Report on the 1st meeting of the User Committee of the NMBP-13 nanotechnology risk governance projects NANORIGO, Gov4Nano and RiskGONE

15 – 16 October 2019
Academy Building
University Utrecht

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nanorigo.eu

gov4nano.eu

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Photo (cover): User Committee at the stairs of the Academy Building of the University Utrecht (from left to right)
First row: *Chantal Van den Bossche, Delphine Bard, Ana Maria Rincon, Heidi Foth, Kees Le Blansch,*
Second row: *David Azoulay, Ulla Forsström, Raquel Puelles, Andrej Kobe*
Third row: *Witold Łojkowski, Martin Köhne, Dalila Antunes, Pieter van Broekhuizen, Susanne Resch*
Back row: *Rudolf Reuther, Daan Schuurbiers*

Report on the 1st meeting of the User Committee

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Glossary

CNT	*Carbon Nano Tubes*
CSO	*Civil Society Organisation*
EPFL	*Ecole Polytechnique Fedrale de Lausanne)*
IPCC	*United Nations' Intergovernmental Panel on Climate Change*
IRGC	*International Risk Governance Council*
FAIR	*Findable, Accessible, Interoperable, Reusable*
MNM	*Manufactured Nano Material*
NMBP	*Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing, EU Work Programme Horizon 2018-2020*
NRGC	*Nanotechnology Risk Governance Framework*
NRGF	*Nanotechnology Risk Governance Council*
PGNP	*Process-Generated Nanoparticle*
OECD	*Organisation for Economic Co-operation and Development*
REACH	*Registration, Evaluation, Authorization and restriction of CHemicals*
UC	*User Committee*
UFP	*Ultrafine Particle*
SAICM	*Strategic Approach to International Chemicals Management (United Nations)*
SbD	*Safe by Design*
SCENIHR	*Scientific Committee on Emerging and Newly Identified Health Risks*
SOP	*Standard Operation Procedure*
TiO_2	*Titanium dioxide*

Preface

The User Committee is an external group of twelve stakeholders from different spheres of society with a particular link to nanotechnologies and (exposure to) nanoparticles. It consists of members that are evenly spread over science/research, industry/enterprises, regulation/governmental organizations and civil society/non-governmental organizations. The UC is organised within the NMBP13 project NANORIGO, in close cooperation with the other two NMBP13 projects Gov4Nano and RiskGONE. Responsible for organisation and reporting of the UC are the research and consultancy organisations Bureau KLB and ENAS, both within the NANORIGO project.
The UC is a key element in the projects' stakeholder engagement activities and an effort to operationalise the social economic dynamics and civil societies interests within the Nano Risk Governance Framework (NRGF) and the Nano Risk Governance Council (NRGC).

The UC will meet 4 times during the 4-years project period, once every year. The UC will critically monitor the NRGF/NRGC development by using an iterative process that guarantees a continuous exchange between the UC and the project partners (from the three NMBP13 projects) that are engaged in building up the NRGF/NRGC. As such the activities of the UC will generate a critical input for all the three NMBP13 projects.

The UC plays an overarching role in the projects, as a stimulus to include societal and market-related dimensions in the NRGF and the NRGC, and to assure openness and a balanced and democratic approach, i.e. tuning the NRGF to practical and societal needs and values. UC members will also play an essential role in the conception of the NRGC that is to be established.
This means that the UC will significantly contribute to the development of the NRGF so that it will be fit-for-use for professional end-users and the general public. Likewise, the UC will also support and guide the NRGC to provide the content and means, which main stakeholders identify as a strong need for the responsible use of nanotechnologies in society.

This report reflects the results of this 1st UC-meeting, condensed in a comprehensible and readable format. It includes as well the UC-members' 'third thoughts' as generated after the actual meeting. As such this report can be considered as a 'living document'. It contains the minutes, merged with remarks and thoughts of UC-members made up until the end of November 2019.

Amsterdam, November 2019

1st User Committee

NANORIGO, Gov4Nano and RiskGONE

15 – 16 October 2019
Academy Building University Utrecht

Participants

Members UC

Researchers

Ulla Forsström (VTT)	FI	
Heidi Foth (Martin-Luther-Universität)	DE	
Witold Łojkowski (University Warsaw)	PO	

Industry

Martin Köhne (Robert Bosch)	DE	
Vladimir Vrečko (Cinkarna Celje)	SI	Absent with prior notice (see 4.2)
Raquel Puelles (Avanzare)	ES	

CSOs

Chantal Van den Bossche (WECF)	NL	
David Azoulay (CIEL)	CH	
Representative trade union		Absent without prior notice

Regulators

Delphine Bard (HSL/HSE)	UK	
Andrej Kobe (EC ENV B.2)	EU	
Ana Maria Rincon (EFSA)	EU	

Organizational team

NANORIGO

Pieter van Broekhuizen (Bureau KLB)	NL
Kees Le Blansch (Bureau KLB)	NL
Rudolf Reuther (ENAS)	DE
Daan Schuurbiers (DPF)	NL

Gov4Nano

Susanne Resch (BNN)	AT

RiskGONE

Dalila Antunes (FactorSocial)	PT

AGENDA of the meeting

Day 1 – 15 October 2019

14.00 Opening of meeting
Opening by the chairperson of the full meeting: Kees Le Blansch

14.05 Getting to know the participants
Short round of formal introductions: who is who, from which Institute, in what position and in what line of work?

14.40 About the User Committee (UC)
*A short description of and questions on the role and functioning of the UC. see **Annex 1***

15.00 About Gov4Nano, NANORIGO and RiskGone
*Rudolf Reuther presents the goals, structures, commonalities and specificities of the three cooperating NMBP13 projects, followed by questions and discussion. Presentation see **Annex 2***

15.15 Coffee Break

15.30 UC wishes, requirements and ideas for Nano risk governance
The discussion of the wishes, requirements and ideas of UC members is started by making an open inventory.

16.30 Refreshment break

16.45 Questions from NMBP 13 work package teams
*The UC is asked to give their critical view on the needs and requirements of future users of the NRGF and NRGC. Actual key questions for this, as formulated by WP-leaders from NANORIGO, Gov4Nano and RiskGONE are being discussed. **Annex 3***

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
Reflective issues after a rethink of the discussion of day 1

9.40 Nano risk governance cases: selection and formation of subgroups
*Discussion of examples of possible actual information needs, real-life concerns and risk governance issues. A summary of cases is included with the agenda documents. **Annex 4***
Discussed in two subgroups.

10.00 Discussion of cases
*Each subgroup discusses its (three) selected cases (**Annex 6**) 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
Proposals are discussed for a next meeting of the UC (place and time).

12.30 End of the meeting

Executive summary

On 15 and 16 October 2019 the first meeting of the User Committee (UC) of the Horizon 2020 NMBP 13 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. The first one 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).

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.

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?

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.

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.

The UC will have three more meetings in the course of the NMBP13 projects. During this period, it wishes to be kept informed on the projects' progress on a half-yearly basis. Preparations for the next meeting (before summer 2020) will commence shortly.

1. Introduction

The full session was moderated by *Kees Le Blansch*
Minutes: Pieter van Broekhuizen, Rudolf Reuther and Daan Schuurbiers

The members of the UC introduced themselves, their professional (and private) position and their expertise and involvement in (the debate on) nanotechnologies and nanomaterials. Some of them already brought forward some key issues that may be relevant to discuss this 1st UC meeting or in one of the follow-up meetings. The main points are summarized.

General points

- It is important to underline that all UC-members do speak on a personal level, based on their own expertise, ideas and concerns. They do not speak *on behalf* of their company/institution, and as such they do not need a mandate to bring forward a specific position. Nevertheless, they have been invited to contribute from the perspective of their specific stakeholder groups.
- The UC will *not* strive towards agreements or consensus. In contrast, differences in points of view are important.
- The minutes will be made, as much as possible, on 'the meta level', not necessarily mentioning the name of the person that brought forward the position or idea. The stakeholder background of the person making a statement may be mentioned if it is thought to be relevant for the argument. In practice, this means that statements from UC-members may not always be anonymous. The UC members agreed to this. After approval by all members of the UC, the minutes will be made public. They will be available for (and used by) the three projects NANORIGO, Gov4Nano and RiskGONE and being placed on the publicly accessible website as deliverable.

Principle introductory remarks

- The remark was made by Heidi Foth that we should be careful in our use of wordings, terminologies and explanations in the 'nano'debate, because these may easily give rise to misunderstandings based on different interpretations of one and the same term or definition we use. One of the examples, as Heid Foth brings forward, is the term 'risk'. What exactly do we mean by risk? Risk relates to hazards and adverse effects that may become manifest in practice, but a question is, what needs to be protected and how? And what level is, or should be acceptable, or is accepted? Is there already a discussion on this issue? And if we take the Precautionary Principle into consideration, is this to avoid the risk, or is this to avoid damage? Risk is the common denominator but at some detailed points risk avoidance may principally differ from damage avoidance in management choices. The opinion was brought forward that it is rather the damage that is to be avoided, while not hampering innovation (although this was not further discussed here).
- Another point made is that we have to be very clear in that, in this UC we in principle are talking about risk *governance* of which risk assessment is only one of the 'building blocks'.
- Then a second critical issue came up (raised by CSO and scientific UC participants): innovation, in these discussions, is imputed as an issue with a positive identity, i.e. as an issue with a default positive identity. But what is the innovation for? A critical approach towards specific innovations is essential. We should be careful not to promote innovation for its own sake, we do not need 'unnecessary' innovations. If you are to promote it, the focus should be on the responsible innovation and the one that addresses societal challenges.
- A third issue is the simultaneous occurrence of manufactured nanomaterials (MNMs) and 'incidental' nanomaterials at workplaces and in urban air and other media.
- The role and positioning of the NRGC are key issues, these should be complementary to (and not double) the role or activities of existing councils, boards or institutions.

