ANTICIPATORY INTERVENTIONS AND THE CO-EVOLUTION OF NANOTECHNOLOGY AND SOCIETY

HAICO TE KULVE

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prof.dr. Arie Rip

Preface

During one of the last days at my former job at a company, an older colleague approached me. He gave me a note in which he predicted the conclusions of my PhD research. I carefully stored the note - a time capsule – curious as I was how I would respond after a PhD trajectory. Now, a few weeks before the public defense of my dissertation, I felt it was time to open the time capsule. The note claimed that humans would continuously adjust tools (including nanotechnologies) available and the environment in which they would be deployed, in order to satisfy their objectives, but that humans themselves would not change.

Looking at the note, all kinds of questions and responses entered my mind. More importantly, I realized that my PhD experience had strongly influenced my thinking in ways I could never have imagined when I received the note. I am grateful for having had the opportunity to undertake, and finish, a PhD project. I would like to thank everyone who supported me in grappling with the challenges which arise when doing a PhD – *luctor et emergo*! And for having fun, inside and outside of the office.

Special thanks go to Arie Rip. I am thankful for his willingness to accept me as one of his apprentices to study the craft of research, for his support and for his feedback on many draft versions of pieces of text. I found our conversations highly rewarding and this dissertation owes a lot to his thoughtful, creative, and pragmatic comments and suggestions. I also thank Arie for his wonderful anecdotes and for fun during our occasional travels (“enjoy!”).

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I would like to thank those within the STEPS department at the University of Twente for their hospitality and for offering me a stimulating environment for research and teaching activities. I would like to thank Evelien Rietberg, Hilde Meijer and Marjatta Kemppainen for support in bigger and smaller matters. I would like to thank Stefan Kuhlmann for his support in writing a research proposal. Thanks to Ellen van Oost, Adri de la Bruhèze and Willem Halffman for giving me the opportunity to engage in teaching activities which I found most rewarding. Thanks to Wim Smit for inviting me to join him in the PRIME INNOMIL project and for co-authoring papers. It was a pleasure to continue our co-operation in the field of defence technology assessment and innovation studies. A big thank you to my fellow PhD students at STEPS. In particular I would like to thank Frank van der Most ("Is it already finished?") and Louis Neven ("30 seconds!") for sharing office space, fun, and the life and sorrows of a PhD student. I am grateful that you will accompany me as my paranymphs through the final stages of my PhD project.

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Last, but not least, I am greatly indebted to Anneke for her patience, confidence and bright perspective. Thanks to Tristan, for being there and vividly reminding me of other matters than dissertation matters.

Borne, March 2011

Contents

PART 1

Chapter 1

Introduction

1.1 Setting the scene

In contrast with earlier emerging technologies, in the case of nanotechnology there is a lot of anticipation surrounding how it might, or should, become embedded in society.[1] Strong claims are made about doing things differently than before. Already in 2000, at the time of the launch of the US National Nanotechnology Initiative, the US National Science and Technology Council sponsored a workshop about (future) research on societal implications of nanotechnologies. Societal embedding was recognized as a challenge, and the inclusion of research on ethical, legal and societal aspects (ELSA) of nanotechnologies was seen as an opportunity:

> "The NNI is balanced across five broad activities: fundamental research; grand challenges; centers and networks of excellence; research infrastructure; and societal/workforce implications. Under this last activity, nanotechnology's effect on society – legal, ethical, social, economic, and workforce preparation – will be studied to help identify potential concerns and ways to address them. *As the NNI is commencing, there is a rare opportunity to integrate the societal studies and dialogues from the very beginning and to include societal studies as a core part of the NNI investment strategy.*" (Roco and Bainbridge 2001, p.2) [2, 3]

In fact, pro-active activities with respect to societal embedding of nanotechnologies appear to be widespread, rather than merely occasionally happening. This is not only in number, but also in terms of variety of contexts related to emerging nanotechnologies and across sectors of industry.

First, we see different firms now engaging in dialogues with stakeholders during early phases of nanotechnology developments. Chemical firms such as

[1] Here, both nanosciences and nanotechnologies are covered under the umbrella term nanotechnology.
[2] Italics in original.
[3] This quote reflects a key idea among promoters of nanotechnology: 'this time we'll make everything right from the start'. This phrase was actually used during the workshop by Mihail Roco, a key person in the NNI (personal communication Hans Glimell to Arie Rip, 29th October 2005). In their call for a collaborative effort for "an early and open examination of the potential risks" of nanotechnologies, Environmental Defense Fund and DuPont used the phrase "Let's get nanotech right" (Krupp and Holliday 2005).

Degussa (now part of Evonik Industries) and BASF are involved in public discussions. BASF have developed their own code of conduct with respect to handling nanotechnologies.[4] Firms in the food sector, such as Unilever, are known to have engaged with stakeholders (Stilgoe 2007). Interactions between stakeholders about societal aspects of nanotechnologies also take place in broader settings, such as the 'Nanotechnology stakeholder meetings' organized by the Confederation of the Food and Drink Industries of the European Union (CIAA), the 'Nanotechnology Safety for Success Dialogues' organized by the European Commission, and the 'International Dialogue on Responsible Research and Development of Nanotechnology' initiated by key persons in the US National Nanotechnology Initiative and the Nanomaterials and Processes Program of the European Commission (Mihail Roco and Renzo Tomellini, respectively).

At the level of research programmes, pro-active activities take the form of inclusion of ELSA-type research. My dissertation research is actually enabled by such pro-active activities. It is part of the Technology Assessment (TA) programme within the Netherlands NanoNed R&D consortium, financially supported through special knowledge-infrastructure funding distributed by the Dutch Ministry of Economic Affairs. To include such a TA programme was proposed early on by key nano-scientists (in particular, David Reinhoudt of the University of Twente) who drove the initiative and felt that it was important to include societal aspects from the start (see for further details Robinson (2010)). The proposal could be taken up by scholars (in this case, Arie Rip) in Science and Technology Studies (STS), because of their interest in supporting and stimulating pro-active activities through Constructive TA. This appears to be a general trend in STS, cf. Barben et al. (2008) who also refer to nanotechnology when they observe an emerging program within the STS community characterized as "one of building capacity for anticipatory governance" (p. 989).

Pro-active activities also occur from the side of the economy and society. Chemical firm DuPont, together with Environmental Defense Fund, an environmental advocacy NGO, developed a risk framework for the 'responsible development of nanomaterials' (Environmental Defense-Dupont Nano

[4] See further BASF's and Evonik's corporate websites' special sections devoted to nanotechnology (Evonik 2010; BASF 2010).

Partnership 2007). The European Commission launched a code of conduct for 'responsible nanosciences and nanotechnologies research' (Commission of the European Communities 2008). A key figure in promoting the code of conduct, and in the responsible innovation of nanotechnologies in general, was Renzo Tomellini, head of the "Nanosciences and Nanotechnologies" unit of the European Commission. Nowadays, responsible development and innovation of nanotechnologies is an important theme and visible in policy debates in the European Union and the United States (Ferrari 2010).

While pro-active activities with respect to emerging technologies are not a new phenomenon, they are particularly salient in the nanoworld. There are explicit attempts to avoid mistakes of previous new and emerging technologies and to mobilize stakeholders for pro-active action. The importance of avoiding impasses in nanotechnologies akin to those in genetic manipulated technologies is often addressed, and returns in arguments about 'doing better this time' and engaging in stakeholder dialogues (as a way to do 'better') (The Royal Society & The Royal Academy of Engineering 2004; Rip 2006).

Such pro-active activities are occurrences of interventions in ongoing processes of technology development and societal embedding. However, these are not interventions merely to change ongoing activities in the here-and-now. Actors consider the embedding of nanotechnologies an important challenge and want to do something about it. They anticipate challenges and possible issues (expected 'benefits' and 'risks') in the further development and embedding of nanotechnologies by creating framework conditions and 'prospective structures to be filled in by agency' (Van Lente and Rip 1998) for their introduction in society. A relevant question then becomes in which direction such interventions are unfolding and which patterns are emerging in societal embedding processes of nanotechnologies.

At this moment, nanotechnologies are still in an early phase of development with a small number of nanotechnology enabled products on the market.[5] Anticipation-oriented actions and interactions will have effects on processes of societal embedding, but cannot be fully assessed yet as they are still ongoing.

[5] For an overview of nanotechnology enabled products, see the consumer products inventory developed by Woodrow Wilson's project on emerging nanotechnologies, http://www.nanotechproject.org

However, through actions and interactions, processes of 'anticipatory interventions' can add up to patterns in the here-and-now of how our society is coping with the further development and societal embedding of emerging nanotechnologies.

The move in the nanoworld toward anticipation of societal embedding does not stand on its own. It is part of a more general move toward 'reflexive co-evolution of science, technology and society'. The emergence of patterns in reflexive co-evolution is part of a long term development (Rip 2002a). Historically, there exists a separation between the generation and selection of technologies. Technology actors had 'a mandate' to develop new technologies and could confront society with new technologies when linked with ideals of progress. Even if this mandate is not taken for granted anymore, it has led to institutions and divisions of labour with respect to 'promotion and control' of new technologies which cannot easily be undone.

From the 1960s onwards, a variety of approaches have been developed which precariously bridge promotion and control of new technologies (Rip 2002a, 2002b): science policy, technology policy, various technology assessment approaches (including participatory forms); but also evaluation and foresight. Anticipation of embedding in the nanoworld, such as the inclusion of ELSI/ELSA in nanotechnology research programmes, 'fits' within a broader development in which actors are increasingly reflexive with respect to emerging technologies

For specific anticipation-oriented actions and interactions in the nanoworld one may identify historical antecedents. The Human Genome Project and the inclusion of research on societal aspects thereof can be conceived of as a predecessor for the inclusion of societal aspects research in nanotechnology research programmes. Research on ethical, legal and social issues (ELSI), or ethical, legal and social aspects (ELSA), started as 'an additional component' in the Human Genome project and has become a taken-for-granted acronym. ELSI research became institutionalized at the Department of Energy and the National Institutes of Health which devoted 3-5% of their budget for the human genome project on ELSI research (Rip 2002b).

Interactions and attempts to bridge promotion and control may now well enter into a new phase with nanotechnology. With the emphasis on issues of embedding already in an early phase of technology development and introduction, nanotechnology may act as a lead domain, and if successful, as a model for how to anticipate embedding of emerging technologies. Insights into dynamics in the emergence and development of anticipation-oriented actions and interactions in the nanoworld provide building blocks for an assessment of patterns in how our society deals with societal embedding of emerging technologies.

Positioning anticipation of embedding of nanotechnologies into broader change processes allows me to further specify my general question about emerging patterns in embedding processes of nanotechnologies; specifically into a question regarding the emergence of patterns in reflexive co-evolutionary processes. This broad question will serve as a background question for this dissertation.

In this dissertation I will analyze dynamics in anticipation-oriented actions and interactions, 'anticipatory interventions', and examine emerging patterns (if any) in reflexive co-evolutionary processes. By doing so, I take up a double challenge: a substantial challenge in understanding dynamics and patterns, and a methodological challenge in analyzing emerging phenomena. How, then, to research dynamics in 'anticipatory interventions' in ongoing processes of societal embedding of emerging nanotechnologies?

1.2 Research questions

Societal embedding processes and anticipation-oriented actions and interactions involve multi-actor, multi-level dynamics. Actors need not be fatalistic and wait for the 'invisible hands' of the market or, in evolutionary terms, the selection environment, to do its proverbial work. Instead they interact with their broader environment to work towards what they consider to be desirable societal embedding. Such pro-active interactions go beyond the promotion of promises of nanotechnology enabled products in anticipation of the opening up of new markets.

As Deuten et al. (1997) put it in their firm-concentric discussion of societal embedding, market success of newly introduced products involves more than attractive sales figures. They argued for broadening the notion of market success by thinking in terms of successful societal embedding. They characterized societal embedding by three dimensions (p. 132):

- Integration: new technologies need to be integrated in industries and markets; that is, within business practices and repertoires of users.
- Admissibility: new products need to be acceptable according to rules and standards within the sector or set by the government.
- Acceptance: new products have to be accepted by the public. That is, societal concerns should not be too strong, there should be sufficient articulation in order to make well-informed choices, and the product should actually be used.

To analyze dynamics in anticipatory interventions in processes of embedding it is necessary to take a broader perspective than a firm, or single actor, concentric focus on embedding. Societal embedding involves a variety of issues which create openings for different actors (with different interests in, and perspectives on, emerging technologies), to engage in strategic actions and interactions. In the nanoworld, firms, governmental bodies, scientists and NGOs are involved in interactions with respect to one or more dimensions of societal embedding. The substance of actors' activities, including anticipations, become entangled with other actors' activities during interactions, and this may sediment and shape further actions and interactions. Or, as Garud and Karnøe (2003) put it in their discussion on distributed technology entrepreneurship: "actors become interwoven into emerging technological paths that they shape in real time. In turn, the accumulating artefacts, tools, practices, rules and knowledge begin shaping actors over time"(p. 281) Important dynamics in anticipation of embedding exist at the level of a domain or sector faced with emerging nanotechnologies, rather than at the level of individual entrepreneurs. Both are played out against a backdrop of the overall 'landscape' of society and its evolution.

The enabling character of nanotechnologies will play a role in the dynamics in embedding processes. Nightingale et al.'s (2008) conceptualization of a system of innovation of nanomaterials suggests that (application) domain specific dynamics as well as generic dynamics will be relevant. They schematically

represent the enabling character by conceptualizing a technology system of innovation of nanomaterials as an 'hourglass': on the one side, there are a variety of scientific disciplines (the left hand side in their graphic representation) contributing to generic technologies for fabricating nanomaterials (the middle) which end up in many different sectors of industry (the right hand side).

This 'hourglass' conceptualization draws attention to the different dynamics of upstream and downstream issues coupled through the generic, enabling character of nanotechnologies. Nightingale et al. "suggest that when policy-makers are thinking about innovation, rather than assuming a single nanomaterials innovation process, conforming to a traditional linear 'value-chain analysis', they [should] think instead in terms of an hour-glass model, in which a broad range of inputs, from a variety of institutional sources converge on a range of technologies that share an ability to exploit nano-scale phenomena, and then are diffused to a wide range of product markets and customers." (2008, p. 4). They point out that upstream interventions, while useful, will not be able to steer innovation processes towards desirable ends, because there is no linear causality in these processes.[6] This is a well-known point, but their hourglass conceptualization makes it more specific and explicit for nanotechnologies. The model also explains why upstream perspectives on nanotechnologies, starting from the left hand side of the model, remain quite general: there is no direct link with domains of application.

Empirical studies of how actors in the nanoworld take into account broader societal considerations provides further indication for the importance of dynamics at the level of a domain. Rip and Shelley-Egan (2010) showed how actors in the nanoworld position themselves with respect to responsible innovation. In their interviews they find a division of moral labour, and that actors fall back on standard repertoires. Changes in divisions of labour and repertoires, however, go beyond an individual actors' sphere of influence. Actors are embedded in practices and organizational routines which they need to take into account. According to Rip and Shelley-Egan "ethical reflexivity of actors is caught between individual agency and institutional role. [...] for change to occur, there have to be openings at the institutional level." (p.37) In

[6] They suggest that more attention should be paid to downstream governance.

a similar vein, a 'laboratory engagement study' aimed at enhancing reflexivity of scientists pointed out the context specific factors (and institutional forces behind them) affecting researchers' room to manoeuvre and incorporate broader societal aspects in their activities (Fisher 2007).

Misa (1994) developed an argument regarding why analysts of technological change in general should focus on the meso-level. According to Misa the level at which scholars conduct their research influences what they can see and analyze in terms of forces shaping interactions between technology and society. Micro level analyses tend to emphasize contingency and how social forces construct technologies, whereas macro level analyses tend to technological determinism. To overcome 'this methodological bifurcation', Misa directed attention toward analyzing the meso level, "the institutions intermediate between the firm and the market, or between the individual and the state". (p. 139) This is a further reason to adopt a meso-level perspective while taking into account linkages with other levels, especially the macro-level.[7]

In particular, I will examine dynamics at the level of a sector. Werle (1998) argues that Misa's 'intermediate institutions' are meso-level phenomena which are "used in institutionalist theorizing in political science and in economics to describe sectoral governance structures and innovation systems and to explain technological innovations" (p.5) Analyzing dynamics at the level of a sector is a productive operationalization of the general suggestion to analyze meso-level phenomena.

Empirically, I focus on dynamics in anticipatory interventions at the sectoral level. By taking interventions at the sectoral level as the entrance point, the analyst can trace emerging structures as well as attempts at creating them which can add up to new patterns in (reflexive) co-evolutionary processes. [8] Focusing on interventions, the analyst uses them as a 'window on the world' (Rip 2003), which shows what is happening in terms of emerging patterns in

[7] For analyses of interventions at the micro level of nanotechnology developments, see Fisher (2007) and Schuurbiers and Fisher (2009).

[8] My focus here is on interventions, and attempts at the creation of new rules and practices at the sectoral level. Clearly, to analyze stabilization of new rules and practices one should also analyze reception of such promoted new institutions. However, as activities are still ongoing it is too early to analyze stabilization, even if I will look at early indications of stabilization.

embedding processes at the sectoral level through the lens of these interventions (which themselves are part of such processes). There are two ways of doing so (and these then relate to different modalities of anticipatory interventions). The traditional way is to follow the interventions, and assess (as a contemporary historian would do) what they add up to, thus telling us about the world. The other is to intervene oneself, not as a change agent, but by creating a window on the world for actors to respond to. While there is a change agent element (actors may now change their ways), the responses of the actors, in interaction with other actors, offer indications of the world they live in and perceive. The anticipatory intervention is now also driven by the desire for better understanding.

For the first modality I draw upon literature regarding change agents in institutionalization processes: institutional entrepreneurs & fora. The concept of institutional entrepreneurs has drawn much attention in organization studies and institutional analysis literature (Garud et al. 2007; Battilana et al. 2009). The concept of institutional entrepreneur was introduced to revive interest and agency in analyses of institutionalization processes. Institutional entrepreneurs are change agents, individuals or groups of individuals "who, whether or not they initially intended to change their institutional environment, initiate, and actively participate in the implementation of changes that diverge from existing institutions."(Battilana et al. 2009, p. 70) Institutional change can also occur through spaces for interaction, such as fora to promote new technology. In a sense, the spaces (or fora), then contribute to institutional change rather than activities of institutional entrepreneurs. See further discussion in chapter 2.

By using interventions by institutional entrepreneurs and fora as an entrance point I can further specify my research theme of dynamics in anticipatory interventions. My first research question is:

> *Which dynamics shape the evolution of institutional entrepreneurship initiatives and how do these initiatives contribute to changes at the sectoral level, shaping embedding processes of nanotechnologies?*

The second modality of anticipatory interventions is inspired by the approach of Constructive Technology Assessment and interactive strategy articulation

workshops.[9] While an intervention, they are also probing into the force fields in a domain of technology. They provide an occasion for the analyst – a 'window on the world' – to learn about ongoing and (possible) future dynamics in interactions in the embedding processes. In my dissertation research I will organize CTA workshops including scenarios to support discussion, in order to 'probe the force fields'. Given that the workshops include institutional entrepreneurs and are also used to explore future institutional entrepreneurship initiatives (supported by scenarios), this will generate prospective data about future institutional entrepreneurship actions and dilemmas. At the same time these workshops are interventions which, as part of the Constructive Technology Assessment tradition, through their methodology and set-up aim to stimulate reflexivity in participants' actions and interactions with respect to technology development and embedding. Early interactions between stakeholders in a domain of technology aimed at open-ended learning occur in these workshops, and are a means to stimulate reflexivity. The effect of such workshops – as a CTA-type of intervention – can be that early interactions will continue in their own right. So it is a modality of intervention, but a second-order intervention: no specific change is envisaged and worked towards, but actors are encouraged and enabled to work towards hopefully productive changes. Their responses, during and after the workshop, are an indication of the existing force fields in which they are located (and thus offer data about the force fields), but also about propensities for change; in particular, about anticipation of societal embedding.[10] My second research question is:

> *Which dynamics in societal embedding processes of nanotechnology become visible in actions and interactions between relevant actors, including institutional entrepreneurs, within the context of a CTA workshop, which includes scenarios to support discussion?*

This dissertation offers studies of interventions in embedding processes at the meso level in two empirical domains. Each of these studies has value in its own right, however taken together they contribute to a picture of dynamics in early-stage emergence of patterns in co-evolutionary processes. For the larger

[9] Within the TA NanoNed program a lot of experience has been gained in doing and evaluating CTA workshops, by my fellow PhD students Rutger van Merkerk, Douglas Robinson and Alireza Parandian.

