MAKING A DIFFERENCE?

NANOTECHNOLOGY AND THE QUEST FOR RESPONSIBLE INNOVATION

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Publiekssamenvatting

Wat is het probleem?
Aan het begin van deze eeuw investeerden veel landen massaal in nanotechnologie. Nanotechnologie gaat over het veranderen van materiaaleigenschappen op moleculair of zelfs atomair niveau. Daar kunnen fantastische dingen mee gedaan worden en de beloften voor nuttige toepassingen zijn groot, zoals nieuwe medicijnen of vervangers voor zeldzame grondstoffen. Maar er waren ook grote zorgen. Bijvoorbeeld over de veiligheid van nanomaterialen, maar ook over de mogelijkheid om onze hersenen aan het internet te kunnen koppelen. Is het veilig? Willen we dit? Wie wint en wie verliest?

In het publieke en politieke debat over deze vragen werd een nieuwe term geïntroduceerd: Responsible Innovation, in het Nederlands: verantwoord innoveren. De achterliggende gedachte is dat voor het goed en tijdig rekening houden met maatschappelijke gevolgen van wetenschap en technologie, de manier waarop wetenschap is georganiseerd en technologie wordt ontwikkeld zélf moet veranderen. De afgelopen twintig jaar zijn er dan ook veel activiteiten ontplooid onder de vlag van Responsible Innovation. Maar tot grootschalige verandering lijkt dit nog niet te leiden.

Dit proefschrift buigt zich over de vraag hoe een algemeen begrip als Responsible Innovation, waar niemand op tegen is en iedereen toch verschillend over denkt, richting kan geven aan de manier waarop wetenschappelijk onderzoek en technologische innovatie worden gestimuleerd. En hoe daarbij van losse activiteiten toegewerkt kan worden naar brede verandering.

Hoe heb ik het aangepakt?
Als eerste heb ik een onderzoeksmodel ontwikkeld dat helpt om de nieuwe ideeën over verantwoordelijkheid in de discussie over Responsible Innovation te begrijpen vanuit historisch en sociologisch perspectief. Wie en wat zit er achter het begrip en voor welke problemen moet het een oplossing bieden? Het model biedt ook een manier om te onderzoeken hoe die nieuwe ideeën hun weg vinden in bestaande organisaties en netwerken. Zo heb ik gekeken naar de manier waarop overheid, wetenschap, bedrijven en andere belanghebbenden samen moeten werken om mogelijke risico's van nanomaterialen voor gezondheid en milieu te voorkomen. Ook heb ik onderzocht hoe in grootschalige onderzoeksprogramma's op het gebied van nanotechnologie is geprobeerd om rekening te houden met maatschappelijke vraagstukken.

Een tweede bijdrage van dit proefschrift is de manier waarop ik dit heb onderzocht. In de aanpak die ik heb gevolgd staat het begrip transformatie centraal. Dit begrip wordt gebruikt om aan te geven dat onderzoek en innovatie niet zomaar moeten veranderen, maar radicaal. Maar het begrip transformatie drukt ook uit dat verandering geleidelijk gaat. Het nieuwe moet in en uit het oude groeien. En dat is bij Responsible Innovation extra ingewikkeld, want juist de oude manieren waarop over verantwoordelijkheid in onderzoek en innovatie wordt nagedacht geven bestaansrecht aan wat onderzoekers, ontwikkelaars en hun organisaties op dat gebied doen. Het onderzoek in dit proefschrift richt zich precies op dit soort spanningen.

Wat is er onderzocht?

Het onderzoek telt vier casestudies, twee in Nederland en twee in de Verenigde Staten. De eerste Nederlandse casus gaat over vier pilotprojecten waarin werd geëxperimenteerd met de samenwerking tussen overheid, werkgeversorganisaties en vakbonden. Het doel was hierbij om voorzorgsmaatregelen te ontwikkelen voor het veilig gebruik van nanomaterialen. De andere Nederlandse casus gaat over het onderzoeks- en innovatieprogramma NanoNextNL. Hierin werd een groot deel van het budget vrijgemaakt voor onderzoek naar mogelijke risico's en andere maatschappelijke vraagstukken rond nanotechnologie. De uitdaging in deze casus was om inzichten uit dit onderzoek te integreren in het nanotechnologie-onderzoek.

Voor de eerste casestudie in de VS heb ik gekeken hoe overheidsorganisaties informatie van bedrijven wilden verkrijgen over het gebruik van nanomaterialen en hoe ze in het onderzoeksprogramma National Nanotechnology Initiative (NNI) samen hebben gewerkt om de risico's van nanomaterialen te onderzoeken. De tweede casestudie gaat over een centrum voor 'nanotechnologie in de samenleving' en hoe dit centrum heeft geprobeerd bewustzijn over de maatschappelijke gevolgen van nanotechnologie te stimuleren binnen het NNI.

Wat zijn de conclusies?

Uit alle vier de casestudies blijkt dat de nieuwe ideeën over verantwoordelijkheid maar beperkt ingang hebben gevonden. Dat is op zich niet verwonderlijk, want daarvoor waren de onderzochte activiteiten in de casestudies te veel afhankelijk van hoe er in het algemeen met vragen over veiligheid in het algemeen wordt omgegaan; of in de manier waarop onderzoeksprogramma's worden georganiseerd. Wat het onderzoek echter duidelijk maakt is dat deze situatie in stand wordt gehouden door de manier waarop de betrokken partijen zowel individueel als gezamenlijk onvoldoende leren om kritische factoren te herkennen en te ondervangen.

Als gevolg hiervan bleven de aanpak en uitkomsten van de activiteiten die zich richtten op de veiligheid van nanomaterialen te veel afhankelijk van onzekerheden over die veiligheid, terwijl juist die onzekerheden geadresseerd moesten worden. De vergelijking tussen de initiatieven in NanoNextNL en in het NNI laten de sterktes en zwaktes zien van de aanpak die in beide onderzoeksprogramma's is gevolgd. NanoNextNL kende een programmabrede structuur voor de integratie van het onderzoek naar mogelijke risico's en andere maatschappelijke gevolgen, maar dezelfde brede structuur zorgde ook voor versnippering in de aanpak van die integratie. Het centrum dat is onderzocht in het NNI kon wel een duidelijke koers uitzetten, maar miste de middelen om de integratie van dat onderzoek over de breedte van het NNI-programma te bewerkstelligen.

De uitdaging voor dit proefschrift is om ook oplossingsrichtingen aan te dragen voor de geconstateerde problemen. De aanpak die is ontwikkeld in dit proefschrift heeft een beter begrip opgeleverd van de wijze waarop bestaande manieren van denken en opvattingen over de invulling van verantwoordelijkheid van invloed zijn op hoe partijen zich tot elkaar verhouden. Vervolgens laat dit proefschrift zien hoe deze denkwijzen en opvattingen kunnen worden doorbroken. In de casestudies over de veiligheid van nanomaterialen waren overheden meer zelf partij in het spel, dan dat ze boven de partijen konden staan. In deze situaties kan de rol van het parlement als controlerende macht versterkt worden. In onderzoeksprogramma's, zoals NanoNextNL en het NNI, kan onderzoek naar maatschappelijke gevolgen beter worden geïntegreerd, als de manier waarop dat onderzoek wordt georganiseerd onderdeel is van leren en evalueren van het programmamanagement. In het proefschrift werk ik uit hoe deze oplossingsrichtingen concreet vorm kunnen krijgen.

Part I – Problem and Approach

1. Introduction

1.1 Responsible Innovation – what's the problem and how to approach it?

Is there a need for Responsible Innovation? The question has been asked ever since the notion has been introduced. Not so much about the need for responsible innovation – lower case, but for Responsible Innovation – capital: Responsible Innovation as a *guiding idea*. As for 'responsible innovation' the argument seems clear. Normally, claims about innovation have a positive ring. Innovation is about making new things, or about making things better. But introducing new things can also have unintended consequences, or reinforce unsustainable behaviour. Such is the case in discussions about Responsible Innovation, where innovation refers to science, technology and their applications, ranging from the development of new fields, such as biotechnology or nanotechnology, to particular products and services, such as electric vehicles, or total-body-scans. Typically, these developments come along with promises for progress as well as concerns about problems. Nanotechnology promises miracle materials and smart electronics all over the place, but also raises concerns about the safety of these materials or the potential surveillance infrastructure that is enabled by the same electronics. Battery electric vehicles promise a dramatic decrease of polluting emissions, provided they are charged in a sustainable way, but also require extensive mining of materials in countries which do not profit automatically on equal rate. Total-body-scans promise early detection of diseases, but also pose tricky questions about accuracy and further commercialisation of a health-culture. Etcetera.

That science and technology can have both positive and negative consequences is already widely acknowledged. What 'Responsible Innovation' adds to this, is that we still have to do better in anticipating consequences, including society in research and innovation and in directing these more consciously towards serving societal needs and challenges. However, after two decades of discussions about the concept and experiments in practice, local change in the way research and innovation are being performed has been reported, but broader, systemic change still seems far away (Owen, von Schomberg et al. 2021, Griessler, Braun et al. 2023). Consequently, calls have been made to 'reinvent' Responsible Innovation (Fisher 2020, van Oudheusden and Shelley-Egan 2021).

This thesis engages with the quest for Responsible Innovation and the challenge of making a difference beyond local efforts and activities. I will do so by approaching the quest for Responsible Innovation from two ends: on the one hand I will argue that efforts for transforming responsibility in research and innovation have to move beyond the specific debate about the *concept* of Responsible Innovation. As the quest for

Responsible Innovation builds on wider trends in the evolution of social accountability in research and innovation, the challenges in it are emblematic for a much larger set of ideas, policies and practices striving to address societal needs and challenges by science and technology. Responsible Innovation supports the still modern[1] belief that if we make a genuine attempt to do *better* and if we work *together* in doing so, we will be able to create sustainable prosperity for all. I will show that the new responsibility conceptions advocated under the heading of Responsible Innovation are not so new at all and yet still have to take root in existing responsibility distributions. Making a difference with Responsible Innovation, therefore, is about guiding processes of transformation rather than crafting new responsibilities or institutional structures on top of existing ones.

On the other hand I will empirically explore how transformative change can be pursued in concrete settings. After all, to change a system, one needs to understand it. The vantage point taken in this thesis is that all kind of barriers identified as hampering change, should not be treated as obstacles to overcome in the first place, but as the very thing to work with, since they represent various kind of logics and credibility cycles in research and innovation. The added value of this approach is that it enables reflexive feedback to actors in the field. Instead of throwing new concepts and frameworks to the actual challenges they are concerned with, I will make an effort to construct pathways for broader transformation in the particular settings studied.

What's the problem?

To become a guiding idea for steering research and innovation, Responsible Innovation has to be more than just a phrase. It has to become part of the vocabulary in science and technology development, pursued by policies, captured in definitions and operationalised with instruments. This presents a first challenge. 'Science and technology', 'or research and innovation' encompass a broad range of activities, organisations, markets, regulations and networks. What is responsible, then will be differently valued for an emerging field of science and technology, like nanotechnology, or for a specific service, like a total-body-scan. Moreover, it raises the question of organising responsibility: what is to be done, by whom and what can be considered responsible in the end?

A second challenge is that there are already manifold ways in which research and innovation are being directed in relation to societal goals and values. Think of safety regulations, prioritisation in research funding, ethical reviews, policies for stimulating

[1] Allusion to Latour's (1993) claim that "we have never been modern". According to Latour the modern (and largely Western) project of thinking nature and culture, or science and society, as belonging to different spheres, is non-sensical. Hence, his suggestion is to completely rethink our relation with facts and objects. While I do acknowledge that ideals come with (dominant) ideas, my attempt to rethink the quest for Responsible Innovation concerns a very practical, yet fundamental first question: how to put up for discussion ideas about responsible innovation in settings where modern ideas prevail?

gender equity, transparency measures, stakeholder and public dialog forums, sustainability goals and more. As a result, the quest for responsible innovation – lower case – as well as for the homonymous policy concept Responsible Innovation, is not uniform, but building on multiple sources and traditions.

The problem taken up by this thesis, is that these challenges have been acknowledged early on. Precisely because there are so many things and factors to be considered in directing research and innovation, and because earlier attempts have not yet accomplished in bringing about desired outcomes, Responsible Innovation has been introduced as an *integrative* and more holistic approach and as a *transformative* vision. No longer should questions of societal benefit be side-lined as an add-on to science and technology development, but become its very object, to be pursued throughout the entire chains and networks of individuals and their organisations involved. In that process integration – in its broadest sense: of values, actors, etc. – can be considered as the aim of transforming responsibility. In turn, it are the challenges of transformation that are of particular interest for advancing the quest for Responsible Innovation.

How to approach it?
The need for inducing broad systemic change has become increasingly acknowledged in scholarly literature about Responsible Innovation. There, it is discussed in various categories of institutional change, comprising challenges of organizational learning (Randles 2017a, Owen, Pansera et al. 2021, Owen, von Schomberg et al. 2021, Wittrock, Forsberg et al. 2021), national networks and contexts (Doezema, Ludwig et al. 2019, Pansera and Owen 2020), as well as institutional provisions (Gerber, Forsberg et al. 2020, Smith, Kamwendo et al. 2021, Stahl, Akintoye et al. 2021) or gaps between academic and corporate communities (Jakobsen, Fløysand et al. 2019). More recently, reflections on a decade of activities under the specific heading of Responsible Research and Innovation (RRI) question whether even more fundamental change is at stake, like 'slow innovation' (Steen 2021), a genuine 'commitment to care' (Albertson, de Saille et al. 2021) or challenging 'the dominant technology-market dyad' (Owen, von Schomberg et al. 2021). While these calls give reason to 'reinvent Responsible Innovation' (Fisher 2021, van Oudheusden and Shelley-Egan 2021) indeed, it all the more puts the challenge of transformation to the fore. What is it that has to be transformed and how?

As stated above, my approach to this conundrum is that heterogeneity, interpretative flexibility, polyvalence, multicenteredness, historical legacies and so on, are not obstacles to overcome, but the very thing to work with. Accordingly, I will develop a so-called 'socio-normative approach'[2]. That is: this thesis constructs a sociological and historical understanding of what the current quest for Responsible Innovation is about. This is an *interpretative* step, which includes normative orientations on responsibility in

[2] This notion is adopted from the Res-AGorA research project (www.res-agora.eu). See chapter 3 for discussion.

research and innovation and the kind of change that is in order and is geared towards the challenges of transforming responsibility in research and innovation systems. I will also develop an *explorative* approach for studying efforts to transform responsibility in concrete situations. The intellectual task then is to link both levels of analysis in such a way that they help to better understand challenges as well as pathways for transforming responsibility (Figure 1). The merit of such an approach is to shift the attention from the institutionalization of a concept and the normative frameworks introduced for that purpose, towards reflexive orientations for guiding the transformation of responsibility itself.

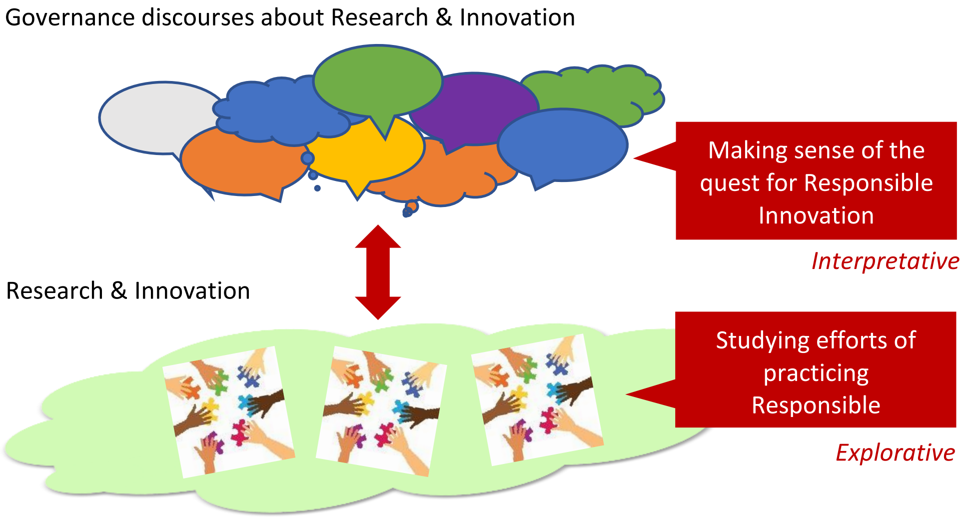

Figure 1: starting point for developing a 'socio-normative' research approach

Developing a heuristic

For developing the socio-normative approach I will use a heuristic approach as defined by Kuhlmann et al. (2016):

> *"1) A means to facilitate creative research, thought and theory-building in unstructured empirical or conceptual fields;*
>
> *2) a search strategy, delineating the scope of search, providing guidance and the lenses through which to search and study;*
>
> *3) the search strategy is informed by research questions and conceptual targets, summarized in (provisional) assumptions (e.g. on factors, actors, interactions, rules, con-figurations, agency);*

4) heuristics can be revised or adapted in the course of research, i.e. they draw on learning;

5) heuristics build a bridge between unstructured research fields on the one hand and achievement of empirical and conceptual or theoretical insights on the other."

Figure 2 shows how the heuristic for this thesis will be developed. Rather than departing from a theoretical framework the development of the heuristic will go back and forth between concepts, analytical orientations and reflection on the contexts of inquiry. As a first step, I will discuss key notions, research questions and empirical scoping in relation to the challenges for Responsible Innovation discussed above and the aim of this thesis. The next section explores how the current discourse on Responsible Innovation started and identifies three analytical lenses to be taken up in the research approach. Section 1.3 presents the actual heuristic and discusses how to go from understanding the quest for Responsible Innovation and the challenges of transforming responsibility, to drawing lessons about it. The heuristic is then further developed in Chapter 2: evaluative frames for (cross-)case analysis (the interpretative step); and in Chapter 3: the explorative approach for empirical investigation.

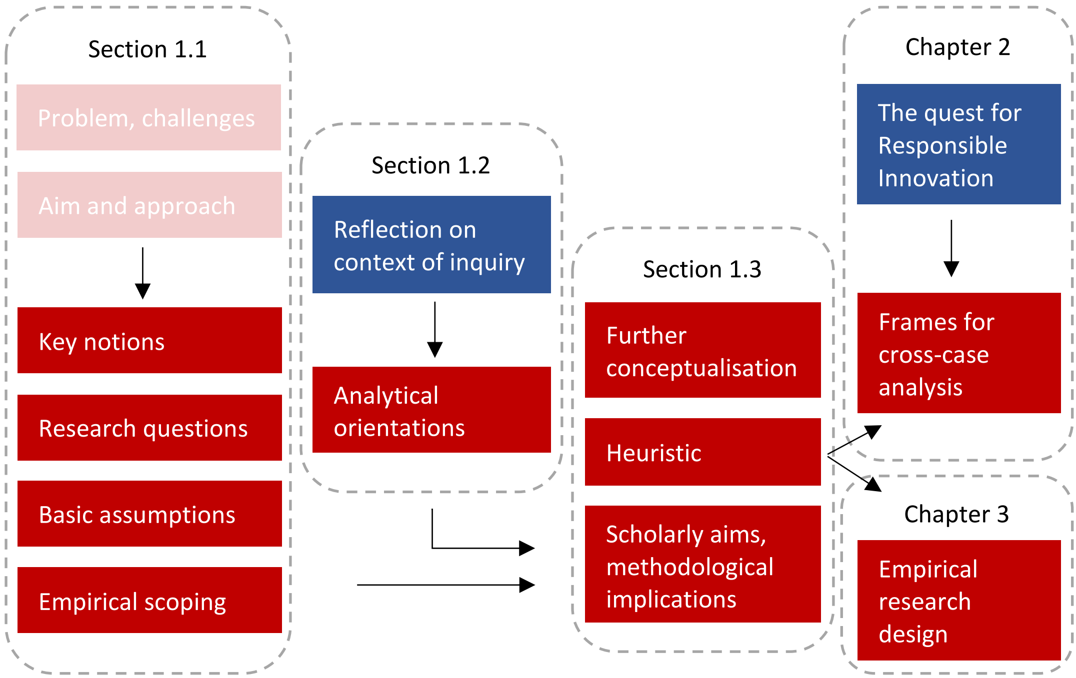

Figure 2: developing a heuristic for guiding the research approach

Key notions

In this thesis the challenge of transforming responsibility in research and innovation is conceived of as a problem of 'governance'. Governance refers to mechanisms of steering and coordination and can be used descriptively (describing how such mechanisms work) as well as normatively (models, principles etc. for how mechanisms should work). Since the purpose of my research is not to build a theory of the governance of Responsible Innovation, but to coherently inform my empirical search strategy and to develop an analytical frame from a historical and sociological understanding of research, innovation and Responsible Innovation, I will focus on how the key notions 'responsible' (and 'responsibility'), 'research', 'innovation' and 'governance' figure in the discourse about Responsible Innovation and how they are taken up in the socio-normative approach guiding the research for this thesis.[3]

In public and stakeholder debate 'governance', 'research' and 'innovation' are often used as catchphrases signifying particular positions. For example, the not so rare belief that governance = regulation = stifling innovation, is not only a particular view on governance in relation to innovation, but it also assumes that innovation pre-exists its regulation.[4] Likewise, the difference between 'research' and 'innovation' is often conceived as 'what happens in the lab' and 'what firms do', often in a linear order: from idea, to research, to product development, to markets and the way these are regulated.

Following Van de Ven et al. (1999), I do acknowledge that such innovation journeys can be tracked retrospectively and are actively pursued indeed. Still, research and innovation are shaped by manifold mechanisms, like markets, supply chains, regulations, rankings and career paths, research funding and evaluation, intellectual property protection, promises and concerns, business and organizational models, etc. These worlds of science, finance, governments, media and other intermediaries have dynamics of their own, thereby introducing all kind of contingencies and feedback loops between the various phases of development. Accordingly, I will approach governance as capturing the mechanisms of steering and coordination in and through which research and innovation unfolds.[5] In section 1.3 I will discuss in more detail how these

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[3] See also Kersbergen and van Waarden (2004) for a discussion about 'governance' in policy and in literature.

[4] Phrasing after Lemke (2007).

[5] For introductions on 'governance', see Mayntz (1998, 2003), Benz (2007) and Hoppe (2010). Governance can be approached as working in different modes (ideal-typically: hierarchical, and/or through networks (organisational coordination), competition (markets) and negotiation (with and between organisations representing stakeholders)), studied in different domains (e.g. international or multilevel governance, corporate governance, regulatory governance or environmental governance). The relevance of these different perspectives to governance for research and innovation is twofold: on the one hand an equally variegated landscape of scholarly perspectives on research and innovation co-shapes the practices being studied (e.g. Jansen 2010, Jansen and Pruisken 2015 on research funding or interdisciplinary collaboration in higher education studies, or classics about firms and competition (e.g. Schumpeter's (1942)

mechanisms can be understood as processes of structuration. I.e. governance is a communicative and political process, dynamic and reflexive, but also patterned and marked by multilevel dynamics. Similarly, research and innovation are simultaneously creative, contingent and societally ordered.

Drawing on these rather open conceptions of governance, research and innovation helps to explore how conceptions of 'responsibility' figure in discourses about the governance of research and innovation. In Chapter 2 I will do so by tracking articulations of Responsible Innovation over time, as well as how these relate to changing conceptions of responsibility in research and innovation.

Research questions

The aim of learning from the quest for Responsible Innovation translates in a descriptive research question as well as a normative-strategic one:

1. *What shapes the governance of Responsible Innovation?*
2. *What can be learned for transforming responsibility in research and innovation?*

Both questions cannot be answered in full scope, but need to be anchored in concrete settings. I will focus on two specific governance domains: risk governance and research governance (introduced later on). Still, the research approach will address general challenges with respect to transformation of responsibility in the governance of research and innovation.

Basic assumptions

From my discussion of challenges it can be inferred that responsibility claims are *always contested* and *never start from scratch*. The former is not to say that there will always be disagreement, but that it is likely that there are struggles about their concrete meaning and implications for operationalisation. As an example one can draw a comparison with the concept of sustainability. The more specifically it is defined (e.g. battery electric vehicles are sustainable), the more it also becomes contested (is it true, enough, realistic, fair?). Yet, because there is a common notion to refer to, discussions about this notion co-shape the trajectories of research and innovation. Whether this changes or reinforces the course of specific trajectories is an empirical question.

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creative destruction; Nelson & Winter's (1982) evolutionary perspective), innovation management (skills, capabilities, resources, entrepreneurship) and innovation systems (e.g. Edquist 1997) in innovation studies (see Shapira et al. 2010 on the dance between theory, policy and practice). On the other hand, the many modes, mechanisms and levels of analysis put evaluative criteria for governance, such as effectiveness and legitimacy, at the heart of actual struggles – including the appreciation of the supposed shift 'from government to governance' (Hoppe 2010, see also Lemke (2007) on 'governmentality' and governance).

As for the notion of Responsible Innovation itself, responses from scientists, business representatives or civil servants vary from excitement to feeling insulted – when raising the term 'responsible' may suggest current activities are irresponsible (Bos, Walhout et al. 2014). Others report confidence in what they are doing is already responsible (European Commission 2013) or have different views on what individuals or organisations are responsible for (Glerup and Horst 2014, Glerup, Davies et al. 2017). Often, however, actors just struggle to make sense of what 'Responsible Innovation' actually means and what makes it different to other guiding ideas. I will use these observations for developing analytical orientations in the next sections and the empirical research design in chapter 3.

Scoping

Struggles about meaning bring interpretative aspects to the fore. With respect to the quest for Responsible Innovation, I will follow accounts that locate the start of the current discourse about Responsible Innovation in the rise of nanotechnology as a 'new' field of science and technology (e.g. Rip 2014), while acknowledging that there are many more preceding discussions, institutional precursors and intellectual movements on which the current discourse about Responsible Innovation builds (Rip and van Lente 2013, Van Lente and Rip 2017, Mody 2016, Owen and Pansera 2019, Owen, von Schomberg et al. 2021, Shanley 2021).

Since the quest for Responsible Innovation is also developing over time, I will stage distinct phases as part of developing the research approach itself. The next section starts with the notion of Responsible Development, introduced in the early years of nanotechnology as a field of big financial investments. This part specifically speaks to articulations of Responsible Innovation that are concerned with the governance of emerging technologies. In Chapter 2 I will discuss how the notions of Responsible Innovation and Responsible Research and Innovation (RRI) followed, extending the scope to research and innovation systems. From then on, relatively large funding schemes for RRI became available and a phase of experimenting and attempts for mainstreaming Responsible Innovation started, including large parts of the empirical research in this thesis. At the end of the thesis (Chapter 9), I will discuss the lessons drawn from my own research in relation to a last phase: the recent round of reflections among Responsible Innovation scholars in looking back at this period of Responsible Innovation efforts.

Scoping the current quest for Responsible Innovation as related to the cognate notions of Responsible Development, Responsible Innovation and Responsible Research and Innovation also implies that other concepts and movements, like the vast body of work on engineering ethics and the responsibility of scientists, Corporate Social Responsibility (CSR) or Responsible Technology, will be discussed only insofar they relate to the quest for Responsible Innovation as captured by the former three terms. The justification for that follows from characterizing the current quest for Responsible Innovation in Chapter

1 as an attempt to move beyond individual responsibilities (whether persons or organisations) to system responsibility brought about by, for example, an institutionalized 'ethics of care' (Stilgoe, Owen et al. 2013) or 'culture of responsibility' (von Schomberg 2013).

Finally, focusing on nanotechnology as an important field of Responsible Innovation experiments may seem a bit outdated, already exhaustively discussed in the literature, or even prone to reifying the kind of 'technoscience' practices, with their (overrated) expectations of trillion dollar markets and endless societal benefits, that would have to be transformed. For the research in this thesis, however, it is exactly the status of nanotechnology as the icon field of 'emerging sciences and technologies' (EST) and the broadening of Responsible Innovation to other domains that shed light on the typical frames and institutionalized force fields at play in structuring responsibility in research and innovation at large.

1.2 Context of inquiry – nanotechnology

The history of nanotechnology and its start as a distinct field of science and technology in the US provides important clues for studying the governance of Responsible Innovation. I will discuss how nanotechnology's evocative image of controlling material properties 'atom by atom' (Amato 1999) fuelled an economy of expectations and gave rise to the introduction of Responsible Development as a policy goal.

Nanotechnology's image

Stories about nanotechnology often follow a story line of technological progress in miniaturisation. 'Nano' is Greek for dwarf and as such it is used to denote very small length scales: one nanometer is a millionth of a millimetre. To get an idea: at the opening ceremony of the NanoLab at the University of Twente in the Netherlands, a short text was burnt axially on a human hair.[6] While this is already an impressive performance, for nanotechnology a human hair is relatively thick – about 70.000 nanometer. Many nanotechnologies, including those developed in the Twente NanoLab, operate at a much smaller scale. Research groups work at making proteins, DNA separation, controlling light or quantum transport. These involve material structures of just tens of nanometers and even smaller scales.

The significance of the opening act at the Twente NanoLab, is that miniaturisation speaks to the imagination of what nanotechnology enables. In many popular histories the birth of nanotechnology is projected in the speech "*There is plenty of room at the bottom*" of physicist Richard Feynman, delivered at the annual meeting of the American

[6] See: https://www.utwente.nl/nieuws/!/2010/11/118453/kroonprins-onder-de-indruk-van-nanolab (publication date 5 November 2010, last accessed 27 February 2023)

Physical Society, late 1959. By that time, the Lord's Prayer had been written on the head of a pin. "*But that's nothing*", Feynman asserted, "*why cannot we write the entire 24 volumes of the Encyclopaedia Britannica on the head of a pin?*" (Feynman 1960). Feynman speculated about storing all information in the world at a pamphlet as big as a copy of the *Saturday Evening Post*, but also about computing on small devices instead of room-filling machines, about the ability to study biological systems at sub-cellular level and about physically synthesising any chemical substance. More importantly, Feynman didn't discuss these just as possibilities, he also challenged his audience, by offering prizes, to work on the technologies enabling his ideas. One of the routes he suggested was ion beaming, a technology the Japanese scientists Norio Taniguchi has been working on when he coined the term '*Nano-technology*' in 1974.

It would be too simple to depict the nanoscientists at the Twente NanoLab as Feynman's heroic intellectual descendants. There is much more to science than hardworking scientists, similarly as there is much more to innovation than companies developing new products. Think of research funding programs, advancements in other technological fields, conferences, markets, regulation, users and consumers, patents, publications and media, education, career paths, all of which influence how research is done or which trajectories innovation takes. However, the very fact that Feynman's speech now is referred to all over again, tells something about what gives nanotechnology its identity. Scientific imaginings in relation to technological progress work as an inspirational driver. Famous examples are iconic images, like the word '*IBM*' written by moving 35 xenon atoms with the tip of a Scanning Tunneling Microscope (STM) in 1989, but also science fiction pictures like the *Fantastic Voyage* submarine travelling through blood vessels or a nanorobot probing a blood cell (Ruivenkamp 2011).

Promises. And concerns.

A more gloomy image of technological development is part of the world of research and innovation as well. In the 80's the nanoscientist Eric Drexler depicted futures of how a world with nanotechnology may look like. These scenarios have not shaped nanotechnology because of their accuracy, but in what they have mobilised in the US. Drexler also used miniaturisation stories, like fitting the entire *Library of Congress* on a sugar grain, but he shifted the attention to *bottom-up* abilities for molecular synthesis and manufacturing mimicking and deploying nature's mechanisms. According to Patrick McCray, Drexler was not only a creative thinker, but a '*visioneer*' who linked radical ideas, powerful imagination, fellow scientists and corporate leaders as well as citizens, journalists and politicians by actively building networks and communities. With that, he prepared the ground for organising nanotechnology as a distinct field in science and engineering (McCray 2012).

But Drexler also has been considered a threat to nanotechnology. In his book *Engines of creation – the coming era of nanotechnology* (Drexler 1986), he introduced a doom scenario of self-replicating, nano-sized robots that could run out of control and destroy all biological life, turning the world into a horrible '*grey goo*'. Drexler has been severely criticized for this scenario, which resulted in even more attention for his views (McCray 2012, Rip and van Ameron 2009). One of his public opponents was Nobel laureate Richard Smalley, who later became involved in the Interagency Working Group on Nanoscience, Engineering and Technology that has been preparing the proposal for the US federal National Nanotechnology Initiative (NNI). To strengthen the legitimacy of investing in nanotechnology, the coordinator of the NNI proposal, Mihail Roco, and colleagues brought in another powerful story line. The ability to work at the level of many biological mechanisms would enable a new Renaissance in science and technology: the technological convergence between key technologies in the hard sciences (nanotechnology, information technology) and in the life sciences (biotechnology, cognitive sciences), jointly applied to improve human performance (Roco and Bainbridge 2001). No less forceful than Drexler's image of the 'grey goo' were the benefits of this Nano-Bio-Info-Cogno (NBIC) convergence biblically being portrayed as ushering into an era where "*[some of] the blind will see again and the deaf will hear again*" (Roco and Bainbridge 2003).

The promise of human progress triggered other responses in turn. *Wired* editor Bill Joy wrote "*Why the future doesn't need us*" (Joy 2000), in which he questioned our ability to remain in control over superintelligence and robots. These concerns were amplified by the publication of *Prey* in 2002, a science fiction novel of Michael Crighton (2002), which picked up on Drexler's story line of self-replication. In 2003 the Canadian action group ETC weighed in with a call for a moratorium in a critical report (ETC 2003) on issues of ownership and control in the new 'Industrial Revolution' the NNI was promising. The ETC group explicitly positioned nanotechnology as the 'the next big thing' after biotechnology, or – more specifically – to genetic engineering, thereby questioning who is in control ('big industry', according to ETC) as much as warning for technologies potentially getting out of control. In the years that followed the potential of nanotechnology has been framed from unethical to halt investments (Bond 2005)[7] to the risks of GM being peanuts compared to the perils of nanotechnology (Feder 2006).

Responsible Development as a response

The possibility that public controversies would extend 'from bio to nano' (Willis and Wilsdon 2003) also triggered institutional responses. In 2000, the outline document for the NNI (NSTC 2000) only briefly mentioned the possibility to include research on Ethical, Legal and Social Aspects (ELSA-research) in an appendix. Yet the concerns about nanotechnology did not go unnoticed by the NNI leadership and a workshop on the societal implications of nanotechnology (see Roco and Bainbridge 2003) was organised. Building on that workshop, both the 'ELSA-model' of the Human Genome Program (HGP) and investing in public understanding of nanotechnology were proposed for the NNI.

[7] Philip J. Bond, US Under-Secretary of Commerce, statement during the SwissRe workshop on nanotechnology, December 2004 (source: Arie Rip, cf. https://slideplayer.com/slide/10229957/ (last accessed 27 February 2023))

However, this mode of addressing concerns was revisited in the efforts of the US Congress to regain authority over the nanotechnology budgets for the NNI, in the 21st Century Nanotechnology Research and Development Act (US-Congress 2003; see also Honda 2004, Fisher and Majahan 2006). During the hearings before the publication of the act, the ELSA-model was criticized for lacking impact on either research and policymaking (Winner 2003, Bennett and Sarewitz 2006). Together with the fear for public backlash this resulted in much more emphasis on the need for integration into the research activities and the active organisation of public input and outreach. The NRDA introduced Responsible Development as an overarching notion for these activities. Meanwhile, the international debate on societal implications of nanotechnology started to focus on uncertainties about the safety of nanomaterials. Environmental, Health and Safety (EHS) became the most prominent theme in the subsequent operationalisations of Responsible Development (e.g. NNI 2004), followed by ELSA research, public input and outreach, and more recently, sustainability. In turn, this agenda for Responsible Development set the tone for international discussions about nanotechnology (Chapter 2).

An economy of expectations: analytical orientations

This brief history of nanotechnology and the introduction of Responsible Development in the US puts to the fore three analytical lenses for studying the governance of research and innovation and the role of Responsible Innovation therein. First, with respect to the basic assumption that responsibility claims are always contested there is the significant role of discursive structuring. This can result in particular dynamics. Feynman's predictions, for example, can be seen as an 'umbrella promise' (Parandian et al. 2012) about mastering materials at molecular level. The umbrella promise allows for more specific promises about the potential impact of nanotechnology across a wide range of application areas, which, in turn, sustains the umbrella promise itself. These specific promises – and the related concerns – are shaped by the specific discursive repertoires and sector characteristics, and thus may result in quite diverging imaginaries about what nanotechnology is and the sort of impacts it may create (Te Kulve et al. 2013). In this way meaning is attributed that shapes action and direction. Promises about (new) fields of science and technology also act as 'imaginaries' – "*visions of scientific and technological progress [that] carry with them implicit ideas about public purposes, collective futures, and the common good*" (Jasanoff & Kim 2015). Unsurprisingly then, promises about powerful technologies may elicit concerns over control and negative impacts as well. Both promises and concerns work as 'prospective structures' (Van Lente and Rip 1998), having a performative effect on science and technology development itself and turning mediating concepts like Responsible Development in junctions for positioning and debate (cf. Rip 2014).[8]

[8] Next to umbrella terms and imaginaries other concepts describing aspects of discursive structuring do apply. For example, Responsible Innovation can be seen as a 'boundary object' allowing for "*adaptation to different viewpoints, while being robust enough to maintain identity across them*" (Star and Griesemer 1989). The 'ideographical' nature of both 'Responsible' and

Second and inextricably related is that expectations do not circulate in a void. Public investments in science and technology are expected to pay off in economic benefits and hence are considered to be of strategic importance for today's knowledge economies (Rip 2002a). This has been especially the case for nanotechnology, where promises (e.g. 'a trillion dollar market' according to Lux research (2005)) and prestige (e.g. 'maintaining leadership' by the NNI) ignited an international funding splurge (Rip 2019). These investments are channelled through existing structures for policy making, research funding and international networks and markets. That the response to concerns didn't start from scratch became visible in the references to biotechnology and the discussion about ELSA-research as a model for anticipating societal concerns. Discussions about Responsible Innovation therefore have to be situated in wider historical and institutional settings of the governance of research and innovation.

Finally, while both discursive and institutional structuring provide a lens on 'mechanisms' of steering and coordination, these should not be understood mechanistically. The brief history of nanotechnology and Responsible Development depicted the role of key individuals, contingencies and strategic behaviour. The NNI for example, would not have been established if the Clinton presidency wished to leave behind a prestigious science initiative in the late '90s. Nanotechnology was brought to the attention of the presidential Office of Science and Technology Policy (OSTP). At that time the National Science Foundation (NSF) sought to institutionalise nanotechnology as a new field, an exploration coordinated by Mihail Roco. When Roco was invited for presenting his ideas for the OSTP competition, the NSF also recognised the opportunity to catch up in budget with the National Institutes of Health (NIH). To this end basic science (physics, chemistry) was positioned as necessary to secure further progress in the 'applied' life sciences (cf. Lane and Kalil 2005)[9] and, in the context of competition with other proposals, complemented with claims about nanotechnology's importance for economic competitiveness (Eijmberts 2013) and, later, about homeland security (Appelbaum et al. 2012). The international funding race that followed showed that nanotechnology itself is more than a field of science and technology and can be considered as a socio-political project (Jones 2011). Albeit contingently, this has affected the change in focus of Responsible Development (McCarthy and Kelty 2010, Rip and Van Ameron 2009).

'Innovation' turns Responsible Innovation into an 'essentially contestable concept' like Rosenfeld (2001) has put it: "*its descriptive meaning depends on the prescriptive meaning ascribed to it.*" This, in turn, allows for strategic interpretation (see Bos et al. 2014 drawing on McGee 1980). Structuration can also be approached historically. Shanley (2021) elaborates on the idea of Responsible Innovation building on Scientific Intellectual Movements (Brundage and Guston 2019), but which explains sources rather than forces.

[9] Note: this idea goes back to Feynmann's speech of 1959. See also AAAS reports for historical overviews of federal support to science and engineering: https://www.aaas.org/resources/rd-budget-reports-and-publications (last accessed 27 February 2023)

1.3 Conceptual frame and analytical orientations – making sense and making change

The history of nanotechnology and the introduction of Responsible Development as a label for the good governance of nanotechnology shows that notwithstanding its ring of radical change, the notion of transformation implies that the new has to grow in and from the old, with all the tensions, interdependencies and incremental change involved in that (cf. Feola 2015). Therefore, another key assumption guiding my research approach is that it are *interdependencies* that present the main challenge for transformative change. This has been reflected already in the basic assumptions about Responsible Innovation being *always contested* and *never starting from scratch*. It is also reflected in the interrelated phenomena described by the analytical lenses above. Hence, the next step in developing the heuristic is to conceptualise the governance of Responsible Innovation (Research Question 1) and transforming responsibility in research and innovation (Research Question 2) accordingly: as shaped by interplay, manifesting itself in politics of implementation. In developing this step, I will also give shape to the socio-normative aspect of my research approach: to *make sense* of the quest for Responsible Innovation in such a way that it can inform efforts for *making change* through processes of transforming responsibility in the governance of research and innovation.[10]

Making sense – understanding the governance of Responsible Innovation
The interrelations between the three analytical challenges express what sociologists call processes of structuration. Discourse is shaped by institutional settings and vice versa, and both ways do not happen mechanistically, but mediated by the actions of sentient actors. Consequently, I will draw on conceptual accounts of governance that reflect this idea of interplay.[11] The first step is to conceive governance as:

> "*the dynamic interrelation of involved (mostly organized) actors within and between organisations, their resources, interests and power, fora for debate and arenas for negotiation between actors, rules of the game, and policy*

[10] Thanks to Niels Mejlgard, for bringing up the phrasing of 'making sense and making change' in the Res-AGorA consortium meeting in Karlsruhe, September 2014.

[11] Other approaches are, for example, 'actor-centered institutionalism' to overcome problems with too much rationalized actors in policy analysis (Scharpf 1997), or prioritizing 'discursive institutionalism' for better explaining change than the traditional institutionalisms of rational choice (award systems), path-dependence (historical) and culturally framed rules and norms (sociological) (Schmidt 2010). Niinikoski and Kuhlmann (2014) use a Foucauldian perspective in which discursive formation is shaped by, but also effects extra-discursive structures, conceptualised as material resources available in institutional form. In the following I will specifically work from the observation that structuration is patterned (esp. the work of Rip and Kemp 1998 on 'regimes'), also over time (e.g. Voß 2007 on 'sedimentation'; Archer 1995 on 'morphogenesis').

> *instruments applied, helping to achieve agreements considered legitimate*" (Kuhlmann 2001)[12]

The above definition conceptualises governance 'as practiced', i.e. the *de facto* design and deployment of governance arrangements as distinguished from their *de jure* legitimation. A next step is in acknowledging that interplay does not equal a continuous free flow, but is patterned by the aggregative effects resulting from it. In this way *de facto* governance can be conceived as:

> "*Interactions, from which patterns emerge including national policy styles, regulatory arrangements, forms of organisational management and the structures of sectoral networks. (…) They comprise processes by which collective processes are defined and analysed, processes by which goals and assessments of solutions are formulated and processes in which action strategies are coordinated.*" (Rip 2010)

Examples of such *de facto* governance patterns in research and innovation are the ways in which project funding is organised or consultation about policy measures takes place. The relation between governance 'as practiced' (intentional) and governance patterns and dynamics as 'adding up' (often un-intentional) can be understood as part of a continuum, but also as reflexive, enabling change. Where actors work towards legitimate objectives and outcomes, these become performed, qualified and institutionalized through various means and strategies and can stabilize into hard and soft regulatory instruments. But they can also loose legitimacy when political contexts shift. For example, involving stakeholder representatives from corporate or civil society organisations is now common place, not only in conducting research projects, but up to the formulation of research agendas.

Finally, we can discern different levels of aggregation, analogous to the multilevel perspective (MLP) as theorized for socio-technical change (cf. Geels 2007, Rip 2012). From this perspective, the quest for Responsible Innovation can be conceived as a 'social innovation' (Rip 2014)[13], drawing on *landscape* level ideas about the governance of science, technology and innovation; is being pursued in *niche* level experiments; and, depending on conditions set by the interrelation between all three levels, may result in *regime* shift – here being a reconfiguration of responsibility in research and innovation systems.

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[12] The phrasing is taken from Res-AGorA D2.2 (Walhout et al. 2014), which draws on Kuhlmann 2001; Benz 2007; Braun 2006.

[13] Note: 'social innovation' is also used in a normative way (with similar aims as articulated for Responsible Innovation), cf. Bolz and De Bruin (2019) or Bhaduri and Talat (2020).

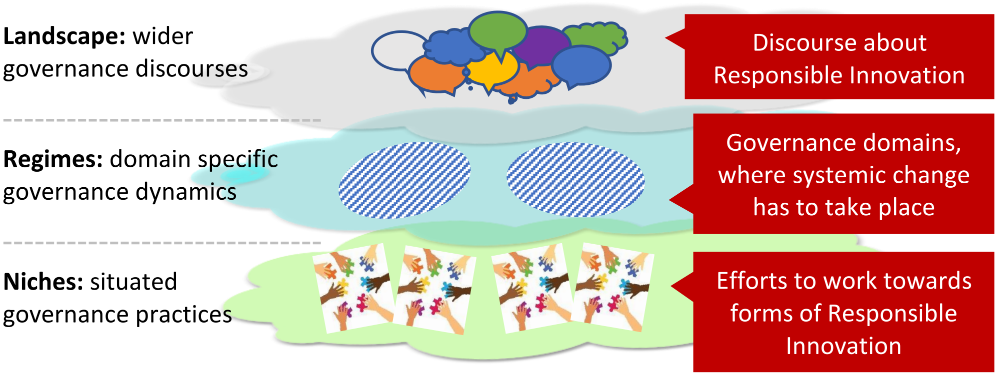

Figure 3: multilevel model of the governance of Responsible Innovation

Following Rip (2014), I will broaden the scope of the landscape level analysis in this multilevel model to 'reflexive modernization' (Beck, Giddens et al. 1994). Reflexivity, in this respect, refers to awareness by actors about social dimensions in and societal impacts of science and technology, but even more to the range of instruments and institutional arrangements that organize this reflexivity as mechanisms of feedback in science and technology development, whether by regulations or in methods for design. (Rip 2016) explores analogies with earlier 'policy fashions', like Big Science, Open Innovation, or Mode 2 Knowledge Production. These have contributed to significant shifts in promoting research and innovation, such as the participation of industry in the public research programs funded by the European Commission (Edler 2003). Likewise, the quest for Responsible Innovation can have such effects for directing and controlling research and innovation, by introducing new orientations as well as through transforming preceding waves of institutionalisation, like ethical review, risk governance or technology assessment.[14] Yet, Responsible Innovation will only make such difference when going beyond successful demonstrations of good practices at niche level and adding up to systemic change (regime level).

Making change – drawing lessons for transforming responsibility

The levels of analysis depicted in Figure 3 also involve different modes of analysis: linking the *interpretative* landscape analysis to the *explorative* empirical investigations involves an *abductive* step with respect to drawing lessons about transformation and systemic change. For drawing these lessons a number of analytical questions have to be addressed. First, a multilevel model itself is agnostic to the nature and direction of change. As such, it can be used reflexively, in helping actors to understand conditions and dynamics of change. One step further are approaches for transition management

[14] In this respect Responsible Innovation can also serve as a 'transition policy' (Heidrun Åm at S.Net 2016 conference), see also Zwart et al. 2014, Van Lente and Rip 2017, Kjolberg 2010, Shelley-Egan 2011.

like developed for sustainable development (Markard, Raven et al. 2012). However, as discussed at the start of this chapter, for Responsible Innovation we first need an interpretative step with respect to what the quest for Responsible Innovation is about and what are key challenges for transformation in it. This is the task for Chapter 2, which will develop an evaluative frame for drawing lessons from attempts to work towards transformative change, see Figure 4.

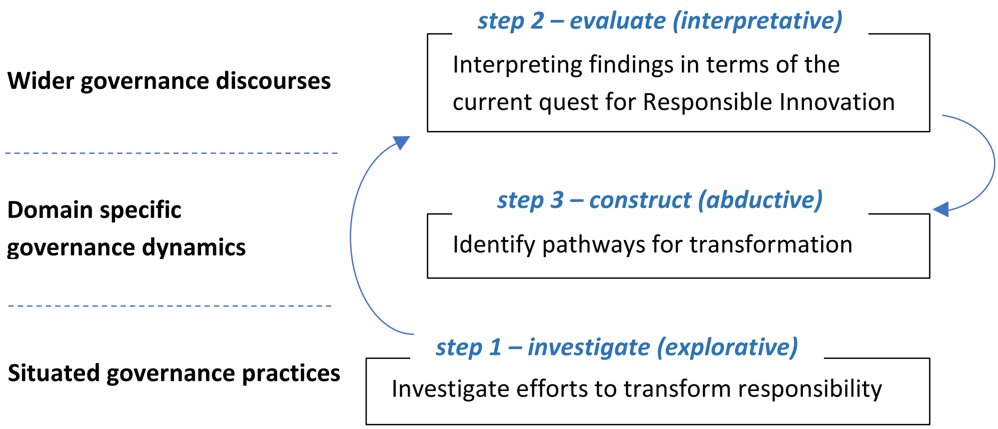

Figure 4: heuristic guiding the levels and order of analysis

Second, while each level of analysis involves interpretative steps, all the more a multilevel model can become just another expert ordering of 'what is the problem and how to approach it'. This may be of limited value for actors involved in specific situations, especially since the levels of analysis are nested in practice.[15] The remedy to this problem is to stay close to the problem and solution frames of actors themselves, both at the level of empirical exploration of efforts to transform responsibility in research and innovation and at the level of the overarching discourse about Responsible Innovation.

For this purpose, I will draw on insights from political sciences as discussed by (Grin 2008) for using a multilevel perspective in guiding system transformations. Grin cites Schön (1983), who argues that actors are not primarily driven by self-interest, but first of all engage in a quest "*to remedy problems, which they construct in conjunction with potential solutions*". This underlines the need for rigorous problem finding before engaging in problem solving, so as to avoid the widely present problem of 'solutionism' (cf. Hoppe 2010), in which problems are defined in light of the instruments available to address them. The implication for my research is that staying close to the frames of

[15] Rip (2012) suggests to speak about 'layers' rather than 'levels', so as to make clear that analytical steps serve to foreground particular phenomena.

actors is not meant to stick to them, but to engage in a form of critical frame reflection that is intelligible to actors involved in specific situations.[16]

Practically, this means that at the level of the empirical investigation I will focus on how well problem and solution frames are not only congruent to each other, but also reflexive about the institutional conditions at hand. At the level of the broader quest for Responsible Innovation I will discuss how main themes and responsibility conceptions in the discourse about Responsible Innovation relate to governance challenges in research and innovation. Both will be brought together in abductively constructing pathways for transformation (step 3). This still cannot avoid the other issue discussed by Grin (2008): that any lesson drawn from expert analysis thus can become subject to politics of implementation again.[17] However, the added value aimed for in my research approach, is that it enables reflexive feedback specifically focused on the modes of stakeholder inquiry by which problem and solution frames are (re-)produced. For that purpose, I will identify what are the relevant accountability mechanisms and construct pathways to transform them. For example, in Chapter 8 I will discuss how organizing double loop learning with respect to impact strategies can grow into wider institutional transformation in research funding and evaluation. For risk governance I will discuss how linking independent system analysis to parliamentary control may mitigate governance challenges and failures, which currently are reappearing for next generation nanomaterials.

Scholarly aims and methodological implications

Above aims and approach have to contribute to what Grin (2006) calls 'Re-structuration': "*the interrelated transformation of structure and action through structuration processes guided by* […] *deliberate Re-orientation* […]". This view on reflexive modernization as a governance question acknowledges that there is no Archimedean point for determining what something like Responsible Innovation is and that the 'polity' involved is itself discursive. Grin suggests that actors can still learn from analyzing strategies for transformation at niche and regime level and normative orientations at landscape level, especially when considered in relation to each other (the Re-orientation in the quote above). This is also the thrust of my research approach.

Drawing on the conceptual and analytic frames of Kuhlmann, Rip and Grin for this purpose, is also a response to Rip's (2002b) call for creating a nexus between Science &

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[16] Not necessarily as systematic as Schön and Rein (1994), but serving apt exchange in deliberative settings. Values like safety, for example, can be discussed as limits in a context of justification, invoking discussions about evidence and expertise. Safety can also be discussed as driver, in a context is of discovery, probing images of responsibility and the good. See Keulartz et al. (2004), or Boenink and Kudina (2020) on values as entities vs. values as dynamic and interactive.

[17] Illustrated by Grin (2008) with the famous statement "*Implementation is the continuation of politics by other means*" (Majone & Wildavski 1978).

Technology Studies (STS) and political sciences. Rip argues that science and technology play a key role in the constitution of our society, which cannot be grasped by traditional political theory alone. Conversely, conceptualisations of, as well as experiments with Responsible Innovation by (STS) scholars often suffer from what Rip calls the 'intra-mural trap': they are conceived of in project or conference settings, where they work as legitimation rather than "*articulating values and approaches which are actually taken into account and make a difference.*" Here, the insights from political science mentioned by Grin, and more broadly the field of deliberative policy analysis, help to stay close to the 'real world'.

Finally, as for the ontological commitments involved in 'making sense' and 'making change' and the methodological implications of studying interplay, two principles from the 'methodological relationism' discussed in Bourdieu and Wackant's (1992) *Invitation to reflexive sociology* do apply. The first principle is about acknowledging the interdependence of theory and method and "*the self-analysis of the sociologist as cultural producer and a reflection on the socio-historical conditions of a science of society*" (p36). The socio-normative approach explored in this thesis fits into a longer tradition linking STS and governance studies and 'engaged scholarship' at the department of Science Technology and Policy Studies (STePS) at the University of Twente (NL).[18] Having worked before at the Dutch office for parliamentary Technology Assessment (the Rathenau Institute), this thesis is far less interventionist oriented than I intended at the start of my PhD. Nonetheless, my aim is to make the combination of STS and policy sciences productive for interventionist approaches that target 'policy floors' (the practitioner domains of policy makers, program managers, ethics officers and the like). In Chapter 3 I will discuss how this thesis builds on the various research contexts I have been working in and which have resulted in papers and book chapters next to this thesis (Bos, Walhout et al. 2014, Walhout and Konrad 2015, Te Kulve et al. 2013, Van Est et al. 2012a,b, Brom et al. 2021).

The second principle is about the "*primacy of relations*" between actor and system while not resorting to either materialism or idealism. Heeding this principle, I will focus on interrelations at each level of analysis: in the interpretative step of deriving analytic frames for cross-case analysis in Chapter 2; in the explorative investigations that are structured by the empirical research approach developed in Chapter 3; and in the abductive step of constructing pathways for transforming responsibility in Chapter 8, see Figure 5.

Together, this set of analytical orientations has to enable the aim of this thesis: informing the quest for Responsible Innovation, by developing a socio-normative approach, for guiding the transformation of responsibility in research and innovation,

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[18] See, for example, https://easst.net/article/engaged-science-technology-and-policy-studies-the-twente-approach/. For a discussion about engaged scholarship, see Beaulieu, Breton and Brousselle (2018)

up to inducing systemic change, so as to make a difference in the end. The proof of the pudding will be in the outlooks presented in Chapter 8 and 9. These have to offer concrete scenarios building on the intellectual quest set out in Figure 1: understanding the relation between the quest for Responsible Innovation on the one hand and challenges as well as pathways for transforming responsibility in research and innovation on the other; in such a way that they can constructively inform each other.

1.4 Thesis setup and reader's guide

The thesis can be read in various ways. Readers with a specific interest in the case studies can follow the order as shown in Figure 5: two case studies in the Netherlands, followed by a contrasting set of case studies located in the US. Each case study discusses a rather prestigious effort of practicing Responsible Innovation in the governance of nanotechnology. Section 3.3 offers a brief introduction on all cases studies. One can also focus on the specific governance domains the case studies relate to, either about the governance of potential risks of nanomaterials (Chapter 4 and 6) or about interdisciplinary collaboration in large research programs, so as to address societal issues with respect to nanotechnology more broadly (Chapter 5 and 7). The cross-case analysis in Chapter 8 is ordered by these governance domains as well.

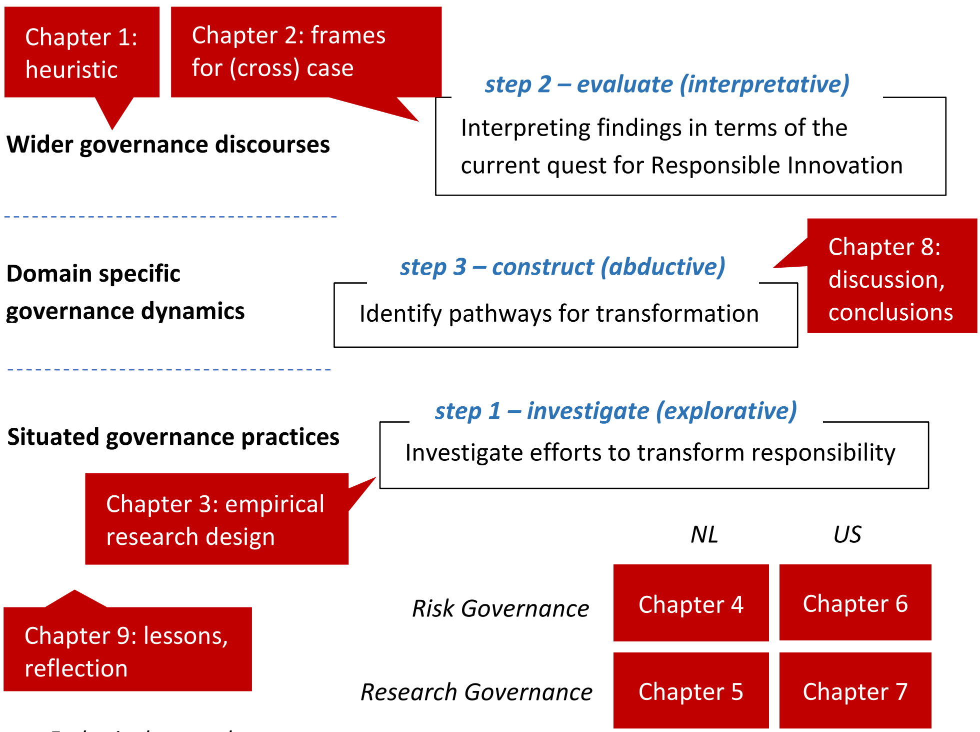

Figure 5: thesis chapter plan

Readers with a specific interest in the research approach can jump to the final section of Chapter 2 (the frames for cross-case analysis), continue with Chapter 3 (empirical research design) and jump further to Chapter 8 (cross-case analysis and domain specific findings) and Chapter 9 (general lessons and reflection). In this way one can skip the rather extensive discussion of the (early) quest for Responsible Innovation in Chapter 2 or the detailed case studies in Chapter 4 – 7.

2. Nanotechnology and the quest for Responsible Innovation

2.1 Following the quest

The quest for Responsible Innovation has been accompanied by various overviews and histories of the concept. At the end of the period discussed in this chapter – from about 2005 till 2015 – the focus of these reviews was on meaning and operationalisation of the concept (e.g. Owen, Stilgoe et al. 2013, Macnaghten, Owen et al. 2014, Koops 2015, Bongert and Albrecht 2015). Later on, when Responsible Research & Innovation (RRI) research projects funded by the European Commission proliferated, genealogic accounts followed, including studies tracing earlier roots of the current quest (e.g. de Saille 2015, Mody 2016, Owen, von Schomberg et al. 2021, Shanley 2021). In this chapter I will engage in a rather extensive discussion of Responsible Innovation articulations as well, for three reasons:

First, a specific review of Responsible Innovation in relation to nanotechnology serves to position the empirical research in the international discussion about 'good governance' of nanotechnology. This is the focus of section 2.2.

Second, in tracing articulations in relation to nanotechnology as well as in the shift to a policy discourse in its own right, I will pay specific attention to relative positioning, of differences between frames, and how these, in turn relate to differences in institutional context. For example, it matters whether Responsible Innovation is institutionalised in large scale research programs with international esteem or in more local programs and policies or single organisation activities. It matters what kind of (internal) support is granted to Responsible Innovation in policy documents or to what extend it stipulates what kind of follow-up has to be realised. It also matters if scholars writing about Responsible Innovation are considered as opinion leaders on the subject. Section 2.3 describes the quest for Responsible Innovation in these terms, until about 2015, when new articulations of Responsible Innovation started to consolidate around two influential sources: the six 'policy keys' (ethics, science education, gender equality, open access, governance and public engagement) defined in the Horizon2020 SWAFS-program of the European Commission and the framework (anticipation, reflexivity, engagement, responsiveness) developed at the UK Engineering and Physical Sciences Research Council (EPSRC) as well as the role of a third influential actor, the Center for Nanotechnology and Society at Arizona State University (CNS-ASU).

This way of tracing the quest for Responsible Innovation as a communicative process in which actors, (peer) communities, institutional agendas and responses over time can be identified, helps to perform a third step in section 2.4: positioning the quest for Responsible Innovation in wider discourses and long term developments with respect to the governance of research and innovation. Building on this discussion, section 2.5 will derive evaluative frames for cross-case analysis (see Figure 6). The first frame discerns typical problem-responsibility relations and informs my selection of sites for empirical investigation. The second frame conceptualises the challenges of transforming responsibility in research and innovation as figuring in the discourse about Responsible Innovation.

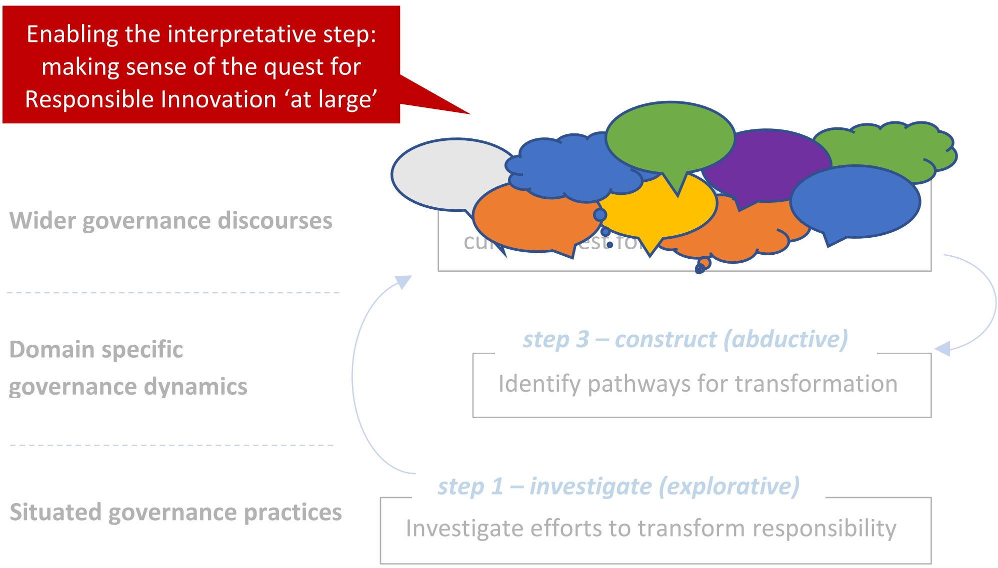

Figure 6: developing step 2 of the heuristic

2.2 Responsible Innovation and the governance of nanotechnology

References to Responsible Innovation in nanotechnology can be discerned in public policy articulations voicing the idea that nanotechnology develops from science to technology and applications, thereby legitimating the large investments in nanotechnology in a double way; and articulations by advocacy organisations from industry, academia and environmental groups, as well as what has been reported about the impact of the various initiatives on nanotechnology research and innovation.

Public policy focus on safety and public opinion

References to Responsible Development in public policy initiatives for nanotechnology reflect a globally developing agenda with particular emphasis on risks and regulation as well as public opinion and dialogue, albeit with some variations. I will illustrate this with examples from countries which mobilised relatively large funds for investing in nanotechnology.

The European Commission (EC), issued a strategy document (EC 2004) and follow-up action plan (EC 2005), outlining the EC's 'safe, integrated and responsible' approach. In both documents, safety received most attention. With 'integrating the societal dimension', the EC referred to public consultation (such as the annual Eurobarometer public opinion poll) and dialogue initiatives, whereas 'responsible' referred to ethics, as stipulated in the EU charter for fundamental rights and enforced by ethical review of research proposals. The notion of Responsible Development is mentioned as well, but in relation to safety issues and less explicitly compared to the US nanotechnology R&D act and NNI goals. However, the overall framing is similar and following international agenda setting at that time: nanotechnology is to be developed responsibly with respect to issues of concern, mainly defined in terms of risks, which will be covered by adapting regulations and by being sensitive to public opinion.

The EC strategy and action plan have been issued as Communications: policy documents encouraging and calling upon the European Union member states to adopt the European Union's strategy as outlined and executed by the EC. The EC itself started to review the European regulatory frameworks (cf. EC 2007a, 2008a, 2009) and to program research on safety issues, ethical issues and societal impact. Most of the community building and public dialogue initiatives funded by the EC, also have been conducted within the funding schemes coordinated by the Directorate-General Research and Technology Development (DG-RTD), while stakeholder input on regulatory adaptation has been part of public consultations as well as the annual Safety4Success dialogues. Finally, acknowledging the required time span as well as limited reach of public policy measures, the EC also included the idea of developing a charter, which had to advance responsible action on a voluntary basis. The operationalisation of this policy line became the development of a code of conduct, which I will discuss further down below.

European member states showed varieties of the EC's response. For example, in the UK, a report by the Royal Society and Royal Academy of Engineering (RS-RAE 2004) – internationally considered as a landmark report for its fair presentation of promises and concerns[19] – introduced Responsible Development as a meta-concept, signifying a comprehensive as well as a tentative approach to dealing with both challenges and opportunities: given the broad scope of nanotechnologies and its dynamic

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[19] Cf. the appreciation of Andrew Maynard (2009, 2014), who has been an influential commentator with respect to nanotechnology governance

development, progress would have to be monitored and evaluated. In its response (HM Gov. 2005), the UK government treated Responsible Development likewise, but in the first progress report (HM Gov. 2007), ethical and social aspects and public dialogue were discussed separately to Responsible Development, which referred to safety aspects. From 2008 onwards the UK discourse shifted from the notion of Responsible Development to Responsible Innovation, due to a number of projects funded by research councils (see next section). This new term was adopted in the UK government supported activities, such as the Nanotechnology Knowledge Transfer Network's online community[20] or the Technology Strategy Board's feasibility contest,[21] but still focused on safety aspects.

In Germany a committee was established, the NanoKommission, which organised and engaged in an extensive range of public and stakeholder dialogue activities. As a result of the first dialogue phase (2006 – 2008) the NanoKommission published five principles for the Responsible Development of nanotechnology (NanoKommission 2008), focused on safety aspects of nanomaterials.[22] The German government started to use the notion of 'responsible' as well in its five year action plans (BMBF 2010, 2015), in which it mainly refers to the government's strategy on safety aspects and to a lesser extent to public communication.

In the Netherlands various frames of Responsible Innovation were referred to in the context of public policy and public dialogue. For example, the Dutch government framed Responsible Development as 'Risk Governance' (Cabinet 2006a), which included an emphasis on stakeholder and public dialogue about nanotechnology, whereas the final report of the Dutch dialogue committee (CieMDN 2011) was titled '*verantwoord verder met nanotechnologie'* [proceeding responsibly with nanotechnology, *BW*], which denoted an overall precautionary approach.

The bigger economies in Asia – Japan, China and India – also have been significantly investing in nanotechnology, but public and political debate about nanotechnology has been less articulate compared to the US and EU. In Japan 'Responsible R&D' of nanotechnology was taken up in the third national Science and Technology Plan, as reported by the National Institute of Advanced Industrial Science and Technology. The main strands of governmental activity have been contributing to (international) standard setting related to safety aspects and stimulating public acceptance (Ishizu, Sekiya et al. 2008). In India and China national efforts under the heading of Responsible

[20] The NKTN portal has been transferred to Innovate UK KTN (last accessed 3 March 2023)
[21] The Technology Strategy Board is now part of Innovate UK
[22] These principles are: 1) Definition and disclosure of responsibility and management (good governance); 2) Transparency regarding nanotechnology-related information, data and processes; 3) Commitment to dialogue with stakeholders; 4) Establishment of risk management structures; 5) Responsibility in the value chain

Development focused on risks and regulation only (cf. Kumar 2014; Sarpa & Anand 2013; Fautz et al. 2015, Beumer and Bhattacharya 2013).

In Australia public and political debate on nanotechnology has been much more prominent, stimulated by the activities of the environmental NGO Friends of the Earth Australia.[23] In this context the Australian government (2009) defined its 'Responsible Management' approach in terms of safety, 'community engagement' and 'achieving social benefit'.