- Additionally, as especially brought forward by UC participants from the EU regulatory organisations (Andre Kobe and Ana Rincon), there is some scepticism regarding the NRGC and its use within, or in the side lines of the European regulatory and advisory systems, as for example the *Nano-observatory* information hub, which was established at the EU-level as 'alternative' for the requested nano registry. The question was brought forward whether a NRGC is really necessary, or that the requirements could also simply be fulfilled with the development of a process because, 'at the end of the day' nano is always part of the bigger system of rules and regulations, as e.g. REACH. Nevertheless, this scepticism was no reason for the UC-members to refrain from discussing the why, where and how of a NRGC.

2. Role and function for the Council and the Framework

The specific features and added value of a Framework (NRGC) and a Council (NRGC) were explicitly discussed in three sessions of the meeting: (1) the session after the introductory sessions on *'UC wishes, requirements and ideas for Nano risk governance'*, (2) the session on *'Questions from NMBP 13 work package teams'*, and (3) (the following day) the session on *'Second thoughts'*. For the first session on *wishes, requirements and ideas* the organisational team had suggested to use the following four issues as leitmotif of the discussion: *(1) (overcoming difficulties with) obtaining information on risks of nano; (2) (overcoming difficulties with) taking appropriate risk reducing measures; (3) (overcoming lack of) coordinated societal response to risks of nano; and (4) (overcoming lack of) an authoritative body in the field of risks of nano.* For the second session, on *'Questions from NMBP13 …'*, a list of questions was prepared subdivided in different topics (see **Annex 3**). To avoid repeating discussions of the first session, the organising team proposed to focus on questions related to the NRGC: 'What concrete recommendations would you have for the composition, purpose, role and remit or mandate of the NRGC, for it to address the needs, concerns and wishes that were identified in the earlier sessions? In other words: what do you think the NRGC should look like to address your needs and wishes? The session on *'Second thoughts'* was again a fully open session. In this reflective session some of the already discussed issues were further elaborated, and some new thoughts were brought in.
For the readability of the report, the reporting of these three sessions is fully merged.

Data needs

- In practice there is a high need among all stakeholders to get robust data, that can be trusted. Data that are accepted for legal procedures and that are reliable for risk assessment. Even when data are known to be existing, they are frequently not available for potential users, kept confidential or unfindable. Or in the case that data are available, the quality may be difficult to assess for the actual user. Sharing of data is one of the key problems, as brought forward by Raquel Puelles. Regulators need these data especially for decision-taking, industry need them for registration, innovation decisions and risk management and users need the data to make their own, independent decisions in risk assessment. Ana Rincon states that regulators need especially the raw data, not those data that are polluted with interpretations. The NRGC should motivate industry to be more transparent and supportive in sharing available data.
- Both participants from industry (Raquel Puelles and Martin Köhne) and from science (Heidi Foth) referred to a role for the NRGC as a central point for the collection of data. The name clearing house was mentioned although it is questionable whether this term is the right term for this. A central point to make data accessible and condensed in an assessed database, to centralize and standardize the needed and agreed approaches towards handling nanomaterials risks, to reduce the costs and operationalise and communicate an accepted way forward. And as regulators (Kobe) brought in that in general reference should be made to existing data structures and processes

(including e.g. new food sustainability and transparency regulation) and ongoing processes on access to chemical data. Moreover, the NRGC should build on it or complement, not duplicate.

- Another problem of unavailability of data relates to the high costs to generate them. For companies, as said especially for the small and medium size enterprises (SMEs) this may be a large barrier. But nevertheless, as Ana Rincon says, within the existing legislation delivering (physical-chemical and risk) data, also for 'nano' is mandatory for the industry and, as added by David Azoulay, costs shouldn't be transferred to the environment or future generations (as is currently often the case).
  The NRGC should provide guidance on how to realize the FAIR data principle and what tests are minimally needed for new MNMs, and so help (industry and society) to save time and costs, as suggested by researchers and industry.
- David Azoulay brings forward the questions on responsibilities with regard to confidentiality, uncertainty and costs: if information (or data) is kept confidential or, if existing information leads to *uncertainty* or *ambiguity*, it is reasonable to ask: "*who should bear the costs for uncertainty?*" This holds especially (but not only) for new innovations as Ulla Forsström adds. For this, balanced evaluations are necessary. Subsequently again, "*who bears the costs for this?"* and *"what is the best compromise?"*, and to what extent are compromises acceptable? A role for the NRGC could be to advise on good, acceptable and 'cheap' methods, and provide guidance for society in considering its needs and interests, and as suggested by Ulla Forsström, to allow for balancing independent decision-making on good and acceptable innovations. An essential element of such a balance includes a risk-benefit ratio, because as Martin Köhne states: '*without benefit, there will be no innovation and no private investment'*.
- Also, a strategic and fundamental question regarding the Framework was brought forward: is the Framework a 'scientific' framework, in which we predominantly focus on acknowledged 'risk data', or will the Framework also address values-based discussions, for which it is not possible to derive unambivalent risk data?

Advice and tools for risk assessment

- An element of risk assessment is exposure assessment, and in this respect the release of MNMs is the key. This relates to the availability of (potentially hazardous) nanomaterials, used in products. Advise is needed on acceptable (and accepted) methodologies to be used. There is also a need for an inventory of existing data, including info on non-release during use, all considered and assessed along the whole life-cycle. This relates to released MNMs as well as to nanomaterials generated in processes (process-generated nanomaterials -PGNPs), including processes that do not use MNMs in their manufacturing process, such as e.g. 3D printing, for which a 'novel' nanoparticulate release may be identified. Non-release may for example relate to electronic equipment products where the applied MNMs as contained in the matrix, are not released during intended use. Martin Köhne stated that this type of use might need a different approach than the 'dispersive' or 'not controlled' use of MNMs. Furthermore, it was highlighted that the exposure data/assessment should take into account the full life cycle of the product.
- As such, a clear and authorized guidance for the selection of appropriate (cost effective) tools for the specific applications and use, is highly needed, although, as others reflect, there are OECD guidelines developed and available that offer standardized methods to meet these needs. But it is clear that quite some uncertainties and controversies remain. Some kind of intermediary function is needed to connect industry and users to 'nano-experts', and to offer support in identifying the availability of appropriate tools.

Simultaneous exposures

- With regard to nanomaterials' risks, it is common to have a simultaneous occurrence, and consequently simultaneous exposure to manufactured nanomaterials (MNMs) and 'environmental' ultrafine particles (UFPs), as well as nanomaterials generated in high-energy processes at

workplaces – process generated nanoparticles (PGNPs). Therefore, the approach of the NRGC (and advices given) regarding risk assessment should allow and support stakeholders and users to make comparative judgements, finding out the needs for using the MNM in a particular application, explaining the consequential release of nanoparticles, compare these with the non-MNM nanoparticulate concentrations, and as such realising some kind of holistic approach for environmental as well as workplace assessments.

Support in early identification and early warning

- The *early* identification of risks of innovations and *nano*products should be a key role for the NRGC. Early identification should reflect on the innovations and their intended use, and reflect as well on the operationalization of safe-by-design principles (SbD).
- Important as well is an extended focus on the phase that precedes the innovation activities, i.e. the prior academic and industrial research. In this phase crucial knowledge is developed and choices are being made which, as well in this phase should be complemented with a foresight on potential risks or adverse effects. And, as Köhne adds, this includes also the risk of disruption and the resulting impact on economy and society. He states that new future nanotechnologies bear also risks of high economic impact due to their potential disruption for existing business models. This risk is also to be considered for early warning on new risks.
  These different angels require for the NRGC to have (or to be able to consult) expertise in the fields of at least toxicology and occupational and environmental hygiene, but it relates as well to the issue of risk perception and economical and business issues.
- Early warning and precautionary approaches should be central elements in the NRGC, when dealing with weak data, to avoid possible damages and to ensure a level of provisional acceptance. The NRGC could help to estimate the likelihood of certain events and their scale of impact, to provide a provisional level of acceptance and to propose research lines to fill the knowledge gaps. However, as was stated, '*we should note that good science does not always lead to good policy*' (the political implementation of the findings of the IPCC was mentioned as an example).
- A further point of discussion was that the relationship between science and policy needs to be articulated. For new developments this holds for example for a role in supporting the science-based understanding of the behaviour of new materials, such as nanobiomaterials, in different applications. For these (future) type of new, so-called next generations nanomaterials, the current risk assessment paradigm (hazard, exposure, risk) might not be applicable, and new approaches towards risk assessment should have to be elaborated and exercised. This should not only reflect terms of functionality but also terms of risk and societal benefit, enabling policy to balance such innovation with these known estimated risks and benefits.
  The NRGC may also function as some kind of a *'think* tank', focussing on emerging issues, to identify 'megatrends', and advising on how to respond to these.

NRGC and trust

- Essential is the building of an environment of trust and assuring reliable communication, including information about good practices.

NRGC and regulation

- As a central player in the field of nanotechnologies' and nanomaterials' risks, the NRGC might as well have a supportive role in the development and implementation of regulations, although it was emphasized that the NRGC should not be a regulatory body.

Format and focus for the NRGC

- The question 'what should the NRGC look like?', generated several suggestions. On the one hand, it was suggested that the NRGC should be some kind of civil service, an authority, to be respected by all stakeholders and the general public in their advices and considerations. On the other hand,

a more intermediary position was advocated as a multidisciplinary interface between science, policy and society, with different experts 'pooled together', not only with toxicological expertise, but broader expertise as well (including science, ethics, ecology and so forth). Strategists might also be included to structure the approach. As such, the NRGC would be a node in the knowledge ecosystem.