[10] For a broader discussion of CTA-type of interventions and their effects, see Robinson (2010).

backdrop to these dynamics I can draw on the literature, but also on what becomes visible in the actions and discourses in the two domains. In addition, I conducted a study on newspaper coverage on nanotechnologies in the Netherlands (reproduced in Appendix 1 of this dissertation).

1.3 Structure of the dissertation

The dissertation is divided into 4 parts. My theme and overall approach requires further conceptualization of societal embedding processes and anticipation of embedding. In part 1, chapter 2 I will discuss the conceptual background and research methods, which will inform my empirical studies.

In part 2 I will examine anticipatory interventions by institutional entrepreneurs, my first research question. In chapter 3 I will analyze dynamics in the evolution of distributed institutional entrepreneurship in the food packaging sector. In chapter 4 I will undertake a follow-on case study for institutional entrepreneurs in the drug delivery sector.

In part 3 I will use anticipatory interventions by CTA agents as an entrance point to discover how actors take into account challenges of societal embedding, my second research question. To do so I will first develop in chapter 5 an approach for preparing CTA workshops supported with socio-technical scenarios of future developments. Then, in chapter 6 I will analyze the workshops which I held for my two domains.

In part 4 I will return to my theme of emerging patterns and reflexive co-evolution which served as a background question for this dissertation. I will position my findings in part 2 and 3 in a broader perspective by providing a sketch of relevant macro-level developments. Taken together, they form the building blocks for a forward look on emerging patterns in the co-evolution of nanotechnology and society.

The appendix reproduces a published study on newspaper coverage in the Netherlands.

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Chapter 2

Conceptual background and research methods

2.1 Introduction

Societal embedding of emerging technologies is understood as an ongoing process, not as an end-state. It is a net result of actors' actions and interactions associated with managing the introduction of novelties. Novelties of science and technology may not easily fit within the existing social order and their introduction to some extent will upset the existing order. Abernathy and Clark's (1985) perspective on different types of innovation and their effects on competition is instructive as it highlights the conservation, disruption or construction of linkages between novelties and technological/production competences or with customers/markets. This perspective could be extended by including linkages between novelties and broader society, such as regulation (Rip 2002a). Embedding of new technologies, then, always involves an element of change, including construction and re-construction of linkages.

Actors can fatalistically wait for embedding, but can also anticipate embedding, which is the starting point for this dissertation. In embedding, a variety of actors are involved, ranging from knowledge institutes, to firms, governmental bodies, associations and consumers. Therefore, a variety of actors can anticipate embedding and engage in strategic interaction to affect its outcome. Their interactions will be shaped by existing social structures, such as institutions, but may also contribute to the emergence of new structures. Dedicated actors, institutional entrepreneurs and fora, can emerge that intervene in ongoing processes and work towards the creation of new structures.

In this chapter I will develop a conceptualization of societal embedding processes and anticipation of embedding. While anticipation of embedding is not a new theme, there is no single body of literature in this area. In this chapter I will take a cross-section of relevant literature to develop my conceptualization. These conceptual building blocks will inform my empirical studies which will further develop conceptualizations relevant for the specific studies.

To do so, I will start with general considerations about change and social order, followed by a discussion of TA NanoNed's overall analytical perspective on

reflexive co-evolution of science, technology and society in which this research project is embedded. I will add and elaborate upon this overall perspective by including multi level phenomena and my empirical-analytical entrance points of 'anticipatory interventions' in embedding processes: (1) CTA agents and (2) institutional entrepreneurs and fora. In the last section of this chapter I will discuss my empirical approach for tracing dynamics in embedding processes of emerging nanotechnologies.

2.2 Change processes and interventions by embedded actors

Emerging nanotechnologies and actors' interventions in their embedding in society may build up to new patterns in our society. I am interested in patterns in reflexive co-evolution and whether that is visible in actors' actions in interactions in the world of nanotechnology.

My theme is a specific version of a more general question about social order: the emergence of patterns, which may outlast the original actions and interactions which contributed to their emergence. These patterns enable & constrain further actions and interactions. Phrased this way, the general question about the emergence of social order reads as a paradox. How can anything change (at all), considering the phenomena of 'enabling and constraining'? While this is not the place to go into foundational issues, a few words are in place as they are relevant for my theme and form the backdrop for my further conceptualization.

A key point is that the enabling and constraining forces of social order are never complete. Multi-actor and multi-level aspects of social order provide openings for change. Insights from studies into the emergence of electric vehicles are instructive and illustrative for this point; see further Hoogma (2000). The automotive regime had been dominated by the combustion engine (petrol/diesel) for years, effectively constraining the introduction of electric powered vehicles. The regime, however, became undermined by credibility pressures at a macro-level and by experiments with electric vehicles. These

credibility pressures and experiments created openings for change in the automotive regime and opened up spaces and platforms for interaction. These spaces can be used for further experiments with electric vehicles, and can be orchestrated or dedicatedly sought after.[1]

The emergence of new spaces for interaction is related to dynamics at different levels and mutual dependencies, 'alignments', between levels. While occasionally strong, such alignments will always be partial as levels have dynamics of their own, enabling and constraining what happens at a level. In the automotive regime, changes at the macro level contributed to frictions between macro-level and meso-level developments and provided openings for change.

Openings for change can be related to frictions between (shifting) patterns at levels, but also to more or less contingent events. The fire incident at Sandoz (Basel, Switzerland), which released poisonous chemicals in the river Rhine in 1986 marked a turning point in attempts at establishing environmental measures. "The Sandoz incident caused a wave of publicity and public concerns in all riparian states. On the 12 November the ministers met to discuss the situation. [...] Now there was political resolve to prevent similar accidents in the future." (Huisman et al. 2000, p. 90)

Actors can respond to openings for change and intervene in the existing order as dedicated change agents. Interventions can have different shapes. Interventions can take place through an authoritative actor such as the state, which will be faced with challenges of implementation. Interventions can take place through entrepreneurial actors who mobilize resources (including symbolic resources such as moral argumentation) in order to acquire legitimacy. A third form of intervention is via modulation, which is the type of intervention by actors such as Constructive Technology Assessment agents (see also 2.3.5). For this type of intervention, there already exist openings and possibilities for change which are then stimulated and orchestrated rather than sought after. This dissertation concentrates on the last two types of

[1] Cf. the approach of strategic niche management (SNM) (Kemp et al. 1998).

interventions as top-down interventions, other than allocating resources for research, are not (yet) particularly strong in the nanoworld.[2]

Still, while actors can intervene by taking advantages of openings in existing order, they will be constrained by the existing order as well. Within institutional theory this is known as the paradox of 'embedded agency'.[3] This is an actor-centric version of paradoxes in change processes: if actors are embedded in structures, how can they envision new structures and convince other (embedded) actors to adopt them? Institutional theorists have formulated an answer to this paradox which is in line with my discussion of the emergence of openings for change emphasizing enabling aspects of structures. In their introduction to a special issue on institutional change agents, institutional entrepreneurs Garud et al. (2007), discussed how to cope with this paradox. They argued that "institutional structures do not necessarily constrain agency but, instead, may also serve as the fabric to be used for the unfolding of entrepreneurial activities." (p. 961-962).

For new and emerging technologies I add that dedicated attempts at intervention will not only build on stabilized structures, but also on 'prospective structures' (Van Lente and Rip 1998a). These prospective structures can, for that matter, act both as an enabling resource for interventions and be mobilized as a resource, part of intervention strategies. Promises of new and emerging technologies also open up spaces for interactions. Such spaces will be spanned up by both existing and prospective structures.

The paradox of 'embedded agency' (and elaborations of how actors may cope with it) is a more nuanced version of Giddens' notion of structuration. According to Giddens "The constitution of agents and structures are not two independently given sets of phenomena, a dualism, but represent a duality. According to the notion of the duality of structure, the structural properties of social systems are both medium and outcome of the practices they recursively organize" (1986, p.25)

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[2] My empirical work does include activities of governmental actors as they may, and actually do, act as entrepreneurs.

[3] Embedded in 'embedded agency', not to be confused with the notion of embedding in my usage of societal embedding

The idea that actors may take advantage of openings for change, via events or through frictions related to structures, implies that actors have some understanding of the situation. This corresponds with Giddens notion of 'knowledgeable agents': "all social actors know a great deal about the conditions and consequences of what they do in their day-to-day lives" (p.281) For analyzing patterns in social order, Giddens suggests "studying the modes in which such systems, grounded in the knowledgeable activities of situated actors who draw upon rules and resources in the diversity of action contexts, are produced and reproduced in interaction." (p.28). This, however, is too abstract and general for the purposes of my study. More specific conceptualization is required of how actors are embedded in and anticipate on co-evolutionary processes.

2.3 Reflexive co-evolution of science, technology and society

2.3.1 Introducing reflexive co-evolution

Scholars of science & technology studies have pointed out that science, technology and society are not independent 'spheres' that interact, but which co-evolve (Sørensen and Williams 2002).[4] Co-evolution of science, technology and society refers to each 'sphere' having dynamics of its own and that the dynamics of these 'spheres' are linked. The linkage between the spheres may have dynamics of its own.

The use of the term co-evolution does not imply that these arrangements co-evolve harmoniously or easily. In our modern societies there exists an asymmetry between those who develop science and technology and those who are impacted by these developments. For one this is related to a difference in timing between development and introduction of new technologies; for another it is related to differences in involvement and perspective of a variety of actors which to some extent is institutionalized in a historically grown division of

[4] See Geels (2006) for an overview of co-evolutionary processes in a variety of fields.

promotion and control labour (Rip 2002a). Thus, while the evolutions of the 'spheres' of science, technology and society are linked and mutually shape each other (co-evolve), there also exist gaps between these spheres which have to be bridged through interactions.

Reflexive co-evolution (Rip 2002a, 2002b) captures the idea of 'bridging gaps' in co-evolutionary processes and refers to anticipation-oriented patterns between the spheres of science, technology and society. It draws attention to knowledgeable actors and complements evolutionary terminology of variation, selection (and retention) with actor-centred analyses, while recognizing broader dynamics. Actors 'experience co-evolution in terms of mutual interdependencies and path dependencies', but also anticipate evolutionary processes such as selection of new products, and anticipate patterns such as emerging industry standards. Co-evolutionary processes are shot through with intentional and strategic action (Rip 2002a).

In reflexive co-evolution, variation and selection processes are not blind. Actors see themselves as part of the co-evolutionary processes they want to influence. Actors anticipate co-evolutionary developments based on their understanding of the situation, including responses of other actors to their actions, and adjust their actions accordingly (Rip 2002b). In so doing they may actually induce changes in the overall situation, although outcomes cannot be attributed to their strategic actions. Even if effects are limited or unclear, such as in early stages of technology emergence and embedding, such anticipatory actions will contribute to more reflexive interactions in evolutionary processes.

Various forms of Technology Assessment, the inclusion of Ethical, Legal, Social Issues/Aspects (ELSI/ELSA) research in nanotechnology research programmes, can be interpreted as instances of reflexive co-evolution. The extent in which they 'bridge the gap', however, is not obvious and the question can be raised whether they institutionalize and add up to a pattern in reflexive co-evolution (Rip 2002b). Van den Belt & Rip (1987)'s analysis of test laboratories and the patent system, then, is a more concrete example of patterns in reflexive co-evolutionary processes and will be discussed in more detail in section 2.3.2 The imagery of 'test labs' as a way to play with co-evolutionary processes in a protected space (protected from outside selection pressures) is helpful for interpreting the potential role of ELSI/ELSA research. The inclusion of Ethical

Legal and Social Issues/Aspects research within nanotechnology research programmes, and before the Human Genome programme, can be considered as creating a test lab through studies (Rip 2002a). In a similar vein, environmental assessment reports (and legislation about it) can be considered creating a 'test lab' leading to pre-selection of options and, possibly, generation of new options, specifically oriented at environmental aspects. A similar point about test labs, through media coverage (and clinical testing), has also been made by Oudshoorn (1999).

In order to locate institutionalization of anticipation of societal embedding within reflexive co-evolution, I will first discuss the phenomenon of co-evolutionary processes associated with technological change, using evolutionary economics and sociology of science and technology literature.

2.3.2 Co-evolutionary processes and anticipation of societal embedding

While evolutionary economics ultimately aims to understand and explain economic change, technological change plays an important role in evolutionary analysis. Different patterns in technology development in sectors are considered to be important variables for explaining differences in economic progress amongst these sectors. In classic economic studies R&D spending, for instance, is used as an independent variable in order to explain differences in economic growth. Evolutionary economics, conversely, argue to endogenize technical change and argue for instance that R&D spending is not an independent variable but in need of explanation itself (Nelson and Winter 1977).

Evolutionary economic theorists reject the classic economic profit maximization hypothesis by pointing out the uncertainties inherent in technological change that hamper choices on the basis of evaluation of 'profit'. Uncertainties apply both to the generation of new technological options and to choosing among new R&D projects (Nelson and Winter 1977). Evolutionary processes will be ripe with uncertainties associated with the development and embedding of emerging technologies. They may also give rise to dilemmas regarding handling new and emerging technologies such as those captured by

the Collingridge Dilemma (Collingridge 1982). The dilemma points out that during early stages technologies are still malleable, but great uncertainty exists about future impacts. In later stages impacts are more clear, but technologies are more difficult to change.

Within evolutionary theories, technology development is conceptualized as involving variation and selection processes (Schot 1992). Variation refers to the generation of technological options during search processes involving trial and error. Selection involves evaluation and implementation of technological options. Variation and selection occur in a particular environment and actors' assessment of emerging technologies will be related to their position with one or the other environment – see also 2.3.4 on enactors and comparative selectors.

The evolutionary conceptualization of variation and selection of new technologies has been further developed by noting that not only technologies are subject to variation and selection. Each 'variation includes a script or scenario that includes also parts of the surrounding environment' (Akrich cited in Schot 1992). In his study of the electric car Callon (1986) showed that engineers not only designed a car but an entire environment in which that car should function. In other words, variation includes the generation of socio-technical options, technologies which are accompanied by notions of how they might be embedded in society.

Variation and selection do not occur at random. Variation processes are guided by heuristics, rules that promise but do not guarantee success of finding a solution to a problem. Similarly, evaluation and decision processes in selection make use of heuristics, although of another type. This does not imply that variation and selection processes in technological change are independent. Van den Belt & Rip (1987) point out that actors make choices and anticipate the reactions of others. Furthermore, they can aim to influence reactions of other actors and change their environments. Selection environments, including among others customers, can be influenced, such as through advertising, which does not mean that they exert no influence on variation. In that respect, they argue, it is more appropriate to talk about a quasi-evolutionary instead of evolutionary theory of technological change.

Anticipatory interactions between variation and selection can occur ad hoc, but also institutionalize. Van den Belt & Rip's analysis of the synthetic dye industry identified such stabilized forms of anticipatory interactions. At the end of the 19th century, test labs and application research departments were created in the German synthetic dye industry to simulate the selection environment (dyers' shops). Tests of performance and effects of dyes helped developers to be prepared for interactions with future dyers by anticipating future selections of dyes. At the same time, the development of test labs and application research also affected the selection environment. Customers of dyes (textile dyers and printers) adapted to requirements of the new products and were supplied with instructions on how to deal with the new products. Van den Belt & Rip call the application research departments and test labs a 'nexus', an institutionalization of anticipatory interactions between variation and selection processes.

The process of societal embedding of new technologies can be understood as involving variation and selection of socio-technical options, including anticipatory interactions between variation and selection. Generation of new socio-technical options includes anticipation of future selection. Selection includes negotiation, such as buyers formulating requirements of their planned purchases and adaptation of new technologies by users for their own purposes, which might be different than intended by the technology developers.

Anticipation of embedding, then, will occur from positions in variation processes, but are not limited to these positions. In embedding processes as they occur, by definition also selection processes are involved. Anticipation of embedding, then, can also take place within selection processes. Here, the phenomenon of 'anticipatory governance' (Barben et al. 2008; Guston and Sarewitz 2002) is relevant. Anticipatory governance is positioned at the selection side in which selection processes anticipate the generation of socio-technical options. "Anticipatory governance comprises the ability of lay and expert stakeholders, both individually and through an array of feedback mechanisms, to collectively imagine, critique, and thereby shape the issues presented by emerging technologies before they become reified in particular ways. Anticipatory governance evokes a distributed capacity for learning and interaction stimulated into present action by reflection on imagined present and future sociotechnical outcomes." (Barben et al. 2008, p. 992-993). In evolutionary terms, this means that the selection environment anticipates

future variations and subsequently changes its selection rules. However, the linkage with variation is less profound as there is no direct feedback to technology development activities, but may be taken up in such activities. The key point here is that anticipation of embedding–oriented interactions between variation and selection processes may institutionalize into a nexus and become a pattern in reflexive co-evolutionary processes.

In evolutionary terminology, actors are not important as it is variation and selection that counts. Still, there are also actors and their strategies. In the world of nanotechnology we see actors who want to do something about societal embedding and who are more or less explicit about their strategies. So, I need to add actors and their strategies in relation to societal embedding processes.

2.3.3 Games of embedding

Deuten et al.'s (1997) discussion of societal embedding was concentric and focused on a single actor's attempts at optimization (in this case 'market success' of a new product). During embedding processes a variety of actors are active and try to shape what is happening. Eventual outcomes, 'successful' embedding, will then be shaped through interactions rather than single attempts at optimization. Attempts at optimization, including anticipatory attempts, may not be productive at the level of society where considerations other than firms' will play a role, or at the level of the firm itself as interactions may produce undesirable outcomes (Rip 1995).

Actors' anticipation of embedding, then, has two analytically distinguishable components: (1) individual actors' assessment of emerging technologies and their embedding, and strategies to cope with embedding; (2) individual actors' assessment of how other actors in the sector are and might be coping with issues of societal embedding, and strategic interaction with these actors.[5]

[5] Here, I use the notion of 'strategic interaction' as articulated by Goffman (1971): "Two or more parties must find themselves in a well-structured situation of mutual impingement where each party must make a move and where every possible move carries fateful implications for all of the parties. In this situation, each player must influence his own decision by his knowing that the other players are likely to try to dope out his decision in advance, and may even appreciate that he knows this is likely.

Anticipation on how new technologies become embedded is already itself difficult, due to uncertainties regarding how new products will eventually look and their impacts. Anticipation of how other stakeholders cope with parts of the embedding process and what this means for individual actors' strategies then introduces further complexities.

Strategic games are a way to analyse such anticipation oriented interactions (Rip 1995). Actors' strategies and moves in embedding processes can be captured metaphorically as plays in 'games of embedding'. The point of games is that outcomes of interactions depend on the structure of the game rather than on individual actors' decisions. I contend that the metaphor of games should be taken seriously, as there are elements of games in embedding processes of new and emerging technologies.

For new and emerging technologies, actors are aware of mutual interdependencies – even if they are not yet fully articulated. Actors can "respond to and often try to anticipate one another's moves." (Scharpf 1997, p.5) This can constitute a game, because a "game exists if [...] courses of action are in fact interdependent, so that the *outcome* achieved will be affected by the choices of both (or all) the players." (ibid, p.7) Even if actors may not recognize the game structure - the other players, rules affording particular lines of action - as embedded actors they will follow rules. Embedded actors' strategies will be shaped by rules and practices in a particular domain.

Clearly, the extent to which actors are interdependent and/or follow rules in games of embedding is not self-evident. Actors may actually ignore rules, cf. the metaphor of 'cowboy firms'. New and emerging technologies introduce further complexities for articulating and following rules. Through interactions, new rules (in games) can emerge and be followed – cf. 'structuration' – which can be formalized for game theoretic purposes (at least in theory). Stabilization into rules will only be partial, as the development of rules will be fluid and open-ended due to uncertainties about future developments, effectively constraining formalization of 'real world games' (Scharpf 1997). Analytically, it is more productive to analyze games in a qualitative manner and conceive of

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Courses of action or moves will then be made in the light of one's thoughts about the others' thoughts about oneself. An exchange of moves made on the basis of this kind of orientation to self and others can be called strategic interaction." (p. 100-101)

games of embedding as constituting a category of a particular set of games, rather than a game in itself where it is clear which players are involved and which rules are followed.

