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Report on evaluation of stakeholder feedback through workshops and conferences

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Abstract

This Deliverable (D)7.4 "Report on evaluation of stakeholder feedback through workshops and conferences" summarizes the feedback collected at the events and surveys within the framework of RiskGONE and the other NMBP-13 funded projects, to provide a possible successor body which is named in this document the "Organizational Form for RG" (OFRG) with the recommendations of the expert community and the public.

Key recommendations for establishing governance in the regulation of nanomaterials were collected and summarised. Regardless of the final design of an organisational form for risk governance, the collected findings and recommendations should be applicable.

The outreach in numbers of these and other activities towards the stakeholders is also reported.

The feedback from the activities performed has shown that the equal participation of all interested stakeholders in the discussion can have a decisive influence on the success of an appropriate organizational form, allowing to take all relevant scientific and societal issues into account.

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List of Abbreviations

CDS - Communication and Dissemination Strategy

Dx.y (x and y are numbers) – Deliverable x.y

EC – European Commission

ENM – Engineered nanomaterial

ECHA – European Chemicals Agency

EFSA – European Food Safety Agency

FAIR – Findable, Accessible, Interoperable and Re-usable (data)

JMx (x is a number) – Joint Milestone

Mx (x is a number) – Milestone x

MNM – Manufacture Nanomaterial

NMBP-13 – EC Call on Risk Governance of nanotechnology

NGO – Non-governmental organisation

NRGC – Nanotechnology Risk Governance Council

NRGF – Nanotechnology Risk Governance Framework

OFRG – Organisational Form for RG

PP - Precautionary Principle

RAC – Risk Assessment Committee (under ECHA)

RG - Risk Governance

RGC - Risk Governance Council

RGF - Risk Governance Framework

RRI – Responsible Research and Innovation

SbD – Safe by Design

SCCS - Scientific Committee on Consumer Safety

SCHEER - Scientific Committee on Health, Environmental and Emerging Risks

SEAC - Committee for Socio-economic Analysis (under ECHA)

SME – Small or Medium sized Enterprises

UC – User committee

Introduction

The purpose of the projects funded in the EC Call NMBP-13 is to achieve governance for the risk assessment of nanomaterials. In the original project proposal, the creation of a Risk Government Council (RGC) was considered. Since developments at the European level have now shown that such a council will not be installed, the feedback collected at the events and surveys within the framework of the funded projects will be summarized here to provide a possible successor body which is named in this document the "Organizational Form for RG" (OFRG) with the recommendations of the expert community and the public.

Stakeholder engagement in RiskGONE and in the NMBP-13 cooperation

The Communication and Dissemination Strategy (CDS) of RiskGONE was developed to engage with identified stakeholders to ensure awareness of the project and its activities and outputs, and the processes via which stakeholders can contribute to the project activities, originally in the context of the development and possible launch of the RGC. The CDS included the messages to be delivered, the target audiences, the tools which were made available and the timeframe / planning for the implementation of the strategy.

In brief, the actions and measures planned included the following:

- Website, LinkedIn and regular newsletters
- Stakeholder analysis, identification of multipliers and international bodies
- Establishment of an Organisational form for Risk Governance OFRG (RGC before the amendment)
- Collaboration with other European and national projects and the Nanosafety Cluster
- Identification of important conferences at which to disseminate project outputs
- Organisation of webinars and workshops to target specific stakeholders
- Publications in printed journals.

A stakeholder analysis has been performed to clearly define the target audiences of the RiskGONE communication activities. RiskGONE dissemination activities are targeting:
- Scientists
- Regulators
- All Industry sectors utilising or potentially utilising engineered nanomaterials (ENMs) and nanotechnologies
- Governmental bodies
- Non-Governmental Organisations
- Scientific and industry associations
- Consumers and consumer associations
- Trade unions and other worker representatives
- Other research projects and their partners, as well as the EU NanoSafety Cluster, the Pilot Production Lines Network and other relevant integrating organisations.

Due to the established cooperation with the other NMBP-13 projects, stakeholder engagement has been organized jointly to avoid duplication of stakeholder engagement. Therefore, a common database of contacts has been established and is managed by the core group on stakeholder engagement. The database is intentionally kept simple, it consists of an Excel file in which the company name, country and affiliation (industry, university, NGO etc.) as well as the e-mail address of a contact person, if available, are listed. Further information is optional. The database is stored on the project consortium's sharepoint.

User Committee

RiskGONE partners have actively participated in the NMBP-13 projects User Committee (UC) group (initiated by NANORIGO). The User Committee includes 12 resident members representing perspectives from academia, industry, regulation and civil society organizations. NANORIGO predicted 6 meetings with this group for them to provide input and insights to the work being developed by the NMBP-13 projects.

RiskGONE participation in the User Committee Organizing Team included active engagement on:

- Producing RiskGONE contributions for the Strategic Dialogue Agenda for the UC and updated reports for revising it.

- Participation in UC preparatory meetings, UC meetings and webinars.

- Contributions for presentations to the UC.

- Establishing the connection with RiskGONE members to provide them information on UC inputs on one hand, and to get awareness on how UC can support RiskGONE activities development to inform UC preparation meetings.

- Active role in developing and revising UC meeting reports.

- Sharing meeting reports with RiskGONE members and use of relevant information to link with RiskGONE work and embed it on the development of the RGC and RGF development (mainly through the excel file mentioned above).

- FS has led the activities of RiskGONE in the planning of UC meetings and the respective reports produced.

Activities of the NMBP-13 cooperation

The RiskGONE project members participated in many dissemination activities throughout the project, resulting in more than 66 presentations and 22 posters presented at conferences, webinars, workshops, etc. Among the most relevant events, we can mention Nanosafe 2020, Nanotox 2021, Eurotox 2021 EuroNanoForum 2021, the European Researchers' Night, as well as NanoSafety Cluster events and the EU-Asia Dialogue on Nanosafety.