Continuity, contingency and change

Highlighting the emphasis on risks and regulations and on public opinion and dialogue is not to say that attention for wider issues, such as global equity, or privacy in an ever more digitalised world, has been absent. The European Commission for example, as well as EU member states have commissioned several ethics committees and research projects. In this respect, attention for Ethical, Legal and Social Issues (ELSI) was part of a global public policy agenda on nanotechnology governance,[24] but less referred to in relation to the notion of Responsible Development and at larger distance from policy. These differences in institutionalisation also became visible at the level of international coordination in the OECD. In the OECD two working parties have been established: one on nanotechnology policy in general (WPN) and one on manufactured nanomaterials (WPMN). Whereas the WPMN developed rather targeted input for policy making, the WPN has been more focused at governance themes (e.g. Risk Governance, Sustainable Growth, Public Engagement). Before its transformation in a converging technologies oriented WP, the WPM did release a country report on Responsible Innovation (OECD 2013). In that report countries mainly have been listing all of their policy activities for nanotechnology, again with the main emphasis on safety and dialogue. Although differently profiled, both the WPN and WPMN operated in an 'established' institutional setting, together more likely to reproduce that setting (technical on safety and cataloguing on wider issues and governance itself) than to transform it.

This has been different for the International Dialogue on the Responsible Research & Development of Nanotechnology, which has been initiated by US and EC officials and yielded three meetings between 2004 and 2008. The topics discussed at this platform developed from establishing commitment (Virginia 2004) and initial emphasis on safety (Brussels 2005), to ELSI, Education & Capacity (Tokyo 2006, see AIST 2006) and developing countries and societal engagement (Brussels 2008, see Tomellini & Giordani 2008). These meetings didn't have any direct follow-up, but contributed to awareness raising and granting legitimacy to the wider policy contexts nonetheless. For example, according Ishizu et al. (2008) the Japanese strategy was inspired by the 2nd edition of the

[23] See list of publications and activities at http://emergingtech.foe.org.au/nanotechnology/ (last accessed 3 March 2023)

[24] Reflected in, for example, the report by UNESCO (2006): "The ethics and politics of nanotechnology"

International Dialogue on Nanotechnology taking place in Tokyo, against the background of the (mainly Western) controversies on genetic modification.

There are more contingencies present with regard to the examples discussed above. The focus on safety by the national NanoKommission in Germany coincides with the active participation of its large chemical industry. The association between Responsible Development and Risk Governance in the Netherlands had to do with a recently adopted risk governance strategy by the Dutch government (see Chapter 4). In UK government circles, the meaning of Responsible Development changed from an overarching label to safety in two years and to 'Responsible Innovation' later on, without changing much in content, while it did in UK scientific communities. And the 'achieving social benefit' goal of the Australian government in 2009, was in spirit with the times, but also in the context of fierce campaigning by Friends of the Earth Australia. These examples show that particular settings have shaped national variations in public policy induced articulations of Responsible Development, in being linked to a globally connected discourse about the governance of nanotechnology, but without an equally developed discourse on Responsible Development/Innovation (with a status like 'sustainability'). This, in turn, has shaped later trajectories in the quest for Responsible Innovation, as I will show below for Responsible Development as a policy concept in the governance of nanotechnology.

The fate of Responsible Development for nanotechnology in US federal government and European Commission

In the US Responsible Development was taken up in the 21st Century Nanotechnology R&D Act. In the adversarial political system of the US this has been regarded as an important step (Fisher and Majahan 2006). The act did, however, not define Responsible Development, but stipulated activities to be conducted by the NNI, as well as a one-time study "*to assess the need for standards, guidelines, or strategies for ensuring the responsible development of nanotechnology*" (US-Congress 2003). This study, drawing on a workshop in 2005, has been conducted by the National Research Council (NRC) – in the context of the first triannual review of the NNI. In that context the NRC report framed Responsible Development as:

> "*the balancing of efforts to maximize the technology's positive contributions and minimize its negative consequences. (..) It implies a commitment to develop and use technology to help meet the most pressing human and societal needs, while making every reasonable effort to anticipate and mitigate adverse implications or unintended consequences*." (NRC 2006)

As I will also discuss in Chapter 6 the vocabulary of 'positive contributions' and 'negative consequences' is important in US federal politics, where cost-benefit discussions to regulatory measures play a central role. In this respect, 'commitment' and 'reasonable' actually span up the space in which the new flavour of 'Responsible (Development)' has to find its place. But the discussion of the definition in the NRC report is very short and not translated into requirements for action. Instead, the report reviews the activities deployed by the NNI as well as abroad, mainly focusing at uncertainties about risks and public opinion and education in light of that. With this framing (in the report as well as its *de facto* acceptance) the defined 'balancing' nature of Responsible Development was located in the (political) evaluation of an activity portfolio, itself structured by prevailing ideas about good governance of nanotechnology. Similarly, the later reference to 'responsible stewardship' in the 2011 NANO Act (US-Congress 2011) reflected the by then increased attention to the role of (chemical) companies and practices of self-regulation (see below).

In the European Commission policy Responsible Development had a less prominent place. Initially, it mainly referred to ethics. However, in following up on the idea of a voluntary charter, a 'code of conduct for responsible nanosciences and nanotechnologies research' (EC 2008b, hereafter the 'EU-CoC') was developed within the EC. The EU-CoC is not a code of conduct in the regular sense, targeted at individual researchers and organisations, but written as a recommendation to European Union member states, giving guidance on how nanotechnology research should be organised responsibly by the member states, research funding bodies, research organisations and individual researchers. It does not specify what is 'Responsible' in a definition, but lists seven principles, to be read as a declaration rather than actionable principles:

1. *Meaning*
2. *Sustainability*
3. *Precaution*
4. *Inclusiveness*
5. *Excellence*
6. *Innovation*
7. *Accountability*

In addition to these principles, the EC Recommendation on the EU-CoC provides a list of guidelines for implementation, organised in three sections: 'good governance', 'due respect for precaution' and 'wide dissemination'. This particular content and structure of the code has been produced in a specific setting. The task for crafting the code has been taken up by the Ethics and Gender unit of DG-RTD, which coordinated the 'Science in Society' program of the EC. The principles as well as the guidance of the code clearly reflect the evolving discussions about the governance of new and emerging science and technologies in academic communities of social scientists and ethicists participating in the Science in Society program at that time. Moreover, within these communities, the key institutional entrepreneur's role of EC officer Rene von Schomberg has been recognised. According Von Schomberg the code is an attempt to go beyond individual role responsibility and to facilitate the establishment of a 'culture of responsibility' (cf. Von Schomberg 2009).

The differences between the US and EU settings can be understood as carried by different political cultures, resulting in different governance 'styles' (cf. Beumer 2015). Laurent (2012) describes the US-EU difference in terms of a focus on expertise in the adversarial political culture of the US against a focus on mutual construction in the EU corporatist culture. In a narrow sense this difference didn't matter much for the overall outcome of Responsible Development in the governance of nanotechnology. Where the NRC's balancing frame resurfaced in the political dilemma of "*rapid versus responsible*" development (Fisher and Majahan 2006),[25] the EU-CoC framing of responsible nanoscience was severely criticized for being toothless as a voluntary instrument, for duplication of other codes, for not being embedded in a wider strategic plan, for its academic language issues and its accountability principle (Widmer et al. 2010, Mantovani et al. 2011) and only a very few organisations have formally adopted the EU-CoC.[26] For both the US and EU this left the status of risk research, stakeholder and public dialogue and, to a lesser extent, ELSA-research hardly touched in the governance of nanotechnology.

Yet, the same tensions and criticisms also became new sources for further trajectories in the quest for Responsible Innovation. With all the criticisms, the EU-CoC actually did work as a conversational device, not at least in contributing to a rebranding of research activities in the EC Framework programs with references to Responsible Innovation (Fisher and Rip 2013). In the US, where ELSA-research and public dialogue had been delegated to academic Centers of Excellence, these became the same sites for both critique and experimenting with new framings and approaches to Responsible Innovation (cf. Bennett and Sarewitz 2006, Fisher and Majahan 2006).[27]

Multinationals, membership organisations and academic communities

Discussions about the governance of nanotechnology were not the domain of governments only. Intermediary organisations, such as research funding organisations and (regulatory) agencies, as well as consultancy organisations, civil society organisations and membership organisations in academia and industry, became involved in discussions about nanotechnology. Sometimes their contributions and

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[25] Fisher & Majahan locate this dilemma already in the 21st Century Nanotechnology R&D Act pushed by Congress: "The congressional balancing act between winning the global nanotechnology race and responding to the prospect of public resistance to the new technology is indicative of a more general convergence of larger trends that poses a growing dilemma for science and technology policy makers. In short, blindly obeying the technological imperative to push forward innovations as quickly as possible may jeopardize both the public interest and, ironically, the necessary public support for such innovations. On the other hand, without international cooperation, US policy makers will be greatly reluctant to risk slowing technological activities and limiting productivity, thus sacrificing competitive advantage."

[26] See, for example Arnaldi 2017. In Chapter 5, I will discuss how the EU-CoC became a funding requirement for the national nanotechnology program NanoNextNL.

[27] See Chapter 7, for a detailed discussion of the Center for Nanotechnology in Society at Arizona State University (CNS-ASU).

interventions have been ascribed a particularly agenda-setting role, such as for the call for a moratorium by the Canadian ETC group (see Chapter 1), or the re-insurance company Swiss-Re entering the scene by organising a workshop already in 2004 (Swiss-Re 2004). Overseeing the initiatives discussed below, one could say that the involvement of stakeholder organisations added to the credibility of governmental policies on nanotechnology more than challenging it, thereby sustaining the early trajectories of the quest for Responsible Innovation by references to the notion of Responsible Development. However, while public policy activities mainly concerned nanotechnology as a field of research and innovation, stakeholder organisations added articulations of Responsible Development from the perspective of how and what individual actors – first of all research and business organisations – should take responsibility for.

With respect to the notion of Responsible Development, actors in the public domain mainly mirrored the public policy discourse, including its geographical variations. In the early years of nanotechnology in the US, when concerns were about issues like super intelligence and self-replication in molecular manufacturing, Eric Drexler introduced '*Foresight Guidelines for Responsible Nanotechnology Development*'[28]. This approach took embedded controls and self-regulation as a reference point, inspired by the Asilomar conference at the time of high concerns about recombinant DNA. In the institutes Drexler was leading[29], training programs and instruments for self-assessment were developed. An affiliate of the engineering ethics organisation World Care, The Centre for Responsible Nanotechnology (CRN), developed community awareness raising activities.[30] Both centres didn't receive much attention outside their own communities, since Drexler had been publicly discredited for his molecular manufacturing scenarios (see Chapter 1.2).

In the context of the NNI, attention shifted to health and environmental materials. Vicky Colvin and colleagues at the Center for Biological and Environmental Nanotechnology (CBEN) of Rice University started the multi-stakeholder forum ICON (International Council on Nanotechnology) for information exchange and sharing best practices. ICON focused on health and environmental risks, for which it developed the '*GoodNanoGuide*'[31]. Vicky Colvin herself has been advocating *Safety-by-Design* as the more appropriate philosophy towards ensuring the safety of nanomaterials than research and development followed by regulatory approval (Kelty 2009). Later, Barbara Karn, having worked at one of the main agencies participating in the NNI – the Environmental Protection Agency (EPA, see also Chapter 6) – initiated the establishment of the Sustainable Nanotechnology Organisation (SNO),[32] which in a similar vein

[28] Published online at http://www.imm.org/policy/guidelines/ (last accessed 3 March 2023)
[29] Institute for Molecular Manufacturing (IMM), Foresight Insitute (last accessed 3 March 2023)
[30] See http://crnano.org/ (last accessed 3 March 2023)
[31] The GoodNanoGuide is available at https://nanohub.org/groups/gng (last accessed 3 March 2023), the ICON website does not exist anymore.
[32] http://www.susnano.org/ (last accessed 3 March 2023)

attempts to broaden pro-active approaches towards safety with sustainability goals, for example by developing Life Cycle Analysis (LCA) approaches. Both organisations kept a mainly academic character (also having research project budgets as the main source of funding), in which references to Responsible Development or Responsible Innovation have been used occasionally only. However, their missions reflect the integrative character of Responsible Innovation ambitions.

In Europe, academic communities in the field of nanotechnology also picked up on the emerging discourse about Responsible Development, although largely carried by the interest of social scientists. In the Netherlands for example, a workshop was organised on Responsible Research and Innovation (RRI)[33] by researchers from the Technology Assessment program in the national NanoNed consortium, seeking to make sense of the various codes of conducts and other voluntary measures developed for nanotechnology (Robinson 2009). In Europe, stakeholder interaction and codes of conduct were prominent approaches. A very explicit reference to Responsible Innovation in such a code was made by the '*Responsible NanoCode*' (Sutcliffe 2008) in the UK. The initiative for this code came from the Royal Society in following up on their policy advice on nanotechnology by actively seeking the involvement of industry in the governmental platform Nanotechnology Knowledge Transfer Network (NKTN). Contrasting to the EU-CoC which had a general declaration character, the Responsible NanoCode is clearly written from an actor perspective, providing principles for widening the regular circles of responsibility.[34] Activities for disseminating the code did not take off as the organisations involved could not agree on who and to what extent had to take responsibility for the required funding[35].

The active involvement of chemical industry in discussions about nanotechnology further strengthened the emphasis on risks and safety. Chemical industry companies and associations also brought in their own *Responsible Care®* scheme for safety and sustainability,[36] which was further specified for nanotechnology with reference to the notion of Responsible Innovation (CEFIC: 2008, 2012; ACC: 2005, DSM: 2005)[37]. In addition, a number of chemical companies have been involved in policy and stakeholder platforms (eg. joint statement of principles by the American Chemistry Council (ACC)

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[33] See http://www.responsible-innovation.eu (last accessed 3 March 2023). According de Saille (2015) this has been the first use of the notion 'Responsible Research and Innovation'.
[34] These principles are: *1) Board accountability; 2) Stakeholder Involvement; 3) Worker Health & Safety; 4) Public Health, Safety & Environmental Risks; 5) Wider Social, Environmental & Ethical Implications and Impacts; 6) Engaging with Business partners; 7) Transparency & Disclosure.*
[35] Original documentation (blog Sutcliffe) not accessible anymore. Brief impressions still can be found at https://www.societyinside.com/ (Last accessed 3 March 2023)
[36] The Responsible Care charter emphasizes 'stewardship', which implies pro-active and cooperative behavior (see https://icca-chem.org/focus/responsible-care/; last accessed 3 March 2023).
[37] These position documents are not available online anymore

and Environmental Defense Fund (EDF) (EDF-ACC 2005); The German Evonik and Bayer participating in the International Dialogue series, the VCI working party on Responsible Production and Use of nanomaterials (VCI/DECHEMA 2008; DECHEMA/VCI 2011) and BASF subscribing to the five principles of the German NanoKommission as well as organising its own dialogue and transparency forum[38]. These activities show that chemical industry has been well aware of its position as the sector primarily associated with nanomaterials, thereby building on mechanisms which were developed in response to earlier crises, such as the Responsible Care® program.

In addition, the liaison between chemical company DuPont and EDF in the US has been much referred to as an important instance of Responsible Innovation in nanotechnology (Walsh and Medley 2008, Krabbenborg 2013). The liaison had been initiated by the Woodrow Wilson Center, which had started an analysis and engagement project on nanotechnologies.[39] The Woodrow Wilson Center also facilitated the work on the resulting Risk Frame for nanomaterials and subsequent training program was, which were called '*a framework for responsible nanotechnology*'[40]. The framework has been adopted by several organisations, yet, much like the UK Responsible Nanocode, the Dupont-EDF framework has been more important as a visible initiative than for its adoption and impact. The latter was foreseen to be facilitated by a Nano Policy Forum, supporting ISO standardisation and adoption by insurance companies, but which hasn't been established (Fiorino 2010).

At international level, the Nanotechnology Industry Association (NIA) and the Business and Industry Advisory Committee to the OECD (BIAC) profiled Responsible Innovation as part of coordination and standardisation activities in the OECD WPMN, the International Standardisation Organisation (ISO) Technical Committee on nanotechnology (TC229)[41] and the European Committee for Standardisation (CEN). NIA labelled its activities as '*sustainability and shared responsibility'*[42], BIAC issued a position paper on Responsible Development in which it called for ensuring safety in light of benefits by developing regulatory frameworks (BIAC 2013). Within the CEN TC352 committee French members attempted to make Responsible Development part of the standardisation activities by

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[38] See https://www.basf.com/za/en/who-we-are/sustainability/we-produce-safely-and-efficiently/resources-and-ecosystems/nanotechnology.html (last accessed 3 March 2023)

[39] Archive available at http://www.nanotechproject.tech/ (last accessed 3 March 2023). See also Chapter 6.

[40] See https://www.edf.org/news/environmental-defense-and-dupont-jointly-launch-nano-risk-framework-evaluate-and-address-potent (last accessed 3 March 2023)

[41] https://www.iso.org/committee/381983.html (last accessed 3 March 2023) Wickson and Forsberg (2015) have described standardisation initiatives like the TC229 as important sites where Responsible Innovation is shaped, but also criticized the inclusive qualities of it.

[42] Between 2012 and 2015, current statements can be found at https://nanotechia.org/about/mission

including transparency measures.[43] This, however, failed because of ongoing discussions about defining nanomaterials and France starting a notification systems itself (Laurent 2012).

In conclusion
Four features can be singled out from above discussion:

1) As a policy concept, Responsible Development mainly was used as a qualification, i.e. as a label for good governance. It didn't institutionalise according to specific interpretations of the notion itself, but has been used as a frame for policy mixes for nanotechnology. Instruments were concerned with handling potential negative consequences of nanotechnology research and applications, according to the 'Development' frame: directions and applications remained unquestioned (i.e. in as far as articulations concerned the meaning of Responsible Development). In the context of large public investments in nanotechnology and against the background of earlier controversies about biotechnology, this served as a warrant for investing in contested science.

2) The dominant framing of Responsible Development in terms of risks and regulations was part of a globally interconnected policy discourse in which uncertainty about safety was mainly treated as a knowledge problem and stakeholder and public dialogue activities largely were geared towards risk issues. Broader social impact received less attention and mainly were the domain of ELSA research and ethical committees, except for some more visible discussions about global equity, amongst others with reference to the Millennium Development Goals (e.g. EC 2005).

3) Public policy articulations of Responsible Development were framed from a system perspective; i.e. governance processes and outcomes for nanotechnology as a field and its impact in society. Articulations by multinationals and membership organisations have been focusing on responsibilities of actors, typically of producers/employers with regard to safety issues, much less about wider societal impact.

4) In the institutional settings in which Responsible Development was articulated, it has been mainly linked to the governance of research and innovation in terms of funding, education, regulation, etc. and less to science and engineering practices directly. Established policy instruments and arrangements were called upon (e.g. Responsible Care® in chemical industry), but a new repertoire of stakeholder interaction, codes of conduct and other voluntary measures emerged as well. Most of these initiatives existed only temporary and have not

[43] See Laurent (2012): working group WG 2/ PG2/ TS N 48 - Nano-responsible Development

been widely disseminated.[44] Yet they did create new networks[45] and contributed to the overall credibility of Responsible Development as a policy goal.[46]

From the material discussed in this section it can be argued that the discourse on Responsible Development in nanotechnology has sustained trends in the governance of research and innovation rather than inducing these. It also created new openings, such as the crafting of the EU-CoC. The latter served as a stepping stone for the SiS/SWAFS group in the European Commission to extend their 'Responsible Research' along the value chain and expanding the scope to wider concerns and societal challenges.

2.3 Responsible Innovation and emerging technologies

After the first wave of policy documents on nanotechnology the notions of Responsible Innovation, or Responsible Research and Innovation (RRI), took over Responsible Development's position. This change happened in the context of two interrelated shifts: while 'innovation' became a key topic in science policy, calls for moving "*from the governance of risk to the governance of innovation*" (Davies et al. 2009, Stilgoe, Owen et al. 2013, Pellizzoni 2015) emerged as well. Where Responsible Development signified that uncertainties about negative consequences would (have to) be taken seriously, Responsible Innovation also channelled calls like "*taking the knowledge society seriously*" (EC 2007b) for addressing societal challenges, such as (global) health and sustainability. At the same time, the discussions about nanotechnology further evolved into discussions about 'emerging technologies' in general. Where nanotechnology once was being heralded as the next big thing (after biotechnology), other developments in science and technology quickly followed with similar claims (neuro, synthetic biology, geo-engineering). As such, they generated a continuous production of questions about impact as well as direction. The decline of Responsible Development and the rise of Responsible Innovation thus marks a shift in the use of Responsible Innovation as a policy concept.

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[44] E.g. the International Dialogue, the EU-CoC, the UK Responsible NanoCode, the German code of conduct

[45] For example, the Woodrow Wilson Center and the DuPont-EDF liaison; the Meridian Institute and the International Dialogue (also running a series of dialogues and a newsfeed on 'nanotechnology and the poor'), Hillary Sutcliffe (Responsible Futures, Responsible NanoForum, MATTER, Society Inside) and UK NanoCode as well as European Commission activities, Dialog Bases and the BASF NanoForum as well as European projects.

[46] For example, ICON provided a space for awareness, reflection, debate and experiment; the DuPont-EDF liaison didn't solve systemic challenges in the US federal regulatory framework TSCA, but it challenged both chemical industry and NGO's in taking responsibility.

Much of that shift has been taking place in interactions between policy settings on the one hand and academic and corporate settings on the other, sometimes resulting in interchangeable references to the notion of Responsible Innovation, sometimes co-existing in different tones and interpretations. For example, while the Responsible Development discourse in nanotechnology has been firmly criticised for its narrow focus on risks and public acceptance (cf. Davies et al. 2009), it also has been positively portrayed for capturing a comprehensive set of activities and developments in the governance of nanotechnology, without sharp lines between Responsible Development and Responsible Innovation (cf. Morris, Willis et al. 2011, Roco, Harthorn et al. 2011).

Responsible Research and Innovation (RRI) in the European Commission

The most well-known site is the Horizon2020 research funding program of the European Commission (EC). In the regulations of Horizon2020 RRI has been defined as a cross-cutting issue[47], which means that "*linkages and interfaces*" will have to be developed throughout the entire program. De Saille (2015) traces the history behind this status of RRI back into the reorganisation of the EC's research and innovation activities into the European Research Area (ERA). In response to the evaluation of the Lisbon Treaty on stimulating the knowledge economy, ERA would have to provide a better integration of research and innovation. The financial crises which started in 2008 contributed to a strong framing of ERA in terms of competitiveness and economic growth. At the same time the thematic structures in stimulating research and innovation were criticised for hampering the development of solutions for "the grand challenges of our time" (Lund declaration 2009), such as climate change, energy security and ageing societies. In this context, the Ethics and Gender unit of DG-Research pushed RRI as a guiding concept for realising the transformation of European research and innovation by appealing to another European ambition: *integration* through active interactions between researchers, technology developers, stakeholder groups and citizens.

With its status as a cross-cutting issue, RRI potentially could have a big impact on the governance of research and innovation. Its actual trajectories are, however, shaped by the interplay between the same unit, which adopted a 'mainstreaming RRI' task for developing the linkages and interfaces as stated in the Horizon2020 regulation, and the community of researchers, mainly from the social sciences and humanities, it funds in the Science With And For Society (SWAFS, formerly: SiS – Science in Society) program of Horizon2020. In the EC unit, RRI has been pushed by a relatively small number of EC officials, in particular by Rene von Schomberg, who had been coordinating the development of the EU-CoC for responsible nanoscience. Von Schomberg (2014) defined RRI as a follow-up to the EU-CoC's ambition of stimulating a general culture of responsibility and explicitly positioned it as a move from "*the Responsible Development of Technologies to Responsible Innovation*" by emphasising the integration of values as defined in the European Treaty through active interactions:

[47] Regulation EU (2013) – Article 14, 1-l

"Responsible Research and Innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)." (von Schomberg 2011, von Schomberg 2013, von Schomberg 2014)

Von Schomberg also discussed RRI as to be realised by an integration of the topics and governance instruments the SiS unit and program had been concerned with: Technology Assessment and Foresight, applying the Precautionary Principle, normative/ethical principles for technology design, innovation governance, stakeholder involvement and public engagement (von Schomberg 2014). All of these would have to facilitate that actors become mutually responsive. In 2011 the unit set out on the ambition to write a EC recommendation on RRI. This has been discussed with a wider group of experts in a workshop (Sutcliffe 2011) and brought into the negotiations on ERA. Over time, the unit has amended the definition a couple of times, and increasingly started to emphasise the themes it is responsible for in DG Research as 'keys' to RRI (de Saille 2015):

Gender
Open Access
Education
Ethics
Engagement

Later on, 'governance' has been added as a sixth key. Adopting and amending these keys next to RRI's definition, such as happened in the subsequent SiS and SWAFS programs and bi-annual conferences (Copenhagen 2012, Rome 2014)[48], allowed for the specification of various research topics. This has resulted in an equal variety of articulations of Responsible Innovation in the SiS and SWAFS research projects on RRI, reflecting disciplinary backgrounds and earlier research interests (from ethics and global equity to governance and of Corporate Social Responsibility). With that, an active discourse on Responsible Innovation developed, but limited to a relatively small circle of mainly academia and without an overarching philosophy and strategy for integration into the European Research Area.

Responsible Innovation in business and academia

References to Responsible Innovation from businesses are often statements from multinationals, denoting CSR policies for R&D activities.[49] In relation to the EC activities, business association EIRMA (European Industrial Research Management Association)

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[48] See resp. Denmark Ministry of Higher Education and Science (2012) and Archibugi et al. (2014)
[49] References to R(R)I by multinationals often have been replaced by notions of sustainability (e.g. UN SDGs).

did set up a task force[50] to link up with discussions about RRI in Horizon2020. In the UK, consultancy organisation MATTER has reworked the principles of the ResponsibleNanoCode (see previous section) into business principles for Responsible Innovation. A number of university research groups adopted Responsible Innovation as its research object, partly by participating in SiS and SWAFS research projects on RRI, but also in local networks and communities, often building on earlier research themes.[51]

More formalised activities have been taking place as commissioned by research councils in the Netherlands, UK and Norway. The Dutch NWO started the research program *Maatschappelijk Verantwoord Innoveren* (MVI; Societally Responsible Innovation),[52] which focuses on societal issues in science and technology, partly in liaison with WOTRO on innovation for developing countries, and stakeholder interaction by user committees. In this program Responsible innovation is not conceptualised in a specific definition, but used as a label and working as a theme for the annual conferences. The MVI program has developed rather independently from the discussions about RRI in the European Commission, with strong input from the Dutch Ethics & Technology community.[53]

In the UK the notion of Responsible Innovation also has been in the air for a longer time, first in relation to nanotechnology, later in the fields of ICT, synthetic biology and especially geo-engineering[54]. Most of these activities have been funded by the Engineering and Physical Sciences Research Council (EPSRC) and Economic and Social Research Council (ESRC). Like Rene von Schomberg and colleagues in the EC, individual researchers like Richard Owen, played a key role (cf. Owen and Goldberg 2010). In the context of their work on geo-engineering Owen and colleagues developed a framework for Responsible Innovation at the EPSRC (Owen, Stilgoe et al. 2013). After a publication in the journal Research Policy (Stilgoe, Owen et al. 2013) this framework and their definition has become as well-known in academic networks as the Von Schomberg / European Commission definition of RRI. They positioned their definition of Responsible Innovation as designed for deployment in (publicly funded) research projects. To that end their definition is short, taking inspiration from the Brundtland definition of sustainability:

> *"A commitment to care for the future through collective stewardship of science and innovation in the present."*

[50] See EIRMA website (last accessed 3 March 2023)
[51] For example: University of Nottingham, University of Oslo, Ecole des Mines
[52] https://www.nwo.nl/en/researchprogrammes/responsible-innovation
[53] e.g. the work on Value Sensitive Design (VSD) by MVI chair Jeroen van den Hoven
[54] Resulting in the 'Oxford principles' (Rayner et al. 2013) as well as the framework by Owen et al. (2013)

The accompanying framework which has to facilitate Responsible Innovation is positioned as a synthesis of various preceding attempts to account for societal values, needs and impact in research and innovation, resulting in four dimensions:

Anticipation
Reflexivity
Inclusion
Responsiveness

In the publication these dimensions are framed as evaluative orientations. In the final framework endorsed by the EPSRC the dimensions have been translated into verbs (Anticipate, Reflect, Engage and Act). According to (Murphy, Parry et al. 2016) this makes the framework more actionable, but also losing out on its overall reflective nature. The EPSRC states that it expects researchers to work according the framework principles and report any barriers and dilemmas if encountered.[55]

In the US the Center for Nanotechnology in Society at Arizona State University (CNS-ASU) did put forward its vision on Anticipatory Governance as a philosophy to stimulate Responsible Innovation. Barben et al. (2008) have conceptualised Anticipatory Governance as comprising 'Foresight, Engagement and Integration'. Different from the dimensions of the framework by Owen et al., these are operationalised in (sets of) activities, aiming at capacity building for foresight, engagement and integration rather than performing these as functions itself. In this respect, Anticipatory Governance is understood as a 'broad-based capacity' (Guston 2014), transforming the governance of research and innovation itself in forward-looking, collectively oriented and integrative practices, without structuring along substantive values, such as provided in the definition of RRI by Von Schomberg. To realise such a goal, CNS-ASU positioned its center-model as a promising trajectory, for providing spaces of stimulating bottom-up interaction between citizens, social scientists and engineers (capacity-*building*), as well as interlinking foresight, engagement and integration activities ('ensemblisation', see Valdivia and Guston 2015).

In Chapter 7, I will discuss in more detail how the efforts of CNS-ASU and its host institution CSPO not only provided for a third source of conceiving Responsible Innovation, but also strengthened the position of both references to RRI and the EPSRC framework through transatlantic academic peer communities, such as the Society for the analysis of New and Emerging Technologies (S.NET), in which Responsible Innovation has been discussed as a key topic.[56] Besides close ties to the journal NanoEthics, CNS-ASU launched the international network ViRI (Virtual Institute for Responsible

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[55] See https://www.ukri.org/about-us/epsrc/our-policies-and-standards/framework-for-responsible-innovation/ (last accessed 3 March 2023). A reflection on the 'making' of Responsible Innovation in the EU and UK is provided by Macnaghten (2020).
[56] http://www.thesnet.net/ (last accessed 3 March 2023)

Innovation)[57] and hosted the editorial office of the Journal of Responsible Innovation (JRI). In turn, many of the researchers involved, also participate in academic communities on science and innovation policy studies, Technology Assessment (TA) and science communication.[58]

Scientometric analysis performed in the Res-AGorA project (Tancoigne et al. 2016) shows that the academic publications on Responsible Innovation come from a relatively small number of people, often in relation to their participation in RRI projects funded by the European Commission. So far this corpus of texts exists as a separate branch in the literature, hardly connected to the (much bigger) corpus of literature on responsibility in science and institutionally separated from the physical and engineering sciences as measured by cross-linked authorships. Instead, the Responsible Innovation literature heavily draws on earlier themes and institutional settings as Ethics, Impact Assessment and Corporate Social Responsibility. Against this background the Responsible Innovation literature until 2015 has been converging on advocating:

- a widening of societal actors participating in the governance of R&I
- orienting research and innovation towards addressing societal problems (grand challenges)
- a shift from retrospective accounts (accountability, liability) to prospective (anticipative) future-oriented accounts of responsibility (Randles, Larédo et al. 2016)

In conclusion
This section has shown that the discourse on 'Responsible (Research and) Innovation' largely emerged from the earlier discourse on 'Responsible Development' in nanotechnology. But it didn't replace it. While references to Responsible Development were declining after the first wave of public attention to and investments in nanotechnology, the positioning of nanotechnology itself as important for economic growth has contributed to a more general discourse on technological innovation. Scholars working on 'science and technology', often in the field of nanotechnology, moved along in adhering to the newer discourse on 'research and innovation', but also in seeking more radical, normative, comprehensive or integrative perspectives and approaches on the governance of research and innovation. From above discussion, a number of features can be singled out for further discussion:

1. Where Responsible Development often served as a qualification of the governance of risks, Responsible Innovation is framed more as a normative model for the governance of research and innovation. However, there are multiple models advocated, as reflected in the rationales behind definitions

[57] https://cns.asu.edu/viri (last accessed 3 March 2023)
[58] E.g. Eu-SPRI, Gordon research conferences, PCST

and frameworks, ranging from interactive arrangements for integrating values (Von Schomberg), activities on key themes (SWAFS-program), reflexive orientations (Owen et al.), prioritisation and stakeholder interaction (MVI), to capacity building (CNS-ASU). The differences between these philosophies to stimulating Responsible Innovation correspond to the institutional settings and trajectories they have originated in.

2. All instances share a collective and forward-looking orientation and an emphasis on addressing societal challenges, reasoned from a system perspective, although differently operationalised. Compared to the notion of Responsible Development, Responsible Innovation also emphasises stakeholder interaction and public engagement, but adds issues of direction and anticipation, as well as a stronger emphasis on integration in research and innovation. 'Responsibility' is defined accordingly, in terms of care/stewardship and responsiveness, or it is translated into goals and keys.

3. Although Responsible Research and Innovation (RRI) has been defined as a cross-cutting issue in the Horizon2020 research and innovation funding program of the European Commission, the science-policy discourse about it has been mainly confined to social scientists and institutionalisation limited to experiments in research projects.

In sum, the emerging discourse on Responsible Innovation both continued and changed the discourse on Responsible Development. Upfront still are *addressing issues* with regard to societal impact of science and technology (safety, equity, desirability) and governance functions and arrangements to do so (precaution, dialogue, Corporate Social Responsibility, ELSA-research). However, the shift from Responsible Development to Responsible Innovation also shifted the attention to the research and innovation *systems producing* these issues. This move opens up to issues beyond concerns about the impacts of emerging technologies, while at the same time affecting them by adding themes, functions and qualities to be accounted for in the governance of research and innovation (anticipation, direction, inclusion, reflexivity, capacities, access, gender, education). Paradoxically, this broadening of scope happened in smaller circles, as the new discourse on Responsible Innovation has been less directly connected to practices of engineering and policy making for emerging technologies.

2.4 Responsible Innovation as part of larger shifts

In this section I will further situate the quest for Responsible Innovation in wider discourses about the governance of research and innovation. The purpose of this step is to bring together actual challenges in the governance of research and innovation with respect to aims of Responsible Innovation and a deeper understanding of how new responsibility conceptions voiced in the discourse about Responsible Innovation, relate to long term drivers and developments in research and innovation. As mentioned in section 1.1, this is an interpretative step, for which I will take the debate about nanotechnology again as a proxy for the challenges involved in the responsible governance of emerging fields of science and technology. Next I will discuss how the new responsibility conceptions voiced in the discourse about Responsible Innovation are thought to address these challenges. Finally, I will associate both challenges and ideas to historical and sociological accounts, so as to identify a set of key challenges for *transforming* responsibility in research and innovation.

Challenges in issues and institutional arrangements

The debate about nanotechnology features a familiar list of issues with respect to emerging technologies: questions about risks and safety; broader impacts such as socio-economic effects, as well as moral issues; and claims about stakeholder participation and democratic control (Hanssen et al. 2010). Each of these categories hold specific institutional challenges, discussed below.

Uncertainty about the safety of nanomaterials has been the most prominent issue. Traditionally, this is an issue dealt with in highly institutionalised and expert driven practices of (regulatory) risk assessment and management. However, these practices have been gradually evolving towards communicative approaches. With that, questions of precaution and participation have become more prominent. This shift has been labelled as a move from Risk Management to Risk Governance and further organised into frameworks. A leading example is the framework of the International Risk Governance Council (IRGC, see Renn 2005, Renn and Roco 2006). The basic reasoning of the IRGC is that aspects of complexity, uncertainty and ambiguity, each require specific participatory strategies for stakeholder involvement and public dialogue.[59] In many national and international policies for nanotechnology governance, elements from Risk Governance strategies have been adopted.

However, in regulatory settings evidence and scientific consensus remain the core focus. As a result, uncertainty about health and environmental effects remains to be treated as a knowledge problem, also in participatory settings. Calls for 'more research' induce an 'uncertainty paradox' (van Asselt and Vos 2006): uncertainty is addressed with knowledge development, which often raise new questions and uncertainties. This problem is exacerbated in dealing with merging technologies, where it is novelty that is the main sources of uncertainty. In addition, nanosafety research is struggling with (international) coordination, quality control and regulatory relevance (Krug 2014).[60] It

[59] The shift towards Risk Governance thinking has been co-evolving with new directions in the domain of Technology Assessment (Van Est et al. 2012)

[60] These problems can be seen as a form of 'manufactured uncertainty', not as a result of malicious intent (as in Michaels 2006), but rather as 'organised irresponsibility' (Beck 1992): the

is, therefore, of no surprise that the effectiveness of risk governance approaches in nanotechnology have been questioned (Hansen et al. 2013, Miller and Wickson 2015). As for nanomaterials, agreement on precautionary measures has been feasible only in the area of occupational safety, while more proactive approaches, like Safe-by-Design are still at experimental level. In this setting the challenge for Responsible Innovation is one of institutional transformation indeed, in both advancing the effectiveness of participatory practices and improving anticipation of novel questions.

Issues about socio-economic impact, such as equity and privacy, and moral questions about artificial life or human enhancement have been discussed mainly by social scientists and from ethical perspectives. This situation has rendered various strands of critique: while existing mechanisms, such as ethical reviews in Europe and broader impact assessments in the US have been discredited for becoming either tick-box or paper-based exercises (Johnsson, Eriksson et al. 2014), the emerging nano-ethics community would be either too speculative (Nordmann and Rip 2009) or just cataloguing concerns without a clear relation to nanotechnology, rather than exploring paths and solutions (Davies et al. 2009, Kermisch 2012). Furthermore, parallel research on ethical, legal and social issues (ELSI) has been critiques as a model already at the start of nanotechnology investments (see section 1.2). The challenge of integration has been the focus of approaches like Constructive Technology Assessment (Rip 2018), Value Sensitive Design (van den Hoven 2013) and Social Technical Integration Research (Fisher and Guston 2012) and positioned as proof-of-concept instruments in the discourse about Responsible Innovation (Fisher and Rip 2013). By the same token they face challenges of institutional uptake and mainstreaming.

The many initiatives in stakeholder involvement and public debate about nanotechnology have been heralded as the responsible way forward as well as discredited for being toothless and predominantly focused on risks. Information campaigns and public debates have not increased controversy, but neither led to increased awareness or informed decision making (Chilvers 2010). Most efforts are quite remote from actual research (Doubleday 2007) and aim for public acceptance rather than public engagement (Groves 2011). Trade unions, consumer associations and environmental organisations have been given much space for voicing concerns, but without changing practices of regulatory risk assessment and risk management. Moreover, the idea of moving public engagement ‘upstream’ (Wilsdon and Willis 2004) – already in the very early phases of nanotechnology development – largely has been drawing on theories about deliberative democracy and dialogue techniques which have not been designed for coping with the uncertainties in discussions about future impact (Chilvers and Kearnes 2020).

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funding of risk research on nanomaterials long relied on competitive funding schemes, which hampered developing a knowledge base.

Above challenges of anticipating novelty, classical problem frames, integration and 'making science public' are again interrelated. An important dimension in these recursive practices is the interplay between actor level and system level responsibilities, playing out across public-private borders. While corporate involvement in public research and innovation programs has significantly increased (Edler 2003) this also affects the articulation and distribution of responsibilities. In settings of stakeholder involvement, businesses are often represented by internationally operating industries. These relatively large firms have adopted Corporate Social Responsibility (CSR) schemes, which already go beyond compliance to legal requirements (Scherer and Palazzo 2011) and include economic, legal, ethical and philanthropic social responsibilities, as well as attention for good governance and stakeholder involvement (Carroll 1991, Carroll 1999). While this doesn't provide for a full warrant against malicious behaviour[61], the challenge for responsible Innovation lays in the related schemes of standardisation, accreditation and auditing[62], which are less geared towards adapting to new issues and collective action and coordination. Smaller companies often lack the capacity to engage in such activities at all.

Changing conceptions of responsibility

A big question for Responsible Innovation thus is how new responsibility conceptions can help transforming responsibility in research and innovation in such a way that institutional challenges are being addressed. In the discourse about Responsible Innovation various authors have discussed what responsibility entails. In the field of science and engineering ethics taxonomies of responsibility concepts have been developed (e.g. Vincent 2011) on the difference between virtue-, role-, outcome-, causal-, capacity- and liability-responsibility). Others present genealogies, in order to highlight change in conceptions of responsibility (e.g. Grunwald 2011, Doorn and van de Poel 2012, Grinbaum and Groves 2013)), highlighting particular aspects, such as care ethics and collective responsibility (e.g. Groves 2015, Pellé 2016), or investigating differences and commonalities between Responsible Innovation and Corporate Social Responsibility (Blok and Lemmens 2015, Pellé and Reber 2015, Pavie 2014)[63].

The attempts to disambiguate responsibility can be helpful to inform governance strategies by linking responsibility conceptions to specific governance modes and

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[61] e.g. Volkswagen leading in 'diesel-gate', while claiming commitment to 'clean tech' and being top-rated for its social programs.

[62] https://www.iso.org/iso-26000-social-responsibility.html

[63] Recent typologies are provided by, for example, Moan, Ursin et al (2023) and Sonck (2023). Both build on distinctions similar to those of Arnaldi, Gorgoni et al (2016), which I will take as a reference for characterizing the new responsibility conceptions voiced in the discourse about Responsible Innovation. Both also construct normative orientations for governance as informed by the various responsibility conceptions, whereas I will do so by linking the shift in responsibility conceptions to historical and sociological trends in research and innovation, thereby developing a 'socio-normative' approach.

rationales. Swierstra (2014) for example, did express the four dimensions of Owen et al. in a responsibility vocabulary more close to science policy (aspirational for anticipation, democratic for inclusion, collaborative for reflexivity and comprehensive for responsiveness).[64] Swierstra's responsibility conceptions also voice the more positively toned responsibility language of Responsible Innovation: 'responsible' is often understood virtuously, emphasizing pro-actively taking care for the future rather than being concerned with accountability or liability for impacts in the past or present, which has become dominant in regulatory contexts (Pellizzoni 2004), even with respect to the precautionary principle. Closely related, responsibility ascriptions highlight collective and participative aspects.

The new ascriptions of responsibility do not replace older ones, but come on top of these, although differently exercised in the governance of research and innovation. According to (Arnaldi, Gorgoni et al. 2016) four basic (though overlapping) paradigms of responsibility can be discerned: 1) the classic idea of the responsibility of individual moral agents being accountable, 2) its expression in collective settings by the paradigm of solidarity, 3) the specifically political and anticipatory paradigm of precaution in case of uncertainty about safety, and 4) the idea of Responsible Innovation, which extends the paradigm of precaution into steering research and innovation towards desired goals. The different responsibility paradigms are enforced with different regulatory mechanisms (hard and soft regulation or combinations). These 'new' governance arrangements, such as voluntary and participative instruments, neither replace older ones, but interact with other governance instruments and arrangements shaping research and innovation.

However, how these governance arrangements can bring about the desired transformation of responsibility in research and innovation still is an open question. At individual level, for example, scientists and engineers assume a number of responsibilities for science in general (Frankel 2015). Empirical investigations of how responsibilities under the heading of Responsible Innovation are understood show many variations and degrees, e.g. with respect to the EU-CoC (Kjolberg and Strand 2011), the Anticipatory Governance program of CNS-ASU (Davies, Glerup et al. 2014), or at Nottingham university (Hartley, Pearce et al. 2017). Likewise, responsibility frames at the level of research and innovation systems been diversifying in different directions, ranging from 'the republic of science', risk-benefit weighing, the 'participation society', the 'citizen firm' or moral globalisation to 'science for society' (Randles, Larédo et al. 2016). What is more, the increasing emphasis on research and innovation for solving societal challenges, also revitalises technology push orientations (Lindner et al. 2016). Therefore, we first have to zoom out again, to contexts and drivers for responsibility ascriptions in research and innovation.

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[64] Swierstra also adds dynamic responsibility to avoid classical conceptions of subjects governing objects and to account for mutual shaping with the materiality of science and technology.

Change in the context of larger shifts

The current quest for Responsible Innovation can be seen as an expression of a longer trend in extending responsibility beyond individual responsibilities (e.g. of scientists and engineers) and organizational responsibilities (e.g. Corporate Social Responsibility), into organizing responsibility in research and innovation systems. In the discourse about Responsible Innovation it is framed as, for example, a culture of responsibility (von Schomberg 2013), a broad-based societal capacity (Guston 2014) or an institutionally supported ethics of care (Stilgoe, Owen et al. 2013).

A joint thrust in the new responsibility conceptions is that responsibility is conceived as both *open* and *active* (Arnaldi, Gorgoni et al. 2016). Both features reflect longer term developments with respect to social accountability in research and innovation, which have been discussed in, for example, the work of (Jonas 1984) on responsibility in a technological age, or of (Beck, Giddens et al. 1994) on reflexive modernization. Recognition of wide scale societal impacts, such as environmental pollution and the sociological understanding of science and technology practices that followed on the one hand, have pushed *democratization* of what was once called 'Science and Technology'. International competition and the idea of innovation systems, have pushed *economization* of what is now called 'Research and Innovation' on the other. These two shifts have become interrelated and further evolve in various modes of anticipatory coordination (Joly, Rip et al. 2010, Rip 2012). For example, the expectations about new sciences and technologies discussed in the previous chapter are actively produced in practices of foresight, roadmapping, business intelligence or various forms of Technology Assessment (Alvial 2016).

According to (Rip 2014) these developments reinforce a move "*towards increasing social accountability of professionals and institutions*". Individual scientists and engineers as well as organisations are increasingly expected to be good citizens. However, anticipatory coordination also connects to other logics, such as new public management modes of monitoring and evaluation in the context of economic reorientation in research and innovation (cf. Kaiser, Kurath et al. 2010) '*the rise of an assessment regime*'). Moreover, in the context of increasing emphasis on economic relevance, tensions between the various responsibilities (solve societal problems, do not cause harm, be transparent, make profit, etc.) may increase as well. These tensions may be handled differently, and hopefully more constructively, but they cannot be resolved completely and thus remain a source of value conflict. Just as well, it is exactly the dialectical relation between 'promotion and control' (Schot and Rip 1997) in research and innovation that has sparked the open and active understanding of responsibility. These central themes, therefore, represent a set of key challenges for the governance of Responsible Innovation and its object of transforming responsibility in research and innovation.

2.5 Key challenges in the quest for Responsible Innovation

The task for this section is to make sense of the quest for Responsible Innovation as discussed so far, for interpreting case study findings later on. Section 2.2 and 2.3 have rendered the quest for Responsible Innovation as simultaneously comprising a list of goals (safety, equity, desirability), the mobilisation of typical governance functions and institutional arrangements to achieve these goals (precaution, dialogue, Corporate Social Responsibility, ELSA-research) and various attempts to transform the governance of research and innovation in general (anticipation, direction, inclusion, reflexivity, capacities, access, gender, education), drawing on new conceptions of responsibility.

How this polyvalent and polycentric quest would have to transform responsibility in research and innovation at large, certainly wasn't a clear-cut picture at the time. When a new round of EU funded RRI projects took off, working on mainstreaming and institutionalisation, Responsible Innovation was pitched as "*an idea whose time has come*" (Van den Hoven 2014), "*here to stay*" (Swierstra 2014) or which "*the conditions are now right for*" (Rome Declaration 2014). However, scholars listed a number of gaps, ranging from a lack of cross-cultural perspectives, multiple production of meaning, fluidity of object to issues of political economy (e.g. Macnaghten, Owen et al. 2014). Hellström (2003) and Grunwald (2011) positioned Responsible Innovation as an evolution of Technology Assessment (TA), while van Lente, Swierstra et al. (2017) interpreted Responsible Innovation as a critique of TA. Scholten and Blok (2015) call for extending to the domain of Corporate Social Responsibility. Van Oudheusden (2014) warned for Responsible Innovation as a depoliticising concept, while Hartley, Pearce et al. (2017) reported the opposite for university settings. Von Schomberg (2011, 2013) listed precaution as a core element, while the European industry association EIRMA (2016) concluded that "*understanding and applying the principles of RI could help delay regulation, and act as a counterbalance to the demands of the precautionary principle*." In the US, Valdivia and Guston (2015) stated: *"Responsible Innovation is not a doctrine of regulation and much less an instantiation of the precautionary principle."*

Yet, the discussion in section 2.4 helps to understand why such divergence of positions is more than a struggle about meaning. Apart from confirming the basic assumptions of Responsible Innovation as always contested and never starting from scratch (see section 1.1), there are central challenges and recurring tensions to be addressed in any attempt for working towards transformative change. In this respect two analytical orientations can be established from the discussion in this chapter. The first orientation is derived from my analysis of the various articulations of Responsible Innovation and concerns the difference between actor and system perspectives (see section 2.2 conclusions). These perspectives constitute two typical problem-responsibility configurations, each of which affects the prospects of transforming responsibility differently. The second orientation concerns the set of key challenges that have been identified in discussing the quest for

Responsible Innovation as part of larger shifts (section 2.4). This set of challenges provides a frame for evaluating dynamics of interplay.

Governance domains and problem-responsibility configurations

In Chapter 4 – 7 I will investigate four major efforts of working towards forms of Responsible Innovation in the governance of nanotechnology, comparing efforts in the US and the Netherlands: addressing uncertainty about safety in risk governance and integration of societal considerations in research governance. These domains have been selected for reflecting two typical constellations of learning between actors. For nanosafety governance, the analysis focuses on organising concerted action between more or less independent actors, like authorities, regulatory science institutes, business and civil society organisations and departments of government. When it comes to practical implementation of policies, these actors interact horizontally, though in "*the shadow of hierarchy*" (Scharpf 1997). They have to respond to uncertainty about safety as an emerging problem, *out there*, no matter whether differently understood by the actors involved. Here, the key question is: how do actors have to cooperate towards responsible outcomes?

For interdisciplinary collaboration in research and innovation programs the analysis focuses on 'post-ELSI initiatives', i.e. the challenge of integrating (insights from) research on societal impacts and dimensions. Here, actors work within the institutional boundaries of a program responding to responsibility claims from outside and building new functions in the program accordingly. Hence, the perspective is *from within*, in learning about the problems and goods that are produced in relation to the core activity the program is identifying with (i.e. research and innovation) and taking care for potential outcomes. The key question in this respect, is about self-organisation: what should an actor do in order to act responsibly?

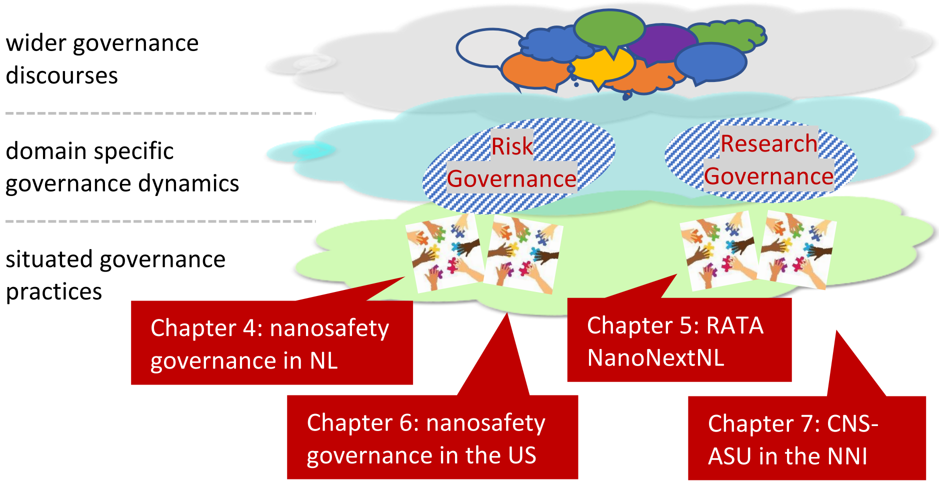

Figure 7: cases studies and governance domains

Key challenges and their interrelation

The central thrust of an open and active understanding of responsibility is often referred to as *anticipation* and *inclusion* in the discourse about Responsible Innovation. The related challenge for transformation is twofold. First, anticipation and inclusion are *interrelated* modes of reflexivity, aiming to address positive and negative impacts proactively (anticipation) as well as inclusively (from participation and deliberation more directly, to system conditions for education, access to scientific publications and gender equality). Second, as I have shown for emerging technologies, they are linked to a corresponding set of interrelated governance challenges: dealing with novelty and emergence and aligning promotion and control in research and innovation accordingly.

Together, this dual set of interrelated challenges reflects the transformation of responsibility as it can be discerned in the quest for Responsible Innovation. As such, it will serve as an analytic frame for evaluating case study findings. In each of the cases working towards systemic change has been linked to the challenge of aligning promotion and control under conditions of indeterminacy. How well these attempts have been playing out, has been crucially affected by how anticipation and inclusion are interrelated: what is being anticipated depends on who is included and how, and vice versa. By recasting the findings from the case studies in this way, I will flash out the key interdependencies involved and the conditions under which these have been reflected upon by the actors involved.

Crucially, this evaluative frame is not to be understood as a set of independent criteria, but a composition of analytical lenses, enabling a relational understanding of governance conditions and dynamics: for each situation as well as for the quest for Responsible Innovation 'at large', a joint thrust is to anticipate societal dimensions in research and innovation, to deal with novelty and emergence in that respect, to align promotion and control accordingly and to do so truly inclusive. The aim of evaluating my empirical findings in this way is to understand how these concurrent orientations affect each other.

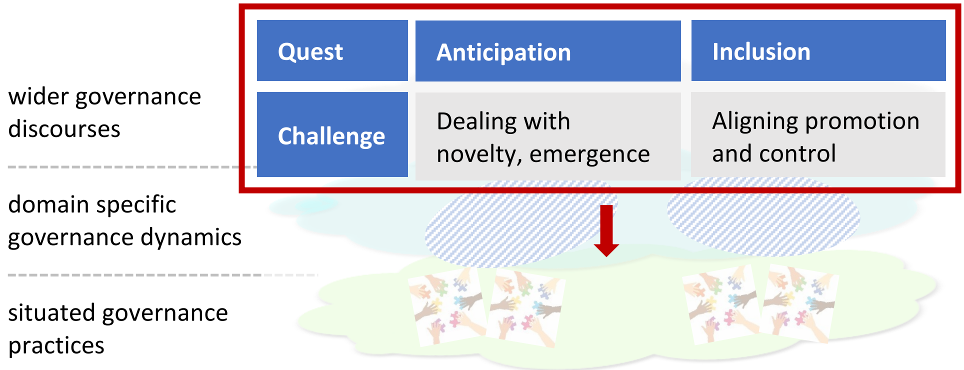

Figure 8: evaluative frame for interpreting case study findings

3. Empirical research design

3.1 Introduction

This chapter develops the research approach for the explorative part of the heuristic: studying concrete efforts to transform responsibility in research and innovation. The approach builds on the conceptual frame and analytical orientations discussed in Chapter 1 and the findings of Chapter 2. Section 3.2 specifies what aspects will be investigated in each case and how these will be presented in a narrative structure that works towards evaluation in terms of the key challenges in the broader quest for Responsible Innovation. The other finding from Chapter 2 – typical problem-responsibility settings – organizes the selection of the sites for empirical investigation. These are discussed in section 3.3. Section 3.4 closes with discussing sources and methods.

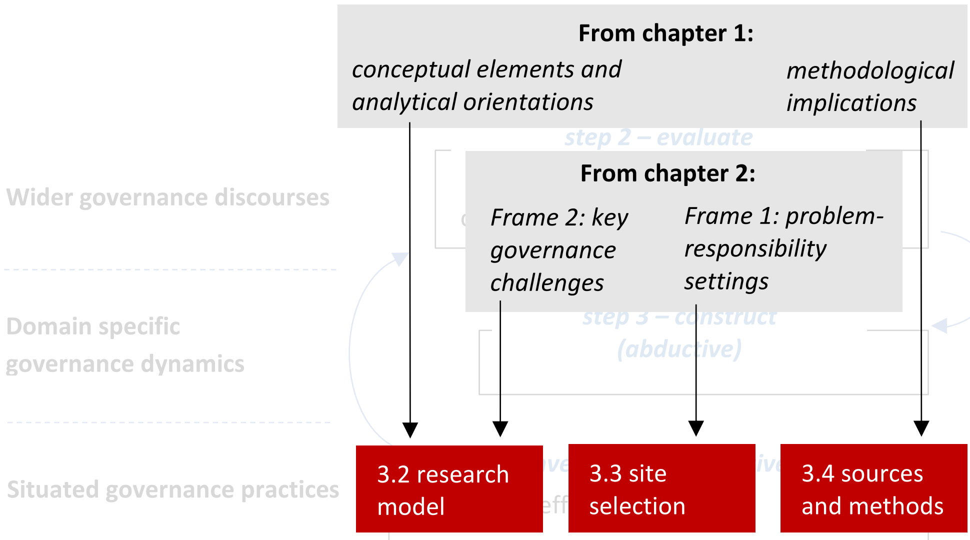

Figure 9: developing the research approach for empirical analysis

3.2 Research approach for empirical analysis

For studying concrete efforts of 'doing' Responsible Innovation I am drawing on the concept of 'practices' and, more specifically, 'logic of practice' as conceptualised by Bourdieu (1990) and as discussed by (Arts, Behagel et al. 2013) for studying governance.

Practices refer to forms of collective action, but with specific attention to the elements that go into it and the spaces in which they are performed. Importantly, these forms of collective action are recognised by the actors involved as constituting an entity bringing forth a particular kind of action (Barnes 2001, Pickering 2008). For example, the practice of 'doing science' is recognised as involving procedures by which theories or experiments are qualified as 'scientific'.

The empirical investigation in this thesis is concerned with governance practices of Responsible Innovation. The aim of these investigations is not to discuss all elements of such a practice in detail, but to investigate how they *change*, so as to bring about the envisioned transformation of responsibility in each case, and the other way around, how practices shape this transformation. For the latter, I will specifically pay attention to 'logics' structuring, but not determining action. Practices follow logics as ways of doing, guided by expectations, drawing on resources, sometimes solidified in routines, in other occasions responding to change in contexts. With this in mind, I will investigate how Responsible Innovation is practiced, looking at action as not just random or rational, but enabled and constrained by social as well as material features.

Logics of practice also correspond to the notion of *regimes* in multilevel thinking. In research and innovation there are numerous practices, such as measurement, evaluation, market research, compliance checks, communication, policy design, etc. These practices do not exist in isolation, but are related to each other. The more they become intertwined, the more robust regimes are formed. They can emerge as a result of conscious action, but then as well they will be the result of interactions and mutual dependencies, shaped by even wider cultural and political contexts. Science, for example, is performed in a multitude of (local) practices, but strongly shaped by science as a practice, with specific rules and norms, such as for quality control, data management, citation, etc.

The role of such regimes is particularly relevant for investigating the efforts of doing Responsible Innovation as governance practices in research and innovation. In Chapter 1.3 I have introduced governance as processes of structuration, marked by interplay. This orientation is reflected in two sets of analytical lenses that will be guiding the empirical investigations. The first set aims at understanding how outcomes and dynamics result from interplay, focusing on conditions, positions and dynamics. Figure 10 shows the three basic dimensions by which I will investigate these aspects. Typical aspects that will be investigated for each dimension are listed in Table 1.[65]

[65] This set of 'descriptors' builds on the empirical research approach developed in the Res-AGorA project (Walhout et al. 2014), see also section 3.4)

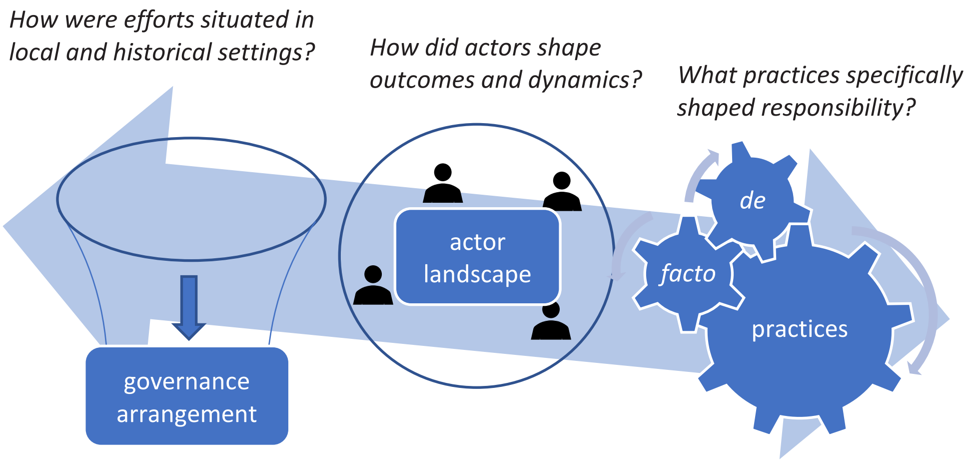

Figure 10: understanding positions, conditions and dynamics

For each situation I will start with discussing the central governance arrangement that has been mobilised in virtue of the Responsible Innovation discourse in that context (i.e. serving a particular goal). This can be a series of policy experiments (chapter 4), a research agenda, voluntary measures (chapter 6), or organisational structures for interdisciplinary collaboration (chapter 5 and 7). Specific attention will be paid to where these arrangements 'come from', i.e. the historical and institutional context in which they have been developed.

The second dimension is close to the first, discussing who were the actors (not) involved: what have been their positions and actions and how can these be understood in context? For the latter, I will pay attention to how actors did frame problems and solutions in relation to their own position and responsibilities, as well as their capacities to act accordingly. The third dimension focuses on where and how the interplay between actors and arrangements specifically has been shaped, i.e. the physical and institutional spaces[66] and frames that predominantly structured responsibilities in each case.

In practice, all three dimensions are interrelated. However, for the purpose of drawing lessons it makes sense to analytically discern governance arrangement and actor landscape: all relevant dynamics come together in the *de facto* practices, but it are actors (the polity) and arrangements (the policies and instruments) that can be targeted by strategies for intervention. The set of descriptors listed in Table 1 has been applied in an open and explorative manner, so as to grasp how the various elements have been interrelated and what specific concerns and conditions are coming to the fore. The gist

[66] The fora for debate, the rules of the game, etc. See also Joly, Rip and Callon (2010).

of this analysis is reflected in the diagonal of *Goals – Positions and relations – Construction of responsibilities*: understanding how 'responsibility' figures in the relation between goals, positions and responsibilities on the one hand and is shaped by context on the other.

Governance arrangement	**Actor landscape**	***de facto* practices**
Goals	Frames and stakes	Timing, political context
Resources, instruments and modes of enforcement	Positions and relations	Spaces
Institutional context	Capacities	Construction of responsibilities

Table 1: descriptors for empirical analysis

Case-level evaluation

The second set also focuses on interplay, but now by investigating how well problem and solution frames (discourse) have been deliberated with respect to action, as well as to the conditions at hand. This is a more evaluative step, which takes inspiration from the notion of 'congruency' and the idea that synthesis rather than compromise is preferred in case of conflicting viewpoints of actors (Grin et al. 1997, Grin 2006). In my analysis I will apply this idea to the dual challenge of Responsible Innovation as being always contested and never starting from scratch (the basic assumptions discussed in Chapter 1). For each case I will draw lessons about resolving this dual challenge, by using two sensitizing concepts:[67]

- *Contestation*: how actors reflect and deliberate on questions of why, what and how in the face of complexity, uncertainty and ambiguity; how these problem and solution frames structure the transformation of responsibility
- *Responsibilisation*: how actors can and do assume responsibility; whether and how responsibility is transformed

[67] Both concepts are inspired by literature, without adopting their specific meaning. Peeters (2013) discusses Responsibilisation in the context of public management (addressing citizens as part of the problem and of the solution in youth policy issues) as "*politisation of behaviour*" and actors as "*co-operators of political will formation*". Dorbeck-Jung and Shelley-Egan (2013) define Responsibilisation as "*disposing actors to assume responsibility for their action*", for example, by building capacity, commitment and trust. "*In the context of regulation this means facilitating, enabling and stimulating regulated parties to take their regulatory responsibilities seriously. Responsibilisation is related to the moral agency of regulators to care for their duties and uncoerced application of certain values.*" 'Contestation' is introduced to emphasise the political aspect of deliberation. This doesn't have to be conflict in the sense of clashing positions, but can be as well probing and testing. Cf. Mouffe (2005) on 'agonism' as a political function in otherwise consensually oriented practices.

The categories of Responsibilisation and Contestation can be viewed as functions[68] for learning from interplay in the governance of Responsible Innovation. That is: they enable a reflection on 'how well' things played out in each case. For substantiating the latter, a corresponding set of descriptors is introduced. These build on the notion of 'productive interactions' (Spaapen and Van Drooge 2011) as discussed in the context of evaluating societal impact of research and the challenge of organising actors towards common goals.[69] Applied to 'Responsibilisation' and complemented by a descriptor for 'Contestation' I will then evaluate in what respect interactions have been:

- *Productive*: actors change behaviour or attitude in line with new understandings of responsibility
- *Constructive*: problem and solution frames are in line with responsibility claims, acknowledging the pluralism involved in appreciating these claims (always contested) and accounting for institutional conditions (never starting from scratch)

Empirical chapter structure
Chapter 4 – 7 are organised identically (yet with some differences for Chapter 5 as indicated at the start of that chapter) and present the investigative step as well as the evaluative step for each case in a narrative form that links them together in working towards lessons to be drawn from each case, see Figure 11.

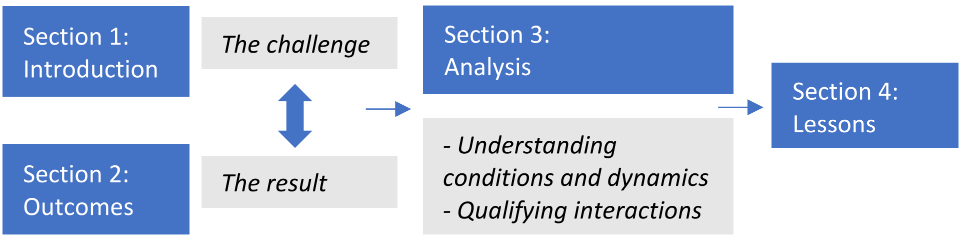

Figure 11: structure of the empirical chapters

[68] Functions do not have to be understood as deterministic or essentialist, but as analytical constructs guiding analysis. For example, in corporate governance it is common to distinguish purpose (working towards goals), risk (defending against threats) and accountability (operating in compliance with internal and external structures) as guiding dimensions for management (cf. OECD website). For public policy analysis Hoppe (2010) discusses the governance of 'problems' and distinguishes three dimensions in practices of problem structuring: puzzling, powering and participation. Borrás and Edler (2014) are interested the phenomenon of (socio-technical) change and distinguish "*1) the relation between opportunity structures and capable agents; 2) the instrumentation through which intentional definitions of collective solutions are put into practice and 3) the sources and hindrances of legitimacy in the process of governing change.*"
[69] SIAMPI project (last accessed March 23, 2023).

Each chapter starts with a brief introduction about the specific governance challenge for which actions referring to Responsible Innovation have been taking place. The introduction also discusses how challenges, as well as strategies and actions, correspond to the key governance challenges of anticipation and inclusion and of dealing with novelty and emergence in aligning promotion and control as identified in Chapter 2. These starting points for analysis are summarized in a table. In the final section this table is complemented with findings from empirical analysis, see Figure 12.

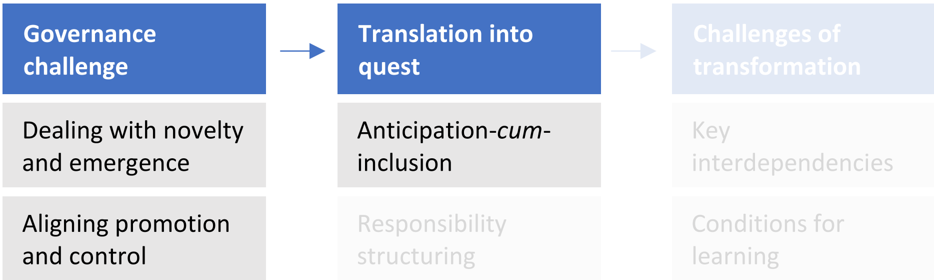

Figure 12: starting points for analysis

The second section of each empirical chapter summarises the main outcomes with respect to the question to what extent responsibility has been transformed. This discussion provides clues for further investigation: how did this specific outcome come about? (understanding) and in what way did efforts serve the challenge in case? (evaluation). Each third section then presents relatively 'thick descriptions'[70] of the governance arrangement, actor landscape, *de facto* practices and their historical context. The final section of each empirical chapter discusses the investigative and evaluative steps in relation to each other and will draw case-specific lessons by inferring how, given conditions in the specific situation, the interplay between action and discourse can be 'restructured'[71].