Within Deuten et al.'s definition of societal embedding there is room to identify different types of games of embedding and involved players. Each dimension of societal embedding is linked with a particular environment and actors with which a firm maintains relations. Within each dimension one can already indicate the existence of interdependencies between actors. Integration in relevant industries and markets will definitely involve games in which players of the business environment will be involved (suppliers, customers, knowledge institutes). In product value chains, interdependencies exist between downstream and upstream players. Admissibility according to rules and standards will involve games in which, in addition to a firm, players of the regulation environment will be involved (governmental bodies, regulatory agencies, standard setting bodies). Interdependencies also exist here, such as between firms and regulatory bodies. Regulatory bodies are to some extent dependent on firms, as their existence is predicated on firms' activities. Broader societal acceptance will involve games in which, again in addition to a firm, players of wider society may be involved (consumer organizations, environmental groups, opinion leaders, media). Here, interdependencies may be less clear, but nevertheless exist. Consumers are to some extent dependent on firms which offer products, and firms depend on consumers buying products. Consumers may organize themselves into consumer organizations or public interest groups. As an organized actor, they may influence firms' decision making via credibility pressures, although the force of such pressures cannot be attributed to interest groups alone.

To empirically identify games it is important to demonstrate the existence of pressures which influence whether or not specific actors may not exit from a game. A socio-technical landscape may offer such pressures. I illustrate this with a fictional, though plausible, game involving competing supermarkets. Supermarkets nowadays have to pay attention to the diffuse idea of sustainability. Supermarkets may choose not to spend efforts in this area, which will save them money in the short run, but may end up losing customers and sales, because of lack of a 'green image' in the long run. While the real world will be more complex, the point is that the game metaphor may capture

some of the dynamics in interactions between supermarkets. I will provide two examples to further illustrate games of embedding.

The extent to which rules and practices are articulated and hold legitimacy for new technologies by the players in the game, may reduce uncertainties as to how the players can and should deal with new and emerging technologies, cf. the Collingridge Dilemma (Collingridge 1982). On the other hand, rules of the game may not be sufficiently articulated. Activities associated with new technologies may face a relative lack of legitimacy resulting from 'unfamiliarity among stakeholders with the new activity and disputed conformity to existing institutional rules' (Aldrich and Fiol 1994). Waiting games might then be unavoidable when interdependent actors are faced with technologies (1) which are associated with promises which cannot be ignored; (2) which have high levels of uncertainty about impacts and how other actors would cope with them; and (3) where no actors are willing to take a risk. Waiting games may then result in an impasse, preventing the further exploration of potential benefits and risks, as well as ways to cope with them. Indeed, waiting games are visible (such as in the food sector where developers of nanotechnology-engineered packaging materials are waiting for regulators to come up with guidelines on how to assess safety, and regulators for manufacturers to provide materials in order to develop guidelines). See further discussion in chapter 3.

While interactions around technologies may end up at an impasse (such as with waiting games), the opposite, a race, can happen as well.[6] An arms race is one example, but there are more. Competition between countries with respect to public funding in research & development can develop into a race. In the case of nanotechnologies one can speak of a funding race since the launch of the NNI in 2000s. Governments across the globe steadily increased funding into nanotechnologies from 432 million US$ in 1997 to 3,739 million US$ in 2004 (Roco 2005). In the Netherlands, the Dutch Research Council NWO selected nanotechnology as one of the themes eligible for extra funding in 2001. The 'invest in order not to lag behind' argument played an important role.

Waiting games and funding races are one way in which complexity in games of embedding is reduced. A lock-in into a particular set of rules is another form of

[6] In economics, technological competition has been analyzed in terms of races and waiting games (Hoppe 2000; Dasgupta 1988).

reduction. Insights from developments linked to information and communication technologies (ICTs) are instructive on this point. Early on, no clear rules of embedding were visible, until after recurrent problems, especially with the introduction of ICTs in organization (automation). Consideration of users became an important rule to anticipate possible problems of the embedding processes. Often, it led to procedures for participation of users, not necessarily to substantial anticipation of embedding. But it did reduce complexity.[7] With further experience, there were attempts to bring back some complexity.

What actors perceive as a desirable outcome, or payoff, of their strategies in games of embedding will differ among the actors involved. There will likely also be some contesting of the rules in games of embedding of emerging technologies.

2.3.4 Enactors and comparative selectors

For understanding actors' activities and interactions the actor typology developed by Garud and Ahlstrom (1997) is helpful. Garud and Ahlstrom emphasize the structural difference in the ways actors assess technologies. They relate differences in views and action perspectives to two different positions: insiders and outsiders with respect to technologies. To emphasize the difference in position and style, rather than inside/outside boundaries, the terms enactors and comparative selectors have been proposed (Rip 2006).

As we formulated in the yearbook Nanotechnology in Society (Rip and Te Kulve 2008), enactors (i.e. technology developers and promoters, who try to realize (enact) new technology), construct scenarios of progress, and identify obstacles to be overcome. They thus work and think in 'enactment cycles' which emphasize positive aspects. This includes a tendency to disqualify opposition as irrational or misguided, or following their own agendas. For nanotechnology, enactors now also anticipate obstacles similar to the ones

[7] See also Van der Meer and Roodink (1991) who describe a social simulation approach which demonstrates complexity in automation processes and can be played by members of an organization. The interactions contribute to assessments and warnings, but not necessarily to anticipation.

which occurred for GMO (Genetically Modified Organisms) in agriculture and food, cf. Colvin (2003).

While enactors identify with a technological option and products-to-be-developed, and see the world as waiting to receive this product, "the world" may well see alternatives, and take a position of comparing and selecting. Thus, the other main position to be distinguished is the one of comparative selectors (not necessarily critics). There are professional comparative selectors (regulatory agencies such as the US Food and Drug Administration) which use indicators, and develop calculations to compare options with alternatives (e.g. versions of cost-benefit analysis). There are also citizens, consumers as *amateur* comparative selectors – who can range more freely because they are not tied to certain methods, and to accountability. Spokespersons for citizens, consumers react and oppose (rather than just select); some NGOs become enactors for an alternative (as when Greenpeace Germany pushed for an environmentally friendly refrigerator – Greenfreeze (Verheul and Vergragt 1995)).

Enactors can, and sometimes must, interact with comparative selectors; formally as with the US Food and Drug Administration, or informally as in marketing and in the recent interest in interactions between strategic management of firms and spokespersons for environment and civil society. They may also interact in a "domesticated" version: in test-labs such as Philips Home-Lab (Philips Research – Technologies) and the RFID (Radio-Frequency Identification Device) -filled shop (RFID Journal 2003) in which people are invited to try out the new products, services and infrastructure.

The further step is to recognize that enactment cycles and comparative-selection cycles interfere anyway, and to identify (possible) interference locations and events and what can happen there. Garud & Ahlstrom (1997) speak of 'bridging events' and identify some examples and their limitations. Bridging events may not only include 'events', but also structural interaction. Cowan (1987)'s analysis in terms of a consumption junction is one example. Van den Belt & Rip (1987) 's point mentioned earlier regarding testing laboratories and patent systems as nexuses which carry and shape interactions between variation and selection processes are further examples in which enactors and selectors of new technologies structurally interact.

Some enactors, and for that matter also selectors, may take initiatives in order to shape societal embedding processes at a collective level. Enactors will definitely be important to be included in my analysis. They will play a key role as promoters of emerging technologies. Anticipatory interventions by enactors are interesting in themselves as they provide indications for more reflexive co-evolutionary patterns.

Entrepreneurial actors may work towards shaping structural interactions between enactment and selection cycles (cf. 'bridging events') by proposing novel rules and practices linked to the introduction of new technologies before they enter (in large numbers) the market. Or they may take initiatives which turn out to help shape such processes. This phenomenon is captured by the notion of institutional entrepreneurs and fora which will be further developed in section 2.5.

Bridging events constitute linkages between enactment and selecting cycles, which may institutionalize. Bridging events can be constructed on purpose, by actors from enactor or selector positions, and by more disinterested actors such as Constructive Technology Assessment (CTA) agents and macro-alignment actors (Rip 1995), who are stimulating reflexive interactions between variation and selection processes.

2.3.5 Constructive Technology Assessment

The approach of Constructive Technology Assessment (CTA) has been developed since the 1980's and has become a key methodology within the field of technology assessment. It aims to broaden design, development and implementation processes rather than only assess impacts on novel technologies (Schot and Rip 1997). In CTA, technologies and their impacts are not seen as given. "For CTA, the dynamics of the process are central, and impacts are viewed as being built up, and co-produced, during the process of technical change. Many technology studies have shown that impacts are not just passive effects of a given technology on its environment, but are actively sought (or avoided) by technology producers, users, and third actors such as governments, unions, and pressure groups alike" (Schot and Rip 1997, p. 257). Technologies and their impacts co-evolve, and actors involved try to shape this

process and make assessments of what is happening or could happen. CTA does not aim to introduce assessment – as enactors/selectors are making assessments the entire time- but rather to modulate ongoing processes of assessment and feedback into actor decisions and strategies with respect to technology development and introduction. In particular it aims to stimulate actors' first- and second-order learning and reflexivity with respect to co-evolutionary processes of technology development and their 'embedding in society' (Deuten et al. 1997).

While CTA events are an intervention, they are also a tool to understand what is happening in a particular domain of technology. They provide an entrance point to elicit perceptions of enactors and comparative selectors in an interactive setting. CTA events orchestrate and support bridging events between enactors and selectors. As we formulated it (Rip and Te Kulve 2008), it is creating and orchestrating spaces where interactions occur, even if the interactions between citizens/consumers and technology developers and promoters will always be partial (because of their difference in perspective). There will be "probing of each other's realities" (as Garud and Ahlstrom (1997) called it), with more or less contestation.

In interactive workshops, probing and commenting can be supported by socio-technical scenarios. In the case of nanotechnologies, socio-technical scenarios are necessary to address their doubly fictional character (Rip and Te Kulve 2008). Many of the expected applications enabled by nanotechnologies (and nanosciences) are still envisioned, part of 'science fiction'. The eventual impacts of such applications are unclear, and attempts to find out about impacts amount to social science fiction. Socio-technical scenarios capture ongoing dynamics and develop assessments of future developments. They show the effects of interactions between enactors and selectors which provides more substance to interactions in workshops as actors can draw upon the scenarios for inspiration.

The use of scenarios and interactive workshops has further effects. They provide participants in workshops with competences to support anticipation and strategy articulation. Tools such as scenarios, which are based on insights in ongoing dynamics (Rip and Te Kulve 2008) and debates during interactive workshops, provide actors with understanding of the overall situation and clues

for how to take into account ongoing developments and future impacts. So, while actors will likely value anticipation of embedding as a prudent strategy relevant for their own activities, they now are also provided with some skills to fill in such strategies.

Interventions based on understanding of the situation occur all the time. Constructive Technology Assessment initiatives build on actors' understanding, as it forms an entrance point for CTA actions. CTA agents aim to support and further articulate actors' understanding with a view to improve reflexivity in societal embedding processes. To do so it is important to move away from enactor perspectives on affecting change, although one still needs to recognize enactor perspectives in order to be able to link up with them during CTA actions. Moving away from enactor views is important, however, to develop a richer picture of ongoing co-evolutionary processes. For one, to create added value, and therefore some legitimacy in the eyes of the primary target group of CTA activities - enactors of new and emerging technologies. For another, it is important to capture complexity in co-evolutionary processes and be able to support more productive attempts at modulation towards desirable societal embedding.

To develop a richer picture, in particular of dynamics in institutionalization of anticipation on societal embedding, further conceptualization of co-evolutionary processes and roles of actors and interventions is required in which multi-level aspects are incorporated.

2.4 Multi level dynamics in alignment processes

2.4.1 Multi actor, multi level aspects in co-evolutionary processes

My further conceptualization consists of three steps. The first step consists of taking into account the distributed character of co-evolutionary processes. Garud and Karnøe (2003) speak of distributed agency in technology entrepreneurship to bring attention to a multiplicity of actors and their practices involved in the development and introduction processes of new

technologies. Not only are actors involved who are concerned with discovery and creations of new ideas, but also those who 'develop complementary assets'; actors who are involved in 'institutional forums' and customers. They point out that "actors become interwoven into emerging technological paths that they shape in real time." In turn, the emerging paths begin shaping actors over time. "In being entrepreneurial, actors cannot do anything they please. As *embedded* actors, they can entrain certain possibilities and not others." (p. 281)[8]

The distributed notion has implications for conceptualization of the meso level, or interactions at the sector-level, which is the key entrance point for my empirical studies. Evolutionary economists have already argued the importance of broadening the notion of industry structure and taking more actors and relationships into account (Malerba 2002; Nelson 1995). Institutions regulate interactions between a variety of actors, which points to the relevance of non-market relationships and transactions. In their study on the electricity industry, Granovetter and McGuire (1998) offer an approach to analyzing social structures in sectors of industry which takes into account broader interactions. They propose a broader view of industry structure than merely a constellation of actors producing similar products. They argue that economic rationality explanations are not sufficient and suggest explanations that characterize and emphasize interactions and dependencies between a broad variety of actors such as upstream and downstream trading partners, trade associations, unions, government agencies, political parties and voluntary associations (1998, p. 148-149).

To analyze institutionalization (processes), a further expansion of the notion of industry structure is necessary. Expectations play an important role in the dynamics of new and emerging technologies (Van Lente and Rip 1998b; Borup et al. 2006). Expectations not only relate to possible benefits and risks of new technologies, but also to divisions of labour about who should actually do something about these benefits and risks. Expectations can also include visions about new competitive advantages and changes in buyer-supplier relationships. Social structures of an industry, then, do not only comprise current, historically grown institutions shaping interactions between actors and technologies, but also expectations about future social structures which may or may not 'be filled in by agency' as Van Lente & Rip (1998a) phrased it. I will use the term

[8] My italics.

'industry structure+' to indicate this broadened conceptualization of industry structure, including more actors and prospective structures.

Developments at the meso level take place against a broader backdrop, a 'socio-technical landscape' (Rip and Van Amerom 2009). Just as a 'real' landscape, a socio-technical landscape can be thought of as plains, hills and valleys with different gradients enabling and constraining movements of actors and technologies. Sahel (1985) offered a visualization of such a landscape with evolving innovations. Other visualizations are possible, such as a 'fitness landscape' (Jelsma 2003) or a potential field such as in electromagnetic theory (Rip and Van Amerom 2009).

Socio-technical landscape includes discourse which can provide direction for actors' actions and interactions, including interventions in social orders. Lawrence and Philips' (2004) argued that "discursive activity at a macro level can act to provide building blocks for new institutional fields, but how these building blocks are used to construct a field depends upon local action and the strategies of local actors." (p. 690) Macro-level debates are part of societal agenda building processes, which contribute to framing what are considered to be relevant issues. Such debates add to a 'cultural repertoire' (Swidler 1986), which actors can draw upon for their own strategies. Macro-level developments do, however, include more than discursive activities. They also comprise emergence and stabilization of overall institutional arrangements such as national and supranational legislation, and technological infrastructure such as railways and airports. Repertoires, institutional arrangements and technological infrastructure together constitute a socio-technical landscape co-shaping actors' perceptions and providing 'affordances' (Hutchby 2001) for interactions, and, for that matter, interventions.

The second step consists of differentiating between various forms of variation-selection interactions. Anticipation of societal embedding includes anticipation of future selection and negotiation in selection. More relevant interactions between variation and selection can be identified. The generation of socio-technical options is guided by heuristics, but also requires resources. Resources can be of various kinds, such as people, their skills and knowledge, equipment and funds, but can also be symbolic such as legitimacy, trust and expectations. To pursue the development of a new product or a new scientific project, actors

can draw upon their access to resources, but most likely also need to collect new resources. The process of mobilizing and allocating resources is of importance in itself as it sets boundary conditions for the generation of variations – quasi selecting new variations. The mobilization of resources is itself subject to variation and selection. For instance, the funding and legitimacy of a new R&D project may be constrained by the existence and set up of governance arrangements such as regulatory and funding schemes and broader debates on legitimacy of technologies.

Analytically, the discussed interactions between variation and selection can be conceptualized by distinguishing between different levels of activities and linkages between these activities. Evolutionary processes, then, involve multi-level phenomena. Thus, for understanding societal embedding processes and institutionalization of anticipations of embedding, one should take into account multi actor as well as multi level aspects.

Multi level phenomena have been the subject of several studies across disciplines. Within science and technology studies: research systems (Rip and Van der Meulen 1996), multi-level perspective on technical change (Geels 2002; Rip and Kemp 1998), levels of work organization (Fujimura 1987); and within organization studies (Klein and Kozlowski 2000) and in evolutionary economics (Dopfer et al. 2004). Formulated in general terms, multi level analyses recognize the relevance of different levels or layers related to a particular phenomenon. While each of these levels to some extent has dynamics of their own and have enabling and constraining structures, they are to some extent also interdependent with the other levels.

I use the work of Fujimura (1987) as inspiration as I am interested in processes and ongoing activities and interactions of actors, rather than hierarchies of socio-technical structures or organizational entities. Fujimura uses a multi level perspective to analyze and construct do-able problems. Scientists typically choose to pursue problems that are do-able. Fujimura conceptualizes do-ability as the alignment of several levels of work organization. These levels include the experiment as a set of tasks, the laboratory as a bundle of experiments and other tasks, the social world as the work of laboratories, colleagues, sponsors and other players, all focused on the same family of problems.

Fujimura's conceptualization of levels of work needs to be broadened for the purposes of this study. Her approach is concentric, focusing on the research actor making her research doable by aligning the experiment, lab, and wider social world. In order to account for the distributed nature of development and embedding processes of emerging technologies further actors and activities should be included. In other words, the black box of Fujimura's 'wider social world' needs to be opened up. For societal embedding processes, the following 'work floors' are (analytically) identified; see also Rip, Robinson & Te Kulve (2007):

- 'macro': broad societal debates and decision making, embedded in cultural repertoires and overall arrangements in societies ('socio-technical landscape').
- 'meso': interactions between actors, networks which are directly involved in embedding processes, but also third party actors such as re-insurance companies, embedded in strategic games and industry structure + .
- 'micro': ongoing work on the lab floor, and also on other 'lab floors' such as of policy makers, marketers and users of emerging technologies, embedded in practices (routines).[9]

This conceptualization is a further development of Deuten et. al.'s (1997) conceptualization of societal embedding as alignments between a firm's production creation process and their business, regulation and broader societal environments.

2.4.2 Societal embedding as multi level alignment processes

The third step is to articulate societal embedding in relation to multi level phenomena. In Fujimura's (1987) study, scientists achieved alignment (and thus do-ability) by articulating - considering, collecting, coordinating and integrating tasks - between levels of organization. They make problems do-able by organizing and reorganizing their work. For example, a scientist

[9] Note that (1) use the terms micro, meso, macro as short-hand, not to be confused with sociological associations with these terms; for a discussion on micro/macro distinctions in sociology see Knorr-Cetina and Cicourel (1981); (2) the distinction of these levels will be a reduction of complexity, albeit a productive one in order to contribute to multifaceted understanding of societal embedding processes.

(experiment level) discussing his request for new measurement equipment with the lab director (laboratory level). A problem is do-able when scientists can align tasks to three levels of work organization (Fujimura 1987).

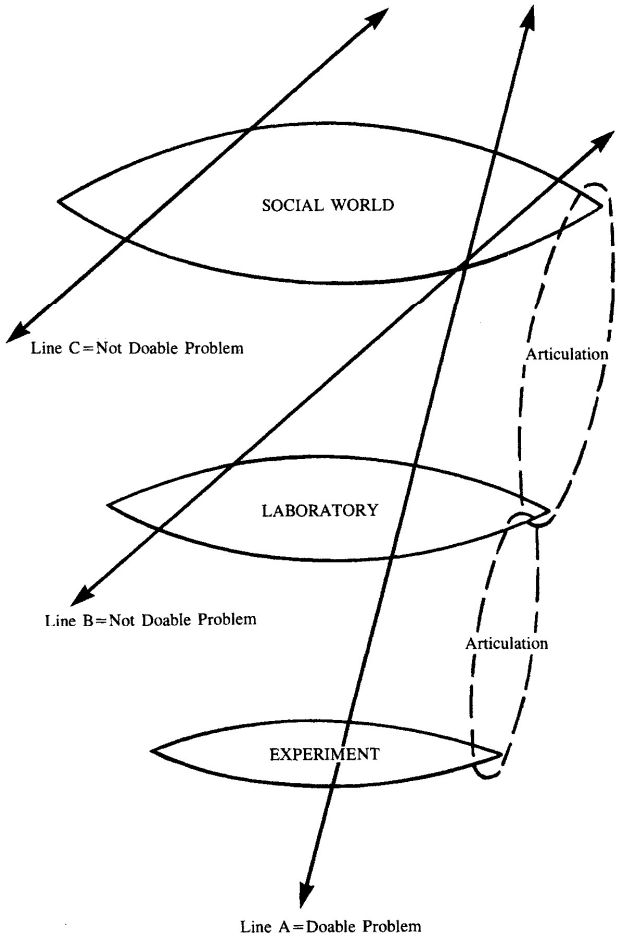

Figure 1: Aligning levels of work organization[10]

In alignment processes, Fujimura discerned two different kinds of work: production and articulation. Production includes carrying out a relatively well-defined task. Articulation is the work of pulling together everything that is needed to carry out production tasks. Articulation tasks are carried out

[10] Source: Fujimura (1987)

between levels of organization. Moreover, an articulation task in one perspective is a production task in another. According to Fujimura, the work process breaks down if there is lack of articulation. She wants to make more visible the efforts that make things work. Articulation also includes adjusting a task within a particular level of work organization in response to contingencies and constraints as they develop, but always in the context of aligning that task with those at other levels. She states that her notion of alignment is similar to Latour's 'enrollment of allies' and 'keeping [these allies] in line' in the construction and maintenance of scientific facts. Her notion is compatible, but Latour dislikes levels. Do-ability is low if articulation is difficult or neglected.

