

Integrating societal considerations in nanotechnology risk governance

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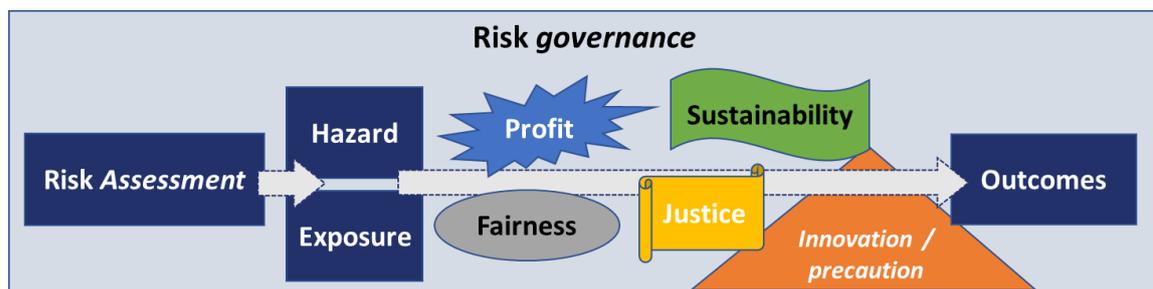
In this presentation I will argue that the effective integration of societal considerations, or ‘other concerns’, as they have been called in the NANORIGO project, is an essential condition for the success of the nanotechnology risk governance framework that is currently being developed by the three projects funded under the NMBP-13 call on risk governance in nanotechnology ([NANORIGO](#), [GOV4NANO](#) and [RISKGONE](#)).

To understand the reason why ‘other concerns’ matter to risk governance, I would like to go back to the original call text from the European Commission that gave rise to the NMBP-13 proposals, which says:

“Significant progress has been achieved in relation to research regarding the safety of engineered nanomaterials and the transfer of this knowledge into regulation. Still, more needs to be done as nanotechnology reaches the market. To fill this gap, transdisciplinary risk governance is required based on a clear understanding of risk, its management practices and the societal risk perception by all stakeholders.”¹

There are a few important observations that can be gleaned from the text:

1. The Commission considers that risk governance includes *more* than understanding the risk of engineered nanomaterials;
2. It sees risk governance as a *transdisciplinary* endeavour;
3. It recognizes the relevance of the risk perceptions of all stakeholders for risk governance.



So the image that emerges looks something like this: we’ve made a lot of progress on risk assessment of engineered nanomaterials in the last 15 years or so, assessing potential hazards and exposure pathways. But as nanomaterials reach the market, we find that the actual, quantifiable risks are only one consideration among many that determine the use of nanomaterials. Other considerations like profitability, sustainability, fairness or justice

¹ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/nmbp-13-2018>

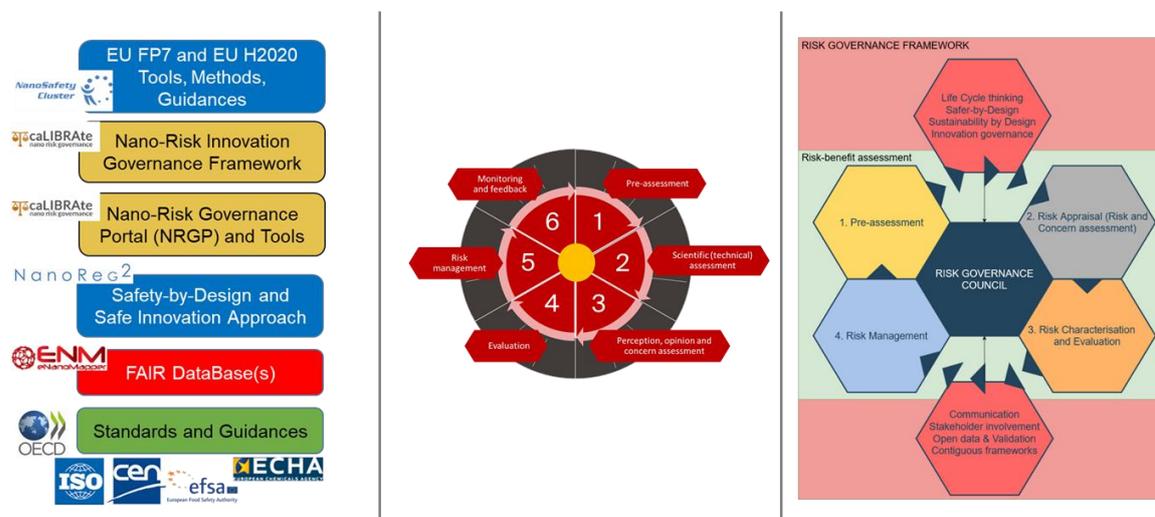
play equally, if not more important roles in determining the uptake and impact of nanomaterials in society. In other words: *risk assessment* is a scientific activity, but *risk governance* is a social process. To understand how society responds to new technologies, we must broaden the horizon of risk governance. Johanne Patenaude, a Canadian medical ethicist, has suggested that:

“There must be a shift in our approach to risk governance. Not only the toxicological impacts of nanotechnologies must be considered but also the social impacts of the various uses of nanoproducts. Moreover, such a shift also implies re-examining the role of values and value judgements in the process of ethical assessment and understanding how they operate in decision-making. Finally, it challenges democratic societies to open up to public debate the social choices involved in developing a specific technology.”²

Developing a technology is a *social choice*, and those choices are determined by *values* – and different stakeholders hold different values. And the whole process of risk governance is about making choices based on the consideration of all these different values.

So the million-dollar question for the three risk governance projects funded under the NMBP-13 call for proposals is: how on earth do we integrate all those different values from all those different stakeholders in a Risk Governance Framework, as a basis for our social choices to promote or regulate nanotechnologies?

How (on earth) to address ‘other concerns’ in the Risk Governance Framework(s)?



I argue that *this question* constitutes the truly innovative contribution that the NMBP-13 projects have to offer. This is not to downplay the complexity of all the challenges around hazard and exposure assessment, life cycle, environmental and social impact assessments, data quality, interoperability, FAIRness and so on. These questions are difficult enough as it is – let alone collaborating with more than 80 partners. And yet I insist that beyond all

² Patenaude, J., Legault, G., Beauvais, J., Bernier, L., Béland, J., Boissy, P., . . . Tapin, D. (2015). Framework for the Analysis of Nanotechnologies' Impacts and Ethical Acceptability: Basis of an Interdisciplinary Approach to Assessing Novel Technologies. *Science and Engineering Ethics*, 21(2), 293-315.

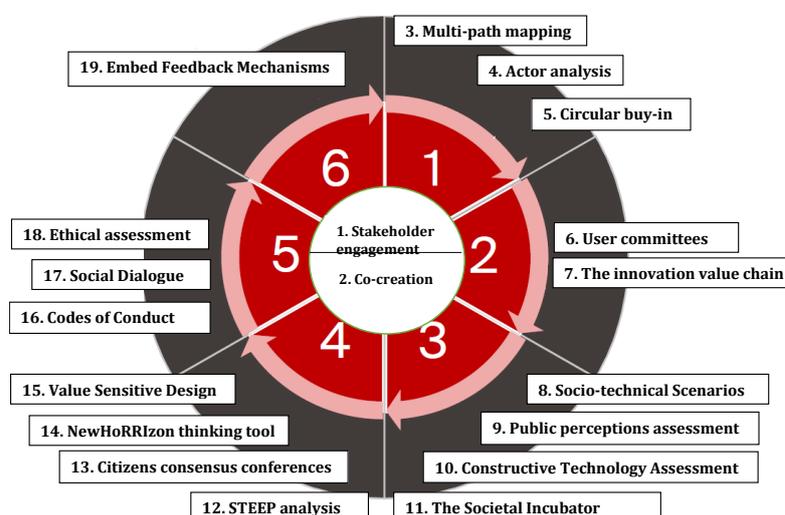
the scientific challenges, the question of the social organisation of the risk governance framework is the fundamental challenge.

The sobering conclusion is that what we need doesn't exist yet. Despite the importance of integrating societal considerations in risk governance, a recent literature review by NANORIGO on tools to integrate societal considerations suggests that we still have a long way to go. We haven't succeeded yet in linking quantifiable evidence on risk with inherently qualitative societal concerns - yet that is precisely what we need to become better at if we want to govern nanotechnologies.

What we've seen in the biotech area (in Europe at least), is that if societal concerns are not channelled through effective institutional arrangements, the result is what you might call 'governance by brute force': public resistance results in outright banning or blocking of the technology. We must do better in nanotechnologies.

That is exactly why the current work on a Risk Governance Framework and Council in NMBP-13 is so endlessly fascinating. This is an opportunity to build a better governance framework that doesn't repeat the errors from the past. But it requires truly innovative thinking, a willingness from all actors to get out of their comfort zone, and deep institutional change – and none of these are easy.

As a first step towards finding what solutions might work to integrate societal considerations in the risk governance framework, the NANORIGO project is currently reviewing existing tools, and mapping them onto the framework.