All these events provided an occasion to discuss with participants and collect feedback on the goal of RiskGONE and the NMBP-13 collaboration. Key feedback from those events and documents were collected and thematically grouped into the statements which are detailed below.

As part of the NMBP-13 collaboration, RiskGONE partners have had an active participation in the design process of the RGC, in close cooperation with the other NMBP-13 projects (co-creating and developing the RGC blueprint and keeping track of information on RGC and RGF NMBP-13 deliverables). In addition, a series of workshops with regulators (and other stakeholders) has been organised in the spring of 2021 to explore the opportunities for the establishment of the RGC, which was accompanied by a series of individual interviews with stakeholders on the RGC blueprint, its content and a possible implementation. Feedback received has been incorporated in the revised version of the blueprint, which is under preparation in June-July 2022 by the Gov4Nano and NANORIGO partners (not a contractual obligation for the RiskGONE project).

The process for exploring the establishment of an OFRG included the following main activities:

- Discussions on the development of the RGC and its potential structure.
- Organisation of workshops (March 2021) for exploring the possibility of hosting the RGC in regulatory agencies such as ECHA, EFSA, SCCS and others, led by NILU. As the European agencies expressed less interest in pursuing the development of a RGC, RiskGONE partners participated constructively to the NMBP-13 discussions on the alternative routes for the RGC.
- Co-creation process for the development of the RGC within the NMBP-13 collaboration environment.

- Joint coordination with NMPB13 projects on developing the RGC and the RGF, by participation on regular Core Group meetings and Task Force for deciding on the RGC trends, preconditions, positioning, mission and the design of possible scenarios for the RGC.
- Fulfilment of the joint milestones related to the RGC topic, as developed for guiding the collaboration among the three NMBP-13 projects. Specifically, leading the development of Joint Milestone 6, and active engagement on Joint Milestones 7, 8 and 9.
- Representation of the RiskGONE project on the NANORIGO/3 NMBP-13 projects User Committee (UC) and making the bridge between topics of interest from RiskGONE to be discussed by the UC and UC discussions content to include on RiskGONE development. Promoting dissemination of RG developments on the UC meetings.

In close connection to the activities listed above, partner FS has led the collection of inputs and the analysis of the information coming from the three NMBP-13 projects, in the forms of reports/deliverables/papers and more, related to the development of the RGC and the RGF, by updating the database (in Excel format) that has been created earlier in the track of the activities for managing NMBP-13 inputs to RGC and RGF. The updated version of the document included input from the following documents: NANORIGO D4.2, NANORIGO D4.3, NANORIGO D4.4, NANORIGO D4.5, 1st, 2nd, 3rd and 4th UC reports, NMBP-13 Joint Milestones reports.

Collected feedback and analysis

The section below provides an overview of the collected feedback, through the various stakeholder engagement activities that took place, and the outputs of RiskGONE and the NMBP-13 projects.

The text is following the scheme that in each **grouped feedback**, single **feedback** topics are cited. These topics result from RiskGONE/NMBP-13 projects events and documents which are listed in brackets after the feedback itself. Because we cite from earlier documents, citations are still pointing to the formation of a RGC/NRGC, the wording was not adapted but can be mentally replaced with OFRG. Thus, the feedback addresses the requirements that should be met for the formation of an OFRG. Afterwards a **measure** is formulated (respecting RiskGONE D2.1 results) for each feedback topic containing a recommendation, which conditions must be fulfilled and finally the **suggestion** of RiskGONE for an OFRG summarizes how to achieve the goal.

Grouped Feedback #1 on the need for transparency in the OFRG work

"a transparent, self-sustained and science-based RGC" (RiskGONE D2.1) "Credibility is built on trust, integrity and transparency." (RiskGONE D7.3)

"The RGC must establish and define overarching values in the priority areas identified (Governance and Effective Risk Governance; Independence and Trustworthiness; Openness and Transparency; Scientific Robustness; Prevention, Precaution, Wellbeing and Sustainability) that directly influence the implementation of the RGC,'s mission;" RiskGONE D7.3)

"In order to appropriately manage and support innovation, commercial and regulatory decisions must be clearly guided by a broad set of civil society interests and should be supported by clear, reliable, relevant, and understandable scientific outputs and data, which must also be legally sound and defensible." (RiskGONE SMALL Publ.) [https://doi.org/10.1002/smll.202003303]

"The NRGC will ensure that the work and outcome of the council are transparent and accepted globally by regulatory, academic, industrial, insure organisation and stakeholders." (NANORIGO - D4.1)

"... the NRGC may indeed develop as an independent, multi-stakeholder, scientific advisory board that provides and translates all the needed information in a transparent way to governments, industries and civil societies on possible risks to human health, to the environment as well as on relevant socio-economic and ethical aspects that may be or may become associated with the production, use and disposal of advanced materials" (NANORIGO - D4.1)

"The Council will be a transparent, self-sustained and science-based organisation." (NANORIGO D4.4)

"Availability of and access to robust data (...) are problems for most stakeholders. This is due to confidentiality and competition constraints and to lack of transparency." (UC M1)

"Transparency in data is a premise." (UC M1)

"The NRGC must establish a more suitable set of rules that constitute an improvement to existing intellectual property regime that better support openness and transparency" (RiskGONE - D7.3)

"it will be important to maintain the fine balance between independence and openness" (RiskGONE - D7.3)

"When developing the risk governance framework for the NRGC and the subsequent processes that the NRGC will carry out, it is important to evaluate how these processes and obligations will impact the freedom for the organisation to fulfil commitments to openness and transparency." (RiskGONE - D7.3)

Measure to reach the identified goals:

Make sure that all outputs, assessments, and assumptions as well as the code of conduct, i.e., the rules of procedure and criteria are shared with the public in a transparent and concise manner.

