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Deliverable Report

Deliverable D 3.7	Concept paper on how to address civil society's and insurances' needs within the organisational form for Nano Risk Governance
Due date of deliverable	*2022/12/31*
Approved by MC	*2023/02/06 (by written procedure)*
Actual submission date	*2023/02/06 (to EC)*
File name	D3.7_G4N_Concept paper on how to address civil society's and insurances' needs within the OF for NRG

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Work package/task:	WP3 / Task 3.4
Document status:	draft / final
Confidentiality:	confidential / restricted / public
Key words:	Civil society; (Re)Insurance industry; User Committee; Multistakeholder engagement; Societal acceptance

DOCUMENT HISTORY

Version	***Date***	***Reason of change***
1	2022/09/14	Creation of first draft (BNN)
2	2022/11/10	Revision of document and integration of content (BNN)
3	2023/01/26	Final proof-reading (BNN)

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

Lead beneficiary for this deliverable: BNN (04)

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Dissemination Level:			
PU	Defined in the DoA	Public	PU PP RE CO
PP		Restricted to other programme participants (including the Commission Services)	
RE		Restricted to a group specified by the consortium (including the Commission Services)	
CO		Confidential, only for partners of the consortium (including the Commission Services)	

1.	Gov4Nano Advisory Board	Yes
2.	NMBP-13 NANORIGO	Yes
3.	NMBP-13 RiskGONE	Yes

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1 Summary

This report summarises the findings and conclusions obtained during the four years runtime of the Gov4Nano project (2019 – 2023) and its activities focusing on how (i) civil society and (ii) the (re)insurance industry can best be involved in the organisational form for Nano Risk Governance.

Nanotechnology risk governance is a collaborative effort among various stakeholders, each with their own areas of responsibility, to ensure the safe development and use of this technology. The organisational form for Nano Risk Governance should take into account all the different needs of the stakeholders and ensure that they are adequately considered and addressed. Both the (re)insurance industry and civil society have specific needs related to nano risk governance. Based on desk research, qualitative expert interviews, a stakeholder survey, and dedicated "User Committee" meetings, the needs and views of these two stakeholder groups were identified and considered throughout the project implementation.

As far as the (re)insurance sector is concerned, it can be concluded that there is currently no particular interest or need with respect to nanotechnology. While some insurance companies decided to react to potential nano-related risks with the announcement of 'exclusions' of all nanotechnologies (with a focus on nanomaterials) from their policies, the majority of (re)insurance companies, however, decided to count on experts' opinions and subsequently set up nanotechnology-monitoring activities. Currently, they would not participate and engage themselves heavily in further activities related to nano risk governance. However, the organisational form for Nano Risk Governance could act for the (re)insurance industry as expert knowledge provider, if any new findings/scientific results are available, specifically to new advanced (nano)materials and potential associated risks.

With respect to civil society, two levels were considered: (i) the general public, who are affected by nanotechnology primarily as end users of nano-enabled products in their daily lives (without additional knowledge; considered as lay-persons with respect to nanotechnology), and (ii) civil society organizations (CSOs), which operate independently of government and industry and work for the public good by representing the interests of the specific groups or communities they serve or whose causes they advocate.
Drawing on studies on public perceptions of nanotechnologies and based on expert interviews, eleven recommendations were formulated for general, lay-people-oriented public communication of nanotechnologies. Following these recommendations would allow the organisational form for Nano Risk Governance to publicly communicate in the most effective way, as they are providing practical and real-life relevant guidance.
To engage CSOs, a "User Committee" format was used to enable multidisciplinary discussions between different stakeholders. Next to that, a public stakeholder survey on nanotechnology risk governance was conducted, with more than 25% representation from CSOs/NGOs. One question in this survey was addressing the engagement of civil society, if any – the provided recommendations from this survey are very much aligned with the suggested best practice public communication actions. The organisational form for Nano Risk Governance should act as trusted source of information and monitor public discussions, education and training activities, focusing on communicating risks as well as benefits of nanotechnologies and nano-enabled products.

In summary, this report provides best-practice guidance on how to address two specific stakeholder groups, namely (i) civil society and (ii) the (re)insurance industry, within risk governance initiatives. Follow-up activities for the organisational form for Nano Risk Governance are currently under discussion and should consider the findings and recommendations from this report in future activities. Next to that, this report could be useful for every initiative interested and/or actively involved in risk governance. Based on gained practical experience of multistakeholder engagement, this report provides recommendations for public communication and a best-practice example on how to engage with different stakeholder groups, supporting better decision-making including and addressing multi-stakeholders' positions, views and perceptions.

2 Description of task

In Annex 1 (part A) of the Grant Agreement No. 814410, on page 33, Task 3.4 is described the following:

> *"Based on the identified indicators, Task 3.4 focusses on the integration and conceptualization of the two pillars "civil society" as well as "insurance" into conditions for an organisational form for Nano Risk Governance. Task 3.4 will thereof elaborate and integrate into conditions for an organisational form for Nano Risk Governance, the structure on (i) how to involve civil society and (re-)insurance industry needs, and (ii) how to monitor the successful interaction with these stakeholders. Building the two pillars will be achieved by screening relevant literature, implementation and evaluation of questionnaires, and specific user committee-workshops. Furthermore, public risk perception on nanotechnology and its application in different products will be monitored through the project runtime, especially before and after dedicated engagement activities, enabling a quantitative evaluation of the relation between risk perception and increased knowledge about nanotechnologies. This task will build on Task 3.1, Task 3.2 and Task 3.3, working in close collaboration and feeding information to WP5. This will guarantee that the information collected in this WP is fed into the conditions for an organisational form for Nano Risk Governance. A main action will be including the civil society/(re-)insurance industry's views into the mission of the organisational form for Nano Risk Governance. In particular, needs and views of these stakeholders will be used to develop the operational structure of the organisational form for Nano Risk Governance (link to Task 5.1). Moreover, cooperating and feeding into WP6 ensures that "civil society" as well as "insurance" are represented and included into the overall organisational form for Nano Risk Governance stakeholder framework. Key Actions: (i) Literature recherché and discussion meetings to conceptualize the structure of the two pillars. (ii) Developing questionnaires, establishing user committees, and organizing/performing workshops."*

3 Description of work & main achievements

3.1 Background of the task

Civil society and (re-)insurance companies have to deal with uncertainties about risks of nanotechnology. It is important to identify, analyse and understand their needs. Within Gov4Nano, WP3 focussed on the characterisation of how risk perception is formed in (i) in civil society, and (ii) (re)insurance industry. Specific focus was put on identifying the particular information needs of these two specific stakeholder groups.

Starting from the general public perception about nanotechnology and its application in different products, WP3 aimed to identify indicators that influence risk perception, to define criteria that form different perceived risk levels, and to understand how risk information is communicated and received by an individual (see D3.1. "Report on parameters, elements and information forming and influencing the risk-perception of different civil society groups"). Moreover, WP3 aimed to elaborate how training and education can help that non-experts to build their own unbiased opinion. Based on the identified indicators and criteria, the aim of this report is to elaborate and integrate into the conditions for an organisational form for Nano Risk Governance the structure on how to involve and take into account civil society and (re-)insurance industry needs and views. Therefore, dedicated stakeholder engagement activities were performed, raising awareness through contemporary dialogue formats and utilizing social media, and dedicated training and education activities were conducted.

This work serves the optimised development of the organisational form for Nano Risk Governance, to understand how to specifically address these two stakeholder groups. Together with WP6, this work builds the overall stakeholder strategy for the organisational form for Nano Risk Governance.

3.2 Description of the work carried out

3.2.1 Addressing (re)insurances' needs

The Gov4Nano project had initially planned to develop a tailor-made information service regarding the developments in understanding the risks posed by nanotechnologies; the service would form an integral part of the organisational form on Nano Risk Governance. After nine months of dedicated presentations and engagements with representative of the (re-)insurance industry, however, it became clear that nanotechnology was not high enough on their agenda to dedicate any time to it. A single insurance expert, who had agreed to an interview with the Gov4Nano team, explained that the insurance industry had not lost interest in nanotechnology, but the understanding was that the 'nano'-label was no longer needed.

> *There are still open questions [surrounding nanotechnology], but that applies to many emerging risks from new technologies.* (Risk Engineer at Allianz Group (2019))

It was thus agreed to conduct a review of the (re-)insurance industry's initial interest in and active engagement with nanotechnology in the early 2000s, and the developments in the field in the subsequent 15 years.

3.2.2 Addressing civil society's needs

3.2.2.1 Elaborating best-practice guidelines for communication, information provision and engagement

Although the current public opinion on nanotechnologies can be described as positive, the changes in public discussion of emerging technologies bear some risks. The more and more central role of social media and the emergence of different social media "influencers" have led to a stronger unpredictability of the "civil society". Domains and topics that were previously left for scientific experts are more often discussed by people with limited scientific background – who do not necessarily share the principles of technical risk assessment, but at the same time may enjoy larger audiences than scientific organisations or public institutions do.

Considering these developments, possible needs for public communication of nanotechnologies and possible communication roles for an organisational structure of Nano Risk Governance were discussed in Gov4Nano. The aim was to lay foundations for possible dialogue and communication activities by the organisational form that would support the overarching aims of the project, fostering safe and societally desirable development of nanomaterials and related products.

Drawing on studies on public perceptions of nanotechnologies, findings of sociological risk research and an analysis of current public discussion patterns (e. g. in the context of the COVID-19 pandemic) stakeholders as well as bloggers and social media influencers not primarily focused on nanotechnologies were interviewed on current needs for public communication of nanotechnologies. Based on the interviews, eleven recommendations were formulated for public communication by the possible organisational structure of Nano Risk Governance. The recommendations and the deliverable report D3.2 ("Best-practice guidelines for communication, information provision and engagement") however are to be viewed as a synthesis by task leader DIALOG BASIS: They do not necessarily represent the opinions of all individual persons and organisations involved.

3.2.2.2 Collaboration with the NMBP-13 sister projects NANORIGO and RiskGONE

From the very beginning of the Gov4Nano runtime, the collaboration with the two NMBP-13 sister projects NANORIGO and RiskGONE was initiated. This collaboration was facilitated through so-called NMBP-13 Core Groups addressing the key topics within the projects. Engaging stakeholders was one crucial topic where collaboration and good coordination was needed – the aim was to join forces and engage with external stakeholders in a structured way, to not ask them the same questions multiple times. BNN as WP3 leader and NIA as WP6 leader were nominated to represent Gov4Nano in the NMBP-13 Core Group on Stakeholder Involvement. Monthly meetings were organised to discuss and align all stakeholder activities. A common NMBP-13 stakeholder database

was also established, including CSOs and NGOs. All NMBP-13 Core Groups also met on regular basis (every two or three months) to discuss their progress and plan next steps.

3.2.2.3 Joint stakeholder survey including the potential participation of civil society in risk governance

The NMBP-13 projects decided to make one joint online survey for external stakeholder focusing on their views and needs related to risk governance. The following questions were asked:

- Personal information:
  What is your full name? What is your email address? What is the name of your organisation? Which country are you located in? What type of organisation are you affiliated to?
- Are you personally satisfied with how risks from engineered nanomaterials (ENMs) currently are assessed, managed and regulated in Europe?
- Are you confident that the current regulatory system in place in Europe will enable satisfactory and sustainable risk assessment and management of ENMs in the future? (e.g., 3rd generation, smart/active ENMs)"
- What, if anything, do you think should be done to enhance trust between industry, regulators and societal stakeholders?
- What, if anything, do you think should happen to ensure the participation of civil society?
- Do you think that a new organisation tasked with governing new and emerging risks from ENMs, that also considers wider societal and ethical concerns, would be necessary/beneficial to you?
- If you answered "No. There are other existing organisations that can do this.", which organisations do you consider these to be
- If you answered 'Yes, there is no suitable organisation in Europe', please answer the following questions:
  - What benefits do you expect from a new organisation?
  - What form should it take?
  - Who should contribute funding to it?
- Would you be interested in participating in such an organisation?
- If yes, how would you see yourself participating in such an organisation?
  - Data Management and Curation
  - Methods for Testing, Characterisation and Standardisation"
  - Online Tools
  - Stakeholder Engagement
  - Governance of SSbD (Safe and Sustainable by Design)
  - Skills and Competences (training)
  - Other
- In terms of other project outputs, would you benefit from:
  - A framework that helps you assess, manage and communicate (i.e., govern) current and potential future risks associated with next generation ENMs?
  - Online tools to assess specific risks associated with ENMs?
  - Data on risk assessment of ENMs that could be used in combination and/or in comparison with your own data?