In this dissertation, societal embedding processes are understood as the development - as it occurs - of linkages, up to alignments between various levels of actors' activities. Alignment refers to the eventual entanglement of actors and activities in such a way that they are mutually dependent; they cannot move completely independently. There is then some mutual accommodation, like parts fitting together, a form of co-ordination resulting in a 'configuration that works' – which *de facto* steers actors' activities and interactions in certain directions. For example, alignment between activities on levels means that actors, while conducting activity a, take into account activity b, typically through adjusting their conduct so that it is congruent with activity b in some way. In that sense, alignments become part of structures enabling and constraining activities at different levels.

When linkages are taken up by actors in their ongoing activities, and perhaps consciously maintained by 'custodians' of such linkages, these linkages become increasingly difficult to break (cf. notion of 'emerging irreversibilities' (Van Merkerk and Robinson 2006)) and become entanglements, "associations that last longer than the interactions that formed them" (Callon and Latour, 1981, p.283). Clearly, the extent to which alignment occurs can differ. In other words, alignment may only be partial.

Alignment processes and their (emerging) outcomes can have different modalities, characterized by how they are entangling different levels and modulate developments at levels. To illustrate this point I provide some examples. Multi-level alignments can act as patterns visible at the micro level, as emerging routinized practices taking into account developments at

meso/macro levels. Researchers responding to calls and societal pressures for 'relevance' in research programs, or researchers participating in multi-disciplinary design practices, in both of which they need to co-operate with various stakeholders, are examples of such patterns. Multi level alignments can be visible as patterns in an emerging game at the meso level taking into account micro/macro level developments and shaping micro/meso-level actions and interactions. Implementation of sector informed codes of conduct for responsible innovation in which there are routinized interactions with stakeholders at the meso level, the outcomes of which are taken up in ongoing research and product development activities, is one such pattern. Multi level alignments can be visible as a pattern at the macro level shaping meso/micro developments. An example would be when anticipation of the health risks of emerging technologies becomes a taken-for-granted pattern at the macro level which would induce actions and interactions at the meso and micro levels to control health risks of a variety of emerging technologies.

In my empirical work, I focus on emerging patterns visible at the sectoral level involving multi level alignments processes. I am interested in emerging rules and practices – institutions: 'patterns which have become taken for granted and act as stable designs for repeated activities of which deviation is difficult or costly in some manner' (Garud *et al.* 2007). These patterns can include formal regulations, but also informal codes of conduct, norms, and established practices with routinized (and legitimate) ways of behaviour – all 'rules of the game' (North 1990). Through actions and interactions at the sectoral level, new patterns can emerge. In the case of new and emerging technologies, for a long time, stabilization into patterns will only be partial as the development will be fluid and open-ended given uncertainties about future developments.

Patterns in reflexive co-evolution may extend sectoral boundaries and may have the characteristics of what Nelson and Winter (1977) have called a 'natural trajectory'. A natural trajectory structures a variety of technology development through a broad heuristic, a 'super heuristic'. Heuristics (which promise success of particular directions of problem-solving, here in design and development of a technology or product line) shape technology development trajectories, and constitute a technological paradigm for "normal" development (Dosi (1982), after Kuhn (1996)). A super-heuristic indicates fruitful approaches across a variety of technologies, and is thus second order with

respect to particular technology developments. Examples of super heuristics are mechanization and automation. When the trajectory of mechanization or automation has become stabilized, through accretion in terms of its articulation and spread across instances of technology development, and anchored in technology development activities, such a trajectory will structure technology developments.

Thus, a natural trajectory is more than a trend; it is a structure enabling and constraining actors' technology development activities: a second order path. I can talk of a 'path' because the heuristics (and to a lesser extent the super-heuristics) are then no longer one option among a set of heuristics to choose from (if known at all), but are historically grown and not easy to deviate from. Natural trajectories show characteristics of path dependency, although as Nelson remarked in a later publication, actors can choose to deviate from them in order to differentiate themselves. The path dependency here does not refer to previous phases in the second order trajectory, but to historically grown linkages between the second order trajectory and technology development. To be able to speak of a trajectory, it must not just be a promising way, but also an (emerging) irreversible way (i.e. it will be difficult to deviate from this general way of coping with emerging technologies). Indicators for the emergence of a second order path of anticipation of embedding would be actors' propensity to co-ordinate activities with other actors' activities in particular anticipation of embedding.

Now that I have conceptualized societal embedding as involving multi level alignment processes, the question is how such alignments emerge. As we have formulated it in Rip et al. (2007), alignments can emerge because actors and activities accommodate to the same environmental constraints. They can also be actively pursued by dedicated anticipation-oriented interventions in societal embedding processes.

2.5 Anticipatory interventions

2.5.1 Openings for embedded interventions

Dedicated attempts to create new alignments will take place amidst ongoing development and embedding processes of emerging technologies. While actors are embedded in existing and prospective structures, which constrain attempts at change, openings for change can emerge, because constraints will never be complete. New spaces for interaction will then open up, as it occurs, or by intentional design. They provide a venue for anticipatory interventions and can act as a vehicle for anticipatory interventions.

Here, spaces are understood as empirically identifiable "more or less bounded spaces [..] allowing a variety of actors to assemble for deliberation, negotiation and aggregation, and which enable and constrain interactions and the aggregation of products (from new understanding to innovation to policy design)."(Rip and Joly 2004, p.2) The political science concept of arenas is similar, but is more specified.[11] In fact, arenas can be considered as particular, more or less stabilized manifestations of spaces, which make spaces a more general category. By using the terminology of spaces I want to emphasize the unstable, yet unspecific character of spaces under development. In this dissertation, I am not so much interested in what these spaces are, but more in what happens in such spaces.

For one, spaces opening up can become venues for entrepreneurial interventions and may, for that matter, be actively sought after. Conferences, and for that matter also CTA workshops, may act as venues for interventions. Workshops are spaces which are clearly sought after and orchestrated, or better 'modulated' as the organizers cannot fully control what is happening, in terms of actors present and themes discussed. Entrepreneurial action may also occur through spaces, for example in a forum to promote a new technology. Fora are similar to arenas- more stabilized and specific, but foreground co-operation for a common objective, rather than agonistic interactions. For societal embedding,

[11] Rip and Joly (2004) characterize a number of arenas such as economic and political arenas, and (among others) their associated key actors, products and resources.

spaces developing into 'hybrid fora' are particularly important. In hybrid fora heterogeneous actors are involved in debating a heterogeneous set of questions and problems (Merkx 2008). When actors from both the variation and selection environment are involved, such hybrid fora may construct linkages between these environments and contribute to reflexive co-evolutionary interactions. In a sense it is the space (and how it is used by a variety of actors) which becomes a vehicle for change.[12]

Interventions by knowledgeable and embedded actors, within and through spaces opening up, will be informed by their understanding and diagnosis of ongoing and future developments and will shape their actions on that basis. Actors' envisioning, creating, and working towards establishing new alignments is driven by anticipation of embedding. In that sense, they can act as a 'co-evolutionary mechanism' in reflexive co-evolution (i.e. they can contribute to bringing about reflexive patterns in co-evolutionary processes).

The created alignments will likely have an emphasis on specific aspects of embedding, related to the enactor/selector perspective employed in dedicated initiatives. Initiatives with an enactor/selector orientation can be expected to be more myopic compared to disinterested CTA agents or macro-alignment actors. For the latter, articulation of reflexive societal embedding processes is an objective in itself and, therefore, will take a broader view on embedding processes.

The formation of new alignments will not be straightforward, partially due to pre-existing alignments between levels. Alignment processes across levels, then, are particularly important also because they introduce vicarious stabilisation: if actors or circumstances appear to move in other directions and might actually be able to do so on their own level, they will be constrained by the links to another level with its own dynamics, which makes it more difficult for these actors to effect change at the other level.

The implication is that actors who can work at two (or more) levels – 'linking-pin entrepreneurs' – play a key role in multi-level alignment as they may be able to exploit openings at different levels of activities. Linking-pin entrepreneurs operate at a collective level and their attempts to create new

[12] See further chapter 3, section 2.1.

alignments share similarities with what is captured within organization studies by the notion of 'institutional entrepreneur'. In my studies I will use the concept of institutional entrepreneur. 'Linking pin entrepreneurs' is an analyst term to highlight multi level phenomena, activities across levels, but not necessary for the argument in my studies.

The other key role is played by spaces for interaction – also called (hybrid) fora – where actors (which may operate at different levels) can mutually position their activities and strategies in relation to emerging technologies. Meetings of such spaces, fora, can contribute to what has been called 'field-configuring events' (Lampel and Meyer 2008). Institutional entrepreneurs and fora are important concepts for my analysis of interventions that promise to contribute to insights in institutionalization of anticipations of societal embedding. I will introduce these concepts and examine parts of the literature relevant for my theme.

2.5.2 Institutional entrepreneurs & fora

The concept of institutional entrepreneurship was introduced by DiMaggio (1988) to revive interest and agency in analyses of institutions and institutionalization processes. Institutional entrepreneurship comprises the activities of actors who are mobilizing resources in order to create new institutions or transform existing institutions through tying disparate institutions together (Garud et al. 2002; Maguire et al. 2004). Garud *et al.* (2007) argue that in order to qualify as institutional entrepreneurs, actors need to both break with existing rules and practices and establish alternative rules and practices. In their review of the institutional entrepreneurship literature Leca *et al.* (2008) add that entrepreneurs do not have to be successful in order to be classified as institutional entrepreneurs. They also point out that recent research on institutional entrepreneurship moves away from earlier approaches criticized as presenting institutional entrepreneurs as "heroes who were disembedded from their institutional environment" (Leca et al. 2008, p. 5).

Leca et al. thus already note a trend in which a more distributed notion of institutional entrepreneurship is emerging and more attention is paid to the embedded character of entrepreneurs; see also Lounsbury and Crumley (2007).

However, until now, studies on institutional entrepreneurship associated with emerging technologies have focused on single instances of entrepreneurship rather than taking into account distributed aspects of entrepreneurship (Garud et al. 2002; Hargadon and Douglas 2001; Jain and George 2007; Munir and Philips 2005).

Institutional entrepreneurship has been studied as a phenomenon in its own right, while it instead should be analyzed as part of dynamics at the sectoral level. Garud and Karnøe, (2003) emphasize that institutional entrepreneurs are not completely 'free' in their movements, but are enabled and constrained by sectoral structures (Garud et al. 2007). As embedded actors, institutional entrepreneurs not only shape sectoral dynamics, but are equally shaped by them.

To study institutional entrepreneurship in relation to sectoral dynamics is particularly important when actors in a sector face new and emerging technologies and contemplate whether structural changes are required in order to address them. Additional effort is necessary because of the uncertainties about the value, and about customer and societal legitimacy, of these new technologies. This also implies that more types of actors will play a role, for example regulatory agencies and, increasingly, NGOs. Since such non-industry actors may also take initiatives, entrepreneurship relevant to the industry will not only be embedded and distributed, but also heterogeneous.

Thus, institutional entrepreneurship with respect to new technologies is distributed and embedded. Having recognized this, a further step can be made: institutional change can also occur through or within spaces for interaction, in the sense that the actual dynamics are shaped by such spaces, e.g. a forum to promote a new technology, rather than the activities of individual institutional entrepreneurs.[13] They can create new spaces (arenas, fora) for interactions, or exploit opportunities of spaces that emerge. Professional associations are one convenient venue for institutional entrepreneurship (Aldrich and Fiol 1994; Greenwood et al. 2002), and their conferences may act as field-configuring events (Garud 2008; Lampel and Meyer 2008).[14] Consortia – with their

[13] See also chapter 3 about distributed institutional entrepreneurship.
[14] Lampel and Meyer write about field configuring events as if they were agents, whereas I would prefer to think of 'field-configuring' as a possible outcome of

meetings and conferences – also provide a space. The configuration of a space and the variety of actors it is composed of then become important: if more heterogeneous actors are involved, also more aspects of distributed innovation will be captured.[15, 16]

In order to understand anticipation-oriented interventions it is important to analyze the type of initiatives (in terms of actors' backgrounds) which are emerging and the substance of their activities (what they do). Institutional entrepreneurship literature identified enabling and constraining conditions for entrepreneurship at either a field or organizational level, and, to lesser extent, at individual levels (Battilana 2006). Organizational fields differ in the extent to which they offer openings for actors to introduce novel patterns and offer opportunities for resource mobilization. Dorado (2005) argued that opportunities are dependent on (1) multiplicity of the field, the "extent to which organizational fields are uncoupled and open to practices and resources from other fields"; and (2) the degree of institutionalization of the field, "which defines the determining, constraining, and enabling effects of institutions on actors".(p. 392) The social position and skills of an individual are further enabling characteristics to act as an institutional entrepreneur (Battilana 2006; Fligstein 1997; Maguire et al. 2004).

Leca *et al.* (2008) noted that several studies argued that it is either central, powerful actors, actors at the margins of a field or at the interstices of different fields, who are more likely to act as institutional entrepreneurs. Maguire et al.

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interactions within spaces. They define field-configuring events as "temporary social organizations such as tradeshows, professional gatherings, technology contests, and business ceremonies that encapsulate and shape the development of professions, technologies, markets and industries." (Lampel and Meyer 2008, p. 1026) Lampel and Meyer suggest that field-configuring events "create a social space in which individuals can represent both themselves and their organizations. [...] These events give relatively greater scope for interaction, but are at the same time "structured in conformity with the institutional logic of the field. In effect, field-configuring events protect individual initiative and creativity from the relentless isomorphic pressures of institutional field logics, but then select from the outputs of these events those novel products, ideas, or actions that come to be valued within the field."(2008, p. 1028-1029)

[15] Such heterogeneous spaces may actually reduce the distribution of institutional entrepreneurship in terms of locations and separate activities as they may collect a variety of actor interests.

[16] Consortia, especially when there is strong leadership, can also be conceptualized as institutional entrepreneurs themselves, cf. the notion of 'collective institutional entrepreneurship' (Wijen and Ansari, 2007).

(2004) suggest that which actors are more likely to act as institutional entrepreneurs may vary depending on the maturity of the field. In their study of institutional entrepreneurship in the emerging field of HIV/AIDS treatment advocacy they pointed out that actors who are traditionally not associated with dominant subject positions, but who are endowed with high legitimacy by various stakeholders in the case of HIV/AIDS treatment advocacy, are more likely to act as institutional entrepreneurs. Their study contrasts findings of studies of mature fields in which institutional entrepreneurs are dominant actors who have access to and control of key resources. Which actors act as institutional entrepreneurs is significant, because it is proposed in the literature that the "identity of the institutional entrepreneur distinctly impacts the legitimacy building initiatives undertaken" Jain & George (2007, p. 538).

A distributed perspective on institutional entrepreneurship (and spaces) makes propositions regarding which actors are more likely to act as institutional entrepreneurs more complex. Still, one can start with the basic point that actors who act as institutional entrepreneurs possess sufficient resources to be productive in a particular situation. These resources can take the form of legitimacy, such as formal authority or leadership, their position in social networks, the ability to gather allies, co-ordinate collective action, access to and control of scarce resources (Leca, Battilana et al. 2008). When fields evolve, opportunities for institutional entrepreneurship and the distribution of resources change. Thus, one should expect the actors that are more likely to act (and be productive) as institutional entrepreneurs not to be fixed in processes of embedding, but changing over time.

While institutional entrepreneurs have been introduced in the study of institutional change at a field level, the meso level in my analysis, they also have a macro-level counterpart, at least analytically.

2.5.3 Macro-level interventions

Macro level developments, and their analysis, are a topic in itself. I will limit their examination to a brief sketch, which will be sufficient for understanding important dynamics in my two domains. Important here is the recognition that entrepreneurs can also operate at the macro level, which requires dedicated

work. A considerable part of this work consists of putting issues of societal embedding, and anticipation thereof, on the agenda within societal and political debates.

Two types of actors intervening at the macro-level, 'macro level entrepreneurs', can be distinguished. First, institutional entrepreneurs with specific interests in one or more domains may pursue their activities also at the macro level (see my notion of 'linking pin entrepreneurs'). Second, macro level entrepreneurs can also be more disinterested and aim to optimize societal embedding at the level of society, cf. 'macro-alignment actors' (Rip 1995). The explicit discussion of nanotechnologies and their embedding, and interventions in ongoing embedding processes at a societal level, provides the analyst with loci where interventions in macro developments take place: (1) dedicated entrepreneurs building agendas and proposing institutional arrangements and (2) media reporting about and adding to debates surrounding nanotechnologies.

Macro level entrepreneurs attempt to shape societal debates through agenda building and framing, and shape overall institutional arrangements by proposing rules and practices to be followed. For agenda building I am particularly interested in societal agenda building. While agenda building in specific arenas, such as within governmental agencies, is important, a strict focus on specific agenda building processes neglects the distributed character of innovation. Societal agenda building emphasizes multi-actor, multi-arena aspects in agenda building process in which no single actor can determine the outcome.

With respect to agenda building in general, media such as newspapers are relevant as a further empirical entrance point for analyzing macro level developments. While the impact of media debates is often overstated, newspaper coverage does contribute to framing issues and agenda building (Nisbet et al. 2003; Nisbet and Huge 2006; Anderson et al. 2009). Journalists select, frame and shape news items (Schudson in Schmidt Kjærgaard (2010)). They reflect and add to macro level discussions at the same time. In a sense, journalists and their products are interventions, although of a different type than dedicated change agents such as institutional entrepreneurs. Newspaper coverage is conceptualized as contributing to and solidifying an evolving 'repertoire' (Swidler 1986) about nanotechnologies from which actors can

select elements to shape their actions and solve their problems; see Te Kulve (2006) reproduced in this dissertation as an appendix.

2.6 Tracking processes of emerging technologies and their embedding

2.6.1 Requirements of process analysis of emerging phenomena

Not yet stabilized outcomes generate particular challenges for a study of interventions in embedding processes of emerging technologies. Eventual outcomes of interventions, i.e. their role in and effects on embedding processes, may only be recognized retrospectively. So, my study will have an element of speculation. Still, insights in intervention processes will contribute to understanding of (early stage) emergence of patterns in reflexive co-evolutionary processes. How to study such processes involving emerging phenomena?

A process can be defined as "a sequence of individual and collective events, actions, and activities unfolding over time in context." (Pettigrew 1997, p. 338) Process analysis, then, is about "describing, analyzing and explaining the what, why and how of some sequence of individual and collective action." (ibid, p. 338) To do so, I will develop basic requirements for process research of emerging phenomena based on Pettigrew (1997). These requirements will be used as a heuristic in my empirical research.

The first requirement is to recognize the embedded character of actors' actions and interactions across different levels. My understanding of societal embedding processes as a multi-actor, multi-level phenomenon forms a key starting point for empirical research activities. In his discussion of guiding assumptions about processes, Pettigrew emphasizes multiple levels of analysis. In the context of his interest in organizational processes, he suggests that the analyst should not only look at the level of the firm, but also to the level of a

sector in which a firm is involved. Here, I add developments at the macro-level which act as a backdrop for actors' actions and interactions.