Have an early identification process for risks of innovations, focusing on the innovations' intended uses while also reflecting on safe-by-design (SbD) principles.

Suggestions from RiskGONE:

(1) Foster transparent and public-facing sites with data and model availability.
(2) Provide guidance on how to realize FAIR (Findable, Accessible, Interoperable and Reusable) scientific data and what tests are needed for new ENMs.
(3) The OFRG should motivate industry to be more transparent and supportive in sharing available data.
(4) Policy must be put in place that allows researchers the capacity to better understand ENMs to convey the risks and rewards to the public

Grouped Feedback #2 on members and the possible competences of an OFRG

"The NRGC will have "members" who represent their stakeholder groups [which] most certainly include:

- Scientific and research organisations
- Innovation agencies

- Production and manufacturing (industry)
- Finance and insurance
- Environmental and societal non-governmental organisations (NGOs)
- Attention should also be paid to non-organised stakeholders (consumer groups) (...)." (NANORIGO - D4.1)

"The members of the Council will be representative of the five pillars (scientific, research and academic institutions, industry, regulatory bodies and policymakers, NGOs representing organised civil society, other stakeholders)" (NANORIGO D 4.2)

"it is essential to integrate a variety of types of stakeholders as a group of people from the industry, regulatory bodies, science/academia and civil society/NGOs and other stakeholders." (NANORIGO D4.5)

"The RGC risk governance framework must be future-proof and agile to keep pace with nanomaterial innovations and evolving regulatory needs;" (RiskGONE D7.3)

"The NRGC should gain a 'multidimensional authority'." (UC M1)

"Regarding the NRGC, we do a 'gaps and needs analysis' with the objective of finding out how the NRGC can complement, without overlapping or competing with existing institutions" (UC M2)

"The NRGC could be the institutional body that related to all other bodies and institutions, such as ECHA and EFSA." (UC M2)

"Adopting a risk governance approach requires interdisciplinarity. (...) Nanotechnology risk governance must be multi-stakeholder, which means that all relevant and affected stakeholders should be involved." (NANORIGO - JM1)

"[…] a list of options that could be considered:

- Membership or appointment (by election, nomination, or as representative/delegate of an entity) to the Council
- Members may have differentiated rights and obligations depending on the stakeholder group that they belong to.
- 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)." NANORIGO D4.2

"[…] some participants preferred the bottom-up approach, which is represented by the Roundtable and the European Centre. The approach could gather information about emerging risks, especially for advanced materials, deliver better services in dialogue and transfers of information compared to the top-down approaches." (NANORIGO D4.5)

Measure to reach the identified goals:

Ensure a specific distribution of experts, actors, and individuals is in the OFRG. The OFRG should consist of people with a wide area of competences. They should be able to

- Aid persons and companies preparing the information of the materials which are presented for reviewing
- Communicate with all stakeholders (authorities, bodies and institutions, scientists, NGOs general public, social media)

- manage the OFRG and moderate meetings to facilitate the internal or external discussion respectively

Suggestions from RiskGONE:

(1) Establish quotas for specific skillsets to be on the council.
(2) The OFRG should include representatives of EU and other international bodies, and work to ensure collaboration with such institutions to prevent silos or inconsistencies.
(3) The OFRG should robustly seek to avoid undue influence by mistrusted parties. Follow ECHA's Risk Assessment Committee Rules of Procedure specifies independence under Article 9 of its Terms of Reference.
(4) Members could be individuals or organisations. However, attention should also be paid to non-organised stakeholders who can be very influential on social media platforms and contribute to shaping public opinion.
(5) It may be useful to establish chapters where members of respective stakeholder groups meet separately to generate priority issues for discussion and propose participants of represent the chapter in a regular global forum.
(6) Each member of the OFRG must be recognized 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 anno risk governance issues
(7) The OFRG could be:
    a. a group of experts expressing their own view about ways to monitor, promote, and maintain standards in risk assessment, including through the provision of consulting services
    b. a neutral place to deliberate
    c. a neutral place for multi-disciplinary and multi-stakeholder dialogue
    d. a scientific advisory board that is respected by all stakeholder groups
    e. a policy institution with the mission to help resolve trade-offs between safety, precaution, and innovation
    f. a regulatory body that would have authoritative power to decide about technical requirements for risk management and assessment

Grouped Feedback #3 on the general mission and operations of the OFRG

A council performs activities like "the identification, analysis, perception, management, and communication of nanotechnology risk" (RiskGONE D2.1)

"... the NRGC should not add more complexity. Instead, it should aim to simplify things, fill gaps, (...) or help unify and harmonize the field" (NANORIGO - D.4.1)

"The NRGC could be: 1) A group of experts (...); 2) A neutral place to deliberate (...); 3) A multi-disciplinary and multi-stakeholder neutral place for dialogue (...); 4) A scientific advisory board (...); 5) A policy institution or "pre-regulatory" body; 6) A regulatory body" (NANORIGO - D4.1)

"[…] the Council is not viewed as tasked with the development of regulation, because existing organisations already do this. Even the production of guidance and advice should be clearly defined, in complementarity to what others are already doing" (NANORIGO D4.3)

"Success will depend on the legitimacy of the institution, which the Council should receive through an official mandate provided by the EU or by the inclusion and representativity of legitimate stakeholders. So even if the Council would act as an independent bottom-up body, it should have an official EU mandate to provide recommendations to the EC" (NANORIGO D4.3)