- Would you be able to make direct use of:
    - A framework
    - Individual tools
    - Data
- Would you need expert advice in order to do so?
    - A framework
    - Individual tools
    - Data
- How often would you need to make use of these project outputs, e.g., to meet any regulatory demands?
- Would you be willing to pay to access any of these services in the future?
    - The portal (all tools within it are freely accessible)
    - Individual tools
    - Expert advice
    - Other (please indicate)
- Can you suggest any additional services/support, as part of the risk governance process, that would be beneficial to your organisation? (For example, the use of standardised OECD test guidelines to comply with regulatory requirements)
- Would you be interested in providing further feedback to the projects? If so, please include your contact details if you have not already done so.

This online survey was promoted and shared by all three projects, via email, social media (i.e., LinkedIn and twitter), and personal contacts from project partners.

For this report, mainly the question on "What, if anything, do you think should happen to ensure the participation of civil society?" was evaluated; the results of the other questions feed into the stakeholder Deliverables in WP6 as well as into D3.8 "Evaluation of how public risk perception evolved from the beginning of the project until the project's end".

3.2.2.4 Joint NMBP-13 "User Committee" to facilitate multistakeholder engagement, including CSOs

NANORIGO established a "User Committee" that consisted of individual experts representing different stakeholder groups. To ensure effective collaboration and join forces also on this topic, it was decided to transform the NANORIGO User Committee into a joint NMBP-13 "User Committee". BNN was nominated from Gov4Nano to take a co-lead in this activity and joined the Organisational Team of the "User Committee".

Within the "User Committee", a number of 15 committed experts from 12 organisations representing four different stakeholder groups (i.e., researchers, industries, CSO's and governmental agencies) were engaged in a total of six two-half-days meetings (physical, online as well as hybrid) held during four years (from 2019 to 2022). Every meeting was carefully planned content- and setting-wise, exhaustive reports were produced after the meetings ad shared and discussed with all NMBP-13 project partners.

3.3 Results

3.3.1 Addressing (re)insurances' needs

The (re)insurance industry's initial interest had been caused by a number of reasons, ranging from the genuine worry that the uncertainties and 'unknown unknowns' surrounding nanotechnologies would render the technology entirely 'uninsurable' (i.e., similar to nuclear worst-case scenarios), to the view that nanotechnology harboured lucrative growth opportunities in the form of novel commercial and industrial insurance covers and defence costs. While some insurance companies decided to react to the former worry with the announcement of 'exclusions' of all nanotechnologies (with a focus on nanomaterials) from their policies, their more opportunist colleagues responded to the latter by offering new, nanotechnology-specific policies; the majority of (re-)insurance companies, however, decided to hold dialogue meetings with experts and laypeople, conducted in-depth analyses of nanotechnology and its risks, and subsequently set up nanotechnology-monitoring activities.

The ongoing advancement of nanotechnology-based processes and products over the past 20 years demonstrates that nanotechnologies could be covered by commercial and industrial insurance policies, and that even incidents like that of Magic Nano (i.e., a bathroom sealant spray that had hospitalised around 100 users with (sometime severe) respiratory problems upon inhaling the product's aerosol) did not lead to any nanotechnology-specific losses. The insurance industry did, however, treat the Magic Nano incident as a 'wake-up call' to the entire nanotechnology community, in that it learnt to give a higher weighting to the reputational risks of a technology, and to consequently emphasise analyses of reputational damage exposures and crisis communication.

Until 2017, several (scientific) papers were published, which re-iterated the problems that nanotechnology could pose for the insurance industry, and that had originally been raised by the (re-)insurance industry itself, when it engaged with nanotechnology in the early 2000s. It is interesting, however, that very few publications are authored by the insurance industry itself.

So, what does the (re-)insurance industry think about nanotechnology, and why is not running down the door of those collaborative projects that aim to provide them with tailor-made information regarding the risks of nanotechnology, or even the insurability of nanotechnology, as suggested by the NMBP-13 projects.

In 2005, the Allianz Group concluded its first dedicated nanotechnology-report with the following statement:

> *[…] it seems neither feasible nor appropriate to start a debate about a general exclusion of nanotechnologies from the insurance coverage today.* (Allianz Group, et al., 2005)

The insurer seems to have subsequently lived by this initial verdict, as well as its pledge to *'put its feelers out on the subject'*, and to adopt a *'balancing act of risk-taking by limiting transaction costs, improving the evidence base and coping with a degree of uncertainty.'*

The insurance industry confirmed that it continued to monitor the technology as an emerging risk. One of its tasks is the assessment of risks spanning across the life cycle of nanomaterials; this was increasingly done together with external partners.

The risk assessment of a company's liability exposure is based on the analysis of the inherent risk and the maturity level of the company to handle those risks (= risk management performance).

> *This situation [of significant risk] has never occurred in the broad field of nanotechnology, which means that […] very few or non-nanospecific cases of claims have occurred. This also explains why the insurance industry classifies nanotechnology as an emerging risk but "merely" under monitoring based on the current state of knowledge.* (Risk Engineer at Allianz Group (2019))

Thus, the Gov4Nano team had to abandon its initial plans to conduct a detailed analysis of the (re)insurance industry's knowledge of nanotechnology and to subsequently develop an information service for the industry as part of the organisational from on Nano Risk Governance service offering. Nevertheless, this deviation from the initial work plan represents no defeat, but a positive result for the nanotechnology community: all evidence appears to indicate that **the**

insurance industry has been able to cover commercial and industrial advances in nanotechnology as part of its regular approach to new and emerging technologies; there has been no nanotechnology-specific loss.

The (re)insurance industry's ongoing monitoring of the nanotechnology, as well as its classification of the latter as a 'medium risk' with an associated 'first significant impact expected within 1 – 5 years' (CRO Forum, 2019), however, indicates that the technologies' 'phantom risks' or reputational risks remain high. Thus, efforts should were put in support of the development of crisis-management and -communication procedures and recommendations; this new objective froms both an output and a potential permanent service by the organisational form for Nano Risk Governance, and thus support the (re-)insurance industry and the versatile nanotechnology industries alike.

3.3.2 Addressing civil society's needs

3.3.2.1 Best-practice guidelines for communication, information provision and engagement

In general, two audiences – with different interests – can be identified for the possible organisational form for Nano Risk Governance and its communication activities:

- **Stakeholders from the industry, public authorities, scientific organisations and CSOs** would count as primary audience of the organisational form. They would need to be informed about its work, the services, tools and recommendations it would provide.
- **The general public** on the other hand cannot be expected to be widely interested in the work of the organisational form. If it would communicate to the general public, the focus of this communication should be set on the safety and risks of nanomaterials in relationship to the benefits of these materials.

Although it would be possible to communicate exclusively towards the expert community and stakeholders, it can be argued that the organisational form for Nano Risk Governance would do wise to monitor public discussion and communicate towards the general public as well. Not only would this strengthen the existing information channels in the sense of allowing informed choice, but also contribute to trust and societal acceptability of nanomaterials and related products.

Based on the expert interviews, the following recommendations can be formulated for lay-people-oriented public communication of nanotechnologies:

1. **The organisational form for Nano Risk Governance should provide scientifically sound foundations for informed choices.** In the sense of fostering safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe, interested persons should be able to receive sound information and not have to resort to dubious sources.
2. **The organisational form for Nano Risk Governance should not duplicate existing initiatives.** As laypeople-oriented information platforms on nanotechnologies (EUON, DaNa 2.0) already exist in Europe, setting up another consumer information platform is not needed. The existing initiatives should however be supported and linked to.
3. **The organisational form for Nano Risk Governance could monitor public discussion on nanomaterials and nanotechnologies and provide foresight.** The work of stakeholders could be supported by means of "horizon scanning" and identifying possible emerging topics in the public discussion.
4. **Based on this monitoring function, the organisational form for Nano Risk Governance could react to emerging topics and communicate what is known about the risks and safety of different nanomaterials in the context of their benefits.** Building on the planned portal, it could be compiled and communicated what is known about the safety of different nanomaterials in a nuanced way – especially in situations when specific materials attract more public attention.
5. **The organisational form for Nano Risk Governance could develop and use easy-to-share information formats.** Existing information platforms could be complemented

with smartphone-compatible infographics, factsheets or explanatory videos that often reach wider audiences than traditional websites.

6. **The organisational form for Nano Risk Governance could use social media.** Social media platforms such as Facebook, Instagram, YouTube or Reddit could be used for laypeople-oriented topical communication and for complementing the existing websites.
7. **The organisational form for Nano Risk Governance could pay attention to influencers.** On social media, established institutions enjoy less attention than heavily followed YouTubers or TikTokers, especially in younger age groups. If (individual) nanomaterials would gain strong public attention, influencers taking part in the discussion could be provided with specific information.
8. **The organisational form for Nano Risk Governance should make its laypeople-oriented communication available in different European languages.** Whereas the expert community can be informed in English, the information directed at the general public – especially less-educated groups – should be made available in as many languages as possible.
9. **The organisational form for Nano Risk Governance should allocate resources for its communication activities.** All the possible aforementioned activities require personnel resources, from scientific expertise to journalistic and graphic design competences.
10. **The organisational form for Nano Risk Governance should have its communication activities evaluated regularly.** If an active role in the public discussion is taken up, a qualitative evaluation of the activities – also compared to other institutions active in public communication – is called for.
11. **The organisational form for Nano Risk Governance should be transparent on itself.** Easy-to understand information on "Who we are" and "What we do" is required for strengthening the trustworthiness of the organisational form and its public communication.

3.3.2.2 Results of the stakeholder survey regarding the potential participation of civil society in risk governance

The joint NMBP-13 online stakeholder survey on nanotechnology risk governance included (among others) the following open-end question:

> *Q. What, if anything, do you think should happen to ensure the participation of civil society into the organisational from on Nano Risk Governance?*

In summary, the following recommendations were provided:

- **Consistently release information** aimed at lay people
- **Make decisions available with an accessible terminology**
- **Offer incentives.** There need to be clear benefits and incentives for individuals from civil society to participate. Financial incentives (honoraria), and other incentives can work well in many cases.
- **Make sure you have a diverse range of participants** that represent different demographic groups to ensure a range of perspectives. It shouldn't only be individuals who have time/interest, but should also include others who may be especially vulnerable from potential impacts and risks.
- **Use all possibilities and channels to inform about scientific evidence on risks and non-risks**

- **Create more awareness, increase communication and provide scientifically-sound information** that prevents public misinformation related to potential risks and benefits of nanomaterials
- **Be transparent about the currently existing knowledge deficits**
- **Engage civil society in open workshops for ENMs**
- **Establish public focus groups and a one-stop-shop, where society can get information** about current knowledge on nanosafety
- **Create an overarching and independent European organisation** for conducting meaningful participatory processes for co-producing knowledge on design processes and acceptable technological future scenarios
- **Monitor and support education at schools** to ensure that a maximum number of people have basic scientific knowledge
- **Work with media** to ensure misleading headlines are minimised
- **Keep campaigning for participation in the organisational form for Nano Risk Governance** from academia, societies, policy makers, and producers from a wide range of disciplines

3.3.2.3 Best-practice example for multistakeholder engagement including CSOs – the "User Committee"

Among other formats for discussing risks and benefits of a (new) technology among different stakeholders, the **User Committee** is one best practice example how to reflect on actual and perceived risks and benefits of advanced (nano)materials. It is one way to facilitate the integration of different needs and views from various stakeholder groups early in the risk governance procedure. The established NMBP-13 User Committee was an interdisciplinary group of individuals from different spheres of society with a particular link to nanotechnologies and (exposure to) nanoparticles. It consists of members that are evenly spread over (i) science/research, (ii) industry/enterprises, (iii) regulation/governmental organizations, and (iv) civil society/non-governmental organizations. The composition of the members and its format should be adapted based on the topic at stake and its social and political environment. Regular dialogues (e.g., on (bi)annual basis) with the User Committee helped to improve awareness about potential risks and to understand, how risk perception is formed in different stakeholder groups. It is also a strong tool to identify trends and facilitate risk communication on new (nano)materials at early stage.

Based on our four years' experience with this methodology, the following key recommendations could be derived:

1. **Develop a common understanding**

   When working in a multistakeholder setting, make sure that enough time and space is given to develop a common understanding of specific terms related to risk governance. This is facilitated by not only confronting the different stakeholder group representatives with content, but also allowing them to present their views and perceptions separately.

2. **Process the stakeholders' input transparently**

   Feedback, concerns and input from the stakeholders should be collected and further considered and addressed transparently within the risk governance process. It should be publicly accessible (while following the GDPR rules, e.g., anonymising the feedback) and shared with the relevant institutions. Any follow-up activities such as responses, reactions to it, evolving processes etc., should be monitored and presented to the User Committee members in a timely and transparent manner.