- This led to the discussion what is expected of the NRGC. Is it a consultancy that provides advice to certain audiences? Or is it an expert body? One participant asked if it should be a *NRGC* at all – or should it perhaps be a procedural description on how to move forward under certain circumstances, for instance if critical issues arise?
- Also, a reference was made to social media, as a possible useful medium for the NRGC to moderate strategic questions, e.g. with a carefully moderated blog or a Facebook page where questions are addressed.
- Regarding the actual set up and used procedures for the NRGC we could learn from other existing bodies, as for example from the IRGC at EPFL.

NRGC as science-based

- The Description of Action (DoA) for NANORIGO mandates a 'science-based approach' as the basis for the NRGC, but it is questionable how broader concerns could be addressed in the NRGC, if it is purely science-based.
- Also, it was suggested that the NRGC might function as a science-policy interface and a kind of network of networks. In this respect, reference were made to the ongoing discussions under SAICM to establish a science to policy interface, which addresses a lot of the issues mentioned during the discussion.

Preconditions for the NRGC

- Two main preconditions for the NRGC emerged from the discussion:
  - First, the NRGC should not duplicate existing efforts. There are several relevant bodies like SCENIHR that already advise on related risk issues. Also, regulations are already in place for several sectors and fields of application (consider for example the regulations on cosmetics, food, biocides, medical devices or REACH);
  - Second, the NRGC can't do everything. It should therefore be made clear what the specific purpose, scope and role of the NRGC will be.

- Defining a relevant and functional NRGC will therefore require finding 'niches', tapping into existing networks, building on existing institutional structures and providing specific information that is not being covered by other bodies. It was suggested that the focus of attention should be on unregulated fields of application (consumer products - like ball pens - were suggested as an example). However, as a comment to these minutes, it was noted that these types of products are NOT unregulated – the General Products Safety directive capture them all. Manufacturers are responsible for ensuring safety. There is however indeed important difference in the amount of scrutiny received, compared to e.g. REACH.

3. Discussion on Risk Governance cases

Nano risk governance cases: selection and formation of subgroups

*In order to discuss examples of possible actual information needs, real-life concerns and risk governance issues, several imaginary cases were formulated for the UC members to reflect upon. These cases were sent to them preceding the meeting included with the agenda documents (**see Annex 4**).*

Wherever necessary, short clarifications of the cases were provided. Also, there was opportunity for UC members to propose their own suggestions for specific cases to discuss.

The questions were discussed in two subgroups. Both subgroups convened in separate meeting rooms (both in the Academiegebouw). Each subgroup selected approximately three cases for which they felt a special interest to reflect upon.

Instruction for the 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?

Subgroup 1

Moderated by: Pieter van Broekhuizen
Participants: Ulla Forsström, Raquel Puelles, Witold Lojkowski, Ana Maria Rincon, Daan Schuurbiers, Rudolf Reuther, Pieter van Broekhuizen, Susanne Resch (minutes)
Selected cases: 3, 8 and 4

Case 3

Imagine …
Advanced measurements in the vicinity of some highways and main roads within the EU (including urban and nature-conservation areas and worksites of road maintenance workers) have shown the presence of large quantities of ultrafine particles (UFPs) including nanotube-shaped wear particles of rubber tyres.

For case 3, the most important need is to know what sort of UFPs are released from the polymers (i.e., what material in which shape etc.), and how dangerous these particles are. There is concern of a possible contamination of the environment through UFPs that are released into the air. These UFPs could be inhaled by humans and may cause adverse effects. It would be necessary to know, how toxic exactly these UFPs are. For humans, exposure via inhalation is very likely, the UFPs can potentially cause asthma etc.
Also, it is important to differentiate the following:

- Are the UFPs coming from a nanomaterial that was specifically added to the tyre? (i.e., manufactured nanomaterial)
- Are the UFPs generated from the polymer itself? (i.e., process generated nanoparticles)

In any case, there is a need to know how many particles are released, and how toxic these are.

If nanomaterials are added and embedded into the polymer matrix, the material is called nanocomposite. A nanomaterial released from that matrix that has nanotube shape, could potentially have effects like asbestos. On the other hand, it is questioned if nanotubes can get out of the matrix easily and are released to the air one by one.

There is a need for dedicated scientific studies to get the knowledge if nano-additives are released from the matrix or not, and if the potentially released nanomaterials can cause damage to human health and the environment or not. Graphene for instance is added to tyres as well, which is even more difficult to assess. Thus, we need to study their toxicity in more detail.

There is the possibility for the tyre producing industry to substitute the nanomaterial that is used as nano-additive (if needed). This could be achieved by using a different material that shows the same functionality but is less toxic. On the other hand, this could also open a "pandora box". For example, replacing zinc oxide by nano-zinc oxide, the amount of zinc can be reduced, but zinc ions can be released in the environment and cause toxic effects. It is important to ensure assessment across the whole lifecycle and balance risks and to take also other aspects into account. For example, driving in general can become safer by using modified tyres with improved parameters. Safe by design is an approach where innovation considers all these aspects already early in the design of the material/product.

Consumers that want to buy new winter tyres could make use of a portal on the internet that shows all parameters of different tyres, including their emission of nanoparticles during their lifetime. This could help the general public to decide, which product they want to buy. Of course, the regulators may also already in advance restrict specific uses/solutions based on this information.

There is a strong need to understand, which particles are released, in relation to a clear definition of these particles and their comparison to appropriate threshold values.
Firstly, it is important to know the quantity of the particles that are released and how to measure that appropriately, and secondly, the identification of the particles needs to be evaluated (which particles are released, what's the source of them, and what causes the problem). As one of the UC-members remarked, the government should be in charge of these measurements, and, as brought in as comments to the minutes, these measurements need to be reliable and non-biased, but there is a responsibility of the industry as well to provide these data as part of their safe-by-design approach. Measurements in the lab scale are different to real life measurements. Real exposure under real conditions should be assessed. As a next step, possible risk mitigation measures should be established. Based on the outcomes of the measurements, the government (e.g., ministry of traffic) ultimately needs to take a decision (e.g., ban the material from the market). Industry often has a lot of influence on governmental decisions due to their contribution to economy in the country. The government needs reliable data to build its decision on, thus, research institutes should be asked to provide robust data.
As noted after the meeting, a study is actually in progress under OECD with quite similar parameters. Industry is involved together with some national regional agencies.

Workers on the road are the most endangered. A study could be done, that investigates the exposure level for 8 hours. Currently, there are no sufficient occupational exposure limit regulations. Until it comes to the definite regulation, the NRGC could provide guidance and advice.

Also, it needs to be evaluated, from which tyres exactly the UFPs are released, and specific advice to industry should be provided. The government should not ban any materials/products before it is clear what exactly causes the toxic UFPs. Of course, if needed the precautionary principle should be used in this assessment. A multidimensional environmental finger print of the tyres could be developed that informs consumers.

If the studies find out that the UFPs are CNTs or Graphene, the researchers could go back to a database to see if these materials cause problems or not. Available data/information should be made accessible for everyone.

The NRGC should support/conduct studies, were the functionalities of different tyres are compared and less toxic ones can be chosen. The NRGC should propose solutions for the industry and for the regulators, and should coordinate all nano-related data, ensuring that this data is reliable and accessible (i.e., it does not have the data itself, but can give access and tell users, where to find it).
It can hold the position of a mediator. In that case, it is important to be a trusted institution. It could also provide consulting between data producers and tyre manufacturers. The NRGC should support concerns of all stakeholders while not losing the innovative character. It could decide on research priorities based on public concerns. Additionally, it can be a forum to ask questions in order to get different opinions on the same topic.

Case 8

Imagine …
The French government is pushing the European Commission to issue a ban on nano TiO_2, not just for food but for all applications. The Commission appears to be seriously considering this option. The European Parliament invites you to speak at a public hearing about this possible ban.

As brought in by Puelles, industry/companies are affected by a material ban. There was a specific case related to nano-TiO_2. Industry that produces bottles asked for help to avoid damage of food by light. Thus, a nano-coating for outside the bottle was developed, using nano- TiO_2. This coating is considered as food contact material, although it is used only on the outside of the bottle with no migration. Moreover, tests proved that the material stays on the outside surface and is not released. A ban of TiO_2will ban this product from the market and cause a great economic loss for the producing companies.
It is perceived by a member of the UC that governmental decisions are currently mainly politically driven and not based on science. Scientific proven advantages and disadvantages of products/materials should be taken into account by regulators. The decisions should not be based on public fears and public opinions. (But as added after the meeting: '*One is to say that a decision needs to be knowledge-based, otherwise one cannot say not to take the principal stakeholder into account*'.)
The perception of the public can have the power to put bans into place. However, it is difficult to talk to the general public. Any new technology has some people that are against it. From a pure scientific point of view, as stated by one of the UC-members, $TiO_2$is not of concern. However, this point is contested after the meeting: '…..*apart from being a suspected carcinogen when inhaled, as determined by a regulatory assessment body, and presently in process of introduction in CLP… Even for the actual product the TiO2 may pose a risk at the different life cycle phase.*
(Another point added after the meeting refers to recycling and the SbD principle: *"Bottles, both glass and plastic ones, are recycled as material. This is common practice for glass (100% can be recycled) and PET bottles that are collected, sorted and material is reused. In that case the nanocoating will end up in the new glass bottles (glass can be recycled several times) or products produced from PET material (in the future more and more also PET bottles or other packages. And additionally, it is also interesting and known that such additions (cannot claim for this hypothetical one) actually cause process-problems in recycling to start with…)".*
A great problem is that industry never gave clear data to the regulators. The NRGC could provide information to all stakeholder groups and act as a mediator between them. For Case 8, a substance-specific approach could be substituted by an application driven ban (i.e., the TiO_2 coating on the outside of glass bottles would be still ok, but other applications might be banned). The NRGC could also influence public risk perception by providing reliable science-based information. Public communication is different to scientific communication. Researchers need to learn how to speak to the general public. The NRGC could help here.