"Ultimately the goal is to design a Council that will stimulate safe and sustainable development, use and disposal of engineered nanomaterials." (NANORIGO D4.4)

"The Council will not compete with or duplicate existing organisations. Instead, it will work to complement and add value. Analysis of needs and gaps in existing institutions suggest that the Council could: (a) work to support regulatory coordination, harmonization and implementation, where possible, in Europe and internationally; (b) engage stakeholders in deliberative approaches for informed decisions; (c) understand, reduce and learn how to cope with uncertainty and ambiguity; and (d) support responsible research and innovation. It should acquire legitimacy and authority through various means, including a mandate from the EC, trusted members and creating value for stakeholders" (NANORIGO D4.4)

"... NRGC should not duplicate existing institution and efforts." (UC M1)

"... role for the NRGC as a central point for the collection of data." (UC M1)

"The NRGC may also function as some kind of a 'think thank', focusing on emerging issues, to identify 'megatrends', and advising on how to respond to these." (UC M1)

"... support the existing Risk Governance organisations." (UC M1)

Other tasks: foresight, public dialogue, education, future research directions. (UC M1)

Potential tasks: (1) review the scientific data for nanomaterials; production of science-based expert opinions about specific RG aspects upon the request of the European Commission; review and integration of the Risk Governance Cloud Platform with future developments; provide guidance and advice on the development of TGs and SOPs." (RiskGONE - D 7.3)

"The operational practices of the forthcoming NRGC should therefore include a level of agility that allows the organisation to keep pace with the evolving needs of nanomaterial risk governance." (RiskGONE - D7.3)

Measure to reach the identified goals:

Establish set requirements for membership composition, internal roles in OFRG operations, and meeting etiquette.

Develop documents that identify when OFRG decisions are reached, and what levels of assent are required for the OFRG to adopt or communicate a decision.

Suggestions from RiskGONE:

(1) Establishment of quotas for a 'quorum' of OFRG activity. Prevent specific communities from dominating the voice of the OFRG unduly.
(2) Assign a specific POC for core questions, set reminders for meetings, follow Robert's Rules of Order

(3) Establish specific roles for operation (clerical, financial, etc).

(4) Communicate neutrality in all issues, with only focus upon scientifically informed conclusions

(5) Establish protocol that ensures equality of participation opportunity for different groups on OFRG.

(6) Require simple majority for small issues, supermajority (2/3 +1) for cases requiring a major decision or departure from existing policy. Allow feedback mechanism for all points of view to be recorded.

(7) Include mechanisms to assess
   a. recurring and regular workload, and
   b. horizon scanning for emerging nanotechnology risk governance problems.

(8) Prioritise quality over quantity concerning formal opinions or recommendations relating to nanomaterials, supported by a framework that sufficiently balances efficiency with the fundamental need for robust scrutiny, supported by protocols that suitably frame the risk assessment process.

(9) Accept and communicate scientific findings that refute earlier assumptions and perceptions of risk.

(10) Assist with construction of regulations with pertinent organizations but clarify status as a non-regulatory body.

(11) Members could have access to the head of various working groups and research leadership.

(12) A shared website/database could be created for members

Grouped Feedback #4 on scientific mission and public communication of the OFRG

The RGC will foster "Promotion of […] of the SbD concept […] help innovation governance, to support responsible research and innovation (RRI) […] Communication among stakeholders through bi-directional communication tools […] Guidance and standardization documents […] open data and global data availability […] (FAIR) data and promoting the FAIRification processes […] Utilization of risk governance tools (both existing and those to be developed) and incorporation of decision trees that will guide the users […] Resources will include guidance documents, standardization documents, public summaries, internet resources (databases, information portals), communication tools and scientific tools." (RiskGONE SMALL Publ.)

"[…] the RGC's activities, based on the RiskGONE consortium vision, should be […] making use of OECD/EURL ECVAM (European Union Reference Laboratory for alternatives to animal testing/European Centre for the Validation of Alternative Methods)" (RiskGONE SMALL Publ.)

"The NRGC will: significantly enhance current risk communication and consider stakeholder and societal risk perception and acceptance, ensuring involvement of the whole product value chains and circular economy; (...) implement consistent integration of new scientific data and their transfer into regulatory applications" (NANORIGO - D4.1).

"Mission: the NRGC at the interface between material innovation, risk science and regulation" (NANORIGO - D4.1).

"Advising on how to balance innovation and precaution" NANORIGO - D4.1)

"[…] four ideas regarding possible purposes of the Council, which could act as a platform to (a) share information on risks and benefits, (b) help stimulate safe and sustainable innovation, (c) serve to explore the future of engineered nanomaterials, and (d) help monitor, evaluate and communicate matters related to safety and sustainability." (NANORIGO D4.3)

"[…] the Council could start by looking at the many contested risk assessments developed by various scientific and other organisations, [and/or] produce reliable and trusted information, translate and communicate it in a meaningful and useful way to the various stakeholder groups, including society" (NANORIGO D4.2)

"Most participants recommended that the Council should be designed in a way to have real impact and deliver useful services and to be more than being simply a platform for provision and sharing of information. There would be added value in considering a Council that would deal not only with engineered nanomaterials but also with advanced materials or converging technologies that include a nano component. There would also be value in considering a role in relation to responsible research and innovation to help balance innovation and precaution" (NANORIGO D4.3)

"In terms of thematic focus, this report suggests that the Council could: (a) prioritize the effective implementation of risk governance, considering the two priorities of precaution and innovation; (b) address a specific new problem, such as the need to better understand and address emerging risks, in particular from advanced materials; (c) work to help stakeholders make the best use of the life cycle concept, both in developing and using LCAs and in supporting the development of circular economies; (d) work for the long-term sustainability of engineered nanomaterials and nano-based systems; (e) work to implement Responsible Research and Innovation (RRI); and (f) be European-focused but with global relevance and outreach." NANORIGO D4.4)

"Participants recommended that the Council could not be limited to environmental sustainability only, but focused issues should include human health too." (NANORIGO D4.5)

"The NRGC should play a role in early warning and a precautionary approach." (UC M1)

"Early warning and precautionary approaches should be central elements in the NRGC, when dealing with weak data, to avoid possible damages and to ensure a level of provisional acceptance." (UC M1)

Measure to reach the identified goals:

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, SCCS, SCHEER etc.) and the regulatory bodies. Offer recommendations for ENMs that seek to have a positive influence as an innovation.