3. **Provide feedback on the stakeholders' impact**

   The stakeholders' input should be taken into account in further research and policy setting activities related to the discussed concerns by initiatives that are actively dealing with risk

governance, and its impact should be demonstrated transparently to the User Committee members.

Annex 1 (pp. 16) provides the collected executive summaries of all joint NMBP-13 "User Committee" meetings held in the last four years (2019-2023).

The organisational form for Nano Risk Governance should adopt the "User Committee" format and make sure that CSOs are well presented in the dialogues.

3.4 Evaluation and conclusions

Early dialogue between different stakeholder groups is key to ensure effective risk governance practices that serve society and support innovative materials and technologies. Multistakeholder engagement in the governance process leads to more effective solutions and helps in setting priorities.

For the (re)insurance industry, nanotechnology is not a in the focus currently – nevertheless, new findings and scientific knowledge is monitored by them to keep pace with research.

Civil society needs to be addressed through tailored communication and education activities, especially if new advanced (nano)materials and related risks/crises occur. Therefore, the pubic dialogue on different media should be monitored. CSOs should be included into multistakeholder engagement activities to represent views, needs and concerns from different interest groups.

Although nanotechnology is not a "hot topic" anymore, this report provides some recommendations that are also applicable for new advanced (nano)materials and new challenges connected with them, including Safe-and-Sustainable-by-Design (SSbD) approaches.

The "User Committee" as structured approach to facilitate multi-stakeholder engagement serves as best practice for future stakeholder involvement in risk governance.

4 Deviations from the work plan

Small deviations from the initial work plan occurred mainly due to the extensive collaboration with the NMBP-13 sister projects NANORIGO and RiskGONE. BNN, as WP3 leader, was nominated to the joint NMBP-13 Core Group on "Stakeholder Involvement", which allowed close collaboration on all stakeholder involvement issues to all stakeholder groups (including (re)insurance industries and civil society). The "User Committee", originally initiated and installed by the NANORIGO project, became a true joint activity from the very beginning and allowed to heavily use the User Committee's reflections and feedbacks within all three projects. The COVID-19 pandemic and related lockdowns were perceived as minor shortcomings especially with respect to engagement and training/education activities with civil society. Nevertheless, most of the planned activities were turned into fully online events and, thus, could still allow an sufficient integration of stakeholder activities as planned.

5 Performance of the partners

All WP3 partners contributed to the planning, organisation and implementation of engagement activities with the (re)insurance industry and civil society (i.e., lay people-oriented for the general public, civil society organisations as well as communication experts) as expected. A great number of interviews, workshops, trainings and meetings were held. BNN, as WP3 leader, coordinated the activities and ensured the collaboration with the two NMBP-13 sister projects NANORIGO and RiskGONE. Regular WP3 meetings were organised by BNN on monthly basis to discuss the progress and next steps with Gov4nano partners.

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Annex

NMBP-13 User Committee Collected executive summaries 2019-2023

NMBP13 User Committee Collected executive summaries 2019-2023

December 2022

User Committee – Organising Team

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Projects under The European Union's Horizon 2020 Research and Innovation Programme Grant agreements 814530, 814401, 814425.

NMBP-13 User Committee Collected executive summaries 2019-2023

Contents

Introduction

In the period 2019-2023, within the EU research programme Horizon 2020-NMBP13[1], the consortia NanoRigo, Gov4Nano and RiskGONE collaborated to set up a nano risk governance framework (NRGF), for the practice of nanomaterials' research and use of nanoproducts; a user-friendly framework for innovation and for governing the risks of process-generated nanomaterials. The NRGF includes risk management models, tools and approaches relevant to nanomaterials, as well as methodologies for nano-oriented LCA and grouping, and takes into account socio-economic aspects and risk-benefit assessment. Challenging in this activity is operationalizing concern assessment within the risk governance framework cycle because of its qualitative nature, which differs from the quantitative nature of risk assessment. Additionally, another core activity of these projects was to set up a European nano risk governance council (NRGC), that should implement, guide and maintain the NRGF and should allow for engaging with the stakeholders. In the course of the project, and in consultation with the European Commission, the preliminary proposal for the establishment of this council was cancelled, and replaced by a proposal for an *'Organizational Form'* (OF) for guiding and supporting risk governance activities. The reason behind this remarkable change was to better integrate the structure into the current European chemical risk governance infrastructure.

As an external point for critical reflection the three projects organised a joint User Committee (UC). This UC with participants from across Europe represented twelve stakeholders from science, industry, civil society and regulators (see Annex 1). They reflected on the current issues at stake in the projects. Their reflection took place in a personal capacity, based on their own expertise and (professional) backgrounds, without any obligation to coordinate the input in advance with the respective constituency. Also, in the discussions within the UC, the aim was not to seek for an agreement or a common position. Rather, the UC critically reflects on the use and added value of the developed concepts. The UC's assessments, demands, expectations and wishes were exchanged with the project partners and intended to (help to) steer the projects towards establishing an appropriate framework for governance of the risks in the practice of nanomaterials' development and use.
The format and tasks for a User Committee acting withing a European research project is somewhat experimental, although some experience with this independent and external project activity has been gained in a former EU project[2].

The initial planning was to have 4 UC (2-day) meetings in the 4-years project period. But the COVID-19 pandemic hampered this planning, resulting in only 2 live meetings (the first and the last year) and 6 virtual meetings. Project partners that presented 'their' topic, or took part in the discussions are shown in Annex 2.

This report collects the executive summaries of the reports of the UC-meetings. Also, an excerpt of the Strategic Dialogue Agenda (SDA) is included as Annex 3. This SDA, as prepared after the 1st UC-meeting, was based on an inventory amongst the NMBP13 project partners about potential topics for the following UC-meetings. Full reports of the UC-meetings can be found on the website of the NANORIGO project[3].

[1] NMBP = Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing

[2] www.NanoDiode.eu

[3] https://nanorigo.eu

1st UC Meeting, October 2019

UC-members' own needs and requirements in relation to nano risk governance

Figure 1, The UC in Utrecht, NL (2019)

AGENDA of the meeting

Day 1 – 15 October 2019

14.00	Opening of meeting
14.05	Getting to know the participants
14.40	About the User Committee (UC)
15.00	About Gov4Nano, NANORIGO and RiskGone
15.15	Coffee Break
15.30	UC wishes, requirements and ideas for Nano risk governance
16.30	Refreshment break
16.45	Questions from NMBP 13 work package teams
17.45	Any other business for today
18.00	End of day 1

Day 2 – 16 October 2019

9.00	Opening of day 2 of the UC meeting
9.10	Second thoughts
9.40	Nano risk governance cases: selection and formation of subgroups
10.00	Discussion of cases

Each subgroup discusses its (three) selected cases, one-by-one, led by the following series of questions:

(1) For each of the subgroup-members:

a. *What are your main concerns in the case that is presented? (if at all)*
b. *What do you need in order to be able to 'deal' with these concerns? (i.e. information, definitions, norms or threshold values, tools, insight in possible risk reduction measures, etc.) (if at all)*
c. *Who (which societal party) would you wish to address with your concerns? (if at all relevant)*

(2) Subgroup as a whole:

a. *What are your common needs and requirements when faced with this case position?*
b. *Which potential role(s) do you see in this case for a NRGF and a NRGC?*

11.30 Coffee break

11.50 Wrap up and future business

12.15 Finalization of meeting

12.30 End of the meeting

Open agenda, needs and requirements for nano risk governance

On 15 and 16 October 2019 the first meeting of the User Committee (UC) of the Horizon 2020 NMBP13 projects on nano risk governance (NANORIGO, Gov4Nano, RiskGONE) was held in Utrecht, the Netherlands. The UC consists of members with different stakeholder backgrounds (industry, science, civil society and governmental). The role of the UC is to critically and independently reflect from a future users' point of view on the products that are being developed by the aforementioned projects.
This first UC Meeting had a predominantly 'open' agenda, inviting members to put forward their own needs and requirements in relation to nano risk governance.
Three issues were most of all discussed.

Nano Risk Governance Council

The first issue concerned the role and added value of a Nano Risk Governance Council (NRGC; the establishment of which is one of the main objectives of the NMBP 13 projects). Some UC members questioned the added value of an NRGC, given the existence of other relevant institutions. There was a general understanding that a NRGC should not duplicate existing institution and efforts. Also, the NRGC can't do everything. Different approaches and scope were discussed (from most ambitious to more focused), and It was made clear what the specific purpose, scope and role of the NRGC will be. Specific possible niches were discussed, like foresight of megatrends and early warning on new risks, or areas that are not specifically regulated for nano (like general consumer articles).

Data Quality

The second issue concerned the availability of proper data. Availability of and access to robust data that meet specific user purposes, are problems for most stakeholders. This is due to confidentiality and competition constraints and to lack of transparency. (Not all UC members agree on the extent to which data are lacking). It could be the role of an NRGC to support the sharing of data, act as a clearing house and to provide general data requirements. The question who should bear the costs for the generation of data – and for dealing with uncertainty –, was a matter of discussion.

Reliable tools

The third issue concerned the availability of authorized methods. This issue is at the basis of sound, trusted, as well as efficient and cost-effective risk management. The NRGC could highlight which methods can be applied in all aspects and stages of proper risk governance. There was discussion about the extent of the methods – should they also include social, ethical and value-oriented criteria? This also reflects on the composition of the NRGC: should it be pure science-based and should these sciences include ethical and socio-economical sciences, or should societal interests be represented as well?

Cases

The UC also discussed specific nano risk governance cases. These cases ranged from 'classic' risk issues of nano additives to mixtures, to 'future' convergence of nano, bio- and other technologies, leading to new and broader risk considerations. The case discussions resulted in concrete requirements for risk governance, as well as to a further elaboration of the issues described above.

Key remarks

The several detailed discussions are summarized in the following key remarks and statements:

- Risk assessment is only one of the several building blocks of risk governance, besides health and environmental risks it includes at least as well social economic aspects (SEA) and issues related to

perception.

- Innovation is not by default a positive identity. I.e. a critical approach towards specific innovations is essential.
- A life cycle approach for risk assessment of innovations is needed. This means as well that the release, and non-release of nanomaterials should be assessed and be already available in the ready-to-market state of the innovation.
- A Safe-by-Design approach should be operationalised for MNMs and nano-enabled products. I.e., in case of identified hazards, a safe use should be explored and ways for substitution should be provided.
- A holistic approach towards risk assessment and risk management should be applied for simultaneous occurrence of MNMs and PGNPs / UFPs. I.e., risk assessment and management should take into account possible simultaneous exposures to all airborne nanomaterials originating from different sources.
- Transparency in data is a premise. I.e., the need for information on what data are available (hazard *and* exposure data), where they can be found, generated by whom, their quality, and how to 'open up' confidential data.
- There is a need for robust, reliable raw data, as well as fit-for-use data. The need refers to regulators, industrial manufacturers as well as end users.
- Transparency in the costs for uncertainties, *who bears the costs*? I.e., transfer of costs towards other sectors of society, the environment or the future for so far uncertain or ambiguous adverse effects (which might 'pop-up' later) should be made perfectly clear in advance. This holds for nano-enabled products as well as for near to market innovations.
- The NRGC should gain a well-respected and used position as an authority for advice and considerations in the many different fields where converging nanotechnologies find their way in processes and products. Inherent to the multidimensional nature of nanotechnologies, the NRGC should gain a 'multidimensional authority'.
- The NRGF should be a scientific as well as value-based framework. I.e., besides addressing the data and tools needed for risk assessment the framework should evenly address social-economic aspects to take into consideration in accepting and selecting nanotechnologies, nanomaterials and nano-enabled products.
- The NRGC could be a central point for collecting reliable data and tools, including data on social-economic aspects, and making these accessible and as such providing information on an accepted way forward.
- The NRGC should be complementary to other already existing institutions and *not* duplicate them.
- The NRGC should play a role in early warning and a precautionary approach. I.e., their role relating to independent advice on safe and acceptable use of nanotechnologies, nanomaterials and nano-enabled products should extend as well to a pro-active early warning initiative and to advice on how to make a precautionary approach operational for actual situations in practice.
- The NRGC could function as well as a think tank for megatrends.
- Further elaboration is needed on a risk paradigm for future manufactured nano(bio)materials.