The second requirement is to understand how events are connected throughout time. For a study into emerging phenomena, a combination of retrospective, real time and prospective approaches is fruitful. Real-time observations alone may not reveal emergence of alignments across levels of activities. Then a combination of approaches is important. By using prospective approaches such as scenario analysis, possible relevant future events (including associated predecessors) can be identified and assessed which would not have been possible by using only retrospective and real time approaches. For understanding ongoing and future developments, insights into historically grown dynamics are important. Or, as Pettigrew puts it: "Antecedent conditions shape the present and the emerging future."(1997, p. 341) In the development of scenarios, understanding of ongoing dynamics is actually a key requirement and taken up in the notion of 'endogenous futures'; see Rip and Te Kulve (2008) and my chapter 5 about pre-engagement.

The third requirement is to link processes to outcomes. My challenge is to get as far as possible with this requirement. As this is such a critical and challenging requirement, I will pay relatively more attention to this point. Analysis of emerging phenomena is not a simple version of tracing events and their relation to outcomes, as identification of relevant events is more complex given that processes are still unfolding. To identify events we have to take a broad view of what is (and might be) happening, supported by conceptualization; see also my discussion of the second requirement. So, identification requires anticipation by the analyst. I will return to anticipation by the analyst in section 2.6.2. where I will discuss data collection strategies.

Even if outcomes are not yet stabilized, one can (and should) identify stretches of actions and interactions with an 'intermediary' outcome. This allows the analyst to analyze a still-unfolding process, and link actions and interactions with outcomes. For the analysis of stretches I will follow a 'narrative strategy' (Langley 1999) of process research to make sense of what is happening. Such analysis, however, needs to comprise more than telling a story of embedded interventions if one aims to identify dynamics in processes of interventions. To

go beyond mere description, stretch analysis should aim to reveal underlying logics in the unfolding of the identified stretches.[17]

The above described general requirements for analysing emerging phenomena has implications for data collection for my dissertation.

2.6.2 Data collection strategies

The emergent character of my object of study offers challenges for systematic data collection. One way to address this challenge of capturing processes as they occur is by collecting heterogeneous data while 'moving about'. Within the TA NanoNed program, we have actually followed two strategies for this type of data collection. A few more words are in place to make these strategies explicit. For this I will draw upon an unpublished text which circulated in the NanoNed program.[18]

One strategy is to 'move about' as a visitor in the world that is to be studied. The other is to 'insert' oneself in that world (temporarily); i.e. accept the needs and views of the actors in that world and work with them, even if not identifying with them. As I did the former, I will discuss the 'visitor' approach. For an extended discussion of the 'insertion' approach, see Douglas Robinson (2010), building on his own experience with CTA workshops.

'Moving about' can be seen as simply a data collection strategy, but there is more to it. The term may suggest that it is arbitrary, contingent. While to some extent it is (but that is not unusual for research, as it is often 'messy'), moving about is guided by expectations which build on conceptualizations of where to find and learn about interactions between actors relevant for a research theme / question. That is, the analyst will need to make explicit which patterns are

[17] See also Pettigrew (1990) who distinguishes between types of research output from process studies, ranging from analytical chronologies to interpretative/theoretical cases and meta level analysis across cases. For process analysis of emerging phenomena, the analytical chronology with 'clarification of sequences, suggestions of causal linkages and development of early analytical themes' constitute a minimum requirement. An analytical chronology is often a first step for a more developed analysis such as the interpretive/theoretical case where there is a stronger emphasis to develop 'analytical themes within the case and their linkages with wider theoretical literature'.

[18] 'Intellectual charter TA NanoNed', March 2006; 'Methodology Notes', August 2010

emerging and where actions and interactions are unfolding where one may find indications and contra-indications for such patterns. For moving about, the analysts do not anticipate results from experiencing an emerging world, but from their own analysis and insights from the literature.

Moving about refers to visiting sites where the analyst expects to gather relevant data to support or adjust analyses. In that sense, moving about is also informed by attempts at 'triangulation'. When visiting research sites (texts such as reports, web sites) one can also see references from actors to other relevant actors and themes as suggesting linkages, routes available to actors. So, such references are providing indications for emerging patterns. Linkages and routes can also be traced by attending meetings and listening to the linkages that actors make or offer.

Observations in meetings and documents indicate emerging alignments if particular linkages are taken for granted by actors. Moving about allows mapping of linkages being made, accepted or refused, possibly supported by arguments, and so can serve as a first-round mapping of force fields. This is more than ethnography, because the analyst (ethnographer+) can mobilize data other than what he has encountered on location. So, data collected will be heterogeneous and can be characterized as 'multi-site ethnography'.

As I take actors and their interventions as my entrance point, identification of relevant actors will be particularly important and will be discussed explicitly in the chapters concerned. When moving about I will be particularly sensitive in identifying relevant actors and sites and will ask actors explicitly about this. In a sense, moving about shares similarities with 'snowballing'. Snowballing is about identifying further relevant actors (that have to be interviewed) and promising sites for further research, such as where new rules and practices shaping embedding of nanotechnologies are developed. It might not always work with emerging technologies. Actors may not be aware of what important developments are, actors and locations (this may always be the case, but particularly in the case of new and emerging technologies when things are still uncertain and fluid). So, asking actors about relevant sites can only be a part of a strategy for identifying relevant actors and events.

Identification of possible relevant future developments requires data generation through prospective studies, which is also part of anticipation strategies of the analyst. I conducted CTA workshops in which actors were invited to assess ongoing developments and develop strategies on that basis. These workshops were supported by scenarios of future developments. To generate robust data about future developments through workshops, dedicated methodologies are required and are discussed in this dissertation in my chapter on pre-engagement.

Even if contra-indications are sought after, 'moving about' may suggest that issues of circularity are at risk, i.e. one finds the pattern one is looking for. Considering my theme and questions, it would be interesting to search for instances of increased reflexivity in co-evolutionary processes. However, to prevent issues of circularity I take one step back. I focus on dynamics in processes of intervention and subsequently will discuss whether anticipatory interventions are adding up to patterns in reflexive co-evolution.

I focus on actions and interactions at the meso level; therefore sectoral structures will be important in shaping actions and interactions. In order not to be overly dependent on sector specific aspects in the identification of dynamics in intervention processes, I collected and analyzed data from two contrasting domains. By studying contrasting domains I aim to flesh out how sectoral circumstances and how more specific nanotechnology related themes (say, debates about nanotechnologies in general), work through in anticipatory interventions. Examining dynamics in different domains, then, will contribute to acquiring rich insights in dynamics in anticipatory interventions and indications for emerging patterns across domains (if any).

To do so, my empirical studies will concentrate on the domains of food and health. The world of food is known to be conservative about emerging technologies and its promises, whereas the world of health & medical technologies is more positive about emerging technologies, cf. debates on red/green biotechnologies. Specifically, I focus on the application of nanotechnologies for food packaging and drug delivery as these two domains of applications receive great attention. In terms of composition of the sector, both consist of intersecting product-value chains, which introduces complex interdependencies for actors in these chains. By taking intersecting value

chains as a key comparable dimension, I aim to capture the enabling character of nanotechnologies involving both generic debates about ‘nanotechnologies’ and domain specific dynamics.

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PART 2

Part 2 addresses my first research question regarding dynamics in institutional entrepreneurship activities. In chapter 3, I focus on the food packing sector, and elaborate my approach of distributed and embedded institutional entrepreneurship. I then map the main instances of institutional entrepreneurship and follow their evolution over time. In chapter 4, an analysis of institutional entrepreneurship initiatives in the drug delivery sector is offered, building on the insights garnered from the study of the food packaging sector, and recognizing differences.

In contrast to the usual approach in STS, I do not offer detailed case studies of actions and interactions. I do refer to assorted data about the various initiatives and background developments in the two domains, but focus on the overall story at the meso-level and possible emerging patterns. This allows me to map anticipation of societal embedding of nanotechnology not just as individual activities and their vicissitudes, but as overall changes in how the two sectors address the opportunities and challenges of anticipating societal embedding.

Chapter 3

Emerging technologies and waiting games: Institutional entrepreneurs around nanotechnology in the food packaging sector [*]

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Emerging technologies and waiting games:

Institutional entrepreneurs around nanotechnology in the food packaging sector

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Abstract

While nanotechnologies are expected to generate wonderful benefits for food packaging, there is reluctance in the uptake of these promises. Still, things are changing and there are dedicated attempts – by institutional entrepreneurs – to shape future embedding of these new technologies. Thus one can examine the evolution of sectoral changes before the actual introduction of new and emerging technologies, which is relevant for studies on emerging technologies and industrial change processes. The main question of this paper is how institutional entrepreneurship linking up with emerging nanotechnologies in the food packaging sector has evolved and contributed to changes at the sectoral level. To do so, I mapped instances of institutional entrepreneurship and constructed a narrative of the evolution of these initiatives, taking a broad view of institutional entrepreneurship-in-context. I found a pattern of a succession of waves of initiatives which contributed to an evolving patchwork of rules and practices. This patchwork will, eventually, shape societal embedding of nanotechnologies in the food packaging sector.

1 Introduction

While the improvement of food packaging materials through nanotechnologies may seem straightforward as an innovation, fueled by the promises about nanotechnology since the late 1990s, it appears not to work out that way. A journalist who attended a nanotechnology and food conference in 2006 observed: "The food industry is hooked on nano-tech's promises, but it is also very nervous" (Renton 2006). Of course, the food sector is known to be conservative with respect to new and emerging technologies, having had their setbacks and disappointments. Packaging might be considered as relatively safe, and has actually been identified as the most promising application area for nanotechnologies as to scale (Chaudhry et al. 2008). But even in this area, actors are cautious.

One factor might be the structure of the food packaging sector, which introduces complexities for the introduction of nanotechnologies. The sector is the intersection of food product-value chains and packaging product-value chains. This intersection increases the variety of actor interests and dependencies, and thus the occasions where actors wait for others to take initiatives. Definitely, the reluctance will be related to the uncertain uptake and societal embedding (Deuten et al. 1997) of nanotechnologies by firms and other stakeholders in the food packaging sector. The association with food introduces substantial challenges for embedding nanotechnologies for packaging, not just in terms of performance requirements, but also with regard to regulatory compliance and broader societal acceptance at the level of a sector.

Still, things are happening. At the same time when the US National Nanotechnology Initiative emerged, Kraft Foods Inc., one of the largest food and beverage firms in the world, established the Nanotek consortium. This consortium aimed to link the development of food and food packaging products with nanotechnology research. According to the director of the consortium, Manuel Marquez, Kraft wanted "to keep a leadership position in food science" (Gardner 2002a). Through its high visibility, Kraft's Nanotek provided a model and legitimation for the combination of nanotechnologies and food packaging.

However, Kraft's initiative faded away for contingent reasons – but not the notion of promising nano food packaging technologies. Other initiatives emerged that took up the concrete promotion of the combination of nanotechnologies and food packaging. This continued as issues of broader societal impacts and risks became important, attracting a wider variety of actors who attempted to promote rules and practices in order to shape the embedding of nanotechnologies in the food packaging sector. While the application of nanotechnologies in the food sector is still at an early stage and with only a few food & food packaging products on the market (Chaudhry et al. 2008), the overall situation at the sectoral level has changed through the promotion of these 'proto' rules and practices. Thus, sectoral changes can occur before structural changes in terms of product/firm entries or shifts in size and distribution of firms associated with particular products. How can we understand such sectoral developments in the food packaging sector?

Clearly, we have to include an institutional dimension. As Aldrich/Fiol (1994) emphasized, the development of new activities often faces a lack of legitimacy, resulting from 'unfamiliarity among stakeholders with the new activity and disputed conformity to existing institutional rules'. Embedding new technologies in the sector then does not occur automatically, but requires the dedicated creation of legitimate new rules, which support development and introduction of new

technologies, through reducing uncertainties.

The dedicated creation of new rules and practices is what institutional entrepreneurs try to do. The concept, originally introduced by DiMaggio (1988), refers to actors who mobilize resources in order to create new institutions or transform existing institutions, especially through tying disparate institutions together (Garud et al. 2002; Maguire et al. 2004). As Garud *et al.* (2007) phrase it: institutions are patterns 'specifying and justifying social arrangements and behavior, both formal and informal'. When taken up, these patterns become 'the rules of the game' in a sector.

The concept of institutional entrepreneurship is useful to understand dedicated attempts at creating new patterns. However, it should be expanded to take into account the broad variety of actors that are likely to play a role in shaping the embedding of emerging technologies. Institutional entrepreneurship, in the case of emerging technologies, will thus be distributed across a number of actors. In general, innovation processes have become complex and diffuse with a variety of actors interested in shaping development and introduction of new technologies. For emerging technologies, such as nanotechnologies, in an early phase of development and with a strong open-ended character, processes and effects of dedicated initiatives will be even more diffuse.

This paper aims to contribute to the understanding of sector-level developments during an early phase of development of nanotechnology engineered food packaging materials. The main question is: How does institutional entrepreneurship, linking up with emerging nanotechnologies in the food packaging sector, evolve and contribute to changes at the sectoral level?

To answer this question, I will first review institutional entrepreneurship literature relevant for my theme and expand on it for the purpose of my paper. In addition, I need to develop an approach for identifying and analyzing real time instances of institutional entrepreneurship, when it is not yet clear what the outcomes might be.

2 Distributed institutional entrepreneurship and sectoral changes

It is necessary to expand on the notion of institutional entrepreneurship, as discussed and studied in the literature, in order to capture the variety of actors involved in newly emerging technologies and their embedding in society, and the importance of anticipation and prospective coordination. This, then also allows me to indicate how to study such broader dynamics as real time developments.

2.1 Distribution of institutional entrepreneurship in a sector

The concept of institutional entrepreneurship builds on the concept of entrepreneurship, but foregrounds different types of change. Battilana *et al.* define institutional entrepreneurs as change agents, individuals or groups of individuals "who, whether or not they initially intended to change their institutional environment, initiate, and actively participate in the implementation of changes that diverge from existing institutions."(2009, p. 70) They add that the institutional entrepreneurs do not have to be successful in order to be classified as institutional entrepreneurs. They also argue that business entrepreneurs can act as institutional entrepreneurs, when they create new models diverging from the dominant business models, rather than follow these existing models. However, creating new business ventures is not an essential element of institutional entrepreneurship.

Studies in the literature have analyzed institutional entrepreneurship as a phenomenon in its own right, rather

than as part of dynamics at the sectoral level. Institutional entrepreneurship studies associated with technologies mainly focused on single instances of entrepreneurship (Hargadon/Douglas 2001; Garud et al. 2002; Munir/Philips 2005; Jain/George 2007). But to understand what is happening, we need to take into account a broad variety of actors in a sector that have an interest in promotion and/or control of such technologies – all of whom may act as institutional entrepreneurs.

Actors in a sector, including institutional entrepreneurs, cannot move freely with respect to emerging technologies. They need to take into account the promises, and are subject to sectoral developments. Institutional entrepreneurs are enabled and constrained by sectoral structures (Garud et al. 2007). Garud and Karnøe (2003) emphasized the heterogeneous involvement of actors in innovation processes and added structural features when they spoke of 'technology entrepreneurship as distributed and embedded agency'. Actors "become interwoven into emerging technological paths that they shape in real time." (Garud/Karnøe 2003, p. 281) Actors are also embedded more broadly within the sectors in which they operate - relatively independently from particular paths.

Thus, institutional entrepreneurship, in general and with respect to new technologies, is distributed and embedded, cf. (Lounsbury/Crumley 2007). Having recognized this, a further step can be done: institutional change can also occur through or within spaces for interaction, in the sense that the actual dynamics are shaped by such spaces, e.g. a forum to promote a new technology, rather than the activities of individual institutional entrepreneurs. They can create new spaces (arenas, fora) for interactions, or exploit opportunities of spaces that emerge. Professional associations are one convenient venue for institutional entrepreneurship (Aldrich/Fiol 1994; Greenwood et al. 2002) and their conferences may act as field-configuring events (Garud 2008; Lampel/Meyer 2008). Consortia – with their meetings and conferences – also provide a space. The Kraft-led Nanotek Consortium in the food packaging sector was such a space, in which new relations between actors could be developed, connecting relatively disparate practices and resources. The configuration of a space and the variety of actors it is composed of then become important: if more heterogeneous actors are involved, also more aspects of distributed innovation will be captured.[1] In a sense, it is the space (and how it is used by a variety of actors) which becomes the change agent.[2]

Our understanding of institutional entrepreneurship as described, links up with criticisms of earlier studies, where institutional entrepreneurs are presented as "heroes who were disembedded from their institutional environment" (Leca et al. 2008, p. 5) It also moves on, by considering the complexity of enabling and constraining factors, (see also Maguire et al. 2004; Dorado 2005; Battilana 2006; Leca et al. 2008). If we start with the basic point that actors who act as institutional entrepreneurs must possess (or acquire) sufficient resources to be productive in the particular situation,[3] it is clear that when fields evolve (e.g. because issues such as regulatory and societal acceptance

[1] Such heterogeneous spaces may actually reduce the distribution of institutional entrepreneurship in terms of locations and separate activities as they may collect a variety of actor interests.

[2] Consortia, especially when there is strong leadership, can also be conceptualized as institutional entrepreneurs themselves, cf. the notion of 'collective institutional entrepreneurship' (Wijen and Ansari, 2007).

[3] These resources can take shape in the form of legitimacy, such as formal authority or leadership, their position in social networks, the ability to gather allies, co-ordinate collective action, access to and control of scarce resources (Leca et al. 2008).

in the development and societal embedding of new technologies become foregrounded in addition to expectations on economic prospects) the distribution of resources changes and thus the opportunities for institutional entrepreneurship. Thus, I expect that the type of actors more likely to take initiatives (and be productive) as institutional entrepreneurs will change over time.

2.2 Sectoral changes associated with emerging technologies

New institutions give rise to new patterns of behavior in a sector. 'Patterns which have become taken for granted and act as stable designs for repeated activities of which deviation is difficult or costly in some manner' (Garud *et al*. 2007). These patterns can include formal regulations, but also informal codes of conduct, norms and established practices with routinized (and legitimate) ways of behavior – all 'rules of the game'. Through interactions, orchestrated by institutional entrepreneurs, new patterns, and hence, new games can emerge. In the case of new and emerging technologies, for a long time, stabilization into patterns will only be partial, as the development will be fluid and open-ended, given uncertainties about future developments.[4]

This is an important phenomenon to understand changes at the sectoral level. Changes in a sector of industry involve more than changes in competition and in exchange relations. Evolutionary economists have already discussed the importance of broadening the notion of industry structure and taking more actors and relationships into account, including non-market relationships and transactions (Nelson 1995; Malerba 2002). Relevant actors in a sector include upstream and downstream chain relations, customers, regulatory authorities, researchers and NGOs involved in this sector (Granovetter/McGuire 1998), see also (Garud/Karnøe 2003) and (Scott/Meyer 1994). Anticipation on future relations between actors and technologies are particularly relevant for emerging technologies and are by now part of how games are played in a sector.

Expectations are known to play an important role in the dynamics of new and emerging technologies (Van Lente/Rip 1998; Borup et al. 2006). The anticipation on the embedding of new technologies helps to reduce the costs of learning by trial-and-error (Deuten et al. 1997). At firm level, firms can assess their future products' conformity with existing regulatory schemes or the risk of rejection by public interest groups, and adjust product development strategies to have a better chance. At the sectoral level, uncertainties may lead to waiting games, but are also fertile grounds for institutional entrepreneurship.

Actors in a sector are aware of each other and more or less of their interdependencies. Interdependent actors can hope that other actors will act to reduce uncertainties and thus wait before they themselves invest. Waiting games are sometimes almost unavoidable. A particular kind of institutional entrepreneurship might arise, trying to break through the waiting games. This goal constitutes a collective good, so there will be reluctance to work towards it, while identification with the promise of the new technology may be a positive incentive. Other considerations might also play a role, especially a possible lack of legitimacy in the introduction of new technologies, and the need to be clear about regulations that are applicable. This gives rise to new patterns, which pre-date the actual introduction and embedding of new technologies.

Adding such anticipation-oriented, "prospective" patterns to the broaden-

[4] Further development of these 'real world games' (Scharpf 1997) for game theoretic purposes would require more work as outcomes are unclear.

ing already identified by evolutionary economists, it is clear that industrial structures are much richer than traditional industrial economics conceived them. Rather than developing this in more detail, I introduce the term 'industry structure+', as a reminder that the richness of industry structures has to be part of the analysis, especially when looking at sector-level changes.

Embedded actors, including institutional entrepreneurs, shape sector-level dynamics related to technologies, but are also shaped by them. Sectoral structures and their associated institutions with respect to technology development and their embedding in society co-evolve, and institutional entrepreneurship is an important part of the co-evolution (see also Nelson 1995; Malerba 2002). In a sense, institutional entrepreneurs are just as much a vehicle for change as independent change agents. One can even take a further conceptual step, and consider the occurrence (and nature) of institutional entrepreneurship as an indicator for emerging entanglements between technologies, industry structures and associated institutions, shaping industry structure+. Then, analyzing institutional entrepreneurship is a way to follow sectoral changes.