[70] 'Thick descriptions' typically refer to ethnographical studies (see Science Direct overview page). The empirical research for this thesis does not feature such long term participatory observation. Still, I have tried to apply the holistic gaze that is pursued in thick descriptions

[71] In Chapter 1.3 I have discussed how I am taking up the idea of Re-structuration of Grin (2006) by pursuing a relational understanding of Responsible Innovation, so as to better understand how it moves forward in both discourse an practice, conditions and dynamics and in making sense and making change. These conceptual pairs build on the duality of structure and agency, in which the relation between the elements is not only dialectical, but also self-reflexive. The latter provides an inroad for advancing societal learning: by disentangling social complexity in parameters relative to each other, one can draw attention to the interdependencies involved in transformation. I have explored this way of looking in my research approach for empirical investigation: by analysing conditions and dynamics in relation to each other (in arrangements, actors and *de facto* practices), as well as discourse and practice at each site (evaluated in terms of *Contestation* and *Responsibilisation*.

The final step, also performed in section 4, is to recast the case-specific lessons in terms of the key governance challenges in the quest for Responsible Innovation. Here, key interdependencies that have been involved in the efforts for transforming responsibility and the conditions for learning about resolving these, will be discussed in relation to the specific governance challenge each chapter started with, see Figure 13.

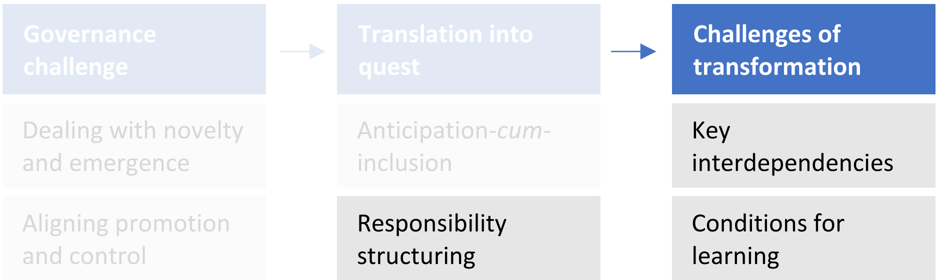

Figure 13: findings in relation to starting points

3.3 Site selection

My sites of empirical investigation concern four prestigious efforts of working towards forms of Responsible Innovation in nanotechnology development: a series of pilot projects for developing precautionary measures with respect to safety questions about nanomaterials in the Netherlands (Chapter 4); the integration of Risk Analysis and Technology Assessment (RATA) in the Dutch research and innovation program NanoNextNL (Chapter 5); the federal inter-agency cooperation and response towards safety aspects of nanomaterials in the US (Chapter 6); and the anticipatory governance program of the Center for Nanotechnology in Society at Arizona State University (CNS-ASU, Chapter 7). These have been prestigious activities, because of the relative big efforts involved, but as much for the characteristic attempts to do better and make a difference indeed. All cases show efforts to transform institutions, in different cultural-political contexts, in different ways, at different levels. So they lend themselves to serve as cases for analysing what shapes the governance of Responsible Innovation (research question 1) and what can be learned for transforming responsibility in research and innovation (research question 2).

All four initiatives have been linked to political discussions about Responsible Innovation. That is: the notion itself didn't figure as a guiding idea, but references to 'responsible' or 'responsibility' have been guiding what in each situation was perceived already as the way to go: facilitating stakeholder (inter)action in the Dutch pilot projects; a program-wide effort in NanoNextNL; inter-agency collaboration and voluntary measures by the US authorities; and engaging with technologists rather than technologies by CNS-ASU.

The cross-case analysis in Chapter 8 is structured by the findings from the previous chapter. There I have identified key themes in the governance of nanotechnology, from which I take *precaution* in risk governance and *integration* in research governance as topical aims associated to the discourse about Responsible Innovation. Both aims also reflect the dual governance challenge of anticipation and inclusion. Finally, the initiatives feature typical modalities of governance (stakeholder and governmental action in risk governance; change agents in research governance) in typical political settings (more adversarial in the US; more consensual in NL and EU)[72]. As such, they reflect the different problem-responsibility constellations discerned in the previous chapter. The risk governance cases are concerned with orchestration at system level; of regulatory science (Jasanoff 1990), public policy and private actors, as well as interest groups and democratic order watched over by parliamentary control. The research governance cases are concerned with the internal dynamics of research programs, which I will approach as organised actors. These dynamics involves orchestration as well, but mainly *within* research systems, at a relative distance from political debate and typically designated to change agents having to work their way into existing modes of research organisation. Together, these distinctions organise the empirical analysis as depicted in Figure 14.[73]

The timeframes discussed for each activity also differ. The Dutch pilot projects have been running from 2009 till 2011, while US EHS research coordination for nanomaterials has been part of the NNI from the start and still continues. RATA in NanoNextNL has been running from 2011 till 2016, while CNS-ASU has been operating from late 2005 till early 2016. However, for each of the activities I will discuss how they are situated in the discussions about nanotechnology in each situation , as these have been evolving from the start of this century. Significant developments after the periods studied are discussed as well.

[72] cf. Beumer (2016) on governance styles, or Laurent (2012) on the difference between *judging* and *making* values in US and EU expert cultures.
[73] For Risk Governance my cases differ more than for Research Governance: where the activities studied in the Netherlands (Chapter 4) have been clearly shaped by their relation to action at European level, the latter is more equal to the activities studied of US federal authorities (Chapter 6). In addition, the activities studied differ in provisional (Dutch pilot projects) vs. structural orientation (US risk research and oversight). As will turn out, however, domain specific conditions and dynamics, such as typical problem framings and the significance of action by government vis-à-vis parliament, characterise both situations.

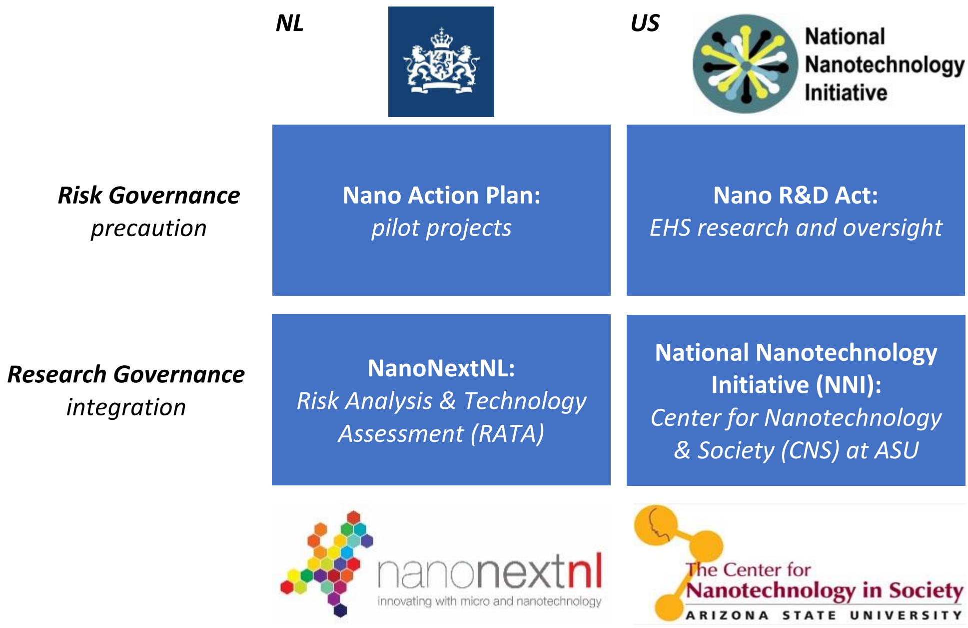

Figure 14: sites of empirical investigation and their ordering for cross-case analysis

3.4 Sources and methods

3.4.1 General approach

The approach to empirical investigation and analysis resembles what has been described by Rip and Robinson (2013) as 'moving about in the nanoworld': a mode of inquiry, informed by ethnographic and sociological research practices, including reflexivity of being both an analyst and interventionist; going back and forth between observations, individual views, the reconstruction of (causal) relations and how these have been documented in texts or displayed at events. However, methods and sources have been significantly different for the Dutch and for the US cases. In the Dutch sites of empirical investigation I have been both researcher and participant, which enabled me to 'follow the quest' and to critically engage with it.[74] First as a parliamentary Technology

[74] Cf. Heyward and Rayner (2013) and Downey (2021) for discussions about critical participation as a researcher (these have been part of the aforementioned WTMC training). 'Following the quest' is inspired by 'following the actors' in Actor Network Theory (ANT, Latour 2005) and refers to the reconstructions of the quest for Responsible Innovation in this thesis, both at the level of the case studies and in wider discourses about the governance of research and innovation.

Assessment officer at the Rathenau Institute[75], with respect to the Dutch pilot projects in nanosafety governance, thereafter as a PhD researcher in the RATA theme of NanoNextNL.[76]

These positions provided access to national and international activities and discourses about Responsible Innovation as well as about the governance of nanotechnology, from which the research for the US cases has been benefitting as well. As for nanosafety governance this included keeping track of national and international news and views on the governance of nanotechnology, which I started already for my master thesis at the Technical University of Eindhoven (TU/e) in 2004 and still continue in my current position as policy advisor at the Netherlands Institute for Public Health and the Environment (RIVM).

The research for RATA NanoNextNL primarily drew on the PhD position funded by the NanoNextNL program. Contacts from my position at the Rathenau Institute[77] provided leverage to actively contributing to integrating RATA in NanoNextNL, by participation in program meetings, contributing to the RATA course for NanoNextNL PhD students, serving as a 'RATA-coach' for the follow-up research activities of one of these PhD students (Gümüscü 2016) and occasionally presenting on behalf of the RATA management at various occasions. This collaborative style of doing STS research in the context of a large technology and engineering oriented research program has been building on the Constructive Technology Assessment (CTA) work developed at the University of Twente (cf. Konrad et al. 2018, Rip 2018) and its relation to international peer contacts, in particular to Arizona State University.[78]

As for following and engaging in the discourse about Responsible Innovation, my position at the University of Twente gave access to relevant national and international

[75] At the Rathenau Institute I have been actively facilitating political debate about nanotechnology through research, agenda setting and participation in stakeholder and policy networks (as reported in Van Est and Walhout 2010, van Est et al. 2012a,b, Brom, van Est et al. 2021). When moving to the University of Twente for my PhD research, I have received a small research grant from the Rathenau Institute for investigating roles and responsibilities in nanosafety governance in the Netherlands.

[76] My PhD position "*Practices, Institutionalisation and Impact of Responsible Innovation in Nanotechnology*" has been funded as part of the RATA NanoNextNL program and hosted by the University of Twente school for Behavioural and Management Sciences (BMS), section of Science, Technology and Policy Studies (STəPS, now part of KiTeS)

[77] E.g. I have been coordinating contacts and activities with the Technology Assessment flagship program of the research program NanoNed that preceded the RATA activities in NanoNextNL

[78] In particular with Erik Fisher interacting with the TA NanoNed flagship program led by Arie Rip (2005-2009, cf. Fisher and Rip 2013) and as visiting scholar in the Tech4People program (2015, see Fisher et al. 2016)

academic communities.[79] Moreover I have been involved in the European FP7 research project Res-AGorA, which developed a governance framework for Responsible Research & Innovation (RRI).[80]

For the US cases the research is much more relying on interviews. Consequently, the number and style of interviews also differs. In the Dutch cases I have been conducting relatively few interviews, as a means of fact checking, next to informal contacts and feedback on (written parts of) the analysis. For the US cases, I have conducted thirty formal interviews (one to two hours) and two longer discussions during a research stay in the US in February 2015. These interviews have been an important source for understanding the driving forces at play and the positions of the interviewees in each situation. The US interviews were prepared as semi-structured interviews. During the interviews I have used the list of descriptors in Table 1 for keeping track of topics covered.

Equally important has been my approach to engage in symmetrical conversations as much as possible. Practically, this involved an active staging of both interviewees and myself as actors involved in the quest for Responsible Innovation, situated in specific contexts and carrying professional backgrounds and personal experiences. In most interviews I started with inquiring about current positions and valuations of outcomes, followed by questions about barriers, driving forces, challenges and conflicts or trade-offs that could explain the status quo. From there, I have been asking and/or highlighting particular frames or constructions of responsibility for discussion and feedback during

[79] Nationally: training and supervision for this research has been part of the Netherlands graduate research school of Science, Technology and Modern Culture (WTMC) Internationally: the Society for the Studies of New and Emerging Technologies (S.NET) and the European Forum for Studies of Policies for Research and Innovation (Eu-SPRI), as well as the close links between STePS and colleagues from Arizona State University (the Consortium for Science Policy and Outcomes (CSPO), which hosted CNS-ASU (now School for the Future of Innovation in Society (SFIS). CNS-ASU, in turn, hosted the international Virtual institute for Responsible Innovation (ViRI).

[80] In Res-AGorA, I have investigated a broad range of Responsible Innovation articulations (documented in Chapter 1 and 2, selection published in Walhout and Kuhlmann 2014); coordinating the development of the empirical research approach (Walhout et al. 2014), conducting the case study about RATA NanoNextNL (Walhout and Konrad 2015) and co-developing the governance framework (Lindner et al. 2016). The approach taken in this thesis further develops the conceptual and analytic foundations of the Res-AGorA research model for empirical analysis, specifically by focusing on interplay as a key governance challenge in working towards transformative change (see Chapter 1.3). In this respect, I deviate from the Res-AGorA goal of developing a framework with guiding principles as an instrument of Strategic Intelligence (Kuhlmann et al. 1999). Instead, I am further exploring typical dynamics of structuration, so as to inform strategies for 're-structuration' (Grin 2006) and the identification of *pathways* for transforming responsibility in research and innovation.

the conversation. In processing the interview results I have discerned actor positions as factors in the overall dynamics and as topics for further analysis.

The distinction between actor positions and actor views also applies to the findings from document analysis. As discussed in section 3.2, each situation studied will be presented in a narrative form, with a storyline that subsequently addresses the particular quest for transforming responsibility in each case, an evaluation of outcomes and dynamics and the lessons that can be drawn from that. The reconstruction of what was the quest for the actors involved and what were the relevant conditions and dynamics partly draws on accounts by actors involved themselves, either from documents or from the interviews conducted, and my interpretation of these accounts in relation to other sources. This implies that I will be discerning actor positions as factors in the overall dynamics (descriptive) and as views on the key governance challenges in each case (evaluative).

With respect to actor accounts, two further notes are in order. First, the research design is geared towards analysing frames and actions at the level of organisational entities (being the main 'actors' in my analysis). Hence, I will put individual action centre stage only where relevant. Information from interviews will be referred to by using <#name>. Second, my triangulation of this information involves a relatively broad set of other sources that were analysed and selected in an explorative way. I.e. focusing on understanding the quest in each case as guided by the descriptors presented in Table 1, but not in a strict systematic order. A drawback of this approach is that both the number and heterogeneity of the available sources limits possibilities for a systematic account and triangulation. Therefore, I will discuss the sources and methods used for each site specifically below. Further details are presented in the Appendix.

3.4.2 Case specific tailoring

Nanosafety governance pilot projects in the Netherlands (Chapter 4)

My analysis of the pilot projects for developing precautionary measures in the Netherlands mainly draws on my work as a parliamentary Technology Assessment officer at the Rathenau Institute. In that position (as well as before and after, see previous section) I have kept track of both national and international developments in nanotechnology governance and actively engaged in expert-stakeholder discussions about it. For the Dutch pilot projects I have been building on an event history report prepared for the Rathenau Institute, which covered the start of national political discussions about nanotechnology in 2003 till the final evaluation and update of the policy principles for dealing with risks by the Dutch government in 2014. The report, as well as the analysis in this chapter, has been validated through interviews, workshops and informal conversations with individuals who have played a key role in nanosafety governance in the Netherlands (see table below and the Appendix). My participation in RATA NanoNextNL (see below) further extended this network. Finally, my current position as policy advisor at the RIVM has informed my discussion of findings from cross-case analysis (Chapter 8).

Category	Area, approach	Sources, respondent organisations
Background information	Nanotechnology governance (general and safety specific): personal record keeping about news and views	*Newsletters*: Bergson and Campbell Nanotechnology & Law blog, RIVM/Kir-Nano, NanoHouse, NIA, NanoNow, AzoNano, NanoRegNews *Twitter feeds of key experts*: see Appendix
	International activities	FP6/7/8 project meetings (2005 – 2019), OECD conference (2008)
Document analysis	*Event history*: chronological ordering and referencing *Actor positions*: frame analysis	Professional reports, policy and parliamentary documents, position papers, minutes of meetings
Participatory observation	*Expert-stakeholder*: network, workshops, debates *Government/parliament*: network, hearings, public debate	*Self-organised*: nano risk governance expert-stakeholder workshop (2006), parliamentary hearing (2009), risk governance lessons workshop (2011)
	Science/industry: conferences, stakeholder networks and contacts	*Participating*: NVWA expert platform, KIR-nano stakeholder platform, (TA) NanoNed program meetings, Micro-NanoNed conferences, national NanoDialogue, (RATA) NanoNextNL meetings, IenM risk governance policy workshop (2012), RIVM policy support activities (2015 – present)
Interviews	5 semi-structured interviews: policy officers, policy consultants, industry representatives	MinVROM/IenM, KLB, DSM, VNO-NCW, IVAM (see Appendix for details)
	3 commentators (factchecking):	RIVM, NWO/STW, HZuyd (see Appendix for details)
Publications		van Est and Walhout (2010), van Est et al. (2012a, 2012b), Brom, van Est et al. (2021)

Table 2: sources and methods for chapter 4

Integrating Risk Analysis and Technology Assessment in NanoNextNL (Chapter 5)

The chapter structure discussing the efforts of integrating RATA in NanoNextNL slightly differs from the other chapters, since the analysis has been ordered and published following the Res-AGorA case study approach[81]. The empirical investigations for this purpose only covered the first half of NanoNextNL's lifetime (until midterm review). In Chapter 5, this has been addressed by adding an addendum discussing later activities and what they add to the earlier findings.

[81] cf. footnote 80

Category	Area, approach	Sources, respondents
Background information	Personal records of discussions about the research agenda and funding of NanoNextNL	Networking activities during my position at the Rathenau Institute.
Document analysis		Policy documents on funding conditions and the role of RATA, NanoNextNL publications and annual reports
Participatory observation	Informal discussions, presentations and discussions during annual program symposia	NanoNextNL researchers, RATA management, executive board, see Appendix for details
	Sharing data and observations with fellow researchers	RATA NanoNextNL theme, see Appendix for details
Interviews	1 semi-structured interview NanoNextNL program office	See Appendix for details
	Data from 63 (co-)interviews by fellow NanoNextNL researchers	See Appendix for details
Publications		Van Est et al 2012b, Bos, Walhout et al. 2014, Walhout and Konrad 2015, Te Kulve et al. 2013

Table 3: sources and methods for chapter 5

As for sources and methods with respect to NanoNextNL's full lifetime I have been building on my position at the Rathenau Institute, in which I had kept track of and engaged with the political discussions about funding NanoNextNL and the role of RATA in it, for example, in response to both the publication of the European Code of Conduct for Responsible Nanotechnology research and the series of national public dialogue events (see Chapter 5 for details). Personal contacts with researchers, board and program officers from that time helped me to continue informal discussions with members of the RATA management as well as with members of the Executive Board during the program, thinking along with them by discussing their and my views as well as asking feedback on written outputs of my analysis. In addition, sharing observations and data with fellow RATA researchers extended the empirical base to draw on. In a more active mode of engagement I have been operating as a RATA practitioner myself in contributing to the RATA PhD course for all NanoNextNL PhDs and occasionally speaking on behalf of the RATA management in other research theme meetings in the program.

Federal agency coordination on nanosafety governance in the US (Chapter 6)
For reconstructing nanosafety governance dynamics in the US I could also rely on my record keeping of the international debate on nanotechnology, including participation in a Dutch delegation visiting US federal authorities in 2007.[82] However, for understanding institutional conditions and political dynamics, my analysis heavily draws on interviews conducted during a short research stay in the US in 2014.

[82] Study program organised by the Atlantic and Pacific Exchange Program (APEP).

Category	Area, approach	Sources, respondents
Background information	personal record keeping about news and views on nanosafety governance	See above discussion of sources for chapter 4
Document analysis	Primary literature for actor positions	NNI (self) evaluation reports, agency position papers
	Secondary literature for reconstructing the broader context of US science and environmental policy	e.g. Bosso 2010, Eijmberts 2013, Hodge et al. 2010, Morris 2012, Rip and Van Ameron 2009, Marchant, Abbott et al. 2013
Interviews	10 semi-structured interviews: representatives from the federal agencies studied and from expert/stakeholder organisations	EPA, FDA, NIOSH, CPSC NSF, Woodrow Wilson Institute, CTA, ELI See Appendix for details
	3 extensive conversations, with a government official, a key opinion leader and a policy scientist	See Appendix for details. Policy scientist Christopher Bosso also provided input for selecting interview candidates and has been commenting on chapter 6.

Table 4: sources and methods for chapter 6

The interviewees are officials from the agencies as well as commentators from organisations involved in public and political discussion about nanosafety governance in the US. The list is exploratory, not representative for the views of all actors involved, if only because regulatory agencies are large organisations, with multiple individuals from different departments involved.

Moreover, I have not been able to arrange interviews with a number of organisations.[83] These limitations have been addressed by linking the interviews to other sources and secondary literature.[84] Overall, the analysis focuses on organisations as the actors involved. A number of interviews with actors directly involved in the process, though, has been crucial for understanding actor positions and the role of individual action, especially where interviewees provided competing accounts.[85] Because of the wide

[83] Sometimes for practical reasons (e.g. Environmental Defense Fund (EDF)), but also because of sensitivity of the subject (e.g. Consumer Product Safety Commission (CPSC), American Chemistry Council (ACC)).

[84] These sources are official documents and position papers issued by the NNI and individual agencies, reflections and assessments by insiders (eg. Roco et al 2011, 2013, Karn and Schottel 2016) as well as critical followers (e.g. Woodrow Wilson Institute: Project on Emerging Nanotechnologies (publication list); Environmental Law Institute: Breggin and Carothers 2006; Breggin and Pendergrass 2010).

[85] An interesting example in this respect is the difference in the interview account of Morris and his book about nanosafety governance in the US (Morris 2012). For example, chapter 6 specifically discusses the role of individuals Roco, Karn and Teague resulting in the NNI-NEHI. E.g. interviewee Maynard focused on research as the most important action line, while Davies

range of actors covered, Chapter 6 offers less detail about specific actors (e.g. a House committee) compared to Chapter 4.

Center for Nanotechnology and Society at Arizona State University (Chapter 7)
The analysis of CNS-ASU also has been profiting from contacts with CNS-ASU dating back from the interactions between the Rathenau Institute and TA NanoNed.[86] Yet, the investigation mainly draws on interviews by people working at CNS-ASU, conducted during a two-week visit in 2014. The visit allowed me to be around in the office and to attend several activities organised by CNS-ASU during my visit (e.g. a class, a department meeting, a lunch lecture and a science café). In addition, I have briefly visited the Center for Nanotechnology in Society at the University of California in Santa Barbara (CNS-UCSB) for collecting contrasting materials and feedback to my preliminary impressions in a presentation and discussion session. Afterwards I have been participating in meetings of the Virtual institution on Responsible Innovation (ViRI) that was coordinated by CNS-ASU. To a great extent the documents and interviews referred to in the analysis are self-accounts by CNS-ASU researchers and management, including later self-evaluative academic output (e.g. Radatz, Reinsborough et al. 2019, Youtie, Shapira et al. 2019, Dabars and Dwyer 2022).[87] For example, I have not been able to interview NSF officials about the appreciation of CNS-ASU's work. To account for this bias, I have actively pursued interviewees to reflect on assumptions and their relation to demonstration of impact and on my own observations or those of other visiting researchers. In the discussion section of Chapter 7 I have included responses of CNS-ASU director Dave Guston to my and others' questioning of CNS-ASU's claims as well as to observations about the contrasting approach of CNS-UCSB. The analysis presented in Chapter 8 has been commented by a CNS-ASU interviewee and by a former visiting researcher at CNS-ASU (see Appendix).

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focused on oversight. Karn and Schottel didn't mention the activities of Vicky Colvin, but see McCarthy and Kelty (2010) for a detailed discussion of the role of Colvin. According to Morris (2012) and confirmed in my interviews, another key individual with respect to articulating concerns about nanosafety as well as the weaknesses of the institutional structures in which the uncertainties about nanosafety have to be addressed, is Richard Denison from environmental organisation EDF. Denison is quoted as an authoritative expert in the NRC (2009, 2012) reviews of the NNI EHS research strategy. This may tell something about the composition of the NRC committees, but what is at stake in the analysis of chapter 6 is that the NRC reviews never had a decisive role in political discussion about the NNI. Hence my focus on institutional settings.

[86] Especially with Erik Fisher, for example as invited speaker on midstream modulation at the Rathenau Institute (2007). Later on, Fisher has been a visiting researcher on the internal project Tech4People at the University of Twente and has been invited for organizing a small STIR-event with colleagues from RIVM. My understanding of the rationale, affordances and limitations of CNS-ASU's approach has been greatly benefitting from the personal interactions on these occasions.

[87] For example, I didn't manage to interview a representative from NSF, which has been involved in the reviews of CNS-ASU (proposal, annual progress and end of grant).

Category	Area, approach	Sources, respondents
Document analysis	CNS-ASU philosophy, approach, output and impact	CNS-ASU output and annual reports
Participatory observation	Visiting researcher	Visiting a class, a department meeting, a lunch lecture and a science café Presenting my own research, including observations about CNS-ASU
Interviews	19 semi-structured interviews, about the CNS-ASU philosophy, approach, output and impact, as well as contrasting experiences at CNS-UCSB	Academic staff, management, program office. Visiting researchers See Appendix for details
	2 commentators (fact checking)	See Appendix for details

Table 5: sources and methods for chapter 7

Part II – Empirical Analysis

4. All in the game? – organizing responsibility in nanosafety governance in the Netherlands

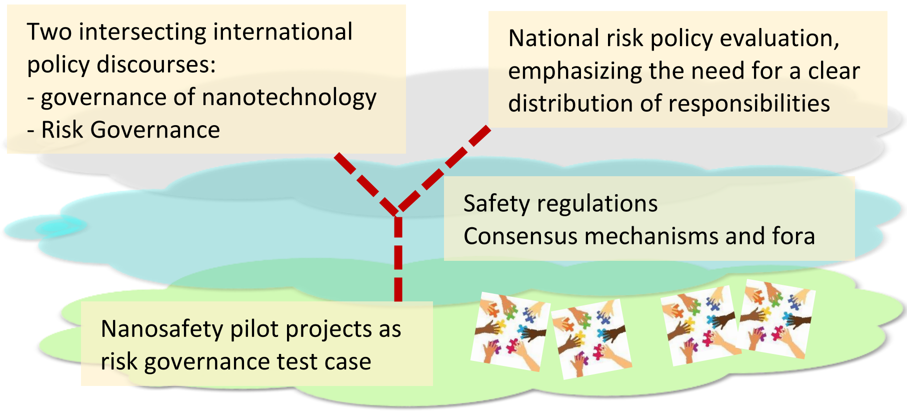
4.1 Introduction

Risks and safety are familiar issues to science and technology. Over more than a century many measures and organisations have been put into place to protect human health and the environment. Just as well, risks remain sources of conflict, especially when it is not entirely clear what the risk is, exposure is involuntary, distribution is not fair, or there is a lack of confidence in expert assessments. All of these issues have been raised in relation to nanomaterials, fuelling concerns about nanomaterials as 'the new asbestos' and turning nanosafety into the most dominant concern about nanotechnology (see Chapter 1.2). Also, research into health and environmental safety (EHS) effects of nanomaterials poses new questions with regard to the safety of nano-sized fractions in existing materials (e.g. paint, food additives). For both new and old, the difficulty to measure, model and assess health and environmental impact of nanomaterials raises questions of prudence and fairness.

In Chapter 2 I have shown that ideas about risk and Responsible Innovation build on two longstanding and discussions: on *precaution* – about what is due action in case of uncertainty about safety – and on *participation* – about the role and involvement of stakeholder organisations and citizens in decision making about risk. Both strands came together in the emerging policy discourse about *Risk Governance*, which, in turn, has been intersecting discussions about the governance of nanotechnology. Together, these discussions have further pushed the calls for opening up narrowly defined and expert driven procedures of risk assessment and risk management towards a broader range of values and publics involved in decision making about risk.

All three terms – precaution, participation, risk governance – are key to the situation discussed in this chapter. I will discuss the efforts of Dutch policymakers to facilitate firms in applying precaution. In doing so, a radical interpretation of participation has been applied, by giving stakeholder organisations the lead in developing precautionary measures. This approach has been referred to as 'Risk Governance for the Dutch situation'. With that background the pilot projects discussed in this chapter formed an experiment in risk governance, responsible development of nanotechnologies and in the related reconfiguration of responsibilities, among lead actors and in prevailing institutional contexts, see Figure 15.

The title of this chapter summarises the process: developing precautionary measures involves a *game* – a political game of (re)organising responsibility. *All in the game* have been structures, stakes and tensions between individual and collective responsibilities and between action at national and at European level. But not *all* have been involved equally.



Governance challenge	
Novelty and emergence	- uncertainty about health and environmental safety of nanomaterials - knowledge development takes years, so provisional measures needed
Aligning promotion and control	- enabling oversight by sharing information about use (EHS) - developing and adopting preliminary measures (OHS)
Translation into quest	
Anticipation-cum-inclusion	- developing the precautionary measures by stakeholder involvement ('precaution' and 'participation')

Figure 15: the nanosafety pilot projects as a testcase for Risk Governance policy

4.2 Outcomes and achievements

The analysis in this chapter focuses on four government facilitated pilot projects[88] that have been conducted between 2008 and 2011, as well as the uptake of their outcomes later on. Pilots are an important category in public policy responses to the uncertainty. At the time it was estimated that it could take a decade before validated models for

[88] Initially, the Cabinet (2006a) referred to pilot projects only with respect to a series of first toxicological studies to be conducted by regulatory science institutes in the Netherlands. However, in later documents and correspondence with parliament pilot projects referred to other activities as well, see section 4.3.1.

assessing the safety of nanomaterials would have been developed. Therefore, proceeding with nanotechnology science and engineering was considered acceptable if precautionary measures were taken. What is more, by emphasising the economic and societal benefits of nanotechnology, proceeding with due caution has been framed as the *responsible* way forward for the Netherlands (cf. Cabinet 2006a, 2008; CieMDN 2011).

Interpreting and applying (pre)caution involves political questions about who is going to reap the benefits and who has to bear the burden. As such, the responsibility question quickly moved beyond the world of public research programs, into the domain of public vs. corporate responsibilities. It is in this domain that the four pilot projects had to establish a first line of safety measures: two projects on occupational exposure to nanomaterials and two on knowledge sharing, among businesses and from businesses to government.

Information sharing: SME support (government to business)

The first initiative was an information centre for Small and Medium sized Enterprises (SMEs), lobbied for by NanoHouse, a partnership of research and business organisations for exploring nanotechnology R&D opportunities established in 2006[89]. SMEs often lack the capacity to maintain a knowledge base about the safety of new materials and develop risk management strategies accordingly. The pilot plan involved funding from the Ministry for Economic Affairs, Agriculture and Innovation (MinELI) to investigate the needs of SMEs, granted to NanoHouse and the Dutch chemical industry association VNCI early 2009. In 2012, the resulting plan has been adopted by the Dutch government by funding NanoCentre.[90] NanoCentre is hosted by the applied research organisation TNO and contacted a couple of times a year by companies seeking information about nanosafety and regulatory expertise.

Information sharing: oversight (business to government)

The other way around, knowledge sharing by businesses to government, about production and use of nanomaterials, as well as the affordances and limitations of safety measures, is an important condition for effectively developing precautionary measures. As a first step, MinSZW (the Ministry of Social Affairs and Employment) and MinVROM (the Ministry of Housing, Spatial Planning and the Environment) commissioned an industry wide survey in 2007. The results (Borm et al. 2008) provided a first overview, but since the volume of processed nanomaterials was expected to increase rapidly, a bi-annual and more comprehensive follow-up was recommended. In 2009, MinVROM asked employer association VNO-NCW to cooperate in taking follow-up surveys among

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[89] Not be confused with the European research project NanoHouse (2010 – 2014) on the safety of nanomaterials in paint. In his project the Dutch paint and ink industry association VVVF, has been involved, together with TNO and IVAM. See section 4.3.4 for a discussion of the concurrent national pilot project in this sector.

[90] www.nanocentre.nl (last accessed 6 March 2023)

its members for working towards a national system of knowledge sharing. Together with a first set of nanomaterial safety evaluations, this system would have to become a stepping stone for establishing notification requirements for nanomaterials at European level. However, the industry associations represented by VNO-NCW could not agree on a joint approach with the Dutch government and the surveys failed to provide a better picture than the initial study.

Occupational safety: nanomaterial reference values (norms)
The third project concerned the development of provisional norms for occupational exposure to nanomaterials. Developing this measure took a long path through many institutions. In 2007, the Ministry of Social Affairs and Employment asked the SER (Socio-Economic Council), a tripartite council of government, corporate and trade union representatives, for advising on the operationalisation of precaution in occupational exposure to nanomaterials. One of the recommendations of the SER (2009) committee was to develop 'reference values', as a provisional alternative for scientifically derived exposure limits. This recommendation received political backing in a resolution by parliament. MinSZW first asked for an expert opinion (Dekkers and De Heer 2010) on determining which method would be appropriate and then funded a feasibility study (Van Broekhuizen et al. 2011a) for the selected approach. This feasibility study has been coordinated by representatives from employer association VNO-NCW and from trade unions FNV and CNV and served as input for a new report by the SER (2011). In this report, the SER recommended active stimulation and enforcement of the Nano Reference Values (NRVs) in corporate risk management strategies. MinSZW agreed to include the NRVs in the guidance document developed by the same partners (see below) and in the self-inspection tool issued by the labour conditions inspectorate (Inspectie SZW).

Active stimulation, however, would also depend on whether exposure registration would be required. This had been recommended in a concurrent advisory report of the national Health Council (2012). MinSZW asked the same partners again for a feasibility study on this subject (Van Broekhuizen et al. 2015). The latter study underlined the availability of the NRVs as an appropriate precautionary measure, making mandatory registration redundant. In 2017, the added value of the NRVs was evaluated again and a process of updating the NRVs has started[91]. Meanwhile, nanosafety paragraphs in corporate risk management strategies have to account for whether and how NRVs have been part of protective measures.

Occupational safety: guidance document (practices)
The fourth project, in which the employer association (VNO-NW) and both trade unions (FNV and CNV) cooperated again, has been the development of a guidance document

[91] See https://www.rivm.nl/nanotechnologie/arbo/op-weg-naar-gezondheidskundige-grenswaarden-voor-groepen-van-nanomaterialen (last accessed 6 March 2023)

(Cornelissen et al. 2010) for the safe handling of nanomaterials at the work floor. MinSZW funded the work needed to redesign and validate the guidance document (Van Broekhuizen et al. 2012a) for uptake in occupational safety practices databases.[92] This went relatively easy and without discussion.

A transformation of responsibility?
The four pilot projects provide an interesting set of activities by which the Dutch government has engaged in negotiations with stakeholders, in the context of, and preparatory to, adjusting regulatory frameworks for nanomaterials. All four activities have been discussed in a stakeholder wide platform (the *Klankbordgroep Risico's Nanomaterialen*). Especially the joint development of the NRVs has been considered as a success by the stakeholder representatives involved.

However, the overview also shows particular asymmetries. Instruments by which individual firms can take responsibility have been developed (provisional norms, guidance and expert support), but on governmental budgets and for occupational safety only. In contrast, the efforts to establish oversight, which requires collective action with respect to information sharing, failed to provide a knowledge base for consumer product and environmental protection. The difference between these outcomes can be attributed to the greater levels of scientific uncertainty and social complexity in organising collective responsibility for protecting Environmental Health and Safety (EHS) as compared to Occupational Health and Safety (OHS). However, if so, then it would have to be exactly here that *Risk Governance* or *Responsible Innovation* has to make a difference. How these questions have been discussed and have shaped action is the topic for further investigation in the next section.

4.3 Analysis

4.3.1 Governance arrangement: pilots for precaution

What happened in and to the pilot projects has been situated in the context of two intersecting streams of political agenda setting (cf. Kingdon 1984) in the Netherlands. The first is about the emergence of nanotechnology itself, the second about the corporate versus governmental responsibility in protecting health and environment, see Figure 16.

[92] See https://www.arboportaal.nl/onderwerpen/arbocatalogi for an overview of these databases.

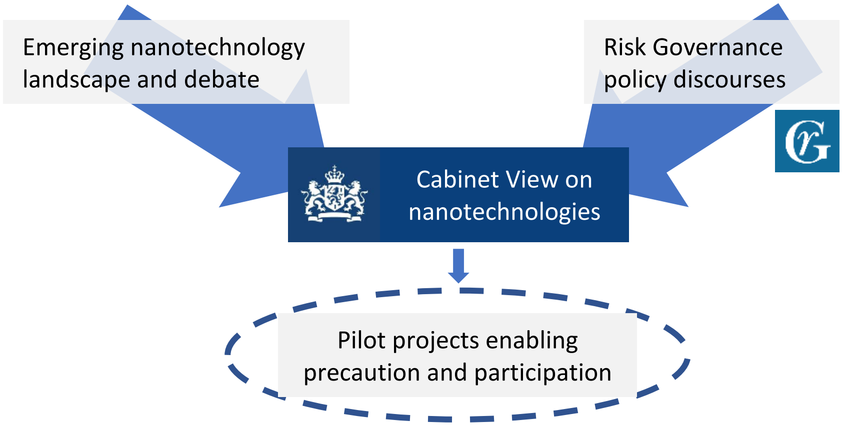

Figure 16: the pilot projects at the intersection of two policy discourses

Nanotechnology in the Netherlands: from the lab to corporate responsibility

Like elsewhere, the start of nanotechnology in the Netherlands has been building on a number of national scientific strengths, such as particle physics and supra-molecular chemistry, as well as the R&D activities of multinationals with national roots in the electronics and chemical industry, like Philips, DSM or Akzo-Nobel. Before 2000, Dutch nanoscientists and industrialists tried to get the multidisciplinary field of nanotechnology integrated in the disciplinary structures of science funding, but only partly succeeded (Van der Most 2009). From 2002 onwards, they were more successful, by capitalising on the international funding competition in nanotechnology starting with the US NNI (see Chapter 1.2). The promise of economic potential, building on national strengths fitted well into national debates on the knowledge economy, innovation performance and the reorientation of science and innovation policies and funding schemes.[93]

[93] Researchers from the Technical University Delft (TUD), the University of Twente (UT) and the University of Groningen (RUG), tried to acquire funding for nanotechnology already in 1996, but unsuccessfully as their collaboration was considered too new (Van der Most 2009). After the networking activity of a foresight exercise by the Study centre for Technology Trends (STT, Ten Wolde 1998) and several smaller research projects funded by the national research council NWO, the group successfully acquired funding from the Ministry of Economic Affairs (MinEZ) for the € 22 mln program NanoImpuls and the invitation to participate in the new round of gas revenue investments in the national knowledge infrastructure (ICES/KIS-III). From these funds NanoNed was rewarded, a national research program of € 235 mln, running from 2005 till 2009. For its follow-up in NanoNextNL (see Chapter 5), the nanotechnology community also had to rely on the gas revenues, now in its final round of availability (FES-scheme). In this round, '*valorisation*' through public-private-participation became part of the 'top-sectors policy' in science funding (cf. Bos 2016). After these two rounds, the national roadmap for nanotechnology (HTSM 2014) was expected to be integrated in general funding schemes (MinEZ 2016).

Like elsewhere too, public funding of nanotechnology also charged the government with responsibility for addressing societal concerns. In the Netherlands, the parliamentary Technology Assessment (TA) office Rathenau Instituut, organised a public hearing for the House committee on technology policy. Several ministries funded exploratory studies (COGEM 2004, Ellen et al. 2005, Roszek et al. 2005, De Jong et al. 2005). The ministry in charge for nanotechnology, MinOCW (the Ministry of Science, Culture and Education) asked the Dutch Royal Academy of Sciences, the KNAW, for a position paper (Koeman et al. 2004) and subsequently called upon the responsibility of public knowledge institutes in response to parliamentary questions (Parliamentary Papers 2005a). At the same time, the international discussion about nanotechnology had been gearing up, amongst others by the publication of the landmark report of the British Royal Society and Royal Academy of Engineering (RS-RAE 2004). Preparations for following up on the just recently funded national research program NanoNed had already started, the Ministry of Foreign Affairs (MinBuZa) got involved in discussions about the EU Action Plan for nanotechnology (EC 2005, Parliamentary Papers 2005b) and the first nanoproducts were expected to enter the market soon. Even though these products had little or nothing to do with the research funded by the Dutch government, the Cabinet announced that it would start to coordinate activities at Cabinet level and invest in international coordination (Parliamentary papers 2005c). In the resulting 'Cabinet view' (Cabinet 2006a) the approach to dealing with risks was prominently discussed, with an emphasis on long term efforts for international coordination of research and regulation and calling on corporate responsibility in the meantime. In this white paper, the Cabinet referred to the notion of Responsible Development and summarised it by the motto "*seizing opportunities, addressing risks*".

Dealing with risks, dealing with responsibilities

Precaution was a leading theme in the Cabinet view. In response to earlier reports, such as the KNAW position paper, the Cabinet outlined how it interpreted the precautionary principle, amongst others by invoking the principle of proportionality. This position differed from the way precaution had been discussed in the main input for the Cabinet view, the advisory report of the Health Council (2006). The Health Council discussed in detail what a *risk governance* approach would imply for the way in which the classically distinguished functions of risk assessment, management and communication would have to be organised. Referring to the framework of the International Risk Governance Council (IRGC, Renn 2005), the Health Council called for actively inviting and involving stakeholders and guiding the overall process by continuous critical reflection on expertise, decisiveness and integrity and on openness and accountability of each responsible institution.[94]

[94] Although the IRGC framework report received a lot of attention, its uptake in the Health Council report was not self-evident. In 2006, risk governance was a rather new concept and the Health Council committee initially had used a risk-benefit evaluation approach commonly used in the medical domain. The IRGC risk governance framework was incorporated upon an external review of the draft report (source: personal communication Arie Rip).

By approaching the often polarised debate on precaution[95] from a risk governance perspective, the Health Council highlighted the procedural dimension of *realising precaution* as much as its substantive interpretation of the precautionary principle.

The Dutch government, however, had also drawn lessons from recent controversies about electromagnetic radiation (from power lines), genetic modification and asbestos. In these cases, the Cabinet observed, there are dilemmas in "*the distribution of responsibilities set against patterns of expectation and the role of risk perception for decision-making processes*" (Cabinet 2006a). Just recently, the government had adopted a list of five policy principles for dealing with risks: 1) transparent decision making; 2) making an explicit statement on (the distribution of) responsibilities; 3) early involvement of citizens in decision making; 4) risk–benefit weighing and 5) taking into account the possible accumulation of risks (Cabinet 2006b)[96]. According to the Cabinet, these principles provided a model for "*risk governance for the Dutch situation*". Nanotechnology happened to be the first instance for applying these principles (Cabinet 2006a).

The move of the Cabinet, in positioning its risk policy as the risk governance strategy the Health Council called for, was more than just having a strategy in place already. It was part of ongoing positioning with respect to the relation between corporate and governmental responsibility. In discussing its overall policy towards nanosafety, the Cabinet (2006a) did put most emphasis on the second principle, about a clear distribution of responsibilities. Businesses were assumed to take responsibility first for safe products and safe work places. Interventions by authorities were envisioned only if needed. This position of the Cabinet has been directly related to the shift in the burden of proof in demonstrating safety of chemical substances towards industry, which had been approved at European level in the new chemicals regulation REACH (Registration, Evaluation Authorisation and Restriction of Chemicals)[97]. The Dutch government, in particular MinVROM, had been heavily involved in establishing REACH and postponed policymaking on nanosafety until the most important work for REACH had been done, not only for capacity reasons, but also to avoid interference with establishing REACH (Le Blansch and Westra 2012).

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[95] As fueled by the communication of the European Commission (2000) on the precautionary principle.

[96] This risk policy strategy was called *Dealing Sensibly with Risks* (in Dutch: *Nuchter Omgaan met Risico's*). It was crafted to supplement the so-called million provision (nobody in the Netherlands should be exposed to a risk related to big accidents, hazardous substances or radiation that have a risk of death of more than one in a million), for which it had been pointed out that this provision is difficult to apply when 1) solving the bottlenecks is too expensive; 2) calculated death estimations are not a good measure for public acceptance; and 3) complexity of scientific uncertainty is high (RIVM 2003).

[97] http://ec.europa.eu/environment/chemicals/reach/reach_en.htm

Responsibility in the pilot projects: stakeholders coordinate, government facilitates
The design of the pilot projects builds on the shift in responsibilities that both REACH and the Dutch risk policy had to enable. While context and purpose differ for each of the four pilot projects discussed in this chapter, they share a similar design: government granted a budget to a consultancy organisation to gather information and develop a plan, or a set of recommendations, in cooperation with or coordinated by, one or more stakeholder organisations. As such, the pilot projects can be conceived of as policy *instruments*. However, the uncertainties for which the pilot projects had to operationalise 'precaution', extended into potential financial implications and disparate stakeholder opinions about necessity and appropriateness. With that, the pilot projects reflected a specific political environment in which the Dutch government has been seeking to organise responsibility according its newly adopted policy principles for dealing with risks. Exactly by acknowledging conditions of uncertainty and (potential) controversy, the pilot projects have been positioned as means through which stakeholders – especially corporate actors – were assigned to bear collective responsibility. In this way the pilot projects served as a governance *arrangement* for providing preparatory and complementary measures to updating regulations, while the Cabinet would take care for working towards negligible risks of nanomaterials in the long term.[98]

4.3.2 Actor landscape: existing networks and emerging audiences

The pilot project model provided a rather open approach to align corporate responsibility in simultaneously realising precaution at national level and working towards harmonised protection at international level. Much, therefore, would depend on the way in which corporate actors became mobilised. Whereas in academia

[98] Other pilot projects funded by the Dutch government have been a public meeting on nanotechnology in cosmetics (organised by NCV and VNO-NCW in 2009); an information sharing pilot project in the paint and ink industry (Van Maanen-Vernooij et al. 2012) and in the construction sector (Van Broekhuizen et al. 2011b), a specific guidance for research institutes (Cornelissen et al. 2014). The update of Stoffenmanager, an occupational safety tool developed in the Netherlands as well as research projects by RIVM, RIKILT and participation in OECD projects were also marked as pilot projects. For the long term goals various ministries invested in regulatory research programming at both national and international level, expecting these would work towards adjusting regulations. A third line of action, specified in the Cabinet view (Cabinet 2006a) as well as in the subsequent Action Plan (Cabinet 2008), involved the establishment of a stakeholder wide platform on nanosafety (*Klankbordgroep Risico's Nanomaterialen*) and a public dialogue on nanotechnology in general. Finally, the observatory and linking pin between all policy strands, KIR-nano (*Kennis- en Informatiepunt Risico's Nanomaterialen*), was hosted at the Netherlands Institute for Public Health and Environment RIVM. Together, these policy action lines had to enable a nationally coordinated and supported approach in dealing with uncertainty about the safety of nanomaterials, as a stepping stone for regulatory discussions at European level.

‘nanotechnology’ provided a natural entry point for discussing nanosafety as related to specific research activities and related organisations, most business and civil society organisations were still taking position, if at all involved in discussions about nanosafety. Consequently, the Dutch government dealt with stakeholder group representatives, like the spokesmen of business associations or trade unions, as their positions emerged in multiple processes of agenda setting in institutional networks.

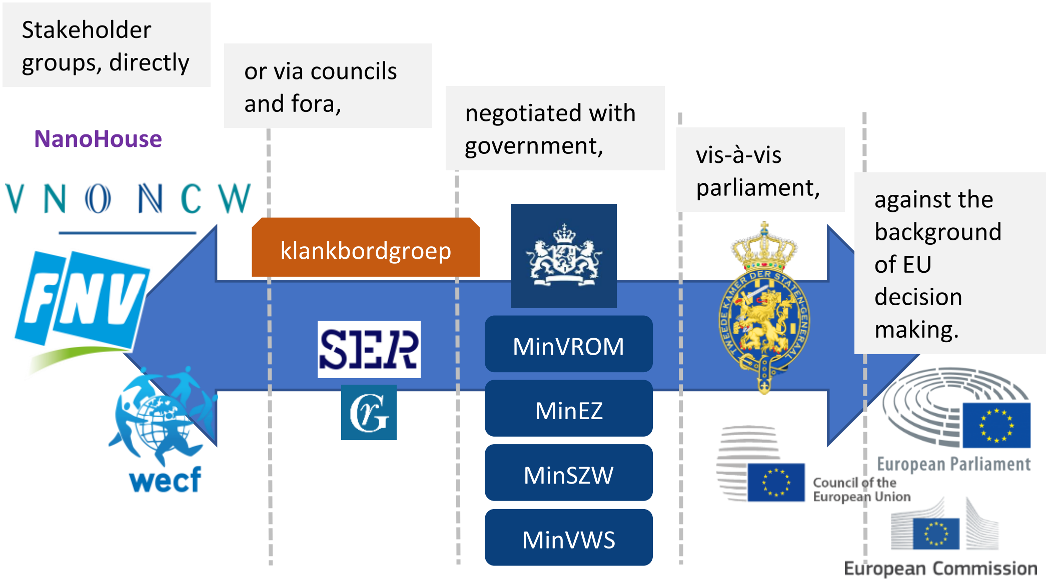

Figure 17: actors and arenas in nanosafety governance in the Netherlands

My discussion of these evolving relations between corporate, governmental and other actors below, is loosely structured along the chronological lines of the pilot projects and focuses on the frame conditions set by political, public and expert domains. The question of interest is how actors actually assumed responsibility in relation to the intended distribution of responsibilities. I will show that outcomes and dynamics have been highly contingent, yet decisively shaped by political logics.

Interdepartmental coordination

The most immediate conditions can be found in the way both governmental and corporate responsibilities were represented. In the Dutch government physical safety issues are the domain of departments like MinVROM[99] (environment), MinSZW (working conditions) or MinVWS (consumer protection). MinVROM has been in charge for coordinating the nanosafety policy actions in a interdepartmental working group, the

[99] Currently: Ministry for Infrastructure and Watermanagement (MinIenW), see also section 4.3.3

IWR (*Interdepartementale Werkgroep Risico's nanomaterialen*). The IWR, in turn, commissions the work of KIR-nano, an observatory and linking pin for all nanosafety activities, hosted at the Netherlands Institute for Public Health and the Environment RIVM.

This set-up led to the first pilot project – the investigation of SME needs and the design of a SME helpdesk by NanoHouse. As a regulatory science organisation RIVM was not allowed to cooperate with individual companies. NanoHouse repeatedly raised this issue in the KIR-nano stakeholder platforms, upon which the question was channelled to the interdepartmental coordination council for nanotechnology ION (*Interdepartmentaal Overleg Nanotechnologie*), chaired by the Ministry of Economic Affairs (MinEZ)[100]. While MinEZ normally would leave policy actions on safety to other departments, it also held close contacts with business organisations calling for action on nanosafety. In this context MinEZ decided to allocate budget for SME support on nanosafety itself.

NanoHouse building on regional coalition

The initiative taken by NanoHouse originated from a specific actor constellation too. Human and environmental exposure to nanomaterials is most directly linked to the primary, and often high volume, synthesis and processing activities in chemical industry. Especially chemical company DSM engaged early and actively in discussions about nanosafety.[101] These activities spilled over in NanoHouse, which as a one-person business opportunity brokering consultancy, was initiated from a cooperation at regional level, between DSM and SME platform Syntens-Zuid, trade union De Unie and the applied sciences department of Zuyd Hogeschool. Key support came from DSM spokesperson on nanotechnology Germ Visser[102] and CTO Jos Put, as well as nanoscientist, entrepreneur and toxicologist Paul Borm.[103] These contacts helped NanoHouse to investigate the needs of SMEs in cooperation with chemical industry association VNCI.

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[100] The leading position of MinEZ was not self-evident as well, since initially, nanotechnology was at the desk of the Ministry of Science, Culture and Education (MinOCW). However, in 2007, responsibility for the nanotechnology dossier moved together with the Minister (Maria van der Hoeven) to MinEZ.

[101] DSM issued its first position statement on safety, transparency and dialogue about nanomaterials in 2005.

[102] Germ Visser has participated in most major public meetings on nanotechnology in the Netherlands and has chaired the nanotechnology committee of the Dutch standardisation organisation NEN.

[103] Paul Borm has been member of an early stage European expert review on nanosafety (Borm et al. 2006) and works on medical applications of nanomaterials at the Centre of Expertise in Life Sciences (CEL) of Zuyd Hogeschool. He could build on this network when conducting the first inventory on the use of nanomaterials in Dutch industry and research institutes (Borm et al. 2008) commissioned by MinSZW.

Employer association VNO-NCW: both spokesperson and platform

For industry at large, the picture looked much different. The study by Borm et al. (2008) had showed that no communication about (potential) hazards of nanomaterials was present in value chains and that only a few companies had a policy for handling nanomaterials. This underlined the need for information sharing, about the use and potential risks of nanomaterials, along value chains as well as with government for purposes of oversight. The confederate industry and employer association VNO-NCW acted as spokesperson of Dutch business. VNO-NCW started an internal working group in response to the upcoming debate about nanosafety and the launch of the government's Action Plan in 2008.[104] The secretary of this working group as well as other staff have been involved in the pilot projects on information exchange as well as the development of instruments for guidance in occupational safety protection and stakeholder dialogue. However, in acting as spokesperson, VNO-NCW had to represent different corporate domains with disparate stakes and views on nanosafety regulation.[105] Since many of the members operate across borders, the need for sharing information was continuously discussed in the context of ongoing discussions about regulation at European level.

Government vis-à-vis parliament: attention focusing on occupational safety

In the parliamentary arena the specific actor constellation discussed above led to a further shaping of government-industry interactions. In the absence of public controversy, parliamentary attention to nanosafety has been low and intermittent.[106] Nonetheless, it did shape governmental action both decisively and contingently, as becomes visible in the way immediate concerns with respect to occupational exposure overruled more structural questions about the organisation of responsibilities.

MinVROM crafted its nanosafety strategy according to its newly adapted policy principles for health and environmental safety, thereby also responding to new advisory

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[104] Before, VNO-NCW had published a general position statement on precaution with respect to nanosafety in its magazine in 2005, but without a follow-up until 2007, when VNO-NCW participated in a stakeholder discussion about nanosafety, facilitated by MinVROM.

[105] For example, for chemical industry (VNCI) regulation of synthetic nanomaterials is much more obvious than for industry sectors dealing with process-generated nanoparticles, like industrial technology (represented by FME-CWM). The food industry (FNLI) still has the controversies about genetic modification fresh in mind, while the cosmetics industry (NCV), which is also vulnerable to public controversy, had already reached an agreement with the European Commission. Other members of the VNO-NCW working group were automobile repair business organisation FOCWA, the paint and ink formulators organisation VVVF, the association of insurers (*Bond van Verzekeraars*) and the retailer employers association (*Raad Nederlandse Detailhandel*).

[106] In the parliamentary agenda, nanotechnology has been moving from the parliamentary theme committee on technology policy in 2004 to the standing committee of science, culture and education (*cie-OCW*) in 2006 to the standing committee on economic affairs (*cie-EZ*) from 2007 onwards.

reports on dealing with uncertainties (WRR 2008) and applying the precautionary principle (Health Council 2008). According to MinVROM (2009a), the uncertainties about nanosafety required an internationally coordinated approach in the first place, but for which agreement with and among business at national level would be equally important for effectively operating in international arenas. With this position MinVROM safeguarded its attempts to shift responsibilities for chemical safety towards industry in the context of the European directive REACH[107] and simultaneously urged business, represented by VNO-NCW, to cooperate in sharing information. At the same time, it made clear that questions of responsibility for nanosafety and discussions about precaution, participation and risk governance would play out in relation to the international context. Later on, however, when parliament pushed for a national system of notification (Parliamentary Papers 2009a, see section 4.3.3),[108] this interdependency of national and international action turned into a central ambivalence in the pilot project on information sharing.

In the first parliamentary debate fully dedicated to nanotechnology (June 9, 2009), however, the strategy letter of MinVROM (2009b) hardly has been discussed. Instead, most attention went to the advisory report by the nanosafety subcommittee of the committee on working conditions in the Socio-Economic Council (SER 2009). Since SER reports represent the outcomes of negotiations between industry and trade union, this report was the most important document to parliament at that moment. Also, MinSZW published its response just one day before the debate, which caused members of parliament (MPs) and their staff to quickly adjust their position, in order to respond to the most recent information.

MinSZW supported most of the SER's recommendations, claiming that most of the actions called for by the SER were already subject of the pilot projects on supporting SMEs and on information sharing. In addition, MinSZW was willing to facilitate the pilot project for documenting best practices as well as the development of a self-inspection tool for nanomaterials. With respect to the recommendation of deriving nano-reference values (NRVs), however, MinSZW replied that attributing any legal status to such a measure exactly would relieve employers from the responsibility they had to take: making deliberate choices in working with nanomaterials.

A majority of MPs participating in the debate strongly objected to this interpretation, since it had been the Cabinet itself asking 'the social partners'[109] for advising on precautionary measures. Moreover, other measures recommended by the SER, like

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[107] The Dutch involvement in REACH has been informed by the preceding national trajectory of SOMS (*Strategie Omgaan Met Stoffen*) led by MinVROM.
[108] This parliamentary resolution was directed to MinVWS, but directly affected the negotiations with business, for which MinVROM was in charge.
[109] A term used in Dutch political discourse for the negotiations between employer association VNO-NCW and the trade unions, often in the context of the Socio-Economic Council (SER).

adjusting safety data sheets, would face problems of uncertainty as well. In this context, MPs stated that NRVs could provide a meaningful starting point for enabling precaution in practice (Parliamentary Papers 2009b). In a subsequent voting session, cie-EZ forced MinSZW to commission KIR-nano for developing NRVs for the most used nanomaterials (Parliamentary Papers 2009c). MinSZW then asked KIR-nano to develop an expert opinion (Dekkers and De Heer 2010) on the usability of available approaches, upon which in the subsequent pilot project a feasibility study of the selected approach has been conducted.

With these actions, parliamentary control shaped the organisation of responsibility for a second time. In 2004 and 2005 it had been parliamentary pressure that accelerated a coordinated government approach, which interlinked the otherwise diverging policy orientations of MinEZ and MinVROM as well as their respective contacts with business organisations and civil society organisations (CSOs). The follow-up debate and parliamentary resolutions on establishing a notification system and on deriving reference values, again pushed on the two pilot projects that mostly depended on the willingness and ability of firms to take *collective* responsibility (by agreeing on a system for information sharing and an approach for deriving reference values) for enabling *individual* responsibility (sharing information and limiting occupational exposure).

Civil Society Organisations (CSOs), media attention and parliamentary Technology Assessment

Parliamentary discussion and action also has to be understood in relation to the wider public domain. While media coverage of nanosafety in the Netherlands has been limited, it included the agenda setting activities of the parliamentary Technology Assessment (TA) department at the Rathenau Instituut. In 2009, the contacts between the Rathenau Instituut and parliament drew heavily on individual action, but with successful engagement of the full committee (cie-EZ).[110] Prior to the 2009 debate, a parliamentary hearing was organised, with a discussion paper (Walhout et al. 2009) as agenda. However, more than the discussion paper, it was the selection of stakeholder representative that caused the immediate concerns of oversight and occupational safety dominating the parliamentary debate.

The CSOs which had been paying attention to nanosafety, mainly did so in line with their history in either lobbying or campaigning (cf. Van Est and Walhout 2007), but mostly through representing stakeholder positions in various fora, hardly in actively mobilising members. Until 2009 some smaller groups, like *Leefmilieu* and the Dutch chapter of *Women Engage for a Common Future* (WECF) did some campaigning, while a broader range of interest groups has been participating in the stakeholder wide platform on nanosafety (*Klankbordgroep Risico's Nanomaterialen*) as well as in the national societal

[110] The individual action referred to actually concerned MP Gesthuizen and me; but see Van Est et al. 2012a for a broader overview.

dialogue on nanotechnology (MDN – *Maatschappelijke Dialoog Nanotechnologie*) in 2010. Overall, CSO activity mainly contributed to a more general frame of 'proceeding with caution', including public acceptance (cf. Koeman et al. 2004, Health Council 2006, CieMDN 2011), less to specific positions. In the pilot projects on occupational safety measures, the two largest trade unions in the Netherlands, FNV and CNV, have been directly involved, with a leading role for FNV, which was enabled by participation in the European capacity building project NanoCap.[111]

Regulatory science institutes, consultancies, inspectorates and authorities

Finally, national and international research programs, as well as inventory studies of the Dutch food and consumer product safety authority NVWA, advisory committees of the Health Council and the development of a self-inspection tool by MinSZW, created overlapping networks of nanosafety experts, with the public regulatory science institutes RIVM, TNO and RIKILT as important nodes. In addition, three consultancy organisations played a key role in conducting the pilot projects. Bureau KLB has been organising and analysing the surveys being held in the information sharing pilot project, safety expert organisation IndusTox helped to develop and update the guidance document on best practices and IVAM, the health and environmental research and consultancy service of the University of Amsterdam, got the lead in conducting the feasibility study on the use of NRVs. These three organisations have acted as trusted parties in government-industry interactions, with individual experts working in alternating combinations in various nanosafety activities. Specifically, a key role has been played by Pieter van Broekhuizen (IVAM) for guiding the process of deriving the nano-reference values. Van Broekhuizen represented trade union FNV in his capacity as coordinator of NanoCap, was active in the SER subcommittee on nanosafety and has been advocating the use of reference values in the related pilot project as well as the feasibility study on exposure registration.[112]

Responsibility claims evolving politically

The above discussion shows that the difference between individual and collective responsibility for corporate actors has been further shaped by political logics. The Dutch government made an explicit statement about the prime responsibility of firms by positioning the pilot projects and the functions these had to enable – support, oversight, tentative norms, guidance – as instrumental to its newly adopted policy principles. The related game of organising responsibility has been a precarious process. Government-industry interactions took place in a context of low public awareness and with almost all Dutch CSOs that paid attention to nanosafety enrolled in dialogue structures facilitated by government. Actions in the corporate domain ranged from the local initiative of NanoHouse to the central role for VNO-NCW, willing to cooperate, but also representing a heterogeneous industry landscape, with some convinced and pro-active, others

[111] Next to FNV also environmental group *Natuur en Milieu* (SNM) participated in NanoCap. Like FNV, SNM is a lobby organisation, with direct contacts in parliament.

[112] See Van Broekhuizen 2012 (PhD thesis) for a personal account of his advocacy.

affected and above all the parallel discussions at European level. Together, the number of individuals involved has been relatively small (about fifty to hundred, depending on level of engagement), of which some (about twenty) have been directly involved in the pilot projects. In this context, parliamentary scrutiny, however contingent and limited, has been the space in which the pilot projects for collective action, though not phrased as a responsibility problem, emerged as such politically. However, it did so mainly in discussions about occupational safety. That provided the development of reference values with specific political support, while broader action with respect to enabling oversight was left open for discussion.

4.3.3 *de facto* governance practices: interactions at the level of representatives

To understand how progress in the pilot projects has been evaluated in light of the evolving debate about nanotechnology, I will take a closer look at the specific spaces and contexts in which the government-industry interactions took place. A key role is that of parliamentary control again, but now because of its absence. Parliamentary elections moved up to 2010, thereby delaying the next annual debate on nanotechnology that was to be held from 2009 onwards while changing the political landscape. MinVROM merged with the Ministry of Transport, Public Works and Water management into the Ministry of Infrastructure and Environment (MinIenM) and MinEZ merged with the Ministry of Agriculture, Nature Conservation and Food quality (MinLNV) into the Minstry for Economic Affairs, Agriculture and Innovation (MinEL&I). I will show how public and political scrutiny faded at the same time, affecting the ability to transform responsibility through the pilot projects (Figure 18).

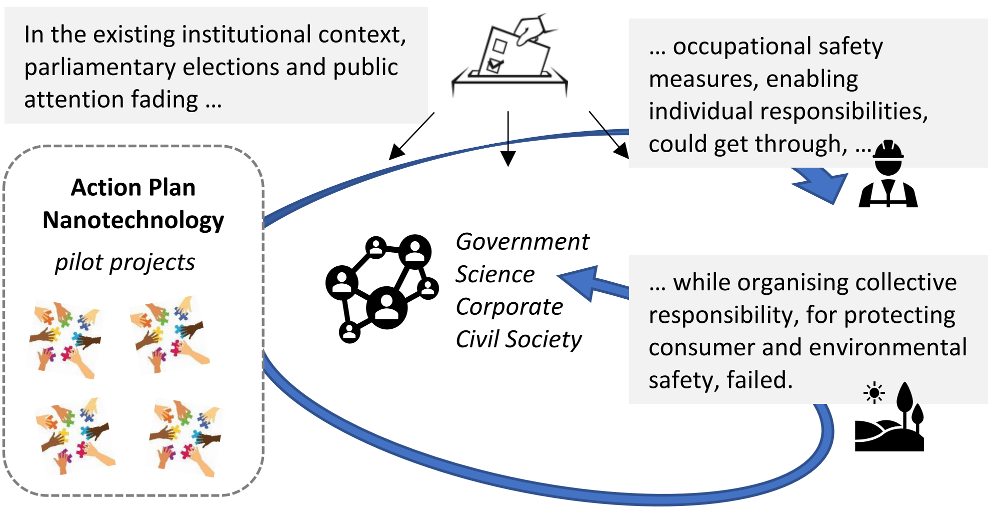

Figure 18: de facto dynamics in nanosafety governance in the Netherlands

Guidance and support

The first pilot project affected by the parliamentary elections in 2010 was the helpdesk for SMEs. NanoHouse had recommended this function to be realised as part of existing structures for R&D support with input from public health and safety expertise. Due to the parliamentary elections and the discontinuation of ION in 2011, it took until 2012 before the various departments agreed on an alternative construction. NanoCentre would be hosted at national research organisation TNO (MinEZ budget), in cooperation with RIVM (joint KIR-nano budget of MinVROM, MinVZWS and MinSZW). In this way, NanoCentre could build on the nanosafety expertise and tools already available (e.g. *Stoffenmanager Nano*, or the guidance document discussed below). The budget didn't allow for increasing its visibility in professional networks, which has been considered as a drawback from the start.

In contrast, the guidance document for safe handling of nanomaterials could be finished without interdepartmental negotiations. IndusTox and IVAM completed a first version in 2010 (Cornelissen et al. 2010), followed by updates (Van Broekhuizen et al. 2012a) and uptake in the national repository of worker safety guidelines (*Arboportaal*) facilitated by MinSZW. These versions included the nano-reference values as recommended by the SER (2012), as well as an exposure registration module.

Information sharing

In 2011 the elections affected the attempts for information sharing by business to government. Following up on the inventory commissioned by MinSZW (Borm et al. 2008) VNO-NCW had agreed to investigate the production, use and trade in nanomaterials in more detail among its members. Within the VNO-NCW working group, chemical industry association VNCI took the lead in organising surveys, which have been distributed by industry associations FME-CWM (metal and instrumentation), NCV (cosmetics), VNCI (chemicals) and VVVF (paint and ink) and by research institute FOM. Food industry association FNLI did not participate and submitted a position paper instead. Bureau KLB was asked to evaluate the results (Westra and Van Damme 2010). It turned out that the investigation had not been a success. The data suggested that nanomaterials were mainly used for R&D, not for manufacturing; and in consumer product trade for the cosmetics sector. But conducting the surveys was complicated by a lack of awareness and of an established definition, reluctance to disclose information and legal provisions blocking data gathering from subsidy overviews. Hence the list created by Borm et al. (2008) remained the most accurate.

Underlying the difficulty in sharing information have been the diverging interests of the association represented by VNO-NCW. Until 2011 MinVROM stated in its letters to parliament that VNO-NCW and VNCI were still working on the issue (MinVROM 2009a,b, Cabinet 2010). No sign of difficulties also has been documented in the minutes of the stakeholder platform (MinIenM 2012a). But just before the second parliament debate MinIenM (2011a) acknowledged that the process had been very difficult and, on top of that, the intended covenant with industry had not been realised. According to MinIenM this was because many companies were reluctant to share confidential information and because the industry associations represented by VNO-NCW could not reach internal agreement. Later evaluations (MinIenM 2012a, Le Blansch and Westra 2012) pointed to legal difficulties in establishing a definition as well as in protecting confidential information. One day before the parliamentary debate VNO-NCW (2011) sent a letter of intent to MinIenM in which it didn't mention the covenant or the pilot, but yet reiterated the willingness of industry to cooperate with government as set out in the strategy by MinIenM and the active communication by VNO-NCW about nanosafety among its members.