Suggestions from RiskGONE:

(1) The OFRG 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.

(2) These opinions and guidance will be provided in the form of expert advice, standardised frameworks, valid/validated methods, risk assessment tools, material specifications, etc. This includes a mixture of quantitative and qualitative insight.

(3) Seek to provide guidance on optimal governance of ENMs overall. Consider where the most valuable contributions could lay with respect to regulatory processes and existing gaps in the evaluation of nanomaterial risks and uncertainties. This includes consideration of various research and production processes, as well as product categories.

(4) Utilize a scientifically valid peer review process for reviewing any type of information is produced and communicated to the public.

(5) The OFRG should aim to provide an overarching opinion across all substances rather than limited to certain areas of application to account for the range of exposure pathways possible in realistic conditions.

(6) Need to adapt testing, measurement, and evaluation methods with the aim of regulating safety for humans and the environment while keeping pace with innovation.

(7) The OFRG will not "reinvent the wheel" but collect, select, organise, and recommend best criteria, tools and practices, available on the NANORIGO web-based framework. In this sense, it will be as a clearing house.

(8) The OFRG will allow and support stakeholders and users to make comparative judgments, finding out the needs for using the ENM in a particular application, explaining the consequential release of nanoparticles, compare these with the non-ENM nanoparticulate concentrations, and as such realizing some kind of holistic approach for environmental as well as workplace assessments

(9) The OFRG must establish and define overarching values in the priority areas identified (Governance and Effective Risk Governance; Independence and Trustworthiness; Openness and Transparency; Scientific Robustness; Prevention, Precaution, Wellbeing, and Sustainability) that directly influence the implementation of the OFRG's mission)

Grouped Feedback #5 on financial stability and sustainability of the OFRG

"... members will contribute in relation to their capability. For example, one should except that large companies will pay higher membership fees than NGOs. " (NANORIGO - D4.1)

"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" (NANORIGO - D4.2)

"[…] the workshop participants reflected on four possible scenarios and different services of the future Council: the European Intergovernmental Panel on Nanomaterial (1), the European Scientific Advisory Committee on Nanomaterials (2), the European Centre on Risks of Nanomaterials (3) and the European Roundtable of Nanomaterials (4). […] The majority of participants liked the most government-led scenarios (scenario 1 and 2) because the structure is better defined and would be by financed by public government funds." (NANORIGO D4.5)

"Success and sustainability will depend on the legitimacy of the institution and financial viability, which the Council should receive through an official mandate and funding provided by the EU or by the inclusion and representativity of legitimate stakeholders. So even if the Council would act as an independent and neutral bottom-up body or governmental body, it should have an official EU mandate to provide recommendations to the EC." (NANORIGO D4.5)

"a membership fee could be a limitation for stakeholders to participate in the Council because some members could not afford it." (NANORIGO D4.5)

"The NRGF will be an open access, free of costs. Costs are integrated within the NRGF from the beginning." (UC M2)

"The model for a sustainable NRGC should therefore not rely upon targets for risk analysis and decision-making alone, but a broader range of governance activities which represent the foreseen NRGC's impact on risk governance in Europe." (RiskGONE D7.3)

The Council […is…] 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. (NANORIGO D4.2)

Measure to reach the identified goals:

Ensure the ability of the OFRG to meet all financial obligations, fund critical scientific research directly relevant to its core mission, and fund staff activities.

Independence is a key framing element for the OFRG, as operating practices that support and demonstrate greater independence both economically and scientifically are preferred.

Suggestions from RiskGONE:

(1) Have a Chief Financial Officer with corresponding rights and privileges on the OFRG board
(2) Produce annual budgets to be voted and approved by OFRG leadership.
(3) Require budget to be balanced.
(4) Fundraising activities should be formalized. A portfolio of options may include
    a) funding through EU or international government sources, which will ensure a foundational level of activities that a OFRG would be required to carry out, or
    b) voluntary and/or dues-based contributions by participating organizations.
(5) Funding should, at a minimum, be able to cover stipends for OFRG 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.
(6) Generate emergency fund to cover reasonable shortfalls.
(7) Create financial incentives for members of small and medium-sized enterprises

Grouped Feedback #6 on general guidance for professionalism, neutrality and topicality of the OFRG

"[…] preferably it shall be nested within relevant European agencies (e.g., ECHA)" RiskGONE D2.1

"(...) operating rules may differ according to whether the NRGC is a governmental institution (...) or whether the NRGC is a private institution." (NANORIGO - D4.1)

"The vision suggested by NANORIGO is to better balance precaution and innovation towards the future, especially through the development of new, advanced and innovative materials, considering responsibility, environmental sustainability, trustworthiness and legitimacy" (NANORIGO D4.4)

"Common deficits in risk management: Framing, Scope, Problem of scarcity of quality data, Lack of transparency, Inequity, Accountability, Paralysis by analysis, Lack of trust." (UC M2)

"What is it [governance]? It's fundamental logic of organising decision in a horizontal way, integrating the relevant issues for decision-making, as opposed to vertical, hierarchic top-down way." (UC M2)