What actors can do as institutional entrepreneurs, depends not only on their position, but also on developments with respect to institutionalization of emerging technologies in the sector. Institutional entrepreneurship initiatives may build on such developments. Perkmann and Spicer (2007) already speculated on this aspect of distributed institutional entrepreneurship in which an 'institutional project' may be pursued by various actors. For example, one individual may pioneer a novel institution, but it is taken further, propagated by another actor. For the embedding of emerging technologies, the situation is more diffuse. Institutional entrepreneurs will still build on earlier initiatives, but the overall effect is a patchwork of prospective patterns at the sector-level rather than a specific 'institutional project'.

2.3 Real time analysis of sectoral developments and institutional entrepreneurship

For a new technology with only few concrete products, we are in an early stage of co-evolutionary processes. To understand what happens, tracing ongoing activities and emerging patterns is important. Mapping eventual outcomes is not enough. Our entrance point is to map and characterize instances of entrepreneurship-in context.

Instances of institutional entrepreneurship in relation to the uptake of nanotechnologies were identified by analyzing the positioning of actors in various texts,[5] with supporting data from observations during meetings and informal interviews. We collected data from various sources.[6] I used the following criteria to identify

[5] The creation and circulation of texts is a key strategy in institutional entrepreneurship (Munir/Philips 2005) and discursive practices are a central topic in entrepreneurship studies, (see Philips et al. 2004; Lawrence/Suddaby 2006; Leca et al. 2008).

[6] I retrieved articles containing the terms nanotechnology and packaging that appeared during 2005-2008 in a specialized online food magazine and a website focused on nanotechnologies in general: foodproductiondaily.com and nanowerk.com. I attended various conferences: MinacNed seminar Food & Nutrition (Utrecht, 2006), Packaging Summit Europe (Amsterdam, 2007); final SustainPack conference (Prague, 2008); Nanotechnology and the Law: The legal nitty-gritty for nano foods, nanocosmetics and nanomedicine (Leuven, 2008). Presentations of conferences were retrieved: Future of Nanomaterials (Birmingham, 2004); Nano4food 2006 (Atlanta, 2006); Nanotechnology in Food and Agriculture (Washington, 2006); Food Packaging Innovations: The Science, Current Research and Future Research Needs (Baltimore, 2006). Reports on and publications of identified instances of institutional entrepreneurship were consulted. In addi-

institutional entrepreneurship: actors should be (1) mobilizing resources; (2) promoting the broad diffusion of rules, norms and practices related to nano enabled food packaging outside their own organization; (3) introducing 'institutional novelty', e.g. through combining disparate institutions, and or breaking with existing institutions in the food packaging sector. In addition, I collected and analyzed background information on developments in the food packaging sector in general, and nanotechnologies in particular through reports, interviews and attending nanotechnology and packaging conferences.

The research strategy of identifying real-time instances of institutional entrepreneurship (in context) and sectoral changes as they occur has limitations: it depends on what is visible. As nanotechnologies, and for that matter also sectoral changes, are still emerging, not all instances of intentional and unintentional institutional entrepreneurship will be visible immediately, while they could already have effects. Entrepreneurs can also dissemble strategically, downplay the radical nature of promoted new technologies and institutions in order to facilitate acceptance, and only later foreground the pioneering and radical aspects of their activities (Aldrich/Fiol 1994; Hargadon/Douglas 2001). While this will occur, it is problematic for the heroes-and-winners narrative of institutional entrepreneurship (Leca et al. 2008). By focusing on interactions of actors and spaces as sites of entrepreneurship, strategic dissembling is less of a problem in data collection.

An additional element to our mapping approach builds on the anticipatory activities of actors, how these entertain possible futures, and how future developments are shaped already by present industry structure and the entrepreneurial activities of actors. Thus, controlled speculations about future developments are possible, and these can be considered further data on sector-level change. In particular, as part of an interactive scenario workshop in February 2009 to explore future developments of nanotechnologies for food packaging technologies, we developed three scenarios, using as a baseline a situation, which emphasized risk avoidance in the food packaging sector, with stakeholders waiting for each other to make a first move.[7] Each scenario was constructed by envisaging a particular type of institutional entrepreneurship trying to resolve this impasse.[8] The scenarios will be used at the end of section 4 to discuss possible further developments.

3 The domain: nanotechnologies & the food packaging sector

Packaging is an omnipresent technology. Since the early 20th century it has become part of everyday life and subject of significant industrial activity. Nowadays, a wide variety of packaging materials is used in different forms and shapes from basic material such as wood, plastics, textiles, paper and paperboard, as well as additional materials such as inks and glues (Sandgren 1996). Global food packaging sales were valued at US$ 168 billion in 2003 and were expected to have grown to US$ 228 billion in 2009 (World Packaging Organisation/Pira International 2008).

3.1 Nano enabled food packaging technologies

Nanotechnologies are expected to have "the potential to transform food packaging materials in the future". (Brody et al. 2008, p. 113) In their re-

tion findings were discussed with actors in the food packaging sector.

[7] The workshop was organized together with the Netherlands Packaging Centre, a 'branch' organization for the packaging value chain. Firms involved in food packaging, interest groups, researchers and governmental agencies, attended.

[8] For a description of the scenario methodology see (Rip/Te Kulve 2008).

view of the usage of nanotechnologies in the food sector Chaudry, Scotter et al. (2008) identified four main applications for what they called 'food contact materials' (FCMs): FCMs incorporating nanomaterials to improve packaging properties (e.g. gas barrier properties); active FCMs that use nanoparticles with, for instance, antimicrobial properties; intelligent materials, for tracking and tracing purposes or incorporating sensors to monitor food conditions; biodegradable nanocomposites. Doyle (2006) identified additional application areas for nanotechnology such as pigments, inks and adhesives.

The development of nanotechnologies for packaging is not totally new. High expectations of their application can be traced back to the 1990s. In particular, the development of nanocomposites received much attention (Manolis Sherman 2004; Lagarón et al. 2005). Nanocor, a supplier of nanoclay additives, was established "in 1995, after market research suggested that nanocomposites would be a burgeoning field" (Gardner 2002b). Nanocomposites are not only useful for packaging. As a set of enabling technologies they are expected to be useful for a wide variety of products. At the end of the 1990s Sherman noted: "From auto parts to barrier packaging, the race is on to commercialize nanoclay thermoplastic composites (Sherman 1999)."

Approximately 10 years later, a relatively small number of nanotechnology packaging materials have entered the market – although market estimates vary. Nevertheless, market studies and packaging experts expect a steep rise in introduction of nanotechnology & packaging products (Brody et al. 2008; Chaudhry et al. 2008). In a report on the application of nanotechnologies in the food sector, the European Food Safety Authority (EFSA) referred to market studies that suggest that packaging will constitute the majority of applications in the food sector and even make up 19% of nano enabled consumer products by 2015 (Barlow et al. 2009). The report argued that the underlying dynamic in the growth of food packaging materials is the expectation that these applications are not likely to have 'any significant exposure to consumers' due to the embedded or fixed nature of nanotechnology engineered materials in packaging applications. Siegrist, Stampfli et al. (2008) also argued that the application of nanotechnologies for food packaging is perceived by consumers as less problematic, than their use for food.[9]

Still, while the application of nanotechnologies may seem to entail promising novel food packaging applications, the materialization of the promise is not straightforward. One reason is that risks of new nanotechnology engineered materials that come into direct contact with food are not fully understood. Furthermore, as we will see below, there is also the challenge of linking requirements of different players in a fragmented sector, which is generally cautious with respect to new technologies.

3.2 Actors and their position with respect to new technologies in the food packaging sector

The structure of the food packaging sector is conducive to actors' reluctant uptake of emerging technologies such as nanotechnologies. What are the key players and their position in the sector? And how then does the overall situation in the food packaging sector introduce challenges for embedding emerging technologies?

When discussing food packaging, it is somewhat misleading to talk about 'the food packaging industry', as this would suggest well defined boundaries to which actors begin and end to

[9] The food sector is known to be conservative with respect to new and emerging technologies, while innovations are often related to packaging (Beckeman/Skjöldebrand 2007).

engage in food packaging production activities. The development, manufacturing and use of food packaging takes place through a number of steps, which are spread across a variety of actors. For actors involved in packaging, packaging is not likely to be their sole focus. Although material suppliers may not always see themselves as part of the packaging sector (Pira International 2003), they are still relevant, as they deliver the 'innovative power' for new packaging technologies (Prisma & Partners/MinacNed 2006). With such qualifications, the packaging sector is a chain of actors involved in the development, production and processing of packaging (cf. (Cottica 1994). Packaging is used for a number of products, food, but also for non-food items and pharmaceuticals, each of them having their own value chains. Thus, the food packaging sector is an intersection of the food and packaging chains.

Characteristic for packaging is that it is not an end product in itself, but 'a function to a product' (Nieuwesteeg 2007), such as protection of food or communication to stakeholders (e.g. of a preferred date for consumption). What actors consider valuable functions of (food) packaging is different throughout the chain, what increases problems of co-ordination along the chain. For brand owners, packaging acts as 'the silent salesman' of their product, which is reflected in their attention to packaging design, and aesthetic aspects of packaging (Alfranca et al. 2004). For retailers other functions may be (more) important. Whereas brand owners may favor novel sensors indicating food quality, such as freshness, retailers object to the incorporation of such sensors out of concern that consumers will only buy the freshest products.

A further challenge for coordinating the development and introduction of new packaging is the fragmentation of packaging knowledge, because relevant knowledge for packaging innovation is distributed across the sector. Brand owners value differentiation through unique packaging and increasingly take the lead in the development and introduction of new packaging.[10] They experience the fragmentation and cope with it by appointing packaging innovation managers, who need to develop partnerships with other actors in the sector and specify requirements for novel packaging. Upstream actors, such as material suppliers, may have more knowledge of novel technologies, while downstream actors know more of consumer demands. Signals downstream may not always reach upstream actors and vice versa.[11] This is another reason that actors may wait for each other to make the first step.

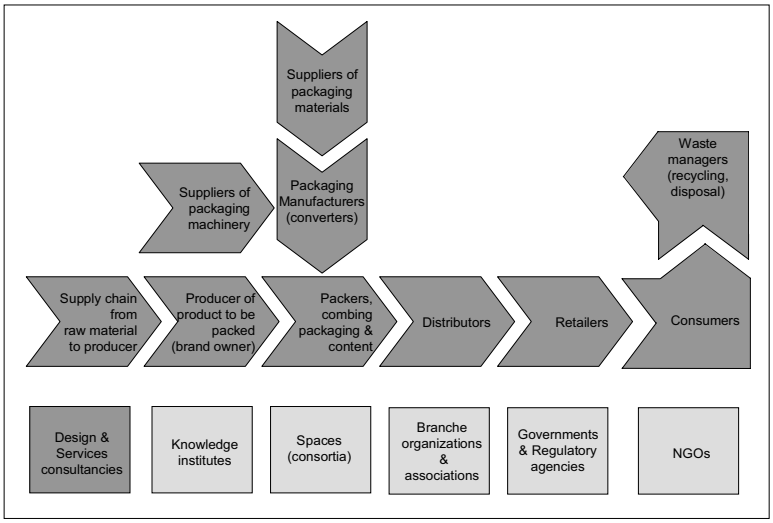
As to the distribution of firm size, large firms can be found, although not exclusively, at the beginning and end of the food packaging chain: Large packaging material suppliers, big food production companies (brand owners) who 'fill' the packages and at the other end, large retail chains, which can take initiatives and set requirements. The room to maneuver for packaging manufacturers (so called 'converters') is limited, as they often find themselves 'squeezed in between' their suppliers of materials, and their customers, such as brand owners and retailers (Pira International 2003).

Retailers act as gatekeepers for new products. In interviews with experts in the food packaging sector, retailers were identified as having a major influence in whether novel nanotechnology enabled packaging applications make it to the market, or not (Nanologue 2006). Uncertainty about retailers' position with respect to nanotechnologies will then make actors

[10] Correspondence with J. van der Heide, Product & Market Development Manager, Corus Packaging Plus, 29th May 2008.

[11] Based on observations and interviews during Packaging Summit Europe (2007) and Sustainpack (2008) conferences.

Table 1: Players in the food packaging sector



hesitant to initiate activities to introduce such packaging materials.

As I have argued in the previous section, for the development and embedding of new technologies, non-business actors, such as government regulatory agencies and civil society groups, constitute another significant set of actors, in general and definitely in the food packaging sector. Health, safety and environmental regulations are important drivers in food packaging development (Sonneveld 2000). Environmental considerations in general are prominent. Civil society groups voicing (consumer) concerns on impacts of food packaging on the environment have left their footprint on the packaging sector. Since the 1960s the sector, including governments, has taken a succession of measures to address concerns on packaging's impact on the environment. Packaging firms have established recycling programs, and product stewardship programs have been launched (Lewis 2005).

By now, sustainability is the buzz word in packaging conferences.[12] While the notion of sustainability may create openings to introduce new materials, such as nanotechnologies, uncertainties of their actual conformity to the (diffuse) notion of sustainability make actors reluctant.

Uncertainties on the distribution of costs and benefits as well as on health, environmental & safety issues make actors across the food packaging sector reluctant with respect to uptake of nanotechnologies.[13] If I add this to my earlier considerations, it is not surprising that there are waiting games, where even big players are reluctant to innovate.

Figure 1 offers an overview of the players in the food packaging sector. Additional players, such as suppliers specialized in inks, adhesives, additives and coatings; firms offering packaging machinery, design, testing and printing services; knowledge institutes and professional associations are shown as well.

[12] Observations during Packaging Summit Europe (2007).

[13] Interview with Dr. G. Yilmaz, Agrotechnology & Food Sciences Group, Wageningen University and Research Centre, 02-07-2008.

Table 1: Overview and characterization of distributed institutional entrepreneurs

Distributed Institutional Entrepreneurship	Theorization	Mobilization	Implementation
Kraft *Brand owner*	Acquire competitive advantage through novel combinations of nano and food	Financial resources; position of, and ambition of being a, leading brand owner; involving nanotechnology researchers	Creating a space for interaction through Nanotek consortium; linking up with trends in the packaging sector such as health and safety of food.
Sustainpack *Consortium*	Establish fibre based packaging as preferred packaging material through developing nano improved sustainable materials.	Acquisition of funding from interested parties and EU; fibre based packaging as recyclable and valuable sustainable materials	Creating and co-funding a space for interaction through involving nano scientists and actors throughout the packaging chain; linking up with sustainability repertoire and commercial interests.
ETC Group *NGO*	Prevent undesirable impacts through regulating introduction of nanotechnologies	ETC's expertise; position of NGOs as spokespersons for public interests and concerns	Engage with regulatory agencies and nano developers individually and with other NGOs; linking up with concerns to take into account civil society views.
MinacNed *Professional association*	Increase business for nanotechnology firms by developing novel nano & food (packaging) combinations and taking into account both business and societal considerations.	Support from the Ministry of Economic Affairs; co-operation with a management consultancy; expertise from nano & food experts	Creating a space for interaction between nano & food organizations, structured around a roadmap; linking up with trends in the sector such as health and safety, but also commercial and risk considerations.
DuPont & Environmental Defense *Material supplier / NGO*	Fill the gap in regulatory and risk assessment & management practices through developing a risk framework guide.	Expertise & legitimacy of both a large material supplier and an NGO; public consultation of a draft scheme	Broad dissemination of the framework and engagement with firms to implement the guide; linking up with nano risk assessment and management repertoire.
UK DEFRA *Government department*	Fill the gap in information to assess and manage risks through a voluntary reporting scheme	Legitimacy of regulatory authority; public consultation of a draft scheme	Dissemination of the scheme and engagement with firms; linking up with valued nano risk assessment and management repertoire
IG DHS *Professional association*	Fill the gap in regulatory practices and ensuring consumer confidence through a code of conduct	Retailers position in the chain; co-operation with risk management consultancy in drafting the code; signatures of retailers	Engagement with retailers to implement the code; linking up with expected consumer requirement of transparency of nano products.
Responsible Nanocode Working group *Consortium*	Establish more pro-active involvement of business in shaping regulatory practices and standards through a business focused code of conduct.	Involvement of actors throughout the supply chain, NGOs, scientific authorities; public consultation of a draft scheme;	Dissemination of the scheme and engagement with firms; linking up with business concerns on their (lack of) involvement in institutionalization processes.

4 The evolving patchwork of embedding nanotechnologies in the food packaging sector

This section develops a narrative account of an evolving patchwork of initiatives and their outcomes over almost a decade. To start, I give an overview of the thrust and strategies of typical initiatives (Table 1). I characterized their activities on the basis of some relevant literature showing that institutional entrepreneurship comprises three sets of activities: 'theorization', i.e. the articulation of chains of causes and effects, of framing problems and justifying innovations (Greenwood et al. 2002; Maguire et al. 2004), 'resource mobilization' and 'implementation' strategies and activities. In 'theorization', expectations play an important role in envisioning new institutions (Garud et al. 2007) and in convincing others to adopt new institutions. While actors will possess some relevant resources already, generally they need to engage in resource mobilization activities (Dorado 2005), enroll allies and create a better position for themselves. Depending on their position in the field (Maguire et al. 2004; Battilana 2006) entrepreneurs have access to limited resources, and will therefore work with existing relations in the sector. By "linking the new practices to existing organizational routines [....] aligning them with the values of diverse stakeholders" institutional entrepreneurs are known to implement new institutions (Maguire et al. 2004).

4.1 Early institutional entrepreneurship initiatives: promoting combinations of nanotechnologies and food packaging

My story begins in 2000 with the promotion of nanotechnologies for food packaging applications, visible in narratives of expectations of new products with wonderful packaging properties. This was the time of a steep rise in the interest in nanotechnology.[14] Governmental and commercial investments were increasing, and this was accompanied by a flood of publications on nanotechnologies' revolutionary potential (McCray 2005).

The first attempt to actively shape the embedding of nanotechnologies in the food sector was the establishment of an international consortium of researchers and funded by Kraft Foods Inc., while at the same time the Clinton Administration presented the National Nanotechnology Initiative to the US Congress. The consortium consisted of physicists, chemists and engineers from universities, governmental laboratories and start-up companies within the United States and Europe (Gardner 2002b; Goho 2004). As a large collaborative network researching the application of nanotechnologies in food and food packaging (Feder 2006; Berger 2008) and sponsored by one of the largest food and beverage firms in the world, the launch of the NanoteK consortium created legitimacy for the use of nanotechnologies in the food and food packaging sector.

While nano engineered packaging technologies were no new phenomena (work on nanocomposites already existed since the 1990s), Kraft, in striving to be a leader in the field, provided the field with a new impulse, also because of their high visibility in the sector. The pursuit of novel combinations by Kraft became was expressed in an interview with Kraft's vice-president of technology strategy: "Finding technologies that are not obviously applicable to the food business is both a challenge and an opportunity that could help improve our products and packaging [....] For Kraft the consortium opens new ways of thinking." (Fones 2005) The actual entrepreneurial action came from

[14] Nanotechnology is an 'umbrella term' covering a variety of technologies and research areas (Rip/Voß 2009), see also Wullweber (2008) on nanotechnology as an 'empty signifier'.

Manuel Marquez, who became director of the consortium. The consortium functioned as a space for interaction between different actors, and this was recognized by a participant: "Manuel has somehow gotten these people with many different areas of expertise, and the consortium lets us interact." (Gardner, 2002)

The promotion of the combination of nanotechnology and food packaging as a way of developing new packaging technologies was also pushed in Europe. In 2002, the research institute STFI-PACKFORSK in Sweden started to prepare the Sustainpack project (Johanssen 2008). Although not the first consortium related to nanotechnologies and packaging in Europe, Sustainpack stands out in size and scope.[15] Sustainpack claimed to be the largest packaging research program in history with a budget of 36 million euro, co-funded by the European Union. The four-year research project was launched in 2004, and was conducted by 35 partners, consisting of universities, research institutes and firms including a large UK retail chain. Sustainpack's institutional entrepreneurship is pronounced in their ambition to establish nano-engineered fibre-based packaging as the 'industry standard by 2015'.