Without the parliamentary elections the sudden withdrawal of VNO-NCW would have caused a great stir in parliamentary debate. After all, the covenant was a crucial step in managing the relation between national and international action. The international dimension had reached parliamentary attention already in 2009, when the European Parliament (EP 2009a) had been pushing for including nanomaterials in food in the Novel Food directive (implying much stricter risk assessment procedures) as well as labelling all consumer products containing nanomaterials (EP 2009b). With respect to the latter, the EP committee had become very critical, because nano-specific measures for adjusting regulation had not been developed yet and oversight was still missing.[113] Neither the Dutch government or VNO-NCW would support labelling or separate registries for establishing oversight, but the unanimously supported resolution of the EP was of direct relevance for national parliaments.[114] In its strategy letter MinVROM (2009a) therefore had put the efforts on information sharing and the intended covenant with industry explicitly in the context of a three-step strategy towards adjusting regulations at EU level.

For the first step, RIVM evaluated the safety aspects of nanosilver as a case study for REACH (Pronk et al. 2009). The second step then would be to develop a more general screening model, together with industry and building on the information sharing efforts in the pilot project. In the third step the screening model would be brought to the European level. Until 2011 MinVROM used this argument in response to (follow-up questions on) the parliamentary resolution on notification at national level. However, industry sectors had opposing views already with respect to the properties by which nanomaterials would be captured in a regulatory definition, which was negotiated at European level. Moreover, in the internationally heightening debate about nanosafety, firms showed a decreasing willingness to talk about nanosafety, let alone share

[113] The European Parliament resolution has been written in response to the nanosafety regulatory review progress report of the European Commission (EC 2009).
[114] In the Netherlands, the Rathenau Instituut had brought into contact MP Gesthuizen (keeping nanotechnology at the agenda of cie-EZ) and E-MP Liotard (leading the EP-ENVI committee on reviewing the Novel Food directive), both member of the Socialist Party, in the context of a television broadcast about nanosafety.

information with government (<Streekstra>). Despite these difficulties the VNO-NCW working group secretary had been working hard for reaching agreement among the working group members. But then the election factor kicked in: prospects for the liberal party were positive and the board of VNO-NCW blocked the intended covenant in anticipation.[115]

Nano-reference values (NRVs)

The trajectory of introducing nano-reference values (NRVs) for occupational exposure developed much different. Some members of the VNO-NCW working group opposed the use of NRVs in risk evaluation procedures as well, since they would also cover nanoparticles other than intentionally produced. These are particles present in background concentrations (for which employers do not bear direct responsibility), but also the nano-sized component of bulk materials ('nano-fractions', sometimes the result of grinding or other ways for breaking down larger structures) and 'process-generated' nanoparticles (PGNPs), which commonly occur in high energy processes (like welding). Applying the NRVs for the latter category would conflict with other, often less stringent, exposure limits like those for diesel exhaust gasses.

Actual measurement of exposure to nanoparticles has been much dependent on available technology. In the pilot project this has been tested in twelve companies. In addition eighteen interviews have been conducted. While all respondents preferred scientifically derived and legally binding exposure limits, most respondents considered the NRVs as a means to build trust, or simply "*better than nothing*". Yet ambiguity was noted as well, since no indications of harm could be derived in case of exceeding the NRVs. Others pointed to differences in compliance cultures (e.g. between larger and smaller firms) as more significant (Van Broekhuizen and Dorbeck-Jung 2013).

An important factor for continuing the NRV route is the stretch in occupational safety management that would be still allowed for after acceptance of the NRVs by the Labour Inspectorate as a valid tool for determining safety measures. A legal study commissioned by the government had pointed out that taking stock of nanosafety could be legally required (Vogelezang-Stoute et al. 2010). On top of the general 'As Low As Reasonably can be Achieved' (ALARA) principle for occupational exposure to nanomaterials as recommended by the Health Council (2006), the NRVs could be used to determine when additional safety measures would be needed. Since such a measure easily fits in the mandatory risk identification and evaluation schemes, establishing the NRVs as an officially accepted tool then quickly would set a standard for appropriate care in dealing with nanomaterials. However, while the use of NRVs is now endorsed, it has not been enshrined in law. If scientifically underpinned, employers are still allowed to use alternative approaches, such as control banding.[116] Furthermore, while the

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[115] Source: personal communication of W.H. Streekstra in relation to the interview (see Appendix).

[116] Using the NRVs is a hazard banding approach.

regulatory definition of nanomaterials as proposed by the European Commission (EC 2011) supported the inclusion of process-generated nanoparticles (SER 2011), these PGNPs can still be left out in exposure assessments through specific calculations.

Another important factor contributing to the progress of the NRVs, is the way support was built in various arenas. The results of the pilot project (SER 2011) fed into a new advisory report by the SER (2012), not at least because of Van Broekhuizen's membership of the SER sub-committee on nanosafety. Part of this trajectory included an international workshop (Van Broekhuizen et al. 2012b), organised by the SER, attributing to the official status of the NRVs. At national level, not all industry associations were supportive though. However, from 2012 onwards, the prospects for using the NRVs became linked to another occupational safety measure for nanomaterials – exposure registration – for which a study by the Health Council (2012) had been running in parallel.[117] The Health Council advised positively on exposure registration, which if accepted, would require significant efforts for agreeing on and implementing a registration system. MinSZW then asked Bureau KLB and IVAM again to conduct a feasibility study, in which Van Broekhuizen was involved as well. Van Broekhuizen et al. (2015) concluded that exposure registration would not be necessary if exposure levels would remain under the NRVs and hence underlined the importance of the NRVs. With this package deal all industry associations participating in the stakeholder platform on nanosafety (the *Klanbordgroep Risicobeleid Nanomaterialen*) as well as the Labour Inspectorate supported the NRVs in the end (<Le Blansch>).

Political discussion

The difficulties in information sharing and the careful positioning of the NRVs underline the significance of problem framing and process evaluation. From the publicly available part of the minutes of the first ten meetings of the government initiated stakeholder platform (*Klankbordgroep Risicobeleid Nanomaterialen*, MinIenM 2012a) it appears that interactions mainly have been confined to exchanging information about each other's activities (also due to intermittent participation) for keeping a finger at the pulse rather than developing the joined position towards EU level action as wished for by MinIenM. The minutes do not cover any responses to the difficulties in the pilot project on information sharing or the reasons why the covenant between government and industry failed.

Parliamentary debate, in contrast, took off much more critically in 2009, when nanotechnology moved from being a sub-topic in debates on innovation policy, to an annual and committee wide debate about nanotechnology itself.[118] However, this political momentum didn't last long. Already in the fall of 2009, questions from

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[117] Upon the parliamentary resolutions of 2009, MinSZW simultaneously asked the RIVM to draw up an expert opinion on the use of NRVs (MinSZW 2009a) and the Health Council to advice on exposure registration (MinSZW 2009b).

[118] As urged by MP Gesthuizen (socialist party), with support from MP Besselink (labour party)

individual MPs following up on the parliamentary resolutions, hardly got space for discussion (cf. Parliamentary Papers 2009d). After the elections in 2010, all MPs in cie-EZ changed position, except MP Gesthuizen, who had been driving the parliamentary debate about nanotechnology from 2008 onwards. Yet, in the new composition of cie-EZ and with decreasing public attention nationally as well as internationally,[119] most MPs were not inclined to take firm positions on government's progress with respect to nanosafety (cf. Parliamentary Papers 2011). After the debate on nantechnology early 2011, nanosafety only has been addressed in written parliamentary questions by the socialist party[120] in response to specific topics, such as regulatory discussions about carbon nanotubes (CNTs). Progress in the pilot projects hardly has been discussed as such, nor did policy evaluations (MinEL&I 2011, Le Blansch and Westra 2012, MinIenM 2013a) raise any follow-up responses.

Transforming responsibility in institutional context and political landscape: contingent lock-inns

The discussion of *de facto* dynamics and outcomes of the pilot projects has shown that the starting point for my empirical investigations in this chapter – the difference in outcomes between the four pilot projects – indeed reflects a difference between operationalising precaution in occupational safety (OHS) and in environmental and consumer safety protection (EHS). In OHS, uncertainty about hazard and effects is less problematic since exposure can be controlled. In EHS, uncertainty about hazard and effects is much more dependent on information about (potential) exposure, which if lacking, easily traps approaches to addressing uncertainty. The difference is also reflected in the outcomes of the less politically charged pilot projects – the guidance document and the SME helpdesk – which are mainly geared towards OHS.

However, the difference is as much institutional as it is substantial. OHS regulations are largely enforced at national level, building on and sustained by longstanding tri-partite interactions between industry, government and trade unions, especially so in the corporatist political system of the Netherlands (with the SER as a prime instance). The NRV pilot project has been clearly operating in connection to these networks and fora. For EHS, regulatory frameworks at the European level have been much more important, especially so because of the international scope of many firms dealing with nanomaterials in the Netherlands. Yet the survey exercise in the pilot project on information sharing has been delegated to individual industry associations, while the diverging interests of their members were negotiated at both aggregated national level (VNO-NCW) and European level.

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119 Public attention spiked in 2010, nationally also due to a series of public dialogues on nanotechnology (see CieMDN 2011). The same attention, however, had resulted in initial actions in many countries as well as at European level, thereby moving from agenda setting to the – more boring – formation and implementation of policy measures.

120 The political faction of MP Gesthuizen

If progress stalls, this can still be acted upon in evaluative structures. However, this didn't surface in the stakeholder platform. The parliamentary arena was marked by logics of control (e.g. discussing government's progress reports and responses to advisory reports; or sustaining and coordinating follow-up questions across committees and debates by parliamentary factions) as well as logics of representation (e.g. ordination of topics at parliamentary agendas, or close links between trade unions and the socialist party), but didn't get hold on the organisation of responsibility either. In the absence of articulate public attention, these logics have been highly contingent on individual advocacy. As a consequence, MinIenM was bound to its own position with respect to the precedence of EU level action for information sharing and creating oversight, as well as its approach to stakeholder deliberation and negotiation at national level.

4.3.4 Nanosafety governance in the Netherlands: constructive and productive?

For drawing lessons about the Dutch pilot projects and the challenges of transforming responsibility in nanosafety governance in the next section, I will now move to the second set of analytic lenses and evaluate how *contestation* and *responsibilisation* have been interrelated. Ideally, problem and solution frames are *constructive* towards the problems at hand, and *productive* in terms of effectively enacting responsibilities or reconfiguring them if needed. Dominant tropes in the policy discourse about nanosafety governance, however, contributed to the lock-inns discussed above.

Contestation
Discussions among actors about nanosafety governance in general and the pilot projects specifically, have been marked by a set of three tropes, which are rather common in the world of risk policies: 1) uncertainty is a knowledge problem, which has to be addressed by scientific research informing regulation; 2) as long as knowledge is incomplete, precaution in the production and use of nanomaterials is due; 3) for the latter, all actors have to cooperate.

These frames fit relatively well to developing the guidance document and establishing the SME helpdesk, since the related actions are a no-regret action for all companies and concern minimal investment for small companies. Hence, there is not much directly at stake for government, individual companies or industry associations. The three tropes also hold for the process of developing preliminary reference values for limiting occupational exposure. Here, diverging stakes and interests became manifest after completion of the pilot project, at the level of industry representation, but these could be reconciled in the stakeholder platform.[121]

[121] It should be noted that the NRVs have not been actively 'implemented'. In 2017 about 60 companies attended a symposium about the NRVs. Informal discussions indicated that insurance

For information sharing this has not been the case. Oversight is a crucial element of operationalising precaution, but critical stakeholders have not been involved. Of course, information sharing, between firms and with government, is a sensitive topic and requires a protected space. However, in the absence of sustained political debate, it has been left to the ability and willingness of industry to overcome diverging interests at national level. That the same problems apply for the European level – for example in establishing a regulatory definition of nanomaterials – has been acknowledged, but not articulated in terms of political choice. In fact, the Cabinet's emphasis on the prime responsibility of industry exacerbated the tension between action at national level and European level, since it juxtaposed the tension between emphasising individual responsibilities and enrolling in collective action.

These tensions with respect to the third trope then also revealed the problematic nature of the first trope, about uncertainty as a knowledge problem. Even in 2011, in the update of the nanosafety strategy, MinIenM stated that because of a lack of knowledge it was not clear where to apply precaution (MinIenM 2011b). Stated as such, this is almost opposite to what the Health Council had defined as a starting point for crafting the nanosafety policy in 2006 and was supported by the ministry itself (MinVROM at the time). Practically, the statement of MinIenM referred to the underlying problems of identifying what nanomaterials are (definition problem in regulation), how exactly they may pose risks (knowledge problem in risk analysis) and where they are used (resulting oversight problem). However, precisely the interrelations between these sub-problems show that with respect to precaution is not a problem of knowledge, but of choice, in taking precautionary measures that serve protection as well as continuous and targeted knowledge development. Otherwise the knowledge problem is sustained by political choice.

Responsibilisation

In the pilot projects, stakeholders have engaged in taking collective responsibility. However, looking at the outcomes, responsibilities have been reproduced rather than reconfigured.[122] On the one hand there are the guidance document, the SME helpdesk and the NRVs. As a result of stakeholder interaction, these outputs can be considered as a success. But credits would have to go to government, for financing the work, including budget of the department of Economic Affairs (MinEZ). Also, while these measures are available, they are not part of active dissemination and support actions. The relevance

companies have been playing a role in the use of the NRVs by firms (source: RIVM colleagues in response to presentation of findings). Also, the 'package deal' with the stance on exposure registration rather glossed over the argument of the Health Council (2012) that monitoring could contribute to knowledge development.

[122] For the contrast between reproduction and reconfiguration I have borrowed from 'reconfiguring responsibility' – the title of final report of the FP6 DEEPEN project (Davies et al. 2009), which argued for going beyond the responsibility as framed in the discourse about Responsible Development (of nanotechnologies).

of the guidance document is dependent on information sharing. NanoCentre has strong links to regulatory science, but less so to R&D communities. And while the NRVs can act as 'soft regulation',[123] this will depend on the way they will be actively supported.

More importantly, the effort in specifically organising collective responsibility through information sharing in the end has been put back by VNO-NCW as a responsibility for creating oversight at the desk of government. Almost ironically then is that the Cabinet's emphasis on a clear distribution of responsibilities ended up with government taking the lead in addressing uncertainty about the safety of nanomaterials. In the process evaluation of the nanosafety policy of the Dutch government (Le Blansch and Westra 2012), this outcome has been attributed to the fact that government-industry interaction didn't go much beyond the level of (spokespersons of) industry associations. The significance of these outcomes has been well illustrated by the results of a later pilot project on information sharing in the paint and ink industry. Only two companies participated (Van Maanen-Vernooij et al. 2012). Still, paint and ink industry association VVVF claimed its initiative for the pilot project as well as its participation in the also publicly funded European research project NanoHouse as demonstrating responsibility.[124]

Over time, the discussions about safety did affect the general policy principles for risk governance of the Dutch government. In 2009 already MinVROM (2009a) added *precaution* to the list. Upon the process evaluation of the nanosafety policy actions (Le Blansch and Westra 2012) by then MinIenM added two more principles on involving society in risk governance (MinIenM 2013a).[125] These principles don't affect the organisation of responsibilities, however. As for the conclusion of the process evaluation that government could have showed more teeth towards industry, MinIenM argued that this would have to be resolved at European level (MinIenM 2011b, 2012b, 2013a) and started a number of actions urging the European Commission to take action, amongst others by aligning EU member states in consensus conferences (MinIenM 2013b, c). At European level, the struggle for creating oversight continued years afterwards, with recurring problems reported for national registries, as well as notification under the EU directives for cosmetics and novel foods. Only recently (January 2020), registration of nanomaterials under the EU Chemicals directive REACH has entered into force. With

[123] Dorbeck-Jung (2011) participated in the NRV pilot project and describes these as co-regulation between stakeholders, based on a negotiated expert proposal. Dorbeck-Jung argues that even though the NRVs are not legally enshrined ('hard regulation'), such measures are not without coercion.

[124] V&I magazine #31 (2014); not accessible at March 28, 2023.

[125] 1) Involve society throughout the policy process, from early signalling to risk management, and engage in dialogue about emotions, risk perceptions and ethical issues; 2) Make use of existing knowledge in society to the full for early signalling of (potential) risks. [translation BW] Later on, the extended set of policy principles has been consolidated in a new policy (*Bewust Omgaan met Veiligheid*, MinIenM 2014).

that, anticipation of the novel risks associated to nanomaterials has been morphed back into adaptation of regulations.

4.4 Discussion

The analysis in this chapter has discussed the various contexts in which the four pilot projects have been conducted. Some aspects have only briefly been highlighted, such as the other action lines on research and public dialogue in the national nanotechnology policy, the corporatist traditions in Dutch policymaking, or the bureaucratic structures that further channelled problem and solution frames in policy within government as well as vis-à-vis parliament.[126] In fact, this is the 'Dutch situation' that would have to be addressed by the risk governance strategy of the Cabinet. Just as well, the national policy on nanotechnology not only followed the international dynamics of agenda setting (about 2004 – 2006), policy formation (about 2006 – 2008), implementation, including the pilot projects (about 2008 – 2011) and evaluation and reordering of research and innovation agendas (2011 – 2013), but also actively contributed to it.

In this respect, the pilot projects have been even more important to the idea of Responsible Development of nanotechnology. They had to operationalise *precaution* – taking due measures in the face of uncertainty about the safety of nanomaterials – and do so through the active *participation* of stakeholder groups. That both have been difficult because they are interrelated exactly reflects the challenge of organising collective responsibility – a hallmark in the discourse about Responsible Innovation. That is not to say that the pilot projects as well as the broader Dutch policy actions on nanosafety haven't brought protective measures as well as proactive initiatives in international arenas (this has been the case indeed, see Chapter 9). But it didn't transform responsibility needed for improving the effectiveness of risk governance. In the context of existing distribution of responsibilities, organising collective responsibility is exactly about that: the *deliberate* organisation of responsibility, not just calling on responsibilities. Where such organisation fails, it actually sustains '*organised irresponsibility*' (cf. Beck 1992).

Table 6 shows two concurrent interdependencies that have been brought to the fore in the analysis. Both constitute a conundrum in the role of government in governance. First, governments can offer direction in a distributed process. But given the limits on resources and the democratic accountability of their expenditure, too much governmental steering may well take away the responsibilities of businesses, or of

[126] For example, policy actions for nanotechnology had to be approved general committees for interdepartmental coordination and at Cabinet level. For nanotechnology these respectively were the Committee (CEKI) and Council (REKI) of Economy, Knowledge and Innovation; each of which introduces specific logics in convoluting decision making processes.

European institutions. Second, successful policy action at EU level relies on well-developed input from member states, while coordination at national level is subject to subsidiarity to EU level and actors participating in both arenas.

Governance challenge	
Novelty and emergence	- uncertainty about health and environmental safety of nanomaterials - knowledge development takes years, so provisional measures needed
Aligning promotion and control	- enabling oversight by sharing information about use (EHS) - developing and adopting preliminary measures (OHS)
Translation into quest	
Anticipation-cum-inclusion	- developing the precautionary measures by stakeholder involvement ('precaution' and 'participation')
Responsibility structuring	- explication of responsibilities - aligning positions at national level to strengthen impact at EU level
Challenges of transformation	
Key interdependencies	- calling on responsibilities, while trying to reconfigure them - stakeholders participate in both NL and EU arenas, agree on primacy of EU level action, but with disparate stakes
Conditions for learning	- actors caught in horizontal interactions, also inside government - playing out in concurrent arenas

Table 6: findings for nanosafety governance in the Netherlands

The lesson for governance is that if these conditions are *all in the game*, governance strategies can benefit from explicating these. Negotiating with spokespersons of industry associations in the context of nationally enforced regulation, for example, is much different from enrolling industries in a strategy towards common action at European level through these associations. More generally, this chapter has discussed the *game* of organising responsibility as political choice in three concurrent dimensions: 1) calling on responsibilities while reconfiguring these, 2) in a multi-level governance setting, 3) public scrutiny in stakeholder interaction and parliamentary control. For the pilot projects all have been involved, but not equally well.

5. Practicing Responsible Innovation in NanoNextNL

This chapter has been published as Walhout and Konrad (2015) in Bowman, Dijkstra et al. (2015). I have added and hence organised an extra section (5.7), which discusses how the analysis fits the Research Approach discussed in Chapter 3 and what happened after the timeframe covered in the original chapter (2014 onwards). Instructions for readers have been changed accordingly.

5.1 Introduction

'Every researcher in this field has to consider the consequences'. With this statement Dave Blank (2011), chairman of the executive board of NanoNextNL, marked the ambition set for the large public-private research consortium that had just begun its work. The statement as well as what happened afterwards reflect a transition in science systems towards, at least rhetorically, demonstrating societal relevance and responsiveness to societal concerns. Considering the place and impact of science and technology in society is becoming mainstream, also for science and technology promotors. Perhaps more importantly, the statement also reflects ideas that science and technology promotors (have to) take responsibility themselves. In the same interview, Blank (2011) states that outsourcing the consideration of societal aspects to a couple of experts would be nonsensical.

In this chapter we discuss the ambition set for NanoNextNL as exemplary for the current calls for Responsible (Research and) Innovation. The notion of Responsible Innovation (RI) pulls together various normative orientations for the outcomes, processes and directions of research and innovation. These can range from anticipating risks, addressing societal challenges, involving publics and taking care of moral concerns, to fostering gender equality and global equity or ensuring open access. But whether RI definitions pull all these orientations together in terms of a responsive stance towards societal concerns (von Schomberg 2013), care for the future (Stilgoe, Owen et al. 2013) or inclusive and collaborative processes (Rome Declaration 2014), they all position RI as a forward looking and collectively exercised virtue.

For this chapter we are, however, not so much interested in definitions of RI as such, but rather in the challenges faced when trying to put such ideas into practice. According to (Rip 2014), the emergence of the RI discourse, both reflects and contributes to shifts in the 'division of moral labour' between those who feel responsible for 'promotion' of scientific and technological developments (typically scientists, corporate actors, also governments and intermediaries such as research councils) and those who exercise 'control' (typically regulators, civil society organizations, customers). But these shifts will not go without struggle. While some social scientists and policy makers think of RI not only as an integrative approach, but also as a characteristic (which should become) mainstream in the governance of research and innovation, it is far from self-evident that the new responsibility conceptions voiced under the banner of RI are equally understood and institutionalized. Therefore, we approach RI initiatives as adding to the list of 'experiments' in the governance of research and innovation (Stilgoe 2012), exemplifying the tentativeness of many current governance approaches to new and emerging sciences and technologies (Kuhlmann, Stegmaier et al. 2019).

One strand of experiments has been the practicing of ideas about participation and deliberation by public and stakeholder dialogues and consultations. These ideas have become fairly mainstream, no matter the differences in the quality of activities and ongoing discussions about their legitimacy and effectiveness. Another strand consists of the various methods and approaches to modulate research and development (R&D) practices (such as Constructive Technology Assessment (CTA), laboratory engagement, Value Sensitive Design – see (Fisher, O'Rourke et al. 2015) for a discussion on 'socio-technical integration approaches'). These mainly have been local experiments. Our case–NanoNextNL–reflects a combination of two other strands: professional formation of (early career) researchers and the inclusion of parallel research activities in large, publicly funded research programs, which have to identify (at least) and address (if envisioned) societal aspects at stake for the kind of research and innovation these programs are contributing to.

One of the main critiques to 'parallel research', most notably with regard to the Ethical, Legal and Social Aspects (ELSA) research in the Human Genome Project, has been that it functions as an add-on, lacking impact on the research itself or on political decision making. In our case however, the integration of Risk Analysis and Technology Assessment (RATA) in a national research and innovation program, did start from integrative aims, connecting to notions of Responsible Development and Risk Governance. In NanoNextNL, RATA has not only been defined as a research program with substantial budget (~18%) allocated to it, but also as an integrated (professional activity for all PhD researchers) and integrating (through inter program collaborations) activity. This renders RATA NanoNextNL as an attempt to mainstream ideas of RI on a scale that is quite uncommon. By mainstreaming of RI we refer to the ambition to turn considerations of safety and societal embedding into a concern for all projects in the program, respectively the program as a whole, rather than an approach limited to specific projects. Together with the high ambitions as set by the chairman of NanoNextNL, we therefore consider the integration of RATA in NanoNextNL as a highly interesting 'experiment' (although most of the actors involved probably would frame it as 'implementation') to learn from, since high ambitions also raise the question under which conditions these can be realised.

In the next section we will first discuss what it is that we can learn and how. Section 5.3 discusses frame conditions for the integration of RATA in NanoNextNL. In section 5.4 we discuss the actual integration process. Section 5.5 closes with lessons that can be drawn from our case for the governance of Responsible Innovation. The conclusions in section 5.6 are followed by an addendum in which I will discuss the findings of this chapter in terms of the heuristic for this thesis.

5.2 Learning from de facto governance

Our approach originated in the research project Res-AGorA, which had to build a governance framework for RI (see Chapter 3). This is no straightforward task, since RI is still a fairly open concept, articulated in a diffuse policy discourse, which is likely to remain so for some time. An important starting point for the project, therefore, has been to learn from a range of existing cases, exhibiting situations in which actors have attempted to navigate research and innovation in ways they thought to be responsible (whether or not labeled as RI). What can be learned from these cases, from a governance perspective, is how actors, in their specific setting, interpret and construct responsibility claims in relation to the governance instruments applied. This can be conceived as learning from *de facto* governance: we analyze governance 'as practiced', in a *dynamic interplay* of 'actors and factors' rather than foregrounding *structural elements* of (formal) arrangements, mechanisms and instruments.[127]

Part of *de facto* governance are the histories and aggregative effects (Rip 2010) on which actual governance dynamics build. The inclusion of RATA as a separate research theme in NanoNextNL is a case in point: including parallel research is a, by now, rather common approach to anticipating societal issues in research and innovation. However, as will turn out, ideas and ambitions for RATA also have been reinterpreted in light of new developments. For example, the statement of NanoNextNL's chair, cited above, appeared in a Dutch newspaper on the occasion of the closing event of a series of national dialogue activities about nanotechnology. At that time NanoNextNL was about to kick-off and just had been required by the Dutch government to comply with the *European Code of Conduct for Responsible Nanosciences and Nanotechnologies Research* (EC 2008b, hereafter referred to as the EU-CoC). This code, adopted by the European Commission as a recommendation to the member states in 2008 and stating principles on, for example, clarity of meaning, safety and sustainability, had been rather critically received. As we will show, against this background the program office of NanoNextNL decided to subsume the requirement to comply to the EU-CoC in the

[127] In the Res-AGorA research heuristic governance is defined as 'the dynamic interrelation of involved (mostly organized) actors within and between organisations, their resources, interests and power, fora for debate and arenas for negotiation between actors, rules of the game, and policy instruments applied helping to achieve legitimate agreements' (Kuhlmann 2001; Benz 2007; Braun 2006)

activities for the integration of RATA. It is exactly these kind of moves we want to understand and account for in our 'learning for governance'.

To this end, we will structure our investigation of governance dynamics and conditions in two steps. The starting conditions for the integration of RATA discussed in section 5.3 concern aspects of RATA as the governance arrangement under study (purpose, history and relation to other relevant governance mechanisms) and characteristics of the 'actor landscape': who are the actors involved, how do they frame the aim of integrating RATA and the problem it has to address, and from which position and power. Section 5.4 describes the actual integration process by focusing on places and spaces of interaction and negotiation, dominant problem framings and the construction of responsibilities.

Being researchers in the RATA research theme ourselves, we draw on our roles as 'observing participants' as well as on document analysis, interviews and feedback from key individuals, often figuring in the analysis below and documented in an internal case study report for the Res-AGorA project. Part of the observations also draw on interviews conducted by Colette Bos, a fellow PhD researcher in NanoNextNL, documented in a co-authored publication (Bos, Walhout et al. 2014). Where our discussion primarily reflects statements or feedback obtained from conversations with actors other than formal interviews, we have indicated this in footnotes.

5.3 Frame conditions

Situating RATA in NanoNextNL

NanoNextNL is a Dutch national R&D program on micro and nanotechnology, involving 130 partners covering universities, research centers, multinationals, small and medium enterprises (SMEs) and medical centers, running from 2011 till 2016. The program is explicitly positioned as an innovation program, succeeding the earlier national program NanoNed, which was mainly research oriented. The funding scheme for NanoNextNL is administered by the Ministry of Economic Affairs, financed from national gas revenues and meant for strengthening the national knowledge infrastructure. The research grants provided by this scheme require 50% matching money from the participating partners in a public-private partnership and a substantial effort to create application potential, measured in key performance indicators for 'valorization'.[128]

A core group of nano-scientists had already started with the design of the research program of NanoNextNL in 2005. At that time both promises and concerns about nanotechnology became part of the political discussion and the Dutch government

[128] Valorisation is a policy term used by the Dutch government, following up on the European Lisbon strategy to improve the (economic) utilisation of scientific knowledge. Interpretations of this notion vary from 'societal relevance' to 'commercialisation'.

pushed for including 'risk research' in the research agenda. This was framed as an essential part of the government's policy on the responsible development of nanotechnology (Cabinet 2006a). While over time the nanotechnology program was increasingly positioned as an innovation program with a significant share of application oriented research, paying attention to risks was seen as essential for successful innovation by the nanoscience community as well, as presented in the Strategic Research Agenda (SRA) which sketched the main topics to be included in the NanoNextNL programme (Nederlands Nano Initiatief 2008).

Nonetheless, the risk research theme was threatened to be skipped from the research agenda when the SRA for nanotechnology had to merge with the micro-technology proposal to strengthen the economic potential of both, thereby increasing chances for funding. Drop-out of risk research was prevented by the political warrant of allocating at least 15% to risk analysis, as set in a parliamentary debate on nanotechnology (Parliamentary Papers 2009a). In addition, the Ministry of Agriculture demanded to include a Technology Assessment (TA) program as had been the case in NanoNed, but now serving the Ministry's wish to include research on consumer attitudes and acceptance. After a quick composition of the TA program, the RATA theme was back in the agenda again for granting the funding in 2010.

Just like the other themes in the research agenda, RATA has been organized as a collection of mainly PhD-research projects, structured and performed according to the academic and institutional setting in which each project is located. For RATA the projects have been organized in three programs, covering human health risks (assessment, detection, exposure, bio-availability and toxicity); environmental risks (methods and tools, fate, modelling, accumulation & ecotoxicity and integration) and the TA part (dynamics of nanotechnology developments and their societal embedding, society's response, governance and regulation, governance of responsible development and ethics). As in the other themes, these research topics reflect the specific expertise and interest of the participating knowledge institutes and university departments, as represented during the composition of the research agendas for RATA.

However, as illustrated by Figure 19, as a special theme, RATA has been positioned as a cross-cutting theme, designed to interact with all other research themes. Moreover, in moving from the SRA of 2008 to the submitted research proposal in 2010, the committee preparing the proposal renumbered the research themes and deliberately placed RATA as number one. This particular move has occurred against the backdrop of increasing political and public attention towards nanotechnology. A number of leading Dutch nanoscientists, among those the chairman of NanoNextNL, participated in national dialogue events. In this context the listing of RATA as the first theme was meant to demonstrate the commitment of NanoNextNL to address risks and societal impact.[129]

[129] According to Dave Blank (chairman of NanoNextNL) at MicroNanoConference 2010.

In addition, the Dutch government included compliance to the EU-CoC as a funding requirement. Both the EU-CoC and the public dialogue had strengthened the awareness that considering the many uncertainties with regard to safety and societal impact, the responsibility born by the entire nanoscience community would have to go beyond the inclusion of a RATA research theme. This was translated in the final grant decision letter (MinEZ 2011) as the requirement that every PhD thesis delivered by NanoNextNL should discuss potential risks.

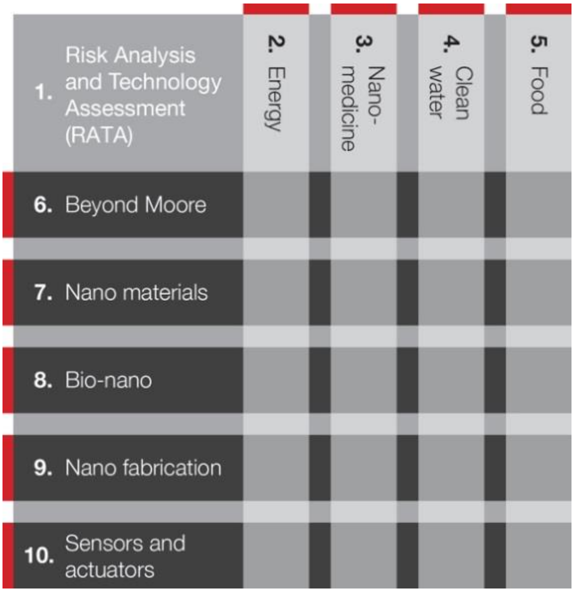

Figure 19: NanoNextNL research program

The actors involved

NanoNextNL is managed by an Executive Board, supported by a program office and a business director. The program office is located at Stichting Technologie en Wetenschap (STW), a former funding agency of the Ministry of Economic Affairs and now part of the national research council, the Nederlandse organisatie voor Wetenschappelijk Onderzoek (NWO). STW has experience in coordinating public-private partnerships in research and had run the program office for NanoNextNL's predecessor NanoNed as well. Supervision and feedback is organized by a supervisory board, with members of the main partners, and an international advisory council, consisting of nanoscientists from public research labs as well as industry representatives. The Dutch national institute for public health and the environment, the RIVM, has been charged with a supervision role for RATA by the government.

The business director and executive board members have a natural science or engineering background. They have played an important role in establishing the research agenda and represent a number of key organisations in the NanoNextNL consortium. All executive board members can be expected to be aware of discussions in media, parliament and public dialogue activities. Moreover, the chairman, as well as the executive board member responsible for RATA (a food scientist), have been actively participating in these discussions. Overall, the executive board publicly acknowledged the importance of RATA, including its potential to boost credibility, and framed the position of RATA as instrumental to the commercial potential of the research in NanoNextNL.

The management of RATA consists of the RATA program officer, the RATA theme coordinator, a toxicologist employed by an institute with a central role in the regulatory science policy interface in the Netherlands, and the RA and TA program directors coordinating the research on human health and environmental risks (Risk Analysis) and societal embedding of nanotechnology (Technology Assessment).
The composition, implementation and integration of RATA in NanoNextNL has been mainly a program-internal affair. Next to RATA, NanoNextNL publicly has committed itself to continue dialogue with stakeholder groups and citizens (in following up on the government funded societal dialogue activities). The program office has been following up on this commitment by participating in the European FP7 projects EST-Frame, NanoDiode and a new European project, Seeing Nano. In addition, STW, which hosts the program office, is involved in a couple of annual communication and outreach activities. The obligation to have each PhD thesis pay attention to potential risks is actually controlled by the executive agency of the Ministry of Economic Affairs, the Netherlands Enterprise Agency (RVO), as the main actor to which the management of NanoNextNL has to demonstrate the progress of NanoNextNL.

While the RATA theme was designed to produce knowledge products in its own right, the main ‘target group’ of the integration ambition are the research projects in the other NanoNextNL research themes. These projects are mainly organized as PhD research projects, supervised by a principal investigator (PI) from a university or other knowledge institute, acting as the project leader, and a co-PI from industry, SME or start-up. However, interviews with PhD researchers and PIs from the solar panel program (energy theme) and sensor program (sensors and actuators theme) show that in the second year of NanoNextNL there was still little to no awareness about the topics being covered in RATA, the requirement to comply with the EU-CoC or potential societal issues related to their research projects. When asked for, interviewees framed the idea of RI in terms of safety or considering consequences, however without a concrete idea how that could be organized in their own project (Bos, Walhout et al. 2014).

Multiple faces of RATA at the beginning of NanoNextNL

The discussion of the frame conditions shows that 'the' integration of 'RATA' could not be expected to be a straightforward task. Already at the beginning of NanoNextNL, RATA had developed different faces, evolving from a separate *research theme* to an *integrated activity*, partially pushed by public and political debate, and resulting in an additional *obligation* to pay attention to potential risks in every (PhD) project. However, how these different, but connected ambitions had to be realized, did not become part of the consortium agreements. During the design of the consortium contract almost all of the negotiations had been concerned with intellectual property rights, while the RATA obligation and EU-CoC compliance requirement were not translated into binding and mutually agreed procedures.

5.4 *de facto* integration of RATA in NanoNextNL

In 2011, when NanoNextNL kicked off, the program office (Gielgens 2011) stated that NanoNextNL would live up to the EU-CoC compliance requirement by having:

a) the RATA theme
b) educational and supporting activities for the researchers in the other themes, and
c) the required paragraph in each PhD thesis.

According to the program office, this would be a reasonable and legitimate approach, since all three elements would be implemented following a strategy that would fit the situation and needs of the individual researchers. The secretary leading the program office team framed the requirement to comply with the EU-CoC as:

> *"You don't want to prescribe things people already do (…) 95% of the researchers already comply with the code of conduct. (…) It is the same as with the law. One obeys the law, although one doesn't know what is in the law books."*

In this view, inspiration from and interaction with RATA would be more effective than telling people what they already do (Bos, Walhout et al. 2014). Consequently, the program office has been stimulating both lines of 'inspiration and interaction' through developing a two-day RATA course for the PhD researchers and by supporting networking activities of the RATA management at program meetings and other events of the other research themes in NanoNextNL. In this section we will discuss both lines of action as these developed until the midterm review of NanoNextNL by the end of 2013.

RATA course for PhD researchers

The RATA course is a two-day program with introductions to Risk Analysis and ways to anticipate the societal impact/embedding of new technologies (the TA part), as well as group discussions focusing on the identification of potential issues with regard to the research projects of the participants. The course was developed by the two instructors (a RA and a TA expert) during the first year of NanoNextNL (2011–2012). The main goal of the course has been to support PhD researchers with identifying a topic, which they can elaborate in the required part of their thesis or in a separate paper. However, while the course was being developed, this RATA obligation was renegotiated with RVO and lowered to the PhD students located in the programs deemed relevant for RATA, which concerned 56 out of about 180 PhD researchers. According to the RATA program officer, the reasons for this renegotiation were the little knowledge and awareness about RATA in NanoNextNL, which would have made a full coverage of the PhD population difficult to manage, since mandatory participation of the PhD researchers from the exempted research themes was assumed to require a different format.[130] However, invitations were send out to all PhD researchers. In the end, about 90 PhD researchers have attended the course, which has been organized in five shifts at a conference venue.

About half of the participants were following the course on invitation by the program office, the other half was 'pro-actively subscribed' by the program office. In approaching PhD researchers and their supervisors the program office repeatedly encountered reluctance or even resistance to participation. This attitude towards RATA was also regularly observed in the interviews by (Bos, Walhout et al. 2014), and reflects broader concerns about increasing demands to the scientific practice in general. In most cases it has been sufficient to remind the researchers and their supervisors that there was a formal RATA obligation.

To most of the participants the idea of RA made good sense, although for most of them it was far from easy to think about where to start with incorporating RA elements in the research project (if only the question whom to cooperate with). The significance of TA was less straightforward. The course instructors chose to position TA as starting from analyzing how a particular research project is situated in the innovation domain (who are the actors to which the research might be interesting). Over the subsequent editions of the course, the emphasis shifted towards thinking about business creation as a first start to explicate the relevance of thinking about societal embedding. This shift was also aimed at overcoming initial resistance of the participants in later editions, who, in contrast to the first editions, mainly participated because they had been subscribed by the program office.[131]

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[130] Information obtained by feedback of the RATA program officer to earlier versions of this chapter.

[131] As observed by author in participating in the first (July 2012) and fifth (July 2014) edition of the RATA course and confirmed by course instructor.

Participant evaluations, filled in at the end of each shift indicate that the course has been very helpful in providing participants with first ideas how to think about societal aspects of their research, since many of them had no idea before participating in the course. Moreover, initial reluctance and resistance among the participants often turned into enthusiasm during the program. The course, however, could only provide a first introduction, thereby giving little means for the participants to develop follow-up actions once back to their research projects.[132] The RATA program officer and the course leaders attempted to bridge that gap with offering RATA coaching. About ten PhD students have signed up for this and were linked to a researcher from the RATA theme.

In one research project, a Constructive TA (CTA) workshop was organized after attendance of the RATA course. In this workshop, various stakeholders brainstormed on the possible paths of follow-up research in the context of commercial, regulatory and societal developments. This initiative was supported by a RATA post-doc who had been in contact with the supervisor of the PhD before. The outcomes of the workshop have resulted in a full chapter of the PhD thesis (Stimberg 2014). This initiative has become an 'icon-project' to the RATA theme and created significant leverage for RATA in a strategy meeting of the NanoNextNL management at 13 March 2014, where follow-up actions in response to the mid-term evaluation were discussed (see below).

RATA collaboration

Facing the lack of awareness, reluctance and resistance among the 'target group', the RATA management has participated and presented at program meetings of other research themes and initiated a series of RATA FOOD dinners, to which theme coordinators and program directors were invited. These events served to inform and inspire the management of the other research themes on the relevance of RATA for their research, so as to build support for attending the RATA course and other RATA activities. These meetings as well as the participation in program meetings seem to pay off in terms of gaining awareness and first explorations of opportunities to collaborate (NanoNextNL 2013a). So far, this has resulted in a couple of follow-up meetings between NanoNextNL researchers and RATA experts. Collaborative activities have not been reported so far.

The RATA researchers have been working in relative distance to the program level activities, focusing on the progress in the individual research projects in the RATA theme. From the RATA research theme three of about thirty projects scheduled interactive events with NanoNextNL researchers from other themes. In the Human Health risks program a decision support tool for predicting the likelihood of hazardous effects of nanomaterials was developed. Little interaction took place in the design phase, but wishes and requirements for the use of the tool were inventoried through a questionnaire that was circulated via the NanoNextNL newsletter. In the TA program a

[132] As reported by a course instructor to the RATA program officer in preparing for the mid-term evaluation of NanoNextNL (email 10 March 2014).

workshop was organized, building on the use of Constructive TA methodologies in NanoNextNL's preceding program NanoNed. In this workshop, researchers, industry and other stakeholders from inside and outside NanoNextNL explored potential use and strategic issues of nano-enabled sensors in the food and water domain. While the issues discussed in this workshop might not immediately affect the (technical) research projects on sensor development in NanoNextNL, participant evaluation forms showed that the workshop had produced strategic insights for sensor development (Te Kulve 2013, Te Kulve and Konrad 2017).

Next to the mentioned project activities a number of program level activities have been organized. The RIVM facilitated two matchmaking workshops for RA (on measurement and on kinetics of nanomaterials). RATA also has been more explicitly profiled in the new community building concept for an annual Dutch conference on micro and nanotechnology (NanoCity), by a separate RATA parallel session and RATA masterclass. Finally, the RATA management was involved in a closed workshop with external actors on the concept of 'Safe by Design' in the context of the European FP7 project NanoReg. The workshop resulted in a strategy document (NanoNextNL 2012). While these activities have strengthened the profiling of RATA within NanoNextNL, they were not designed as explicitly contributing to the integration of RATA throughout NanoNextNL.

Reframing the RATA ambition upon mid-term evaluation

In December 2013 the International Advisory Council held a midterm evaluation based on a self-assessment report (NanoNextNL 2013a) and a meeting with the Executive Board. The self-assessment report discussed the RATA integration strategy of raising awareness and stimulating interaction and concluded that only first steps had been taken, if one considers that each NanoNextNL project is a potential RATA case. The International Advisory Council concluded that NanoNextNL was well underway and living up to its ambitions in scientific output, but falling behind on business creation. The latter was stated as the main goal for the second half in the NanoNextNL program. RATA was positioned as a unique and essential part of the program, but with little interaction so far and a need to re-orient RATA towards creating business opportunities. The latter was framed as ensuring that potential applications would pass safety regulations (NanoNextNL 2013b). In its response, the Executive Board took over the focus on business creation as the central theme and underlined the role of RATA therein (NanoNextNL 2013b).

The strong business focus for RATA, however, met opposition from the RATA project leaders, since the RATA projects had not been designed and budgeted in this way, and objected against a 'service orientation', which was deemed neither feasible nor desirable. In a brainstorm session facilitated by the RATA management following the mid-term evaluation, presentations on the CTA workshop on sensors for food and water and on the CTA workshop organized in the above mentioned PhD project were positively received by a number of theme coordinators and program directors and opened the way towards a more reflexive positioning of what RATA could offer. However, the language in which RATA was discussed remained focused on risks and public acceptance. In the follow-up, the TA program director developed the idea of a quick scan instrument and setting up a 'societal incubator'. In parallel, both the RATA management and an executive board member worked on an integrated assessment format in the context of an EU program. At the moment of writing this chapter, the executive board is awaiting the results of this project before taking further steps. In the meantime, part of the RATA budget has been allocated to facilitate follow-up coaching for the participants of the RATA course. The obligation to include a specific chapter, section or paragraph in the PhD theses is, however, no longer actively pursued.[133]

5.5 Learning from RATA, for the governance of RI

What can be learned from the integration of RATA in NanoNextNL? From an outside perspective results may seem mixed. While RATA as a *research program* even overachieved its performance indicators, requirements for fulfilling the RATA *obligation* have been reduced and efforts to *integrate* RATA throughout the program have resulted in a limited number of interactions. From an inside perspective the very attempts for integrating RATA have been visible though. The strong commitment to both business creation and RATA (no matter if at a somewhat superficial level), and the enforcement of formal obligations (even while negotiated), actually created a considerable awareness among NanoNextNL researchers of RATA as being an inseparable element in the way NanoNextNL is being branded as an innovation program. In addition, the networking 'diplomacy' of the RATA management has paid off in the form of changes of attitudes at (research) management level and of PhD researchers in the RATA courses.

For our aim of 'learning for governance' we are interested in how these outcomes have been conditioned. Investigating the integration of RATA in NanoNextNL as resulting from a dynamic interplay between actors, governance arrangements, spaces, problem framings and construction of responsibilities, enables us to see that the limited success of integrating RATA is only partially a result of political struggle and diffuse frame conditions. It is one thing to start with substantial budget and high ambitions, but quite another to transform a large research program according to new ideas. In our view, the distributed character of NanoNextNL as an organization is one reason why actual integration has been limited. We will first discuss this aspect and next elaborate on what the actors in NanoNextNL have or have not been learning.

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[133] Information obtained from discussions with the TA-director and other participants of the brainstorm session.

Integrating RATA as a distributed problem

Although NanoNextNL exhibits a corporate identity and governance structure (through the program office), it mainly functions as a multidisciplinary, collaborative interinstitutional expert network, organized in a familiar mode of research funding through public-private research consortia. Having an integrated RATA theme in such a program is a fairly new structure and requires dedicated integration work. The executive board was supportive of RATA, however without an articulated vision on how the integration of RATA would have to be accomplished. Most of the members of the executive board knew each other for a long time, while being located in different institutions. As key representatives of the Dutch nanotechnology community, the executive board was particularly concerned with living up to the promise of nanotechnology by demonstrating business potential. In line with that, RATA was largely perceived as a key feature in moving forward in this direction, as became apparent in the mid-term evaluation. However, actual integration work has been mainly left to the RATA management.

The RATA management, in turn, relied heavily on opportunities for networking and advocacy to raise awareness of the relevance of RATA among the other projects and for stimulating interaction. However, the members of the RATA management had to get to know each other first, as well as many of the executive board members, program officers, theme coordinators and program directors in NanoNextNL. This had consequences for the mobilization of the RATA research theme itself. The RATA theme consists of multiple disciplines. While annual meetings have contributed to the RATA identity, the RATA project leaders were not closely engaged in the quest for integrating RATA in NanoNextNL and the RATA research activities concentrated on local project dynamics and kept a disciplinary focus, even though interaction with other themes has been part of the Key Performance Indicator scheme and budget for such activities was available.

RATA as a learning process

To introduce something new as ‘doing RATA’ in a network type of organization like a research program involves different things to be learned by different actors. For RATA as an *integrated* activity, those in charge of the research projects and programs (including, for example, researchers and theme directors) have to learn which societal aspects and dimensions are at stake, for specific research projects as well as for the thematic research clusters more broadly. However, how such an integrated activity can be conducted in practice requires learning as well, in terms of training researchers and of building support from supervisors, program directors and theme coordinators, the program office and the executive board. Crucially, this kind of learning is also largely improvisational, due to the relative novelty, to changing interpretations and expectations, and because of the distributed (network) character of research consortia like NanoNextNL.

An important factor shaping the learning process is the way in which responsibilities with respect to RATA were understood in relation to how RATA has been framed as an activity. While Risk Analysis (RA) *expertise* actively has been offered in NanoNextNL meetings and in the PhD course, RA itself mainly has been presented as *research*, thereby emphasizing *knowledge* rather than the *interactions* needed to develop targeted knowledge, either for training or for specific assessment. For TA, executive board members as well as participants of the RATA course repeatedly kept framing TA as having to do with public *acceptance*, to be addressed by communication and dialogue, despite efforts to emphasize aspects of *anticipation* and *societal embedding* in a broader perspective.

As reflected in the executive board's conclusions on the Mid Term Review, but also observed for researchers from other themes, these framings of RA and TA support the expectation that RATA, as a research theme, will *sort out* societal issues and how these have to be addressed, instead of doing so by *finding out* together. Similarly, enrolling PhD researchers in the RATA course in order to facilitate the RATA obligation of paying attention to potential risks, although lowered in number, has been accepted, but ideas about involving their supervisors as well didn't take off. In effect, both the framing of what RATA is about and how RATA translated into responsibilities, may explain why in-depth exchange between RATA and the other research themes remained an occasional, rather than common process. As a result, there still is more to learn: about what constitutes the most relevant societal dimensions in the research projects, and how these could be addressed, as well as about how RATA as an integrated activity has to be organized as an interactive process.

An opportunity for learning which has been used only to some extent has been the interaction with stakeholders on societal aspects in general, or RATA specifically. Apart from the negotiations with the governmental agency RVO on the interpretation of the RATA obligation and the mid-term evaluation by the International Advisory Council, the ambition of integrating RATA mainly has been a program-internal affair. The CTA workshops showed that this type of learning is important for identifying societal dimensions and appreciated as such by the participants. For learning about how to organize RATA as an integrated activity, interacting with 'outside' actors might have benefitted the process as well. For example, through consultation and evaluation by external expertise on professional formation in research environments, or by opening up the design questions for integrating RATA to (critical) stakeholders.

Lessons for research governance

So far, our investigation of the integration of RATA in NanoNextNL has shown that transitions in the science system, towards demonstrating societal relevance and responsiveness to societal concerns, are taking foot at the level of large research programs. Still, the practical implementation is not a straightforward process, but rather an ongoing search, experimenting and learning process, which does not guarantee substantial transformation within the time frame of a research program. However, this only confirms the need to learn from cases like NanoNextNL as explorative steps into institutionalizing Responsible Innovation in research governance. From our discussion of the integration of RATA as a learning process and the governance conditions that have shaped the integration of RATA we suggest to draw three lessons:

Firstly, because integration, and even more so the mainstreaming of it at a program level, is a learning process, it should be designed as such. This implies that learning about societal dimensions and societal embedding is not only organized at the level of individual researchers, but also collectively, including the question how such learning should be facilitated. In addition, as shared understandings of goals and appropriate strategies are not a given, but have to be developed, change agents are important and should be carefully supported. In the case of NanoNextNL, the designated change agents were mainly the members of the RATA management. However, their abilities to 'make change' have been limited by a lack of opportunities for in-depth exchange, in particular with regard to the question how RATA as an integrated activity would have to be (collectively) organised.

Secondly, incentive and accountability structures are crucial. Since learning is channeled by obligations and commitments, processes of learning are affected and conditioned by evaluative structures. For example, the first moment of in-depth evaluation took place in the context of the mid-term review conducted by an international advisory committee. Even though there was resistance to the specific conclusions, it opened up a space for discussions and further interactions. Realizing a beneficial structuring is however far from straightforward: approaching RATA as a learning process requires reflexivity, vision and support, all the way up to executive boards and funding procedures. In this respect it is interesting to note that RATA as an *obligation*, however narrowed down, did positively contribute to the integration of RATA as an *ambition*. Although not sufficient, accountability thus is an important element in facilitating learning.

Thirdly, learning in terms of identifying and addressing societal dimensions in research activities involves trade-offs between developing generic capacities and dedicated collaborative efforts. Identifying for all research projects the societal and risk dimensions to be considered and how these can be addressed, quickly puts a strain on the resources and capacities available. Moreover, a well-known feature of societal dimensions in research and innovation is that these are partly potential or unknown. Therefore, identifying societal dimensions benefits from stimulating reflexive and anticipatory abilities. At the same time, for the very idea of integrating RATA as well as for pedagogical reasons, learning also has to be 'relevant' and tailor-made. This tension comes with two implications for learning how to organize 'integration' of 'parallel research' like RATA. First, it is hard to see how integrating, or mainstreaming, can do without a strong and self-aware core, in our case the RATA research theme. However, the RATA research theme has not been designed to serve interaction and RATA researchers have only to some degree been seeking opportunities for interaction as well, most likely enforced by the same incentive structures as those withholding researchers from the other programs, like being absorbed by their usual research work and disciplinary requirements. Second, even with such a core, learning about societal aspects benefits from interaction with outside actors. This, in turn, requires commitment as well as capacity from executive boards and program and project leaders, to facilitate and evaluate such learning processes.

5.6 Conclusions

The ambition of integrating RATA in NanoNextNL reflects transitions in the science system, towards demonstrating societal relevance and responsiveness to societal concerns. Together with the substantial budget allocated for RATA as a research theme, this makes the integration of RATA in NanoNextNL an interesting case for learning about explorative steps into the mainstreaming of activities like RATA and the institutionalization of RI in research governance. Our discussion has shown that the actual transition may develop rather slowly, because of the interdependence of learning at different levels, which does not guarantee substantial transformation within the time frame of a research program. However, this only confirms the need to learn: 'doing' RATA constitutes a learning process in itself, both with regard to what societal issues and themes have to be anticipated and to organising RATA as an integrated activity in a large research program. This kind of learning can be expected for other attempts to mainstream RI as well.

From our analysis of the integration of RATA in NanoNextNL we can conclude that living up to the ambitions of RI, requires governance strategies and accountability structures that facilitate learning by dedicated integration work. For collaborative research networks like NanoNextNL, these strategies have to account for the distributed character of learning and integration. For example, the integration of RATA in NanoNextNL could have been helped with more integration *within* RATA as a research theme by developing a shared identity and coordinated approach for liaising with other research themes. However, a more distributed match-making, as happened with coaching trajectory in following up on the RATA course for PhD researchers, seems to be a possible way as well, and may circumvent that first lots of effort is needed for internal adjustments, discussions, and settling of disagreement. Such choices, in turn, require reflexivity about context specific conditions and the tentative, up to experimental, governance of Responsible Innovation as a dynamic goal.

5.7 Addendum

Activities after the period discussed

After the Mid Term Review program wide activities for RATA have been scaling up, together with outreach, community building and valorisation activities in NanoNextNL in general. RATA activities have been presented and discussed at the second annual conference (NanoCity'15), in public outreach and in peer networks.[134] RATA questions have been incorporated in the valorisation program and a special grant has been provided for experimenting with the idea of a 'societal incubator' (Rerimassie et al. 2016). Following up on the RATA PhD course, six PhD researchers have engaged in a RATA-coaching trajectory and did include a special RATA chapter in their thesis (Allijn 2016, Gümüscü 2016, Mulder 2016, Schulze Greiving-Stimberg 2014, Sidhu 2016, Van Oene 2016).

Further inquiries into the content and impact of these activities do confirm the lessons and conclusions presented in the previous sections. As is reflected in the End Term Review report (NanoNextNL 2016), public outreach activities and follow-up plans for NanoNextNL,[135] the broad range of activities further strengthened RATA as a key element in the corporate identity of NanoNextNL. Also, uptake in participating organisations and peer networks has been demonstrated. For example, at the University of Twente the successful Constructive Technology Assessment (CTA) workshop (see section 5.4) has been followed up by a postdoc position on developing a 'CTA toolbox'[136], providing analytic tools based on those developed in the RATA programme, that are used as an obligatory element throughout various engineering bachelor and master programmes (including nanotechnology), and occasionally in research projects and workshops (Greiving and Konrad 2017, Ardo, Fernandez Rivas et al. 2018) or in collaboration with spin-off companies. For the RA themes, RIVM hosted a second NanoNextNL workshop on Safe-by-Design and Safe Innovation. These activities, as well as advocacy by Dutch government officials, have fed into other European research projects and OECD working groups (e.g. OECD 2020), up to the Safe and Sustainable by Design (SSbD) action line in the European Chemical Strategy for Sustainability (CSS).[137]

Overall, however, the RATA activities have been strengthening the related disciplinary fields rather than integration within NanoNextNL. An evaluation of the RATA PhD course showed that researchers in NanoNextNL did become aware of RATA activities, but often

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[134] Outreach has been linked to NanoCity'15 (RTL-Z television broadcasts) and interviews in public and professional media (e.g. tijdschrift Milieu). Outreach in peer networks particularly happened in the Dutch MicroNanoConferences and in regulatory Risk Assessment networks by RIVM (e.g. EU Nano Safety Cluster).

[135] NanoNextSteps, Nano4Society and workshop of the Nationale Wetenschapsagenda (NWA)

[136] See: www.cta-toolbox.nl

[137] See https://environment.ec.europa.eu/strategy/chemicals-strategy_en (last accessed 7 March 2023)

in a late stage and enrolment hardly supported by supervisors.[138] Moreover, for the majority of respondents, the analysis showed first order learning in terms of acknowledging that RATA is important to societal embedding of science and technology, but little second order learning in terms of when and how RATA would become relevant for their own research. Instead, the responses indicated that RATA still was expected to be done by others (Touw 2016). Likewise, the success of Safe-by-Design (SbD) or Safe-and-Sustainable-by-Design as a policy concept also reinforced risk assessment approaches that treat uncertainty as a scientific rather than a societal problem (see Chapter 4 on precaution).

Outcomes in terms of the research approach
As noted at the start of this chapter, the chapter structure deviates from the other case study chapters. Still, it covers the conditions, positions and dynamics as discerned in Chapter 3 (RATA as a governance arrangement in NanoNextNL, the actors involved and the practices in which RATA has been exercised). Apart from allocating extra budget for RATA activities (RATA coaching, the societal incubator experiment, RATA checklist in the valorisation program) these factors didn't change much in the final years of NanoNextNL. Similarly, the extent in which problem and solution frames were *constructive* with respect to the challenges at hand (contestation) and whether interactions have been *productive* with respect to the integration of RATA in NanoNextNL (responsibilisation) has been the same for the later activities.

Table 7 summarises the findings from this chapter in terms of the interrelated challenges for transforming responsibility as has been identified for the quest for Responsible Innovation 'at large' in Chapter 2. A key factor standing out is the framing of RATA 'sorting things out' for nanotechnology scientists and engineers instead of 'finding out together'. In various occasions this became visible in the reframing of (RA)TA into 'Technology Acceptance'.[139] The resilience of such a frame reflects the effort and strategies required for changing existing practices and institutions. RATA in NanoNextNL has been strongly shaped by its main organisation as a research theme. This has enabled successes such as the examples discussed for the University of Twente and the RIVM. Yet in both cases it have been these home institutions that carried not only their disciplinary output, but also the efforts for interdisciplinary collaboration – more than the organisation of NanoNextNL has been contributing. For these organisations NanoNextNL has been a platform for further developing their integrative activities rather than the other way around.

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[138] The End Term Review report of NanoNextNL lists 76 participants for the RATA PhD course (instead of 90 as stated in section 5.4), out of 200+ PhD researchers in the initial target group.
[139] e.g. in the program wide communications about enrolment in the valorisation program, but also in the societal incubator experiment (Rerimassie et al. 2016), which has been organised as a stakeholder workshop only loosely drawing on the initial CTA foundations proposed for it (see Van Lente 2015).

Governance challenge	
Novelty and emergence	- potential risks and broader societal implications - in relation to (projected) innovation pathways
Aligning promotion and control	- early stage consideration of risks and social dimensions
Translation into quest	
Anticipation-cum-inclusion	- integration of (otherwise) parallel research in research program
Responsibility structuring	- building mechanisms for integration as the programme evolved - RATA framed as instrumental to commercialisation aim
Challenges of transformation	
Key interdependencies	- waiting game of expectations in demonstrating relevance (showing what RATA can 'sort out' vs. 'finding out together') - change agents hampered by the same structures to be changed (e.g. disciplinary demands)
Conditions for learning	- distributed leadership with respect to the integration of RATA in NanoNextNL hampered conciliating diverging views on what RATA is about

Table 7: findings for integrating RATA in NanoNextNL

Lessons for research governance

The drawback of this configuration becomes clear from the lack of institutional learning displayed at the end of NanoNextNL's lifetime and the vulnerability of RATA in follow-up proposals. The End Term Review report (NanoNextNL 2016) presents the integration of RATA into NanoNextNL as a success with tools "*ready to use*" for scientists and engineers, ignoring internal evaluations[140] as well as the considerable efforts by RATA experts that went into it.[141] While this perhaps can be expected from a document like an End Term Report for NanoNextNL as a whole, a joint publication by the RATA management (van Wezel, van Lente et al. 2018) didn't substantiate efforts and evaluations as well. The evaluation of the RATA course, for example, showed that personal interest has been very important for the learning by PhD researchers and suggested to tailor integration strategies accordingly (Touw 2016). Without such reflections on RATA as a collective learning process, the framing of RATA as concerning scientific and societal issues to be 'solved' has been reinforced.[142] When both science

[140] Critical evaluations by Touw (2016), Walhout and Konrad 2015, and Bos (2016), as well as personal feedback from the RATA theme leaders and the teachers of the PhD course have been actively shared with the RATA leadership as well as the Executive Board of NanoNextNL long before the End Term Review has been completed.

[141] High quality outputs for the RATA thesis chapters all have been heavily drawing on input and supervision of RATA experts. Chapters produced without such support display a lack of second order learning as reported by Touw (2016) (e.g. Sidhu 2016 starting with a reference to Miller and Wickson 2015 and then continuing a line of argumentation that exactly is being criticized by Wickson et al.).

[142] As observed by RATA researchers participating in workshops for a new national research agenda (Nationale Wetenschap Agenda).

policy support and political attention to nanotechnology faded, this has put RATA again at risk in follow-up funding schemes.[143]

The overall course of action for the later activities thus reiterates the need for integration strategies that account for the efforts involved for transforming otherwise recursive practices. Discursively, the process of integrating RATA can be characterised as reflexive logics being 'encapsulated' by modernist logics (cf. Kunseler 2017). Institutionally, this played out in a distributed network, across different levels of coordination and as part-time duties for the whole leadership involved. In this context integration strategies thus have to facilitate institutional learning as much as individual learning.

[143] This was the case back in 2008/2009 when an annual funding of nanotechnology research in the Netherlands of € 100 mln during ten years had to be decided upon. The political warrant for allocating at least 15% to RATA appeared as contingently as it disappeared. During the funding negotiations RIVM had indicated that a maximum of € 15 mln. could be absorbed annually by the regulatory science community at that time. In the process that followed the 15% allocation to RATA was documented as minimally required. In 2009 the parliamentary committee discussing the governmental policy on nanotechnology demanded the 15% level to be set for all nanotechnology research (see Bos 2016). After parliamentary elections in 2010, however, no attention has been paid anymore to this resolution (see Chapter 4.3.3). Currently, the Nano4Society consortium that has been continuing the NanoNextNL network has submitted a proposal to the NWA research funding program which includes a Safe-by-Design research track. This again is to be attributed to the advocacy work of individual researchers from RIVM.

6. Agency and authority: nanosafety governance in the US

6.1 Introduction

In this chapter I will continue the brief history of nanotechnology and Responsible Development introduced in Chapter 1.2: the new federal interagency coordination in the US National Nanotechnology Initiative (NNI) and the focus on addressing uncertainty about the safety of nanomaterials in its goal of supporting Responsible Development. I will focus on two lines of action: *research* into potential health and environmental impacts of nanomaterials and *oversight* of nanomaterials (soon) entering the market (cf. Maynard 2006). These are two modes of knowledge development that have to inform each other for enabling the overarching goal: ensuring the safety of nanomaterial use and development. Research into effects has to inform innovators as well as regulators what to look for in assessing and managing risk. Oversight of development, production and use of nanomaterials has to inform regulatory research in what to focus on for informing protective measures.

Both lines of action followed a core policy belief. Concerted action, from an early stage and with substantive budgets, was expected to be key for reducing uncertainty about safety. The NNI organisational structure enabled such coordination, as well as significant budget. Just as well, it involved key challenges for organising responsibility. First, large scale cooperation between *basic research* agencies focused on science and engineering (e.g. the National Science Foundation (NSF)) and *mission oriented* agencies (e.g. the Department of Energy (DoE), or the Department of Defense (DoD)) has been unprecedented in US federal policy, let alone cooperation with *regulatory* agencies (e.g. the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC) and the Occupational Health and Safety Administration (OSHA)). Second, while coordinating a safety research agenda in this context required a shared commitment and responsibility of all agencies involved, oversight primarily has been regulated by legislations for regulatory agencies individually. The organisation of responsibility, therefore, involved inter- as well as intra-agency coordination, with various rationales for both research and oversight.[144]

[144] For example, oversight has to enable transparency and traceability in the first place (cf. Noorlander et al. 2013). Informing research agendas is a responsibility that extends beyond individual agencies.

Together, this provides the following starting point for analysis:

Governance challenge	
Novelty and emergence	- uncertainty about health and environmental safety of nanomaterials
Aligning promotion and control	- knowledge development (research agenda) to inform oversight (on use, indications of risk) and vice versa, in the context of the NNI
Translation into quest	
Anticipation-cum-inclusion	- interagency coordination of federal authorities (NNI research agenda) - involving stakeholders in operationalising nanomaterial oversight (EPA)

Table 8: challenges in US nanosafety governance

The aim of this chapter is to take a broad look at the way efforts in research and oversight have been playing out at federal level. This concerns an enormous area of activities and includes large organisations. For example, in the years studied the EPA alone already had about 15.000 employees and received an annual budget of 8 billion US dollar. Moreover, action at federal level is shaped by local, state and international level as well. It is at federal level, however, that efforts to align corporate and governmental responsibilities in protecting health and sustainability face the most systemic forces in US politics. The authority granted to the federal agencies to 'research and review' is hedged by heavy demands for scientific evidence in cost-benefit calculations, while the research needed to establish an appropriate knowledge base goes beyond the scope of each individual agency and requires coordination up to international level. Hence, organising the relation between research and regulation involves a significant challenge for democratic governance, including questions of acceptability, fairness and voluntariness.

For this thesis such a wide scope comes with a number of practical choices. In sketching the main dynamics and outcomes (section 6.2), I will limit to the four main regulatory agencies mentioned above.[145] In the analysis (section 6.3) I will further focus on the EPA because of its central role in chemical safety regulation (to which nanomaterials present a novel class) and because of its leading role in nanosafety research in the NNI. Figure 20 shows what activities will be covered: EHS research coordination in the NNI working group NEHI (Nanomaterial Environmental and Health Implications) and the efforts by the EPA to create oversight under the Toxic Substances Control Act (TSCA) and the voluntary NanoMaterials Stewardship Program (NMSP) for industry. It also shows the main political actors that have shaped the actions in both activities: the Office of

[145] More regulatory agencies have been involved in the NNI, but with smaller roles (see http://www.nano.gov/partners for an overview of agencies participating in the NNI). Also, the medical domain (under purview of the FDA) is not discussed here.

Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP), both of the White House Executive Office of the Presidency, and relevant committees in the U.S. Senate and U.S. House of Representatives. Finally, for evaluation (section 6.3.3) and lessons (section 6.4) I will be drawing on a selection of secondary sources. The timeframe investigated stretches until 2016, but the validity of findings has been checked by later sources (see Chapter 3).