1st and 2nd Interim UC Meeting, June 2020

Nano Risk Governance Framework

Figure 2, Screenshot of the UC (2020)

Agenda for the 1st Interim UC

1. Short presentations on the proceedings of the NMBP13 projects by Susanne Resch
2. Selection of the points for the agenda for the October meeting
3. Other issues

Agenda for the 2nd Interim UC meeting

1. Tour de table: Introduction of the participants to the meeting
2. Preliminary remarks on the 'why' of the NRGF (Marie-Valentine Florin)
3. Short introduction to the NRGF (Piet Sellke)
4. Clarifying questions
5. Mentimeter exercise
6. Perspectives of the UC-members (each UC-member will get the opportunity to shortly reflect on the NRGF with their opinion, its practicability, its usefulness for the specific stakeholders, comprehensibility, gaps, etc.)
7. Request for further involvement in specific project parts.
   Invitation for UC-members to comment on approaches and questions of some of the NMBP13 research teams
8. Other issues

Introduction

Corona interfered strongly in the planning of UC-meetings. So, on June 3, 2020 a 1st virtual interim meeting with the UC was held to decide about the agenda for the 2nd (possibly and preferably) face-to-face meeting of the UC, which was agreed to take place in Lisbon on 6 and 7 October. Due to the many insecurities raised by the corona-crisis regarding safe travelling possibilities (and formal

restrictions) and safe meeting facilities, the decision to actually meet face-to-face was postponed until August/September 2020. Then we will decide whether and how we will proceed with the face-to-face meeting in October, and if not F2F, we will discuss the format for an alternative (virtual) approach.

Also, at the 3 June meeting, the topics raised in the Strategic Dialogue Agenda for the UC were accepted by the UC (see annex 2). It was concluded that a discussion on the merits of the Nano Risk Governance Council for this October meeting was highly preferred, as well as a discussion on some of the available tools that will be included in the NRGF. At the same time the UC expressed its interest to have another, more substantive meeting about the 'why' and 'how' for the NRGF, since a draft for this framework was available already June 2020. It was decided to have another (virtual) interim meeting on 29 June to discuss the framework. For this, a 1,5 hours meeting was scheduled, but this turned out to be a too limited time slot for this complex and multi-dimensional issue.

Nano Risk Governance Framework
Experts from the NANORIGO and the Gov4Nano projects, responsible for the development of the NRGF, were invited to introduce and explain the concepts.

Also, after the detailed introductions about the 'why' and 'how' for the NRGF the UC members expressed their appreciation for the thorough structure of the framework, being well-aware that it is only a framework that needs to be filled up with data and tools. As said, the NRGF can create a new kind of a blueprint that may have an impact on many aspects of innovation and development, including modern view on sustainability. It can act as a risk-based decision tool for all stakeholders to have the freedom to participate in decision making. As a real challenge and a bright approach, it may be a blueprint for any other area where the regulatory framework is not yet fit-for-purpose. But some scepticism remains towards the real needs for this NRGF and about its added value in practice.

Key issues as brought forward can be summarised as follows:

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

- So far, it is not clear who will (or have to) take the lead in this 6-step process. The role of the mediator, as touched on shortly in the introduction, needs further interpretation, especially because it seems to be a tough job for an SME. It is not clear who is in charge and who should take what actions.

- So far, a clear reference towards foreseen tools in the NRGF is urgently missing, as is for example the case for the costs to be made for carrying out the full cycle. There is the impression that the full process will turn out to be an expensive activity that can count on resistance within industry. Although, as was brought in, these costs could (should) be calculated as part of the investment costs.

- There is as well doubt regarding the trust that can be generated with this 'voluntary' framework, which is essential to get all relevant stakeholders involved. As such acceptance of advised tools by national regulators is a key.

- Public perception is another issue that should be handled with care, also in relation to timing of the activities within the 6-step process. Public perception may build up rapidly, while agreeing on normative issues is usually a slow process. The acceptability of risks and processes is an issue that is extremely complex.

- And what about precaution? How do we handle to get agreement on this issue?

- The trickiest point remains however the relation of the NRGF with existing regulations and guidelines and tasks for existing agencies and authorities. On this point the Council will play a key role, especially for what concerns the relation to and tasks of existing bodies. But it holds also for agreements, norms and standards derived in other settings that should get a clear position in the NRGF.

2nd UC Meeting, October 2020

The Nano Risk Governance Council, Tools and Multidimensional Weighing

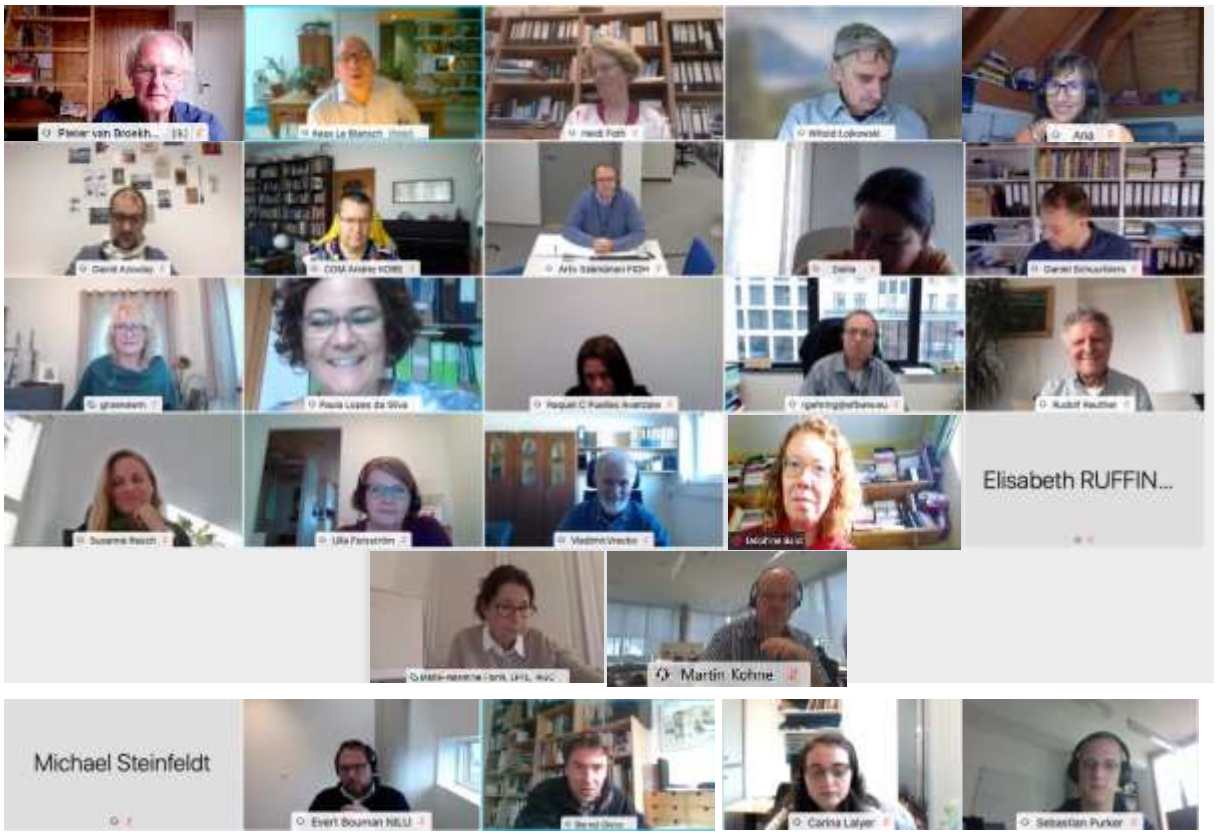

Figure 3, Screenshot of the UC (2020)

Tuesday 6 October 2020, "General issues and development of the Nano Risk Governance Council"

9:30 – 9.45 Welcome and introduction

9:45 – 10.30 Progress update NMBP13 projects + feedback input UC,
Monique Groenewold

10:30 – 10:45 Break

10:45 – 11:45 Nano Risk Governance Council (NRGC),
Monique Groenewold / Marie-Valentine Florin

11:45 – 12:00 Other issues

Wednesday 7 October 2020, "Practical and specific approaches"

10:00 - 10.10 Welcome, practical issues

10.10 – 11:45 Dealing with multidimensional weighing in the assessment tools

Michael Steinfeldt: Prospective Early Risk Screening Tool (PERST)
Bernd Giese / Carina Lalyer: Multi Criteria Decision Analysis (MCDA)

Evert Bouman: *Risk Benefit Assessment (RBA)*

11:45 – 12:00 Break

12:00 – 12:15 Concepts and semantics used in NMBP-13 projects

12:15 – 12:30 Planning post-corona UC Meeting

Introduction

The topics debated on the first day were the actual proceedings of the NMBP13 projects with a strong focus on the nano risk governance council and the current ideas for its format and character. The second day focussed more practically on developments of some specific decision support tools as being developed within the projects, tools dealing with multidimensional weighing for assessment purposes. The different topics were presented by invitees, responsible for the specific topic development within the projects, using power point presentations.

The introductions on the proceedings of the projects, including the NRGC ideas, are highly welcomed, but criticism is brought forward regarding the time needed for UC-members to provide for well-considered feedback. In this respect, a sufficient preparation period, i.e. to be informed about ideas and debatable issues *well in advance*, is needed in follow-up sessions of the UC.

Also, the need is generally felt and brought forward for a more thorough consideration and elaboration (in the UC, and this holds probably as well for the projects) on fundamental concepts and starting points that are used for arguing the building of the council, framework and tools. This includes as well the broader positioning of the public debate on the developments of nanotechnologies in society in relation to general health and environmental (risk) governance issues.

Nano Risk Governance Council

In summary, key remarks and statements made in the first day of the meeting, ***"General issues and development of the Nano Risk Governance Council"*** (not necessarily reflecting common feelings or ideas agreed upon by all UC-members) are:

- The proposed structure for the development of the four scenarios for the NRGC, distinguishing between role and positioning, is a valuable starter for brainstorming about its structure, character and tasks.
- Key in the choices to be made for the NRGC is a clear understanding of who in fact will be the end-users, what their needs are regarding (support in) nano risk governance, and how mutual stakeholder relations between different end-users will determine (and allow) their future use of the council. For example, as stated by CSOs, if the ultimate format for the council in a 'roundtable setting' will be the funding by their users, then it is likely that less well-off CSOs will make less or no use of the services of such a council. That might even lead to a non-round table with an (undesirable) dominant position for a particular stakeholder (in this case, the industry and other funding agencies).
- As such, the funding of the council should be one of the first issues to decide, because this will determine to large its content and its possible structure.
- Another point regarding the identification of the needs of the end user is in fact the extreme heterogeneity which may exist within apparently uniform social groups. Interests and needs may differ considerably.
- Issues as *risk perception* and *social position* of the end-user of the NRGC are important issues that should be central in the thinking about preferences for the scenarios.
- Also, the preferred and possible role and impact of the NRGC on nanotechnological innovations and developments needs to be clear, especially as well with regard to the timing of their external governance advices. Too little too late would not be acceptable.
- Preferences for a specific NRGC-scenario may relate to the social position of the user, although none of the UC-members explicitly prefers one of the proposed scenarios. Rather, different social groups advise to elaborate different mixes of the proposed scenarios, while assuring a multi-stakeholders' deliberative format.
  The industry emphasizes that a not too centralized setting of a mix of the 'scientific committee' and the 'roundtable' is desirable, to be able to join forces of different stakeholders and inform politics and the general public.

On the other hand, scientists express their preference for a non-governmental 'risk centre' scenario, in order to obtain reliable data and information and stimulating innovation, although also a scenario as the intergovernmental panel is assessed positively.
From regulators side the scientific committee scenario is advocated as most appropriate, probably somewhat mixed with the 'risk centre' scenario, working horizontally.
CSOs express their fear that a council with a 'round-table' format, funded by the users, might risk to be 'controlled' by the industries' interests, and therefore, so far, have some preference for the intergovernmental panel scenario.

- Regarding the content, the importance and complexity of a prospective role for the NRGC is emphasized, which is an issue that becomes especially clear with 'new substances', which will put high demand on the foreseen dialogue between stakeholders. This public dialogue function is key for the functioning of the NRGC.
- Key is as well a full clarity about the concepts used and the way values are operationalised within the foreseen NRGC activities. This holds for example for the operationalisation of the *precautionary principle (PP)* and the inclusion of goals as formulated for *sustainability*, but it also refers to seemingly self-evident topics such as 'what is nano' and to what extent this concept extends throughout the life cycle. This holds for the products' life cycle, the products' use and nanomaterials' release and the different actors involved, but in the same time, the nano that goes into the process or product is not necessarily (and often is not) the same nano that comes out.
  The chemicals strategy for sustainability, as part of the EU Green Deal, is reflected as an issue to take seriously into account within the considerations to be made for the contents of the council.
- As stated as well in earlier UC-meetings, interference and/or synergy with other existing institutions and organisations (JRC, OECD, Agencies) should be taken into account in NRGC design, whether or not the council would become an independent or 'part of' institution.