To convince retailers, who act as gateway to consumers, was an important feature in Sustainpack's strategy. Sustainpack aimed to realize a standard "by creating a European research community focused on sustainable packaging which will pressure retailers to accept natural packaging as the way forward (Nanowerk News 2007b)." In this way, they also linked up with those retailers which were already prescribing the use of 'sustainable' or 'green' packaging technologies to their suppliers (Caul 2007; Wal-Mart 2007). Analyzing attitudes of retailers and consumers to prospective food packaging technologies was a further activity of the consortium (Østergaard 2008).

Sustainpack's entrepreneurship differs from Kraft/NanoteK's in the sense that it promotes a broad variety of products to be packed with new fibre based materials (and does so through addressing the packaging chain rather than a set of food packaging products). Whereas Kraft emphasized the food safety benefits of novel nano-engineered food packaging products, Sustainpack also emphasized broader benefits, i.e. desirable environmental aspects of their new fibre-based packaging materials. Sustainpack's positioning derives from ongoing competition between plastic-based packaging industries and paper/cardboard packaging industries, and the discourse on sustainable packaging within the sector.

By the mid 2000s there were still high expectations of nanotechnologies in general and for packaging in particular, but the overall situation in which actors contemplating nanotechnologies found themselves, was changing. The combination of nanotechnology and food packaging, and claims of their contribution to food safety and environmental impact, were now very visible in reports of industry observers such as PIRA International and Helmut Kaiser Consultancy (Moore 2004; Anonymous 2005). At the same time, debates on possible risks associated with emerging nanotechnologies surged, notably when re-insurance company Swiss Re entered the stage in 2004 (Rip/Van Amerom 2009). This overall shift from high expectations to concerns about risks of emerging nanotechnologies formed the backdrop to - and created openings for - new institutional entrepreneurship initiatives.

[15] SOLPLAS, EU funded project ran from 2002-2005.

4.2 Second round of initiatives: promoting and controlling combination of nanotechnologies and packaging

When the Sustainpack program was in its early years and Kraft/NanoteK continued its activities for some more time, a second wave of initiatives emerged. These pushed for the incorporation of broader societal and risk aspects in embedding nanotechnologies in the packaging sector.

Interestingly, in this second round actors outside the food packaging sector were important. Actually, given the enabling character of nanotechnologies actors not involved in the food packaging sector might have been expected to come in early, spreading the good message, and incumbents to follow. However, as relative outsiders they would not be able to become (and be readily accepted as) institutional entrepreneurs. It requires a certain initial level of (perceived) legitimacy and/or reference to earlier initiatives, for actors outside the sector to appear as institutional entrepreneurs.

Actors in this second round turned out to comment on possible developments of nanomaterials, rather than only on the specific combination of nanomaterials for food packaging applications. Here, it is the open-ended character of nanomaterials and nanotechnology as an umbrella term, which shape the emergence of institutional entrepreneurship activities within the food packaging sector. These entrepreneurs have a stronger technology-push or upstream focus than Kraft/NanoteK and Sustainpack (who already have a relatively strong technology push).

One interesting institutional entrepreneurship initiative from outside the packaging sector was pushed by the ETC Group. The ETC Group is an expert organization dedicated to sustainability issues and marginalized groups (ETC Group 2003, p. 80). The ETC group picked up on the steep rise in interest in nanotechnologies, including Kraft's NanoteK activities, during a time in which "civil society and governments [still] focus on genetic modification" (ETC Group 2003, p. 5) In 2004 the ETC Group published a report in which they assessed possible risks of the application of nanotechnologies for food and agriculture, including packaging (ETC Group 2004). They articulated concerns about the transfer of responsibility for food quality to consumers through the application of smart packaging (ETC Group 2004; Thomas 2006). The ETC Group proposed the development of new regulatory practices, up to a moratorium on nanotechnologies until these have proven to be safe.

While ETC Group's advocacy of new regulatory practices is broader than just food packaging, they played a relevant role as members of the ETC Group were involved in meetings on nano-engineered food and food packaging (Thomas 2006; Halliday 2007). Next to establishing cognitive legitimacy of new regulatory practices, they also aimed to push for new practices, such as through filing legal petitions. The ETC Group participated with Friends of the Earth and the International Center for Technology Assessment in ad hoc coalitions calling for regulation of nanotechnologies (Thomas 2006; Nanowerk News 2007a). Their entrepreneurship was mainly directed towards creating new framework conditions for further development.

Actors in the food packaging sector now found themselves in a different situation, as promotion of nanotechnologies became subject of critique by NGOs and other actors such as reinsurers, focusing on potential risk. New initiatives to promote development of new packaging technologies with help of nanotechnologies needed to take the strong debate on risks into account to maintain legitimacy.

This is visible in the initiative of a Dutch micro- & nanotechnology 'branch' association called MinacNed. MinacNed's primary mission is to stimulate economic activities based on micro- and nanotechnologies in the Netherlands, by developing and supporting networks, collaborations and identifying opportunities, using roadmapping as a tool (MinacNed 2007). In December 2005 the association initiated the development of a Food & Nutrition roadmap, including the theme packaging. It articulated expectations of benefits of nanotechnologies but also discussed potential health, environmental and safety risks.

MinacNed's initiative can be seen as building upon the first round of initiatives. The eventual roadmap document referred to an interview with a senior manager of Kraft in a newsletter, who remarked: "We're sponsoring research at these institutions to help us imagine the future of the food industry in the years ahead [...] We believe eventually nanotechnology may be a significant method by which we can deliver what consumers want." (Prisma & Partners/MinacNed 2006, p. 27) The document also referred to the importance of sustainable packaging materials and argued that plastic packaging can be replaced by bioplastics and cardboard packaging - reflecting the ambitions of the Sustainpack project.[16]

The roadmap initiative did not result in the formation of 'innovative clusters' desired by MinacNed.[17] During a seminar in which the roadmap was presented, participants commented that it was very difficult to bring actors in the food industry together and that they would be hesitant with respect to nanotechnologies. Potential participants were reluctant to take up nanotechnology projects. For them, both the feasibility and manufacturability of these technologies was too uncertain.[18] Actors waited for the availability of (large volumes of) nanotechnology-engineered materials before they were prepared to invest in the development and marketing of nano-engineered products.

Kraft's move to the background as an institutional entrepreneur and thereby putting a partial end to the first round of initiatives, is a further indicator of a changing overall situation. Kraft distanced itself from the NanoteK consortium by moving it to a subsidiary of Altria[19] and the consortium was renamed, possibly out of concern for controversies about risks of nanotechnologies (Feder 2006). Researchers from Kraft attending conferences emphasized that Kraft was only exploring possibilities of nanotechnology, and would take great care when deciding to introduce new nano products (Couttenye/Arora 2006). The overall climate in the food sector had become ambivalent about nanotechnology. This atmosphere is well captured in a phrase from a reporter attending a nanotechnology oriented food & health conference (which I quoted already in the opening paragraph of this paper): "The food industry is hooked on nano-tech's promises, but it is also very nervous" (Renton 2006).

Possible risks of nanotechnology-engineered food packaging were now firmly on the agenda. Another wait-

[16] The Sustainpack program emphasized the importance of risk assessment too, but except for some mapping, no explicit risk research activities were carried out in addition to the technology development activities.

[17] There was an attempt to form such a cluster in the Netherlands, not initiated by MinacNed. Called Nano4Vitality, and aiming at research and pre-competitive development of new nano enabled technologies, it was co-funded by two Dutch provinces. It referred to the roadmap in their call for tenders (Nano4Vitality 2007).

[18] Interview by the author, 19th March 2007.

[19] The Altria Group, previously named Philip Morris Companies, was Kraft's parent company from 1988-2007, see <www.altria.com>.

ing game emerged, now between firms and regulatory agencies. While regulatory schemes were in place, the problem was concrete assessments whether nanomaterials, including food packaging, would pose unacceptable risks. This was not at all straightforward. According to the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks, but also to the European Food Safety Authority (risk assessment body food and feed safety) and US Food and Drug Administration (regulatory agency), more knowledge was required to develop risk assessment methodologies to evaluate potential risks of nanotechnologies (Scientific Committee on Emerging and Newly Identified Health Risks 2006; Food and Drug Administration 2007; EFSA 2008). Firms in the food packaging sector wanted to be assured about the safety of their nano-engineered products before market introduction and preferred clarity on the implementation of regulatory regimes.[20] On the one hand, regulating authorities awaited products so that they could test their compliance with safety regulations. On the other hand, firms in the food sector had become increasingly careful in mentioning their nanotechnology-related activities since mid 2000s, see Berger (2008). Thus, firms and governmental actors were waiting for each other to make the first step. This waiting game formed the backdrop, and created incentives for new institutional entrepreneurship initiatives, to break through this waiting game.

[20] In 2007, the Grocery Manufacturers Association and the Woodrow Wilson International Center for Scholars in the US took up this theme on a collective level and initiated a study to assess regulatory aspects and issues involved in nanotechnology-engineered food packaging materials (Taylor 2008).

4.3 Third round of initiatives: resolving the impasse

In the second half of 2000s a new round of institutional entrepreneurship activities occurred, partly overlapping with the second round. Now, initiatives did not mainly focus on legitimating the combination of nanotechnologies and packaging, but on how nanotechnologies in general should be developed and introduced on the market. While generic in nature, the impact of these initiatives on the food packaging sector lies in the fact that actors involved in these instances of institutional entrepreneurship were also embedded in the food packaging sector. The effect of the new round of initiatives included the resolution of the impasse between actors in the food packaging sector, although these initiatives often did not position themselves explicitly with respect to the food packaging sector.

All these initiatives had in common that they articulated general rules of behavior and ways of dealing with uncertainties about benefits and potential risks of nanotechnologies. Often they were framed as bridging a gap, proposing temporary measures until more certainty on risks and implementation of regulatory schemes existed. A common thread in these initiatives is that they promoted interactions between actors at different positions in the food packaging sector and/or promoted taking into account broader societal aspects.

One such initiative explicitly aiming to address the general impasse is the institutional entrepreneurship activity of DuPont together with Environmental Defense. Already in 2005, DuPont and Environmental Defense published an article, which discussed the need for more research and regulatory practices related to potential risks of nanotechnologies (Krupp/Holliday 2007). They compared nanotechnologies with earlier emerging technologies, which had unintended effects,

such as the impact of the release of CFCs on the ozone layer. In their advocacy piece they argued that early assessment of possible risks and enactment of safety standards can "reap the benefits while minimizing the risks." DuPont and Environmental Defense called for 'a collaborative effort' between firms, academia, governments and public interest groups that "could set interim standards for nanotechnology around the world while regulations are under development." Later, their 'collaborative effort' would meet resistance by NGOs, exactly because of the 'interim' character of their approach (Civil Society-Labor Coalition 2007).

In 2007 they launched their Risk Framework 'offering guidance on risk evaluation and management, and communication with stakeholders' (Environmental Defense-Dupont Nano Partnership 2007, 14). The alliance did not position itself with respect to the food packaging sector due to the generic rather than specific nature of their risk framework, but one of the cases they used to 'test' the framework was a new titanium dioxide-based product to protect plastics from sunlight causing changes in color of plastic packaging (ElAmin 2007). They definitely had impact on the food packaging sector, also because the partnership believed that the framework could support a model for government policy on nanotechnology safety.

Governmental authorities also became entrepreneurial by trying to resolve the impasse through voluntary measures rather than top-down policy making. The Department for Environment, Food and Rural Affairs (DEFRA) in the UK was pro-active concerning the uncertainties associated with health and environmental safety issues of nanomaterials (including packaging), through launching a voluntary reporting scheme.[21]

The occasion was provided by the UK Food Standards Agency (FSA) 2006 Report, which argued that although there were no major gaps in regulations, there nevertheless existed gaps with respect to risk assessment and information of manufactured nanotechnology products (Food Standards Agency 2006). Following the FSA, DEFRA launched a voluntary scheme in September 2006, a form of 'soft law' (Dorbeck-Jung 2007), to provide the UK government with information on properties and characteristics of new 'free' nano-engineered materials. In particularly it was expected to generate information to test existing regulatory measures. In this way, UK DEFRA aimed to bridge the gap between firms and regulators, with respect to uncertainties related to compliance with regulations. Responses to the scheme were relatively low and UK DEFRA had to put effort in getting responses. In March 2008 the UK Minister for Environment concluded that responses were disappointing and urged firms and researchers to commit to the scheme. The UK Minister hinted that more compulsory measures would be necessary when there was too little commitment to the scheme (Woolas 2008).[22]

A simultaneous approach to cope with uncertainties associated with risks of nanotechnology and implementation of regulatory frameworks was the development and promotion of voluntary codes of conduct.[23] One distributed institutional entrepreneurship initiative also relevant for the food packaging sector was set up by the UK Royal Society, Insight Investment and the Nanotechnology Indus-

[21] The US's Environmental Protection Agency (EPA) launched its own voluntary 'stewardship program' in 2008 (Environmental Protection Agency 2008).

[22] By July 2008 the EPA schema had also received limited responses. Interestingly, some branch organizations recognizing the importance of the scheme for the credibility of the nanotechnology sector, tried to push their members to participate, see (Kearnes/Rip 2009).

[23] See also (Bowman/Hodge 2008).

tries Association. In the preparation, health, environmental and safety issues, regulation and voluntary reporting schemes, but also views put forward by NGOs such as the ETC group were topics for discussion (Sutcliffe/Hodgson 2006). One of the identified gaps was that businesses were too little involved in risk assessment developments (Royal Society et al. 2006). A working party was set up, which included actors from the food packaging sector: BASF (material supplier), Tesco (retailer) and Unilever (brand owner). The working party developed a code of conduct to bridge a 'transitional period', before there would be more certainty on implementation of regulatory frameworks. The code promoted a pro-active approach from companies towards assessing and mitigating possible risks of nanotechnologies, including the involvement of stakeholders (Responsible NanoCode 2008).

In 2008, the Swiss retailers organization IG DHS launched, in co-operation with a risk management consultancy, a code of conduct related to the application of nanotechnologies in food and food packaging (Jones 2008). One reason to launch such an initiative was that the Swiss federal government was working on a risk assessment and management framework, but in the meantime relied upon the responsible behavior of producers. They also referred to NGO viewpoints, such as articulated by the ETC Group and Friends of the Earth (Miller/Senjen 2008) regarding mandatory labeling of nano engineered products. Interestingly, IG DHS was explicitly referring to consumers' concerns. The association argued that Swiss consumers valued product information and that local retailers were in favor of labeling of nanoproducts. As retailers could not achieve this by themselves and needed co-operation across the food and packaging chains, a code of conduct could function as a tool to achieve this. The code obliged retailers to "require producers and suppliers to provide all the information necessary for assessing the safety of a product." (IG DHS 2008) IG-DHS was weaving another piece in the patchwork of emerging institutions.

While new initiatives emerged, other activities ended. In 2008, Sustainpack, one of the early entrepreneurial initiatives ended its activities. While the coordinator emphasized at the final conference that the heterogeneous consortium had proved to be able to successfully connect different aspects of packaging and could function as a platform for further developments, there was no clear prospect of continuing institutional entrepreneurship when the project was finished.[24]

4.4 Exploring future developments in the food packaging sector

The three waves of institutional entrepreneurship show how dedicated actors emerged, responding to changing situations in the food packaging sector and beyond. However, they had no apparent lasting effects yet in terms of innovation. By the end of 2008, relatively little was still happening regarding (known) product introductions engineered by nanotechnologies (Chaudhry et al. 2008). On the other hand, there are indicators for the uptake of proposed generic rules and practices. By the end of 2008 the EU confederation of food and drink industries (CIAA) was considering to adopt a code of conduct inspired by the Responsible Nanocode.[25]

What could be happening now? I suggest that there might be a fourth wave of initiatives defining themselves as attempts to break through the impasses, which are widely recognized. The promotion of generic rules and prac-

[24] Observations by the author during Sustainpack's final conference in May 2008.

[25] Observations by the author during Nanotechnology & the law conference in Leuven (2008).

tices about responsible development of nanotechnologies further paved the way for new institutional entrepreneurship. To explore this suggestion I refer to the scenarios we constructed for a stakeholder workshop about nanotechnology and food packaging.

The three scenarios had different starting points for institutional entrepreneurship: a group of technology developers revamping sustainability promises of nanotechnology engineered packaging materials; some pro-active regulators creating a financial safety net for liability claims; and a broad stakeholder platform exploring technological options and stakeholder requirements. Each scenario then explored actions and reactions, and shifts and changes over time. This is not the place to go into details. Suffice to say that none of the scenarios had an across the board uptake and acceptance of nanotechnology engineered products in food packaging as its outcome. Each initiative had limitations (up to blind spots), which created constraints on their uptake and the eventual outcome. They added a patch to the patchwork. The stakeholder platform achieved the most, which indicates the importance of such broad spaces for interaction, but in the scenario it eventually collapsed because the broad variety of participants led to internal struggles.

During the workshop, participants recognized the importance of co-ordination and the relevance of a broad stakeholder platform, and were interested in institutional entrepreneurship initiatives to create a breakthrough. Still, waiting games appeared to be on their minds. They were cautious about co-operation with other players and taking an initiative. Participants waited for their upstream or downstream partners to come up with concrete proposals (and materials). Their arguments referred to the importance of short term (3 years) return on investment, and pointed out uncertainties about actual performance (added value) of new packaging materials and whether these would fit existing production equipment. Anticipation on societal embedding was considered important, so important that one of the participants was willing to stop a nanotechnology food packaging product development trajectory, if there were concerns about lacking sustainability.

While the fourth wave of institutional entrepreneurs, possibly leading to sector-level changes, might draw on actors embedded in the food packaging sector, the latter appear to be constrained by the present structures and the attendant waiting games. Other actors, embedded in multiple sectors (like materials suppliers) and/or with an interest or stake in the embedding of nanotechnologies (as in the alliances between nanotechnology promoters and government funding agencies), will be more prepared, and more able, to start entrepreneurship initiatives. Authorities can introduce new patterns, such as standards or testing procedures to test compliance with regulatory proposals. This fourth wave and activities of authorities would further reduce uncertainties on societal embedding of nanotechnologies in the food packaging sector.

5 Conclusions

Through the lens of tracing institutional entrepreneurs and their activities, I was able to show a pattern of development in the food packaging sector where rules and practices emerged before the envisaged nano-enabled technologies entered the market. Anticipation on eventual embedding of these technologies drove the institutional entrepreneurs. Over time, further aspects of eventual embedding became important, and other kinds of institutional entrepreneurs became involved, including NGOs and regulatory agencies introducing voluntary schemes. The net effect is the emergence of a patchwork of rules

and practices which extend further than industry structures as traditionally conceived. It is this patchwork which will act as a 'soft' framing condition for further developments in the uptake and embedding of nanotechnologies in the food packaging sector.

Considering how this patchwork emerged, there are, of course, factors and circumstances specific to the food packaging sector. But there are also general dynamics related to the uncertainties inherent to emerging technologies. This is clear in the waves of institutional entrepreneurship that were found. In the beginning, around 2000, the uncertainty about the eventual performance of nanotechnologies was addressed by actors promoting the legitimacy of the combination of nanotechnologies and food packaging technologies. This first 'wave' of dedicated initiatives was followed by a second wave in which other actors pushed for the incorporation of broader societal aspects and risks in embedding nanotechnologies in the packaging sector. Initial enthusiasm for nanotechnologies shifted to caution. Uncertainties related to risk assessment created a further waiting game between firms and regulatory authorities, in a sector which was already prone to the emergence of waiting games. Then, institutional entrepreneurship initiatives emerged that tried to break through these waiting games and overcome reluctance. Many of the initiatives, while focused on risk issues, maintained an appreciation of the potential benefits of nanotechnologies, but that did not lead to dedicated entrepreneurship promoting nanotechnology engineered materials. This implies that the whole notion of 'responsible development' of nanotechnology became important and that it became illegitimate to go for just promotional institutional entrepreneurship. Still, it might be possible that such institutional entrepreneurship occurs. One of the scenarios speculating on a next wave of activities did include such type of activities, but ran aground on waiting games in the food packaging sector. A next wave will likely be initiated by actors with broader interests than just food packaging, such as material suppliers, or coalitions of actors across the innovation and product value chain.

Thus, the conclusion about how a patchwork of anticipation-oriented patterns is emerging at the sector-level, before these technologies enter the market, extends beyond the food packaging sector. For all new and emerging technologies uncertainties have to be reduced to overcome waiting games. Such reductions will start with the promises of emerging technologies, and then address possible concerns. Actually, waiting games are also a reduction of uncertainties, by doing nothing (which will not appeal to technology promoters).