Figure 20: main actors and initiatives discussed in this chapter

6.2 Outcomes and achievements

6.2.1 Nanosafety research in the NNI

The need for addressing uncertainties about the safety of (engineered) nanomaterials has been recognised early on in the formation of the NNI. Although not upfront, it was mentioned in the report by the Interagency Working Group Nanotechnology (NSTC 2000) that proposed the establishment of the NNI. Further down the process of Presidential and Congressional approval the passages about societal implications were left out. However, IWGN chair Mihail Roco contacted regulatory agencies and initiated a workshop on societal implications (Roco and Bainbridge 2003) in parallel. The involvement of EPA officials, in turn, led to the organisation of two other workshops, which formed the start of both an agenda and network for nanosafety research in the NNI (Karn and Schottel 2016).[146]

Interagency coordination

While the NNI consortium was further developing its program, political discussion about nanotechnology established further support for nanosafety research. NNI researchers (e.g. Colvin 2003a,b) as well as environmental organisations (e.g. ETC Group 2003) testified in congressional hearings preparing for the 21st Century Nanotechnology Research and Development Act (US-Congress 2003), hereafter referred to as US NRD), which had to approve the NNI budget and program. In 2003, a special Nanotechnology Environmental and Health Implications (NEHI) working group[147] was established, which had to coordinate the Environmental, Health and Safety (EHS) research in the NNI.

Actual coordination, however, has been strongly criticized and found actually lacking since the NNI had no legal authority of its own. NEHI produced EHS strategy documents as part of the triannual NNI strategies. The first NNI strategic plan (NNI 2004) only listed the EHS research already funded at that time. Two years later, NEHI published an overview of research needs for the various regulatory agencies (NNI 2006). The subsequent EHS research strategy (NNI 2008), however, failed on providing an actual strategy and a proper base for budget allocation (cf. Maynard 2007, GAO 2008, NRC 2009, Karn and Schottel 2016). Meanwhile, budgets for EHS research increased, with large shares for the National Institute for Occupational Safety and Health (NIOSH, developing guidance for handling nanomaterials at the work floor), the National Institute of Standards and Technology (NIST, instrumentation and metrology) and the EPA (a.o. setting up two research centers on environmental implications together with the NSF).

Safety and sustainability

In 2011, the EHS research strategy document (NNI 2011a) started anew and introduced 'sustainability' alongside research on risks. According to Barbara Karn, one of the EPA-officials that have been involved from the start, this strategy finally linked nano-EHS research to nanotechnology R&D, amongst others by including Life Cycle Analysis (LCA) and sustainable design methodologies (Karn and Schottel 2016). Later, this strand of EHS research created its own platform in the NNI affiliated network Sustainable Nanotechnology Organisation (SNO).[148] SNO has established a scientific community, but structures for actual integration and evaluation towards either R&D or regulatory

[146] EPA's '*Nanotechnology and the Environment'* STAR progress review workshop in August 2002 and NNCO sponsored workshop in September 2003 (Karn and Schottel 2016)

[147] http://www.nano.gov/nehi

[148] http://www.susnano.org/index.html

practices had not been developed (<Canady, Davies, Karn, Shatkin>) and are not likely to happen. For the regular EHS research, the 2012 review of the EHS research strategy (NRC 2012) stressed that NEHI itself is still lacking budget and authority for appropriate coordination. Later strategy and review documents (NASEM 2016, NNI 2016) do not specify if and how this critique has been addressed.[149]

Integration

In sum, EHS research on nanomaterials largely has been accommodated, but not yet integrated: harmonisation within EHS-research is starting to develop, but still “lacked context” (NRC 2013)[150], while EHS material characterisation work in the NNI is not accessible to developers (NASEM 2016). These gaps are not unique to the US situation. When nanosafety had been put at policy agendas around the world, about 2005 to 2007, there was a widely shared expectation that it would take a decade before research into health and environmental impacts as well as the validation of methodologies and testing requirements would be developed and taken up in regulatory frameworks (RS-RAE 2004; Taylor 2006; Greenwood 2007). The expected period has been prolonged with another decade (Krug 2014, EEA 2013; Westra 2015) and currently are still under discussion. Therefore, the question for analysis and evaluation in this chapter is how the outcomes so far, have been linked to the way in which responsibility has been organised.

6.2.2 Nanosafety guidance and oversight

The second line of action concerns the way in which federal regulatory agencies have tried to establish mechanisms of oversight for monitoring ongoing developments in human and environmental exposure to nanomaterials. In 2005, ‘nanoproducts’ were reported to be already on the market. In media coverage as well as political discussion about nanotechnology this often has been framed as demonstrating the success of nanotechnology and underlining its promises, even though many of these products have little or nothing to do with ‘nanoscale research and engineering (NSE) funded in the NNI. However, along the same line, discussions about nanosafety increasingly focused on whether and what regulatory action would be needed. The regulatory agencies took different paths, depending on their statutory authority as defined by the regulatory

[149] The triannual review process also had moved from National Research Council committees that included toxicologists to a material scientist committee of the National Academies of Science, Engineering and Medicine.

[150] The statement is from 2013, but still holds. The EPA-NSF center CEINT, for example, has to develop into a key platform for integration and coordination, according the 2016 NNI strategic plan (NNI 2016). However, CEINT is seeking integration through collaboration with initiatives like the US-EU Communities of Research (CoRs, https://us-eu.org/) and nanoHUB (https://nanohub.org/), which are the same consensus oriented networks lacking leadership, authority and adequate inroads to industry as subsequent reviews of the NNI EHS research (NRC 2009, 2012) strategy have pointed out.

frames they have to enforce, as well as their institutional status in the US federal government.

Environmental Protection Agency (EPA)

The EPA is most well-known for administering the Toxic Substances Control Act (TSCA), which deals with chemical safety. EPA's research department ORD (Office of Research and Development) had been one of the first agencies involved in the NNI. EPA's Office of Pollution Prevention and Toxics (OPPT) published a first regulatory strategy already in 2005 (Federal Register 2005). Under TSCA, EPA first initiated a voluntary reporting scheme, the Nanoscale Materials Stewardship Program (NMSP). Later EPA started to issue mandatory Pre-Manufacture Notices (PMNs) by considering nanomaterials as 'new chemicals'. The PNMs, in turn, enabled EPA to impose additional safety measures, such as Significant New Use Rules (SNURs) issued for fullerenes and carbon nanotubes.[151] The voluntary program, which was open for submission in 2008, yielded 29 companies registering 123 nanomaterials (Bergeson 2007). In 2015 EPA had received about 160 PMNs. Other regulatory action by EPA has been taken under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act), in particular with respect to nanosilver as an antibacterial agent in, for example, food containers. In 2011, EPA granted conditional approval for two nanosilver products[152], requiring testing and monitoring over a number of years, so as to gain scientific evidence about health and environmental impacts.

Whether EPA created effective oversight with above measures is heavily doubted. While TSCA formally may provide robust statutory authority for addressing nanosafety (Bergeson and Plamondon 2007), various reports pointed out that a lack of resources and organisational deficiencies make this power difficult to use, for chemicals in general (GAO 2005) and for nanomaterials in particular (Davies 2007, Landy 2010, EPA 2011). Moreover, the PNMs do not cover all nanomaterials (<Morris>), are still based on chemical risk assessment (EPA 2011) and the 90 day response time is not allowing for proper screening (Eisner 2010). Problems with information gathering and the prevalence of 'least burdensome' action under TSCA have been widely acknowledged for long, but only addressed in the 2016 revision of TSCA[153], much of which still has to be effectuated.

While this situation is not uncommon to regulators across the globe, EPA in particular has lost the momentum of wide and constructive stakeholder engagement, which was present in 2005. The EPA had been relatively early in outlining its strategy, seeking

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[151] Two features have to be noted though: 1) fullerenes and carbon nanotubes perhaps have been the most researched nanomaterials; 2) EPA has issued multiple SNURs for various types of these materials, but also had to withdraw a number of them after litigation, see http://www.lawbc.com/news/nanotechnology.

[152] HeiQ20 and NanoSilva

[153] The Frank Lautenberg Act (FRL), signed into law in 2016. See Schmidt (2016) and Bergeson et al. (2017) for discussion.

stakeholder involvement and proposing a voluntary reporting scheme. However, the pace in which EPA has been following up on this, has been disappointing to environmental organisations (Bergeson 2007). In addition, the EPA had difficulties with regulating antibacterial nanomaterials under FIFRA, such as nanosilver, touching on the increasingly controversial topic of antimicrobial resistance (Bergeson and Backstrom 2013). Meanwhile, industry associations and environmental organisations retreated to earlier positions, including several lawsuits challenging the approval of specific nano-products.

Food and Drug Administration (FDA)[154]

The FDA responded to the discussions about nanosafety in 2006. It established an agency wide task force[155] which advises on addressing knowledge and policy gaps to date. The task force developed a position paper (FDA 2007), which articulated the position the FDA has taken over the years. One element in the FDA's position is that, although no adverse effects related to nanosized materials in consumer products (including food) have been reported, nanomaterials cannot be considered proven to be safe either. The other element is that the FDA regulates products, not technologies[156] and therefore takes a case-by-case approach in assessing the safety of nanoproducts. In 2011, the FDA has specified whether an FDA regulated product is considered as a nanoproduct (FDA 2011). Guidance for manufacturers on food ingredients, food contact materials, cosmetics and food for animals has been published in 2014 and 2015. A database of nanoproducts, announced in the position paper, has not been developed.

Stakeholder organisations and commentators' opinions about FDA's approach and activities have been ranging from 'measured' (Bergeson and Cole 2008, <Maynard>) to 'slow' (<Hanson>). Not making any categorical statements about nanotechnology and pursuing a case-by-case approach has been generally accepted as legitimate, but how to follow-up on this position, has been dividing opinions from the start.[157] Analyses from the Woodrow Wilson Institute (Taylor 2006, Schultz and Barclay 2009) pointed to the little research capacity of the FDA and an increasing lack of resources to keep oversight in areas like dietary supplements and cosmetics[158] – precisely those consumer products

[154] The most important act authorising the FDA's activities is the Food, Drugs and Cosmetics (FDC) Act. This chapter does not look into activities in the medical domain (drugs, devices).

[155] http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm2006658.htm

[156] Cf. FDA's policy position on nanotechnology https://www.fda.gov/scienceresearch/specialtopics/nanotechnology/ucm301114.htm (accessed August 2016)

[157] See, for example, the testimonies of the public meeting in which the FDA position paper has been discussed: http://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=N%2BFR%2BPR%2BO&D=FDA-2006-N-0100

[158] A result of the way Congress had enacted the Dietary Supplement Health and Education Act of 1994.

which have casted doubt about the safe application of nanomaterials. In the end, the FDA finalised the long awaited guidance documents, but didn't develop further oversight mechanisms.

Consumer Products Safety Commission (CPSC)

The CPSC, which is responsible for the safety of consumer products, became active in 2011. In the years before, the (relatively small) research budget had been increased slightly, so as to include nanotechnology, but with no one tasked (Rejeski 2009). Resource problems and weak support in Congress have prevented the CPSC to promulgate safety standards for new products (i.e. related to emerging technologies) since 1970 and have caused a growing gap in keeping pace with the growing number of consumer products. Furthermore a rapid decrease in staffing resulted in a poor capacity for oversight of nanoproducts (Marla Felcher 2008). From 2011 onwards, the CPSC has been investing two million dollars annually on nanotechnology for research on testing methods (CPSC 2016). CPSC wanted to expand these research activities in a new NNI center,[159] but this didn't take off. Research has been focusing on standard development, together with ISO, and screening methodologies. Specific efforts towards oversight of nanoproducts are not mentioned.

Occupational Safety and Health Administration (OSHA) / National Institute for Occupational Safety and Health (NIOSH)

In the occupational domain OSHA is the regulatory agency in charge. For long, OSHA has been referring to external sources, such as the Good Nano Guide or the Nano Risk Framework[160] for providing guidance for protecting workers, before releasing a factsheet itself (OSHA 2013). The factsheet largely build on the work by NIOSH, a research agency in the NNI, which has been focusing on standard setting and guidance for occupational exposure (Bergeson 2013, <Maynard, Davies, Pendergrass>). Apart from avoiding formal regulatory action by OSHA[161], standard setting and guidance is of direct relevance to NNI researchers and endorsed by industry representatives. NIOSH (2016) also published a guide for Small and Medium-sized companies. A preliminary

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[159] Center for Consumer Product Applications and Safety Implications of Nanotechnology (CPASION), see CPSC 2015.

[160] See https://www.osha.gov/dsg/nanotechnology/ (last accessed 8 March 2023). The Good Nano Guide has been developed by ICON (International Council of Nanotechnology), an initiative of the first NNI center on nanotechnology and the environment CBEN at Rice University. The Nano Risk Framework has been developed in a cooperation of the chemical industry company DuPont and the NGO Environmental Defense Fund (EDF). Both initiatives have been explicitly positioned as instances of Responsible Development; see Chapter 2.

[161] NIOSH develops Recommended Exposure Levels (RELs), OSHA sets Permissible Exposure Levels (PELs). The latter require more scientific evidence and cost-benefit analysis. Bergeson (2013) praises the OSHA factsheet as "*augment[ing] the many excellent publications prepared by NIOSH*"

evaluation of the NIOSH Nanotechnology Research Center (NTRC) indicates that NIOSH outputs are used in the field (Landree, Miyake et al. 2015).

Guidance and oversight: addressing uncertainties?

The US regulatory agencies have taken different paths in establishing oversight and providing guidance to producers of nanomaterials and products. Basically, all activities have been relying on what is known about (potential) risks of nanomaterials. This is the normal mode of regulatory action, but it doesn't resolve questions about what is not known. For occupational exposure this doesn't have to be a problem: the knowledge base is relatively well developed and exposure can be controlled. This allows for enabling protection by providing guidance on risk mitigation regardless of remaining uncertainties. In the NNI, for example, many partnering organisations have published guidance documents for nanotechnology laboratory safety[162] and the coordination office NNCO has started a series of webinars, aiming at "*Applying a Lab Safety Culture to Nanotechnology*".[163]

For other domains, the uncertainties are more problematic. The EPA started out proactively, but approached nanomaterials as new chemicals, which limits the questions asked and the scope of materials reviewed. The FDA developed guidance for food and cosmetics, but as long as testing the presence and effects of nanomaterials remains difficult, a case-by-case approach provides weak protection if not substantively resourced. The CPSC joined in lately, but is mainly focusing on research into measuring nano-consumer products exposure, while the number of reported nanoproducts has been growing.[164] Without information gathering geared towards reducing uncertainties about handling nanomaterials as a particular class of materials, nanosafety measures will not go beyond a case-by-case approach (which validity is challenged), unless EHS research efforts can make the difference (which still is a long term challenge, see previous sub-section). This diagnosis has been widely shared by actors involved in the NNI and influential commentators. In the analysis, therefore, I will pay particular attention how this problem has been handled.

6.3 Analysis

For a better understanding of the processes in research coordination as well as in regulatory oversight, I will first discuss both lines of action separately again, in terms of the research approach: NEHI as the central governance arrangement for EHS research coordination in the NNI, with the key actors involved and *de facto* practices of research

[162] See http://www.nano.gov/LabSafety (last accessed 17 February 2022)

[163] See http://www.nano.gov/node/1601 (last accessed 17 February 2022)

[164] Primarily those listed in the Nanotechnology Consumer Product Inventory (CPI) maintained by the Woodrow Wilson Institute, see section 6.3.1

coordination; and EPA's oversight actions as exemplar for the challenge of creating oversight more broadly, also playing out in a particular actor landscape and *de facto* practices. The discussion of these aspects also follows the activities in chronological order, by investigating institutional histories for the governance arrangements (where did they came from), followed by discussing how actors gave shape to actual processes and particular factors therein. In section 6.3.3 I will then bring problem and solution frames crosscutting both research coordination and regulatory oversight together and discuss how these have shaped the relation between both lines of action and vice versa in seeking to reduce the uncertainties about nanosafety.

6.3.1 EHS research coordination in NNI-NEHI

Governance arrangement: NEHI's starting conditions

Starting a working group is a regular response when a particular issue requires coordination of activities. It allows for joint fact finding, problem construction and agenda setting in a relatively open process (as long as strict rules and tasks are not being defined), carried by expectations of actors in and around the working group. For the start of NEHI three relevant drivers can be discerned in this respect: the NNI model for interagency coordination, the positions of participating agencies and the wider context of international agenda setting (Figure 21).

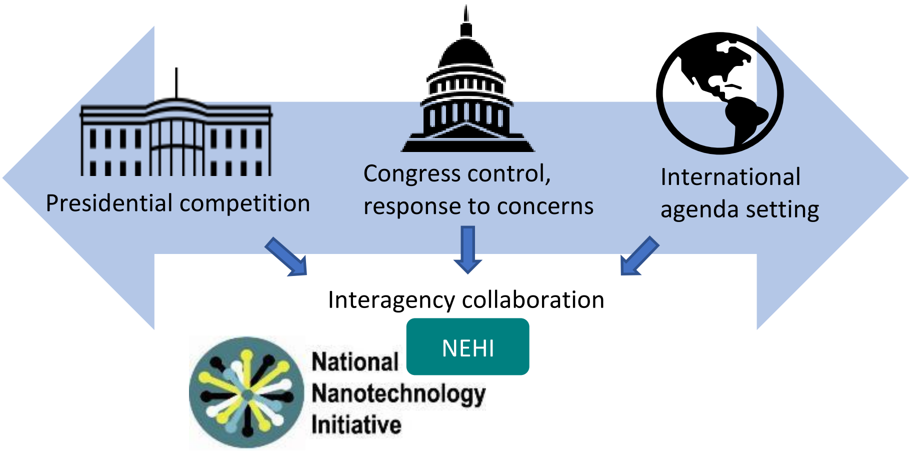

Figure 21: NEHI's starting conditions

NNI organisation

Interagency coordination in the NNI emerged from multiple drivers. To start with, there was the competition for the Clinton presidential science initiative (see Chapter 1.2). In that context NSF had to join forces with other agencies for backing the claimed benefits of nanotechnology (Karn and Schottel 2016). The multi-agency model that was proposed for the NNI also fitted a wider trend in US federal science and innovation policies, in which no longer primarily basic science is funded, but utility and long term efforts are prioritised as well (Mowery 2011, Eisler 2012).[165] Third, in the context of public debate about the promises and concerns of nanotechnology and the critique about parallel disciplinary research (see Chapter 1.2) Congress further forged interdisciplinary research by the NRD Act.[166] However, the NRD Act first of all was an attempt by Congress to take back control over the coordination of the NNI (Honda 2004, Fisher and Majahan 2006) from the Executive Offices of the White House. This resulted in the National Nanotechnology Coordination Office (NNCO), under which NEHI started soon after.[167]

Agency positioning and international agenda setting

NEHI itself also has been established in a variegated context. Initially, the brief mentioning of nanosafety as an issue of concern in the initial NNI proposal had been removed on instigation of the Presidential Council of Advisors on Science and Technology (PCAST), which was advising the Office of Science and Technology Policy (OSTP) about the presidential competition. However, the coordinator of the proposal, Mihail Roco, had already contacted EPA's National Center for Environmental Research (NCER) for contributing to the NNI research agenda. NCER was headed by Barbara Karn, who saw an opportunity in funding nanotechnology research for environmental remediation as a strategic line for EPA's Office of Research and Development (ORD) (Karn and Schottel 2016). Both were aware of questions about nanosafety and a first workshop was organised by NSF and EPA for exploring nanosafety research topics[168]. However, most participants (toxicologists and NIH researchers) still had to be convinced about the significance of 'nanosafety'. In the scientific community this didn't change much until 2005, when the American Chemical Society (ACS) took over the organisation of annual nanosafety workshops (<Schottel>).

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[165] For long US science policy has been marked by the so-called 'Bush doctrine' of investing in 'pure science' (after Vannevar Bush (1945, 'Science the endless frontier'), who was instrumental in creating the NSF. Eijmberts (2013) states: "*The NNI argument of long term effort is as much about economic competitiveness and security as it is about technological innovation.*"

[166] In the NNI interdisciplinary research has been organised in Nanoscale Science and Engineering Centers (NSECs) funded by the NSF.

[167] Before the NNCO, the NNI was coordinated directly by the Nanoscale Science, Engineering & Technology (NSET) subcommittee of the National Science & Technology Council (NSTC), which is part of the presidential Office for Science and Technology Policy (OSTP). The NNCO is more directly linked to the Office of Management and Budget (OMB), which is also part of the Executive Office of the President (EOP), but for which budgets have to be authorised by Congress. Because of the ongoing struggle for control on science initiatives by Executive and Legislative, the NRD Act was signed into law in 2003, but never has been appropriated. Instead, the NNI has been reauthorized by the 2007 COMPETES Act, while revisions of the NRD Act have been repeatedly postponed until the new Nanotechnology Advancements and New Opportunities (NANO) Act (US-Congress 2011).

[168] See announcement and proceedings (last accessed 8 March 2023)

At the same time, wider concerns about nanotechnology as a powerful and disruptive technology led to political concerns about public controversy and economic losses.[169] By 2005 concerns about molecular robots and machine intelligence going out of control had been dismissed widely, at least in scientific communities. Emerging concerns about the safety of nanomaterials were downplayed as well, but the image of endless opportunities turning nanotechnology into a domain of great strategic and economic relevance had been reinforced. But after a number of critical reports and testimonies of NGOs as well as NNI-researchers, the mood changed, particularly when reinsurance company Swiss-Re published a report (Swiss-Re 2004), which underlined the economic relevance of addressing concerns about safety (Rip and Van Ameron 2009).[170] Meanwhile Roco had adopted the notion of Responsible Development in his advocacy for nanotechnology[171] and continued engaging regulatory agencies in participating in the NNI. NIOSH, for example, joined in 2003, though primarily on the basis of research portfolio interests (<Maynard>).

In this context a specific event led to establishing NEHI. In a visit to a NNI laboratory NNCO director Clayton Teague witnessed a student working with carbon nanotubes (CNTs) without protective gear. He took this occasion for inviting all relevant federal regulatory agencies (Karn and Schottel 2016). None of the agency representatives in the meeting was well informed at that time (<Maynard>), yet they agreed to draft a joint NNI EHS research strategy. In a follow-up workshop organised by EPA-NCER and sponsored by NNCO a first research agenda was composed, based on the research that EPA, NIOSH and NIST had started already[172].

In the years that followed EHS research received much more support. The one-time study on Responsible Development (NRC 2006) that had been stipulated by the NRD Act almost fully focused on nanosafety. In 2006 the EHS research strategy (NNI 2006) catalogued regulatory needs[173] and became part of the triennial NNI strategy. In 2007 it was supplemented with a prioritisation document (NNI 2007a). In these years EHS research budgets steadily increased and NEHI started to meet monthly. However, while

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[169] According to <Karn, Schottel> OSTP/PCAST became especially alarmed by the publication of science fiction novel Prey (Chrighton 2002). The concerns about nanobots and superintelligence were also expressed in the NRD Act of 2003.

[170] Rip and Van Ameron (2009) note that Munich-Re had already voiced concerns in 2002. In 2003 the Canadian action group ETC Group (2003) weighed in, but also Vicky Colvin of the NNI center CBEN and toxicologist Günter Oberdörster on one US nanotechnology's icon material, the carbon 'buckyball' (C60 fullerene, see Kelty 2009, McCarthy & Kelty 2010).

[171] For example, in starting the International Dialogue series on Responsible Development in 2004 (see Chapter 2).

[172] See https://archive.epa.gov/ncer/publications/web/html/summary.html (last accessed 8 March 2023)

[173] By and large the agenda has remained the same over the years: (a) instrumentation and analytical methods; (b) effects on biological systems and human health; (c) effects on the environment; (d) exposure of nanomaterials; (e) risk assessment and management methods.

NEHI has been emerging from individual leadership, diverging agency interests as well as a quickly developing context of international agenda setting, its structure and activities were still open to those forces. For example, despite its potential economic relevance EHS research was not a priority to the Executive offices OSTP and OMB. NEHI itself only had budget for convening the working group meetings and had to rely on participating agencies for organising conferences etc. for in-depth exchange (<Canady>). Working from a general strategy towards actual coordination then proved difficult in the end, as I will show below.

Actor landscape: a view from Capitol Hill
Walking back the contexts of 1) public and political debate, 2) agency participation in the NNI and NEHI, and 3) decision making on budgets and activities, it becomes clear that both critical and constructive positions of actors towards the EHS research efforts in the NNI still allowed for political logics hampering actual coordination.

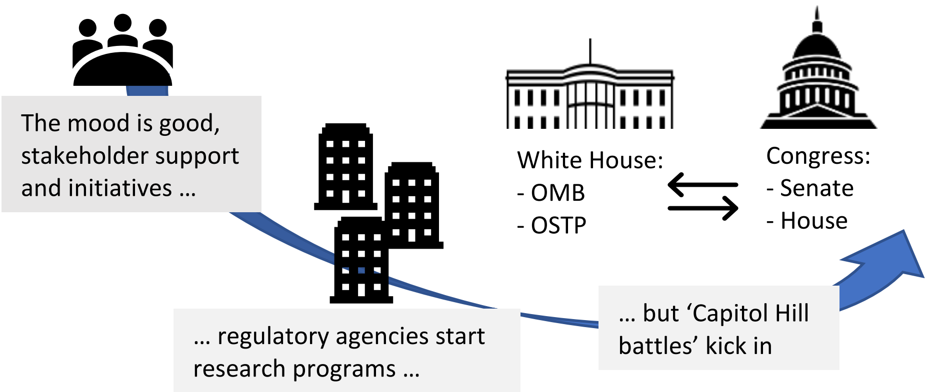

Figure 22: actor positioning for NNI-NEHI

Stakeholder groups
Critical positions particularly have been taken by NGOs, though in different ways. Action groups like ETC Group, Friends of the Earth or Greenpeace called for a moratorium on nanotechnology.[174] This clearly set a sense of urgency. Other NGOs, particularly Environmental Defense Fund (EDF), the International Center for Technology Assessment (CTA)[175] and National Resources Defense Council (NRDC) took critical positions as well, but also sought to support the mood of Responsible Development at that time: together and with substantive budget it would be possible to "*getting it right*" (cf. Balbus et al. 2005, Krupp and Holliday 2005). The activities of these organisations have been heavily

[174] See ETC Group (2003, 2007), Greenpeace (Johnston et al. 2007), FoE (2006)
[175] Most of the CTA staff also works for the related Center for Food Safety (CFS). See: http://www.icta.org/ and http://www.centerforfoodsafety.org/

drawing on the efforts of individual staffers, like Richard Denison from EDF and Jaydee Hansson from CTA, who participated in stakeholder fora, public hearings and partnerships with industry and academia (<Davies, Morris>, Morris 2012).

In 2005, EDF published a joint statement with the chemical industry association American Chemistry Council (ACC) (EDF-ACC 2005) and accepted an offer of the Woodrow Wilson Institute to co-develop a risk management framework with chemical company DuPont (see Chapter 2). In the NNI, the international stakeholder platform ICON was founded by research center CBEN and developed the Good Nano Guide for safe workplaces.[176] In the public and political domain the Woodrow Wilson Institute became a vocal actor by starting the Project on Emerging Nanotechnologies (PEN). PEN published analyses of the regulatory agencies' efforts and actual expenditure on nanosafety. It also launched a Consumer Products Inventory (CPI), which became the most cited source for nanoproducts already at the market.[177] Together with ICON and the DuPont-EDF risk framework this clearly set a baseline of critical, but constructive action in the discourse on nanosafety and Responsible Development. Moreover, it provided for participation in public hearings and consultations by Congress or by regulatory agencies, in which multinationals and industry associations, like the American Chemistry Council (ACC) or the NanoBusiness Alliance, were active as well.[178]

Regulatory agencies

The significance of stakeholder positioning becomes clear when taking a closer look at the participation of the regulatory agencies in the NNI. This participation has been mainly research driven. The Office of Research and Development (ORD) of EPA could start participating through EPA's external grant programs Exploratory futures and STAR. NIOSH operated already as a research organisation, offices of the Department of Agriculture (USDA) participated in developing applications of nanotechnology and NIST has been consuming large shares of the EHS research budget for working on standardisation and metrology. The FDA and CPSC had little research budgets, but their representatives took leading roles in NEHI. The FDA also established an agency wide advisory group. In this setting the collaboration of Roco from NSF and Karn from EPA gave shape to further institutionalisation of the EHS research program. This resulted in

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176 See Chapter 2 as well. Bergeson (2009) and Kica and Wessel (2015) note that ICON's extensive community would be pivotal for implementing, reviewing and updating the Good Nano Guide. However, ICON ceased when the NNI grant to its hosting institute CBEN ended.

177 See http://www.nanotechproject.org/ PEN was funded by the charity organisation PEW (see Chapter 2). The CPI is based on claims by producers, which often cannot be verified or appear meaningless (e.g. nanostructured electronics), see Berube et al. (2010) for a critical review. Despite the criticisms the CPI received, it still is one of the few information sources about nanoproducts at the market.

178 As for PEN: Davies 2006, Maynard 2007, Rejeski 2009. As for EDF: Denison 2007, 2009.

three interdisciplinary research centers (NSECs): CBEN (2001 – 2010), CEIN and CEINT (as of 2008)[179] and a number of workshops on EHS research in the NNI.

The leading role of NSF and EPA came with various effects. In the early years, CBEN coordinator Vicky Colvin played an important agenda setting role in Congress[180], as well as by founding ICON. Later on, CEINT would have to work on integrating EHS research, but focused at the international EHS research community in relative disconnect to the NEHI EHS research agenda (Maynard 2007). Within the EPA integration started with producing a white paper (EPA 2007) and interactions between ORD and the regulatory branches of EPA, in particular the Office for Pollution Prevention and Toxics (OPPT), for setting up an internal research program on nanosafety (2007 – 2011).

Many officials in the NNI and Executive offices, however, were concerned that the activities of EPA and NSF would overemphasise risks. This could affect commercialisation prospects and probably cause industry to pull out (which happened in 2011 indeed, as I will discuss below). Barbara Karn sought to ease these concerns by introducing the framing of 'applications and implications' as an alternative to the 'benefits vs. risks' frame that structures many US federal science and technology policy discussions (Karn and Schottel 2016). The same framing, however, also allowed for tweaking the EHS research budget figures across these categories, which happened upon changes in the political landscape.

White House and Congress

Since nanosafety has been an important topic in the authorisation, coordination and evaluation of the NNI, NEHI's mode of operation has also been subject to the regular 'Capitol Hill battles': the sitting presidency's policies and priorities vis-à-vis Congress. The NNI falls under the responsibility of the OSTP, but in close connection to OMB, which has to perform cost-benefit calculations for all actions by the federal agencies. These assessments are considered as highly demanding, up to being shaped by a strong anti-regulatory climate (<Davies, Maynard, Shatkin>). Congress, in turn, has to authorise budgets, for which it also assesses programs and rationales for action. For nanotechnology and the NNI these were the Committee on Science, Space and technology (subcommittee on Research and Technology)[181] of the House of Representatives and the Committee on Commerce, Science and Transportation of the Senate.[182] Over the years, these committees have organised numerous hearings, with

[179] http://cben.rice.edu/; http://www.cein.ucla.edu/; http://ceint.duke.edu/

[180] In 2003 Vicky Colvin used the much quoted "*wow-to-yuck*" frame, when calling for an EHS budget allocation similar to the research on Ethical Legal and Social implications (ELSI) in the Human Genome Project (3 – 5 %) in a testimony for Congress on the NRD Act. See http://www.patrickmccray.com/2013/02/18/regulating-nanotechnology-via-analogy-pt-2/ Rip and Van Ameron 2009, Kelty 2009, McCarthy & Kelty 2010.

[181] https://science.house.gov

[182] http://www.commerce.senate.gov

testimonies from experts and stakeholders, about nanotechnology in general as well as the NNI specifically and frequently addressing nanosafety.[183] Next to these committees Senator Ron Wyden of Oregon, one of the advocates for the NRD Act, established a Congressional Nanotechnology caucus for facilitating bipartisan support to the NNI. The caucus and committee meetings are prepared by Congressional staff, which interact with stakeholder representatives.

Karn and Schottel (2016) list a number of political moves by the White House and Congress, which affected the EHS research strategy of the NNI directly. First, where the Clinton administration turned the preparatory IWGN into the NSET subcommittee for coordinating the NNI directly under OSTP-NSTC, Congress pushed back by the NRD Act, which shifted budget appropriation to OMB (falling under Congressional authorisation). This move stipulated a triennial update of the NNI strategy and a related triennial review by the National Academy of Science (NAS) as well as the establishment of a National Nanotechnology Advisory Panel (NNAP) advising on societal issues. The subsequent George W. Bush administration removed most original players in the IWGN/NSET committee and put the industry association Nano Business Alliance in. NSET chair Mihail Roco was replaced by an OSTP official to become NSF representative and Barbara Karn was removed as chair of NEHI. Furthermore, the NNAP function was turned into self-evaluation, by designating this task to PCAST (which is hosted by OSTP).

Karn and Schottel (2016) report how EHS research strategy development stopped in these years. The 2007 NNI strategy update did not include a further operationalisation of the EHS strategy, since this was not considered to be needed after the positive evaluation by NAS in 2006 (NRC 2006). Furthermore, the NNAP/PCAST (2008) review urged the NNI to be "*more cautionary then precautionary*" and "*appropriately balance risk benefit*" again. In the final 2007 NNI strategy (NNI 2007b) ELSI research was excluded at all. Moreover, the large share of NNI research on standardisation and instrumentation (mainly NIST work), which had been incorporated in the NNI program as 'application' research, was attributed to 'implications' in the 2008 EHS research strategy document, thereby flattering the image of total expenditure on EHS research. This move was severely critiqued in subsequent reviews (GAO 2008, NRC 2009) and restored under the Obama administration when NNAP was reshuffled again. The 2010 NNAP review did put EHS on equal footing with nanotechnology outcomes and program management, a new series of workshops produced a new EHS research strategy and the 2011 NNI strategic plan (NNI 2011b) reflected a renewed focus on environmental issues stimulated by the Obama administration's as well as the internationally emerging discourse on 'grand challenges'. However, these moves came at cost of the 'applications/implications'

[183] The Senate committee has been focusing on nanotechnology, while the House committee focuses more on the NNI. Along these lines two bills were proposed in 2003 (S189 and HR 766). In the end the (amended) Senate bill has been signed into law as the US NRD Act (P.L. 108-153). The Senate committee organised hearings on nanotechnology already before the establishment of the NNI. All hearings can be retrieved from https://www.gpo.gov.

framing, precisely because of the previous "*muddling of research priorities*" (NNAP/PCAST 2010) and re-introduced the risk-benefit frame again.

***de facto* governance practice: little coordination**

Discussing the actor landscape has brought us closer to understanding why EHS research in the NNI has been substantively facilitated but hardly integrated. Yet, with so many stakeholders involved and critical reviews out in the open, the question still is how this could happen and why the 2011 turning point didn't correct the lack of coordination and integration. I will discuss three interrelated factors here. First, the positive attitude of some NGOs in the early years quickly faded between 2005 and 2007, partly because progress in regulatory oversight (discussed in section 6.3.2) had been stalling as well (Bergeson 2007). In contrast, industry groups withdrew from NNAP after the reshuffling under the Obama administration. According to (Karn and Schottel 2016), they considered the reprioritising of EHS strategy development as actually contributing to a growing uncertainty about safety. The retreat to individual advocacy positions of both industry and environmental organisations then left political discussion about EHS research coordination much more dependent on the bureaucracies of formal evaluations. Second, these evaluative structures gave way to rather skewed evaluations of NNI's dual mission. Third, this has been masked by the relative successful integration of nanosafety research in the domain of occupational exposure.

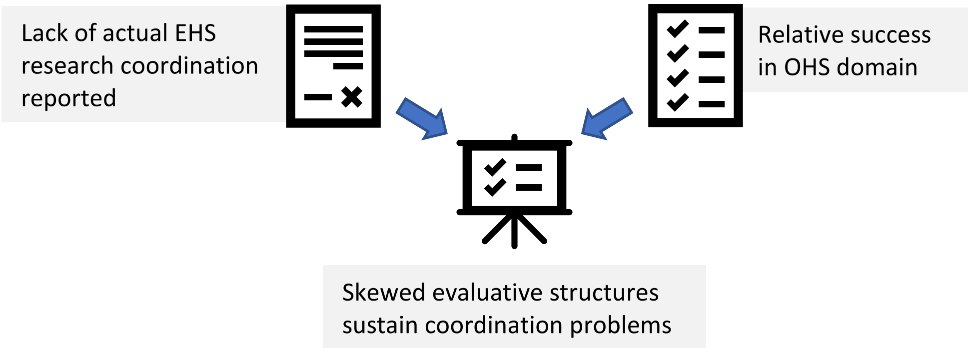

Figure 23: de facto *dynamics of EHS research coordination and evaluation practices*

Critical reviews of the EHS research strategies

The Capitol Hill battles at the start of the NNI had resulted in a dual evaluative structure of triennial evaluations by NNAP/PCAST (reporting to OSTP) as well as by NAS/NRC (discussed by Congress).[184] Discussions in Congress did impact the NNI only when revisions in its legal basis were authorised (2003, 2007 and 2011). On top of these

[184] The evaluation period changed to quadrennial reviews in 2017. See http://nanotech.lawbc.com/2017/01/bill-presented-to-president-obama-would-lengthen-time-between-nni-strategic-plans-reviews-and-evaluations/

evaluative structures, separate reviews of the EHS research strategy have been published, by the NRC as well as the Congressional Government Accountability Office (GAO). In the context of these reviews the lack of effective coordination has been repeatedly brought to the fore in committee hearings, especially during the NNI reauthorisation process (2007/2008) when capacity problems of the agencies were mentioned and commentators stated that the EHS research agenda was "*mistaken for a strategy*" and "*committees and networks in themselves do not yet create leadership*."[185] The critical reports by the NRC and the GAO did sort effect later, under the Obama administration, when EHS received as much attention in the 2011 NNI strategic plan as did Program Component Areas (PCAs), Signature Initiatives (SIs) or Workforce Educational programs.

The NRC (2009) review of the EHS research strategy also strongly urged for a EHS coordinator, which was authorised by Congress in the NANO Act.[186] However, appointing an EHS coordinator turned out to be only a marginal improvement. The next NRC (2012) EHS research strategy review showed that interagency coordination as such was not yet budgeted, stakeholder engagement in strategy development and review was lacking and the relation between promotion and mitigation was still fought over in terms of budget shares and classifications of what counts as EHS research, instead of substantive analysis. The basic problem, according to the NRC, were the accountability structures that gave the NNI a dual mission, but not with equal authority. Following up on this point the NRC discussed at length historical examples of institutional solutions to problems of operation, engagement and accountability. A year later the NRC committee published an EHS research strategy itself (NRC 2013), as asked for by the NNI. In this report, the NRC stretched its point further in calling for a clearer institutional separation of NNI's dual mission.[187]

Next to the NRC, the GAO (2012) raised substantial comments to the 2011 EHS research strategy. While respondents to the GAO survey were positive about the strategy, the GAO repeated its critique of 2008 about flawed reporting of EHS research expenditure due to a lack of sufficiently detailed guidance on this point. Moreover, GAO found the 2011 strategy document failing on a number of its criteria for effective strategy: purpose

[185] Maynard 2007; see also Maynard 2006, Denison 2007 and the minutes of the related hearing at by the House of Representatives committee (last accessed 8 March 2023).

[186] See: minutes of the related hearing at by the House of Representatives committee (last accessed 8 March 2023). EHS coordinators then became Sally Tinkle (NIEHS) and Trye Thomas (CPSC)

[187] NRC 2013: "*NNI would benefit from a clearer separation of authority and accountability for its EHS research enterprise and its mandate to promote nanotechnology development and commercialization. The committee also acknowledges that, in the absence of a change in its statutory mandate, establishment of wholly separate management and budgetary structures and authorities for the NNI's dual functions may not be realistic. Nonetheless, steps can be taken at both the agency level and across the initiative as a whole to address this concern*"

and definition of key terms was considered to be clear, as well as discussing available data. But the strategy does not provide performance measures, targets, and time frames for meeting those measures, nor estimates of costs and resources that would allow stakeholders to evaluate progress towards the goals and research needs of the NNI.

Evaluative structures for the NNI's dual mission

None of the issues raised by NRC and GAO has been addressed in the 2016 NNI strategic plan (NNI 2016), nor in the NASEM (2016) triennial review of the NNI.[188] The NNI (2021) strategic plan only mentions the continuation of EHS research and efforts for wider dissemination. Apparently, the critical reviews have not been centre stage in the relation between EHS research strategy development, political discussion and stakeholders' views. One reason could be that the production of these reviews is the work of one out of so many temporarily organised committees producing NRC of GAO reports. This may well explain, for example, the disconnect between the reviews of the NNI and the reviews of the EHS research strategy. Another reason could be that public and political attention have been fading over the years.

While these will have been contributing factors, the main cause appears to be rooted in the evaluative procedures indeed. For both the Executive and Legislative branch of US government annual budget appropriation is an important mode of exercising authority. These fiscal year cycles reinforce analysis and assessment at the level of policy goals (as defined for the NNI) rather than implementation strategies (as discussed for EHS research). Carried by the pervasive idea that nanosafety knowledge development would inform innovation and regulation, budget shares then could become a kind of self-referential measure for qualifying the EHS research base. Since the EHS research budget has been increasing throughout the timeframe discussed, it would be difficult to deny NNI's efforts in these terms. Particularly striking in this respect is the PCAST (2014) evaluation, which states that the budget share for EHS "*demonstrates support*" of the federal agencies for Responsible Development.[189]

Relative successful integration in the occupational safety domain

In the occupational domain (OHS) tangible products, like guidance documents for protecting workers, have been developed and disseminated independent of the EHS strategy development in NEHI. The prime agency in this respect, NIOSH, attributes this success to partnerships with the private sector, for which it is "*recognised by stakeholders as the most trusted and collaborative agency*."[190] When demonstrating progress in addressing the uncertainties about nanosafety, the NNI (but also others, for example ICON) mainly referred to OHS results.

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188 See footnote 149 on the National Academies of Science, Engineering and Medicine (NASEM) having taken over the triannual reviews of the NNI from the National Research Council (NRC).

189 As of 2014 the PCAST assessments no longer included the National Nanotechnology Advisory Panel (NNAP), see Bos 2016 for discussion

190 According the NTRC director, Charles Geraci 2014 (last accessed 8 March 2023).

In these settings NEHI remained an open space for agency coordination in nanosafety research; i.e. open to political force fields and devoid of budget and authority for proper coordination and integration. Meanwhile, various attempts for integration in R&D processes failed. Back in 2005, the first ACS symposium provided a platform for "*environmental benign synthesis*" (see Karn 2004), but it didn't take off, for being too experimental. In 2011, the sustainable design approach was reintroduced in the EHS research strategy, but still faces waiting game scenarios with respect to gaining regulatory credibility. The same problem has been raised for NNI related network Sustainable Nanotechnology Organisation (SNO) (<Davies, Karn>).[191] Integration of EHS research in regulation much more happened in international fora, where the nanosafety research community still works towards regulatory accepted methods for nanosafety risk assessment. But informing regulatory oversight hardly happened. As a result, more than a decade of nano-EHS research has resulted in an ever growing number of research activities and an enormous production of scientific output, but in a rather traditional institutional structure of regulatory science centers and research projects.

6.3.2 EPA and oversight under TSCA

In this section I will focus on the efforts of the EPA in establishing mechanisms of oversight. Oversight is an important condition for assessing the scope and nature of uncertainties with respect to actual and predicted use (transparency) and to enable regulatory action if needed (traceability).[192] Furthermore, it has to inform priority setting in EHS research and vice versa. The EPA is an important agency in the US federal institutions. Where other regulatory agencies fall under Executive Branch departments, the EPA is an independent agency and its administrator has a position at Cabinet level.[193] The EPA administers a number of environmental protection laws that have been developed after major concerns about environmental pollution in the '70s it. Most relevant to the issue of nanosafety is the Toxic Substances Control Act (TSCA), which deals with the safety of chemical substances. It is the chemical safety assessment paradigm which is most challenged by uncertainties about the safety of material structures at the nanoscale.[194] I will discuss how in the context of TSCA, EPA has tried to

[191] See Te Kulve (2010) for a discussion of 'waiting games' in nanotechnology. In the interviews Karn pointed to such situations as large companies, like BASF, "*are not going to change their equipment*" as long as not backed by regulations.
[192] Actually, research is part of regulatory action as well (as illustrated by the regulatory agency's participation in the NNI research program), but usually 'regulatory action' refers to requirements imposed by authorities to the production, use and administration of materials and products.
[193] In practice, the effect of this position is dependent on whether and how presidencies hold Cabinet meetings.
[194] Next to TSCA the EPA administers a number of other acts relevant to nanomaterials, such as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which has been applied for nanosilver, the Clean Air Act (CAA) and the Clean Water Act (CWA). Food, drugs and cosmetics

chart a path from voluntary to mandatory measures in creating oversight; and how it gave shape to the policy goal of Responsible Development in doing so.[195]

Governance arrangement: TSCA and assessing the safety of 'new chemicals'

In 1976 TSCA has been introduced in response to major health and environmental impacts reported for substances like lead or mercury.[196] At that time more than 60.000 substances were listed in the TSCA Inventory as 'existing chemicals'. Where regulatory measures had not been issued already, these substances are considered to be safe, until EPA reviews prove otherwise. For all 'new chemicals' manufacturers have to notify EPA at least 90 days before production, by submitting a Pre-Manufacture Notice (PMN). After approval by the EPA, or when EPA misses the deadline or exempts the dossier from assessment, these substances are added to the inventory. To date the inventory contains more than 86.000 records.

Under TSCA the EPA can also require specific modes of recordkeeping by manufacturers and importers on production, use, release and exposure. Furthermore, when the structure of existing chemicals significantly is being altered, such as the case for carbon in nanotube form, the EPA can issue Significant New Use Rules (SNURs). TSCA also specifies how risk assessment testing has to be done. The key issue for regulating 'nano' is when and how the different categories of regulatory action have to be invoked. Figure 24 shows that this question is not only shaped by uncertainty about the safety of nanomaterials, but also by wider discussions about revisiting TSCA.

Limitations of TSCA

While TSCA formally grants authority to the EPA to regulate both existing and new chemicals, it has been widely acknowledged that actual regulatory action by the EPA under TSCA critically depends on substantial evidence about risks and EPA's resources and capacities to make a case. All regulatory action under TSCA has to be assessed for risk-benefit balancing – a procedure in which 'unreasonable risks' have to be demonstrated by substantial evidence, knowledge gaps are treated as no risk and the EPA is required to apply the 'least burdensome measures' (Davies 2006). All of these requirements invite for litigation, which has been the case very often (Eisner 2010). In 2005, the GAO reported that the EPA had been able to review only 200 substances listed in the TSCA Inventory. One of the reasons for this low number is because EPA is lacking

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are excluded from TSCA as these are mainly regulated by the FDA. The EPA regulates pesticide residues under the Federal Food, Drugs and Cosmetics Act (FFDCA).

[195] The EPA considered its statutory framework as already supporting Responsible Development, though it acknowledged that proactively setting up partnerships with corporate actors in the context of existing voluntary environmental stewardship principles would be needed as well (EPA 2007). The 2007 position paper translated into the EPA nanomaterial research strategy (EPA 2009a).

[196] For an overview of TSCA, see EPA website and, Markell (2010): "*An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*"

resources to validate confidentiality claims. The review-rate of PMNs is better (Bergeson 2005a), but in many cases the EPA has not been able to respond within the required 90 day period or has been exempting from notification (Markell 2010). Moreover, the PMNs essentially treat nanomaterials as other chemicals, contain little information about risk assessment and the 90-day period does not allow for rigorous review, also given that the EPA has to review about 1500 PMNs each year (Eisner 2010).

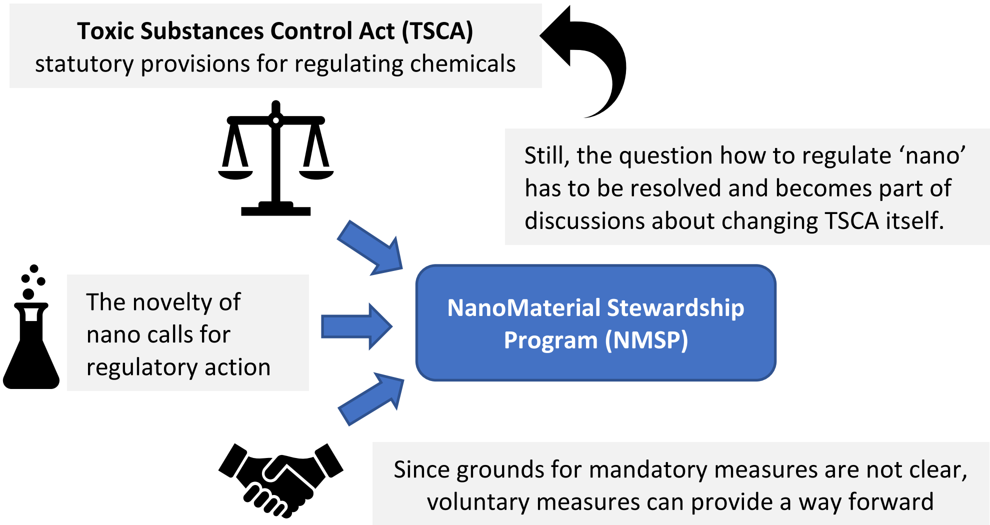

Figure 24: voluntary measures for nanomaterials and discussion about TSCA

Applying SNURs for nanomaterials is difficult as well, as it normally takes years for having resolved what is 'new' (Bergeson 2005b) and requiring a categorisation of nanomaterials for which the costs of deploying such a measure easily can be challenged as not proportionate to the amount of nanomaterial actually used (Eisner 2010).[197] These weaknesses have been debated from the start and TSCA widely has been considered as "*dysfunctional*" (Schmidt 2016). As a result, many states have implemented their own laws (GAO 2005). In this situation, the long awaited revision of TSCA by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (FRL Act) in 2016, received almost unanimous support. To what extent the situation improves under the FRL Act will become clear after the first litigation waves for implementing the new measures (cf. Bergeson et al. 2017 or Ashford 2017[198]).

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[197] Categorisation also is a tough problem in the context of the European chemicals regulation REACH, where information requests for nanomaterials by ECHA have repeatedly been withdrawn for not providing sufficient legal certainty about the interpretation of the notion of 'nanoform' (cf. Chemical Watch Global Business Briefing May 2017 (subscription needed))
[198] Chemical Watch Global Business briefing, guest column "The new TSCA: challenges remain"

Complementary partnerships

Because of TSCA's limitations, the EPA has relied frequently on voluntary measures, such as partnerships with industry (Markell 2010, Landy 2010, Fiorino 2010). For nanomaterials the EPA initiated the Nanoscale Materials Stewardship Program (NMSP), a voluntary program for reporting data about nanomaterials. The NMSP has been running from 2008 to 2010 and provided two modes for participation: a basic mode focused on sharing information and an in-depth mode, in which companies could work with the EPA on testing over a longer period (EPA 2009b). According the EPA's strategic plan on nanosafety, the NMSP fitted in a trajectory of going from voluntary to mandatory regulatory measures[199]. Next to the NMSP, the EPA has been considering an increasing range of nanomaterials as new chemicals, thus requiring PMNs. For some nanomaterials, such as carbon nanotubes and fullerenes, the EPA has issued SNURs and as of 2016 the EPA has finalised a rule on recordkeeping for nanomaterials.

Actor landscape: EPA's position in environmental regulation

Despite broad support at the start, setting up the NMSP has not been a straightforward task, because of the many interactions required internally, with stakeholder groups and governmental bodies as well as international coordination.

Organisation of the EPA

The EPA is a large agency, employing about 15.000 people. It has offices and laboratories across the US and an annual budget of about 8 billion dollar.[200] This size comes with specific challenges for intra-agency coordination. As a federal issue, nanosafety has been on the agenda of several headquarter offices in Washington DC, with leading roles for the Office of Research and Development (ORD) (see previous subsection on ORD's early participation in the NNI) and the Office of Chemical Safety and Pollution Prevention (OCSPP). OCSPP hosts the Office for Pollution Prevention and Toxics (OPPT), which is responsible for implementing TSCA and the Pollution Prevention Act (PPA), as well as for providing public information about chemical risks. The Office of Pesticides Programs (OPP) is responsible for implementing FIFRA. Other offices, such as the Office of Water (OW) and the Office of Air and Radiation (OAR) have been involved to a much lesser extent. However, the activities on nanosafety by these offices are also subject to EPA-wide offices for administration and compliance as well as offices coordinating and advising on scientific questions, such as the Office for Policy (OP), the Office of Science Policy (OSP) and the Science and Technology Policy Council (STPC).[201]

Besides internal offices, the EPA hosts national committees advising on EPA's policies. Committees which have been advising on nanosafety issues are the National Advisory

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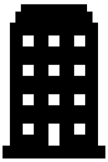
[199] i.e. the 2005 draft version. The final white paper (EPA 2007) was expected to be published early 2006 (last accessed 8 March 2023).

[200] It should be noted that this budget stayed at the same level for long time, which implies that EPA's actual resources have declined.

[201] See EPA 2007: 64 for an overview of EPA offices having to deal with nanotechnology.

Council for Environmental Policy and Technology (NACEPT) on workforce capabilities, the National Toxicology Program (NTP) Interagency Committee for Chemical Evaluation and Coordination (ICCEC) on research priorities, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), which developed the architecture of the NMSP (Bergeson 2007) and the TSCA Interagency Testing Committee (ITC), which has been involved in the SNURs issued for nanomaterials by EPA (Culleen and Logan 2009).



The EPA…
… 15.000 staff, 8 bln. annual budget
… many offices, each having different relations to stakeholder groups as well as to governmental bodies
… subject to many consultation and assessment procedures, in which 'nano' is just one of the issues
… often facing budget restrictions causing capacity problems

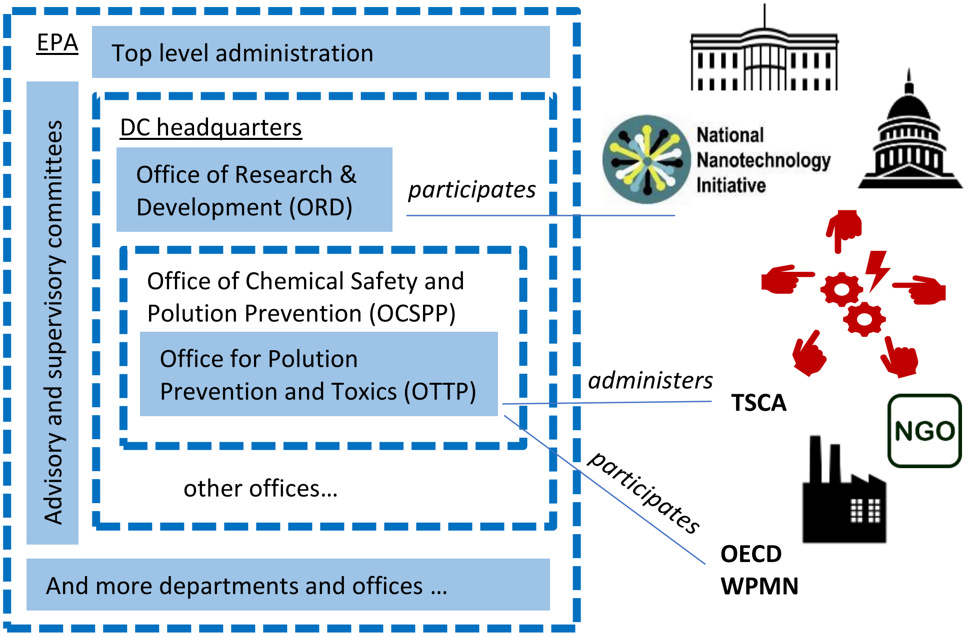


Figure 25: EPA and the challenge of regulating 'nano'

Caught in political force fields

While the numerous committees listed above already turn the challenge of charting a path for regulating nanomaterials into a daunting task for OPPT, the relations to industry and NGOs as well as the White House and Congress did make it even more difficult. NGOs took different positions (as discussed in the previous sub-section) and industry representation has been fragmented across different sectors and commercial activities (e.g. chemical synthesis of raw materials and processing). For example, while individual companies acted as frontrunners (e.g. DuPont being the first registrant under the NMSP (Nel, Grainger et al. 2011), or Dow Chemical urging the EPA for issuing SNURs on nanomaterials (Bergeson 2007), they participated in sector wide litigation at the same time (e.g. the SNURs proposed in the end have been challenged by industry and withdrawn all the time[202]). Regulatory measures also have to pass long procedures and stark demands set by OMB, after which they are frequently challenged by either NGO's or industry groups. As a consequence, EPA is often caught in all kind of litigations – or as the saying goes "*everybody sues EPA*" (<Bosso>).[203] Changes to the legal base of the regulatory provisions under TSCA that could remedy these problems haven't passed Congress because of the same force fields (Coglianese 2010, Landy 2010).[204]

For example, in 2011, OSTP and OMB issued general principles for regulating and oversight of nanotechnology (OSTP 2011). Together with the FDA, EPA had been involved in a preparatory multi-agency process led by PCAST, OMB and OSTP, as well as the National Economic Council (NEC) and the Office of the U.S. Trade Representative (USTR). The final principles have been approved by the White House Emerging Technologies Interagency Policy Coordination Committee (ETIPC). In this setting, much emphasis was put on scientific evidence. The principles urge to consider alternatives to regulatory measures and to avoid the inhibiting of innovation or stigmatizing new technologies (cf. Bergeson et al. 2011). When EPA and FDA then had to start new procedures inviting stakeholders to comment on their policies, these principles were severely critiqued by NGOs, declaring EPA's efforts for death (Ambrosio and Rizzuto 2011).

Capacity issues and international harmonisation

An important complicating factor in this respect, is that the EPA has faced severe budget and staffing deficits (GAO 2005, Fiorino 2010), in particular for addressing new issues like nanosafety (Davies 2007, Coglianese 2010, Eisner 2010, Landy 2010, EPA 2011, <Davies, Karn, Morris, Shatkin>). For example, in 2011 OCSSP (of which OPPT is part of) had only five full-time equivalents working on nanomaterials. EPA's Inspector General Office therefore stated: "*even if mandatory reporting rules are approved, the*

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[202] As reported by Bergeson & Campbell PC (http://www.lawbc.com/), see also Culleen and Logan (2009).

[203] See Davies 2007; 2009 for a discussion of the anti-regulatory climate in the US (also frequently mentioned in my interviews with <Davies, Maynard, Hanson, Shatkin>) The quote is from <Bosso>, but goes back to EPA's early years, as illustrated by a quote in EPA's journal: "*Who brings most of these actions —the industry groups, the environmental group? Everybody sues EPA. I have been in other Government agencies and EPA is almost unique in that regard. Both industries affected and environmentalists' groups sue EPA on a regular basis*." (EPA Journal, Volume 4, Number 2, February 1978).

[204] The revision of TSCA that passed in 2016 (Lautenberg Act) would have to correct for a number of deficiencies, but has been hardly acted upon under the Trump presidency.

effectiveness of EPA's management of nanomaterials remains in question", for reasons of an observed lack of processes for coordination in utilisation and dissemination of the information obtained; the incoherent communication towards stakeholders; the chemical safety models used for reviewing; and reliance on industry-submitted data (EPA 2011). In 2013 EPA faced a 15% loss of staff due to an early retirement scheme, being the result of budget cuts across federal government. Because of these weaknesses in EPA's capacity to act, OPPT has invested heavily in international networks, especially the OECD Working Party on Manufactured Nanomaterials (WPMN) < Morris >. The WPMN has evaluated voluntary initiatives and coordinated the development of new methods and a testing program for a number of nanomaterials since its start in 2006.[205]

***de facto* governance practice: a long road from voluntary to mandatory measures**

In 2005 OPPT announced that nanomaterials consisting of new chemical substances had to be notified (as is required for all new chemicals) (Fed.Reg. 2005). However, to improve the understanding of nanomaterials' health and environmental impacts, OPPT also proposed to set up a voluntary program for reviewing information provided by industry. The voluntary program would provide EPA with a better knowledge base for deciding on regulatory measures, like Consent Orders (CO) or the Significant New Use Rules (SNURs). These may require additional testing and protection, limit application contexts or pose additional information requirements. The other way around, a sound knowledge base could benefit industry in providing more certainty about how nanomaterials would be regulated under TSCA. As have become clear already from above discussion, both voluntary and mandatory measures turned out to be difficult to implement.

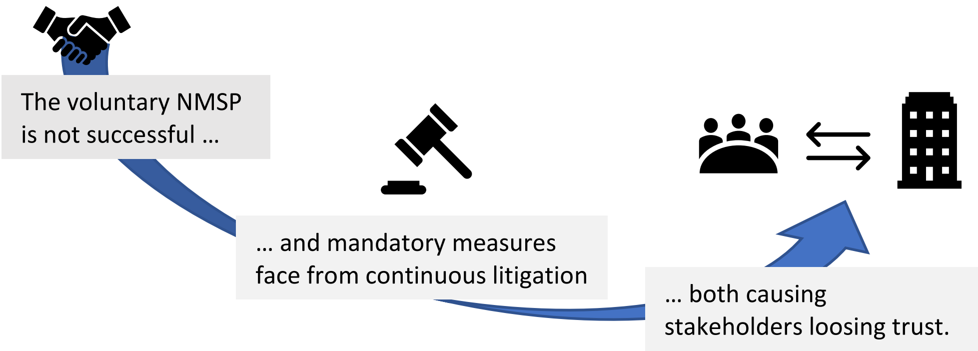

Figure 26: EPA facing litigation and lack of trust

The voluntary path

The voluntary program has not been very successful. EPA had called on the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) to develop the

[205] See http://www.oecd.org/chemicalsafety/nanosafety/

procedures for submitting and reviewing, including confidentiality management. NPPTAC's proposal – the 'Nanoscale Materials Voluntary Program' (NVPP) – was well received in a public meeting by EPA in 2005 (Bergeson 2007). After this meeting, it took two years before the final program, the Nanoscale Materials Stewardship Program (NMSP), started. Deadline for submission to NMSP was set at July 28, 2008. Industry could choose between submitting information in a Basic Program, in which the EPA would review the information, or participate in an In-depth Program, in which safety testing would be developed in collaboration with the EPA. By the end of 2008, 29 companies had participated (4 of which in the in-depth program) and information about 123 nanomaterials had been submitted. In its interim report, EPA (2009) considered this score a success, although it also became clear that when compared to the public databases of Nanowerk[206] and the CPI of the PEN project (see previous sub-section), at least 90% of known nanomaterials had not been covered. The final report of the NMSP has never been published and the Inspector General Office of the EPA criticised the very limited amount of information about safety testing and the minimal industry participation (EPA 2011).

Mandatory measures

Applying mandatory measures proved difficult as well. In 2015, the EPA had received about 160 PMNs on nanomaterials, which again indicates that most nanomaterials are not covered (<Morris>). Furthermore, the PMNs contain little information about safety testing as no test data is required. The EPA has to use its existing models for chemical safety assessment within a relatively short period of 90 days (considering the staffing problem and an annual workload of 1500 PMNs). Moreover, EPA has to assess whether the nanomaterials may present 'unreasonable risk', while characterisation was still under development (cf. Alwood 2015). More successful has been the recordkeeping rule, which increased the notification deadline to 135 days before production and also including import and processing.[207] The rule has been proposed in 2015 and although many comments were expected (Bergeson 2015), EPA has issued the final rule in May, 2017[208], though followed by litigation on the guidance documents afterwards.

Capacity to regain trust

Both voluntary and mandatory measures have been suffering from EPA's capacity problems. For example, for introducing the NMSP, two rounds of consultation were recommended (Fiorino 2010). For the Nanotechnology White Paper (EPA 2007), an extensive peer review meeting had to be organised. EPA also had to respond to the most obvious concerns about nanomaterials falling under its purview: the application of nanosilver used as antimicrobial agent (OPP, since regulated under FIFRA), Cerium-oxide

[206] http://www.nanowerk.com/nanotechnology_databases.php (last accessed 8 March 2023)

[207] This is in line with the revision of TSCA by the FRL Act, approved by Congress in 2016. Low volumes and small companies can be exempted.

[208] See https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under

used in fuel additives (OAR) and the carbon nanotubes and fullerenes (for OPPT). OPPT has been working on SNURs for carbon nanotubes from 2008 onwards, but repeatedly has been forced to withdraw these until 2020.[209] For each step, the SNURs have to be checked for compliance, submitted for public consultation, published within the deadlines set by the federal portal regulations.gov, cross-checked with other federal regulatory actions in the same timeslot, and more. Under FIFRA, the EPA granted conditional approvals for two products containing nanosilver, requiring a four year period of testing.[210] However, EPA's actions in this domain have been challenged continuously as well.[211]

These dynamics have come with a cost. While EPA regularly is discredited for putting up unnecessary barriers to innovation on the one hand, or being too slow and ineffective with respect to protecting health and safety on the other, its path in regulating nanomaterials did not help to improve trust. The positive mood among stakeholders in the early years, had turned into frustration already in 2007, when the EPA presented the NMSP. The NMSP only slightly differed from the NVPP which had been proposed two years earlier (Bergeson 2007). About 2007, progress in the NNI EHS research strategy stalled as well (see previous sub-section). CTA, together with thirteen other organisations, started to file petitions against the EPA (on nanosilver) as well as against the FDA (on sunscreens). To their frustration both EPA and FDA responded only seven years later (<Hanson, Shatkin>).[212] Furthermore, it often took long before OMB had reviewed proposed rules (e.g. two years for the NMSP and more than two years for the recordkeeping rule). OSTP's 2011 principles for regulation and oversight of nanotechnology have been perceived as actually "blocking" all action by the EPA (Ambrosio and Rizzuto 2011). The emphasis on evidence reinforced the need for sufficient capacity (quantitative and qualitative) in addressing uncertainty. Lacking such capacity has kept EPA caught in the many bureaucratic, political and judicial tasks involved in both intra- and inter-agency coordination.

6.3.3 Nanosafety governance in the US: constructive and productive?

The premise for investigating both research coordination and oversight measures was that both had to inform each other as well as nanotechnology research and innovation. Therefore, I will discuss them side by side in evaluating how problem and solution frames affected the organisation of responsibilities and vice versa. Since both lines of action cover a wide range of activities, I will draw on two in-depth studies about

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209 See https://nanotech.lawbc.com/ for an overview of all steps. The final SNUR for CNTs has been published in 2020 (last accessed 8 March 2023)

210 See Chemical Processing December 15, 2011 (last accessed 8 March 2023)

211 See Chemical Processing February 15, 2012 (last accessed 8 March 2023) and Bergeson and Backstrom (2013)

212 See also: http://www.nanotech-now.com/columns/?article=961 (last accessed 8 March 2023)

nanosafety governance in the US: the nanosafety discourse analysis 'Risk, Language and Power' by Jeffrey Morris (2012) and 'Governing Uncertainty' by Christopher Bosso (2010), which deals extensively with the activities of the EPA on nanosafety.[213]

Contestation

The most dominant and pervasive frame cross-cutting both EHS research coordination in the NNI and oversight measures under TSCA is that uncertainty about the safety of nanomaterials is a problem of (a lack of) knowledge. This is true, comprehensible and a widespread problem frame in (regulatory) science communities, but it masks that uncertainty is also a problem of choice (Bosso and Kay 2010). In literature the shortcomings of this frame often focus on the resulting phenomenon of the 'uncertainty paradox' (invoking ever more research, thereby introducing new uncertainties; cf. (van Asselt and Vos 2006); or on the narrowing of public and political discourse to 'managing risk' (cf. Davies et al. 2009). Both have become visible in the NNI research agendas, budget appropriation as well as the demands for 'evidence', such as set by OSTP's (2011) policy principles on nanotechnology regulation. By investigating multiple lines of action, however, the problem for nanosafety governance turns out to be even more entangled: while uncertainty about safety did prompt action, it also challenged the conditions for effective governance of that action. The analysis of Morris helps to understand how this Catch-22 situation has been produced from different positions and by different logics, together contributing to the pervasiveness of framing uncertainty as a knowledge problem. Next, I will discuss how elucidating choice is linked to the responsibilities that are linked to the various logics and positions.

Scientism

Morris discusses the pervasiveness of treating uncertainty as a knowledge problem as a problem of 'scientism': "*What limits discourse is our strict adherence to a calculated system of governance, reinforced by myriad micro behaviours practiced within the scientism narrative*."[214] For the US policy discourse on nanosafety, Morris illustrates this by discerning three discursive categories. 'Technological progressivism', typically voiced by proponents of nanotechnology acknowledges potential risks, but in the context of a strong belief that these will be sorted out while nanotechnology proceeds from the laboratory to the market. Opposite to this frame is 'risk society', which has been voiced by environmental organisations. They have been emphasising the institutional nature of uncertainty about the safety of nanomaterials as 'nano-toxicology' still had to be

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[213] I have interviewed Morris in his capacity as EPA official in charge of nanosafety at OPPT and former head of ORD's internal research program on nanosafety (2007 to 2011). Christopher Bosso hosted me at Northeastern University, Boston.