"The operating practices of the NRGC should prioritise quality over quantity concerning formal opinions or recommendations relating to nanomaterials, supported by a framework that sufficiently balances efficiency with the fundamental need for robust scrutiny, supported by protocols that suitably frame the risk assessment process." (RiskGONE - D7.3)

"(...) independence is a key framing element for our analysis (...). It will be important to identify the optimal level of independence and separation from existing institutions and regulatory practices (...)." (RiskGONE - D7.3)

Other values: "openness and transparency", "accessibility of information", "scientific robustness" aka "sound scientific basis", "efficiency", "effectiveness", "sustainability" (RiskGONE - D7.3)

"holistic approach is strongly recommended for the NRGC to better account for sustainability issues alongside innovation in a more balanced manner." (RiskGONE D7.3)

"The operating practices of the NRGC should prioritise quality over quantity concerning formal opinions or recommendations relating to nanomaterials, supported by a framework that sufficiently balances efficiency with the fundamental need for robust scrutiny, supported by protocols that suitably frame the risk assessment process." (RiskGONE - D7.3)

"Risk governance provides a process: a comprehensive and harmonized guidance for early identification and handling of risks, involving multiple stakeholders." (NANORIGO - JM1)

Measure to reach the identified goals:

Implement general guidance for professionalism, neutrality, and topicality of the OFRG.

Suggestions from RiskGONE:

(1) Establish clear scoping of engineered nanomaterials (e.g., the types of ENMs that will be discussed by the OFRG) without necessarily passing judgment on what legally comprises a 'nanomaterial.'

(2) Acknowledge that risk assessment is an important component of risk governance, but that risk governance is far more than only risk assessment.

(3) The OFRG cannot and should not strive to do everything - tasks and meetings should be prioritized based upon governmental, societal, and industry needs and activities.

(4) Reducing duplication of effort with other organizations and laboratories is essential to preserve limited OFRG resources and time. This can be accomplished by establishing relationships with multiple labs/organizations and identifying core gaps or needs not currently covered by such organizations.

(5) However, the council itself may not be the place to develop new tools. This will take place outside of the OFRG

(6) Members are to provide some expertise as to the needs, safeguards, and requirements to ensure that the OFRG is operational, balanced, and effective

(7) The OFRG may be a governmental institution formed by governments or the EU, following models such as those of the European Union Agency for Cybersecurity or the future European

Innovation Council. Or the NRGC may be a private initiative, following models such as from the Marine Stewardship Council or the Roundtable for Sustainable Biomaterial.

(8) The OFRG could develop European standards that could evolve as global standards, taking the form of transnational private regulation.

The following points refer to a Risk Governance <u>Framework</u> that is considered independent of the organisational form of an OFRG.

Grouped feedback #7 on best practice on interdisciplinarity in a RGF

"[The NRGF] supports and encourages science-based, inter-disciplinary and multi-stakeholder management of safety, risk, as well as long-term view about innovation and sustainability" (NANORIGO - Introduction to NRGF)

"The NRGC will operate the NRGF through relevant and well-placed pan-European and international organisations, ensuring design, manufacturing, economic, social and environmental compliance and sustainability." (NANORIGO - D4.1)

"It seems to be useable for the highly diverse type of stakeholders, such as SMEs, laboratory workers, etc., but it will surely need thorough guidance to lead the user through the full framework." (UC M2)

"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 needed." (NANORIGO D4.2)

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'." (NANORIGO D4.2)

Measure to reach the identified goals:

Creating parallel work tracks across disciplines and activities

Suggestions from RiskGONE:

(1) Foster activities (regular face-to-face discussions; review and evaluate current data, materials, reports, proposed activities, and progress made; assess the state of the art in science) from differing disciplines (e.g., biology/chemistry, engineering, social sciences, etc.) as well as perspectives within the RG process (analysis, management, communication), ensuring no bottlenecks in workflow.
(2) Foster adaptive governing style and procedures
(3) Tools are needed to bring together the variety of stakeholders and knowledge and resolve the trade-offs between risks and opportunities.

Grouped feedback #8 on best practice in a RGF

"A key recommendation from that work was the urgent need for the development of a holistic risk governance framework, whose aim is to integrate scientific data and operational tools, which coupled with guidance and test guidelines can lead to the operationalization of a risk governance council." (RiskGONE SMALL Publ.)

To achieve such an operationalization of SbD and related concepts, scientific and regulatory needs are mapped in parallel with innovation management needs that together with prevention-based and safer-innovation approaches have to be incorporated within the emerging risk governance frameworks. Achievement of such a holistic, operational, and transparent framework, acceptable to and trusted by all stakeholders is the ultimate goal of risk governance research. (RiskGONE SMALL Publ.)

"The risk governance framework will be available as an interoperable cloud platform with a user-friendly interface and operationalized via a set of decision trees implemented into a modular decision support tool providing instruments, guidance and guidelines for different aspects of the risk governance of NMs, such as:
   1) Characterization, fate, and dosimetry of NMs
   2) Human hazard assessment
   3) Environmental hazard/effect assessment
   4) Exposure assessment
   5) Human health risk assessment
   6) Ecological risk assessment
   7) Environmental impact assessment and life cycle analysis
   8) Social impact assessment and risk-benefit analysis
   9) Economic assessment
   10) Risk reduction
   11) Risk transfer
   12) Risk communication
   13) Ethical impact assessment" (RiskGONE SMALL Publ.)