Case 4

Imagine …

A 3D printing machine in a higher education institution only uses 'conventional' (non-nano) chemical substances, but nevertheless proves to generate high concentrations of process-generated nanoparticles (PGNPs).

Due to time constraints case 4 was only 'touched' with a few generic remarks. There was no real discussion, nor an outcome with conclusions. Remarks made were that case 4 is considered as a real-life issue in laboratories. Good laboratory practice guidelines should be implemented by all personnel. Not only the scientific staff and the technicians need to be trained, but also the cleaning personnel. Adequate protection of all workers and education about that topic is not only a nano-related problem, but valid for the whole chemical industry. The NRGC could provide SOPs, recommendations, etc. and spread latest information.

Subgroup 2

Moderated by: Kees Le Blansch
Participants: Heidi Foth**,** Martin Köhne, Chantal Van den Bossche, Delphine Bard, Andrej Kobe, Kees Le Blansch, Dalila Antunes (minutes)
Selected cases: 2 and 5

Case 2

Imagine …

A company with 150 personnel that is located on a business park near a major city, intends to start manufacturing paints containing carbon-nanotubes (CNTs) for conductive properties, e.g. electrically conductive paints, to be used with solar panel applications on houses.

This case was approached on different perspectives, considering risks for:

- workers and occupational hazard (the need to conduct health survey impact on human beings and aggregated hazards), knowledge needs to be provided regarding how to manage products properly when manufacturing;
- environmental impacts;
- people living around the factory, as communities driven by risk perception may work with politicians in order to stop the factory to produce such paint;
- people performing application of paint (and removing the paint, in case someone was supposed to do it) and information to provide them regarding additional health and safety measures to consider on how to apply the paint in order to minimize risks (considering both, professionals who have the proper equipment but perform this work often, and lay people that may apply the paint in their homes).
- people living and/or working on houses painted with such paint. The biggest issue for this group was the uncertainty about knowing more on how the material behaves along time, as tests never mirror 100% the natural conditions (e.g. weather, heat, air pollution (gaseous, liquid, or solid), dissociation by microorganism) to which the paint will be exposed to and tests are condensed on shorter periods to try to understand what might happen on long term.
- Specific characteristics of CNTs were also discussed (specific small fiber structures, can behave like asbestos like if they have the chance depending on type of CNT).

The group also mentioned these information and knowledge should inform and be brought into:

- the product dossier;

- Health and Safety matrix – which can contribute to inform what effects are and to safety by design;
- Information on how to use the product and if additional Health and Safety measures need to be considered). Participants stressed this information shall be precise (e.g. not only use a protective mask, but what type of mask, how often to change it…).
- to community living around the factory, but.. Who will get in contact with people and understand their concerns, be able to communicate with and provide information to them (in an understandable way); the need to have a proper system in place, eventually engage CSOs and build trust – '*Governance is not nano-specific, what is specific is the data*'.

Regarding who is to be engaged on providing information the participants mentioned:

- not only the company but also CNT providers (they will need to operate and communicate in a responsible way);
- if the issue becomes a political issue, national regulators may get engaged;
- the system should consider additional sensitivity regarding NM issues on public communication

As the processes and obligations (general but applicable also to nano-manufacturing) are already quite well established, additional role of NRGC was not completely obvious to the participants in this case.

Case 5

Imagine …

Using different advanced techniques including nanotechnology, scientists have succeeded in reproducing and multiplying slightly modified human brain cells on a membrane (fully apart from a human and its brain) and to connect these cells through nano-electrodes with huge data processors. First basic impulses and reactions have been exchanged between brain cells and data processor (in both ways). A major scientific breakthrough is expected, with the possibility of creating an artificial, more or less autonomous 'identity' or 'self' for the first time.

This case nature led participants into a discussion of something that does not really exists yet and raises several questions that require approach from different disciplines and ethical guidance. On this case there was much more space and appeal for a Risk Governance Council

Participants mentioned this case requires to engage an ethical team working side-a-side, guiding research team by giving them a real problem to solve with a specific relevant goal (e.g. replace injured brain section). Considering the different applications of nanotechnology and cross-boundary for such case it is relevant to define:

- who is in control?
- is there a border line?
- can it be allowed (ethical issue)?
- What are other options/alternatives?

RGC was appointed as one of the first bodies that could rise the right questions (ethical nature questions). Such discussion would be considered good also by bringing different disciplines into it (e.g. bringing in social science and analysing history of society to understand possible implications).

Because this problem raised questions which are:

- Beyond specific expertise,
- Require considerable thought
- Places responsibility on different places (disciplines)

this could be a role for the NRGC.

So NRGC could be a platform to enhance discussion on technologies considering their overall problems/issues. By its multidisciplinary and eclectic nature, this discussion considering future advances, also allows generating new ideas and stimulate scientists to where science can advance to/for.

4. *'Third thoughts' of UC members*

In the weeks after the 1st UC meeting several UC-members took the initiative to further reflect on the discussion and the plans for building a NRGF and establishing a NRGC. The contributions are copied, without further adaptations, in the following paragraphs.
Witold Łojkowski and Andrej Kobe sent a 'third reflection' on the discussions in the UC. Also, Vladimir Vrecko, who was unable to attend the meeting due to the bankruptcy of his travel agency (Thomas Cook) presented his contribution.

4.1 Witold Łojkowski

Some remarks concerning Nano Risk Governance after discussions of the User Committee meeting in Utrecht, 15-16 October 2019
Setting a Risk Governance is setting a structure on an executive level composed of people in charge to reduce risk. Thus, setting Risk Governance is designing a structure composed of people, bodies and/or organizations handling risk issues: who is responsible for what and how they interact.
The UC discussions addressed all levels: nano-risk assessment, nano-risk management, nano-risk communication and Governance. Perhaps the definition and discussion of Risk Governance escaped from focus. At the first meeting people had to organize their ideas.
Need for such an organization seem to be the conclusion of the three projects. It seems that the UC discussion confirms that there is such a need. Despite large efforts and many data, nanotechnology potential is not fully exploited, and one of the reasons is not enough knowledge of risks and methods to control them.
Regulatory organizations and certifying bodies sometimes do not have a clear idea how to certify nanomaterials and whether a special approach is needed for nanomaterials.
A lot of information was gathered and there is a need to capitalize on it.
Nanomaterials display unconventional behaviour and are challenging the established tests methods. Reliability of data is in doubt.
It seems to me that the main roles of the Nano Risk Governance should be to support the existing Risk Governance organisations. This role emerged several times during the discussions. There are established governance organizations and procedures able to handle most complicated issues. However, they need a dialogue with the future Nano Risk Governance. One of the reasons is to make them sensitive to the peculiarities of nanomaterials. Perhaps some procedures need to be adjusted. Nano Risk Governance should be in dialogue regulatory bodies (e.g.1,2) to optimize nano-risk management.
Other tasks were mentioned during discussions, like foresight, public dialogue, education, future research directions. All of them are characteristic of an NGO organization. Perhaps like a Technology Platform (Example European Nanomedicine Platform ETPN). Funded by members fees and various services offered, with options to apply for research projects.
These are some afterthoughts after the fierce debates finished, and I hope can be useful.

1 An organisation to collaborate with is also the ISO/TC 229 committee Nanotechnologies https://www.iso.org/committee/381983.html
2 http://www.oecd.org/science/nanosafety/

4.2 Vladimir Vrečko

There are several ways in which industry has interest in nanosafety issues, but all of them are quite different.

First of all, we are mostly secondary users of information and knowledge, not data on itself. What we struggle with is to find the balance between the innovation potential and regulatory and safety constraints. While we focus main attention to development, production and commercialization of new materials and applications, we are (in contrary to public and NGO's perception) mostly eager to comply with safety recommendations and regulatory rules.

The later has become very costly and very unpredictable endeavor. Companies are rarely in position to prepare demanded dossiers by themselves, so they are forced to join the companies' groups which own the results of many of necessary studies or hire the organizations which are specialized for these tasks. In any case, the direct users of the data and methods are these intermittent organizations and laboratories which they task to do the studies. What industry wants is the dossier which will ensure the compliance with the regulatory demands.

What we have noticed is that on one side we have no or minor influence on the regulations and on the other side we are flooded with the extent of activities necessary to satisfy the regulatory bodies (both in financial terns as well as in terms of work to be done).

What we have observed is exploitation of the situation from the parties involved – for example we have got an offer for the access to one particular study requesting compensation in the amount of 900 k€ and second example, though the procedures generally don't require that only laboratories that comply with GLP can do the studies, the regulatory bodies are inclined to reject the studies of other scientific laboratories, so in the end only the largest labs are in the business.

What is important to industry is that information and knowledge is constantly updated and is accepted as relevant by all stakeholders (it is not constructive to stick to common beliefs that industry is corrupt, that science is unmistakable, NGO's are supermans in service of the society and regulators are only obliged to stick to the procedural rules).

If we ask ourselves what we need information on safety of materials for, there are several basic needs:

- Occupational workplace safety – for this we need to have reasonable safety thresholds and appropriate safety measures, personal protection and workplace technical measures; These should be derived from agreed upon information and knowledge by the government agencies.
- For product SDS – information for customers on how they should handle the material,

Do we have appropriate and valid information?

- Waste management – crucial are impact assessments of the thresholds and limits imposed on industry and waste management facilities in the name of precautionary principle? Are we blocking the circular economy with unreasonable demands in the name of safety, where much wider problems could be solved? Who is responsible for the wider picture and social sustainability?
- For regulatory compliance – who decides which information, measurements and thresholds are relevant for regulatory purposes and who does the quality check of them? Regulatory bodies should not be hostages to the procedures and stick to precautionary principle at all costs just to be sure they will never be to blame.

At the end we think that major users of data are not industrial entities but intermittent stakeholders such as labs and organizations that perform studies for the registration of the substances and the regulatory bodies which prepare the regulations.