[214] Drawing on Foucault (and others), Morris uses the image of power as exerted by way of 'capillary movements': "experts giving testimony before Congress, government agencies hiring communications experts to develop and disseminate nanotechnology-specific messages, NGOs setting up nanotechnology blog spaces, and companies creating alternative forms of specific nanoparticles and testing them in cell cultures." (Morris 2012)

developed and regulators usually are slow to respond. The ultimate consequence of this frame is a moratorium on the application of nanotechnology until all risks are sorted out. The third category, 'administrative pragmatism' then is in between these two extremes, acknowledging that developers and regulators have to move with caution, but that the issue can be fixed by due consultation, dialogue and knowledge development.

What is at stake, according to Morris, is how governments can use their power for social benefit. If, for example, other positive as well as negative consequences of nanotechnology are part of the debate, policy decisions would be taken differently.[215] However, while contestation occurred between these narratives, all three sustain a rather narrow conception of 'risk', thereby limiting the range of arguments allowed. This explains how the Catch-22 situation with respect to regulatory action can emerge in rebound. The tensions in the dual mission of the NNI, for example, have been both resulting from and reinforcing a weak institutionalisation of EHS research coordination. The lack of effective coordination has led to calls for a stronger institutional separation in the NNI, so as to protect research coordination from stakes involved in commercialisation. But it also sustained the scientism approach towards research informing regulation by ignoring different rationales in health and environmental protection.

For example, the question on what grounds nanomaterials should be considered as 'new' has divided agency positions.[216] EPA's Science Policy Council stated that it would not use particle size as a criterion for newness (EPA 2007). From an environmental protection perspective, such a categorical decision could not be sufficiently backed by scientific evidence. NIOSH, however, challenged this position, as in the occupational domain particle size exactly is an important cause of concern, especially for carbon nanotubes. Likewise, EPA's science policy paper (EPA 2007) posed good research questions[217], but answering these questions is extremely complex. Even if broader questions of risk and benefit are left aside, linking research and regulation already involves a myriad of rationales.

[215] As for its consequences he stretches his point even further: "Regulatory science, as an expert system and technology of governmentality, reinforces our system of calculated governance. Science and law jointly support calculation, and in doing so not only shape liberal democracy but also support global capitalism." (Morris 2012)

[216] Newness has two, interrelated, dimensions in discussions about regulating nanomaterials: in terms of material structure and composition vs. functionality and effects; and in natural vs. engineered / man-made (cf. Morris 2012).

[217] Summarised by Morris (2012): "1) What nanomaterials, in what forms, are most likely to result in environmental exposure? 2)What particular nanomaterial properties may raise hazard or exposure concerns? 3) Are nanomaterials with properties of concern likely to be present in the environment in concentrations of concern? 4) If the answer to the above question is "yes," what can be done to reduce the material's potential to create risk?"

Multiplicity and choice

The above examples illustrate that the novelty of 'nano' becomes multiple as object of governance – because of the different logics involved in health and environmental protection, and with that, a specific distribution of responsibilities. For example, starting with the NNI and ending with the EPA, various interrelated logics have been touched upon in section 6.3.1 and 6.3.2:

- For enabling the Responsible Development of nanotechnology in the NNI, involving regulatory agencies and their knowledge about safety, is important. In turn, by being involved regulatory agencies can better anticipate new developments and related implications for regulation. However, 'nano' in the NNI (nanoscale science and engineering) is not the same as nano at the market (products, industrial materials). The connection largely is discursive (in the label as well as by strategic framing). The NNI has pushed nanotechnology as an umbrella term for umbrella promises[218], while due attention for nanosafety had to be balanced with avoiding industry withdrawal.
- Keeping in mind that the regulatory agencies have scarce resources, priorities from a health and environmental protection view differ from the need to keep up with innovation. Other issues can be more pressing, also within the domain of chemical safety; one can focus on 'cowboy markets' (e.g. dietary supplements) instead of trying to cover everything; or the adverse effects reported are already well understood, as is the case for carbon nanotubes.
- On the other hand, nanotechnology and nanomaterials do open a new era for toxicology and risk assessment. New mechanisms and endpoints for testing come into view. Chronic effects still have to be clarified, while new generations of materials are underway. Here, nanotechnology has, as a new and booming field, created a wealth of funding opportunities for regulatory science.
- Cross-cutting these rationales and dynamics are scientific as well as political questions on whether to focus on hazard or risk, engineered or all nanomaterials, materials or products, pristine reference materials or variability in actual exposure. These questions involve a balancing of anticipation and exploration on the one hand and applied, regulatory research and assessment on the other.
- As a federal agency, the EPA had to position itself vis-à-vis political discussion, state level action as well as international research coordination and standardization, while also being busy with the major overhaul of TSCA under the FRL Act. At each level the relation between governmental and corporate responsibilities is affected differently.

The challenge for nanosafety governance is that institutional responsibilities in these different logics have to be reaffirmed as well as reconfigured. Most actors involved will

[218] E.g. statements like "*a new industrial revolution*", "*affecting the lives of billions of people*" at the NNI website (accessed 2012 – 2016).

have been familiar with that, but it remained implicit in official reports and discussions where uncertainty was discussed as concerning truth claims with respect to risks rather than as propositions and hypotheses for learning how to organise responsibility.[219]

Responsibilisation

In the NNI we have seen that assuming responsibility can end up in 'organised irresponsibility'.[220] In this case interagency coordination created openings for reconfiguring responsibilities, but it mainly reaffirmed existing responsibilities in the end. For occupational safety this went well: the NNI provided an infrastructure for translating risk research into guidance and support for safe working conditions. For consumer and environmental protection, EHS research in the NNI also has provided input to international coordination and harmonisation. However, exactly in these domains integration with regulation and innovation needed a reconfiguration of responsibility, but it has been blocked by, and despite of, the dual evaluative structure of the NNI.

In creating oversight the reconfiguration of responsibility much more plays out between corporate and governmental responsibilities and the relation between voluntary and mandatory measures in this respect. The NMSP can be seen as an 'obligatory passage point' in this process. It at least fitted well into the strong and international discourse about the need for 'soft regulation' as an appropriate approach to addressing uncertainty (cf. Dorbeck-Jung 2011). However, this still requires a deliberate organisation of choice and responsibility. Eisner (2010) argues that for nanomaterials regulation can be neither technology based (because of its heterogeneity) or process based (because methods not available yet). Likewise, Coglianese (2010) argues that the third option, management based regulation based on (standardised) principles of stewardship is difficult as well: "*the same conditions which make it attractive, also make it difficult to define good management*".

Similarly Fiorino (2010) discusses the limitations of both hard and soft regulation: "*Regulation imposes a set of constraints; although often essential, these constraints do not necessarily create the conditions suited to learning, adaptation and effective management within the organizations that develop, apply and commercialize nanoscale materials and products. (…) An advantage of voluntary initiatives is their flexibility and adaptability, and the opportunity they offer to try different approaches before locking into a broader or new regulatory scheme. (…) The obvious weakness of voluntary initiatives is that they do not necessarily make anyone do anything*." This was already visible at before the NMSP started. Initially, the NSMP would start in tandem with the

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219 Ku (2013) discusses an illustrative case of choice in means and aims in standardisation for regulatory risk assessment. The bureaucracy needed for establishing precision in creating a Gold Nanoparticle Reference material by NCI and NIST also constrained its actual development.

220 Cf. Beck (1992). Giddens (1999) uses the notion of 'manufactured risk', but this notion is also used to describe deliberate attempts of introducing doubt (cf. Oreskes and Conway 2010).

Voluntary Reporting Scheme (VRS) in the UK. The UK VRS did start immediately, but with disappointing results already at the time the NMSP still had to start (Davies 2007).

According to Bergeson (2007), the NMSP program could have become successful if manufacturers had been organised in such a way that many would sign up (i.e. with an incentive structure similar to other voluntary initiatives run by the EPA). This also could have been done in the context of existing voluntary programs run by the EPA, as discussed by Fiorino (2010): 'Design for the Environment, 'Green suppliers network', 'Green chemistry and Green engineering', 'Sustainable Futures Initiative' (providing training for complementing new chemicals review) and the 'Environmental Results Program' (designed to improve compliance and performance in business sectors made up of small firms). As of 2009 none of these programs covered nanosafety. Taking into account the resource problems discussed, EPA may not have been in the capacity to innovate with these voluntary initiatives for nanosafety.[221]

At corporate side there have been voluntary initiatives as well, most notably the EDF-DuPont framework, but also references to the Responsible Care® program of the multinationals in chemical industry. According to Fiorino (2010), programs like Responsible Care can achieve better environmental performance, but not for complex and dynamics issues like nanosafety.[222] In contrast, frameworks like those of EDF-DuPont may be better suited for this task, but only if they are accompanied by "*systems of learning, lesson-sharing, best practices and expectations of collective responsibility, within groupings of firms*." An important condition for both governmental and corporate initiatives, thus appears to be their embedding in adaptive and collaborative learning systems. So far, the multi-year strategies platforms for stakeholder interaction in (US) nanosafety governance have not been enabling such learning sufficiently.

6.4 Discussion

My evaluation of contestation and responsibilisation in US nanosafety governance has yielded two interrelated issues: 1) the need for deliberate choice, with respect to limited resources for addressing uncertainty, as well as to the multiple rationales and corresponding responsibilities in protecting health and environment; 2) the need for collective learning (social, institutional) in elucidating choice. The final step in the analysis is to discuss how these issues can be addressed, given the dynamics and

[221] As of 2009 EPA spent 1,6% of its resources to voluntary program activities (Fiorino 2010).

[222] "A comprehensive program such as Responsible Care is designed to improve a range of behaviors within an organization, including product stewardship, community engagement, air and water releases, pollution prevention and chemical safety. Yet evaluations of Responsible Care have focused on TRI releases [Toxic Release Inventory], an important but narrow indicator of environmental performance, because that is where data exist." (Fiorino 2010)

conditions discussed for both research coordination and creating oversight. For a full analysis other factors will have to be accounted for as well. For example, with respect to creating oversight I have not looked into local and state level action (e.g. Coglianese 2010, Eijmberts et al. 2011, Porter, Breggin et al. 2011) and its relation to federal level[223], nor the international context, such as EPA's participation in the OECD-WPMN sponsorship program. Furthermore, I have noted the difference in institutional setting and statutory authority between the various agencies, but only discussed the EPA in more detail. However, since other agencies faced similar problems[224] and a similar state of play in nanosafety governance has been reported for other countries, the dynamics and conditions discussed in this chapter can be expected to reflect broader, systemic mechanisms.

Governance challenge	
Novelty and emergence	- uncertainty about health and environmental safety of nanomaterials
Aligning promotion and control	- knowledge development (research agenda) to inform oversight (on use, indications of risk) and vice versa, in the context of the NNI
Translation into quest	
Anticipation-cum-inclusion	- interagency coordination of federal authorities (NNI research agenda) - involving stakeholders in operationalising nanomaterial oversight (EPA)
Responsibility structuring	- positioning implications research as supportive to applications development (NNI) - charting a path from voluntary to mandatory measures (EPA)
Challenges of transformation	
Key interdependencies	- issues in coordination not part of high level evaluation (EHS research) - demands for evidence limit the ability to acquire that evidence (oversight)
Conditions for learning	- recursive demands with respect to evidence and coordination … - … sustained the bias in evaluative structures

Table 9: findings for US nanosafety governance

What comes to the fore from the discussion in this chapter is the social complexity – the sheer number of organisations involved, the multiple logics at work, the contingencies across all levels – as well as the deeply rooted quest for evidence while ignoring contexts of production and application, that hampered effectiveness and accountability in

[223] Although not much appears to have happened, out of concerns about interstate commerce.
[224] e.g. Taylor (2006) about the FDA: a general lack of resources; lack of pre-market oversight tools for cosmetics, inability to acquire information about nanotechnology products early enough in their development to prepare properly for their regulation, inadequate authority for post-market adverse event reporting, difficulty of distinguishing between new and micronized, low research capacity, no structure for information collection.

addressing uncertainty. For both EHS research coordination and the efforts of EPA in creating oversight, these dynamics have been sustained by evaluative structures, see Table 9.

The question thus is in what arenas strategies for coping with both social complexity and dominant problem frames have to be discussed – given that every arena is part of those interactions. What happened with the rise of nanotechnology is that new spaces for horizontal interactions between stakeholders have been suggested. For example, DuPont and EDF recommended a Nano Policy Forum for further development, dissemination and implementation of their framework. Fiorino (2010) made a case for a Nano Stewardship Council. Such fora have been established indeed, like ICON, or the various structures for discussion and consultation in the NNI, including the NEHI working group.

The analysis in this chapter suggests that in both cases horizontal interactions have to be better connected to political choice. In the case of ICON because it has been rather separated from political discussions. In the case of NEHI because the scrutiny that has been provided by subsequent evaluations of the EHS research strategy only have been shaping the course of action when Congress finally reauthorized the NNI by the NANO Act. And even then the *restart* of the EHS research strategy was simply branded as a *start*, including the reference to Responsible Development, which had been stated as a main goal of the NNI eight years before.[225] Actors could not get away with this if public and political scrutiny would have been well organised. For this purpose mechanisms of scrutiny should go beyond goals and ambitions and have to be informed by system analysis of problem frames and institutional logics in evaluating progress.

[225] Cf. the coverage by the Nanotechnology Industry Association (NIA): "*It would require, for example, the National Nanotechnology Coordination Office (NNCO) to develop a report for Congress outlining a national nanotechnology development strategy after consulting with relevant federal agencies, including the U.S. Environmental Protection Agency (EPA), the National Institute of Environmental Health and Safety (NIEHS), and National Institute of Occupational Safety and Health (NIOSH) on nanotechnology's potential risks. Through creation of research priorities for the federal government and industry that will help ensure development and responsible stewardship, the NANO Act looks to remove uncertainty about risk and future federal regulation, resolving uncertainty as one of the major obstacles to commercialization*." (news article not available online anymore)

7. Engaged Scholarship and Big Social Science – the Center for Nanotechnology in Society at Arizona State University

7.1 Introduction

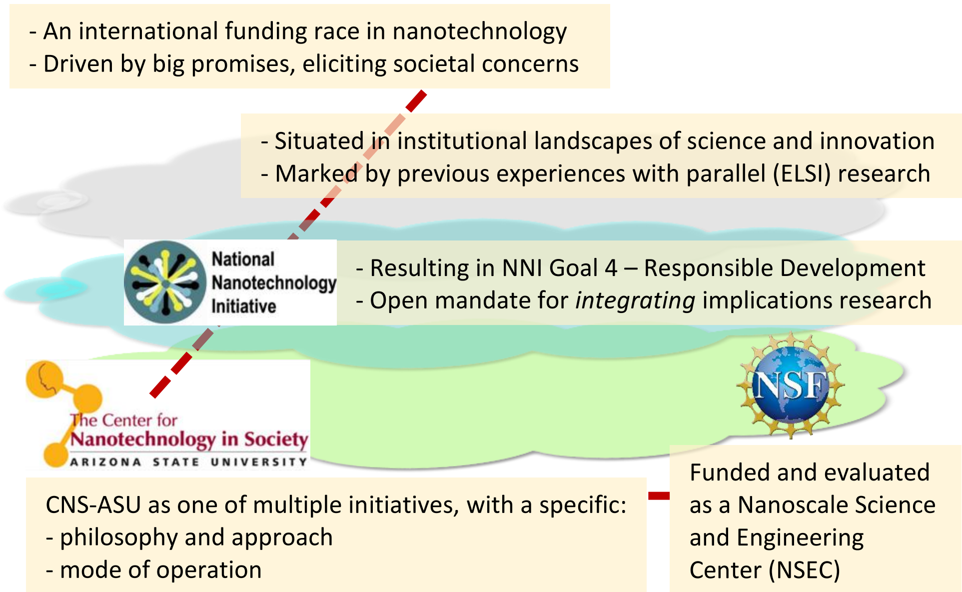
The Center for Nanotechnology in Society at Arizona State University (CNS-ASU) has been the world's largest center for research on the societal aspects of nanotechnology[226] and claimed to have demonstrated a model for advancing the agenda of Responsible Innovation (Guston 2006, 2007a, Valdivia and Guston 2015, Guston, Corley et al. 2016). This is an important claim, for which the center's leadership has put forward two central components: 1) its *philosophy* about integration – i.e. the approach to account for societal dimensions in science and technology and to shape research and innovation accordingly; and 2) its *mode of operation* in the world of science and technology, specifically as part of the large and prestigious US National Nanotechnology Initiative (NNI).

Both features emerged from a specific context. The challenge of integration was defined at the start of the NNI. In response to public concerns about nanotechnology the idea of including research into ethical, legal and social issues (ELSI-research) was proposed. This model of 'parallel research' had been applied for nanotechnology research and innovation indeed,[227] but also was criticized for lacking impact on either science and science policy (see Chapter 1.2). Integrating ELSI-research, therefore, became the new challenge. In the US this specifically has been stipulated by the 21st Century Nanotechnology Research and Development Act (NRDA, US-Congress 2003), which provided an open mandate for experimenting with new approaches (integration "*insofar as possible*"). CNS-ASU took up this challenge by developing and demonstrating a threefold approach of '*foresight, engagement and integration*'. Together and applied more broadly, according to the center, these functions would enable a societal capacity for '*Anticipatory Governance'* (Barben, Fisher et al. 2008).

The other interesting experiment was the new organizational form in which CNS-ASU operated – an NNI interdisciplinary Nanoscale Science and Engineering Center (NSEC). The introduction of these centers reflect various developments in US science policy. Traditional paradigms of 'basic science' were shifting towards 'utility' (Eijmberts 2013), a trend that has been enforced by the claim that investing in nanotechnology would be

[226] As noted on its website https://cns.asu.edu (last accessed 8 March 2023)
[227] In multiple countries, from about 2005 onwards, and in various forms. cf. De Cameron (2006): the 'NELSI-imperative' (nanotechnology-ELSI)

crucial for maintaining US technological leadership. In the context of the competition for the Clinton science initiative that claim was further extended into the promise of a 'new Renaissance' in which natural and engineering sciences would closely work together with social sciences for human progress (see Chapter 1.2). Finally, as the international funding race ignited by the US investments in nanotechnology also resulted in societal implications research elsewhere, CNS-ASU positioned itself not only as an important node in the NNI, but also in international peer communities. This would have to provide for a kind of 'Big Social Science' leverage (Guston 2014, Fisher, Guston et al. 2019).



Governance challenge	
Novelty and emergence	possible societal implications, in relation to (projected) innovation pathways
Aligning promotion and control	early stage consideration of social dimensions and societal implications
Translation into quest	
Anticipation-cum-inclusion	integration of (otherwise) parallel research in the overall research program

⇆

CNS-ASU's mission
Demonstrating a model for: - enabling *Anticipatory Governance* - *engaged scholarship* - *Big Social Science* leverage

Figure 27: setting the scene for investigating CNS-ASU

This chapter approaches the efforts of CNS-ASU as an attempt to work towards forms of Responsible Innovation – against *this* background. That is: in the context of this thesis I am interested in the affordances and limitations of CNS-ASU's approach with respect to transforming responsibility in research and innovation. Yet, to understand how CNS-ASU's approach has been shaped in practice, I will investigate the specific quest of integrating implications research CNS-ASU engaged in and how that played out in the context of the NNI program.

Figure 27 depicts a particular role for the National Science Foundation (NSF) in this respect, for initiating the NNI and administering the Social Dimensions Component Area in it. As one (though largest) of the initiatives in this area CNS-ASU has not been intended to address each and every issue related to nanotechnology, nor having the capacity to reach out to the NNI or US public at large. Instead, CNS-ASU wanted to demonstrate a *model*, a proof-of-concept for 'engaged scholarship' (Radatz, Reinsborough et al. 2019, Youtie, Shapira et al. 2019).

Section 7.2 summarises the main outcomes and achievements of CNS-ASU's activities and reflects on the question how these activities contributed to transforming responsibility. Section 7.3 discusses what factors did shape these outcomes and in what way they have been related to the governance challenge at hand: anticipating societal implications of nanotechnology by integrating implications research in the NNI. Finally, section 7.4 closes with a discussion of affordances and limitations of CNS-ASU's approach and its prospects for mainstreaming in research governance.

7.2 Outcomes and achievements

CNS-ASU was funded in two subsequent grants (from 2006 till 2011 and 2011 till 2016) of six million dollars each, for delivering research, education and outreach. Textbox 1 lists a selection of activities under these headings.[228] The center explicitly added 'partnering' to these activities (Radatz, Reinsborough et al. 2019, Youtie, Shapira et al. 2019). This is reflected in the center itself being based at Arizona State University (ASU), yet with partnering departments of Georgia Institute of Technology and University of Wisconsin-Madison, as well as in additional grants and networks that enabled the centre to double its capacity and to partner with many other institutions, both academic and non-academic. Examples of rather large collaborations are the joint activities with science museums in the Nanotechnology Informal Science Education (NISE) network and the SocioTechnical Integration Research (STIR) program that chose to become associated with CNS-ASU.

[228] Textbox 1 lists the program after the renewal in 2010. When CNS-ASU started in 2005, RTTA 3 was called Deliberation & Participation and RTTA 4 Reflexivity Assessment and Evaluation. TRC 2 started as 'Human Identity, Enhancement & Biology'.

Juxtaposed as the centre's long term goal, is the *methodology* CNS-ASU proposed to develop, called Real Time Technology Assessment (RTTA, (Guston and Sarewitz 2002) and the vision of Anticipatory Governance that CNS-ASU developed in its early years:

> "*to demonstrate and refine the ability to perform RTTA and, in doing so, cultivate reflexivity and build the capacity for anticipatory governance in the NSE* [Nanoscale Science and Engineering, BW] *enterprise broadly conceived. By "reflexivity" we mean a capacity for social learning – by individuals, groups, institutions, and publics – in the NSE enterprise narrowly and society more broadly that expands the domain of and informs the available choices in decision making about nanotechnologies. By "anticipatory governance" we mean a broad-based capacity that extends through-out society that can collect, analyze, synthesize and interpret a wide range of information to manage emerging knowledgebased technologies while such management is still possible.*" (Guston, Corley et al. 2016)

CNS-ASU's leadership has emphasised that for building such a broad-based capacity for integration the components of Foresight, Engagement and Integration should not be organised individually, but connected through 'ensembli-zation' and that the center's program acts as an instrument for that purpose (Guston 2007b, Barben, Fisher et al. 2008, Karinen and Guston 2009, Guston 2014, Sarewitz 2011).

Most of the results documented in the annual reports contend that the activities conducted by and in association with the center are in line with either NSF demands or the Anticipatory Governance vision. As a measure for impact there are numbers about the reach under students and science museums (education, outreach), visiting scholars, networks and publications (research) and the featuring of high profile events like the National Citizens Technology Forum in 2008 (outreach). Occasionally, these numbers are qualified in terms of appreciation or uptake. More substantiated analysis of the kind of impact pursued, is documented in academic output (e.g. Fisher, O'Rourke et al. 2015, Selin, Rawlings et al. 2017). More quantitatively, Youtie, Shapira et al. (2019) have discussed impact in terms of network creation as measured by co-authorship, while Radatz, Reinsborough et al. (2019) discussed acquaintance with social science concepts (like Responsible Innovation or Anticipatory Governance), learning and individual and institutional changes. These sources, as well as the interviews conducted for this research, do not allow for a full evaluation of CNS-ASU's impact, but they do provide an overview of what kind of capacities have been built.

CNS-ASU's research program consisted of four tracks, reflecting the foresight – engagement – integration philosophy of Anticipatory Governance (AG):

1. *Research and Innovation Systems Analysis*: (bibliometric) analysis of trends and dynamics in nanotechnology research publication and developing strategic intelligence based on the analysis of corporate activities
2. *Public Opinion and Values*: polling of expert and public opinions and studying media effects
3. *Anticipation and Deliberation*: developing future scenarios as well as approaches to do so in relation to (public) deliberation events, also organised under this research theme
4. *Reflexivity and Integration*: tracking the influence of CNS at ASU, laboratory engagement (Socio-Technical Integration Research (STIR) project: embedding social scientists in research teams) and studying the integration of societal embedding of nanotechnology at large.

These four research themes constituted the centre's Real Time Technology Assessment (RTTA) program, probing scientific and societal dynamics relevant to nanotechnology, and organising feedback with respect to implications among the centre's audiences. For this purpose also two distinct Thematic Research Clusters (TRCs) were conducted:

- TRC 1: *Equity, Equality and Responsibility*: field studies and workshops with partner institutes in developing countries (esp. South Africa). Development of card game demonstrating inequalities.
- TRC 2: *Urban Design, Materials and the Environment*: mapping problem perceptions, future visions and sustainability issues of (future) nanotechnology applications in the urban environment (multi-criteria assessment, database and speaker series).

CNS-ASU was involved in **education** at many levels, with most of its activities linked to either the schools hosting or partnering in the centre or to its research activities:

- *Graduate*: Master and PhD training in hosting schools, internships and PhD+ (certificate) programs in partnering schools of engineering (e.g. Biodesign Institute, Ira A. Fulton schools)
- *Undergraduate*: courses (e.g. social and ethical implications), honors theses supervision, participation in Innovation Space (2-week interdisciplinary project at ASU)

Training and teaching to other groups much has been related to outreach activities, such as:

- *NISE (Nanotechnology Informal Science Education)*: training of science museums throughout the USA, production of the Encyclopedia for Nanoscience and Society (high school level)
- *Science Outside the Lab (SOtL)*: engineering (grad) students learning about science/policy interfaces during a two-week immersive course/workshop in Washington DC
- *Winterschool*: immersive course/workshop on CNS-ASU's methods and concepts for graduate and post-doctoral students (social sciences)
- *Practitioners training*: science and society module as part of health and safety training for nanotechnology researchers via the National Nanotechnology Infrastructure Network (NNIN)

Finally, training was part of **outreach** activities (ongoing as well as event based), e.g.:

- Public events: *National Citizens' Technology Forum* (NCTF), US citizen panel of *World Wide Views on Climate and Energy*, *Future Scape City Tours* (FSCT, linked to TRC2 and RTTA 3)
- Science café and other events at *Arizona Science Center*:
- Dissemination of (education) models and approaches via international networks and conferences, launch of *Virtual institute for Responsible Innovation* (ViRI)

Textbox 1: CNS-ASU activities (selection, see website [last accessed July 2022] and the final report (Guston et al. 2016) for a complete overview)

In both education and integration research CNS-ASU sought to build individual reflective capacities. An important route for this purpose is the emotional drawing of students and researchers. For example, instead of a traditional ethics course introducing students to questions about societal implications of science and technology, the course ‘Science Outside the Lab’ offers a two-week workshop in Washington DC. Away from home environments and with live confrontations about value conflicts and incommensurable positions, participants learn to appreciate the complexities of science policy making and the relative role of knowledge and scientists in it. Learning goals then were measured by changes in participants’ beliefs about science and society relationships and macro-ethical judgements about these (Bernstein 2016; e.g. the linear model of science to innovation, contributing to societal progress).

Network creation

Building relations and networks alongside building the program has been equally important. Not only ‘target audiences’, like citizens, students, scientists or museum staffers, but also commissioning and peer audiences had to be convinced about the relevance of CNS-ASU’s approach. For NSF, it was important to conduct the program without compromising on academic output and interdisciplinary research. Among peer social scientists CNS-ASU has built a strong reputation, through active participation in networks,[229] hosting a large number of visiting scholars, launching a network for Responsible Innovation scholars (ViRI: Virtual institute for Responsible Innovation) and chief editorship of the Journal of Responsible Innovation (JRI)[230]. (Youtie, Shapira et al. 2019) report that more than 10% of social science publications dedicated to nanotechnology can be linked to the center’s activities, including a high level of publications with interdisciplinary and cross-organisational authorship.

Institutional legacy

At Arizona State University the work of CNS-ASU is being continued in the new School For Innovation in Society (SFIS) and related centers and programs, such as STEM education[231] in the Center for Engagement & Training in Science & Society (CENTSS), deliberative futuring in the Center for the Study of the Future (CSF), or socio-technical integration research in the homonymous STIR program. At the level of the NNI, the CNS-ASU Winterschool on Anticipatory Governance is now offered via the National Nanotechnology Coordinated Infrastructure (NNCI) as the Winterschool on Responsible Innovation and Social Studies of Emerging Technologies.

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[229] For example, next to NISE, CNS-ASU has been involved in the practitioner network Expert & Citizen Assessment of Science & Technology (ECAST). Other network activities have been the organisation of conferences, such as the Congress on Teaching the Social and Ethical Implications of Research in 2011.

[230] See: https://www.tandfonline.com/journals/tjri20

[231] In the US STEM is used as abbreviation for beta sciences (Science, Technology, Engineering, Mathematics)

Ensemblization
The relatively large size of CNS-ASU was an import condition for the 'ensemblization' of the Anticipatory Governance dimensions of foresight, engagement and integration (Guston 2014). For example, RTTA 1 (foresight) introduced bibliometric methods for informing discussions about direction and implications of nanotechnology research with a better understanding technology dynamics (Youtie et al. 2016). In RTTA 3 (engagement), citizens not only engaged in discussions about the future of nanotechnology, but also in the construction of 'futures' themselves, through scenario development and the way these scenarios have been taken up in other activities. In this way both citizens are empowered and practices of 'futuring' strengthened (Selin, Rawlings et al. 2017). In the Socio-Technical Integration Research (STIR) program of RTTA 4 (integration), humanities' researchers were embedded in laboratory teams. How and to what extent these different activities have been interlinked is difficult to trace. Also, not all activities have been enrolled in this philosophy that much. For example, RTTA 2 – Public Opinion and Values – mainly continued the practices of public polling research at partner university Wisconsin-Madison.

Appreciation
From the self-reporting of CNS-ASU (annual reports, papers cited above) as well as my investigation in the next section it can be demonstrated that CNS-ASU did yield a proof-of-concept of its approach to integrating implications research with distinct visibility and continuation at ASU. It covered a broad range of topics related to the social dimensions of science and technology (not just nanotechnology) and has been reaching an equally broad set of audiences, through first contact high profile events with citizens, as well as by in-depth interaction with scientists. In terms of demonstrating a model in the context of national concerted action on nanotechnology, however, it appears that the center's proof-of-concept remained exactly that. After the CNS programs ended in 2016, progress in integrating social dimensions has not been part of the NNI evaluations. The subsequent NNI strategic plan (NNI 2016) briefly framed the CNS accomplishments as having developed a solid basis with respect to addressing ELSI considerations and raising awareness about them, but neither the full approach, nor the capacity has been continued at the level of the NNI. To better appreciate the prospects of mainstreaming CNS-ASU's approach in research governance, the next section therefore further investigates how CNS-ASU's philosophy to integrating social science in nanotechnology, the different modalities of capacity building and the center's leverage to it, have been shaped in practice.

7.3 Analysis

Following the research approach developed in Chapter 3, I will discuss three cross-cuts to CNS-ASU's course of action: 1) it's genesis as a a governance arrangement, 2) the landscape of actors having been involved or otherwise influencing the way in which the center's program evolved and 3) the *de facto* practices in which both actors and arrangement contributed to the way CNS-ASU did shape responsibility in (nanotechnology) research and innovation. The final step in this section discusses in what respect the observed dynamics and outcomes have been constructive and productive to addressing the challenge of integration.

7.3.1 Governance arrangement: geared to demonstration

Establishing centers of expertise is a familiar instrument in research governance, but in the case of CNS-ASU the setting of funding interdisciplinary research, with lead roles for social scientists in the context of a large natural sciences and engineering program was rather experimental. For the Social Dimensions program area in the NNI, the NSF used different funding schemes: rather large budgets for Nanoscale Science and Engineering Centers (NSECs), of which CNS-ASU has been funded, and smaller scale Nanoscale Interdisciplinary Research Team Projects (NIRTs) and Nanoscale Exploratory Research (NER) grants. The various proposals submitted for each category then would provide a range of approaches serving the program area's goal. How a center operates also much depends on the people, ideas and organization backing the proposal. Below, I will pay particular attention to the vision and ambition of CNS-ASU's founders as an important driver, the opportunity provided by the call for integrating implications research and public input in the NNI and the matching institutional space at Arizona State University (ASU). Together, these factors created an environment for demonstrating CNS-ASU's model.

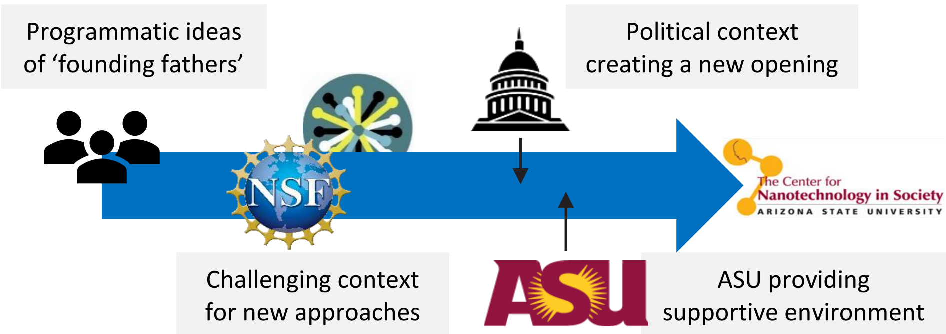

Figure 28: conditioning factors in CNS-ASU's genesis

Driver: the founding role of three political scientists

CNS-ASU's mission and approach is rooted in the work of three social scientists in the late '90s: Michael Crow, Daniel Sarewitz and Dave Guston. They knew each other from Columbia University (New York) and shared ideas and ambitions to transform science and society relations by public input as well as collaboration between social science and natural sciences and engineering.[232] When Guston and Sarewitz wanted to seize the opportunity for experimenting with these ideas in the context of nanotechnology, Crow could provide a matching space as host organisation: CSPO, the Consortium for Science, Policy & Outcomes.[233] CSPO had been founded by Crow in 1999, in Washington DC, with Daniel Sarewitz as director. After Crow had become president of ASU in 2002, CSPO moved over at the time of preparing for the solicitation for CNS-ASU in 2004. Receiving the award enabled CSPO to almost double its capacity. As Principal Investigator (PI) for CNS-ASU Guston joined CSPO as co-director in 2005, while Sarewitz continued heading the office CSPO had kept in Washington DC.

Opportunity: integrating Social Dimensions research in the NNI

Options for integrated rather than parallel implications research in the were already discussed in a 2001 workshop by NSF and in the subsequent NSF solicitation for such research (Bennett and Sarewitz 2006). Guston and Sarewitz submitted a proposal in which they positioned their approach of 'Real Time Technology Assessment (RTTA) vis-à-vis two landmark developments in US science policy: the rise of the ELSI-model of parallel research, which they regarded as a sign of ongoing transformation in research governance, yet expert driven and impact lacking; and the elimination of the Office of Technology Assessment (OTA) in 1995. OTA had been a well-known agency informing Congressional member and committees on issues related to science and technology. Its elimination has been widely discredited as a political move overriding science and, consequently, the perceived position of scientists. Guston and Sarewitz contended to this view, but also took issue with the rational assessment approach of OTA, for reflecting classical ideas about science as objective truth delivery. Alternatively, they proposed "*a new OTA*" with a more incremental, reflexive and deliberative approach; loosely modelled after the Constructive Technology Assessment (CTA) approach developed in The Netherlands (cf. Schot and Rip 1997) and the consensus conferences with citizens developed in Denmark[234]. With respect to the challenge of integration, they picked up on the idea of 'modulation' from CTA as differing from attempts to assess and control new technologies in a predictive manner.

Apparently, these ideas didn't find fertile ground in the NSF review committee. The proposal received explicitly negative critique and other, more regular implications research proposals were funded.[235] To Guston and Sarewitz the response to their proposal had been 'insulting' (<Guston>) and they decided to publish an edited version of the proposal as a scientific paper (Guston and Sarewitz 2002). In the paper they made

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232 This is reflected in, for example, the 'Living with the Genie' conference organised by Crow and Sarewitz, joint work of Sarewitz and Guston (e.g. Guston, Woodhouse & Sarewitz 2001) and the work of Guston (2000a,b).

233 Originally the 'C' stood for Center. When moving to ASU CSPO was renamed.

234 The consensus conference model was developed by the Danish Board of Technology in the '80s.

235 E.g. grantees at Harvard and University of South Carolina.

the case for working close to scientific and technological development again, but they also emphasised the experimental character of RTTA and elaborated on potential problems of scale or lack of acceptance. Being aware of the US context, Guston and Sarewitz stressed the expert character of RTTA though, by giving more emphasis to expert polling and scenario writing. Also, where CTA stimulated reflexivity more institutionally, Guston and Sarewitz focused on eliciting reflexivity of individual scientists.

Changing frame conditions: mandate by the NRDA and a place at ASU

About 2003 public and political debate about nanotechnology intensified. Congress wanted a tighter control on the massive funding that went into the NNI and started preparing the 21st Century Nanotechnology Research & Development Act (US-Congress 2003). At the CSPO office in Washington DC, Guston and Sarewitz were well aware of the discussions in Congress. Langdon Winner, for example (a well-known STS scholar and political theorist), warned the House committee not to replicate the ELSI-model. This reinforced the growing interest among scholars, policy makers and scientists themselves to integrate implications research into nanotechnology R&D as well as R&D policy (Fisher 2005, Fisher and Majahan 2006, Fisher 2019). The NRDA provided a mandate for that, as well as interdisciplinary research centers and public input and outreach through the National Nanotechnology Coordination Office (NNCO). NSF further broadened the range of topics and issued a solicitation for a big NSEC on nanotechnology in society ($13mln.) in 2004. This time the pre-proposal of CSPO was received more positively, but NSF asked for more institutional backing as they questioned whether CSPO could pull off such an approach indeed (<Guston>).

At this point, Michael Crow – now ASU president – could offer his support by instructing an interdisciplinary group of CO-PIs at ASU to cooperate. This has been the start of productive liaisons for CNS-ASU, for example with the BioDesign Institute which brought in own money as well. Together with Ira Bennett, who had moved from the BioDesign Institute to CSPO, Guston further developed a program proposal that built on this ASU network as well as partnerships with the Georgia Institute of Technology and University of Wisconsin-Madison. In the end, however, NSF considered a mix of approaches less risky and distributed the budget over a number of proposals submitted: two larger NSECs – CNS-ASU and CNS-UCSB[236] – respectively receiving $6mln and $5mln and some smaller projects.[237] As a consequence, CNS-ASU had to cut down some parts as well as leaving specific topics.[238]

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236 University of California, Santa Barbara; see: http://www.cns.ucsb.edu/ (archive, last accessed 8 March 2023)

237 Nanoscale Interdisciplinary Research Team Projects: Harvard/UCLA/NBER ($1.7mln); University of South Carolina ($1.4mln); Michigan State University; NanoBank; National Nanotechnology Infrastructure Network

238 E.g. risk and safety issues, which have been covered by CNS-USCB. In this way the two centers tried to work complementary as much as possible.

Conditions for transforming responsibility: contingent, contradictory and well seized
The combination of driver (programmatic ideas) and context (NNI research funding, political debate, ASU environment) has been more than just providing an opportunity. First, the NRDA mandate didn't make the adoption of CNS-ASU's approach self-evident. According to Fisher and Majahan (2006) the NRDA did build on broader trends, such as the 'broader impact' review criterion of the NSF. At the same time, the NRDA continued a language of rapid development. The accompanying frame of determined technological change and societal progress contradicts the frame of science and technology as socially constructed underlying the call for responsible development in nanotechnology. Moreover, the mandate for integration was left open, since the NRDA did not specify the considerations to be integrated, or by what authority that would have to be decided. Instead, the NRDA added "*insofar as possible*" to integration, and "*as appropriate*" to public input and outreach (US-Congress 2003). This open mandate allowed for experimentation, but also left the incumbent frame of science to innovation untouched, as well as the competition of models and approaches to integration in the Social Dimensions program component area of the NNI.

Second, the process of rejection, scrutinising and downsizing further geared CNS-ASU's disposition towards demonstration. Where the response to the first proposal had been 'insulting' to what later became CNS-ASU's leadership, developing a $13mln program for a new approach had been 'insane', adding to the internal bonding of CNS-ASU's leadership (<Bennett>). This was further reinforced by the strong, yet careful positioning of CNS-ASU's approach towards peer social scientists, especially when the budget had to be shared with competing proposals. For example, in the paper Bennett and Sarewitz (2006) developed from the final proposal, they polemically stated that social science had been nowhere when the NNI was starting up, while on the other hand they emphasised the experimental nature of CNS-ASU's approach, inviting others to embark on such experiments as well. As will become clear below, these highly locally and historically situated conditions have been both enabling and constraining the prospects of transforming responsibility in nanotechnology research and innovation as organised in the NNI.

7.3.2 Actor landscape: allowing for the experiment

As much as CNS-ASU's commitments at the start were channelled by social relations, so did the space allowed for practicing CNS-ASU's vision and mission depend on the actor constellation the center had to work in. In particular, the ASU environment did shape the way in which CNS-ASU has been reaching out, to scientists, citizens, students and museum staff. Equally important though, was the traditional academic business model of acquiring peer esteem through publishing and networking, as demanded for by NSF.

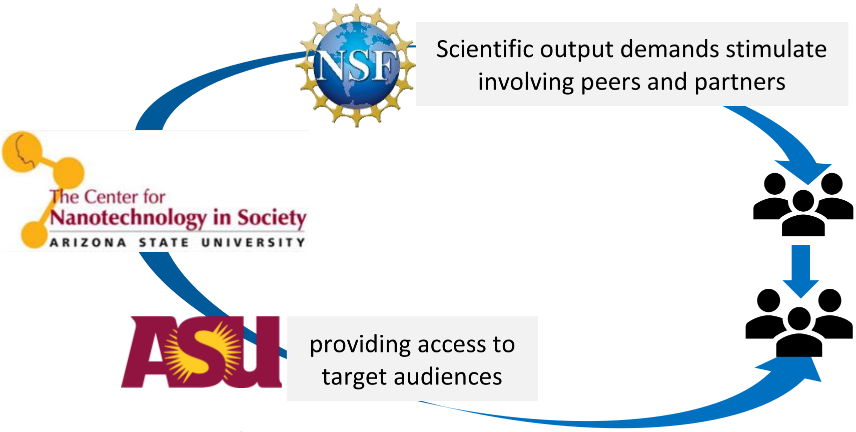

Figure 29: routes towards integration

Reach to primary audiences

An important pathway to integration for CNS-ASU was its involvement in teaching and course development for doctoral, graduate and undergraduate students. The overview provided in the final report (Guston, Corley et al. 2016) lists training of doctoral students as linked to CNS-ASU's research activities, in particular the Public Opinion and Values research in Wisconsin (RTTA-2) and the STIR-project on laboratory engagement (RTTA-4), but also in fellowship programs with the BioDesign Institute and the Ira A. Fulton School of Engineering at ASU (PhD+ programs) or the Human and Social Dimensions of Science and Technology (HSD) doctoral program of CSPO itself. Furthermore, various graduate courses were established at ASU, covering topics like science and policy, sustainability or future scenarios. For ethics courses different models have been tested (e.g. embedded, stand-alone, hybrid), all of which were evaluated better than regular ethics and integrity courses according to the 2016 report. Other education activities involved the Science Outside the Lab workshops (see Textbox 1) or participation in ASU's two-week design workshop Innovation Space.

A large program for both outreach and education was the Nanotechnology Informal Science Education network (NISE Net), for which CNS-ASU developed guides on nanotechnology and society (used for the annual NanoDays by the NNI) and organised a series of workshops for training museum staff. CNS-ASU also actively disseminated its teaching models to collaborating universities as well as professional networks, including the Congress on Teaching the Social and Ethical Implications of Research in 2011 and the Social and Ethical Implications training in the Center for Integrated Nanotechnologies (CINT, Department of Energy) and the National Nanotechnology Infrastructure Network (NNIN; NSF/NNI).

ASU: home and principal

Access to student populations was made possible by starting CNS-ASU with a group of fourteen co-PIs on instigation by Michael Crow. Education activities covered an equally broad range of disciplines as represented by this group (Guston 2010). Moreover, under the presidency of Crow, ASU has been reorganized following the model of the '*New American University*'[239]. ASU's charter and goals are based on excellence, access and impact (Crow and Dabars 2015), in which excellence is defined as responsive, relevant and impactful. Disciplinary oriented schools and institutes have been turned over and new interdisciplinary ones created. This ongoing process is guided by eight principles[240] aiming for societal relevance and also has paid off in an increasing number of students and related financial income, especially from disadvantaged student groups (bringing in aid grants), as well as an increase in awarded research grants (Randles 2017b). The redesign of ASU has been beneficial to CNS-ASU in a number of ways. Interdisciplinary research was stimulated, as well as linking research to education and encouraging an entrepreneurial spirit (Guston 2007b, Randles 2017b). The Crow presidency also forged collaborations all over ASU, including shared positions between engineering schools and CSPO/CNS-ASU.[241]

The tandem CSPO/CNS-ASU created further leverage for both, for example in degree programs administered by CSPO or new educational approaches and instruments developed under the banner of CNS-ASU. Next to financial income through education and further growth by associating other research grants the tandem also allowed for the required professional support (e.g. appointment of a program manager and a communications officer). Furthermore, the co-development of CSPO and CNS-ASU provided inroads and outlets (collaborations, publications, conferences) in different disciplines (e.g. public administration, science and innovation studies, organisation theory) as well as proximity to federal politics and policy making through the DC office (e.g. Congressional briefings, cooperation with PEN[242], conference and book series 'The Rightful Place of Science'). Finally, the joint capacity enabled the launch of a new School for the Future of Innovation in Society (SFIS) as pursued by Crow (<Guston>)

Peers and partners

Beyond ASU, partnerships and peer esteem helped CNS-ASU to increase its reach. Next to the partners at the start, there have been the network of 'friendly competitors' and an increasing number of collaborators and affiliated researchers providing an evolving base to further build on. The partner universities Wisconsin and Georgia Tech not only brought in appealing methods and expertise, such as public opinion research (high attention value) or bibliometric mapping (a relatively new field, strengthening the

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[239] See: https://newamericanuniversity.asu.edu/node/25 See also Dabars and Dwyer (2022).

[240] "*Leverage Our Place; Enable Student Success; Transform Society; Fuse Intellectual Disciplines; Value Entrepreneurship; Be Socially Embedded; Conduct Use-Inspired Research; Engage Globally*"

[241] Source: personal communication of Erik Fisher during my visit to CNS-ASU February 2014

[242] Project on Emerging Nanotechnologies, run by the Woodrow Wilson Institute, see Chapter 6.

scientific image of social science research), but also related networks, like ECAST (Expert & Citizen Assessment of Science & Technology). With CNS-UCSB and the earlier NSF/NNI projects on societal aspects (South Carolina, Harvard, UCLA), which received renewal funding in 2005 as well, CNS-ASU constituted a "*network for nanotechnology in society*".

This network enabled coordination for the social science contributions to the annual NNI NanoDays and NSF NNI Grantee Conferences (Guston 2010), but also served as a stepping stone towards internationalisation. CNS-ASU has been actively involved in broadening the scholarly outlets for social science and humanities research in relation to nanotechnology (e.g. the Springer journal NanoEthics) with the Yearbook of Nanotechnology in Society series (also published by Springer) and establishing the international Society for the Study of Nanoscience and Emerging Technologies (S.NET).[243] This network further pushed the notion of Responsible Innovation, which CNS-ASU together with other S.NET members could further capture in acquiring a NSF grant for establishing a Virtual institute of Responsible Innovation (ViRI) as well as the launch of the Journal for Responsible Innovation (JRI).

The position at ASU as well as the partnerships and the networks contributed to a large number of collaborations and affiliations, including many visiting scholars.[244] For CNS-ASU the latter was an important route. CNS-ASU researchers were linked to members of its peer networks in specific events (e.g. a workshop on synthetic biology linked to a special issue in JRI) as well as the annual Winter School on Anticipatory Governance. Instead of an advisory committee, CNS-ASU had a board of visitors, which members could work as ambassadors. For example, NISE Net Director Larry Bell promoted the Anticipatory Governance vision among science museum projects. The other way around, researchers collaborating with CNS-ASU moved over to the center.[245]

NSF's non-steering assessment regime

CNS-ASU's networking was stimulated by the way NSF has been evaluating the center. Following up on its promotion of nanotechnology as an enabler of technological convergence, NSF stimulated interdisciplinary research in the NNI. In the context of the NNI, this also included mission oriented research, for maintaining US global leadership as well as for integrating societal dimensions research. However, both this latter goal and the interdisciplinary aspect, were far from being taken for granted. Traditionally NSF funds 'basic science', as distinct from mission oriented agencies and departments. The added value of NSECs, and especially CNS-ASU's approach to it, therefore had to be demonstrated within the NSF as well. For CNS-ASU this had different implications. First, the program had to be downsized as NSF split the CNS-budget across different awards (see section 7.3.1).

[243] http://www.thesnet.net/

[244] see Guston et al. 2016 for an overview

[245] e.g. Fisher and Majahan coming from Colorado at the time of the renewal, or Andrew Maynard (board of visitors) and Charlene Cavalier (ECAST network) joining SFIS.

After this start, NSF has been largely ‘non-steering’ in content, up to loosening the requirement of relating to nanotechnology at the renewal in 2010, but all the more applying a strong ‘assessment regime’ (<Guston>). For CNS-ASU this came with a relative freedom in organizing its activities, but strict criteria for documenting and demonstrating that the center was able to generate sufficient academic output in the first place. The output had to cover multiple disciplines and to testify to CNS-ASU’s approach, while in addition, CNS-ASU had to demonstrate networking effects and to meet demands for providing career development. Next to the annual reports, this stimulated CNS-ASU’s self-tracking and self-accounts[246] for demonstrating progress. NSF also commissioned CNS-ASU to analyse the integration of social science in the NNI (Rogers et al. 2011), which indirectly contributed to CNS-ASU’s claim about integration as well.[247]

Actor positions reinforcing starting conditions

The discussion in this section does not allow for evaluating how the activities by CNS-ASU, such as teaching approaches, have been received and in what ways exactly these have contributed to the challenge of integration. I will discuss this question indicatively in section 7.3.4. Above, I have highlighted that the strong commitments CNS-ASU started with, were further channeled by a dual dynamic of its place at ASU and the demands from NSF. The latter not only allowed for experimenting with a new approach, but also stimulated interaction with and outreach to peer audiences. At ASU, the co-development of CNS-ASU and CSPO has been instrumental to the launch of a new school. Together, these factors shaped the way CNS-ASU has been able to reach target audiences.

7.3.3 *de facto* governance practice: CNS-ASU as an ambidextrous organisation

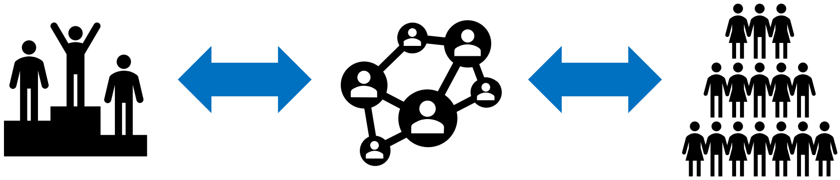
The third cross-cut concerns the way CNS-ASU practiced its vision on supporting Anticipatory Governance *as a centre*. Figure 30 depicts two interrelated features of vision and mode of operation: 1) opportunity seeking and 2) community building.

[246] E.g. Barben et al. (2008) and Guston (2010) in lining up to the renewal < Guston >; Youtie and Shapira (2014) on network creation; Karinen and Guston 2010 and Valdivia and Guston 2015 on Anticipatory Governance.

[247] The analysis for the NSF audit built on earlier bibliometric mapping of nano-social science (Shapira, Youtie et al. 2010) and did not include an assessment of either CNS-ASU or CNS-UCSB.

Opportunity seeking:

- Active venturing and cross-linking
- Meeting external demands



Community building:

- Cultivating a pioneering identity and champion figure
- Inviting others to join in

Figure 30: CNS-ASU's approach to building a center

Opportunity seeking

Like any other academic center, CNS-ASU could fulfil the NSF required functions of research, education and outreach, because of its university based organisation. However, CNS-ASU has been especially active in cross-linking activities. To build CNS-ASU's program, early career scholars were hired, delivering post-doctoral training as output for the centre. The link with CSPO enabled newly hired faculty to develop their careers in relation to the different research strands and associated centers. The other way around, the (doctoral) students receiving supervision and certificates, also contributed to research (Guston, Corley et al. 2016). At program level, research constituted the default institutional base, but also informed and enabled engagement and outreach activities and vice versa.[248] For example, an activity like Future Scape City Tour (Foresight, TRC 2) could build on local collaboration as well as CSPO expertise, while an academic conference like Governance of Emerging Technologies (GET) also benefitted disciplinary output as well as CSPO/CNS-ASU impact.

Especially important for demonstrating the integrative approach towards Anticipatory Governance across the program while meeting output targets for each of its components, has been the leverage created by associating other (research) projects to the center's program. These concerned larger as well as smaller NSF projects, like the Nanotechnology Informal Science Education (NISE) network for RTTA 3 (Engagement), Socio-Technical Integration Research (STIR) for RTTA 4 (Integration), or the Virtual institute of Responsible Innovation (ViRI) and the NSF audit of social science integration

[248] For example, nanotechnology prospects for water treatment have been studied in RTTA 1, whereas related equity issues have been subject of TRC 1 workshops and training (counting as engagement and outreach); methodological development of 'futuring' in RTTA 3 contributed to the Future Scape City Tours (both TRC 2 and outreach), while ideas about 'modulation' in RTTA 4 have been tested in laboratory engagement project STIR.

in the NNI. Cross-linking these activities was part of the vision, as well as necessary to generate the infrastructure, scale and variety of "*big STS*" (Guston 2014) required for the 'ensemblisation' in and of the different program components. At the same time, CNS-ASU strongly relied on associated projects like NISE and STIR in its self-reporting to NSF.

Community building

Closely related to opportunity seeking was community building, which I have synthesized from personal observations and interviews (<Ash, Bennett, Guston, Trinidad, Wetmore>) during my research stay at CNS-ASU (February 2015). Where the center's commitment to demonstrate a model, the entrepreneurial culture at ASU and the champion figure CSPO/CNS-ASU had in both, has been driving opportunity seeking, CNS-ASU's leadership also deliberately cultivated a pioneering identity. The center called itself a 'social lab', doing 'experiments', organising 'lab-meetings' and 'sharing facilities' for visiting and affiliate researchers. In this way, interdisciplinary research had as much to do with practitioners exchange as with disciplinary expertise. Adding to this has been the building of the center trough the building of careers. This is what NSF asked for [249], but also what the center could offer as stimulated by the CSPO leadership.

Internal community building has been important for the challenges encountered in external community building. Despite the favourable conditions at ASU, establishing collaborations with the science and engineering communities was hard work, in which the successful relations were driving on friendships as much as mutual benefits (<Bennett>). CNS-ASU faculty had to be entrepreneurial and constructive, offering fun in education, while preserving expert authority. Building external relationships benefitted from internal cooperation and sharing of experiences. In turn, the center actively and self-consciously opened up its pioneering culture to visiting and affiliate researchers.

Dynamics: situated logics of practice shaping responsibility transformations

(Randles 2017b) situates CNS-ASU's mode of operation in the broader transformation of ASU, towards the model of the New American University, which she typifies as an 'ambidextrous organisation'; i.e. successfully managing the dual process of exploring and exploiting innovation.[250] Likewise is the relation between staff and home organisation: "*the Ambidextrous PI exhibits a capability to work across discipline boundaries including, crucially, across social and engineering sciences. This is a critical capability for addressing societal challenges, albeit facilitated by the organizational structures and incentives provided by the centre of the organization via cross-university interdisciplinary institutes*".

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[249] See Guston et al. (2016): e.g. Bennett, Fisher, Selin, Wetmore. Yet, a number of changes in staff at the time of the renewal has been reported as well.

[250] O'Reilly and Tushman (2004), as referred to in Randles (2017).

CNS-ASU has been both part of and contributing to the transformation of ASU, in the professional formation of its own staff as well as by navigating the center's program between internal commitments and external demands. For example, not every aspect of the community building will have been visible to all actors involved (both internal and external), nor equally successful for each and every part of the program. But it did contribute to the experimental, constructive and entrepreneurial image and identity of CNS-ASU. This role and figure of social science for integrating social dimensions research in science and technology programs, reflected the thrust of Real Time Technology Assessment. Bringing it into action, however, required more than just having the centre located at ASU. It did involve opportunity seeking and community building as two interrelated features in building the center.

7.3.4 CNS-ASU's approach: constructive and productive?

Where the previous sections served to understand how CNS-ASU's activities were shaped in practice, we can now turn to the question in what ways these activities have been constructive and productive to addressing the governance challenge at hand: integrating implications research into nanotechnology science and engineering and facilitating that by an interdisciplinary research center. In Chapter 3 I have defined 'constructive' as congruence in problem and solution framing and 'productive' as the extent to which responsibilities have been (re-)aligned accordingly. For applying these evaluative categories to CNS-ASU, two notes are in order.

First, CNS-ASU engaged in a specific quest (exploring post-ELSI approaches), with a specific appreciation of the challenge of integration. What is at stake for integrating social science in science and technology, according to CNS-ASU's philosophy, is to provide for the right conditions in the first place. Contrasting to assessing values and issues, as in the ELSI-research model, CNS-ASU aimed for enhancing the sensitivity and receptivity of actors involved in science and technology governance to recognise and act on these values and issues. Furthermore, CNS-ASU emphasises that such reflexive capacities have to be broadly conceived, as is the range of contexts in which they have to be found.

Second, CNS-ASU's quest has been situated in the specific context of US science institutions. Laurent (2012), a visiting scholar at CNS-ASU, describes this context as marked by stark demarcations between facts and values and between science and policy, both limiting the role of social scientists to either observer or facilitator. The RTTA approach proposed by (Guston and Sarewitz 2002) challenged these traditional roles and explicitly called for modulating science-society relations. In this respect, the quest of CNS-ASU can be conceived of as a social experiment in reconfiguring responsibility by redrawing the boundaries of social science expertise. The challenge for CNS-ASU has been to show that this can be done constructively, towards target audiences of scientists and engineers, citizens, professional and policymakers, as well as towards its peer audiences of social scientists, for whom the center had to earn and demonstrate credibility.

Discussing the constructive and productive qualities of CNS-ASU's activities, therefore, applies to different levels. For the overall program CNS-ASU had to demonstrate *that* (and how) its Anticipatory Governance vision made sense to target audiences and *that* its center model matters in this respect – or in CNS-ASU's own phrasing: "*to validate Anticipatory Governance as a generative strategic vision*" (Guston, Corley et al. 2016). What cannot be evaluated here, if only because out of reach for CNS-ASU itself, is to what extent the envisioned broadbased societal capacity as conceptualised for Anticipatory Governance indeed works as a constructive and productive response to the challenge of anticipating societal implications of nanotechnology at large and modulating research and innovation governance accordingly. At that level CNS-ASU's vision of Anticipatory Governance works as a proposition for creating constructive conditions, while its component reflexive capacities (in foresight, engagement and integration) have to be productive in relation to other governance structures and strategies (e.g. science and innovation policies, corporate social responsibility, regulations, cf. Guston 2014, Valdivia and Guston 2015).

What had to be demonstrated, though, is that such capacities can be built at all and how to do so in existing institutional contexts. This is where the different modalities of reflexive capacity building discussed in section 7.2 come in: *cognitive* capacities, in changing frames and vocabularies about science and society relations[251]; supported by *social* capacities, in building partnerships through which cognitive capacities could stick; extending into *institutional* capacities, by creating an infrastructure for the integration of social dimensions research. Crucially, for being productive these capacities thus have to enforce each other, in the same way as the components of Anticipatory Governance are thought to make a difference only when they can build on each other.

Here as well, CNS-ASU has not been in the position to demonstrate such 'ensemblisation' for its whole program, exactly because it had to work in existing contexts, to meet multiple demands and to build the program as it developed, including different timelines involved. In order to go beyond CNS-ASU's self-reporting, I will therefore single out two strands of activities CNS-ASU particularly highlighted in its annual reports to NSF, discuss how the center's leverage contributed to the 'ensemblisation' of these and other capacity building activities,[252] but also reflect on the relation between the different levels and modes of capacity building in the broader context of supporting socio-technical integration in the NNI.

[251] "changing vocabularies" is a phrasing of director Dave Guston in the interview during my research stay at CNS-ASU as well as in response to my presentation at a staff meeting.

[252] A comprehensive overview of activities and outcomes would require systematic evaluative materials, such as for the Science Outside the Lab workshops (Bernstein 2016). For most activities these are not available.

Example 1: Futuring

In RTTA-3 (Anticipation and Deliberation, see Textbox 1) the 'futuring' activities dealt with a core topic of implications research: anticipating future impacts of science and technology. CNS-ASU approached the challenge of integration for these activities in two ways: developing methods for how to think about the future and for including relevant voices in future scenario development. (Selin 2007) and colleagues (Selin, Rawlings et al. 2017) argued against the approach of scenarios constructed by experts as a means to predict (possible) impacts of emerging technologies. Instead, they emphasised the socially constructed nature of 'futures' and the dynamic nature of markets and social relationships (Laurent 2012). Accordingly, instruments should not be about prediction, but about a reflexive orientation on plausible futures and the dynamic factors influencing them. Also, acknowledging that "*the future is an active arena*" (Selin 2007) implies that different groups not only have different visions about, or stakes in the future, but also particular roles in the construction of it.

Translating this approach into scenario development activities has been evolving over time. For example, in the early years, the 'doc-in-the-box'- workshop on point-of-care diagnostics (Selin 2008) was a "*more traditional scenario development workshop*" with experts (Karinen and Guston 2009). In this workshop, a concept like 'lock-in' created an inroad for anticipation in a non-predictive manner (ibid.). Lock-in is a rather technical concept, but which makes sense for a public of experts. In contrast, the 'Future Scape City Tours' (FSCT) event towards the end of CNS-ASU's program, was designed around a citizen-led agenda about the future of the build environment. In this event, public engagement, which traditionally is being discussed in terms of legitimacy towards decision making, was explicitly related to futuring, so as to enhance the personal, political and civic capacities required for both thinking about the future and acting upon it (Selin, Rawlings et al. 2017)[253].

According to Laurent (2012) this approach to scenario development also served to demonstrate that the future actually can be intervened in by "*reorienting action*" and "*modifying attention*". This has been an important claim towards peers (ibid.). For NSF-officials questioning the plausibility of the scenarios, scenarios have been constructed and tested in the NanoFutures project, the National Citizens Technology Forum (NCTF) and by feedback of ASU researchers (Laurent 2012). Additionally, material used in events like the 'doc-in-the-box' workshop has been instructive for CNS-ASU's involvement in graduate research (Karinen and Guston 2009).

[253] Selin et al. 2017 list the following design principles: 1) Citizen-set agenda; 2) Social construction; 3) Integrate different expertise; 4) Material deliberation; 5) Tempered futures

Example 2: Socio-Technical Integration Research (STIR)
In RTTA-4 (Reflexivity & Integration), Socio-Technical Integration Research (STIR) has been the main project.[254] STIR was brought to CNS-ASU by Erik Fisher as a separate grant from NSF and several other co-funding sources.[255] STIR is a laboratory engagement activity, in which 'embedded humanists' have been participating in laboratory teams, working together with natural scientists and engineers, but also asking questions and engaging in structured interaction. In this way researchers were made aware of the everyday decisions they make in research design and technological development and stimulated in their deliberation about (potential) societal implications (Fisher 2007). Concurring with the critique on the ELSI-model, Fisher positioned his approach between (upstream) public engagement and (downstream) societal implications research as 'midstream modulation' (Fisher, Mahajan et al. 2006, Fisher and Schuurbiers 2013). STIR also differs from laboratory engagement approaches of ethicists, by *eliciting* reflection in a non-prescriptive or confrontational way, aiming to "*expand scientists imagination and sense of the self as involved in (decision making) in science and technology*".[256]

The STIR final report (Fisher and Guston 2012) suggests that changes in individual attitudes and laboratory team interactions have been reported long after STIR activities took place. Impacts on science and technology trajectories were, however, far more difficult to identify (ibid.), even though numerous examples of changes in material practices, laboratory research developments, and in some cases laboratory research directions were documented empirically (Radatz, Reinsborough et al. 2019). Therefore, STIR first and foremost supported *constructive* interactions as a condition for *productive* integration. According to the final report, this is what actually required the majority of the effort, as socio-technical frames were often met with strong opposition. What STIR has demonstrated is that its interventions are actually possible and that integration does not harm the productivity or advancement of science.

Furthermore, (Radatz, Reinsborough et al. 2019) state that the STIR project and its results served as a proof of concept for the integrative agenda of Anticipatory Governance and provided an empirical and methodological basis for approaches to responsible innovation. This has been achieved through scholars trained in the approach, extending into additional STIR studies, dissemination in academic publications,[257] and the inclusion of STIR in multiple funding awards such as the NSF

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[254] Other work included monitoring integration at ASU (annual interviews) and in research funding (Rodríguez, Fisher et al. (2013), Fisher and Maricle (2014).
[255] Cf. Fisher (2005). Before moving to CNS-ASU, Fisher was working on what became the pilot STIR laboratory engagement project at the University of Colorado, Boulder, which was a member of the Nanotechnology in Society Network.
[256] Quote from Erik Fisher when presenting STIR at the ViRI annual meeting in Brighton, 2015
[257] e.g. Fisher and Rip 2013, Rodriguez et al. 2013; Fisher et al. 2015, Fisher et al. 2016. Also, STIR studies have supported modulations in industrial labs (e.g. Flipse, van der Sanden et al. (2013), engineers have taken the approach up themselves (McTiernan et al. 2016) and different

funded ‘STIR cities’ project (building on TRC-2) as well as several European projects (NanoDiode, TERRITORIES, D-STIR, ROSIE). At the end of this section, I will reflect on this claim with respect to the NNI program as well as academic networks more broadly.

Other activities and center leverage to ‘ensemblization’

For other activities equally variegated achievements in capacity building have been reported. For example, in education, single courses can provide important triggers for changing individual conceptions of science-society relations, but the ability to follow-up on these, is depending on the institutional environment. At ASU, conditions were favourable in this respect, while for participants in the Science Outside the Lab workshops this would be much harder (Bernstein 2016).

An important inroad to the public domain has been the strategic partnership with the Nanotechnology Informal Science Education network (NISE net). This network, also funded by NSF, spans 600 organisations and offered a platform for transmitting a core set of basic ideas about technology and society (on values, relationships and systems[258]). With many science museums involved, NISE Net covered a total annual audience of 10 million visitors. This scale and NISE Net’s budget of $20mln in each of the successive five year grant periods, provided an opportunity for CNS-ASU to “*move the needle*” (<Bennett>) in the US public discourse on science and technology – even more so because the ‘three basic ideas approach’ can be applied to other ‘technologies’ like synthetic biology as well in the new NISE network.[259]

Informing policymaking with bibliometric analysis (RTTA-1) and public opinion research (RTTA-2), in contrast, requires other infrastructure and strategies. For these activities CNS-ASU had to be positioned as a center of expertise in the first place. For example, the long term effort required for running bibliometric studies, underlines the need for scope and scale, stretching even beyond CNS-ASU’s abilities. In order to understand future trajectories of emerging technologies, the partnering team at the Georgia Tech Science Technology and Innovation Policy (STIP) department first had to put much effort in building and maintaining a proper dataset (cf. Youtie et al. 2016)[260]. Policymakers

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conditions for STIR projects have been identified in Eastern Europe contexts (Lukovics and Fisher 2017).

[258] As in CNS-ASU’s guidance for bringing nanotechnology in conversation with museum visitors (Wetmore et al. 2013): “Values shape how technologies are both developed and adopted; Technologies affect social relationships; Technologies work because they are part of larger systems”. CNS-ASU also has been training museum staff and volunteers, participating in the annual NNI NanoDays and developing a mini exhibition on social and ethical issues of nanotechnology.

[259] Cf. the outlook provided by NISE net director Larry Bell and his evaluation at the NNI NSE grantee conference 2016 (last accessed 8 March 2023).

[260] “Five main lessons can be identified that could be useful to other long-term efforts to *conduct bibliometric analyses of emerging technologies. These are: (1) the importance of being part of a social science center oriented specifically toward the technology; (2) taking an agile approach to*

were informed about the publications resulting from the program and in two occasions this has led to references to project reports in PCAST reviews of the NNI (ibid). However, PCAST-reviews have been politically charged from the start (see Chapter 6), which challenged the reflexive uptake of the bibliometric studies. Likewise, the bibliometric research on the use of Environmental Health and Safety (EHS) research (Youtie, Porter et al. 2011) and the shift to active nanostructures potentially intensifying EHS concerns (Subramanian, Youtie et al. 2010) does point to the socially structured nature of EHS knowledge generation and use (a reflexive purpose), but remained rather distant from feeding into EHS research agendas.