We are also looking into some intriguing examples from the biotech area that we might learn from. The Dutch [Committee on Genetic Modification](#) has developed building blocks for an assessment framework for the cultivation of genetically modified crops. This framework considers several dimensions of new biotechnologies, including safety, economic considerations, environmental impact, and broader social values like cultural heritage and freedom of choice. This will need to be translated to the area of

nanomaterials, but it could be a useful starting point to think about how to address the seeming incommensurability of quantifiable scientific data and inherently qualitative social concerns.



Building blocks for an assessment framework for the cultivation of genetically modified crops

TABLE 1: INTEGRATION OF COGEM 2009 BUILDING BLOCKS WITH NATIONAL CULTIVATION PROPOSAL GROUNDS

Building blocks COGEM 2009	National cultivation proposal grounds	Non-exhaustive list of components
1. Benefit to society*		*Overarching: found in one or more of the other building blocks
2. Economy and prosperity	Socio-economic Agricultural policy objectives	<input type="checkbox"/> employment <input type="checkbox"/> efficiency of production processes <input type="checkbox"/> productivity <input type="checkbox"/> income <input type="checkbox"/> competitive position <input type="checkbox"/> export (balance of trade) <input type="checkbox"/> damage to reputation <input type="checkbox"/> Intellectual Property Rights (IPR)
3. Health and welfare	Socio-economic	<input checked="" type="checkbox"/> human rights <input checked="" type="checkbox"/> working conditions <input checked="" type="checkbox"/> employment terms <input type="checkbox"/> recreation <input checked="" type="checkbox"/> food quality
4. Food supply & food security	Agricultural policy objectives	<input type="checkbox"/> ecological footprint
5. Cultural heritage	Spatial (town and country) planning Land use	<input type="checkbox"/> landscape changes <input type="checkbox"/> changes in land use
		6. Freedom of choice & co-existence
		Preventing cross-breeding Agricultural policy objectives
		<input checked="" type="checkbox"/> consumer freedom of choice: labelling <input checked="" type="checkbox"/> manufacturers' freedom of choice: co-existence <input type="checkbox"/> damage to reputation/conflicts <input type="checkbox"/> regional food production
		7. Safety
		<input checked="" type="checkbox"/> food and environmental safety
		8. Biodiversity
		Environmental policy objectives Agricultural policy objectives
		<input type="checkbox"/> agrobiodiversity <input checked="" type="checkbox"/> protection of biodiversity
		9. Environmental quality
		Environmental policy objectives Agricultural policy objectives
		<input type="checkbox"/> energy consumption <input type="checkbox"/> emission of hazardous substances to soil, surface waters and atmosphere <input type="checkbox"/> soil fertility, and resilience <input type="checkbox"/> Integrated Pest Management (IPM)
		Public policy*
		*Overarching: together with one of the other grounds

Covered by legislation and regulations in force
 Partly covered by legislation and regulations in force

The forward-looking regulatory framework for Genetically Modified Organisms, GMOs, from the [Norwegian Biotechnology Advisory Board](#) offers another example.

This framework proposes assessment of GMOs based on the judgement of an expert committee on the extent to which a GMO is ethically sound, is beneficial to society and contributes to sustainable development:

1. If a GMO has strong ethical justifiability, it will go through expedited risk assessment
2. If a GMO has moderate ethical justifiability, it will go through standard risk assessment (current Norwegian system)
3. If a GMO has a weak ethical justifiability, it will not go through risk assessment (the application is denied)³



Bioteknologirådet

A forward-looking regulatory framework for GMO

Example of principles for differentiation based on genetic change: a three-tiered system

Level 0 (exempted)	
Temporary and simultaneously non-heritable changes	
Level 1 Changes that exist or can arise naturally, and can be achieved using conventional breeding methods.	Obligation to notify (confirmation of receipt required)
Level 2 Other species-specific genetic changes	Expedited assessment and approval
Level 3 Genetic changes that crosses species barriers or involve synthetic (artificial) DNA-sequences.	Standard assessment and approval (current system)

Covered by the Gene Technology Act

Contribution to societal benefit, sustainability and ethics required at levels 1-3

³ Many thanks to NANORIGO-partner Kees Le Blansch ([Bureau KLB](#)) for suggesting these examples.

To conclude: as you all know, the answer to the Ultimate Question of Life, the Universe and Everything is 42. This answer was calculated by the supercomputer Deep Thought after seven and a half million years of thought. And this led to the construction of an even larger supercomputer, named Earth, which was tasked with determining what the question was in the first place.

The reason I'm paraphrasing Douglas Adams's [Hitchhikers Guide to the Galaxy](#) is that we will never be able to quantitatively weigh scientific risks against societal impacts: risk governance – making choices on the development of nanotechnologies based on the consideration of social values - has to be the result of a process of *deliberation*, not calculation.



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