The NRGF "emphasizes the role of social, political or economic evaluation about the outcome of the risk assessment, before management decisions are taken" (NANORIGO - Introduction NRGF)

"A life cycle approach for risk assessment of innovation is needed." (UC M1)

"A Safe-by-Design approach should be operationalised for MNMs and nano-enabled-products". (UC M1)

"The NRGF should be a scientific as well as a value-based framework." (UC M1)

"a clear reference towards foreseen tools is urgently missing, as is for example the case for the costs to be made for carrying out the full cycle." (UC M2)

"(...) the NRGF is not an institution or organisation, but a process. (...) the 4 core functions of the NRGF (take into account context and culture, involve stakeholders, assure two-way communication and moderate the process). (...)." (UC M2)

"(...) the NRGF focuses on what does not exist there, works on emerging issues and prepares for the (long-term) future." (UC M2 - Marie-Valentine Florin)

"The NRGF must be future-proof and agile to keep pace with nanomaterial innovations and evolving regulatory process." (RiskGONE - D7.3)

"The NRGF should aim at enable the NRGC to provide an overarching opinion across all substances rather than limited to certain areas of application to account for the range of exposure pathways possible in realistic conditions." (RiskGONE - D7.3)

Measure to reach the identified goals:

Take each methodology separately and integrate gold standard activity. Ensure core stakeholders aggregate, process, and understand all methods and outcomes.

Identifying tests, assays, and other requirements that can be integrated prior to material testing and commodification.

Suggestions from RiskGONE:

(1) Standardizing practice to include Cost-Benefit Assessment, Ethical Assessment, and Life Cycle Analysis
(2) Foster a comparative analysis of the value-added on nanotech products (e.g., why is the nano component necessary?). Then, offer metrics and tests that help evaluate possible risks and uncertainties added by the ENM.
(3) Utilize decision trees to complement relevant toolboxes and guidance materials, to support the OFRG in the risk governance processes.
(4) Allow for iterative, reflexive, and timely updating of guidance at specific periods of time (depending on level of uncertainty of material hazard and exposure properties.
(5) Comparatively evaluating EU nanotechnology risk assessment and policy alongside specific hard law mechanisms and soft law guidance from USA, China, Australia, and other jurisdictions.
(6) A framework for nanotechnology risk governance is expected to:
    a. Provide key knowledge base, (...)
    b. Identify the type of problems (...)
    c. Help identify deficits in nanotechnology risk governance (...)
    d. Be adaptive and flexible (...).
(7) Provide or develop tools for risk assessment including theory and data (advice methodologies; inventory of existing date); tools for risk assessment should connect industry and users.

Grouped feedback #9 on the deliverables and public communication of a RGF

"The RGC risk governance framework should aim to enable the RGC to provide an overarching opinion across all substances rather than limited to certain areas of application to account for the range of exposure pathways possible in realistic conditions;" (RiskGONE D7.3)

"The NRGF will provide (a) guidelines and (b) access to relevant concepts, methods, tools and data." (NANORIGO - D4.1)

"Social perception is an important issue too when to decide whether to label a product as NMs or not. Public perception plays a crucial role, as the general public needs to accept technologies and products to successfully put them on the market." (UC M2)

"The NRGF can create a new kind of a blueprint (...), including a modern view on sustainability, encouraging into action (proactively) before the hazard or perception of hazard has occurred. It can act as a risk-based decision tool." (UC M2)

"The framework does not provide the outcome, but guidelines for how to reach the goal." (NANORIGO - JM1)

"Users of NRGF will have access to concepts, tools, illustrations." (NANORIGO - JM1)

Measure to reach the identified goals:

Ensure that transparency and ease-of-communication is assured within all core deliverables. This includes written and online material to inform the society

Suggestions from RiskGONE:

(1) Work with core cloud products and servers early in the RG Framework process; adopt opportunities to field stakeholder input throughout the Framework-building process.
(2) Provide mechanisms to have nonbinding resolutions that, while not legally enforceable, establish a culture of strong oversight and safety-by-design. Inclusive of hard and soft law mechanisms, scientific data, and operational tools
(3) Independence and trust among other organizations must be provided.

Grouped feedback # 10 on the operations and the quality control in a RGF

"6 steps:

1) Pre-assessment
2) Technical risk assessment
3) Opinion and concern risk assessment
4) Evaluation
5) Management
6) Monitoring and Feedback"

(NANORIGO - Introduction NRGF)

"4 core functions:

1) Considering the context
2) Communicating
3) Engaging with stakeholders
4) Coordinating the process"

(NANORIGO - Introduction NRGF)

"The principal components of risk governance frameworks, such as risk pre-assessment, risk appraisal, risk evaluation, and risk management […] (RiskGONE SMALL Publ.)

"Key gaps that have been identified include the ongoing lack of: i) consensus in a risk management framework for NMs; ii) certified reference materials and positive/negative controls for NMs; iii) official test guidelines for characterization and toxicity evaluation; iv) methodologies for understanding of the social impacts of nanotechnologies; v) consensus strategies for the transfer of acceptable risk arising from NMs; and vi) proper communication toward stakeholders and society." (RiskGONE SMALL Publ.)

"The conditions that trigger policy or regulatory decisions to apply the Precautionary Principle (PP) are determined on a case-by-case basis (...). The NRGF can be used to collect information that is used by policymakers to decide if, when and how to apply the PP." (UC M2)

"There seems to be a communication gap and the development of another framework such as the NRGF should not be done without taking into account what already exists." (UC M2)

"We developed the NRGF and the NRGC for the environment, so it will be operating in the EU." (UC M2)

"The NRGF will be adaptive to future challenges, needs, and future trends in governance." (NANORIGO - JM1)

"Why is a framework needed at the European level? Harmonisation; new challenges of novel materials and converging technologies; various stakeholder expectations; a careful examination of needs and gaps is required."