Tools and multidimensional weighing

Key remarks and statements made in the second day of the meeting, ***"Practical and specific approaches - Dealing with multidimensional weighing in the assessment tools"*** are summarized (not necessarily reflecting common feelings or ideas agreed upon by all UC- members):

- Although many of the UC-members emphasize their non-expertise in this highly technical field, doubts are raised regarding uniqueness (the specific nano-ness) of the early risk identification approach. How does this differ from other tools? The need is brought forward to get more insight in the general (existing) field of early risk identification as being developed within the hazardous chemicals area.
- Doubts are raised whether this PERST tool will take into account physical-chemical activities, such as agglomeration, chemical reactivity, conversion, nanoparticle formation, etc. Also, the appropriateness of used (and less informative) toxicological parameters such as LD50 and median lethal dose is questioned.
- It is emphasized that the PERST tool should be explained on a *simple* and *comprehensible* level.
- The RBA introduction leads to quite some confusion regarding the developmental stage, the used concepts and wordings: e.g. for who is the guidance?, what is a '*regulatory threshold*'? what is an '*ethical threshold*'? Also, a benefit assessment would not only consider the material used, but as well the type of use.
- Questions were raised regarding the limited effort shown to empathize with level of pre-existing information in the UC and the intentions of the UC to discuss this type of issues in an open debatable form.
- Regarding the MCDA questionnaire that was distributed in advance of meeting difficulties were brought forward to fill this in, especially regarding weighting all the criteria.
- The MCDA presentation leads as well to a certain confusion and comparable questions as with the PERST. The uniqueness of the problem of weighing non-comparable topics is maybe a very old.

topic, and not so nano-specific. But nevertheless, the suggestion is that it could be a useful tool and the format of the general approach is appreciated.

- Also, the limited use of data is appreciated, but is questioned as well, since a too rough and hazard driven tool may threaten to be wrongly influenced by risk perceptions. Perception and vision may dominate in the decision, while it even might be that risks are overestimated.
- Some scepsis is brought forward regarding too high expectations. The need for testing the tools in practice is strongly emphasized. 'The proof of the pudding is the eating'.
- And regarding the format for presentation and discussion of these complex tools it was strongly emphasized not to overdose the UC with technical details, but rather to focus on the outcomes and bring these into the debate.

Finally, the need was emphasized to continue this debate with the same topics in short time, providing more preparation time in advance for the UC-members, allowing to reserve much more time for discussion, and also, to introduce topics on the agenda where UC-members themselves can present their vision on the current practical *and* conceptual issues.

3rd UC Meeting, December 2020

Reflections on governance needs from daily practice

Figure 4, Bare beech tree, Charles Donker (1977), (Etching)
Museum Het Rembrandthuis, Amsterdam

Agenda 3rd UC-meeting

Introduction

9:30 - 9:40 Introduction and welcome

First part

09:40 – 09:55 Ulla Forsström, Reflections of a scientist

09:55 – 10:10 Delphine Bard, Reflections of a scientist working for HSE (UK)

10:10 – 10:40 Discussion

10:40-10:50 Break

Second Part

10:50 – 11:05 Rolf Gehring, Reflections of a CSO

11:05 – 11:20 Vladimir Vrečko, Reflections of a company

11:20 – 11:50 Discussion

Third part

11:50 – 12:00 Programme UC 2021, meetings and topics

12:00 End of the meeting

The 3rd User Committee meeting, under the heading '*Reflections on governance needs from daily practice',* was organized on 3 December 2020, in a virtual 2,5-hours session. The full UC participated, as well as seven invited guests from the NMBP13 projects. Including the UC Organising Team totally 26 persons participated.
Four members of the UC, one from each societal sector, were invited to present their reflections on the ongoing developments of the nano risk governance framework and the council (NRGF/NRGC). Each presentation was followed by a discussion amongst the UC-members. The guests were invited to participate as 'listeners', so they did not take part in the discussion.

Scientists position

The actual practice of the use of nanotechnologies, e.g., the use of nanomaterials, nano-enabled products and exposure to process-generated nanoparticles was reflected from the position of the different market actors.
The pre-marketing obligations as CLP (Classification and Labelling of Products) and the REACH requirements, which hold as well for manufactured nanomaterials, are brought forward by different speakers as a large burden, especially for SMEs regarding the required resources, the time and costs of hazard, exposure and (health and environmental) risk assessments, as well as the required knowledge to communicate this with the stakeholders. For them, the finding, identification and selection of appropriate data and information is experienced as a tough and sometimes insurmountable challenge. It was suggested that this burden weighs less on the large industries, who can more easily generate the required data themselves or commit consultancies for further data and advice.
The suggestion was made that the council in the format of the CRNM (Center on Risks of Nanomaterials), as an advising and facilitating institution, might be a solution, especially for SMEs, to support data collection and risk assessment information based on existing reliable data and exposure assessment. However, others argued that the council should *not* deliver decisions on 'safety' of NM or products with regulatory consequences: it was stated that the council cannot be responsible to perform risk assessment.

Scientist at HSE (regulator)

The large diversity of practical tools for assessing health and safety issues was contrasted with the lack of standardization of existing tools and reproducibility of practical tests. The consequence is that many measurement results are not comparable, and also, that long-existing useful tests are insufficiently used for effective workplace control. It was stated that a so-called tier 2 approach for exposure assessment is generally sufficient for a proper monitoring strategy at workplaces when combined with an assessment of the control measures (e.g., checking Local Exhaust Ventilation (LEV) airflow, using a smoke test and providing LEV expert judgement), while the highly qualified tier 3 approach should be predominantly reserved for research. As such, the standardization of the pragmatic and practical methodologies used at this tier 2 level might need to be encouraged. It was suggested that the RGC could play role in promoting standardization.

Trade Unions position

Another tricky point is the workplace practice in 'mobile' workplaces, characterized by highly diverse exposure risks, for which available generic data and information in seemingly identical workplaces can't give an answer. The construction industry, with its long 'life-cycle' from construction to demolition and recycling, is used as an example for this. This often requires a situation-specific approach, for which the input of the workers and their representatives is indispensable. This demands for optimizing the communication between those involved, and in fact between all users of the products. A plea is made to give the RGC an explicit role in optimizing the transparency and access to information for workers, and to stimulate communication and collaboration between the involved stakeholders.

Industries position

The industries' position as profit-focused ready to solve societal challenges safely and sustainably was contrasted with the need to assure reliable communication with stakeholders in the highly vulnerable area with shareholders, regulators, NGOs and commissioned scientists. It was stated that outsourcing of regulatory obligations, such as preparation of safety dossiers and generation of data is not only very expensive, but it also creates the 'risk' that no-effect results generally are not published and moreover that industry-commissioned scientists get stigmatized due to their dependence on external funds.
Again, the finding and selection of appropriate data and reliable information, and especially uncertainties regarding the way this information will be 'handled' by regulators is presented as a burden for industry. The suggestion that poor use of the precautionary principle might lead to excessive regulation was opposed by stating that the past 15 years no new technologies were prevented by applying this principle, and as regulators state, potential actions from regulators are scientifically substantiated.

The final poll regarding the format of the RGC shows an interesting distribution of votes for all the four options, with a slight preference for the non-governmental options, the Round Table on Nanomaterials and the Centre on Risks of Nanomaterials. Nevertheless, preferred tasks for the council, such as independent advice and support, as well as a role for entrance to governmental advice also points in the direction of the scenario for the Scientific Committee on Nanomaterials.

The report ends with a short reflection of the invited guests on the presentations and discussion, their 'take home messages'.

4th UC Meeting, March 2021

Data, uncertainty and risk governance

Figure 5, Archive (2018), (Oil paint}
Pauline van Broekhuizen

Agenda for the User Committee Meeting, Wednesday 31 March 2021

09:15 – 09:30 - Arrivals at WebEx

09:30 – 09:35 - Welcome

Part 1

09:35 – 09:45 - Short overview of data processing activities within the NMBP-13 projects, Rudolf Reuther

09:45 – 11:00 - Knowledge, information and data readiness levels, Damjana Drobne

- Reflections/needs from the perspective of EFSA, Ana Rincon
- Reflections/needs from the position of WECF, Elisabeth Ruffinengo
- Discussion

11:05 – 11:15 - Break

Part 2

11:15 – 12:15 - Precautionary Principle, Heidi Foth

Decision under uncertainty; Implications for RG, data management and deliberation

12:15 – 12:25 - Forecast UC Meeting September 2021, Pieter van Broekhuizen

12:25 – 12:30 - Other issues, End of the meeting

Risk management requires from those who are responsible for taking the decisions a thorough and balanced weighing of the available evidence as well as an initiative to take account of gaps in knowledge related to the perceived risk. With the operationalisation of EU values and standards the management process in cases of complex, uncertain or ambiguous risks, cannot be restricted to straightforward risk assessment, but should preferably be embedded in a risk governance structure that is deliberative by nature, characterised by the timely identification and inclusion of involved stakeholders in the decision and the consideration of their interests.

Data, their identification, selection and processing, are key in this information generating process for hazard and risk assessment and provided that this is supplemented with (data relating to) social, economic and ethical considerations, this may substantiate acceptable and accepted management decisions in a deliberative setting. This relates to innovation processes, as well to the application and use of potentially hazardous substances, nanomaterials and nano-enabled products.
Data management plays a key role in risk governance and reflects existing societal interests in this regard, as well as the wide differences in understanding of this topic between the societal stakeholders and their ability to independently process and use reliable and appropriate data. Also, the identification of gaps in knowledge, being a non-defined area ranging from the experts' identification of gaps, i.e., 'open' areas of knowledge, but designated as essential for making well-balanced decisions (the so-called known-unknowns), along areas where less-informed stakeholders collect their information (unknown-knowns), to the large and dynamic area where epistemic knowledge cannot provide the required evidence because of the systemic uncertainties. Within this full spectrum the precautionary principle, as one of the basic principles within European regulations and international treaties, plays a role that by some stakeholders is experienced as inconvenient because it is said to impede innovation or production, while others experience this principle as a basis for their attempts to postpone production or marketing decisions. Attempts to postpone may follow their assessment that insufficient scientific information is available, while there are reasonable grounds for concern for the possibility of adverse effects and persisting scientific uncertainties, and that as such the prevention of irreversible damage cannot be guaranteed.
The application of the precautionary principle involves deliberation on a range of normative dimensions, which need to be taken into account while making the principle operational in the public policy context. These regard issues such as when to invoke the precautionary principle (act rather than not to act), the level of protection aimed at, a cost-benefit analysis balanced with health considerations, the burden of proof of adverse effects and the timing, the proportionality of precautionary actions, deliberation about uncertainties and lack of knowledge, the seriousness of possible adverse effects, and what level to use as provisional standard.

The three NMBP13 projects, NANORIGO, Gov4Nano and RiskGONE, emphasize the key role of data management in risk governance and the major existing societal interests involved. For their own 'data-activities' they distinguish four main research areas: - Data managements plans, - Quality and Fitness for re-use and scoring of datasets, - Datasets to support the case studies, - Interoperability and automation of data management approaches.
Within this context NANORIGO further elaborates the conceptualization and user needs. RiskGONE further elaborates on the community consensus on data standards (metadata, FAIR principles and metrics) and a stepwise set-up for standard operation procedures for data quality and re-useability. Gov4Nano elaborates further on the operationalization and automation (tooling) to facilitate data re-use, decision making and sustainability.

This 4th User Committee meeting, titled: "Data, uncertainty and risk governance", puts its focus on broad stakeholder-oriented data management and combines this focus with a deeper discussion on how the Precautionary Principle may be used within this context. The ongoing research on this issue within NANORIGO was introduced by Damjana Drobne (University Ljubljana). She elaborated her novel approach for data management within (nano)materials' risk governance: a categorization

system for data, information and knowledge to improve the understanding of data readiness for risk governance and to allow their use, re-use, and sharing by the divergent groups of stakeholders. The precautionary approach was further elaborated by Heidi Foth, member of the UC.

The stakeholders'-oriented data refinement effort is to operationalise the concept: 'from data information knowledge'. In analogy with the industrial concept of technology readiness levels, (TRL) the so-called Data Readiness Levels (DRL) are introduced and translated in a systematic approach, called 'Knowledge, information and data Readiness Levels' ('KaRLs'). With these KaRLs efforts are made to develop a systematic approach to structure the actual existing methods for data refinement in a transparent and comprehensible way, with an improved traceability of the used data sources. The KaRL system is explained on the basis of examples from nanomaterials' manufacturing industry and from the regulatory process around (the carcinogenicity of) nano-TiO2.