What is needed is not better data but agreed upon and updated information and knowledge, building a broader picture, enabling innovation promotion within the reasonable safety frameworks and above all willingness of all stakeholders to build informed decisions based on trust and common goals.

4.3 Andrej Kobe

Please find some quick additions/comments from my side. As said, it was an exploratory meeting, we will grind more concretely as projects start to deliver.

As stated in the report, differences in views between members are expected, appreciated and even actively sought in order to perhaps better pin-down the eventual recommendation. But it is equally important that for providing something coherent ('constructive', as put in one comment), differences would also need to be based in some common data/information/knowledge/understanding, in particular of the existing 'governance' frame (from institutions involved to concepts applied such as precautionary principle or currently discussed innovation principle), nano-specificity, and improvement processes ongoing as we speak.
We should use our experiences but strive to avoid bringing/indulging too many own perceptions, especially about motives of other stakeholders.
E.g., it is hard to entertain notion that public vilifies industry when it is actually the massive consumer of its products and participator as the workforce. Or that public is ignorant and easily misled. On the other hand, excepting that industry has responsibility for how and what it produces is well accepted by whole society including all responsible industry.
And regulation is principally there ensuring that is actually a norm for all industry (and thus deliver result to the whole society). It also corrects for the 'mess' remaining unresolved, arising either from legacy (pollution) and complexity of society as risks/impacts are compounded. We may all differ in assessment of reg's effectiveness and efficiency at any point in time but that is also why it is also always subject to scrutiny and review and managed via public authority to reflect present societal values and abilities. Its weaknesses are expected to be identified and addressed. At these processes we should not look at 'what's in it for me' but what is the optimum solution for the objective it tries to address, judge success based on it, and implement in good faith.
General points that I think can be shared by all? Applies to nano as well.

Reaching a joint understanding of what each (stakeholder/institution) is doing in this field and how a potential new institution/service (the NRGC) can play a role is our common task as I see it – I hope the deliverables of the projects will help us in that task, as at present I am still struggling to find its role.

All of the above is much alongside the message of the last paragraph by Mr. Vrečko – with the possible exception regarding the need for data : I firmly believe it is still in high demand, more and (often) better, also for existing materials/tech; if I am wrong and it's there, than there is something wrong with actually sharing of it. And data will always need to be generated further to underpin 'updated information and knowledge', enabling the innovation to responsibly enter the 'physical domain' via new materials, uses and tech.

And in a lot of cases data will need to be generated using GLP – there are very good reasons for it…

5. Requests from the UC to the NMBP13 projects

- The UC would like to receive biannual progress reports of the NMBP13 projects. It was emphasized that the UC-members prefer a comprehensive executive summary, reflecting clearly the key discussion points, what is foreseen on how these issues will be tackled and the plans that are made for the coming period (of the projects).
  At the same time the UC asks as well *not* to become 'overloaded' with all kind of project-related info or questions. This means that the projects should be restrictive in the amount of information to transfer. Of course, the UC-members have been informed about the existing projects' websites,

where relevant info may be identified as well, and that on their request, the projects will provide any available info to them.

- The UC -members would like to be informed about upcoming events (within the projects) that might be interesting for them. It was emphasized by the organizing team that UC-members are not obliged to attend public events, but are always welcome to join open project meetings, workshops or conferences, but that the provided travel and subsistence costs procedure does not hold for them in those cases.
- The UC is also interested to get feedback about their input from the projects. This is of course a challenge for all projects, and one of the possible ways to comply with this might for example be a separate chapter in the biannual progress reportings.

6. Next meetings

- An attempt in this meeting to already set a date for the 2nd UC meeting failed, but it was agreed that we would send out a doodle early November to find a suitable date. From the inventory made in the meeting, a suitable date for the 2nd meeting might be somewhere in early June 2020. This period was preferred over a meeting after summer holidays.
- For the location there was the urgent request to find a location that does not need a change at the airport. As location it was suggested to organise the meeting in Lisbon (where the partner of the RiskGONE project is located). The third meeting could be organised in Vienna (with the Gov4Nano partner).

Annexes

For the 1st User Committee meeting

(the annexes were already distributed in advance of the UC-meeting)

About the User Committee

For clarity purposes, this document outlines the roles, position and composition of the User Committee (as part of the NMBP 13 NANORIGO, Gov4Nano and RiskGONE projects).
The described principles are yet to be discussed with the User Committee itself on its meeting on 15-16 October 2019.
The User Committee (UC):

1. consists of 12 members from different spheres of society with a particular link to nanotechnology and (exposition to) nanoparticles;
2. consists of members that are evenly spread over (a) science/research, (b) industry/enterprises, (c) regulation/governmental organisations and (d) civil society/non-governmental organisations;
3. consists of persons who speak first and foremost from their own societal role and position, and not necessarily on behalf of a board, management, members or a constituency. Consequently, they do not require anyone's mandate for providing input to the UC;
4. discusses in an open atmosphere on different aspects of risk governance of nanotechnology. It does so without any need of having to convince one another or having to reach agreement or consensus. The UC's strength lies in its openness, its diversity and its room for dissensus;
5. can provide solicited and unsolicited advice to the three projects (which advice is not at all expected to be unanimous);
6. provides inputs during UC meetings that will all (i.e. all different positions taken, and opinions voiced by the UC members) be registered and afterwards documented in the form of written minutes. Minutes will at least reflect the background of the speakers, and, if there is no objection, also their identity;
7. will first receive draft minutes of UC meetings for comments and approval (with a reaction time of two weeks). After that the minutes will become final and will be shared – on a non-confidential basis – with the three project teams;
8. has a semi-independent position to the NMBP13 projects NANORIGO, Gov4Nano and RiskGONE. The UC decides for itself what issues it wants to address and how it wants to operate vis-à-vis the different projects and project teams. Still, the final aim of the UC is to be of relevance to the work of the three projects;
9. provides inputs that are taken into serious consideration by the three project teams. Project teams are not obliged to follow-up on UC members' suggestions and advice, but they will account for their own considerations vis-à-vis the UC members' suggestions and advice;
10. has a lifespan that runs parallel to the three projects (2019 – early 2023). Ideally, in this period the UC has four yearly meetings;
11. consists of members that have *in principle and if possible* accepted to take their positions in the UC for the full period;
12. consists of members that have agreed to participate in (max. 4) yearly UC meetings (including some preparation work). Members are free (but not required) to fulfil a more extensive reflective role to the three projects in line with their UC role after discussion in the UC;
13. is (unless otherwise arranged) fully reimbursed for its travel and subsistence costs for the UC meetings. Working time i.e. salary costs are not reimbursed.

KLB 100915

Annex 2

Presentation about Gov4Nano, NANORIGO and RiskGone

(non-lay-outed version of the power point presentation)

The three NMBP-13 nanotechnology risk governance projects – short overview

Rudolf Reuther, Environmental Assessments, Germany

The three NMBP-13 projects in a nutshell

	Gov4Nano	NANORIGO	RiskGONE
Title	Implementation of Risk Governance: meeting the needs of nanotechnology	Establishing a nanotechnology risk governance framework	Science-based risk governance of nanotechnology
Consortium	32 partners from 13 EU Member States, US, South Korea and South Africa.	28 partners from 14 European countries	22 partners from 15 European countries and 2 non-European countries
EU funding	7,8 mio EUR	4,7 mio EUR	5 mio EUR
Duration	01/01/2019- 28/02/2023	01/01/2019-28/02/2023	01/01/2019-28/02/2023
Coordination	RIVM	AU	NILU

Background

- Nanotechnology impacts a broad range of private and industrial applications
- Significant progress achieved to assess and ensure safety of engineered nanomaterials (EN)

Problem

However, interaction with living systems marked by uncertainties!

Urgent need to develop transparent, transdisciplinary risk governance structures with a clear understanding of risk, especially societal risks and the perception of stakeholders, for consistent management and communication, and transfer of available knowledge into regulation to ensure trust of stakeholders

Perspectives – Solutions?

The European Commission published in 2017 a new Horizon 2020 Call NMBP-13-2018 on Risk Governance of Nanotechnology

- **Risk Governance of nanotechnology (RIA) NMBP-13-2018**
- **Types of action:** Research and Innovation action | **Programme:** Horizon 2020 (Closed)
- ***Opening date:*** *31 October 2017*
- ***Deadline model:*** *two-stage*

Deadline date: *23 January 2018 17:00:00 Brussels time*

Second stage deadline 28 June 2018 17:00:00 Brussels time

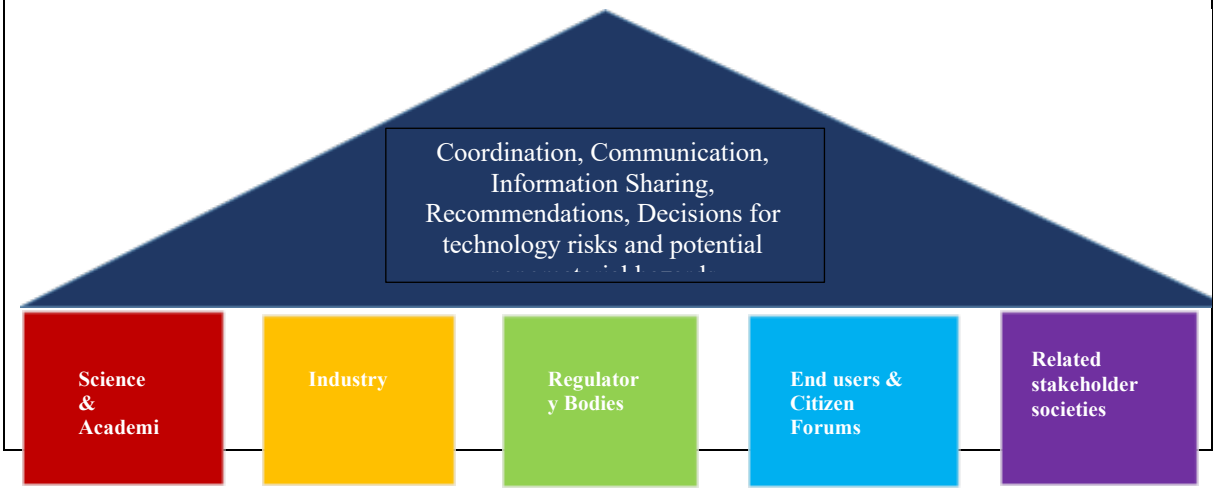
Three large projects came out of this Call, Gov4Nano, NANORIGO and RiskGONE, each receiving funding for a 4-year project starting January 2019

Three projects = one goal!
These three projects share ONE overall objective:

Establishing a Nanotechnology Risk Governance Council (NRGC)

This NRGC should be based on a governance framework or platform integrating the relevant scientific data and tools into a reliable and transparent decision support system serving and reflecting different user and stakeholder needs, perceptions and perspectives

Structure of the multi-stakeholder NRGC



The three projects are committed to cooperate!