Measure to reach the identified goals:

Foster a focused, transparent, and scientifically informed risk governance process that is grounded in principles of responsible research.

Suggestions from RiskGONE:

(1) The framework is expected to support regulatory decision-making as well as business management needs, through the adoption of best practices, the promotion of RRI.

(2) Need to adapt testing, measurement and evaluation methods with the aim of regulating safety for humans and the environment while keeping pace with innovation. An anticipatory approach must be employed regarding capacity and resources.

(3) Overcome limitations of government regulatory activity (e.g., slow time to implementation, dissention, etc.).

(4) Close regulatory gaps by aligning RG Framework with core mission needs of the regulatory actors. Ensure that the framework is designed to be consistent with EU regulatory processes.

(5) Industry should adopt to demonstrate compliance with regulatory requirements. The NRGF will be adaptive to future challenges, needs, and future trends in governance to align with NRGC while keeping pace with state-of-the-art findings.

(6) The framework should include aspects of nanotechnology, synthetic biology, digital and other technology; Need to harmonize ways to evaluate and manage the same risks.

(7) The framework should evaluate the freedom for the organization to fulfil commitments to openness and transparency while having a specific target area.

(8) The framework should establish rules of procedure and demonstrate how the independence and trustworthiness are among other organizations.

Outreach in numbers

## Social media followers

LinkedIn

In the last year RiskGONE gained 53 new followers which amount to a total of 201, whereas 338 people visited the page.

NMBP-13 stakeholder list

Currently (July 2023) the NMBP-13 stakeholder list contains 326 entries from all relevant organisational types including industry, academic institute, press, international institute, NGO, Government committees, etc.

Website visitors

The RiskGONE website has had over 12,000 visitors in 2022 – and more than 64,000 since the opening of the site.
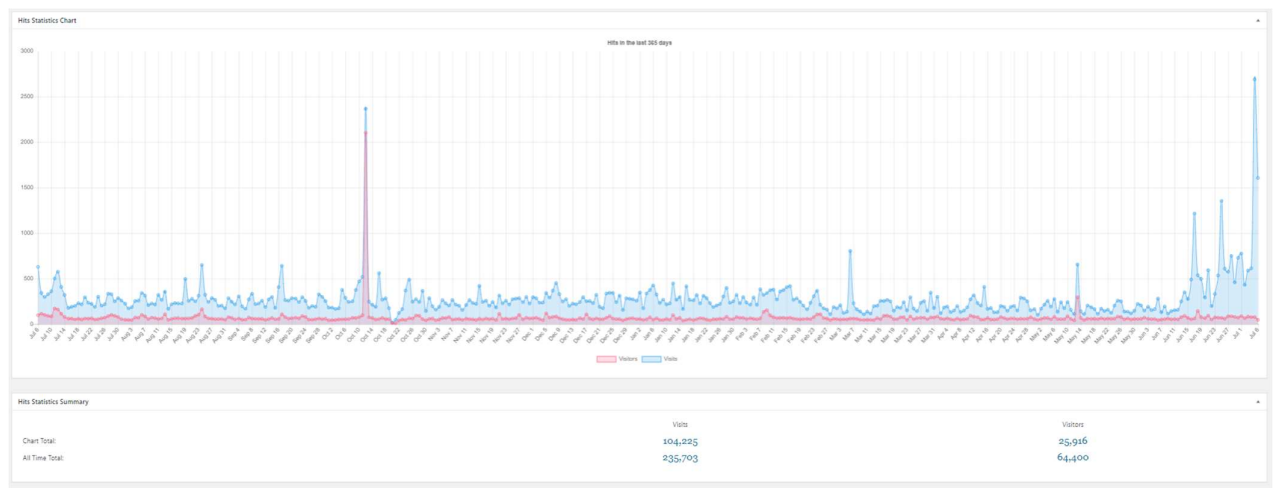
Newsletter subscriptions

Up to July 2023, 65 persons have subscribed to the newsletter mailing list.

Nanohub

RiskGONE is member of the nanoHUB in the group of the NanoSafety Cluster. RiskGONE offers here, together with the other NMBP-13 projects certain educational material.

Zenodo

19 entries uploaded to the platform.

Future plans

Further input from certain user groups, societal groups and institutions will be collected during the completion time of the project. The NMBP-13 project and the RiskGONE consortium plans several conferences in 2022/23, among these there is the common final conference in the timeslot 23-25 January 2023 in the premises of the OECD in Paris and the RiskGONE final conference in 2023. Furthermore a final CDS will be elaborated, based on the preceding CDSs.

Interaction with stakeholders will take place also at conferences which are organized by non-project members.

Because the RGC will not be installed as an outcome of the NMBP-13 projects, more outreaching activities are not planned, this document should be seen as a recommendation from the consortium on what an OFRG might look like, however this might be implemented in the future.

Conclusion

Feedback from the various activities available to us in the NMBP-13 projects has shown that the participation of all interested stakeholders will have a decisive influence on the success of an appropriate organizational form. Equal participation of all stakeholders in the discussion, general access to the available information with as few as possible or no barriers and general independence of the OFRG are the prerequisites for taking all relevant scientific and societal issues into account. For this purpose, the members of the OFRG must contribute to the maintenance of a council according to their financial possibilities - if this is necessary in the existing or planned of the OFRG.

The discussion and the results of a discussion process must always be based on the current state of scientific knowledge, backed up by a scientific peer review process. The results of the internal discussion in the OFRG must be made available to the general public so that they are continuously included in the process and informed about the decisions.

An OFRG must always be fast and flexible enough to keep pace with developments in science and technology and to be able to keep up with regulation, in line with current research.

Frankfurt am Main, 2022-07-31

The publication reflects only the author's view and the European Commission is not responsible for any use that may be made of the information it contains.