The KaRL approach is criticized by the UC by questioning on how this methodology exactly distinguishes itself from current existing methodologies to operationalise data for practical (industrial and regulatory) use. At least the first sequential steps seem to copy exactly the current scientific systematic review. Subsequently it is not directly clear 'where' the governance component is. The introduction of stakeholders' interests and positionings, as emphasized within this KaRL approach, is an issue which is currently already foreseen in public consultations. As such, this KaRL system seems more to be a service for the industry, in which in practice a large part of the data collection and interpretation work is being done by scientific consultancy organizations. Illustrative is the data selection and control in the actual case of the EFSA assessment of nano-TiO2. It shows the enormous complexity of 'digesting' 12.000 data sources, with the knowledge that there are even more, numerous unpublished studies, due to data protection and confidentiality and the restricted exchange of data in between commissions' services.
Also, from the point of view of CSOs, the complexity of collecting the social economical aspects and societal needs is emphasized, added to the problem of finding your way in the official, publicly opened channels of data and information. And as far extraction of data succeeds, it is the interpretation of the data that creates enormous barriers for non-experts. Trust in the reliability of the provided data, within a world where as well deliberate manipulation of data is experienced, is an essential aspect to get a central place in a supportive data management system. The step from the bureau towards the real-life materials' use and exposures is highly needed. In this respect the centrally used concept of 'actionable information' should be made fully clear regarding the required information for whom, including the demand to make this comprehensible for non-experts as well.

The precautionary principle applies when decisions are required if there is lack of scientific data and uncertainties. At the same time the principle allows for innovation to continue its practice of trial and error. The weighing between existing (scientific) uncertainties, taking the risk against avoiding the risk, is a key element of the legally acknowledged precautionary principle, where it should be fully clear what exactly is understood by scientific uncertainty. The lead in this recognition of scientific uncertainties lies with networks of experts, but the authorities have the power and the responsibility for actually invoking the precautionary principle before irreversible impact or damage occurs, while at the same time not ignoring gut feelings and concerns from stakeholders.

There are 4 steps to take, to bring the precautionary principle into action:
1) a science-based risk assessment,
2) a normative risk evaluation,
3) choice of instrument for risk management, and
4) the implementation of the risk management.

In steps 1 and 2 the causes for concern are assessed, i.e., 'qualified', 'quantified' and weighed, and this is where the NMBP13 projects should find their role in developing appropriate tools for

involved stakeholders, especially for those 'new' in the process. The trigger points for qualifying concern assessment are rather vague. Help into this matter to qualify minor, moderate or major concerns seems highly needed. Also, we have to be aware that data gaps are common at all levels of product development, but may 'behave' and 'be perceived' quite differently in different 'protected' areas. For example, there are the highly regulated areas such as biocides and food, but the non-food sector is an example of an area without explicit regulations, but which, in the event of ignorance or negligence, can have a significant impact on the environment.

The follow-up discussion highlights that values may be hidden in the risk decisions. In that respect, step 2, the normative risk assessment, is an essential step in which broader views about what society needs become part of the governance.
Also, as brought forward, there is the need to assure a broad (or even holistic) view on risk assessment, including acknowledging the potential effects of mixed exposures, all along the full products' life cycle. It is questionable whether the precautionary principle should play a role in these matters as well.
It is argued that, in principle, we have competent scientific networks able to assess potential risks in the early stages of development, as well as in a possibly transformed state later in its lifetime, but it are the authorities that have to guarantee that hazardous substances do not enter the market. Some actors blame the precautionary principle as limiting the innovative power of new products, and it is true that we need significant innovations to improve our societies' sustainability, but what we need is a clear classification system for early warning and early action. The NRGC may play a role here.
But also, what should be made clear is what questions cannot be solved, which would be some sort of disclaimer for the NRGC.

In sum:

- The data management approach, KaRL, is an interesting effort for organizing data and transparently translating these into required information for risk governance. It raises questions about its added value. It seems to copy the commonly used approach for a systematic review. Also, the separate steps to integrate the stakeholders' interests appear to run parallel with current public consultations.
- There are questions about *'how'* to make the approach useable for non-experts. The identification and interpretation of data remain a barrier in the efforts to generate reliable information.
- There is the need to clearly operationalise on 'how' social, ethical issues can be integrated in the data management approach.
- The precautionary principle has a key role within risk governance, but how to perform concern assessment is rather vague. Trigger points for qualifying concern assessment to qualify *minor, moderate* or *major* concerns are highly needed. We need a clear classification system for early warning and early action.
- Early risk screening may be an excellent role for competent scientific networks, but it is the task for the authorities to guarantee that hazardous substances do not enter the market (or cannot do harm). It was suggested that the NRGC may play a role in identifying (the need for) early risk screening.
- Data gaps within non or limited regulated areas need attention and a careful analysis.
- How to apply the precautionary principle in relation to mixed exposures is questioned.
- The NRGC may play a role in questions that cannot be solved, which might be used as disclaimer.

5th UC Meeting, September 2021

Nanomaterials, EU Chemicals' Strategy, Concern Assessment and Risk Governance

Figure 6, 'Frozen sculpture' (2015), (Oil paint)
Pauline van Broekhuizen

Agenda 5th UC Meeting

Tuesday morning, 28 September 2021

'The EU Chemicals Strategy, Nanomaterials and Risk Governance'

09:30 – 09:45 - Welcome and introduction guests

09:45 – 10:00 - Proceedings of the NMBP13-projects (Short overview), *Arto Säämänen*

10:00 – 11:30 - State-of-the-Art Nano Risk Governance Council, *Dalila Antunes*

- EU-Chemicals' strategy, nanomaterials and the risk governance approach, *Andrej Kobe*

11:30 – 11:45 - Break

11:45 – 12:30 - Reflection on the needs and expectations from NRG from the position of research and commercialization, *Witold Łojkovski*

Wednesday afternoon, 29 September 2021

'Concern Assessment and Risk Governance'

13:00 – 14:30 - Operationalisation of concern assessment within risk governance, *Daan Schuurbiers*
- Reflection on concern assessment and optimising risk management, *David Azoulay*

14:30 – 14:45 - Break

14:45 – 16:35 ***'Operationalizing concern assessment within the Risk Governance Framework' Role play: 'nano-sized rubber tyre wear'***

- Introduction to the roleplay and to the pilot study (10') *Kees Le Blansch*
- Information phase (20')
  - The 'Scientific Risk Assessment Committee' *Pieter van Broekhuizen*
  - The 'Risk Perception and Concern Assessment Committee' *Daan Schuurbiers*
- Advisory boards deliberation phase (30') *UC-members + invitees*
  - Sub-division of UC into four advisory boards + one reference group
  - Deliberation within boards on questions to be answered
  - Preparation of advice
- Advice phase: each board presents advice (20')
- Evaluation of roleplay, discussion of underlying critical issues (20')

16:35 – 16:45 - Planning 6th UC-meeting 2022

16:45 – 17:00 - Other issues, End of the meeting

As a response to the European Commission's call to the three NMBP13 projects, NANORIGO, Gov4Nano and RiskGONE to work together, the three projects agreed to achieve the three goals:

(1) A Nanotechnology Risk Governance Framework (NRGF) that integrates exposure, hazard and risk assessment tools with those assessing ethical, legal, social, and environmental aspects, and further supports responsible research and innovation (RRI).
(2) A European Nanotechnology Risk Governance Council (NRGC) that implements the NRGF and engages with all stakeholders.
(3) A Nano Risk Governance Portal.

At the heart of these activities, their understandability and usefulness in practice, are many questions such as: 'What exactly is nano-risk governance?', 'Who should take the initiative to start the nano risk governance process?', 'Is there for 'nano' a difference with the governance of conventional substances?', 'Are all identified key indicators sufficiently covered in the framework and is the used risk paradigm suitable to cope with foreseen and forecasted risks related to the development of nanotechnologies and the introduction of new (and smart) nanomaterials in the market?', and last but not least, 'How does (or should) this newly adapted framework and the envisaged format of the council fit within the European legislative framework and the EU chemicals' strategy, in between the already existing European institutions?

Central to the reflection on (nano) risk governance is the observation that, although quantifiable risk assessment (RA) is for many the most appropriate and recognizable activity to start governance with, it is only one of the aspects that forms the basis for responsible risk management. The assessment and recognition of stakeholders' concerns and perceptions, which reflect other dimensions of governance, are essential to ensure a broad basis for the adoption of the technology and its innovative products in society, and can contribute to efforts to address early warning signs. A component in the generally strongly technically oriented governance process is the qualitative nature of concern assessment (CA). However, such qualitative results are not easily combined with the quantitative results of RA.
This balancing act is the flip side of the further complicating trade-offs that must be made additional to the risk management activity: the weighing of the identified and accepted risks against the calculated costs and the predicted benefits of the innovation or product (in turn, the benefits are usually also of a qualitative nature).

With these questions and reflections in mind, and against the background of heterogeneous daily practice, the 5th UC meeting reflected on the developments, findings and dilemmas as presented by the NMBP13 projects.

The actual state-of-the-art of the NMBP13 projects, as presented by Arto Säämänen, shows an impressive list of mapped and newly developed tools to support the risk governance process, including the development of a framework and the council. Distinguished are end-user-oriented tools, to support risk identification and assessment, and expert-oriented tools, such as standard operation procedures (SOPs), technical guidelines (TG) and guidance documents (GD). Next to this is the development of training material. The developed approaches are tested in several case studies, one of which is the rubber tyres pilot that is discussed the 2nd day of this UC-meeting.
A critical remark is on the positioning and alignment of the Standard Operational Procedures, Technical Guidances and Guidance Documents with ongoing OECD debates, findings and developments. New structures or approaches might not be effective as long as existing approaches and concepts are maturing and finding its ways in practical uses.
Key issue is 'the Council', its format and embedding in the European legislative and institutes structures. The other key issue is the concern assessment, its position and its operationalizing challenges within the governance approach. These two issues are discussed in separate presentations, the 1st and the 2nd day.

The state-of-the-art of the development of the Nano Risk Governance Council (NRGC), 'the blueprint', was summarized by Dalila Antunes. Ideas for the format for the Council, crystallize in a mix of the originally presented four scenarios, being a mix of an expert advisory board, contributing to the understanding of the governance requirements, and supporting the improvement of the quality and accessibility of data and risk assessment methodologies, and on the other hand a roundtable, stakeholders' needs-oriented facility supporting deliberation and the governance process in daily practice.
The council's needs, structure and positioning in between the existing European institutions are critically discussed. On one hand, there are UC-members impressed by the planned enormous wide scope, on the other hand there are quite some doubts about the added value such a NRGC might have.
Regulators wondered whether we really need such a council. Most of the UC-members, supported this question. The UC lacks insight into the gaps analysis that was (or should have been) made for drafting the current council model. Without being informed about identified deficiencies in the existing risk governance approaches for substances (that obviously include 'nano'), it is not possible decide whether we need this nano-RGC.
This report includes as well an e-mail exchange that took place in the weeks after the meeting. The topics discussed were the gaps analysis preceding the design of the Blueprint of the Council, and a short reflection on Safe (and Sustainable) by Design.

This request for insight in the gaps analysis led to an additional action of the NMBP13 Council Core Group, who will produce a summary this. This summary is not contained in this report.

Andrej Kobe discussed the embedding of 'nano' within the European chemicals' strategy, predominantly focusing on the existing and envisaged governance of substances. He emphasized that obviously nanomaterials *are* substances that are regulated under REACH including all its principles and dynamics. The Green Deal and the Chemicals Strategy are further policy extensions that zooms in on zero pollution and a toxic free environment for 2030, advocating Safe and Sustainable by Design (SSbD) and the EU market norms as global standards, and a challenging effort for the registration of a plethora of nanomaterials occurring in many different forms. Developed tools may play an excellent role to support this, but again, the added value should be made explicit. It is as yet unclear whether the approaches are sufficient for all advanced materials and emerging technologies. Also, there are still quite some scientific unknowns, such as for example synergies and combinational effects that need further research before we can adequately address these in regulatory assessments.

Witold Łojkowski, in his reflection of the needs from research and commercialization, emphasizes the complex nature of nanomaterials' forms and agglomerating/aggregating behavior and challenges it has for research. He elaborated on an example of nano-sized hydroxyapatite, its potential applications for bone repair and the uncertainties associated with packaging labelling and the use of biocompatibility tests as substitute for animal testing. Forced by the lagging behind of appropriate nano-oriented test systems, a conservative approach is being followed, unnecessarily resulting in a less good product and untransparent and insufficient registration communication.
He stated that it is very difficult even for researchers to find the required information about safety and exposure controls. Here, as well as for SMEs and start-ups, there could be a task for the council, to support these stakeholders in identifying and development of required info for introduction of NMs to the market.