- To establish a common transparent, self-sustained and science-based Nanotechnology Risk Governance Council (NRGC) with appropriate core activities, membership conditions, governance structures and funding mechanisms for sustainable operation and interactions with relevant international organisations and regulatory bodies
- To achieve maximum impact, strong knowledge base, broad engagement with all stakeholders and public acceptance

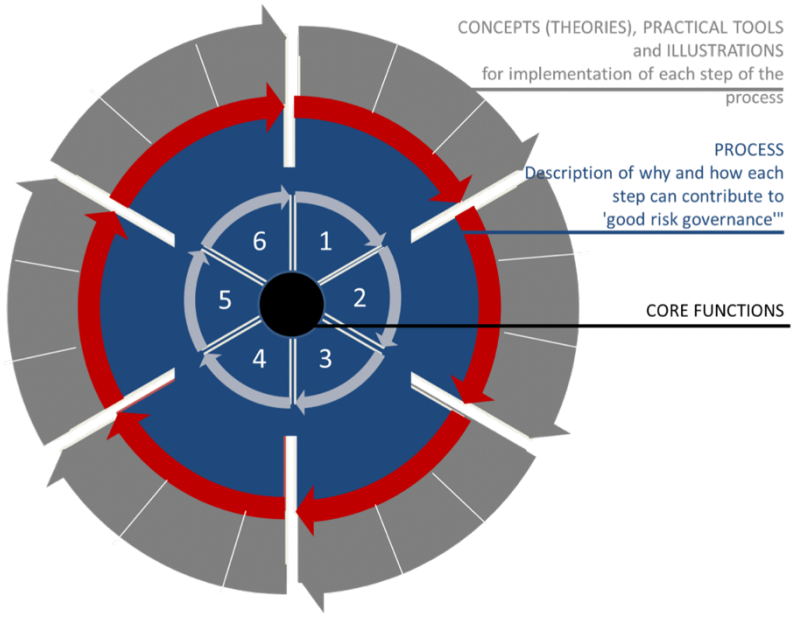
Commonalities and differences

Although the three projects have the same ultimate goal, they use slighly different approaches to complement each other, and use synergies, to be more efficient and save resoures!

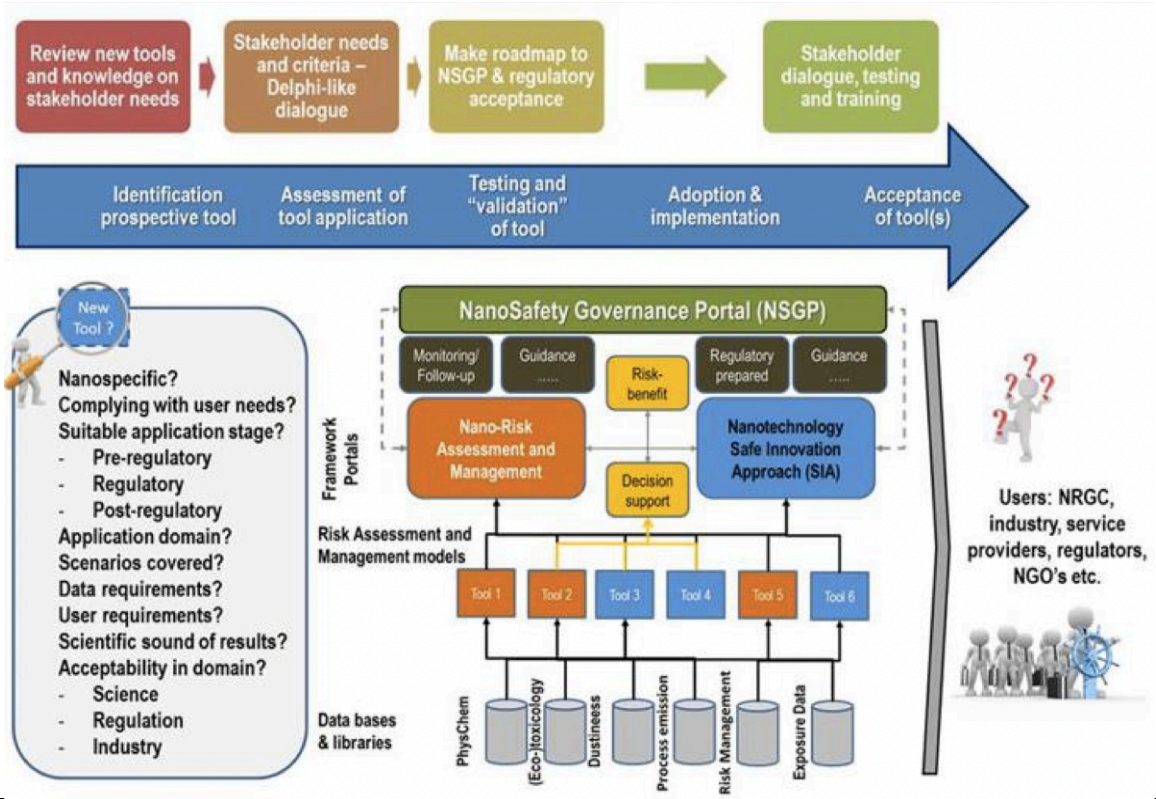
In addition, each project follows some specific objectives, which together reflect the whole spectrum of relevant risk governance issues!

Gov4Nano: strong in regulatory alignment!
NANORIGO: strong in stakeholder engagement!
RiskGONE: strong in technical guidance!

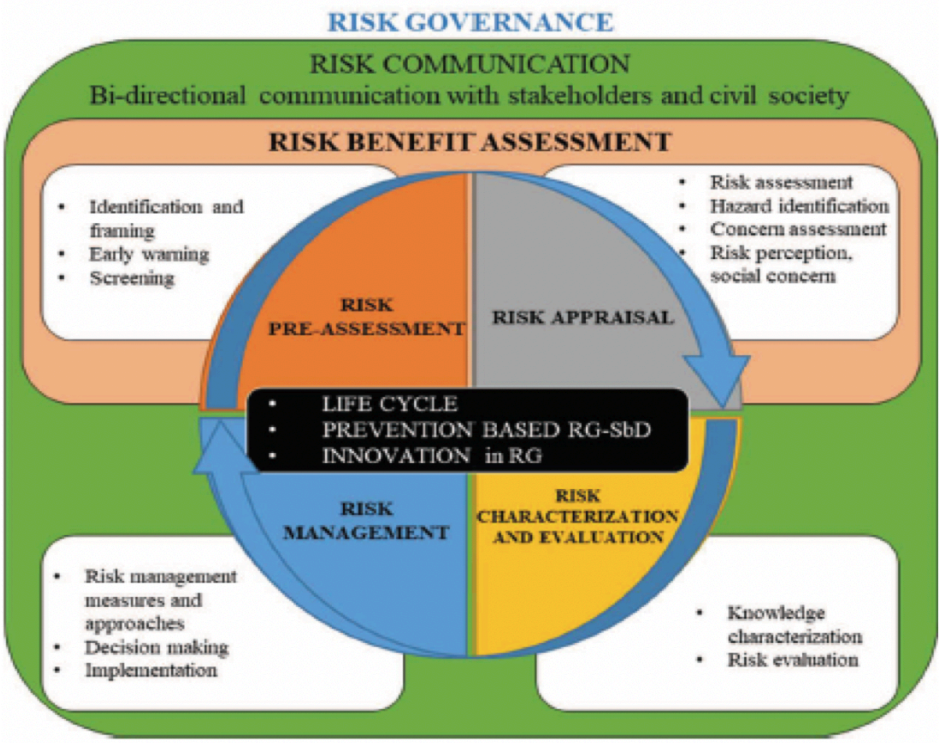
Risk Governance Framework - NANORIGO



Risk Governance Framework – Gov4Nano



Risk Governance Framework – RiskGONE



Goals

Gov4Nano	NANORIGO	RiskGONE
Develop operational transdisciplinary Nano Risk Governance Model (NRGM) based on the IRGC governance framework	Develop science-based transparent, transdisciplinary Risk Governance Framework (RGF) as information and communication platform to ensure good quality data access and clear risk understanding related to social/economic benefits	Establish Risk Governance Framework (RGF) as cloud platform to produce expert opinions and evaluate, optimize, pre-validate and integrate TGs to support method standardization and harmonization
Establish Nano Risk Governance Council (NRGC) to coordinate, guide, harmonize and transfer knowledge, information and needs across various sectors (workers, consumers/environmental safety)	Install self-sustained European Nanotechnology Risk Governance Council (NRGC) embedded in relevant international structures to implement the RGF	Develop transparent, self-sustained Risk Governance Council (RGC) representing stakeholders and EU MS, industry and civil society and acting as science- based governance body based on high quality information
The NRGC uses a self-sustainable NanoSafety Governance Portal (NSGP) as future platform for nanosafety governance with tools to promote dialogues and assess risk perception	The NRGC uses a new risk management approach based on communication with all stakeholders and on high-quality data and advanced scientific tools developed for decision-making	The RGC will incorporate ethical aspects and societal risk perception and manage acceptable and unacceptable risks through transfer or mitigation