The relevant context for working towards systemic change in nanotechnology research and innovation was the NNI program. At this level CNS-ASU facilitated exchange between different activities in the Social Dimensions Program Component Area, enabling a portal function for the Social and Ethical Implications activities in the NNCI[261]. As of the final years of CNS-ASU, the Winter School on Anticipatory Governance and Science Outside the Lab was offered via NNCO. Staffing the latter activities as well as the cooperation with the NISE network have been continued by the new SFIS school at ASU. This is an important part of the institutional capacity contributed to by CNS-ASU. In terms of meeting NSF demands, CNS-ASU's achievements were acknowledged through renewal of the core grant, as well as additional and follow-up grants for a number of activities.[262]

In the larger context of the NNI, however, the joint work of CNS-ASU and other activities in the Social Dimensions PCA has been portrayed as "*The NSF-funded Centers for Nanotechnology in Society have developed considerable capacity to address the ethical, legal, and societal implications of nanotechnology and raised national awareness of these issues. With this strong foundation, ELSI considerations are now embedded throughout NNI activities including, for example, focused efforts within the National Nanotechnology Coordinated Infrastructure. The NNI agencies and NNCO will continue to foster interactions and discussions in national and global forums*" (NNI 2016). While programmatic change at the level of the NNI is not what CNS-ASU has strived for, the NNI positioning of CNS-ASU's (and others') work raises the question whether CNS-ASU's demonstration of its model has been appreciated as such. At least it seems lacking a substantive evaluation of the challenge of integration.

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development and maintenance of the bibliometric datasets; (3) having multi-year participation from a core set of graduate students along with visitors from other countries, and multiple team members with diverse networks and collaboration; (4) dedicated space in a non-academic campus building coupled with performance-driven agile management by the STIP principals; and (5) stable long-term funding." Youtie et al. (2016)

[261] https://nnci.net/nano-and-society (last accessed 9 March 2023)

[262] Guston (2010) also points out that – ironically – most of the Social Dimensions activities have been funded by NSF, while such efforts have to be expected from mission oriented agencies.

The other programmatic aspect to consider is the 'ensembilztion' of activities in working towards Anticipatory Governance as a broad-based capacity. CNS-ASU's reporting on this aim is indicative only. The program covered the breadth of Anticipatory Governance's three constituent strands of Foresight, Engagement and Integration and has linked capacity building in education to research as well as the RTTA strands of research to the capacity building activities in the Thematic Research Clusters (e.g. RTTA-1 bibliometric mapping to TRC 'Equity, Equality and Responsibility'; or RTTA-3 futuring research to Future Scape Cities Tour in TRC 'Urban Design, Materials and the Environment'). While these TRC's conceptually allude to techno-scientific dimensions of global urban culture in the context of capitalism and issues of equity, practically they functioned as spaces for performing education and engagement activities. In this respect, ensemblisation concerned creative exchange and activities building on each other, rather than systematic programming.

Integration and transformation: from local capacities to wider impacts
CNS-ASU demonstrated different things to different audiences. Towards scientists and engineers, citizens, students and professionals, it wanted to convey, in a practical manner, the socially constructed nature of (nano)technology as well as future impacts and the relevance of thinking in terms of anticipatory governance. Towards NSF it were the criteria by which integration has been supported and the models and tools by which it can be mainstreamed. Finally, towards peer audiences it was the underlying philosophy with respect to governance of emerging technologies, discussing the role of social science therein.

What connects the various modes of capacity building, is that it creates conditions for *constructive* interactions. To what extend constructive capacities also render *productive* interactions – the deliberate integration of social dimensions in science and technology development – depends on the institutional pathways available and the affordances as well as limitations of the different activities in making use of these pathways. Here, various trade-offs can be observed. In-depth interactions, like in STIR, or in SOtL, have been able to impact decisions in research or technological design rather directly, but are difficult to scale and require dedicated environments and networks for bringing these further; whereas networks like NISE Net, do allow for widely transmitting a core set of basic ideas about science and technology in the public domain, but which only indirectly may shape technological trajectories. Shaping decisions in policy practices, in contrast, could impact nanotechnology at large, but requires extensive research efforts as well as dedicated translational efforts for achieving impact while preserving reflexive qualities.

More broadly, the accounts of (Radatz, Reinsborough et al. 2019) and (Youtie, Shapira et al. 2019) suggest that CNS-ASU did contribute to what Laurent (2012) called a reconfiguration of social science expertise beyond CNS-ASU.[263] While Anticipatory Governance and its components of Foresight, Engagement and Integration haven't been adopted as a program for STS at large – like (Barben, Fisher et al. 2008) claimed it – the work of CSPO/CNS-ASU has been recognised as a "*forward looking, engagement oriented and results seeking*" alternative to the traditional ELSI-model (ibid.). Likewise, while CNS-ASU didn't reorient the NNI's program, a traditional ELSI-approach most likely would have been received with a similar NNI statement as quoted above, but without demonstrating new modes for the interaction between social science and (nano)technology. In this respect, CNS-ASU has been reconfiguring the NNI's objective of Responsible Development more than the earlier NanoEthics community (Laurent 2012). Reasoning the other way around, one could say that CNS-ASU's approach is what was 'allowed for' in the context of the NNI and as such still signifies the resilience of institutional landscapes in science and technology. As such, the outcomes reflect the ambivalence of qualifying transformation in situ. Only in hindsight and by much broader analysis it may be possible to discern whether CNS-ASU's impact created other niches or also induced wider systemic change. Still, there are lessons to be drawn for research governance, which I will turn to in the final section.

7.4 Discussion

I have discussed two main themes in this chapter: CNS-ASU's specific philosophy about the challenge of 'integration' – of societal considerations in nanotechnology research and innovation and of research into societal implications of nanotechnology to that end – and how CNS-ASU's center model has been instrumental to its approach. Specific factors that have been identified were the center's leadership (section 7.3.1), the ASU environment (section 7.3.2) and the successful navigating between 'external' demands (as put by NSF) and 'internal ambitions' (vision, mission) in exploring and exploiting the opportunities of the NSF research funding in the NNI (section 7.3.3). Section 7.3.4 then discussed the dual nature of the transformation induced so far. The question to be addressed now is what can be learned for inducing wider transformation of responsibility in the domain of research governance. For this purpose Table 10 lists the key factors that have shaped CNS-ASU's impact in terms of the challenges identified for the broader quest for Responsible Innovation (see Chapter 2). These findings reflect the prospects of mainstreaming CNS-ASU's model and approach. After discussing two main findings, I will get back to the difficulty of qualifying the contribution to transforming responsibility by discussing more personal views on this issue, as well as what can be

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[263] In my analysis I have left out regular pathways for impact creation, such as participation in research projects, also when these are contributing to the discourse about Responsible Innovation (e.g. ASU-researchers involvement in the project reported by Doezema et al. 2019, see also https://news.asu.edu/20190207-political-developments-complicate-efforts-responsible-innovation, last accessed 9 March 2023)

learned from contrasting CNS-ASU's approach with that of the other NNI-CNS, hosted by the University of California, Santa Barbara (CNS-UCSB).

Governance challenge	
Novelty and emergence	- possible societal implications - in relation to (projected) innovation pathways
Aligning promotion and control	- early stage consideration of social dimensions
Translation into quest	
Anticipation-cum-inclusion	- integration of (otherwise) parallel research in research program
Responsibility structuring	- demonstrating a model for interdisciplinary collaboration - modulating fact/value and science/policy demarcations in US science institutions by reflexive capacity building
Challenges of transformation	
Key interdependencies	- capacity building with respect to integration dependent on existing venues for integration (e.g. NSF requirements, ASU context) - tensions between normative (but distant) and reflexive (but refraining from assessment) approaches
Conditions for learning	- approach demonstrated as a model vis-à-vis peers, while evaluated as 'activity done' at the level of the NNI

Table 10: key findings for CNS-ASU's approach

A first lesson is that strong centers are important for inducing wider change. CNS-ASU's center model provided for a strong core of social scientists working on the integration of social science itself and its outputs in (education for) science and engineering. Part of that model was Anticipatory Governance as the intellectual premise about reflexive capacities being an important condition for integration. In practice, however, this has been particularly shaping CNS-ASU's identity and approach towards social science peers and NSF. For running the activities, social capacities have been more important (e.g. being able to connect to science and engineering cultures). It also has become clear that CNS-ASU's achievements cannot be separated from its leadership and the institutional capacity provided by the ASU environment. The ASU presidency's efforts to forge interdisciplinary research in particular, as well as the entrepreneurial culture at ASU stimulating societal relevance in general, have been beneficial to CNS-ASU both within ASU as well as in the NNI.[264] Finally, CNS-ASU's approach has been allowed for by NSF's non-steering in content. A specific boost in this respect, was the ability to let loose of 'nano' by taking nanotechnology as exemplar for knowledge-based innovation in general, at the occasion of renewing the core grant from NSF. Here, a mutual reinforcement appeared to be at work: of peer esteem and the NSF assessment regime

[264] cf. Dabars and Dwyer (2022) for a self-report about ASU's transformation serving Responsible Innovation). ASU has been ranked as one of the most innovative universities and acquired substantial funding in the NNI program (last accessed 9 March 2023).

prioritizing academic output and impact numbering. This is a strength in terms of the kind of capacity building CNS-ASU has been pursuing, as well as for the ability to cross-link activities, but also limits what can be brought further specifically for impacting the course of nanotechnology development.

A second, and related lesson, is that CNS-ASU's model and approach cannot be simply copied and that center models have to be tailored to their position in the wider landscape. Overall, CNS-ASU's program suggests that substantial budgets are required for mainstreaming its center model. Since new centers most likely will not work in a kind of demonstration mode like CNS-ASU did, the relation to other governance mechanisms and instruments, such as in research funding, corporate social responsibility, or regulation (cf. Guston 2014, Valdivia and Guston 2015) will become more important. For example, where in-depth interaction generally will be more important for the interactions with scientists and engineers, issues of scale in the public domain scale can be addressed in a 'train-the-trainer' approach, like CNS-ASU already did in the training of museum staff in NISE net, or of professional facilitators for public events like the National Citizen Technology Forum and World Wide Views on Climate Change (see Textbox 1). Finally, where in-depth interactions like in Science Outside the Lab or Socio-Technical Integration Research are difficult to scale because of specific features (SOtL, see Bernstein 2016) or costs (STIR, see Fisher et al. 2016), large projects like the cooperation with NISE net or the organisation of NCTF or WWV equally put limits to what the capacity of an individual center can be used for. These then will have to be adjusted in relation to other governance arrangements.

Implications for working in NNI context, CNS-UCSB as contrasting example

For actual integration being dependent on so many factors and levels, CNS-ASU's claims of modulating knowledge production rather than steering it, also have been questioned for whether or not this implies co-opting with nanotechnology's techno-scientific enterprise. According to Fuller (2009), the collaborative approaches as advocated under the heading of Anticipatory Governance would make social scientists complicit to the techno-capitalist systems of science and technology, because it would not change anything significantly and thereby accommodate existing practices in the end. CNS-ASU director Guston responded to this critique by asserting that modulation is part of the distributed and self-governance of emerging technologies anyway, either implicitly or explicitly (Guston 2014). Still, even when explicitly, centers like CNS-ASU had to deal with the rather disadvantageous conditions of the NRDA's contradictory mandate (cf. Fisher and Majahan 2006) and subsequent low budgets for social dimensions research, most of which has been allocated to education (Guston 2010, Karinen and Guston 2010).

Judging the NNI strategic plan of 2016, it appears that Fuller had it right; the efforts of CNS-ASU, together with those of other social science projects were declared as "*a solid foundation*", with "*ELSI considerations are now embedded throughout NNI activities*" (NNI 2016), while it was far from clear on how that basis would shape the NNI's activities.

Guston's opposing claim is that such change will only work out incrementally and one therefore better can approach it as constructively as possible instead of remaining side-lined with one's critique. One result in the NNI at least, is that training modules developed by CNS-ASU are now supported by the NNCO. More importantly, CNS-ASU has been contributing to a new school at ASU as well as networks both within and beyond ASU which can further help to carry the change.

CNS-ASU's choices in light of the broader course of the NNI, nanotechnology at large and the societal issues raised, also have been a recurring topic in my conversations with director Dave Guston during my research stay at CNS-ASU. One particular topic was the difference with the other CNS, at the University of California, Santa Barbara (CNS-UCSB).[265] In 2005, when NSF decided to split the CNS budget over two centers and some projects, a division of labour has been arranged. For example, CNS-UCSB has been covering the Environmental, Health and Safety (EHS) discussions in the NNI.[266] In outreach activities, like in the annual NanoDays or NSF grantee conferences, the centers collaborated.

CNS-UCSB's program has been differing from CNS-ASU, in deploying a more traditional approach of studying impacts and dynamics, also in its training of doctoral researchers in interdisciplinary work. However, this difference in approach is related to a different mission – to ground the center's work within the disciplinary research at UCSB (cf. Fastman, Metzger et al. 2016), and in a different context: a more traditional (west coast) university culture. Compared to CNS-ASU, CNS-UCSB's program covered more in-depth analysis (eg. socio-tech dynamics in solar energy, or public reasoning about risks and uncertainties),[267] but with fewer connections to wider audiences.

Since these differences underline the importance of context, they also point to trade-offs with respect to integration. For example, the kind of research deployed at CNS-UCSB enabled it to show that the US was quickly losing its innovative potential in solar energy due to a lack of capacities for translational research and foreign take-over.[268] To me, this finding raised the question to what extent CNS-ASU's approach of raising individual awareness about science-society relations sufficiently sensitises to issues in collective action. The case of solar energy is pertinent to ASU in this respect, since ASU visibly has committed itself to using solar energy at ASU, as well as with regard to the positioning of solar energy research at ASU. Likewise, the issue of nanosafety has been left to CNS-

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[265] During my research stay at CNS-ASU, I have briefly visited CNS-UCSB as well, see Appendix.

[266] See, for example, the overview presentation of CNS-UCSB director Barbara Harthorn (last accessed 9 March 2023)

[267] see Harthorn and Mohr 2012 for an integrated overview of CNS-UCSB's work with respect to nanotechnology

[268] The integrative research project "Solar Futures: Science and Business Life in the Race against Climate Change; States of Innovation", headed by Chris Newfield; see http://innovate.ucsb.edu/ for output.

UCSB, but would benefit from much stronger social science scrutiny (see Chapter 4 and 6), especially since nanosafety has been the most dominant concern in the US discourse about Responsible Development of nanotechnologies. To <Guston>, however, both examples actually support the deliberate choice of CNS-ASU to focus on changing the vocabularies by which such issues are discussed in the first place. While indeed limited in what discussions CNS-ASU could be active and at which places and spaces, CNS-ASU's program has, according to Guston, been able to change the tone about science and societal impact a bit in ASU and NNI circles, an effort involving careful positioning and far from being politically devoid.

As for the approach taken in this thesis, both CNS-ASU and CNS-UCSB have been exploiting specific niches in a multidimensional space of capacity building for integration. Guston's responses to my observations about CNS-UCSB as contrasting case therefore can be appreciated as supporting the second lesson for research governance drawn in this section: for working towards wider, systemic change, center models as well as the different capacities being fostered, have to be approached from the question how they can enforce each other in the first place.

Part III – Discussion, Conclusions, Reflection

8. Making sense and making change – *discussion and conclusions*

8.1 Introduction

In the previous chapters I have answered the two research questions for this thesis – 'What shapes the governance of Responsible Innovation?' (RQ1) and 'What can be learned for transforming responsibility in research and innovation?' (RQ2) – for each site of empirical investigation specifically. In this chapter I will move to cross-case analysis and work towards the third step in the heuristic guiding my research: identifying pathways for transformation in the domains of risk governance and research governance (see Figure 31). For each of these domains I will contrast the findings from the Dutch and US cases (section 8.2) and discuss reflexive orientations as well as institutional options to address the specific challenges of transformation as identified by cross-case analysis (section 8.3).

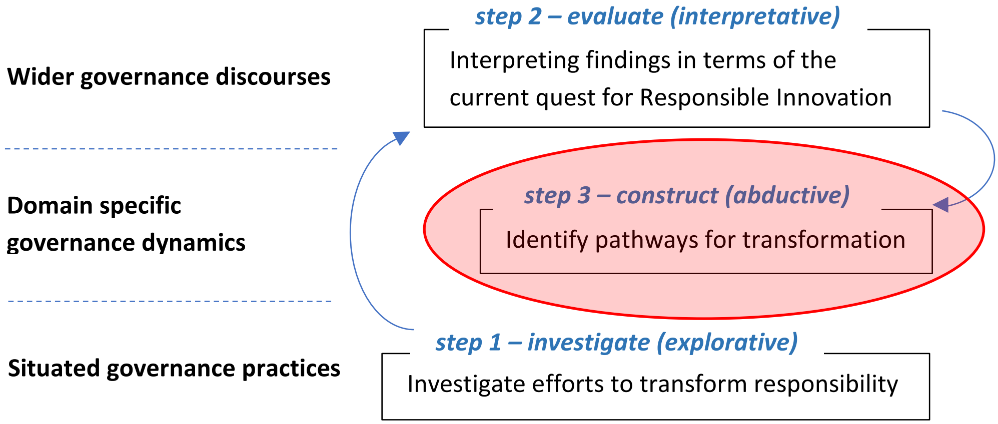

Figure 31: cross-case level of analysis

The approach for cross-case analysis draws on the two analytical frames derived in Chapter 2. First, there is the central thrust in transforming responsibility that I have identified in the quest for Responsible Innovation: to anticipate societal dimensions in research and innovation, to deal with novelty and emergence in that respect, to align promotion and control accordingly and to do so truly inclusive. In the previous chapters I have studied how this set of interrelated challenges correspond to specific strategies and activities, affecting the way responsibility has been structured. The outcomes have been summarised in tables, together with key interdependencies involved in the attempts to transform responsibility in each case and the conditions for learning about resolving these. In section 8.2, I will put these tables side by side and discuss what cross-cutting patterns are particularly relevant to the challenge of transforming responsibility.

Second, while learning about interdependencies has been the focus for each site, pathways for transformation are domain specific. In this respect, I have discussed in Chapter 2 the basic difference between actor level and system level perspectives and how these correspond to the settings studied in risk governance and research governance. These are the domains for which the cases studied would have to induce systemic change. Since the difference in problem-responsibility configurations shapes trajectories of institutional and societal learning, I will construct pathways for transforming responsibility accordingly in section 8.3. At the end of this chapter I will provide a, more speculative, outlook on how these pathways can help remediate current governance failures, respectively in anticipating impacts of new generations of (nano)materials and how to advance sociotechnical integration in approaches for research impact creation. Figure 32 summarises the subsequent steps that will be taken in this chapter.

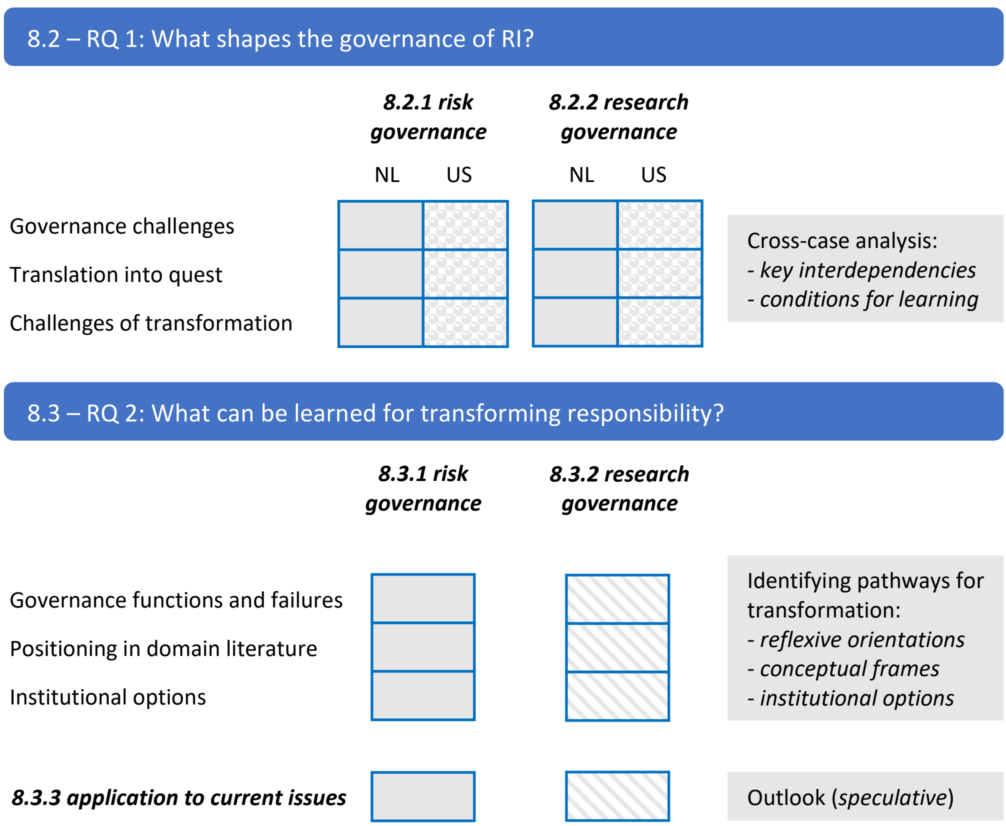

Figure 32: steps in cross-case analysis

8.2 What shapes the governance of Responsible Innovation?

8.2.1 Nanosafety governance: higher level uncertainty

Table 11 lists the findings for the risk governance practices. Both have been concerned with addressing uncertainty about the safety of nanomaterials, yet in different settings and at different levels.

Risk Governance	**NL pilot projects**	**US interagency coordination**
Governance challenge		
Novelty and emergence	- uncertainty about health and environmental safety of nanomaterials - knowledge development takes years, so provisional measures needed	- uncertainty about health and environmental safety of nanomaterials
Aligning promotion and control	- enabling oversight by sharing information about use (EHS) - developing and adopting preliminary measures (OHS)	- knowledge development (research agenda) to inform oversight (on use, indications of risk) and vice versa, in the context of the NNI
Translation into quest		
Anticipation-cum-inclusion	- developing the precautionary measures by stakeholder involvement ('precaution' and 'participation')	- interagency coordination of federal authorities (NNI research agenda) - involving stakeholders in operationalising oversight (EPA)
Responsibility structuring	- explication of responsibilities - aligning positions at national level to strengthen impact at EU level	- positioning implications research as supportive to applications development (NNI) - charting a path from voluntary to mandatory measures (EPA)
Challenges of transformation		
Key interdependencies	- calling on responsibilities, while trying to reconfigure them - stakeholders participate in both NL and EU arenas, agree on primacy of EU level action, but with disparate stakes	- issues in coordination not part of high level evaluation (EHS research) - demands for evidence limit the ability to acquire that evidence (oversight)
Conditions for learning	- actors caught in horizontal interactions, also inside government - playing out in concurrent arenas	- recursive demands with respect to evidence and coordination sustained bias in evaluative structures

Table 11: contrasting findings for risk governance

In the US case I have focused on attempts to reduce uncertainty through knowledge development and regulatory oversight at federal level (comparable to European authorities). In the Dutch case I have been looking for government facilitated stakeholder interaction for developing precautionary measures, given the uncertainties at hand.

In each site particular dynamics have been discussed: concurrent arenas in the Dutch case, Catch-22 demands with respect to evidence and regulatory action in the US case. With respect to responsibility, however, these dynamics did play out in cross-cutting areas of transformation: organising collective responsibility with respect to environmental and consumer protection and supporting individual responsibility in occupational protection. The way these two areas have been related in each case, reveals important conditions for the central tenets of anticipation and inclusion in Responsible Innovation.

Collective responsibility in environmental and consumer protection

In both the NL and US cases calls for concerted action – of governments and authorities, companies and CSOs – have been considered to be the new, responsible way forward. However, they also have been sustaining old divisions of labour. In the Dutch pilot projects this was reflected in the difficulty of developing voluntary mechanisms for oversight, as long as their relation to mandatory systems was not clear (a thing which actually had to be explored in these pilot projects). That difficulty concerned the double interdependency of organising concerted action at national level, so as to induce change at EU level, while all involved did agree that such change actually had to be initiated at EU level, but also did have disparate stakes with respect to the kind of change itself. The other way around, decisive action at EU level relies on the support of member states, who – in the absence of public and political urgency – have to align stakeholders, many of which are involved in EU level discussions themselves via sectoral organisations.[269] This double interdependency became an intractable problem since the novel participatory design was organised along old responsibility claims. In this way, all actors were involved – as deemed responsible – yet leaving the interdependency problem unaddressed.

In the US, the framing of safety research in terms of 'applications/implications' evaded cost-benefit ratio calculations normally required for control measures, but also limited knowledge development to exactly that (research, exploring the new, but serving disciplinary demands rather than regulatory action). At the same time, the voluntary paths for establishing oversight were dragged into catch-22 demands with respect to

[269] Cf. Fritz Scharpf's (1988) 'joint-decision trap': in stakeholder interaction across the pilot projects (*Klankbordgroep Risico's Nanomaterialen*, which continued the preceding *Platform Gezondheid & Milieu*), the role of government largely has been kept out from the deliberations, while the Dutch government vis-à-vis parliament could point to either the lack of progress in stakeholder action or the interdependency on regulation at EU level.

the evidence needed for justifying cost-benefit ratios (while that evidence actually had to be developed by those actions). Not only did this course of action fail to capture the positive mood among stakeholder representatives at the start, it also pushed attempts for establishing oversight towards mandatory measures, such as the reporting rule and significant new use rules. Here, demands for evidence even more hedge attempts for evidence gathering. As a result, the practices of knowledge development and establishing oversight did evolve rather separately instead of informing each other. This has been sustained by institutional sub-ordination of implication research in the NNI: support to coordinate research agendas was lacking, safety was underrepresented in evaluative structures and intra-agency divisions of roles and mandates were reproduced in interagency coordination.

Supporting individual responsibility in occupational protection

Also, in both the Netherlands and the US, progress in the domain of occupational safety contrasted the stalemates in environmental and consumer protection. In the Netherlands a set of reference values have been accepted as provisional limits for regulating exposure to nanomaterials, supported by guidance and dissemination efforts.[270] In the US, occupational safety institute NIOSH produced a range of guidance documents and safety recommendations for specific nanomaterials. NIOSH also runs an extensive strategic research program on nanosafety, which sustains outreach in the NNI. However, as discussed, the relative success reported for the occupational domain may well have masked that the underlying responsibility problem is structured differently. The measures that have been developed, enable individual organisations (firms, research organisations) to take precautionary action in compliance to existing regulatory provisions on duty of care. That this has been accomplished, is not so much a product of concerted action, but of individual entrepreneurialism in the Netherlands (Pieter van Broekhuizen juggling expert and advocacy roles) and of institutional space for exercising soft authority in the US (NIOSH standardisation under the shadow of OSHA). While the actors involved have been happy with these outcomes as 'better than nothing', it has left unaddressed paradigmatic questions of exposure to particulate matter in general, mitigation by material substitution and anticipation of safety issues for upcoming trends in materials development (e.g. 2D and other functional advanced materials).

Implications for anticipation and inclusion

In light of the anticipatory aim of Responsible Innovation, the problem with the outcomes in both the occupational safety and environmental/consumer product safety

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[270] Awareness about nanosafety as well as the availability of tools has been increasing after the SER (2012) report, as is suggested by the level of awareness at a conference of the Dutch association for occupational safety experts (NvvA – arbeidshygiënisten) in April 2017. All sixty participants then were aware of the nanomaterial reference values. About a third of the participants actually had nanomaterials in their purview, from which seven had been able to use one of the tools for nanosafety, while awareness levels in 2016, as observed at a workshop by TNO, were much lower (source: personal communication of RIVM colleagues)

domains is twofold: 1) insofar uncertainty about hazards has been reduced by knowledge development, it has been expanding in terms of what action is needed. Moreover, anticipation itself has been morphed back into an issue of enabling regulatory compliance. 2) This situation has not been translated into questions of (responsible) choice. Instead, uncertainty about what to do (action), repeatedly has been reproduced in terms of what is not known yet (knowledge), including claims about uncertainty as a reason not to act. Contrary to the idea of precaution, this puts the burden of evidence back again to safety research, which is critically dependent of access to information about use and design in order to be relevant. At best, this is an outcome simply not accounted for in deliberate choice, but nonetheless severely slowing the adjustment of control measures to the novel characteristics of nanomaterials. At worst, it allows for a new crises in health and safety to unfold in 'organised irresponsibility' (cf. Beck 1992).

'More inclusion', as practiced in response to calls for concerted action, would just exacerbate the problem, as long as the limitations of the problem and solution frames are not accounted for. Here, the consensual style in the Netherlands (and EU) is no more effective than the adversarial style in the US. In Chapter 6, I have followed Morris (2012) by attributing the lack of effectiveness in the US to the dominance of scientism in the discourse on risk. Focusing on uncertainty as a problem of knowledge, fails to acknowledge that scientific research and regulatory oversight are two modes of knowledge development that have to inform each other, requiring resources, mandates and debate to that end. However, as Morris (2012) argues, this is not just a cognitive deficiency, but a product of Western 'calculative governance', especially so as practiced in the US.[271] Likewise, the contribution of the Dutch pilot projects to addressing uncertainty about safety has been both enabled and constrained by the way responsibility claims have been posited in the Dutch policy discourse on risk governance, which is marked by a corporatist political culture. Policy practices in both the US and NL, therefore, work as a political landscape, which won't change easily, certainly as long as the stakes of technology development and innovation are affected by the way the relation between safety and innovation is constructed politically. As a consequence, attempts for organising concerted action have been hampered by horizontal interlock (i.e. between actors, beyond the scope of hierarchical relations).

8.2.2 Research governance: checked for activity, not for model

The findings for the research governance cases (see Table 12) show a different pattern. Instead of a commonality, complementarity can be observed. Integration of Risk

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[271] Morris 2012, p127: "*Our need to order, number, and quantify is both a strength and a weakness of modern liberal democratic society: it enhances transparency, but simplifies debate; it acts as a disciplining force upon capitalism by forcing the generation of data, but the sheer volume of information it produces results in either important nuances being lost or having messages reduced to shallow outformations that impoverish debate and lend themselves to hijack by political and commercial interests.*"

Analysis and Technology Assessment (RATA) in NanoNextNL has been thought of in terms of a program wide structure and activities. This could be made possible in NanoNextNL as a relatively big program, but with a single agency administered structure and limited in runtime and geographical scope. However, the integration ambition for RATA came in lately in the process of program formation, in response to the upcoming discourse on Responsible Innovation and the European Code of Conduct for responsible nanotechnology research and development. Consequently, mechanisms for integration had to be built on the fly.

Research Governance	**RATA in NanoNextNL**	**CNS-ASU in the NNI**
Governance challenge		
Novelty and emergence	- possible societal implications - in relation to (projected) innovation pathways	- possible societal implications - in relation to (projected) innovation pathways
Aligning promotion and control	- early stage consideration of social dimensions	- early stage consideration of social dimensions
Translation into quest		
Anticipation-cum-inclusion	- integration of (otherwise) parallel research in research program	- integration of (otherwise) parallel research in research program
Responsibility structuring	- building mechanisms for integration as the programme evolved - RATA framed as instrumental to commercialisation aim	- demonstrating a model for interdisciplinary collaboration - modulating the stark fact/value and science/policy demarcations in US science institutions
Challenges of transformation		
Key interdependencies	- waiting game of expectations in demonstrating relevance (showing what RATA can 'sort out' vs. 'finding out together') - change agents hampered by the same structures to be changed (e.g. disciplinary demands)	- capacity building with respect to integration dependent on existing venues for integration (e.g. NSF requirements, ASU context) - tensions between normative (but distant) and reflexive (but refraining from assessment) approaches
Conditions for learning	- distributed leadership with respect to the integration of RATA in NanoNextNL hampered conciliating diverging views on what RATA is about	- approach demonstrated as a model vis-à-vis peers, while evaluated as 'activity done' at the level of the NNI

Table 12: contrasting findings for research governance

The Center for Nanotechnology in Society at Arizona State University (CNS-ASU) in the US NNI, in contrast, was funded as part of a larger range of implication research and outreach activities, delegated to non-governmental centers of academic expertise in the large and multi-agency administered network of the NNI. In this context, CNS-ASU was expected to develop an interdisciplinary program for linking social sciences to natural sciences and engineering. The CNS-ASU leadership took up this challenge with articulate ideas about developing collaborative approaches (Real Time Technology Assessment) that would have to overcome the shortcomings of traditional parallel research programs (notably the ELSI program in the Human Genome Project). Hence, the quest for CNS-ASU became to demonstrate the relevance and viability of the corresponding vision of Anticipatory Governance as practiced at a center like CNS-ASU. For that effort the ASU environment has been strongly conducive.

The cross-case finding to further expand on is that the differences in modality, approach and setting for the two initiatives are mutually related. Both initiatives have been initiated in response to calls for integrating implications research in large nanotechnology research and innovation programs. By contrasting opportunities and limitations in modality and approach I will highlight how these affect conditions for anticipation (of societal implications) and inclusion (societal embedding) beyond their specific constellations.

Modality

The difference in modality concerns the relation between node (RATA, CNS-ASU) and network (NanoNextNL, NNI). The integration of RATA has been benefitting from board level commitment and program wide structures, but under conditions of distributed ownership and lacking a substantial core which could drive the change. CNS-ASU did exhibit such a drive, supported by mechanisms for forging interdisciplinary collaboration at ASU, but lacking similar mechanisms for integration in the NNI at large. The program wide structure of RATA afforded high visibility among NanoNextNL researchers and recognition as part of the corporate identity of NanoNextNL. Integration has been limited though. CNS-ASU in contrast, has been exploring capacity building approaches for integration more in-depth. It also exploited networks both within and outside the NNI, but with limited reach in the loosely structured network of the NNI at large.[272]

Approach

The approach taken in both sites has been corresponding to the differences in modality, but with similar challenges in demonstrating relevance to target audiences. The RATA integration activities have been conducted as invitations to collaboration between RATA experts and the researchers in other NanoNextNL research themes. In the RATA PhD course as well as the visiting talks of the RATA management in meetings of NanoNextNL research themes this consisted of a general introduction, followed by discussions about how follow-up in collaboration could look like. However, in the limited time span of those interactions, there was ample room for resolving tensions in expectations. RATA

[272] These outcomes are relative for scope and audiences. For example, CNS-ASU has been participating in the annual NSF grantee conferences active at the annual NanoDays and reaching out through the NISE network.

experts were mostly seen as instrumental to 'sorting out' societal issues, while that would have to be 'found out together' in collaboration. Consequently, only a few interested researchers participated in follow-up activities. This situation has been exacerbated by a lack of incentives for researchers, supervisors and program managers to conciliate RATA efforts with disciplinary demands in home institutions, including the RATA research theme and management itself, which were not able to resolve the limitations of distributed ownership for a coherent strategy towards integration.

For CNS-ASU, overcoming both cognitive and institutional hurdles for collaboration between social scientists and engineers has been at the heart of its focus on building reflexive capacities. It also was asked for by the NSF demands for delivering research, education and outreach. Exploring multiple venues and trying to make them mutually reinforcing, is what CNS-ASU conceptualised in their vision of Anticipatory Governance as a broad based capacity to be built throughout society. However, focusing on building reflexive capacities is also what has been allowed for among target audiences. As a result, assessment of societal implications itself largely remained in the domain of social science expertise. Though the efforts of CNS-ASU have been aiming to create the conditions in which exactly that could be changed, at the level of the NNI its activities still were judged as having taken care of assessment.

Implications for anticipation and inclusion

Above findings show that anticipation has been shaped by conditions of inclusion, with a mutual relation between cognitive and organisational aspects. Both the RATA management and CNS-ASU had to balance multiple elements of anticipation in collaborative approaches: learning about societal implications of science and technology, learning how these are constituted as part of societal dimensions in research and innovation and learning what integration by collaboration could contribute to anticipation beyond research activities (societal embedding) and to organise activities accordingly. The relevance of these elements differs for different audiences. The pathways chosen therefore have been channelled by 'internal' commitments and 'external' demands. CNS-ASU set out to develop futuring, engagement and integration as collaborative practices and to involve peer audiences in that quest. The RATA leadership has been occupied by reaching out to other research themes in NanoNextNL and making sure that the Key Performance Indicators for integrating RATA (number of meetings with interaction etc.) were met. In both cases learning at program level (NanoNextNL, NNI) did not involve a testing of the model and approach to integration.

8.2.3 Cross-case findings for RQ1 – what shapes the governance of Responsible Innovation?

Three cross-case findings can be established. First, Table 13 lists the specific patterns that have been identified in each domain. In nanosafety governance actors were caught in horizontal interlock, reproducing roles and responsibilities and unable to reconfigure the relation between voluntary and mandatory mechanisms. In the research governance domain the reciprocal relation between cognitive and institutional aspects hampered the ability to learn at program level. These patterns suggest specific conditions for institutional and societal learning.

In Chapter 2 I have discussed the challenge of integrating RATA in NanoNextNL and of Social Dimensions research in the NNI as concerning an ‘actor level perspective’: what does a science and technology promotor (typically an organised actor like a firm, a university or a research program) has to do for acting responsibly? In contrast, addressing uncertainty in the Dutch pilot projects and in US federal interagency coordination concerns a ‘system level perspective’. Here, the challenge is about organising concerted action between more or less independent actors, so as to produce responsible outcomes and processes.

The significance of these perspectives is that the corresponding accountability structures differently shape responses and responsibilities. In the sites of nanosafety governance actors had to cooperate horizontally, though ‘under the shadow of hierarchy’ (cf. Scharpf 1997). They have been responding to uncertainty about safety as an emerging problem, *out there*, as a political problem, which could not be ignored, no matter whether differently understood by the actors involved. The attempts for integrating implications research also have been responding to responsibility claims outside the research programs, but the efforts themselves have been positioned as building a new function within the structure and boundaries of those programs as representing a specific actor entity (‘science and engineering’). Here, the perspective is *from within*, in learning about the problems and goods that are produced in relation to the core activity the actor is identifying with (i.e. research and innovation) and taking care for potential outcomes.

Domain	NL	US	Pattern observed
Risk Governance	pilot projects: *concurrent arenas*	research and review: *catch-22 demands*	*horizontal interlock in relation to a collective problem*
Research Governance	RATA NanoNextNL: *program wide support, distributed leadership*	CNS-ASU NNI: *strong center and strategy, lack of program level uptake*	*reciprocal factors in relation to a mutual problem*

Table 13: domain specific patterns

The second cross-case finding is about the ‘regime resilience’ reflected in the patterns observed. This is a typical phenomenon in multilevel dynamics, here being the policy discourse about Responsible Innovation (landscape), existing distributions of responsibility (regime) and situated governance practices (niches). As such, the patterns are no surprise; it takes more than just experiments to induce systemic change. By the same token, however, this finding underlines the significance of mechanisms for learning. A key finding across all sites of investigation is that the outcomes and dynamics observed hardly have been subject to higher level strategies and evaluations. The site-specific quests – reducing uncertainty about nanosafety and integrating societal dimensions research in research and development – are problem frames resulting from societal interactions, for which the governance arrangements studied (e.g. the Dutch pilot projects, or the US Centers for Nanotechnology in Society) were expected to address these. However, the quest for the lead actors in case (i.e. those responsible for administering the governance arrangements) has been different, because they had to work within existing contexts. Prospects for transformation then hinge on the ability to resolve the difference between the quest for Responsible Innovation as constructed 'from outside' and as pursued 'from inside'. That requires a self-reflexivity about processes of uptake and implementation and the multiple institutional forces in these. My analysis has brought to the fore the significance of accountability mechanisms in shaping prospects for learning with respect to regime resilience.

Finally, the cross-case findings confirm that transformation is radical and incremental at the same time. Advancing the quest for Responsible Innovation towards systemic change is not just a matter of *redesigning* systems (as for risk governance), or of *mainstreaming* niche activities (as for research governance). These are the radical perspectives, necessary for engaging actors in the quest. But they have to engage and to be engaged reflexively. That requires processes of societal learning to be deliberately crafted with respect to the specific governance challenges at hand. Such processes are incremental by nature. Yet, the research approach and cross-case analysis in this thesis have singled out a general (meta) aspect: all key governance challenges discussed above have to do with *interrelations*, manifesting themselves as *interdependencies* that, if not subject to deliberation and negotiation, easily turn into *intractability* for actors involved. Learning then, is being channelled by the way anticipation and inclusion – the central tenets of Responsible Innovation – are related to each other in governance practices: what is being anticipated (and how) depends on who is involved (and how) and vice versa. It is in recognising these interdependencies that the radical can be linked to the incremental.

8.3 What can be learned for transforming responsibility in research and innovation?

For answering the second research question – on what can be learned for transforming responsibility in research and innovation – I will construct pathways for transformation in each domain. The notion of 'pathways' is borrowed from the literature on multilevel dynamics in sociotechnical change, specifically with respect to '*de facto* governance' (e.g. Rip 2010). In this thesis, I have conceptualised *de facto* governance as reflecting processes of structuration. The cross-case findings collected in the previous section fit this frame: pathways for transformation have to account for problem-responsibility configurations; they have to address regime dynamics in multilevel settings; and they have to be thought of in terms of learning and guiding rather than steering. For this purpose, I will be using the notion of 'modulation', which in Chapter 7 briefly has been discussed in relation to the activities of CNS-ASU and the assumptions of incrementalism underlying its philosophy of Anticipatory Governance (Guston 2014).

Furthermore, I will build on the two main findings from Chapter 2 again. Here, the first element – the interrelation of anticipation and inclusion – implies that pathways for transformation will have to account for this interrelation in transforming accountability mechanisms. The second element starts from the observation that the setting and governance patterns in each domain hold specific conditions for societal learning. In the *collective problem* setting of nanosafety governance (see Table 13), the question is how to organise *choice in* measures and priorities, so as to resolve horizontal interlock, while acknowledging the significant costs, burgeoning complexity and uncertainty about what it is good for. For socio-technical integration efforts in research governance the problem setting has been positioned as a mutual problem. Here, the question is how to align actors in *choosing for* constructive modulation of the reciprocal relation between cognitive and institutional aspects of interdisciplinary collaboration and integration.

In this section, I will address these questions by constructing governance functions for modulating the relation between anticipation and inclusion in each domain. I will also discuss these orientations in relation to domain specific literature, since actual policies in risk governance and research governance do draw on problem frames as discussed in this literature. Building on this discussion, I will discuss institutional options by which the governance functions I have constructed can be practiced. Finally, I will sketch how these options may make a difference to actual challenges in risk governance and research governance.

8.3.1 Risk governance: organising scrutiny/choice

The pattern of horizontal interlock in risk governance can be conceived of as resulting from self-reinforcing knowledge-power relations. For the US federal agencies this was scientism (treating uncertainty far more as a problem of knowledge than of choice) in relation to adversarialism (reflected in processes of budget appropriation and the demands for evidence in it). For the Dutch pilot projects it appeared that corporatist modes of interaction playing out in concurrent arenas were most salient. Crucially, the governance failures in both settings did not arise from a lack of awareness about interdependent challenges in addressing the novel health and safety issues. Just as well, these challenges have been lumped together in a broad adherence to either Risk Governance or Responsible Innovation aspirations.

The issue to be addressed in this respect, is that tensions between challenges and aspirations require choice. Authorities have to legitimate what actual threats to focus on, but also have to anticipate long term impacts and developments. Developing a knowledge base for that, requires balancing fundamental and applied science. Both strands of research, in turn, have to be informed by oversight. This always has been a complicated puzzle, as regulatory uncertainty comes with barriers to information sharing (apart from issues of costs, protecting intellectual property and role clarity). These may be lowered by making the interaction between science and business also beneficial to research and development, which has been the thrust of many voluntary initiatives. But in the face of public scrutiny towards claimed benefits and calls for precautionary action, interactions between business representatives and public officials have been a delicate affair. Intractability, therefore, should not come as a surprise. Still, the above interdependencies have been hardly, or only partially acknowledged in public and political debate.[273]

Organising choice, therefore, requires a form of scrutiny. A scrutiny that renders holistic understanding of what choice is about, as well as decisiveness in navigating concerted action. Both demands draw us into the realm of democratic governance. As for the holistic understanding, there are many calls for opening up expert-stakeholder interactions on safety to public questions about direction, desirability and benefits. This can level up policy debate and remedy problems of scientism and 'calculative governance' as discussed in this chapter.[274] But it will only do so if political choice is facilitated indeed. In the absence of actual crisis – which is the very thing to be anticipated – facilitating choice is not likely to be streamlined nor scrutinised.

The analysis in chapter 4 and 6 as well as the cross-case analysis in this chapter carved out the role of 'vertical' scrutiny as performed in parliamentary arenas. The significance of this vertical scrutiny for resolving horizontal interlock is that the latter has been extending into government internal dynamics (e.g. within and between departmental units and agencies), thereby affecting the ability to enact a shadow of hierarchy for the governance practices studied. I also have observed, however, that parliamentary logics and dynamics are not outside 'the system' as well and actually co-constructed and hence replicated knowledge-power relations. For example, critical reports of high-level bodies like the US National Research Council (NRC), the Government Accountability Office

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[273] For example, Andrew Maynard (2014), at the time one of the most visible opinion leaders on nanosafety issues, eloquently argued in Nature Nanotechnology why research strategies should be grounded in plausible scenarios about production and use, but left unaddressed that plausibility in regulatory context critically depends on mechanisms for information sharing.
[274] Continuing the quote in footnote 271, Morris (2012, p127) argues: "*Nevertheless, democracies offer opportunities for discourse not available within nondemocratic regimes, and while calculation may not be removable from democratic institutions, there may be opportunities to alter the biopolitical power dynamic through strategies and approaches that broaden debates on environmental risk.*" There are more challenges to be accounted for, such as the concurrent normative, substantive and instrumental rationales in broadening issues and publics as discussed by Stirling (2008) on power dynamics in public participation efforts. These go beyond the scope of the discussion in this chapter.

(GAO), or the Dutch parliamentary Technology Assessment (TA) organisation, have played important roles in political agenda setting. But the assessments by NRC and GAO have been sub-ordinated in the overall evaluative structure for the NNI and primarily discussed in terms of budget appropriation. In the Netherlands the parliamentary TA activities of the Rathenau Institute have been dependent on political logics of representation (changing positions upon elections) trumping logics of control (holding government to account in evaluating progress).

Organising vertical scrutiny to enable political choice thus comes with three requirements: holistic understanding of system dynamics, decisiveness with respect to guiding concerted action and institutional warrants for preventing scrutiny/choice mechanisms to be drawn into the same horizontal dynamics it has to resolve. For each of these requirements I will discuss institutional options at the end of this section. But first I will take a closer look at contributing factors in (science policy) discourse.

Contribution to domain literature: accounting for emerging risk politics in risk governance

An explanatory factor to the dynamics observed is that policy discourses on nanosafety governance, especially in the EU, have been drawing on ideas about risk governance in which risk politics are often conceived as to be addressed through horizontal learning. Risk Governance frameworks, like those proposed by the International Risk Governance Council (IRGC, cf. Renn 2005) build on specific trends, such as in the domain of health and environmental regulation, as well as wider democratisation movements in relation to science and technology. In chemical risk assessment, for example, there has been a gradual shift from technical and expert driven risk assessment and management approaches towards stakeholder and communication oriented frameworks, even before the notion of 'governance' became in vogue. This trend has been conceptualised in landmark reports like 'Understanding Risk' (NRC 1996) and found its way in ISO standardisation[275] and chemical risk assessment handbooks (e.g. Van Leeuwen and Vermeire 2007). More broadly, public controversies about science and technology and social science critiques with respect to unfettered promises of research and innovation did result in new modes of Technology Assessment, Ethical, Legal and Social Issues (ELSI) studies and discussions about the governance of emerging technologies (e.g. calls for 'moving public engagement upstream' (Wilsdon and Willis 2004) In the case of nanotechnology). Both strands did bring the notion of risk governance closer to the realm of public and political discourse about risk policies (Van Est et al. 2012).

The 'new modes of governance' (cf. Pariotti 2016) as promoted in Risk Governance frameworks thus are not so new at all, but build on longer standing discussions about precaution and participation. This can explain the regime resilience observed in my sites of empirical investigation. Expert communities tend to 'encapsulate' reflexive logics in

[275] In particular ISO 31000

modernist practices (Kunseler 2017). The WHO (2013) report on nanosafety risk governance, for example, simply presents risk governance as the deliberate add-on of communication and participation to risk analysis and risk management, not the opening up of expert agendas. But the problem is broader. Nanosafety governance overviews, like Hodge et al. (2010), merely replicate *aspirations* for new modes of governance. The late lessons from early warnings report by the European Environmental Agency (EEA 2013), which otherwise has been keen on pointing out 'paralysis by analysis', just calls for more concerted action. The IRGC framework has been adapted towards emerging risks, by listing institutional conditions for adaptive and integrative risk governance (Klinke and Renn 2012), discerning dynamics in various contextual spheres (IRGC 2010), scenario based thinking and governance orchestration (IRGC 2015), but still remains an expert ordering of problems and challenges. Finally, in the shift in discourse from Responsible Development to Responsible Innovation risk governance has been treated as either sufficiently speaking to the idea of Responsible Innovation or backgrounded in favour of issues of directionality and soft impacts (see Chapter 2).

The basic tenet in these publications is their consensual orientation. Analysis and exchange are treated as rational rather than political processes. In this way, the focus on horizontal learning becomes prone to facilitating the reproduction of knowledge-power relations. This is especially problematic in the case of new and emerging technologies, where publics evolve as much as promises and concerns. This is not to say that horizontal interactions can't be effective in these contexts. Reichow (2015), for example, shows how stakeholders effectively engaged in substantive, strategic and institutional learning in nanosafety dossiers. But these activities concerned the more structured problem-institutionalisation combinations in the occupational safety domain and left out of scope paradigmatic questions with respect to risks assessment measurements and novel uncertainties or moving beyond case-by-case assessment.

Just as well, there also is a wide array of literature on risk politics, contrasting the belief in horizontal learning, with in-depth studies on the politics of precaution (e.g. Ashford 2007, Vogel 2012), conflicting dispositions explained by cultural theory (after Douglas and Wildavsky 1982), reflections on risk society (after Beck 1992) or analyses of regulatory regimes (e.g. Hood, Rothstein et al. 2001). Furthermore, awareness about the limitations of risk assessment and evidence based decision making have been discussed widely, as well as specifically for nanosafety (e.g. Åm 2011, Morris 2012, Miller and Wickson 2015, Beumer 2015, Forsberg 2012). More generally, alternative approaches to risk governance have been proposed in calls for extended peer reviews (Post Normal Science – Funtowicz and Ravetz 1993), value-based instead of risk-based approaches (Rodríguez 2014) or calls to focus on prudence and commitment instead of precaution (e.g. WRR 2008, de Vries, Verhoeven et al. 2011, Funtowicz and Strand 2011).[276]

[276] De Vries et al. (2011) want do away with taxonomies (such as IRGC framework, which builds on the problem structuring typology of Hisschemöller and Hoppe (1995), since risk issues easily migrate over the categories. More fundamentally: risk is only the calculable part of uncertainty

These latter strands of thinking about risk have been present alongside the emerging discourses about Risk Governance and Responsible Innovation, but appear to be rather separated. This may be attributed to regular limitations of reach and exchange in both academic and policy circles, if only because of the sheer amount of literature on risk[277]. A deeper cause, however, appears to be that both classical (objectivist) conceptions of risk and consensual public and stakeholder debate approaches are more close to the instrumental and positively minded policy discourse about science and technology than reflexive and constructivist approaches.[278]

When incorporating insights from the latter strands of studying risk, three aspects have to be taken into account for conceptualising risk politics in risk governance:

1) Strategies for horizontal institutional learning should be *practice based*. This implies that risk has not only has to be *objectified* (as much as possible), but as much has to be understood and addressed as *constituted* (cf. Lim 2011, Rodríguez 2014). Risks, whether potential or not, are not just dependent on material properties, but shaped by the way they emerge from and are being handled in research and innovation activities.

2) Closely related, if risk is in the system as much as in material properties, the problem in reproducing the technocratic modes of governance which tend to focus on objectifying risk is not so much technocracy itself, but the lack of reflexivity about limitations and actual implementation. The latter should be the object of analysis and assessment, so as to render *reflexivity* about what aspects are relevant to political choice.

3) Additionally, to enable political choice, organising reflexivity has to go beyond just posing another expert ordering of the problems at hand. It has to be *communicative* to the public sphere.[279] This works as a two-edged sword: making technical risk issues communicative to the public sphere, also increases its political relevance.

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instead of the other way around (uncertainty as a feature of risk). Alternatively they call for enforcing pro-activity, by institutionalizing obligation responsibility and strengthening both research and review capacities.

[277] Cf. John Adam's review of Hood et al. 2001 (as cited in this thesis)

[278] While intellectually the opposition between objectivists and constructivists can be resolved (e.g. in Latour's distinction between ready-made science and science in action, cf. De Vries et al. 2011), politically, objectivist reasoning is closer to the instrumental stake in decision making. Cf. Hanssen et al. (2002) for a discussion on the differences between discourses and their deficiencies.

[279] Ironically, it is for this reason that, at least in the Dutch context, using a taxonomy has been put forward to justify the logic behind (differences in) risk governance strategies, serving clarity and applicability over a range of issues (e.g. RIVM 2003, Bijker, de Beaufort et al. 2007).

Outlook: Regulatory System Assessment (RSA)

The three recommendations for risk governance approaches help to reflect on how the lack of vertical scrutiny as discussed for the NL and US settings can be mitigated. I will illustrate this by drawing on experiences with parliamentary Technology Assessment (TA) and system analysis (SA).

In the Netherlands, parliamentary TA activities by the Rathenau Institute did allow for political agenda setting on nanosafety, building on a supportive mandate and deploying communicative methods towards political practices (Van Est and Walhout 2010, Van Est et al. 2012b). But the institute didn't use a proper conception of risk (Van Est et al. 2012a) and only marginally investigated governance practices like the pilot projects investigated for this thesis. Consequently, calls for oversight (e.g. Walhout et al. 2009, Staman 2009) missed out on reflexivity about what kind of choice actually was at stake. In contrast, publications by the US Government Accountability Office (GAO), National Research Council (NRC) and Woodrow Wilson institute (Project on Emerging Nanotechnologies, PEN) did provide topical system analysis on nanosafety governance. However, their reports have been situated in expert body hierarchies and did not achieve a brokering function in political debate.

A broader deficiency in both the Dutch and US assessment reports is that they have been weak in discussing the risk governance in relation to research and innovation governance. The interagency coordination in the NNI provided an interesting opportunity, since both mission oriented agencies and basic research oriented agencies were involved. Yet, the discussion did not go much further than that regulatory agencies had to be included. The same holds for the Dutch funding of nanotechnology research as part of the national science and innovation policies: joint activities by the TA department and Science System Assessment (SciSA) department within the Rathenau Instituut did affect research agenda setting[280], but not the way these agendas materialised in the research program of NanoNextNL.

This brief reflection suggests two institutional capacities that can – when linked to each other – provide for the organisation of vertical scrutiny and political choice: independent system analysis and agenda setting and brokering in political debate. The brokering function has been taken up by various TA organisations already (Hennen and Nierling 2019, van Est 2019, Van Est 2013, Van Est et al. 2015). In the Netherlands, system analysis has been included by establishing a Science System Assessment (SciSA) department in the Rathenau Institute and merging it with the TA department. In the US a similar function can be provided by the new Science, Technology Assessment and Analytics (STAA) team in GAO.[281]

[280] A survey for the project 'Nanotechnologie in Focus' broadened the research agenda in the making of the Dutch nanoscience community (as coordinated by STW).

[281] https://www.gao.gov/technology_and_science, see also plan, press release and commentary (last accessed 10 March 2023). The GAO STAA team provides similar analysis as the

Together, the two capacities can be conceived of as a form of 'Regulatory System Assessment' (RSA). Establishing such a function can build on broader trends, like demands for public accountability as well as the evolving shift towards mission oriented innovation policies. For example, in research proposals it is no longer sufficient to merely state promises or good intentions for realising societal impact, but to specify projected pathways instead. The other way around, public policies on transitioning towards renewable energy and a circular economy actively link goalsetting to co-construction of roadmaps. While such arrangements are also dependent of the way in which actors are involved, they can strengthen political accountability and help to position societal dimensions as a more integral part of innovation policy. Practically, the question then is in what form RSA should be institutionalised. It could be made part of courts of audits and act as a kind of checks and balances in risk governance. Unlike most courts of audit, however, RSA has to be equipped with the same mandates and communicative abilities as parliamentary TA.[282] As for nanomaterials, a natural domain would be the implementation of chemical policies, which in itself already requires long term commitment and vigilance when contexts or arenas change.[283]

8.3.2 Post-ELSI approaches in research governance: double loop learning

For research governance I have studied a different problem setting. Just like the case studies on risk governance the challenge of integrating implications research within research programs has been situated in wider public settings as well, demanding responsibility of respectively NanoNextNL and the NNI. However, different from the setting in risk governance is that these demands are less specific about *how* issues will have to be taken care of. This leaves most of the attempts to integrate mechanisms for societal embedding as a problem for those involved in implications research. Since these are social scientists most of the time, the challenge is to posit integration as a *mutual* problem for social and engineering sciences, embedded in a process of working towards institutional uptake. Thus, double loop learning is involved: about directions, dimensions and implications of research and innovation as well as about processes of embedding science and technology in society.

Congressional Office of Technology Assessment (OTA) did until 1995 (see Chapter 7 for a brief discussion about OTA).

[282] Such capacities thus do not have to be limited for the political arena alone, nor established by a single organisation. On the contrary, just like parliamentary TA benefits from being networked in academia and civil society, so would RSA benefit from operating in such networks.

[283] In Chapter 4 and 6 parliamentary elections turned out to be crucial moments: in the Netherlands the main business representative withdrew from an almost signed covenant, in sight of right wing electoral success. In the US the flawed interpretation of the NNI's dual mission (distinguishing between applications and implications research) has not been noticed by parliament at the time of the elections.

The cross-case findings for integrating RATA in NanoNextNL and CNS-ASU in the NNI showed that the conditions for the mutual learning aspect have been shaped by a dual set of key interrelations: between *node* and *network* and between *reflexivity* and *assessment*. The integration of RATA could be pursued in a network-wide structure, potentially enabling the assessment of societal implications for each research project. But under conditions of distributed leadership, the approach missed a strategy for reflexivity. With respect to thinking about societal dimensions in research and innovation a strategy for interdisciplinary learning has been limited to the PhD course. CNS-ASU, in contrast, did have such a philosophy, but not a mandate, structure and resources for spanning the NNI program. Also, reflexive capacity building, not assessment, is what generally was allowed for in collaborative settings.

The relations between node and network and between reflexive capacities and assessment reflect the dual challenge of both cognitive and institutional transformation in interdisciplinary collaboration. It is, therefore, *in their combination* that they shape pathways for learning about how to conciliate the agonistic functions of applications and implications research in science and technology programs. In other words, the balancing of relations has to be embedded in institutional learning. This becomes all the more important when taking into account that the learning within the scope of a research program is always limited; i.e. learning about directions, dimensions and implications as well as about processes of embedding, extends in longer cycles and wider circles than a research program itself. Therefore, actual anticipation and integration is always limited, even when connections to the outside world are actively brought in.

Even more so, learning about implications has to start with the appreciation that anticipation is not a matter of 'sorting things out', but of 'making sense together' (learning about embedding). Interestingly, both the discussions of RATA NanoNextNL and of CNS-ASU suggest that for sustaining these processes it still does make sense to foster disciplinary implications research. However, different from 'parallel' EHS and ELSI research, it also requires dedicated spaces in which learning is facilitated between designated integration workers (node) and program wide structures (network), across all levels (i.e. supported by board level strategy and commitment), so as to build reflexive capacities across as well as beyond research programs. Before translating these demands in strategies for institutional learning, I will first discuss how the challenge of integrating implications research is discussed in literature.

Contribution to domain literature: modulation at multiple levels

Addressing societal dimensions and implications of research and innovation is a research topic in various bodies of literature, like science and engineering ethics, science and technology studies, or innovation studies. These are partly overlapping areas, rooted in different disciplines, such as sociology, philosophy, political sciences or law. A more specific set consists of discussions about socio-technical integration itself, covering topics like co-producing knowledge (e.g. Zuiderent-Jerak 2015) and critical participation

(Downey 2021), guiding engineering practices (e.g. Value Sensitive Design (van den Hoven 2013), Ethical TA, (Palm and Hansson 2006, Kiran, Oudshoorn et al. 2015) or pedagogical aspects in education (Fisher, Guston et al. 2019). While these different domains of expertise have been actively referred to in Responsible Innovation initiatives, it has only been recently that the importance of institutional change is acknowledged (cf. Gerber, Forsberg et al. 2020, Owen, von Schomberg et al. 2021, Wittrock, Forsberg et al. 2021).

The findings from my research emphasise that for working towards systemic change, guiding processes of institutional learning has to act on multiple levels. For example, in the context of both RATA NanoNextNL and CNS-ASU, Fisher and Rip (2013) have discussed Constructive Technology Assessment (CTA) and Socio-Technical Integration Research (STIR) as 'soft interventions practices' addressing different layers of social-technical change: respectively, the micro level of laboratory practices and the meso level of interaction between societal actors. Accordingly, they position STIR as addressing cognitive *reflection* in *collaborative* approaches (cf. Guston 2000b, Fisher, O'Rourke et al. 2015, Fisher et al. 2016)[284] and CTA as focusing on *reflexivity as feedback*, emphasising the aspect of (constructive) *insertion* (cf. Rip and van Lente 2013[285]). Recognising these different levels, approaches and contexts allows for integration across a range of activities, from laboratory studies (e.g. Doubleday 2007, Ziewitz and Lynch 2018) and understanding scientist's understandings of responsibility (e.g. Glerup, Davies et al. 2017) to research evaluation.[286]

The range of integrative approaches can be further broadened (cf. Fisher, O'Rourke et al. 2015). However, the question of concern is how linking different methods and approaches can induce systemic change. Fisher and Rip (2013) assert that 'modulation' is what one can best hope for: methods have to 'invite' rather than 'prescribe' (like requiring the inclusion of ELSA research or adherence to a code of conduct). However, starting from the level of research governance, one can reason the other way around as well. First of all, both Fisher and Rip acknowledge elsewhere that it have been the very prescriptions for including implications research which created the institutional spaces for performing STIR or CTA. Building on that, institutional uptake of the learning in these activities can be thought through in terms of activity and approach, but also in terms of the institutional arrangements in which they are situated. The latter includes

[284] Cf. Fisher et al. 2015 on differences in rationale – facilitate, augment, problematize, reform – and Fisher et al. 2016 on ways forward for integrative approaches.

[285] Rip and Van Lente (2013) argue that building on the intersection of the rise of ELSA studies and public dialogues about science and technology, the co-evolution of science, technology and society becomes increasingly reflexive. They claim CTA, as practiced in NanoNed (NanoNextNL's predecessor), is serving that purpose.

[286] The discussion in this chapter suggests that deliberately deploying a range of methods is also preferred to merging all kinds of approaches into an encompassing blend of 'comprehensive Technology Assessment' as proposed by Doorn et al. (2013).

accountability structures, ranging from financial arrangements to demands for impact, as well as – on a more practical level – the role of researchers, project leaders, and the like, up to program board members of the commissioning organisations.

In practice, such a comprehensive approach would critically depend on broad institutional support, which in most cases exactly is to be accomplished first. For example, (Randles and Laasch 2016, Randles 2017a) discuss 'deep institutionalisation' as a normative business model, e.g. for universities[287], involving a wide range of activities across all kind of organisational levels. However, they also show that deep institutionalisation is a process indeed, with crucial roles for institutional entrepreneurs with respect to new models proposed *and* active de-institutionalisation of traditional models. Working towards transformative change in research governance, therefore, starts with modulation indeed, but which can be deliberately applied at multiple levels and methodologically tailored with respect to the aforementioned relation between reflexive capacity building and normative assessment.

Outlook: widening circles of engagement

In the analysis of RATA NanoNextNL and CNS-ASU three levels can be discerned. The first level is that of activities and individual learning, typically by students or researchers as target audiences. Here, the discussion of RATA NanoNextNL has pointed out the need to involve supervisors or principal investigators, while the discussion of CNS-ASU highlighted the importance of training reflexive qualities in thinking science-society relations. At the second level, of organisational entities, I have highlighted key conditions set by performance indicators, modes of interaction with stakeholders and leadership.

The third level is about the transformation of social science and implications research itself. Actively engaging supervisors, board members or stakeholders is not a task to be assigned to single PhD or postdoc projects, but requires dedicated centers of expertise. In turn, academic communities in science, technology and innovation (policy) studies[288] can mainstream integration approaches by fostering communities of practice. Just like the history of public engagement in science and technology, there are many guidance documents, evaluations, frames and models. At the same time, each situation will exhibit its own politics of implementation, for which no 'best practice' is to be

[287] Randles and Laasch (2016) have conceptualized their framework for theorizing organisational change , for which they, amongst others, have taken the institutional policy of ASU as deploying a normative business model (the 'New American University') as a case of responsible university governance. Daimer, Berghäuser et al (2023) show that the deep institutionalisation framework can be applied to policy learning as well, but they focus on specific categories.

[288] E.g. S.NET, Eu-SPRI, SDN, 4S or EASST

determined. Centers and networks than can facilitate institutional and societal learning.[289]

Widening circles of engagement however quickly puts a strain on available resources. Therefore, the challenge of transformation also is to incorporate the learning about social dimensions as well as societal embedding in structures and strategies for impact creation more broadly (e.g. education, impact assessment, valorisation and entrepreneurship). In this way, overlapping themes can be addressed as well, like public engagement, open access, diversity, social impact assessment or sustainability goals, all of which – like Responsible Innovation in general – can be considered as 'a going concern' (Guston 2014). It is exactly because of these multiple demands that dedicated spaces are needed to develop integrative approaches.

8.3.3 Cross-case findings for RQ2: what can be learned for transforming responsibility?

Figure 33 summarises the pathways for transforming responsibility in research and innovation that have been constructed in the context of risk governance and research governance. The final step in this chapter is to provide a speculative outlook on how these pathways may help to address actual challenges in both domains. For risk governance I will discuss the challenge of anticipating the impact of new generations of materials, as currently prepared for by the European Commission. For research governance I will discuss the Impact Plan approach from the Dutch research council NWO as a potential vehicle for advancing sociotechnical integration.

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[289] For example, for the Dutch context Sikma et al. 2019 highlight the differences in conditions for public engagement and stakeholder interaction as set by subject and structure of research programs. Chilvers and Kearnes (2020) provide practical orientations to increase reflexivity, create ecologies, being innovative and conducive.

Domain	Pattern observed	Reflexive orientation	Institutional options
Risk gover-nance	Horizontal interlock reproducing systems rather than reconfiguring them	Organising vertical scrutiny for facilitating political choice	Regulatory System Assessment: linking independent system analysis to parliamentary agenda setting
Research gover-nance	Lack of institutional uptake caused by reciprocal relation between cognitive and organisational factors	Aligning node/network and reflexivity/assessment for double loop learning about societal implications as well as societal embedding	Widening circles of engagement: - Individual: involving supervisors - Activity: terms of evaluation - Field: communities of practice

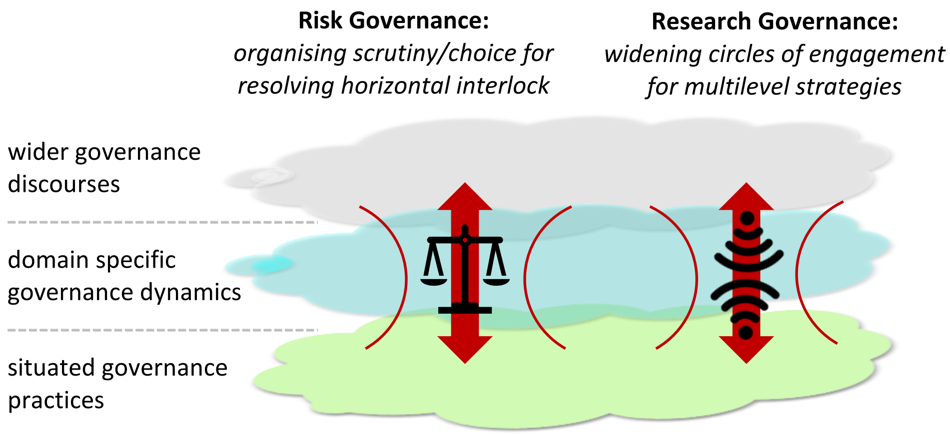

Figure 33: suggested pathways for transformation

Risk Governance: shaping next generations of 'advanced materials'
'Advanced materials' have replaced 'nanotechnologies' as the new label for research funding in material sciences. While the majority of the research activities under the new label can be captured as next generation nanomaterials, new uncertainties with respect to health and environmental safety have been identified as well. In a way the situation thus is similar to that of the first generation of nanomaterials two decades ago. Against this background I will sketch how Regulatory System Assessment (RSA) could mitigate the governance failures observed for nanomaterials in the case of advanced materials.