On the second day…

Daan Schuurbiers reflected on a dilemma of risk management, namely ensuring that concern assessment and risk perception are given an appropriate position in risk management alongside technical risk assessment. The challenge is to operationalise concern assessment as an explicit step in the RGF as essential element contributing to risk management. Due to the fundamental differences in nature, being quantitative for 'technical' risk assessment and qualitative for risk concern, this integration is a tricky operation, requiring a shift in our approach to risk governance. It also implies a re-examination of the role of values and value judgments in the process of ethical assessment and understanding of how they work in decision-making. And ultimately to explicitly recognize the role of societal considerations within a socially robust governance framework.
The concerns, as stated by different UC-members, can take on a life of their own, complicating the valuing concerns even more. Nevertheless, as the EEA report: *Late lessons from early warnings*' notes, qualitative concerns should be taken seriously. Plausibility is required.

Following up on these points, David Azoulay stated in his presentation that technology governance is not a scientific, but rather a political issue, noting as well that generally much of the technical risk research is triggered by qualitative concerns, based on early signs. Risk governance includes data and a technical conversation, but it is not a technical discussion. And adding to this, the discussion on costs-benefits, its interests-related over and under valuations argue for a holistic approach.

In the afternoon, the Rubber Tyres Case was introduced in the UC in the form of a role play, giving the 4 UC-stakeholder groups (regulators, CSOs, science and industry) a role in advising on how to deal with risks and concern assessment in the governance process of using rubber tyres.

- Reporting from the regulators group focus on optimizing communication, improving the EU-tyres label by including the abrasion resistance, and practical source oriented TWP release control. Also, expanding the dialogue between the tyres industry and regulators towards optimizing sustainability, i.e., joining forces, is advised.
- The CSO-group report emphasizes the importance of aligning the scopes of the concern assessment and the risk assessment (which probably also requires communication between the involved expert groups). They advocate a European-wide worst-case approach giving more weight to environment and that give more weight to activities that are harmful to the environment and expand the possibilities beyond the narrow way of avoiding risks and ensuring benefits.
- The scientists group emphasizes the gaps in knowledge, and the need for monitoring micro *and* nano release. They distinguish different levels for risk management, and generation of lacking data. They distinguish the influencing of driving behavior, technical (nano)innovative research, expanding the LCA-approach and drawing consequences from the results of hazard assessments.
- The NMBP13 group also reflects on the existing wide uncertainties on the benefits and risks, and they emphasize arguments to use the precautionary principle. They state that communication with

end-users and citizens, with a focus on risk perception, showing that their concerns are being understood (and dealt with) should be improved.

In summary:

- Actual risk governance takes place in an institutional setting, with existing authorities, rules and regulations, procedures and norms. A model for a 'risk governance framework' must acknowledge and embody this.
- Since nanomaterials are chemicals, they must comply with existing governance arrangements. If changes to the governance system are deemed necessary due to nano dimensions or properties, it must be clearly argued why.
- This holds for the developed Framework and advised tools, as well as for the Council.
- There is a serious lack of insight into the gaps analysis that was made for drafting the current model for the Council.
- Positioning and alignment of the Standard Operation procedures, Technical guidances and Guidance Documents with ongoing OECD debates, findings and developments is essential. New tools and structures or approaches for this may not be effective as long as existing approaches and concepts have yet to mature and find their way into practical applications.
- '*Late lessons from early warning'* prove that *concern* is a valuable trigger for innovative research and an essential element for governance, which as well may provide arguments for a precautionary approach.
- Risk governance requires the integration of quantitative (technical) risk assessment with qualitative concern assessment and risk perception, which should also be consistent in scope. As such, risk governance requires a holistic approach.
- In the development of a method for concern assessment, also questions about communication and education (raising awareness and knowledge about the possible impacts of risks) and about legitimacy (who decides which concerns are considered legitimate?) must be addressed.

6th UC Meeting, October 2022

After NMBP13, Towards inclusive risk governance of nano (new) materials

Figure 7, White, Putti with Lion, (Oil paint) Pauline van Broekhuizen

Agenda 6th UC meeting

Monday 3 October

11.00 1. Welcome and explanation of agenda

PART 1: Latest NMBP13 developments

11.15 2. Update on NMBP13 activities and products, *Monique Groenewold*

12.00 3. After the Council: about the 'organisational form', *Mark Morrison*

13.00 Lunch break

PART 2: Stakeholder involvement in development of risk governance

14.30 4. Introduction to the afternoon program

14.40 5. Looking back: Evaluation of the User Committee, *Pieter van Broekhuizen*

15.55 Tea Break

16.15 6. Looking forward: about stakeholder involvement

17.15 7. Other issues. End of first day.

Tuesday 4 October 2019

PART 3: Future agenda

9.00 8. Opening of day 2 of the UC meeting

9.10 9. Towards a new agenda for governance of nano/new material risks, *Keld Alstrup Jensen*

10.30 10. After the UC

10.50 11. Closing of meeting

11.00 End of meeting

An important change that took place this last year was that the development of a nano risk governance council was called off and that this ambition was converted into the idea to arrive at some kind of Organisational Form (OF). This OF should/could support (nano) risk governance in practice and possibly as well be responsible for maintaining the developed infrastructure for the risk governance framework, the tools and methods as they will be made publicly available via a portal and platforms. The main reason for this change was the disputed positioning of a (new) risk governance council besides existing agencies and institutions with comparable and overlapping missions and mandates, as well as the simultaneous operationalization of the Chemicals Strategy for Sustainability (CSS) within the European Green Deal.

The mission formulated for an OF is quite straightforward: fostering and governing safe and sustainable development, use and disposal of nanoproducts, with (almost obvious) supporting conditions as independence, transparency and trustworthiness, the ability to bridge between knowledge generators, users and decision-makers, as well as to be agile and adaptable.
The projects will propose two (or three) formats for an OF:

1) an independent, problem-solving Roundtable for informal and innovative dialogue, and
2) a 'House', building up the roundtable and adding the management of resources and infrastructures.
3) A third option is to integrate selected activities in (an) existing institution(s).

The suggested formats for an OF are less ambitious than the ideas for the council were, and will even only remain on paper during the course of the project as well-considered ideas of the NMBP13 projects. By the end of the projects, early 2023, two (or three) possible formats for the OF will be formulated with an advice to the Commission to bring at least one of them into practice: as a recommendable format. I.e., to operationalise the preferred OF for nano risk governance.

The future after the NMBP13 is still obscure, but key is that the results of the NMBP13 projects, especially those aimed at practical support of the governance of complex, uncertain or ambiguous risks should not get lost in the overcrowded advisory space. In other words, the nano risk governance framework with its tools and methods, and contained in the portal and platforms should get a recognizable and accessible place within the risk governance landscape. That is why a shifting of the scope of the OF's governance-supporting activities towards advanced (smart) materials should be seriously considered. Point is that in this 'smart and/or new materials' area still large uncertainties exist, and complex (management) decisions will have to be made, whereas for the 'conventional' (simpler) nanomaterials the existing institutes have the means, and a reasonably balanced set of risk assessment and governance approaches available. It is assumed that they do not to need a further specialized 'external' extension.
Against this background the discussion in the UC about a preferred form for an OF took place.

The issue around the development and preferred format for an OF were introduced with an overview of the current state-of-the-art of the NMBP13 projects and with an explanation of the proposed OF-formats.
As a starter for the discussion, UC-members expressed the importance of carefully formulating the required societal needs for performing reliable nano risk governance. Access to data, the sharing of data, the 'cleaning' of data for the specific purpose are essential prerequisites for this. If it is decided not to set up a council, for all stakeholders the trustworthiness of the used data, and consequently of the outcome of the risk assessment process, becomes an important issue. Both in terms of stakeholder involvement and in terms of being able to address new possible risks of new (advanced) technologies, there was a general feeling among the UC that there should be some kind of additional structure or 'place' in order to establish societal trust. Data, information and concerns should get the possibility to be exchanged and shared in a 'trusted' public domain setting,

particularly in stages of technological development that start to extend beyond the lab and that are not yet in mass production phases or tonnage bands for which notification is legally required. Moreover, such a 'public domain'-setting would provide an important entry for CSOs into a proactive dialogue on new risks. Of course, not all UC members were exactly in line with this opinion. Some UC members felt science and R&D can be trusted to do the responsible thing; others were not just looking for an additional structure or place, but for an actual authority. And still, it is not completely clear why the nano-issue should get a separate focus. The critically reflective comment was made as to why we should move away from option 3, not to establish an OR. And although UC members felt that there are (new) domains that are not addressed by the existing institutions, it remains unclear what exactly is not covered yet by the existing infrastructure, and especially whether for nano a separate line would have to be followed.
And of course, questions were raised about the funding for an OF in the form of a Round Table, but especially when the form of a House would be selected. And in this respect, if some independent form for the OF would be used, whether this would be supported by ECHA and whether the EC would accept this. Serious doubts were raised whether a House would only be useable for those who can afford it. Especially regarding the usability for CSO's and SMEs (with their limited funds), expectations are not very optimistic.

Another issue is the status of OF-recommendations, whether they are mere recommendations or whether they should have a more binding character? A certain preference for the latter was expressed. In this respect the authority of the OF was discussed as an important issue, which led again to ideas for some association with ECHA.
As an opinion poll, the UC was asked which of the three OF-alternatives they preferred: round table, house or nothing additional. The outcome showed a slight preference for the House (4), 2 people preferred round table (one of whom only hesitatingly). There was one UC member who abstained, who argued that at least a house would be preferable, or possibly even a more authoritative alternative, but at the same time this UC member did not consider a viable business case for such a model possible. For industry, the return on investment is an important leitmotif.
Finally, the importance of a portal for the EC was also questioned. So far, its value and reliability are considered unclear, so it would make sense if actual use of the pilot would give advantage in communicating with regulatory bodies.

Looking forwards, towards a new agenda for new material risks, and using the provided example of the complex metal-organic framework structures (MOFs), the discussion was repeated on low market volumes, animal tests, workplace risks, in fact a discussion parallel to REACH obligations. Reference was made that for laboratory research the concept of Best Available Techniques would be the way to go. The role of an OF in the assessment of these complex structures (and for example self-replicating systems) was emphasized by the benefits of providing a platform for stakeholders for exchanging and discussing the relevant governance aspects. In this respect, it was stated that the OF might perhaps play also a role in more fundamental/philosophical discussions about risk approaches and acceptance in our society, which as well includes weighing of values. A critical assessment of the need for nonsense products was mentioned as well.

Looking back at the UC's role in the project, the UC members expressed their satisfaction with the topics discussed, their generated input, but indicated that they had little insight into the actual impact of their contribution (see the text box with voting results).

Average grade given by UC members for:	
• Composition and role of UC:	8,1
• Organisation of UC meetings:	8,6
• Content of UC meetings:	7,4
• Impact of UC:	7 (2 abstentions)

The idea is that the UC, as a critical platform of interested persons with very different societal and professional backgrounds, filled a gap in the area between production, society and regulation. Many characterized the UC experience as an important (also mutual) learning process, in which it

took some time to come to a common language that made it possible to come to mutual understanding. Also, discussions didn't have to lead to an agreed position, but nevertheless had an added value in raising awareness about different positions.