Approaches

Define requirements for data harmonization and curation and guidance for handling big data, and build international alliance based on FAIR data	Use of LC perspective and integration of ethical, social, environmental and economic concerns into user-friendly format to be easily adapted and transferred into regulation and risk management	Produce nano-specific guidance documents for RA through "round robins" to improve OECD, ECHA, ISO/CEN guidelines and support the "Malta-initiative" and revision of REACH annexes for nano-substances
Initiate research to support OECD TG for characterization and testing	Case studies to demonstrate RGF and NRGC sustainability of solutions and consistent integration into real regulatory applications	Industry relevant Case studies to demonstrate how RGF and RGC perform on selected EN with known toxicity and economic data (textiles, cosmetics, electronics).
Ensure consistency of science-based RM approaches in EU MS and synergy with similar international actions		

Stakeholder

Establish a representative stakeholder community, and their active involvement in the NRGC to ensure sustainability	Set-up of a User Committee (UC) as operational unit to shape the RGF and guide and ensure the NRGC is credible, objective, transparent and relevant to all different stakeholder groups	Establish mechanisms, tools and strategy for 2-way communication with stakeholders and civil society allowing the RGC to communicate with and receive feedback from stakeholders and the general public
Use dedicated dialogue workshops to create a "trusted environment" and on how risk perception is formed in civil society and insurance industry	UC provides significant (critical) input to the RGF and a format for the NRGC design, and plays a critical role on the outcome of the case study on "Practical experience on the RGF"	The Cloud Platform will serve as a single entry point for stakeholders engaged in the development of SbD or RG of nanomaterials
Building a common stakeholder database		

Nanotechnology Risk Governance Council – short internal survey

Purpose of NRGC
Provide advice to all kind of stakeholders: industry, regulators, policy makers, consumers about risk governance. Develop and publish expert opinions and recommendation for risk assessment, risk management, risk perception
Provide the best possible assessment, regarding the approval/non-approval for introduction of novel (and previous) materials or nano- containing products/applications/techniques on the market.
Reach a position on desirability of specific innovations in nanotechnology, based on a deliberative process involving a broad variety of stakeholders (research, industry, civil society and policy makers) and based on their views of the risks and benefits of the innovation under consideration
Independent entity acting professionally to support safe innovation of materials, support sustainability, circular economy, circular society, green economy, zero waste, and the citizens should trust, the regulators should respect the council
Design of NRGC
All stakeholders groups should be represented so as to have all the different points of views and needs. It should be independent and transparent
Should include the following independent groups, experts – scientists (materials, environmental and human, hazard assessors, risk assessors), the public – users, developers, producers and manufacturers, policy makers
Members of the Council represent their stakeholder groups; positions of the Council based on both 'hard' evidence (toxicological, exposure, economic, social or environmental performance, etc) and broader relevant stakeholder concerns (uncertainty, sustainability, fairness, justice, solidarity, etc.), have to be demonstrably taken into account in market authorizations by regulatory agencies
Should have transparent criteria for decision-making and participation or membership needs to be legitimized by democratic processes in order to assure acceptance (cf. operating rules)

Annex 3

Background document
Additional questions and topics from work package leaders for possible discussion in the 1st User Committee meeting

15-16 October 2019, Utrecht NL

Colophon

Title	Background document; 'Additional questions and topics from work package leaders for possible discussion in the 1st User Committee meeting'
Project	NANORIGO – NanoTechnology Risk Governance Grant Agreement number: 814530
Task Title	T3.1 - User Committee
Activity	1st User Committee meeting 15 – 16 October 2019 Utrecht, Netherlands
Date	September 2019
Authors	Pieter van Broekhuizen [1], Kees Le Blansch [1], Suzanne Resch [2], Dalila Antunes [3] [1] NANORIGO, Bureau KLB - NL [2] Gov4Nano, BioNanoNet - AT [3] RiskGONE, Factor Social - PT
Questions are related to the role and function of the User Committee, the risk governance framework, the risk governance council and the risks related to future developments of nanotechnologies and the relation to other risks, and may play a role in the 1st meeting of the User Committee. The questions were collected in summer 2019 in interviews amongst the Work Package leaders NMBP13 projects, NANORIGO, Gov4Nano and RiskGONE. Also Daan Schuurbiers contributed to the rewriting of the questions.	
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EC Call: NMBP-13-2018, H2020-NMBP-TO-IND-2018-2020

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1. Introduction

This document aims to serve as a background document for the NANORIGO, Gov4Nano and RiskGONE User Committee (UC) meeting at 15 and 16 October in the Netherlands.
Please note that the questions that are listed in this document, are NOT meant to be leading for UC discussions. The prime starting point of the UC discussions in this first meeting is supposed to be in the wishes, requirements and ideas of UC members themselves.
Only in second instance the questions in this document will (or may) be addressed, as possibly useful additional discussion angles to complete the discussion that is already taking place within the UC.
The questions in this document have been raised by work package team leaders of the three projects NANORIGO, Gov4Nano and RiskGONE. These team leaders are already working, with their teams, on their respective work packages. In order to be effective, however, they need to have a clear view on the needs and requirements of future users of their products. For that purpose, they prefer to include a critical view of the UC on these issues and possibly answers to the questions in this document.
Not all questions in this document can and will be discussed at the first UC Meeting. Only those questions will be selected for discussion that (having heard the discussion so far) can add the most value to the exchange of ideas within the UC and to its outcome for the three projects.

2. Risk Governance Framework

Our projects (NMBB13 / NANORIGO, Gov4Nano and RiskGONE) will design a European 'Risk governance framework' for the governance of possible risks of nanotechnologies.

From the project descriptions: The main goal of the projects is:

- to develop and implement a transparent, transdisciplinary and active Risk Governance Framework (RGF) for manufactured nanomaterials (NM) and nano-enabled products (NEP),
- which is embedded in European regulation and legislation,
- based on scientific high-quality data and tools,
- communication and interaction with all stakeholders.
- This RGF will align, integrate, upgrade and transfer the most advanced science-based tools and knowledge on NM physicochemical characterization, exposure and hazard into regulatory human and environmental risk and safety assessment and management.

QUESTIONS:

Overall questions

- What do we need for a successful Nano Risk Governance Framework?
- In an ideal world, what would the Nano Risk Governance Framework look like?

Your needs

- What are your concerns regarding nanomaterials and nanotechnology?
- What information should be considered when assessing nanomaterials use?
- What information would you like to have (i.e. would be useful for you) regarding nanomaterials and nanotechnology so you can make informed decisions on your work?
- How would you like to receive such information (what communication channels)?

Needs and format

- Which needs, interests, concerns, barriers or gaps in current nanotechnology risk assessments do you expect to be addressed by the RGF?
- What format could the UC suggest for the design of the RGF?

Criteria for risk governance tools (see annex 1)

- Which criteria would the User Committee prioritize for the selection of risk governance tools?
  See Annex 1 to this document for examples of criteria that are being used at present.
  Question is, what criteria *matter* to the prospective users of the tools?
  E.g. is simplicity of the tool the main criterion for use of the tool, or is it more important that the tool is comprehensive? What criteria would the tool need to fulfil to achieve regulatory approval? etc.

Experience with risk governance tools

- Are User Committee members experienced in using specific risk governance tools?
  Currently NANORIGO compiles an inventory of risk governance tools. Question is: do UC members use specific tools? If so, what is their experience with the tool?

The Prospective Early Risk Screening Tool

- What does the User Committee expect from a *Prospective Early Risk Screening Tool* (PERST)?
  NANORIGO develops a *PERST,* which is a user-friendly computational tool for the R&D phase of nanotechnologies, which integrates hazard and exposure assessments for new MNMs over the full life cycle, including as well social and economic aspects. Aimed users of the *PERST* are science and industry, but it will also contain elements useful for consultants and insurance companies.

3. Risk Governance Council

Our projects (NMBB13 / NANORIGO, Gov4Nano and RiskGONE) will design a European 'Council' for the governance of possible risks of nanotechnologies.

From the project descriptions: The projects will establish a self-sustained Nano-Risk Governance Council (NRGC) that will:

- Operate the Risk Governance Framework ensuring design, manufacturing, economic, social and environmental compliance and sustainability.
- Enhance current risk communication and take into account stakeholder and societal risk perception and acceptance, ensuring involvement of the product value chains and circular economy.
- Implement mechanisms to monitor progress in key industrial areas.
- Increase availability of high-quality data for stakeholder information and decision making.
- Ensure the councils' transparency and globally acceptance.

QUESTIONS:

Overall questions

- Why do we need a Nano Risk Governance Council (NRGC)? What is the purpose of the NRGC?
- What are the potential benefits of having a NRGC?
- What are potential shortcomings of the NRGC? (pains vs. gains)
- What do we need for a successful NRGC?
- In an ideal world, how would the NRGC look like?

Role and remit of the Council

- What should be the role of a NRGC?
- And what about the remit of the Council? Is it advice, opinion, recommendations, direct input to policy/regulations? What should its mission and vision be? Who decides what topics are assessed?

Priorities for the Council

- What should, to your opinion the main priorities for the Council be?

Structure of the Council

- What is your opinion about the desired structure of the NRGC, in terms of its size and composition, permanent vs ad hoc experts, how it is funded, how it is governed?

Legitimacy of the Council.