Let us assume that, in the European context, the European Environmental Agency (EEA) would be tasked with RSA and in that position has to inform political choice about the governance of new generations of 'advanced materials' by independent system analysis. I will first sketch what kind of activities and interventions system analysis could provide for, by drawing analogies with current issues in nanosafety governance, and then discuss how the link to political choice could move the function of RSA beyond just another voice in expert-stakeholder debates.

System assessment activities

First of all, it then would have to point out that the current interest in advanced materials seems to repeat the history of nanotechnology. At the moment, new programs and governance structures are being prepared for institutionalising advanced materials as a new field of research and innovation. However, these initiatives are largely driven by technology push agendas (e.g. the Manifesto or roadmap on advanced materials)[290]. At first sight, lessons from governing nanomaterials appear to be learned: even while attention for potential risks is raised in a mainly hypothetical way, references to Responsible Innovation are made in this respect. However, similarly as the claims about addressing societal challenges, these references are rather superficial and not applied to the innovation trajectories being proposed.

For example, the application of graphene in batteries could further increase their capacity. Since battery technology is a crucial element in current energy transitions, the application of graphene and other forms of nanosized carbon in it (such as carbon nanotubes), allows for a widespread introduction into the environment of materials still under scrutiny. None of the advanced materials agendas address the challenge that even understanding and addressing the risks of preceding, first generation nanomaterials, are still subject to many uncertainties. To date, there have been no immediate accidents with nanomaterials reported, but concerns about long term effects are still present. Occasionally, this has prompted high impact regulatory action, such as the ban on titanium dioxide in food products by the European Food Safety Authority (EFSA)[291]. Furthermore, the graphene agenda for battery technology sustains particular battery designs for which other unintended effects (such as related to Lithium mining) are increasingly being debated. For these issues RSA can address the overall process of agenda setting on advanced materials, by bringing them to the attention of both Commission and Parliament.

One step further would be proposing which kind of institutional arrangements have to be organised. Above issues have implications for practices of risk assessment, regulatory paradigms and trajectories for sustainable development, as well as the relations between them. As for risk assessment, research in advanced materials basically seeks to continue what has been searched for in nanomaterials before: creating functional

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[290] See European Commission website on advanced materials and ami2030 for the Manifesto and roadmap (last accessed March 10, 2023).

[291] https://www.efsa.europa.eu/en/news/titanium-dioxide-e171-no-longer-considered-safe-when-used-food-additive (last accessed March 10, 2023).

material properties beyond the chemical compound. This then requires new testing methodologies in chemical risk assessment. Provided that such methodologies are developed in time – which is not even the case for first generation nanomaterials – this wouldn't address a more fundamental problem of scale: the many potential variants cannot be assessed effectively by the case-by-case approaches resulting from existing regulatory paradigms. Regulatory science agendas (knowledge development), therefore, have to be informed by regulatory roadmaps that work towards new, physical property based assessment mechanism for prioritisation and hypothesis testing (organising choice). RSA can provide for institutional capacity to either organise participatory settings for constructing such roadmaps, or commenting on them.

Another function of RSA could be to organise feedback between regulatory agendas and R&D programming, i.e. the link between *foresight* with respect to projected scientific and technological developments and *oversight* in keeping track of the prospects for adverse impacts. After two decades of nanosafety research and policy action, mechanisms for foresight and oversight have not become better geared towards the systemic risk of novelty creation by research and innovation (cf. EUON 2021). A typical example, in this respect, are the ongoing discussions about establishing a (single) regulatory definition of nanomaterials. These discussions have not been resolved because purposes of precaution (typically to be achieved by creating oversight) are mixed up with purposes of direct protection (e.g. establishing limit values for emission to the environment, or exposure to workers and consumers) and the evidence needed for that. The intervention that RSA can make here, is to suggest a distribution of roles and responsibilities by which both logics as well as their interrelation can be served.

Finally, integrated approaches for advanced materials would not only include safety and sustainability assessment at the level of materials, but also in sustainable development trajectories for application markets (such as the role of batteries in mobility). This extends the governance of advanced materials research and development into the European Green Deal policy mix, covering policy agendas like the Circular Economy Action Plan and the Zero Pollution Action Plan, under which the Chemical Strategy for Sustainability (CSS) is located. Such actions concern the challenge of policy coordination, for which RSA can provide feedback during both policy formation and implementation.

Leverage by linking up to political choice

The scope and complexity involved in above levels of system assessment suggests that a comprehensive coverage of all related issues would be simply too much for effective policy analysis, even if an organisation like the EEA can draw on national expert networks (like the current EIONET). Instead, RSA has to strike a balance in a holistic understanding of the system transformations at stake and the practical issues in it that require political choice. The 'transformative governance' agenda (Braams et al. 2021) here, is one of thinking the governance of risk not only in relation to novel material properties, but also in relation to the systems producing and responding to these risks. From that perspective, there first are issues of costs and prioritisation, since other health and environmental problems compete for attention and resources as well. Second, the governance failures discussed above touch on more general barriers to innovation in regulatory risk assessment[292] as well as policy coordination across regulatory directives and other instruments. Bringing such discussions to the attention of the European Parliament is far from straightforward, if only because European member states are seeking influence as well. However, proximity to the parliamentary arena can work as a carrier for informing debate about concrete policy dossiers.

A recent opportunity for such concrete discussion would have been the preparatory phase in designing the next European Framework program, Horizon Europe. In this edition, nanotechnology is not taken up anymore as a specific field of research and innovation programming. Since a number of years already, the term nanotechnology no longer works as a fund raiser and nanotechnology policies have been gradually dissolving into broader research agendas and chemical policies. However, in this process key governance challenges, such as the question how to move beyond case by case approaches simply disappeared from policy agendas as well. In such a situation RSA can serve a watchdog role by bringing the lack of proper policy evaluation to parliamentary attention when agendas for advanced materials came up. One way to do so is by pointing out the gaps between (the quality of) policy evaluation and subsequent rounds of policy formation and coordination.

The recent stock taking exercise of two decades of European Commission funded nanosafety research has been organised in another round of research projects provides a good example. Not only are European Framework research projects ill-positioned for organising policy learning and institutional uptake by the European Commission, the way in which these projects have been tendered caused only the toxicology oriented consortia that have conducted the research to be evaluated as de facto eligible.[293]

[292] e.g. see Boullier, Demortain et al (2019) and Laurent and Thoreau (2019) on transparency and capacity problems hampering the adoption of predictive methodologies.

[293] Three research projects funded by the European Horizon2020 Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing (NMBP-13) program (Gov4Nano, NanoRigo and RiskGone) had to develop a Nanotechnology Risk Governance Council (NRGC). As a case of research governance the situation has been suboptimal to say the least. Open competition has been severely limited since preparations for the call are discussed beforehand in the nanosafety research community, organised in the Nanosafety Cluster (NSC), in which the participating organisations all are fully geared towards acquisition of the next round of projects. In fact, the NSC would have to fulfill the role of a NRGC, but never received institutional mandate and resources support for those tasks. The same goes for the requirement for the three projects to cooperate after the budget had been split and distributed across three consortia (together spanning the NSC network). Finally, such institutionally supported cooperation would make sense indeed, since a lot of the work conducted in the three projects concerns standardization, quality control, etc. of risk assessment approaches, as well as

Further interventions even more showed a lack of commitment to policy learning. The stock taking exercise would have to result in the design of a Nano Risk Governance Council (NRGC). Upon evaluating the proposals the budget was distributed across three consortia, which were urged to cooperate, but without providing additional means for that task. Close to the end of the projects, Directorate E3 of DG RTD of the European Commission, communicated that the NRGC was no longer needed since the Commission had adopted the new Chemical Strategy for Sustainability (CSS). While all of these interventions could have been organised as smart policy coordination, it in fact created a new gap in the ability to anticipate novel impacts of the new generations of advanced materials, since neither the CSS or the adjacent partnership for renewing chemical risk assessment methodologies (PARC), features dedicated action lines towards novel materials[294].

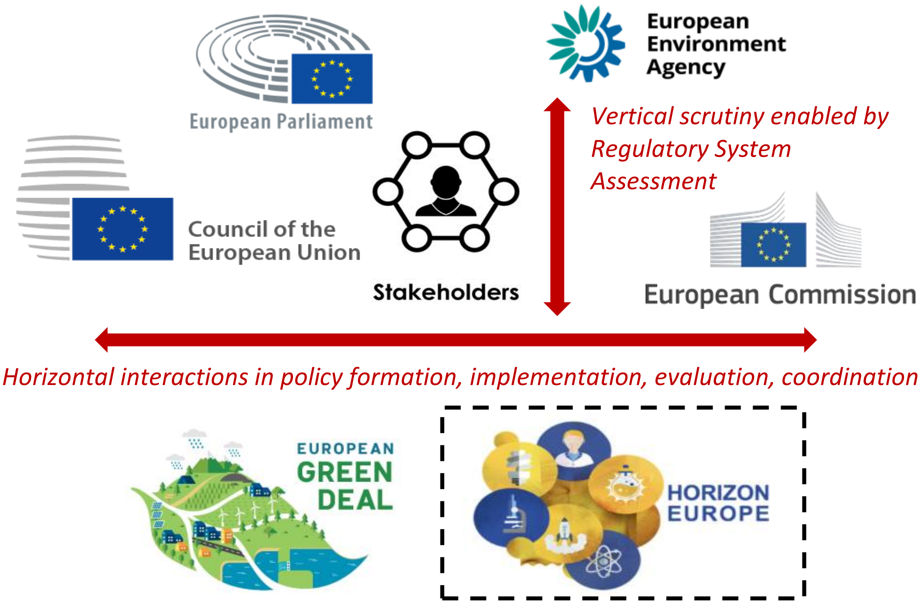

Figure 34: Regulatory System Assessment and European Union institutions

institutional design and positioning (the role of a NRGC in relation to authorities like ECHA and EFSA) rather than research.

[294] Ironically, this is being masked by general references to 'Safe and Sustainable by Design' (SSbD), a policy concept that has been the result of merging Safe by Design (SbD) agendas of the European nanosafety community and the field of sustainability assessment. However, in both the CSS and PARC, SSbD is being geared towards substitution practices for already known chemicals, not to anticipating the impacts of novel generation materials. The OECD (2020) report on SbD topically reflects both the problem framing and institutional support of regulatory science and government officials from the Netherlands in the design of the SSbD framework by the Sustainability Assessment experts of JRC (2022). The resulting framework narrowly draws on methods for risk assessment and life cycle assessment, without an implementation strategy that should take care of all SSbD action lines in the CSS.

If an institute like the EEA, when tasked with institutional capacity for RSA, timely can signal such gaps in policy coordination, is able to frame what is the institutional transformation at stake[295] and can come up with scenarios for remediation, it would gain authority as a watchdog for the European Parliament. In addition, it can play a constructive brokering role, thereby gaining credibility towards experts, stakeholder organisations and policy makers[296].

Research governance: impact strategies as learning devices
The pathway that has been identified for transforming responsibility in research governance featured two orientations: 1) widening circles of engagement for research activities towards double-loop learning (about societal impacts as well as about societal embedding) and 2) integrating this learning in existing accountability structures rather than extending them with further demands. I will discuss how the increasing demand for impact creation, especially in applied research projects, may provide an important opportunity for operationalising these two orientations. Interestingly, key drivers for the demand for impact creation are both economisation and democratisation of public research funding (see Chapter 2.4). While both trends can reinforce each other, there are also tensions between them. A crucial condition for learning then is the way in which a research project considers and interacts with target audiences and broader stakeholders.

An interesting case, in this respect, is the knowledge utilisation strategy of the Dutch research council NWO.[297] One of its more sophisticated instruments is the Impact Plan approach, which is required for proposals in several programs. The Impact Plan approach has been introduced in the context of a national science agenda (*Nationale Wetenschapsagenda*, NWA), which has been crafted from a large public consultation process. The visibility of this process in the public domain created an urge for demonstrating public value. To this end, the Impact Plan approach requires research consortia to specify assumptions on the relations between output, outcomes and impact

[295] Cf. the (political) complexities in addressing climate change, which underline as well as challenge the need for urgent action. Likewise, it is also *because of* the complex institutional landscape in risk governance and sustainable development that the introduction of 'novel entities' has been framed as a problem of crossing planetary boundaries (Steffen et al. 2022), i.e. not in terms of pollution, but with respect to the very ability to anticipate potential harms.
[296] For example, with respect to the current policy discourse on Safe and Sustainable by Design (SSbD) under the CSS, the EEA has contributed by outlining its own vision (EEA 2021). However, industry associations as well as environmental organisations have been propose alternative frameworks as well (e.g. CEFIC 2021, ChemSec). In existing fora these frameworks become part of interest advocacy rather than deliberative negotiation about the different rationales they represent. A brokering role then differs from regular consensual approaches in which choice, or reflexive feedback about organisation is overlooked, or postponed. Most of the time, the focus is on 'what should be done?' rather than 'what should be done, given that not all is possible, or has to be arranged at other levels of coordination?'
[297] https://www.nwo.nl/en/knowledge-utilisation (last accessed 11 March 2023)

of the project (following a theory of change). At the same time, it introduces a reflexive element by monitoring annual progress and asking *why* specific activities have been undertaken instead of merely administrating publication numbers. In this way, the Impact Plan has to become more than an obligatory passage point during acquisition.

The Impact Plan approach can also be used for actively working on anticipating societal issues and addressing these within the projects. For this purpose the scope of actors engaged in the project will have to be broadened. In its present form the Impact Plan approach stimulates the NWO objective of interaction across the 'knowledge chain' (from basic and explorative to application oriented research). Following the strategy of modulation at multiple levels, it will take several efforts to opening up this process to other actor categories. A first line of action is capacity building across the levels depicted in Figure 35. At the level of individual researchers anticipation and embedding can be fostered by requiring principal investigators (and their departments) to actively engage in working towards impact creation throughout project lifetimes. This, in turn, requires research funders – in this case NWO – to arrange funding conditions (e.g. stimulating substantial senior staff participation). Research organisations have to allow for that as well, for example, in balancing research and teaching obligations, but specifically in facilitating interactions with outside actors. The latter than can be supported through the creation of professional networks developing methods, offering training or co-organising events, thereby enabling quality control in approaches to anticipation and inclusion. Finally, all of this requires a broad awareness and understanding by academic researchers of philosophies and approaches with respect to impact creation and societal embedding. Both are increasingly becoming part of higher education.

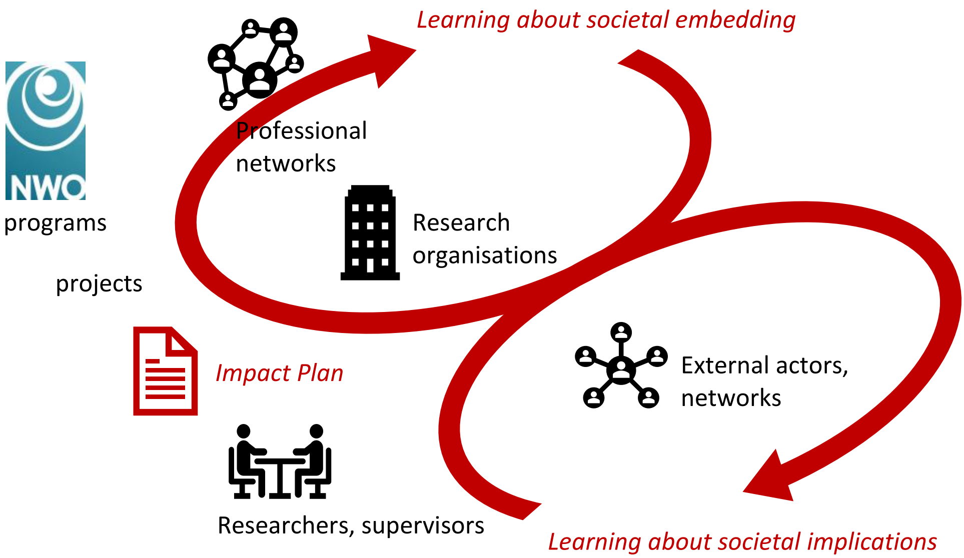

Figure 35: double loop learning for Impact Plans

A second line of action concerns the question how to make this all happen. Interaction with outside actors is highly demanding, especially during the acquisition phase. And most of the actions mentioned above go beyond the scope of project funding. However, a number of requirements, such as involving partners outside academia are already in place. A research council like NWO, can build on this by developing a multilevel strategy as suggested in this chapter. An important starting point is the evaluation of project proposals. If anticipation and inclusion are evaluated in terms of quality rather than as conditions to be met, this would create a strong incentive for competition on the quality of societal embedding itself. Research organisations than have to invest in capacities for meeting these demands.

Since such a measure cannot be implemented at once, NWO would have to resort to organising institutional learning along the process, for example by programs focusing on learning from efforts for strengthening socio-technical integration across projects. Again, this can be made mutually supportive with advancing impact creation in general. For example, Matt, Gaunand et al. (2017) have identified ideal-typical pathways for impact creation in different contexts (e.g. new or existing networks, demand and absorptive capacity). For anticipating societal implications and societal embedding specifically, lessons have to be translated in guidance and criteria, such as on scenario development, stakeholder interaction, reflexive monitoring, etc. Furthermore, review committees have to be trained, preferably in interaction with research organisations (typically universities). In this way institutional learning extends beyond the networks directly involved in advancing socio-technical integration approaches and further strengthens the turn towards greater social accountability already going on. Deliberately organising double loop learning for each of above measures then can accelerate the system transformation like 'a culture of responsibility' (von Schomberg 2013) sought for in the quest for Responsible Innovation.

9. Making a difference? – lessons for Responsible Innovation

9.1 Introduction

What can be learned from the research presented in this thesis for advancing the quest for Responsible Innovation in general? In chapter 1.3 I have summarized the aim of this thesis as "*informing the quest for Responsible Innovation, by developing a socio-normative approach, for guiding the transformation of responsibility in research and innovation up to inducing systemic change, so as to make a difference in the end*." For this purpose the thesis addresses two main research questions: 1) "*what shapes the governance of Responsible Innovation?*" and 2) "*what can be learned for transforming responsibility in research and innovation?*" In the previous chapter I have answered these questions by constructing domain specific pathways for transforming responsibility in research and innovation. In this chapter I will draw general lessons and reflect on the research approach.

The pathways for risk governance and research governance have been constructed by approaching governance *as* learning.[298] A general lesson in this respect, is that new responsibility conceptions have to take root in existing responsibility distributions. Rather than crafting new responsibilities or institutional structures on top of existing ones, making a difference with Responsible Innovation is about guiding processes of transformation. Since the quest for Responsible Innovation itself builds on wider trends in the evolution of social accountability in research and innovation, the contribution of this thesis to the discourse about Responsible Innovation is to further guide these processes of transformation.

For example, where anticipation and inclusion are already promoted in many risk governance frameworks, I have highlighted the particular dynamics that arise from the interrelation between them: what is being anticipated depends on who is involved and the other way around. Similarly, fostering integration of societal considerations in research governance already builds on long standing awareness and attempts to anticipate broader impacts. Yet, actual integration as well as mainstreaming crucially depends on pathways for institutional uptake.

With respect to governance I have shown that the domains of risk governance and research governance are marked by specific accountability mechanisms that shape the way institutional learning unfolds. In the collective problem setting of risk governance

[298] See also Stilgoe (2018) for a discussion of governance and societal learning.

the interrelation of anticipation and inclusion led to reproducing rather than reconfiguring responsibilities. In the mutual problem setting of integrating implications research in large programs the lack of institutional learning can be better characterised by principal-agent dynamics in the way attempts for integration are being evaluated.

The vantage point taken in this thesis is that such dynamics should not be treated as obstacles to overcome, but the very thing to work with, since they represent various kind of logics and credibility cycles (cf. Hessels, Franssen et al. 2019). Likewise, transformation is not just about change, but about change shaped by interdependencies. This is especially relevant for Responsible Innovation, since ambitions and activities under that label, often introduce agonistic orientations with respect to the practices of research and innovation they target. It then is important to investigate how learning between actors is related to resolving the tensions that arise from the interdependencies at stake. For such learning to become institutional learning, it typically are accountability structures that have to allow for that, and thus have to be modulated to that end.

In this final chapter I will reflect on the implications of these lessons in three steps. First, I will position my findings and approach in the context of recent discussions in the scholarly Responsible Innovation community about the lack of structural impact (section 9.2). Then I will provide a speculative outlook, focused on the future of RRI in the activities of the European Commission (section 9.3). Finally, I will reflect on the utility of the research approach developed in this thesis, by discussing its aim, added value, limitations and questions for further research (section 9.4).

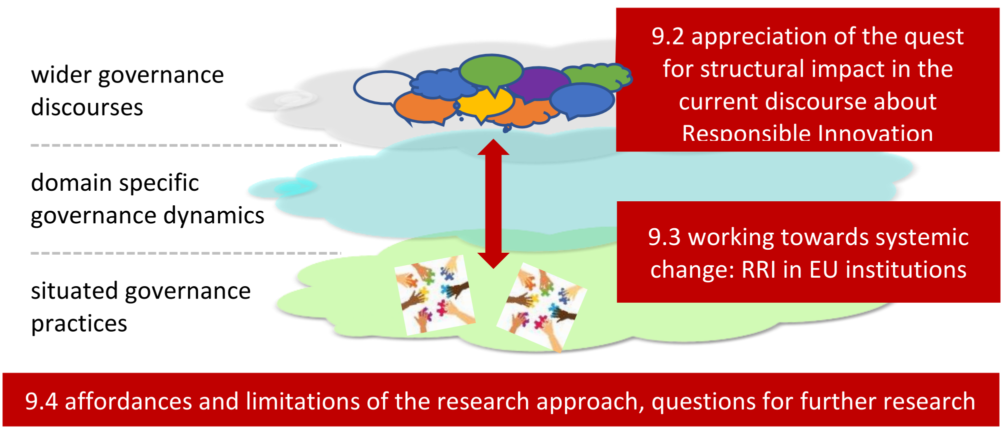

Figure 36: general lessons and limitations

9.2 Back to the future of Responsible Innovation

In Chapter 2 I have investigated the quest for Responsible Innovation until about 2015. From then on, a number of attempts for implementation, mainstreaming and monitoring took off, especially in the 8th Framework Program of the European Commission (Horizon 2020), where projects on Responsible Research & Innovation (RRI) produced a large share of contemporary references to the notion of Responsible Innovation. These projects have been reaching out to industry and higher education, addressed specific technological developments, explored other international contexts, etc. Alongside, there were monitoring efforts, next rounds of academic reflection, including the growth of contributions to the Journal on Responsible Innovation (JRI), and across all this, the evaluative outlooks on the prospects of Responsible Innovation in new research and innovation policies, most notably Horizon Europe, the 9th European Framework program.

Signals

Together, this range of activities address a much broader scope of Responsible Innovation than the specific challenges in the governance of emerging (nano)technologies that have been investigated in this thesis. The question in common, however, is how to work towards structural impact. Among Responsible Innovation scholars and practitioners the lack of such impact has been increasingly recognised.[299] A telling indicator, for example, is the difference between the two declarations that have been issued by these communities at the start of Horizon 2020 – the Rome declaration (2014) – and the Pathways declaration towards the end of it (Brussels 2019, see Gerber, Forsberg et al. 2020).

According to the Rome declaration, the conditions were then right for starting to underpin all European research and innovation with RRI principles and measures. The declaration called for capacity building activities at all levels, the review and adaptation of metrics and narratives, and institutional change fostering RRI in research and innovation performing organisations. Five years later, the Pathways declaration was written in an alarming tone. While it judged the many activities being initiated as an impressive step taken, it also acknowledged that institutional change went slow and that RRI as a policy concept was threatened with dilution in new institutional cycles of research and innovation policy formation.

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[299] See, for example, the edited volume by researchers involved in the NewHoRRIzon project (Blok 2023), the special issue on ten years of RRI of the Journal for Responsible Innovation, discussed in Chapter 1 or the discussions on the occasion of the publication of the 'International handbook of Responsible Innovation' (Von Schomberg and Hankins 2019), see weblog for the notes of the three related discussion sessions and the reflection by Jorrit Smit on the final meeting in Brussels (in Dutch; both URLs last accessed 11 March 2023).

Indeed, as for EU level policies and programs, new policy concerns, like 'open science'[300] (speaking to increasing calls for public accountability) or 'mission oriented innovation policy'[301] (further building on the language of societal challenges) have been taking over. While these do adhere to ambitions voiced under the heading of Responsible Innovation, they also narrow down its scope and reinforce technology push framings. For example, the concern with openness focuses on open access of academic publications as an alternative model to the profit making business of scientific journal owners, while openness in science, especially with respect to societal challenges/concerns/ relevance, is much more dependent on the transformation of research evaluation metrics and mechanisms.[302] On the other end, the radical talk of a 'moonshot' organisation of research and innovation towards addressing societal challenges quickly glosses over the social complexity involved (cf. Kuhlmann and Rip 2018), thereby giving way to new rounds of open-ended promises.

Causes

This outcome can be attributed to the presence of other orientations, like the attention for competitive industries, SME led innovation or investing in key technologies, all of which are still going strong. Responsible Innovation did help to reiterate societal challenges and concerns, be it in relatively new contexts, such as gene drives (Delborne, Kuzma et al. 2018) or autonomous driving (Stilgoe 2018), or in probing existing frames and frameworks, such as for corporate social responsibility (Pavie 2014). But not more. As 'a policy concept seeking implementation'[303] it did become part of the business, but it also allowed for continuing business as usual.

By the same token, the lack of structural impact can be attributed to the way policymakers, scholars and practitioners have been working on the topic of Responsible Innovation[304]. Randles (2017a), Owen, von Schomberg et al. (2021) and Griessler, Braun et al. (2023) point to the fragmentation of the Responsible Innovation policy and practitioners field, in which Responsible Innovation has not been consolidated as a well-developed concept, nor rooted in institutional structures.

Orientations

The question is what can be done about it and by whom. Bottom-up initiatives cannot address this problem as such, while actors in the position to impose top-down strategies,

[300] See European Commission website (last accessed 11 March 2023)
[301] Cf. Mazzacuto report, OECD website, European Commission overview (last accessed 11 March 2023)
[302] Cf. the Dutch 'Plan S', Leiden Manifesto and the launch of the RoRi institute (last accessed 11 March 2023)
[303] Acknowledgements to Arie Rip for this phrasing.
[304] Including myself. A good question for introspection is how 'we scholars' have engaged with the quest for Responsible Innovation. See also the response by van den Hoven (2022) to the special issue of the Journal of Responsible Innovation about ten years of RRI.

most notably the European Commission, internally work along the same forcefields as those outside. Proposals, for either an overall multilevel strategy (Shelley-Egan, Bowman et al. 2018), a comprehensive agenda for 'deep institutionalisation' (Randles 2017a, Daimer, Berghäuser et al. 2023), or a New Public Governance approach (Loeber, Bernstein et al. 2023), therefore are not likely to be taken up by the European Commission as well.

At the same time, other, more prominent policy agendas, such as the European Green Deal or the UN Sustainable Development Goals (SDGs) can be targeted for interventions by instruments that have been experimented with under the heading of Responsible Innovation, like Social Labs (Griessler and Blok 2023) and other mechanisms for co-creation (Robinson, Simone et al. 2021). Various authors therefore suggest to let go of predefined concepts and principles for Responsible Innovation and continue experimenting with instruments for addressing societal challenges as well as for broad inclusion of actors (Ulnicane, Mahfoud et al. 2022, Cohen and Gianni 2023, Loeber, Bernstein et al. 2023).

My contribution to this discussion is that whether working on Responsible Innovation, Circular Economy, Open Science or whatever other label suggesting systemic change, each activity has to adopt a strategy for working from experimentation to broader transformation. Statements about working towards systemic change are all over the place, but many of them without dedicated action for institutional learning beyond local levels of intervention. The analysis in this thesis has shown that an importing starting point for such a strategy are the accountability mechanisms at stake, especially the way programs by which the activities are funded are being evaluated, as well as the (dominant) problem frames and opportunities in the actor landscape.

In addition, I have shown that an explorative and interventionist approach benefits from being informed by a long term perspective on the future of Responsible Innovation. Drawing on Rip (2014), I have traced the quest for Responsible Innovation as evolving from an initial move 'to do better' (the discourse about Responsible Development of nanotechnology in the wake of public controversy about biotechnology), to the shift in attention towards direction and societal challenges (in the broadening to the discourse about Responsible (Research and) Innovation) and the opportunity to interlink approaches that have been institutionalized before (Ethical review, Technology Assessment, sustainable development, …). Considering these historical trajectories helps to evaluate activities beyond the level of direct outcomes, thereby setting the scene for discussions about broader transformation.

9.3 Prospects for RRI in Horizon Europe

Responsible Research and Innovation (RRI) has not been continued as a cross-cutting issue in the Framework Program that succeeded the Horizon 2020 program, Horizon Europe. Formally, it has been taken up by horizontal integration, i.e. through the adoption of principles on open science and gender equality.[305] Outputs from RRI projects under Horizon 2020, as well as those from the Science With And For Society (SWAFS) program more broadly, are positioned as resources for programs which will require inclusion of Social Science and Humanities (SSH) expertise or methods for co-design, co-creation or co-assessment. Clearly, this is not what many researchers participating in RRI/SWAFS projects had been calling for[306]. Instead, Owen, von Schomberg et al. (2021) call for retaining Responsible Innovation the way put it: as a "*transformative vision for reconfiguring science, innovation and society*", while continuing as "*a site for debate, praxis and politics.*" How would the unit within DG Research and Innovation of the European Commission which has to take care of the legacy of SWAFS (the Open Science team) then have to proceed?

Following the research approach developed in this thesis a first thing to consider is the interrelation between problem framings, evaluative structures and communities. Some of the former 'six keys' of RRI have been translated into general principles indeed, but not all, and effects will be strongly depending on the way these principles will be operationalized. Likewise, where societal engagement in the form of co-design, co-creation or co-assessment is encouraged throughout Horizon Europe, quality in terms of reflexivity or societal embedding is far from self-evident. The Open Science team, therefore, will have to rely on the input from the former SWAFS networks for improving support for and quality control of these instruments. This implies that they have to set up a program for that specifically, as well as a strategy for institutional uptake, for example in the 'Reforming and enhancing the European R&I system' programs of Horizon Europe.

Next, the unit could adopt a multilevel strategy similar to what I have been suggesting for the Impact Plan approach of the Dutch research council NWO in the previous chapter. Building on above network creation it can organize a process of double loop learning, in which research on addressing societal challenges and on societal implications of science and technology is informed by research as experimenting with societal embedding and vice versa. Such a process gains credibility if it is linked to current research and policy agendas, such as the key technology programs or the European Green Deal action plans. Concurrently, the unit has to identify supportive

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[305] See the strategic plan (2021), program guide (2022), as well as a presentation by EC officer Linden Farrer.

[306] See, for example, the position paper following up on the Pathways Declaration (author initiative: https://rri-in-horizon-europe.net/about/) / all URLs last accessed 11 March 2023.

contexts for institutional uptake, for example in European Technology Platforms, interservice working groups within the Commission, etc… It can also exploit the networks of national research councils supportive to Responsible Innovation.

Finally, the process of double loop learning has to be guided by ideas for transforming the European Research Area, in particular the funding mechanisms in it. (Loeber, Bernstein et al. 2023), in this respect, observe that a 'New Public Governance' (NPG) style would better fit the aims and ambitions of mission oriented research, including the RRI programs, than the New Public Management (NPM) approach which has been dominant so far.[307] This could start already by organizing learning across the projects administered by the unit itself. In Horizon 2020, for example, researchers working in projects like HEIRRI, Nucleus, RRI Practice, NewHorRRIzon or JERRI, were already quite aware of the lack of structural impact (cf. Gerber, Forsberg et al. 2020, Novitzky, Bernstein et al. 2020, Owen, von Schomberg et al. 2021). Yet, no project has been targeting the 'mainstreaming RRI' unit in the European Commission administering ever new rounds of research projects, tendered among a rather narrow community of researchers.

9.4 Affordances, limitations and questions for further research

This final section reflects on the added value of the 'socio-normative' approach developed in this thesis. In chapter 1 I have discussed that such an approach starts from acknowledging that Responsible Innovation is not an objective out there, but itself under construction.[308] Accordingly, I have developed a heuristic, which links interpretative analysis and explorative research. In this way I further developed the analytic and conceptual foundations of the approach taken in the Res-AGorA project (see Chapter 3). The Res-AGorA project aimed to learn from *de facto* governance, conceiving this task as

[307] In NPM style institutional changes resulting from RRI/SWAFS projects have been reported (Delaney, Iagher and Tornasi 2020) in numbers, ignoring the complaint that European projects are inherently ill-positioned for broader institutional uptake, unless home institutions of the partners involved (typically universities) provide platforms to follow-up on outcomes and results. In the cases studied for this thesis CNS-ASU could grow into the new school SFIS at ASU. At the University of Twente, the section (STePS) has been a place for Constructive Technology Assessment (CTA) development, which increasingly finds its way in educational activities (e.g. Responsible Futures program for University College students).

[308] cf. the argument of Chilvers and Kearnes (2020), who discuss the history of public engagement. They attribute the lack of quality and impact of so many public engagement activities to "*residual realist assumptions*": participation is often thought of as a good in itself and publics as a given, while both have to be deliberately constructed. Alternatively they propose a more relational framework for making participation more "*experimental, reflexive, anticipatory and responsible*".

a question of 'meta-governance'[309] and informing governance strategies by multi-perspective insight.[310] Other meta-governance approaches, like 'reflexive governance' (Voß et al. 2006) or 'tentative governance' (Kuhlmann, Stegmaier et al. 2019), both of which have been developed in response to science, technology and society relations, take a procedural stance, fostering flexibility, interactivity and experimentation.[311]

At the heart of above approaches are ideas about structure and agency and their interrelation in discourse and practice. In this thesis I have built on these ideas in developing more normative analysis and lessons for working towards transformative change. For this purpose, I have drawn inspiration from the notion of 're-structuration' as discussed by Grin (2006). Grin envisions re-structuration as happening through "*discursive will formation in recursive practices*" and provides detailed examples of such processes in efforts for transforming agricultural practices. The question for further research posed by Grin is to link strategies for working towards transformative change at niche and regime level to visions articulated at landscape level. The multilevel perspective in the heuristic that has guided the research for this thesis serves that purpose.

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309 In literature meta-governance is discussed as the "*governance of governance*" (Kooiman and Jentoft 2009), or as "*organising the conditions for governance*" (Jessop 2002). Meta-governance accounts provide reflexive orientations for overcoming or avoiding governance failure. For example, Hoppe (2010) discusses meta-governance as 'responsible governance' by policy-*cum*-institutional entrepreneurs. These can be civil servants, but also advocacy groups. Hoppe's focus is on problem structuring, which is being shaped by processes of 'puzzling, powering and participation'. Carefully taking into account then is the responsible way forward. In contrast, Kooiman and Jentoft (2009) focus on process-structuring by presenting normative principles for ensuring quality of deliberation and learning, as well as ensuring that these processes are part of the democratic order. From the domain of macro-economic issues and welfare state models Jessop (2011) and Benz (2007) discuss meta-governance as the judiciously mixing of modes of governance, which has a parallel in Hoppe's responsible problem structuring. For a discussion about responsibility conceptions and meta-governance, see Moan, Ursin et al (2023) as discussed in footnote 63.

310 The framework developed in the Res-AGorA project (the 'Responsibility Navigator' Kuhlmann, Edler, et al 2016) draws on the notion of Strategic Intelligence (Kuhlmann et al. 1999) and provides guiding principles for improving governance in three dimensions: quality of interactions, positioning and orchestration of instruments and creating supportive environments.

311 For example, Kuhlmann, Stegmaier et al (2019) state: "*Governance can be characterised as tentative when it is a markedly dynamic process to manage interdependencies and contingencies. Tentative governance refers to creating spaces of openness, probing and learning instead of trying to limit options for actors, institutions and processes. Tentative governance plays with flexibility (unlike the steering government) and is enacted incrementally. It applies explorative strategies, instead of relying only on orthodox or preservative means. The reverse sort of governance is the highly routinized, structured, without experimentation and very limited degrees of freedom in design and accomplishment*."

Affordances
The multilevel perspective I have introduced starts from a long term perspective on the evolution of responsibility in research and innovation. I have argued that the challenge of transforming responsibility is to be understood as systemic change resulting from the interplay between concrete efforts of working towards forms of Responsible Innovation (niches), governance domains (regimes) and wider discourses about the governance of research and innovation (landscape). Adopting such a multi-level perspective enables thinking in terms of co-production and the resulting interdependencies inherent to any process of transformation: the new has to grow in and from the old, with all kinds of incremental change involved in that.

Acknowledging the many complexities in processes of transformation, many scholars argue to refrain from top-down, command and control thinking and have resorted to various kinds of incrementalism.[312] This has resulted in sophisticated approaches and strategies, such as developed in transition management. However, these approaches still struggle to address political dynamics in working towards systemic change (Grin 2008). Against this background, the analytical value of my research approach is twofold. First, it enables to go beyond incrementalism (however useful) while fully acknowledging the many complexities involved. Actors are bound to all kinds of conditions and relations indeed, but will "*act as if success is possible*" (Jessop 2002, Rip 2006)[313], thereby providing political leverage to their actions. Moreover, they will do so by referring to landscape level ideas. Hence, it makes sense to qualify these ideas for evaluating attempts of working towards transformative change. To this end, I have derived an evaluative frame from central tenets in the quest for Responsible Innovation in Chapter 2.

Second, I have accounted for politics of implementation and accountability mechanisms that channel learning between actors. Systems, whether local, domain specific or national and international configurations (such as research and innovation funding and operating structures, academic or sectoral communities, or markets and value chains) provide functions and stability to the actors involved. Changing that, always involves

[312] Cf. Kovacic et al. (2019) on the attempts to forge a transition towards a Circular Economy: "*We describe this situation as governance in complexity rather than governance of complexity, following Rip (2006). According to Rip, governance of complexity aims at governing systems "out there". Governance in complexity means that "in its non-modernist version, the governance actor recognises that being part of the evolving patterns, s/he can at best modulate them" (ibid.: 83). Governance in complexity is, therefore, a step back from grand challenges and the ambition to steer systemic economy-wide change, in favour of smaller and more localised interventions, which are updated and adapted to context while being implemented.*"
[313] The phrasing by Jessop and Rip actually refers to adopting a stance of reflexive irony in meta-governance thinking. However, the same stance is also at the heart of the modernist approaches in which reflexive orientation on the governance of research and innovation has to make a difference.

(value) conflict. Even while changes in ideas and preferences are broadly shared, there are trade-offs and interdependencies to be accounted for. My research approach puts these elements to the fore as key challenges for governance in processes of transformation.

Practically, the added value of my approach is that it enables reflexive feedback to actors in the field in terms of the problems they are concerned with (instead of general models or principles). Both in drawing case specific lessons and in constructing the domain specific pathways, I have shifted the attention from the institutionalization of Responsible Innovation as a concept, towards reflexive orientations for guiding the transformation of responsibility itself. This has resulted in presenting the outlooks for risk governance and research governance in the previous chapter, as well as in sketching in this chapter a pathway for further action in the offices of the European Commission for rekindling the meaning of Responsible Research & Innovation (RRI) in European research and innovation funding programs.

Limitations

The main limitations of this thesis are the scope and organization of its empirical base in relation to what I have delineated as 'the quest for Responsible Innovation'. Starting with the organization of the empirical base for each case study, the explorative approach developed in this thesis allows for incorporating a broad set of sources, but also features a relatively loose scoping of the empirical material. In chapter 3 I have discussed by what mechanisms for triangulation I have tried to address this limitation. Yet, between the NL and US sites of empirical investigation differences in rigour still remain. Moreover, since the case studies are positioned at different levels in different political systems, the cross-case analysis cannot compare, but is limited to contrasting findings.

More fundamentally are the limitations concerning the overall scope. I have focused on the governance of emerging technologies, thereby leaving out system orientations like gender equity or open access. Moreover, the empirical research is confined to nanotechnology. Although nanotechnology can be considered as an 'icon' emerging technology, including many of the research and innovation practices that are subject to the discourse about Responsible Innovation, my selection of governance practices, challenges and domains certainly is not representative for research and innovation systems. The more general value of the research in this thesis, therefore has to be demonstrated in offering the heuristic that has guided my research as a diagnostic instrument, sensitising to the intricate relation between Responsible Innovation as a (policy) concern, the historically situated quest for it and the objective of transforming responsibility in research and innovation.

Further research

While the notion of Responsible Innovation is attracting less attention at the moment, the interest in transformative change has increased. The latter has become particular visible in the discourse about ‘mission oriented innovation policy’ and ‘transformative innovation policy’[314]. The focus on addressing societal challenges in these discussions has been an important concern in the discourse about Responsible Innovation as well. A big challenge for these fields of study is that many transition agendas intersect (such as in energy, agriculture and circular economy). Objects of transformation then become multiple. On the one hand this raises the need for ever more integrated approaches. On the other hand the findings from this thesis have shown that crafting such approaches from and in the context of existing institutionalisations, requires a continuous vigilance with respect to the various logics and related power dynamics of the systems to be transformed.

What can be foreseen in this process is a continuous balancing act, in which the interrelation between anticipation and inclusion will be relevant again. Here, the research approach developed in this thesis can be deepened by broadening the scope of sites for empirical investigation into other governance domains and to analyse how patterns of institutional and societal learning can be ordered. Such analysis would also invite to take up earlier insights from studying interrelations in discourse and practice. For example, in my case specific lessons nor in my domain specific pathways I have only partly accounted for issue and policy attention cycles or for the power dynamics involved in either ‘opening up’ a problem frame or in ‘closing down’ towards action (cf. Stirling 2008).

Specifically for the risk governance practices studied I have observed that consensual styles (NL) do not appear to be more effective than adversarial styles (US), since the problem of scientism permeates both. For organising scrutiny this could imply that orientations have to be explored, which better support frame reflection and hypothesis testing, like Mouffe’s (2005) call for more ‘agonism’ in democratic systems. More practically, this could start by conceptualise how a mechanism of democratic checks and balances would look like in navigating processes of societal transformation.

Most important, however, is to link these strands of research to concrete experiments that deliberately work towards broader change; so as to make a difference in the end.

[314] See footnote 301 for articulations of mission oriented innovation. For transformative innovation policy, see Haddad et al. (2022).

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Appendix – List of interviewees and commentators

Chapter 4 (nanosafety governance in the Netherlands)

The main input for chapter 4 is a broad reconstruction of activities as commissioned by the Rathenau Instituut (see Chapter 3). For this research project I have interviewed:

- **Willem Henk Streekstra**, chair of the nanotechnology working group at VNO-NCW, the Dutch employer association, which acted as the main spokesperson for industry (5 October 2012)
- **Arthur ten Wolde**, who played a key role in creating the Dutch nanoscience network (STT 1998), later acting as spokesperson for employer association VNO-NCW (17 October 2012)
- **Germ Visser**, spokesperson of chemical company DSM, involved in government-industry negotiations from the start (9 November 2012)
- **Monique Bosman**, co-chair of the governmental working group on nanosafety, on behalf of the Ministry for Infrastructure and Environment (MinIenM, former MinVROM, later MinIenW), leading government-industry negotiations (13 November 2012)

The analysis for this research has been fact checked and commented (25 September 2013) by:

- **Pieter van Broekhuizen**, researcher at IVAM, who played a key role in coordinating the nanomaterial occupational health activities (including the pilot projects discussed in chapter 4)
- **Leon Gielgens**, coordinator of the Dutch nanoscience network (by STW) and acting as spokesperson for nanoscience in the Netherlands
- **Paul Borm**, early involved as both toxicologist and entrepreneur (HZuyd) in discussions about nanosafety and leading the first investigation on nanomaterials used and produced in the Netherlands (Borm 2008)
- **Adriënne Sips**, chair of the RIVM working group on nanosafety and the policy intelligence hub on nanosafety (KIR-nano)

As of September 2015 I have started as a policy advisor at RIVM. In that position I have received additional feedback on my analysis and conducted one more interview:

- **Kees Le Blansch**, coordinator of the nanosafety policy evaluation (Le Blansch and Westra 2012) and involved in the follow-up program on renewing the risk governance policy of the Dutch Government (*Bewust Omgaan met Veiligheid*), (9 June 2016)

As mentioned in Chapter 3, my analysis also draws on my position as parliamentary Technology Assessment officer at the Rathenau Instituut (2005 – 2011), where I did start international news tracking. An important source have been the Twitter feeds of key experts (next to the accounts of the (professional) news media listed in Chapter 3):

- Andrew Maynard (@2020science)
- ReneVonSchomberg (@vonschomberg)
- Jack Stilgoe (@Jackstilgoe)
- Hillary Sutcliffe (@hillarysutcliffe)
- Richard Jones (@RichardALJones)

Chapter 5 (RATA NanoNextNL)

The (document) analysis of RATA in NanoNextNL has been complemented and corroborated by many conversations with key actors as well as fellow researchers during program meetings, conferences and collaborative efforts before and during the program:

Actors involved in NanoNextNL funding and organization (alphabetical order):

- **Dave Blank**, NanoNextNL chair of Executive Board
- **Leon Gielgens**, coordinator NanoNextNL program office
- **Frans Kampers**, member of Executive Board, responsible for RATA theme
- **Arie Rip**, coordinator of TA NanoNed (preceding NanoNextNL) and involved in writing the RATA theme proposal
- **Ad Ragas**, organizer and lecturer RATA PhD course
- **Daan Schuurbiers**, organizer and lecturer RATA PhD course, collaboration in organizing two RATA PhD course editions and follow-up RATA coaching
- **Adriënne Sips**, coordinator of RATA theme 1a (human health risk assessment)
- **Rens Vandeberg**, program office NanoNextNL, responsible for RATA theme
- **Harro van Lente**, coordinator of RATA theme 1c (technology assessment)
- **Annemarie van Wezel**, coordinator of RATA theme 1b (environmental risk assessment)

Fellow researchers (RATA theme) relevant to analysis:

- **Carla Alvial Palavicino**, STePS colleague, collaboration in joint paper and interviews of NanoNextNL researchers (see below)
- **Colette Bos**, colleague at Utrecht University, collaboration in joint paper and interviews of NanoNextNL researchers (see below)
- **Arnout Fischer**, principal investigator in RATA theme 1a (human health Risk Assessment)

- **Bärbel Dorbeck Jung**, principal investigator in RATA theme 1c, collaboration in EU-project Res-AGorA
- **Kornelia Konrad**, principal investigator in RATA theme 1c, collaboration in joint paper, supervisor
- **Haico te Kulve**, post-doc in RATA theme 1c, collaboration in joint paper
- **Clare Shelley-Egan**, post-doc in RATA theme 1c and former PhD researcher TA NanoNed (preceding NanoNextNL)
- **Tjalling Swierstra**, principal investigator in RATA theme 1c (technology assessment)

Furthermore, the analysis draws on interviews by Colette Bos on Sustainability and Responsible Innovation with NanoNextNL researchers (#26), on Healthy Aging and Responsible Innovation (#15), as well as with members of the executive board and advisory board (#13). Together we also interviewed Leon Gielgens and Rens Vandeberg of the RATA NanoNextNL program office.

Chapter 6 (nanosafety governance in the US)

The interviews listed in chronological order below have been conducted in person as well as by phone. The latter are indicated separately, as well as the interviews that extended in follow-up conversations.

- **Jeffrey Morris**, coordinator of the EPA nanosafety research program (5 February 2014, follow-up interview by phone 6 February 2014)
- **Brandi Schottel**, AAAS fellow, researcher on the nanosafety activities in the NNI (5 February 2014)
- **Terry Davies**, research fellow at the Woodrow Wilson Institute, key commentator on nanosafety oversight (6 February 2014 – phone)
- **David Rejeski** (6 February 2014), leader of the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson Institute
- **Jay Pendergrass**, research fellow at the Environmental Law Institute (11 February 2014 – Skype)
- **Jaydee Hanson**, spokesperson on nanosafety for the NGOs ICTA and CFFS (11 February 2014)
- **Richard Canady**, former nanosafety research program leader at FDA
- **Jo Anne Shatkin**, independent risk assessment expertise (Vireo) (12 February 2014)
- **William Kay**, researcher on NNI missions at Northeastern University (12 February 2014)

- **Jacqueline Isaacs**, professor in bio-nanotechnology at Northeastern University, involved in the Sustainable Nanotechnology Organisation (SNO) (12 February 2014)
- **Christopher Bosso**, professor in public policy at Northeastern University, editor of a volume on nanosafety governance in the US (Bosso 2010) (11 February 2014, follow-up conversation at 12 February 2014; Bosso also has commented on my analysis of US nanosafety governance as well as the cross-case analysis with nanosafety governance in NL in Chapter 8. Finally, Bosso hosted Aline Reichow, fellow researcher at NanoNextNL, who studied nanosafety governance aspects with respect to occupational exposure in the US.
- **Andrew Maynard**, internationally leading commentator on nanosafety governance, previously worked at NIOSH and the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson Institute (14 February, follow-up interview 15 February 2014)
- **Barbara Karn**, coordinator of nanosafety research activities at EPA in the early years of the NNI, founder of the NNI Sustainable Nanotechnology Organisation (SNO) (23 February 2014 – Skype)

Chapter 7 (Center for Nanotechnology in Society at Arizona State University)

The interviews listed in chronological order below have been conducted during a short research stay at CNS-ASU, including a two day visit to CNS-UCSB. At CNS-ASU various interviews extended in follow-up conversations during my research stay. Particularly extensive conversations are indicated separately.

CNS-ASU:

- **Erik Fisher**, coordinator of the STIR program at CNS-ASU, hosting me as visiting researcher (interview and discussing preliminary findings at 16, 17 and 20 February 2014)
- **Ira Bennet**, co-lead on NISE-NET and education (18 February 2014, extended conversations in relation to education)
- **Sharon Ku**, former visiting researcher, involved in interviews on the impact of CNS-ASU (18 February 2014 – Skype)
- **Dan Sarewitz**, co-founder of CNS-ASU and director of CSPO Washington D.C. (19 February 2014 – Skype)
- **Sujatha Raman**, visiting researcher (19 February 2014)
- **Brenda Trinidad**, PhD researcher (20 February 2014)
- **Jennifer Banks**, communications program coordinator (20 February 2014)
- **Dave Guston**, co-founder and director of CSPO/CNS-ASU (2 interviews, 20 and 25 February 2014)

- **Deron Ash**, program coordinator (26 February 2014)
- **James Wetmore**, co-lead on NISE-NET and education (27 February 2014, extended conversations in relation to education)
- **Michael Bernstein**, PhD researcher, organising and evaluating Science Outside the Lab (27 February 2014)
- **Braden Allenby**, CNS co-PI at ASU School of Sustainable Engineering and the Built Environment in Civil Engineering (2 March, 2014)

CNS-UCSB:

- **Barbara Harthorn**, director of CNS-UCSB (23 February 2014)
- **Louise Stevenson**, PhD researcher (23 February 2014)
- **Richard Appelbaum**, co-PI CNS-UCSB (23 February 2014)
- **Patrick McCray**, co-PI CNS-UCSB (24 February 2014)
- **Christoph Newfield**, co-PI CNS-UCSB (24 February 2014)
- **Ariel A. Hasell**, PhD researcher (24 February 2014 – Skype)
- **Brandon Fastman**, program coordinator (24 February 2014)

The manuscript of Chapter 7 has been reviewed by Erik Fisher (CNS-ASU) and Daan Schuurbiers (former visiting scholar of CNS-ASU)

Chapter 8 (cross-case analysis)

The manuscript of Chapter 8 has been commented on by Daan Schuurbiers (focusing on the Risk Governance parts) and Laurens Hessels (focusing on the Research Governance parts).

Summary

Part I – problem and approach

Chapter 1 – What is the problem and how to approach it?
At the start of the century a new discourse about responsibility with respect to science, technology and society emerged. It started in the wake of societal controversy about biotechnology, when concerns about the next technological wave, enabled by nanotechnology, gave rise to the notion of Responsible Development. While that notion was still referring to the *impacts* of science and technology in society, the discourse developed further, into ideas about Responsible Research and Innovation (RRI), aiming to address the way science and technology are *produced* in practices of research and innovation.

This thesis engages with the twin aspiration of propagating Responsible Innovation (and cognate terms) as both an *integrative* and a *transformative* concept. Integrative, because proponents have tried to capture the gist of many efforts that went before in pursuing responsible action in relation to science and technology. Think of safety regulations, sustainable development goals, ethical review, technology assessment, public participation, corporate social responsibility or transparency measures. Transformative, because the idea is to move beyond narrow conceptions of responsibility (e.g. accountability of individual researchers, developers and their organisations, often focusing on avoiding negative impacts) towards open, active and collective conceptions of responsibility that aim for actively redirecting research and innovation to addressing societal challenges (fostering a culture of responsibility focusing on creating positive impacts).

'Transformative' also refers to the ambition to go beyond local efforts and experiments and change 'the system' in which such activities take place. Currently, it is increasingly questioned whether activities over the past decades have been contributing to such change. The aim of this thesis is to go beyond such evaluations as well and to provide strategies for actors in the field to work towards transformative change.

For this purpose, Chapter 1 argues that we do not only need to understand the new forms of responsibility conceptually and normatively, but also historically and sociologically. What thrives the discussion about Responsible Innovation? And what problems is it supposed to address? These aspects are expressed in the first research question:

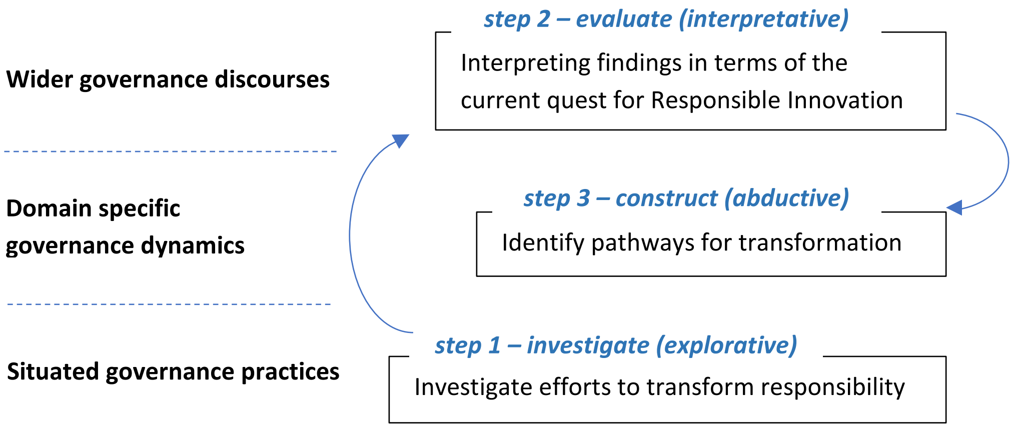
1) *What shapes the governance of Responsible Innovation?*

Next, we need a model for studying how responsibility is articulated, how responsibilities are assumed, organised and distributed, and how transformation towards above understandings of responsibility is shaped in practice. This level of analysis includes the discussion about Responsible Innovation itself, but is not limited to it. On the contrary, the quest for Responsible Innovation as I am studying it in this thesis, is about how new responsibility conceptions have to take root in existing responsibility distributions. This challenge is captured in the second research question:

> 2) *What can be learned for transforming responsibility in research and innovation?*

My focus on the interrelation between discourse and practice(s) reflects a more general idea. The challenges of transformation specifically concern the *interdependencies* involved in it. The new has to grow in and from the old. Since that happens in various contexts, there is a continuous process of interpretation and institutionalization in which ideas, about what is responsible and how responsibilities should be organised accordingly, are *always contested* and *never starting from scratch*.

The main task for Chapter 1, therefore, is to develop a heuristic which enables a 'socio-normative' approach for engaging with the quest for Responsible Innovation. 'Socio' in terms of a deep understanding of dynamics at various levels (making sense). 'Normative' in carefully crafting a set of analytical lenses and steps for guiding the analysis towards identifying pathways for transformation (making change). To this end, the heuristic depicted below, moves across different levels of analysis: exploring concrete efforts of practicing Responsible Innovation; evaluating dynamics and outcomes of these activities with respect to governance challenges that can be derived from reviewing the quest for Responsible Innovation at large; and informing the specific quest for inducing transformative change.



As mentioned, the intellectual task in developing the heuristic is to work with the concepts of responsibility, governance, research and innovation in such a way that it not simply juxtaposes another expert ordering of problems and guiding orientations, but that it can help actors in navigating the problems they are concerned with.

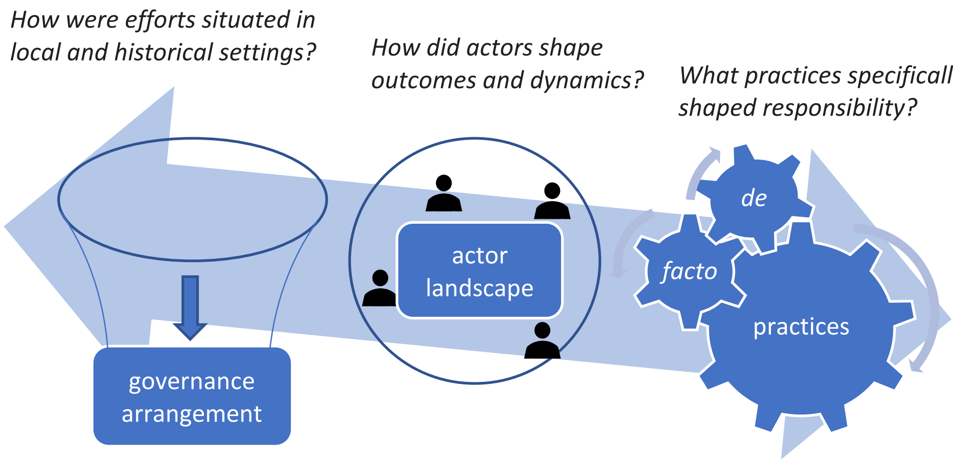
Chapter 2 – Context of inquiry: nanotechnology and governance discourses
Chapter 2 prepares the ground for step 2 of the heuristic. What is the quest for Responsible Innovation about? And which key governance challenges come to the fore? Instead of departing from the key references mentioned in the discourse of Responsible Innovation, the chapter engages in an extensive review of articulations of Responsible Innovation over time. The purpose of this effort is to understand how the settings in which Responsible Innovation is discussed co-define what 'the' quest for Responsible Innovation is about.

The review renders two frames for evaluating findings from concrete efforts in cross-case analysis. The first frame distinguishes two typical settings in which responsibility claims are discussed: an actor level perspective in which responsibility refers to what is being expected from an – mostly organised – actor, like firms of research programs; and a system level perspective in which the organization of responsibility between actors is the key question. The significance of this distinction is that they entail different ways of learning about problems to be addressed by the actors involved.

The second frame presents a set of key governance challenges: to anticipate societal dimensions in research and innovation, to deal with novelty and emergence in that respect, to align promotion and control accordingly and to do so in a truly inclusive manner. This frame reflects the focus on interdependencies in transformation. For example, what is anticipated depends on who is involved and vice versa. Therefore, it is anticipation-*cum*-inclusion that figures as a lens for evaluating empirical findings.

Chapter 3 – Empirical research design
Each case study, presented in Part II of the thesis and summarized below, discusses an ambitious effort to transform responsibility in the governance of nanotechnology. The selection of cases is structured by the first frame derived in Chapter 2. Two cases are located in the domain of risk governance. Here, actors had to make sense of the question whether and how nanomaterials entail a new class of potential risks. The efforts studied in this domain were about organising concerted action. The other two cases are located in the domain of research governance and specifically concern the challenge of fostering Responsible Innovation in large scale nanotechnology research and innovation programs. The selection also involves a contrasting of system conditions in terms of policy and politics, by studying efforts in the Netherlands as well as in the USA for each domain.

Chapter 3 presents the research model for empirical analysis by which these cases are studied. This model captures another form of interrelation, depicted below. Actor positions and instruments shape each other in specific practices, thereby shaping specific forms of responsibility. Furthermore, Chapter 3 discusses the way the empirical analysis is presented and what methods and sources have been used for each site of empirical investigation.



Part II – empirical analysis

Chapter 4 – All in the game? Organising responsibility in nanosafety governance in the Netherlands
The most prominent issue in discussions about the responsible governance of nanotechnology has been the question how to deal with uncertainty about health and environmental effects of nanomaterials. Chapter 4 shows how various strands in these discussions came together in a series of pilot projects for developing precautionary measures in the Netherlands: large public investments in nanotechnology, an international discourse on risk governance, a new national risk policy as well as new evaluations of longstanding discussions about precaution and about participation. In this process government was faced with the tension in calling on responsibilities, while also trying to reconfigure these. The efforts in the pilot projects were further affected by the interdependency between national action and international coordination. The chapter discusses how actors did learn about these challenges, what they were able to do in response and how the interdependencies observed can be resolved.

Chapter 5 – Practicing Responsible Innovation in NanoNextNL
In the context of increasing public debate about nanotechnology, the Dutch government decided to allocate 18 percent of the budget for the national research and innovation program NanoNextNL to Risk Analysis and Technology Assessment (RATA). Chapter 5 discusses the activities that aimed to stimulate the integration of RATA throughout the program. The analysis shows that such integration requires a double loop learning

process about societal impacts of nanotechnology as well as strategies and conditions for societal embedding. The interrelation between these modes of learning, in turn, require dedicated strategies for organising the learning process. While the program wide structure for integrating RATA in NanoNextNL did support for that, it has been hampered by conditions of distributed leadership in the RATA management.

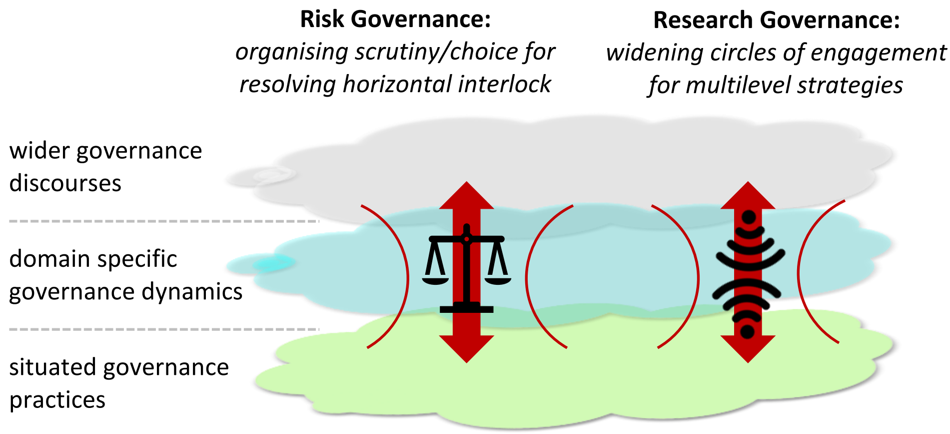
Chapter 6 – Agency and authority. Nanosafety governance in the US
This chapter discusses how the authority of US federal agencies to 'research and review' potential risks of nanomaterials has been playing out in different practices, including an unprecedented space for collaboration in the National Nanotechnology Initiative (NNI). Their efforts, however, have been caught in Catch-22 demands for evidence in the cost-benefit calculations that had to legitimate these efforts: the uncertainty that was to be reduced by research and review also limited mobilizing the means that are needed for that purpose. The chapter shows how this situation has been sustained by the adversarial nature of the US political system, which hampered critical evaluations to reach political decision making.

Chapter 7 – Engaged scholarship and Big Social Science – the Centre for Nanotechnology in Society at Arizona State University (CNS-ASU)
Like RATA in NanoNextNL, the US NNI featured Centres for Nanotechnology in Society (CNS) that had to stimulate integration of research into social dimensions and implications of nanotechnologies within the NNI. Chapter 7 focuses on CNS-ASU that tried to demonstrate a model for advancing the agenda of Responsible Innovation. The centre developed a specific vision for integrating social sciences as well as a center model by which such integration can be put into practice. The chapter shows how the accomplishment of CNS-ASU's mission has been critically dependent on the specific environment of ASU. These conditions have to be taken into account for both replication of the center model as well as the wider challenge of reconfiguring social science expertise in science systems.

Part III – discussion and conclusions

Chapter 8 – Making sense and making change – discussion and conclusions (chapter 8)
The cross-case analysis in Chapter 8 contrasts the Dutch and US cases in the risk governance domain and in the research governance domain. With respect to the first research question – *what shapes the governance of Responsible Innovation?* the chapter discerns specific patterns of recursive knowledge-power dynamics. In the *collective* problem setting of the nanosafety governance practices the critical factor can be best described as *interlock*. For the *mutual* problem setting of integrating social science in natural sciences and engineering programs the critical factor is characterized as *reciprocity*.

Answering the second research question – *what can be learned for transforming responsibility in research and innovation?* – builds on above finding. Advancing the quest for Responsible Innovation towards systemic change is not just a matter of *redesigning* systems (as for risk governance), or of *mainstreaming* niche activities (as for research governance). It are the interdependencies causing the above patterns that have to be accounted for, by the actors involved. Therefore, the final step of identifying pathways for transformation focuses on the relevant accountability mechanisms that come to the fore in cross-case analysis. The figure below summarises the reflexive orientations as well as (a speculative outlook on) institutional options for addressing the patterns in each domain that are offered.



Chapter 9 – Making a difference? Lessons for Responsible Innovation

The final chapter positions the findings of this thesis in the current debate about Responsible Innovation. Rather than crafting new responsibilities or institutional structures on top of existing ones, making a difference with Responsible Innovation is about guiding processes of transformation. The chapter briefly discusses the implications for actual discussions, like transitioning to a circular economy or fostering open science. It also suggests a strategy for next steps with regard to the policy concept Responsible Research & Innovation (RRI) in the European Commission.

Chapter 9 also reflects on the affordances and limitations of focusing on interdependencies, accountability mechanisms and governance *as* learning for the intellectual challenges that have guided the research approach: going beyond incrementalism, while fully acknowledging all complexities involved and providing reflexive feedback to actors in terms of the problems they are concerned with.

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Biography

Bart Walhout started his PhD after working for six years as a Technology Assessment (TA) practitioner at the Rathenau Institute, the Dutch parliamentary TA office. Before that he studied electronic engineering at Rens & Rens in Hilversum (BSc) and Innovation Management at the Technical University of Eindhoven (MA).

Building on his master's thesis on biotechnology and societal controversy, Bart has both been investigating and actively engaging in public and political debate about nanotechnology. At the Rathenau Institute he expanded his scope to synthetic biology, Ambient Intelligence and the ethical dimensions of *converging technologies*. During his PhD at the University of Twente he studied the emerging discourse on Responsible Innovation both as a TA researcher in the Dutch research and innovation program NanoNextNL and by participating in the European FP7 research project Res-AGorA. During these years Bart received a training by the Netherlands Graduate Research School of Science, Technology and Modern Culture (WTMC).

Currently, Bart works as a policy advisor at the Dutch institute for public health and the environment, RIVM. Much like his work on nanotechnology and Responsible Innovation, he now critically engages in discussions about the policy concept *Safe & Sustainable by Design*. At a personal level he explores pathways for transformation – keyword in this thesis – at the Life Force Fitness Institute.

NANOTECHNOLOGY AND THE QUEST FOR RESPONSIBLE INNOVATION

At the start of this century billion-dollar investments in nanotechnology gave rise to public and political debate about the impact of nanotechnology on society. Much like Artificial Intelligence today, developments in nanotechnology were accompanied with high promises, for example on breakthroughs in cancer therapy or in clean energy. But the powerful abilities of nanotechnology also came with uncertainties about safety of nanomaterials for health and the environment and with moral concerns about the evermore intimate relation between humans and machines. A new discussion about responsibility came up, which continues until today. How can we foster Responsible Innovation in such a way that it goes beyond a narrow focus on individual responsibilities and avoiding harm, towards a culture of care for the future?

This thesis engages with the quest for Responsible Innovation by focusing on its main aim: to transform responsibility in research and innovation. It presents a model for analyzing how new ideas about responsibility have to take root in existing distributions of responsibility and how local experiments can be levelled up to changing networks and institutions. This model is applied to in-depth case studies of four prestigious efforts of practicing Responsible Innovation in nanotechnology.

The analysis shows that the challenges of transformation are about interdependencies. The new has to grow in and from the old. Responsibilities are called upon, while they have to be reconfigured at the same time. National action and international coordination are interrelated. What is being anticipated depends on who is involved and vice versa. Etcetera. Such interdependencies cannot be resolved by individual actors alone. But they can move forward by improving processes of learning. This thesis presents a model for making sense of the challenges of transformation, so as to make a difference in the end.

UNIVERSITY OF TWENTE.

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