i. Tools and procedures to inform and engage publics ii. Written versus in-person communication	• WP3 work will provide inputs on risk perception. • For the identification and assessment of risk, guidelines for risk indicators will also be developed in WP3, as well as relevant existing tools set in WP4, 5 and 6, will be collated and assessed for their suitability and relevance for inclusion into the nanotechnologies RG decision trees, as part of the framework toolboxes and guidance materials. • For the governance of nanomaterial development, the elements of hard law (both statutory codes and their pertinent regulatory bodies) as well as soft law (the voluntary codes of conduct via public-private partnerships and multistakeholder consortia) will be reviewed for multiple nanomaterial product categories, as well as throughout the life cycle of a given nanomaterial product. Both T3.5 and T7.3 will contribute significantly for this. • For public engagement and risk communication, the outcome of WP7 will be provided (especially considering T7.4 – Two-way communication tools). • The RG framework and decisions trees will be implemented into a software-based decision support tool in Task 2.4.
3) Identify process for selecting additional members to RGC a. Multi-stakeholder/trans-disciplinary approach b. Quotas for differing groups and Declaration of Conflict of Interest c. Preventing capture/limiting potential for external influence of pressure	• To be developed and refined during RiskGONE based on the experience of AB members.

groups; ensure all opinions are represented in a respectful way	
4) Craft operating procedures for RGC a. Crafting a charter/constitution b. Rules for Quorum? c. Reporting/meeting/note-taking requirements d. Rules for determining assent/consent of the RGC? Majority/supermajority/unanimous? e. How to fill vacancies? f. How to deal with disagreement and/or disruptions? g. How to establish reforms? h. Day-to-day requirements i. How to ensure long-term financial sustainability?	• To be developed and refined during RiskGONE based on the experience of AB members.

5. DEVIATIONS – IMPACT/HOW YOU COPE WITH THEM

Considering the agreed collaboration among NMBP-13 cluster projects, namely RiskGONE alongside NanoRIGO and Gov4Nano, the strategy for developing the RGC and therefore this deliverable has been adjusted to account for additional complexity and time required.

For the development of this particular deliverable, a first draft of the report on RGC needs was developed based on literature review and initial answers of the AB members to a short survey. This draft was then submitted to RiskGONE partners and AB members to provide feedback. Final changes were discussed with AB members during a virtual meeting which took place on 19-09-2019.

6. CONCLUDING REMARKS

This document provides the initial approach to formation and implementation of the RiskGONE RGC, setting the basic common framework for its function, shared among RiskGONE partners and AB members who will support RGC implementation during the project lifecycle.

Hence this document is considered a starting point and a living document that will evolve along time. While RiskGONE project partners will carryout their work and the project will provide the set of required documents to feed RGC implementation and operationalisation, this work will also be framed by the coordination between NMBP-13 cluster projects

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