- Would the NRGC have to be formally recognized? If so by whom – EC, national governments, civil society, industry, etc.? Should it be independent or integrated within an existing agency, such as ECHA, EFSA, EMA?
- What elements in terms of concepts, expertise and composition will be essential to make the NRGC credible and objective and at the same time transparent and relevant for all stakeholders?
- How should the NRGC interact with different stakeholder groups and what should be delivered to them?
- How can different stakeholder needs and expectations be effectively met and harmonized by the NRGC?

Integration of the Council.

- How should the NRGC include different stakeholder groups and how should it balance hard facts with societal beliefs/sentiments that are difficult to quantify but equally valid?
- How and who should obtain whose commitment (time, political support and funding) for founding and sustainability of the NRGC beyond the project?

4. Future of nanotechnologies and relation to other risks

Future of nanotechnologies and the involvement stakeholders

- Future nanotechnologies might be characterized (but not necessarily so) by a need for a paradigm shift in risk assessment approaches. The actual hazard and exposure driven risk assessment approach for concrete particulate nanomaterials may have to be translated in an assessment of system changes for which new risk parameters should be defined. In your view, does this change aspects of stakeholders' involvement, for what objective, and how?

  In the (near) future, in some cases this is happening already today, nanotechnologies will converge with other technologies such as biology, neuro-technology, information technology. This will evolve in complex systems focused on providing services and functions, rather than in the manufacturing of single materials. As such it will be difficult to identify the specific contribution of the various individual technologies to the end product (if possible and relevant at all), and consequently accompanying risk assessment tools or regulatory frameworks may be insufficient and may have to be adapted.

- What future societal challenges and opportunities does the UC see that must be identified and met by the NRGC, also in relation to other non-nanotechnology challenges and opportunities?

Other risks and risk approaches

- What is the relative importance of the risks of nanotechnology when compared to other risks (in particular cases)?

  For nanotechnologies risk research and policies, the primary focus is on the risks of nanomaterials. At the same time, risks as those associated with exposure to hazardous chemicals, or ultrafine dusts (UFPs) may be more urgent and may be of higher strategic importance. I.e. nanotechnologies' risk research may be limited to a dominating innovation scope, while risk research focused on the practical use of nanoproducts should primarily deal with actual occupational and environmental particulate exposures and be related to other non-MNM exposures.
  Therefore, it is good to also allow for a more relative perspective, and to discuss with the UC the relative importance of the risks of nanotechnologies.

- How can we define acceptable risks of nanotechnologies against their benefits and integrate even other risks/benefits not derived from nanotechnologies into future risk governance?
- What are the experiences of the UC to improve risk awareness, perception and acceptance among different stakeholders beyond the regulatory approach?

5. Stakeholders

Engagement stakeholders

- In your view, is the engagement of stakeholders in the process towards <u>decisions</u> about nanotechnology governance satisfactory?

  This may include decisions about hazard and risks assessment, risk management and risk communication

  If not, what are the gaps? What objectives are not met?
- If the three projects are to carry out case studies, which stakeholders should definitely be involved i.e. must not be forgotten? What interest are at stake? Should other stakeholders be involved? Should other interests be taken into account?

  To be acceptable as case study they must address the actual concerns and interests. Next to the interests of industry, probably also interests of workers, consumers and the environment must be addressed. For the case study aiming at underwriters and the insurance sector, it should be questioned who the real beneficiary is.
  An overarching question relates to handling conflicting interests, such as balancing economical activities against environmental conservation.
- What is required from main stakeholders to agree on and apply a more holistic and balanced view and approach, that includes all relevant concerns (economic, social, environmental, ethical, legal), and so avoids and overcomes possible conflicting situations?
- What is needed to develop a broad and balanced consensus among stakeholders to see these aspects as equally important for future innovation?

Annex 1: criteria for the selection/appreciation of risk governance tools

What do we see as 'risk governance tools'?
We include risk and sustainability assessment tools: human (HRA) and environmental (ERA) risk assessment tools, LCA; tools/approaches to deal with lack of data: categorisation/grouping and computational models: QSAR, QNAR, etc.

Below is a list of actual/possible criteria for the selection/appreciation of risk governance tools:

- Availability of the model
- Scientific and regulatory approval of the model
- Availability of guidance
- Cost to calculate and input of all required parameters into the model
- Time running the model
- Level of (required) expertise
- Transparency
- Quality assessment/rating of input data included
- Possibility of adding/changing data as they become available. Easy adaptation of the tool
- Product life cycle perspective: synthesis production, transport, use, end of life
- Number and complexity of input parameters
- Applicability for various NMs and product types
- Possibility of comparing NMs with bulk
- Nanospecific
- Hazard data: kinetic endpoints, in vitro endpoints, in vivo endpoints, exposure duration, exposure routes
- Exposure criteria: inclusion of non-intentional use, aggregated exposures, populations included (workers, consumer, children, elderly, pregnant), exposure estimate (average dose, peak doses, concentrations)
- Spatially resolved by area, from a general or local perspective
- Requires product specific information
- Requires application specific information
- Predicts concentrations in freshwater, sediment, air, soil
- Supports persistent, bioaccumulative, toxic criteria (PBT)
- Presents comparisons of PECs and PNECs
- Include parameters that are required during registrations of NFs: size distribution, shape, surface treatment and functionalization, specific surface area.
- Express these parameters in the same units/categories suggested by the ECHA guidance
- Modelled endpoint. A well-defined endpoint has been modelled
- Database size. Dataset size is highlighted together with the original reference
- Modelling approach. Adopted model/method and descriptors have been reported
- Model validation. Both internal and external validation have been performed
- Statistics and metrics. Proper statistic and metrics have been used
- Applicability; Domain assessment has been performed
- Uncertainty and variability have been assessed
- Model interpretation. A mechanistic interpretation has been provided

Annex 4

Risk Governance cases

User Committee meeting 15-16 October 2019

Please note:

- *The case descriptions below are meant to trigger response and discussion. They are not (meant to be) realistic.*
- *Please avoid discussions on definitions and interpretations of these case descriptions. If necessary, make your own assumptions to obtain a workable case.*
- *Please feel free to invent and add extra features to make cases even more challenging*
- *The questions below should be understood as hinting at risk governance issues (and risk governance framework and/or council issues)*
- *Please pick – within your discussion group – the (three?) cases that trigger you the most*

Question:

Imagine …. that as part of your work (or your role, or in the place of those you represent), you are confronted with the following situation(s). We ask you:

- What are your *main concerns?* (if at all)
- *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)
- *Who* (which organization or institution) *would you wish to address* with your concerns? (if at all relevant)

Case 1

Imagine …
A company with 150 personnel that is located on a business park near a major city, intends to start manufacturing nano-TiO2 containing paints, for external construction wall applications.

Case 2

Imagine …
A company with 150 personnel that is located on a business park near a major city, intends to start manufacturing paints containing carbo-nanotubes (CNTs) for conductive properties, e.g. electrically conductive paints, to be used with solar panel applications on houses.

Case 3

Imagine …
Advanced measurements in the vicinity of some highways and main roads within the EU (including urban and nature-conservation areas and worksites of road maintenance workers) have shown the presence of large quantities of ultrafine particles (UFPs) including nanotube-shaped wear particles of rubber tyres.

Case 4

Imagine …
A 3D printing machine in a higher education institution only uses 'conventional' (non-nano) chemical substances, but nevertheless proves to generate high concentrations of process-generated nanoparticles (PGNPs).

Case 5

Imagine …
Using different advanced techniques including nanotechnology, scientists have succeeded in reproducing and multiplying slightly modified human brain cells on a membrane (fully apart from a human and its brain) and to connect these cells through nano-electrodes with huge data processors. First basic impulses and reactions have been exchanged between brain cells and data processor (both ways). A major scientific breakthrough is expected, with the possibility of creating an artificial, more or less autonomous 'identity' or 'self' for the first time.

Case 6

Imagine …
A revolutionary new cell phone is introduced that has been developed in all secrecy by a Russian- Chinese consortium. It is revolutionary in three ways: (1) the cell phone is very small (it fits on an earring) and applies nanotechnologies that were so far unheard of; (2) its components (and the components of its components) are produced in small workshops throughout the world, close to where the scarce metals that are applied are mined, and are afterwards assembled in 'closed' Russian and Chinese cities; (3) due to this mode of production, the total production costs (in dollars) are so low that in case of malfunction the cell phone can just be discarded (i.e. is waste). Repair will always cost more money than buying a new one.

Case 7

Imagine …
Punjabi engineers have invented a nano food additive that radically breaks down gluten in food. The Inventors claim this will unburden the lives of all Coeliac patients around the world. They promise that within half a year they will make the new additive directly available to whomever wants it via a direct mail order platform on the internet.

Case 8

Imagine …
The French government is pushing the European Commission to issue a ban on nano TiO2, not just for food but for all applications. The Commission appears to be seriously considering this option. The European Parliament invites you to speak at a public hearing about this possible ban.

Case 9

Imagine …
After a couple of incidents the European Commission issues a new regulation that only allows the use of 'new' nano particles in R&D activities after submission (to ECHA) of a full risk assessment report of these new nano particles ('new' meaning: not already registered in one of the Nano Registries that exist in some EU Member States).

Case 10

Imagine ...
As a main outcome of the three NMBP-13 risk governance projects, Gov4Nano, RiskGONE and NANORIGO, a self-sustained and independent European Nanotechnology Risk Governance Council (NRGC) has been established that will be run by an international panel of experts representing main stakeholders and EU Member States. However, due to national and international priorities, the NRGC faces difficulties during the start phase to match existing regulatory, socio-economic and ethical structures in Europe and market challenges, especially related to the harmonization of rules and the classification of new advanced materials with highly complex, cross-sectoral and combined functionalities.
Consequently, within the EU there is unclarity about the applicability and interpretations of rules, standards and norms.

Case 11

Imagine …
…. a case that you would like to bring in yourself?