Figure 8, UC in Lisbon (2022)

Annex 1

The members of the User Committee

Researchers		
Ulla Forsström	*VTT, Technical Research Centre*	*FI*
Heidi Foth	*Martin-Luther-Universität, Halle* *Institute for Environmental Toxicology*	*DE*
Witold Lojkowski	*Polish Acadademie of Sciences* *Inst. High Pressure Physics*	*PO*
Industries		
Martin Köhne	*Robert Bosch GmbH*	*DE*
Vladimir Vrečko	*Cinkarna Celje* *Cinkarna metalurško kemična industrija Celje, P.O.*	*SL*
Raquel Puelles	*Avanzare* *Avanzare Innovación Tecnológica*	*ES*
CSO's		
Chantal van der Bossche (2019) *Elisabeth Ruffinengo (2020-2021)* *Amélie Owen (2022)*	*WECF* *Women Engage for a Common Future*	*NL* *FR* *FR*
Rolf Gehring	*EFBWW* *European Federation of Building and Wood Workers*	*EU*
David Azoulay	*CIEL* *Center for International Environmental Law*	*CH*
Paula Silva (subs) (2020-2021)	*Quercus ANCN* *Organização Não Governamental de Ambiente*	*PT*
Governmental Agencies		
Delphine Bard	*HSL-HSE* *Science and Research Centre*	*UK*
Andrej Kobe	*EC ENV B.2* *European Commission, DG for Environment*	*EU*
Ana Maria Rincon	*EFSA* *European Food Safety Authority*	*EU*
Organisational team		
Pieter van Broekhuizen	*Bureau KLB (NanoRigo)*	*NL*
Kees Le Blansch	*Bureau KLB (NanoRigo)*	*NL*
Rudolf Reuther	*ENAS (NanoRigo)* *Environmental Assessments*	*DE*
Susanne Resch	*BNN (Gov4Nano)* *BioNanoNet*	*AT*
Dalila Antunes	*Factor Social (RiskGONE)*	*PT*
Observer		
Daan Schuurbiers	*De Proeffabriek (NanoRigo)*	*NL*

Annex 2

Invited project partners at the UC-meetings

2nd interim UC		
Marie-Valentine Florin	*EPFL*	*NanoRigo*
Piet Selke	*Dialogic, DE*	*NanoRigo*
Arto Säämänen	*FIOH*	*NanoRigo*
Lya Hernandez	*RIVM*	*Gov4Nano*
2nd UC Meeting		
Monique Groenewold () (MG)	*RIVM, NL*	*Gov4Nano*
Marie-Valentine Florin	*EPFL, CH*	*NanoRigo*
Michael Steinfeldt	*Univ. Bremen, DE*	*NanoRigo*
Bernd Giese	*BoKu, AT*	*NanoRigo*
Carina Lalyer	*BoKu, AT*	*NanoRigo*
Sebastian Purker	*BoKu, AT*	*NanoRigo*
Evert Bouman	*NILU, NO*	*RiskGONE*
Arto Säämänen	*FIOH, FI*	*NanoRigo*
3rd UC meeting		
Arto Säämänen	*FIOH, FI*	*NanoRigo*
Marie-Valentine Florin	*EPFL, CH*	*NanoRigo*
Piet Selke	*Dialogic, DE*	*NanoRigo*
Panos Isigonis	*Univ. Ca' Foscari IT*	*RiskGONE*
Maria Dusinska	*NILU, NO*	*RiskGONE*
Damjana Drobne	*Univ Ljubljana, SL*	*NanoRigo*
Isabel Rodriguez	*Gaiker, ES*	*NanoRigo*
4th UC meeting		
Damjana Drobne	*Univ Ljubljana, SL*	*NanoRigo*
Blair Johnston	*BfR, DE*	*Gov4Nano*
Iseult Lynch	*Univ Birmingham, UK*	*RiskGONE*
Nina Jeliazkova	*Idea Consult, BG*	*RiskGONE*
5th UC meeting		
Panos Isigones	*Univ. Ca' Foscari IT*	*RiskGONE*
Evert Bouman	*NILU, NO*	*RiskGONE*
Marie-Valentine Florin	*EPFL, CH*	*NanoRigo*
Arto Säämänen	*FIOH, FI*	*NanoRigo*
Andrea Porcari	*AIRI, IT*	*Gov4Nano*
Iwona Koltsov	*Univ. Warsaw, PO*	*Gov4Nano*
Ineke Malsch	*Malsh Techno Valuation, NL*	*RiskGONE*
Lya Hernandez	*RIVM, NL*	*Gov4Nano*
6th UC meeting		
Monique Groenewold	*RIVM, NL*	*Gov4Nano*
Keld Alstrup Jensen	*NRCWE, DK*	*Gov4Nano*
Mark Morrison	*Optimat, UK*	*NanoRigo*

Annex 3

Excerpt Strategic Dialogue Agenda, May 2020

The Strategic Dialogue Agenda

The UC is independent and to a large extent responsible to set its own agenda, informed by the NMBP13 team on relevant deliverables and milestones as well as on conceptual issues that need further debate. These are summarised in the *Strategic Dialogue Agenda* (SDA) for the UC, which is a living agenda based on:

a) the NMBP13 timeline: the foreseen developments within the three NMBP13 projects, as reflected in the projects' milestones and deliverables including the *joint milestones*
b) an inventory amongst NMBP13 partners on pivotal choices relating to the building of the NRGF and NRGC, on pilot and prototype designs and on overarching questions.

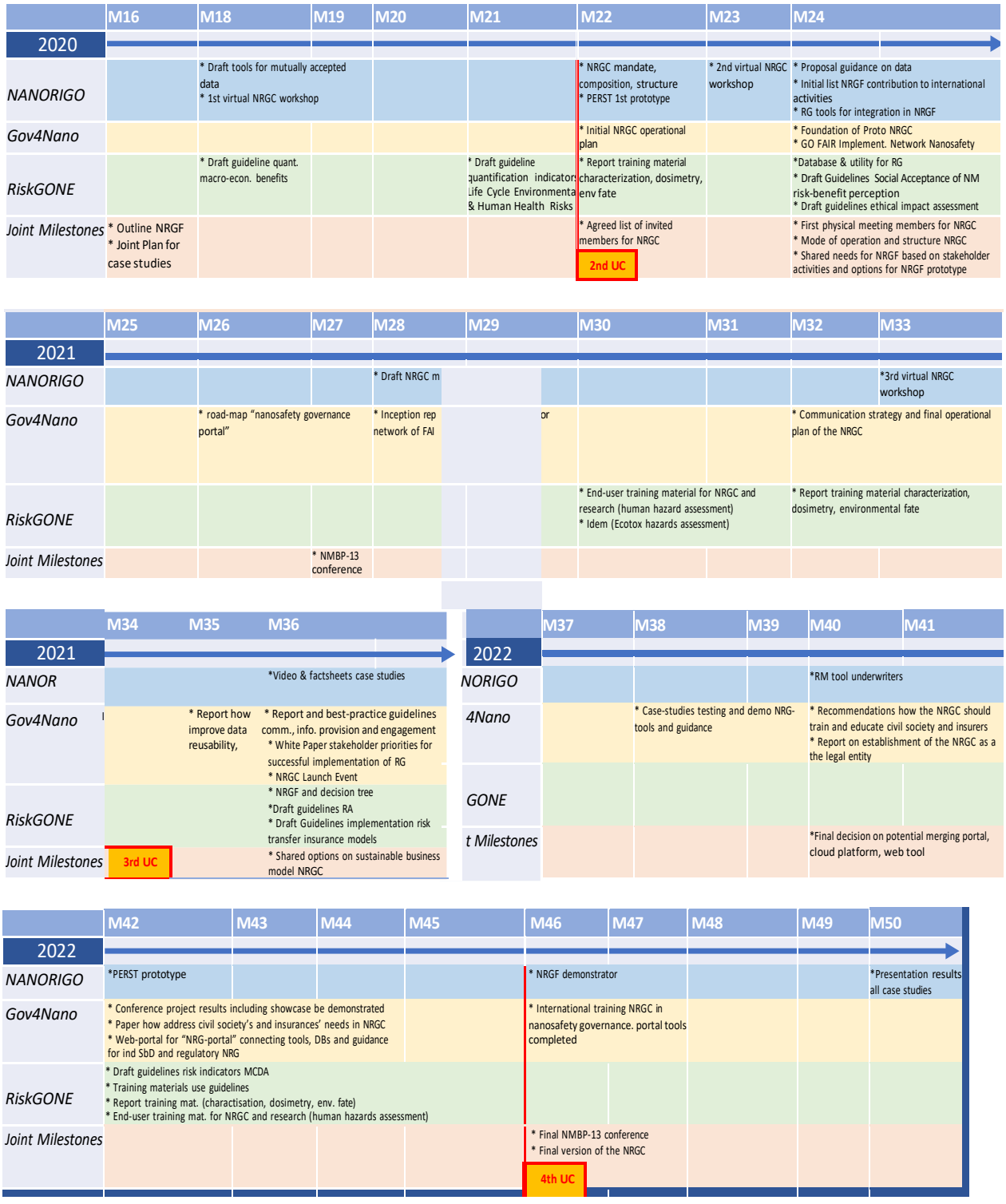

Figure 9, NMBP13 Timeline (represented starting M16)

Selection of relevant milestones and deliverables, *Key points for specific actions and feedback from the User Committee*

The UC determines its own preferences and as such prioritises the points for their next agenda. Their opinions and positionings are fully exchanged with the NMBP13 projects, their work packages and responsible partners.

a) The NMBP13 timeline

This timeline indicates the following topics to be suitable for the October meeting:

- The NRGF outline and its operational plan
- The tools to be used in the NRGF such as:
    - The Prospective Early Risk Screening Tool (PERST)
    - The tool for Mutually Accepted Data (MAD).
    - The quantification of economic benefits and social acceptance of NMs considering risk and benefit perception.
    - The quantification of life cycle environmental and human health indicators.
- Scenarios for the foundation of the NRGC.

b). The partners' identified relevant topics

In order to get an impression of the topics and questions that the NMBP13 partners consider important to discuss with the UC in the 2nd UC meeting, an inventory was conducted among them. These are conceptual topics regarding the building and future use of the framework and the council as well as questions regarding balancing ideas with ethical, societal considerations and efforts to generate a broader critical external input. These issues are summarised under the following bullet points.

- *About the risk governance framework (NRGF)*
    - *who*
        - For whom, in fact, do we make the NRGF? Who will be the users?
    - *what*
        - What is the role of the NRGF in "crises" around NM?
    - *how*
        - How to balance non-quantifiable broader risk-related and socio-ethical aspects with straight-forward risk assessment and evaluation
        - Should NRGF also cover future (generations) nano applications, and how?
- *About the risk governance council (NRGC)*
    - *who*
        - For whom, in fact, do we make the NRGC? Who will be the users?
    - *what*
        - What is the role of the NRGC in "crises" around NM?
        - What is the role regarding info and support on different global and regional standards that must be complied to by industry?
        - Which stakeholder concerns (by whom) are relevant for NRGC? How to deal with power imbalances?
    - *how*
        - Transparent distinction between 'technical' and 'normative' issues is essential. Could a technical Nano Expert Commission (NEC) and an Ethical and Social Aspects Commission (ESAC) within the council structure be useful?
    - *when*
        - At what point in the innovation process should the NRGC operate?

- *About tools (including risk-benefit balancing):*
  - *what*
    - Is there a need for an underwriting tool? (within the NRGF?)
    - Regarding balancing costs, (risks) and benefits, do we need a tool to estimate the forecasted benefits, and to identify who gets these benefits?
    - Identification of the positive and negative aspects of different ways to balance risks and benefits (thresholds, weights…)?
    - Identification of factors influencing the perception on nanotechnology products and the ways to reach a correct and balanced perception on benefits and risks.
    - Identification and weighing relevant indicators for impact categories to be integrated in the Multi Criteria Decision Analysis (MCDA)
    - Reflection on whether an "underwriting tool" should/could be included in the RGF.
    - Reflection on NM's environmental release over the products life
    - cycle and whether this is properly tackled within the RGF.
  - *how*
    - Discussion on advantages (benefits) and disadvantages (risks) that shall be considered when analyzing Nanomaterials and Nanotechnology.
    - Discussion on information sources and how to reach the public and various stakeholders in a timely, efficient and balanced manner
    - Discussion on the prioritising of criteria for selection of grouping, computational tools/approaches
    - How to bring a mutually accepted data approach into practice
  - *who*
    - Discussion on decision-making processes, who to engage and what info needed and who will be affected:
      - for developing research on nanomaterials?
      - for developing innovation?
      - for commercial purposes?
- *About knowledge/data management*
  - *what*
    - Clarify distinction between three target groups with specific data needs (incl. product chain communication in industry)
    - What are opinions and experiences concerning global/mutual accepted data?
  - *how*
    - How to identify gaps on NM knowledge that need to be overcome?
    - Should information on nanomaterials should be more comprehensively systematized?
- *About training*
  - *what*
    - What need is there for explanation/training on the use of tools (in general)?
    - What are the training needs of different stakeholders' groups?
    - What minimum knowledge is required to engage in a discussion?
  - *how*
    - How can a discussion engage different stakeholders?

- *About Communication*
  - *what*
    - Should there be risk communication protocols/practices?
    - What to communicate?
  - *how*
    - Discussion on information sources and how to appropriately reach the public and stakeholders?
    - Shouldn't we transparently show how we operationalize the precautionary principle in the NRGF and in the procedures of the NRGC?
- *About other issues:*
  - *what*
    - Critical consideration of the 'Innovation Principle' in European programmes and rules.
    - Concerning the environment:
      - Which compartments are more/less important?
      - Only hazard or also risk (i.e.: including – local – concentration values)
      - All nanomaterials or specific subgroups?
      - Also release from nano-enabled products?