The nature of the reduction of uncertainties between supply and demand, and with respect to regulation up to broader societal acceptance will depend on the composition of the value chain and articulation of regulations (formal and informal) at the level of a sector. In the case of food packaging, intersecting value chains introduced specific complexities and uncertainties (such as the world of food, sensitive to public acceptance). In other sectors, such as micro/nano-electronics, public acceptance is not a prominent issue. For new nano-enabled materials and surfaces, there appears to be broad public acceptance, but some consideration of risk, with reference to nano-particles. Particularly important, given the enabling character of nanotechnologies, is that intersecting value chains will occur more often, as with nano-engineered delivery systems for pharmaceuticals (drugs) and nutriceuticals (food). Preliminary data of my ongoing research in the drug delivery sector show a first wave of institutional entrepreneurship to promote and legitimize a link

between the promise and possible use, but no second wave (yet).

Thus, the basic dynamics involved in developing and introducing new and emerging technologies in sectors of industry are carried by attempts at reduction of uncertainties, embedded in, and contributing to, sector-level development. This insight is not only a contribution to our understanding of new and emerging technologies. It also adds to the analysis of industrial change by including the dynamics of emerging technologies and how these incite anticipatory action of institutional entrepreneurs which, in addition to their immediate effects on product development, introduce further legitimation requirements and broaden industry structures.

In general, analyses of industrial change processes need to take into account emerging anticipatory patterns and distributed institutional entrepreneurship. Conversely, studies of institutional entrepreneurship need to take into account the distributed and embedded character of institutional entrepreneurship and emerging industry structures.

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Chapter 4

Building and furbishing an emerging world: Institutional entrepreneurs around nanotechnology in the drug delivery sector

4.1 Introduction

The structure of the drug delivery sector will shape openings for the emergence and activities of institutional entrepreneurs, however in a different way than in the case of food packaging. Taking into account the nature of the sector, one might expect that the uptake of nanotechnologies for drug delivery would be relatively easy compared to food packaging. Medical technologies are generally received positively compared to agrifood technologies; see debates on red/green biotechnologies (Bauer 2005). Still, while research in drug delivery technologies involving nano-sized carriers has been underway for decades, albeit not necessarily with the label 'nano', and some have found their way into the clinic (Allen and Cullis 2004), the development and introduction of the combination of nanotechnologies and drug delivery technologies is not yet taken for granted. Therefore the drug delivery sector is also fertile ground for institutional entrepreneurs who want to support introduction of nanotechnologies by proposing rules and practices facilitating embedding. Dynamics in the emergence of institutional entrepreneurship initiatives will be different, however, than in the food packaging sector. Concerns regarding public acceptance will likely be less of a topic. Which dynamics shape the emergence and unfolding of institutional entrepreneurship initiatives in the drug delivery sector – if any?

The case study in this chapter is a follow-on case study. That is, while taking into account sectoral differences, I take findings in my food packaging study as expectations for what I will find in the drug delivery sector about the evolution of institutional entrepreneurship and their contribution to shaping embedding processes at the sectoral level. As in the food packaging sector, waves of institutional entrepreneurs can be expected in the drug delivery sector, because of similarities in the structure of the situation. Also, the drug delivery sector consists of intersecting product-value chains, increasing the variety of actor interests and dependencies, and is faced with promises and uncertainties of emerging nanotechnologies. This structure is conducive to actors' reluctant uptake of nanotechnologies and to the emergence of waiting games. Given similarities in the structure of the situation, one might expect to find a sequence of initiatives which build on each other and reduce uncertainties (including attempts to overcome waiting games).

Clearly, there are differences between the sectors. One striking difference is the well structured regulation of development and market introduction processes. [1] Strong regulation may contribute to drug delivery actors being less prone to uncertainties (and related debates) on health, environmental and safety risks, and public acceptability. A further difference is the central role played by large pharmaceutical companies. Large pharmaceutical companies play a key role in both development and introduction of emerging pharmaceutical technologies in general, whereas this is more distributed across actors within the food packaging sector. While implications for the dynamics in the emergence of institutional entrepreneurs are not immediately clear, the type of interactions that emerge will be different. No waves of entrepreneurs may appear yet, also because drug delivery developments are still very much research-oriented. Thus, there is a chance that I need to broaden my research question to the emergence of anticipation-oriented patterns – if any – relevant for, but not directly focused on, societal embedding of drug delivery technologies.

In any case, promises of nanotechnology enabled drug delivery technologies will open up spaces for interaction, which can be exploited or sought after by institutional entrepreneurs. However, such spaces may not easily stabilize and develop into an emerging world, embedded in the drug delivery sector, in which actors interact about nanotechnologies, cf. emerging world of membrane technologies (Van Lente and Rip 1998). Institutional entrepreneurs working towards the creation of an emerging world then need to mobilize resources other than promises. Against the backdrop of a landscape in which anticipation of introduction of technologies is considered important, initiatives might emerge, and as will be shown, indeed do, which 'refurbish' an emerging world with anticipation-oriented rules and practices. Such a refurbishing with anticipation-oriented patterns is significant as it indicates a move to and pressure on, consideration of future societal embedding during early stages of technology development.

To analyze dynamics in the emergence of institutional entrepreneurship initiatives in the drug delivery sector I will start by examining how background

[1] This is not to say that food packaging is not regulated; see Heckman (2005) for an overview. However, regulation of pharmaceuticals is more elaborate, because of its mandatory market authorization procedures with different pre-clinical and clinical evaluation phases.

developments in the drug delivery sector provide openings for uptake of nanotechnologies. The discussion of the drug delivery landscape will provide the backdrop for my analysis of the evolution of institutional entrepreneurship in section 4.3.

4.2 The domain: nanotechnologies & the drug delivery sector

I will start by examining the composition and salient characteristics of the sector. Then I will discuss how promises of nanotechnologies create openings for institutional entrepreneurship in the drug delivery sector.

4.2.1 Drug delivery sector

A drug delivery system is a formulation or device "that delivers therapeutic agent(s) to desired body location(s) and/or provides timely release of therapeutic agent(s). The system, on its own, is not a therapy, but improves the efficacy and/or safety of the therapeutic agent(s) that it carries."[2] [3] Delivery devices can not only be used as carriers for drugs but can also be applied to diagnostic (medical imaging) purposes and as carriers for nutraceuticals (food).

The drug delivery sector, then, is an intersection of two product value chains involving the 'primary manufacturing' of the active pharmaceutical ingredient (API) and the 'secondary manufacturing', i.e. the formulation (including drug delivery systems) and packaging. Both stages of manufacturing can occur within one (integrated) firm or be outsourced to contractors (Shah 2004).

[2] From www.drugdel.com/glossbot.htm

[3] During formulation the Active Pharmaceutical Ingredient (API) is combined with 'excipients' to prepare the drug's final form for delivery to a patient such as a tablet or fluid. Excipients include "binders to form a tablet, aggregates to keep the tablet together, disintegrants to aid dissolution once the drug is administered, and coloring or flavoring agents. Excipients help keep the drug in the desired formulation until administration, aid in delivering the drug, control the release rate of the drug, or make the product more appealing in some way to the patient." (Barich et al., 2005, p. 64).

Dynamics in the sector come from both chains and their intersection, but also from the environment in which they are embedded. Complexities of the development and introduction of drug delivery systems derive from the link with the domain of health care and its dynamics, such as those related to reimbursement and pressures on health care budgets. For embedding new drug delivery systems, business and institutional entrepreneurs not only need to deal with business dynamics in the world of pharma, but also with broader developments in health care. In addition to firms, there are knowledge institutes, clinicians, patients, governmental actors and health insurers. Figure 1 offers an overview of actors in the drug delivery sector.

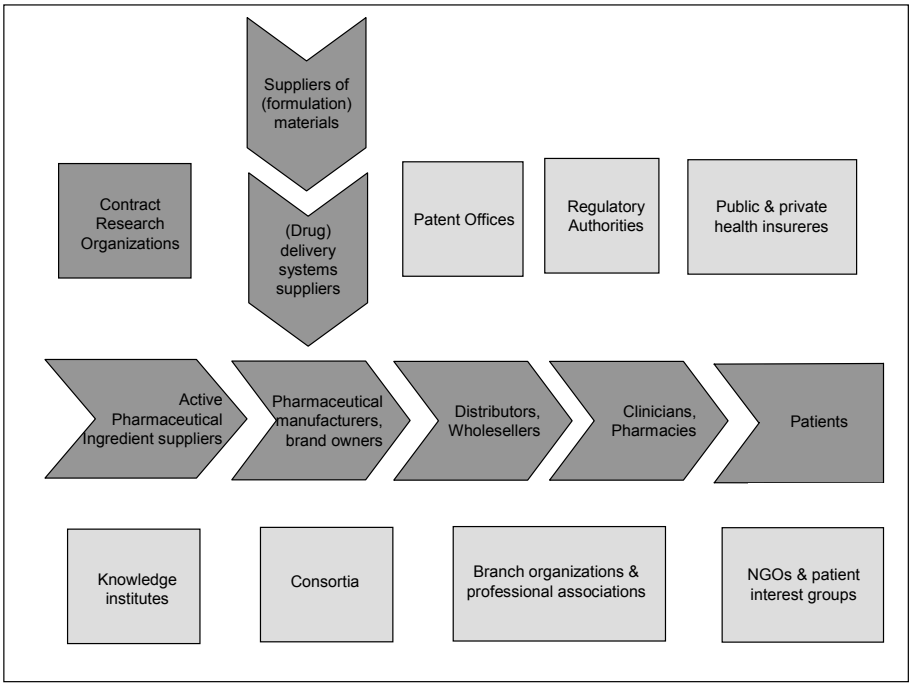

Figure 1: Players in the drug delivery sector

Institutional entrepreneurs promoting new patterns linked to nanotechnology enabled drug delivery systems will be enabled and constrained by dynamics in the sector. An important set of dynamics derives from the positioning of firms in the sector. As to size distribution, large and small firms from both chains are involved in development and production of drug delivery systems. These firms can be 'pure' drug delivery firms or diversified (pharmaceutical) firms

(Gopalakrishnan and Bierly 2006). Furthermore, large chemical companies are involved in the production of pharmaceutical technologies. For the overall impact on development and introduction of combinations of drugs - drug delivery systems - diseases, big pharma plays a key role.[4] They are central actors, not just due to their position in the intersection of chains, but also due to their well-developed marketing and distribution channels and as potential investors for costly pharmaceutical development trajectories.

While the development and production of drug delivery systems has become a recognized part of the pharmaceutical world, its integration into pharmaceutical therapies is not without challenges. Drug delivery companies have found their way to pharmaceutical companies by supplying delivery systems or by acquisition. Alliances between these companies have grown and in general activities of drug delivery companies have increased in terms of production volume and diversification issues since the foundation of the first drug delivery firm in 1960s (De Leeuw et al. 2003; Pillai et al. 2001; Rosen and Abribat 2005). However, co-operation between drug delivery firms and large pharmaceutical firms is not straightforward.

According to Breimer (1999), the "big pharmaceutical industry has not (yet) recognized drug delivery as an essential component for future innovation and growth." Large pharmaceutical companies traditionally focused on developing New Chemical Entities (NCEs) rather than novel formulations (Breimer 1999) and this continues till present day.[5] According to industry participants, collaboration with respect to drug delivery, including nano enhanced drug delivery technologies, ideally would be created as early as possible in drug discovery and drug development processes (Couvreur and Vauthier 2006; Keller 2007). The creation of such interactions are, however, notably difficult as they face issues of protection of intellectual property rights and company secrets (Couvreur and Vauthier 2006).[6] Therefore, promoters of nanotechnology enabled drug delivery technologies may, independent of

[4] According to Farokhzad and Langer (2009) the clinical 'success' of nano drug delivery depends on the right combination of drug delivery system / drug / disease.
[5] Sources: Interview with Professor Storm, Utrecht University, 25-05-2009; Interview with Professor Couvreur, Université de Paris-Sud, 17-07-2009; Interview with Mr. Moore, Institute of Nanotechnology, 02-06-2009.
[6] Source: Interview with Storm, ibid

specific nanotechnology features, face difficulties in involving big pharmaceutical companies.

A salient phenomenon in the sector, which further contributes to challenges of integrating novel drug delivery technologies, is that large pharmaceutical companies adopt a strategy in which they wait for technologies that have proven to be successful. This is a general phenomenon and not specific for nanotechnology enabled drug delivery systems (Wagner et al. 2006).[7] This strategy can quickly lead to waiting games in which firms wait for each other to make the first step. "As smaller companies and start-ups rely on partnering with big pharma that provide funding for the clinical trials" (Wagner et al. 2006, p. 36) waiting games between small firms and big pharma may be unavoidable. Big pharma is not the only source of funding, but the involvement of big pharma also brings in knowledge and experience with respect to development and regulatory processes; see Eaton (2007).

Regulation processes of new drugs, including drug delivery systems, constitute another significant set of dynamics in the sector which may induce and or reinforce waiting strategies and waiting games. Regulation is part and parcel of embedding of new pharmaceutical technologies. Approval of regulatory authorities is mandatory before products can enter the market. The registration procedure is a well-articulated process during which new pharmaceutical technologies have to pass through pre-clinical and clinical (I, II, and III) phases. This also puts constraints on what can and what cannot be changed in drug formulations (Washington 2007). Given the trend toward higher levels of safety and effectivity assessment it is clear that is important to understand which standards and methodologies are required for new pharmaceutical technologies, including nano enabled drug delivery technologies.[8] Uncertainties regarding standards and methodologies for assessments of new nano enabled technologies may then lead to waiting games between pharmaceutical and drug delivery companies on the one hand, and regulatory authorities on the other hand, cf. my food packaging study.[9]

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[7] Sources: Interview with Storm, ibid.; Interview with Professor Crommelin, TI Pharma, 04-06-2009.

[8] Source: interview with dr. Bertens, Nefarma, 06-07-2009

[9] This 'waiting game' is only partial, as authorities also have other means to explore what could be future technologies including literature review and consulting companies. In turn, pharmaceutical companies can consult authorities regarding regulatory issues of

In addition to registration procedures, intellectual property rights (IPR) and reimbursement practices play an important role in development and embedding processes of new pharmaceutical technologies. IPR is critical in the world of pharma as it protects the investments of firms during a particular time in which firms need to recoup their investment costs in order to make a profit. When patents expire, the competition is open for other firms to produce the now 'generic drug'. Pharmaceutical companies presently face significant challenges in this area. With many drugs nearing their patent expiration date, an overall decline in the introduction of new drugs and strong competition from producers of generics, new business models may be attractive; see also Tralau-Stewart et al. (2009).

Finally, reimbursement issues play an important role in embedding new healthcare technologies. Reimbursement practices differ between nations and nations may be more or less attractive for new firms to launch new products (Wagner et al. 2006).[10] According to Wagner et al. (2006) health economic assessments are expected to play an increasing role in reimbursement decisions by statutory and private health insurers. New pharmaceutical technologies not only need to be safe and effective, but also need to be superior in terms of costs and therapeutic value over other therapies. Given the overall pressure on containing health care costs, including pharmaceutical therapies, uncertainties about improved performance of new pharmaceutical technologies can be expected to contribute to reluctance in investments into such technologies.

One further general development in the drug delivery sector is important - the move towards 'translational research'. While in the early 2000s the term was little used, this had changed by 2004 (Atkinson-Grosjean 2006, p. 171). The dedicated activities by the US National Institutes of Health (NIH), in particular their 2003 roadmap activities and the development of translational research centers, are considered to have launched 'translational research'(Atkinson-Grosjean 2006; Butler 2008). Translational research refers to a set of practices which is considered to be bi-directional and often labeled as 'bench to bedside' research (O'Connell and Roblin 2006; Wainwright et al. 2006; Enna and

emerging technologies. This is already happening on an ad hoc basis. The European Medicines Agency hosts 'briefing meetings' with companies and academic centres on specific technologies.

[10] Source: interview Bertens, ibid.

Williams 2009). The bi-directional element is visible in O'Connell and Roblin's quotation of the American Physiological Society's definition of translational research as "the transfer of knowledge gained from basic research to new and improved methods of preventing, diagnosing, or treating disease, as well as the transfer of clinical insights into hypotheses that can be tested and validated in the basic research laboratory." (p. 834)

Different meanings are attached to the term 'translational research' – an umbrella term. As an umbrella term it creates openings for actors to do different things. Wainwright et al. (2006) suggested treating the term as "discourse or rhetoric rather than as simply a normative attribute or fact of contemporary medical knowledge-production." (2006, p. 2053)

The emergence of 'translational research' as an umbrella term can be understood as an attempt to align a range of activities from 'fundamental' research to pharmaceutical and clinical development of new drugs. According to Butler (2008) a divide has developed between basic and clinical research during the past 30 years. Whereas the pharmaceutical industry used to bridge this divide, it is increasingly less so the case according to Butler. This divide is linked to the already discussed gaps between discovery and development activities between firms, but also between scientists of firms and academic centers (Editorial 2006).[11] Translational research is meant to bridge this gap (Butler 2008) and contribute to "improve[d] drug candidate survival and overall productivity" (O'Connell and Roblin 2006, p.834) The emergence of the notion of translational research is an interesting background development as it involves anticipation of future steps in drug development, preparing for introduction in society.

4.2.2 Nanotechnologies & the drug delivery sector

Different drug delivery systems are characterized in terms of controlled release of the active material, how they are targeted to diseased tissue and how they are administered (Barich et al. 2005). The application of nanotechnologies

[11] The pharmaceutical world does not have a strong history of academia and industry working together. Source: interview with Professor Eaton, UCB/University of Nottingham, 16-12-2009. See also Eaton and Weltring (2010).

which has attracted the most attention is the promise of releasing drugs at a particular target. While there are other targeting approaches, nanotechnology engineered delivery systems are considered to be particularly promising.[12] In a conventional delivery system, the drug is distributed systemically across the body, but this may not always be sufficiently (therapeutically) effective or have adverse toxic effects. For targeted drug delivery there are two general approaches. Drugs can be released near the desired location in the body or drugs can be designed for active or passive targeting purposes. In both cases the application of nanotechnologies (devices and molecules) promises to contribute to targeted delivery.

The promise of targeted delivery has a history. The concept of drug targeting is linked with Paul Ehrlich's idea of 'Zauberkugeln', 'magic bullets' introduced over a century ago. The 'magic bullet' refers to the idea of homing in on the target and being effective - in this case affecting only the diseased tissue. Work on what are now considered to be nanotechnology enabled drug delivery systems has evolved since the 1960s (Boyd 2008; Hoffman 2008; Kreuter 2007) – although not exclusively related to targeting. Systems which are currently labeled as 'nanovehicles' have existed for some time, such as liposomes and polymer micelles (1960s), nanoparticles and dendrimers (1970s) (Park 2007).[13] The connection with the term 'nano' can thus be considered as a relabeling of what was already occuring.

Considering the history of drug delivery systems, promises of the application of nanotechnologies may not be very effective in mobilizing actors. According to Boyd (2008) the claim that "advances in nanotechnology are stimulating a 'revolution' in colloidal drug delivery" should be reconsidered given evolutionary developments over the last decades. Whether revolutionary or evolutionary, there is an increasing interest in nanotechnology and drug

[12] Source: Observations by the author during targeted drug delivery workshop, Utrecht, 20-01-2010.

[13] Another set of new delivery systems may result from advances in micro- and nanofabrication techniques: micro- and nano-electromechanical devices (Staples et al. 2006). Further, one can consider nano-sized pharmaceuticals, such as those linked with nano-crystal technologies, as a form of drug delivery. Both sets of technologies have interesting properties but do not speak very much towards the idea of 'targeted drug delivery'. Exceptions in this area are so-called activated therapies in which a carrier releases its drug at a particular site when triggered by an external actuator such as ultrasound.

delivery, visible in the rise of research papers and patents since the early 2000s (Kim et al. 2009).[14] According to Boyd (2008) and researchers involved in drug delivery, the availability of large amounts of research funding has given the field of drug delivery a new impulse.[15] Key sciences involved in nanoscience and nanotechnology such as material sciences and chemistry are also involved, as visible in drug delivery papers.[16]

Nanotechnologies are considered to have 'unique qualities' (Emerich and Thanos 2006) and provide 'extraordinary opportunities' to contribute to targeting problems for major diseases such as cancer therapies (Ferrari 2005). In addition to cancer, nanotechnology enabled drug delivery technologies were also expected to contribute to other disease areas such as infections, metabolic and auto-immune diseases (Couvreur and Vauthier 2006). Available funding related to rhetorics of nanotechnology in general and for drug delivery in particular, as well as advances at the level of materials, have created new openings.

The application of nanotechnology engineered drug delivery systems (NDDS) is expected to be beneficial for the generation of novel pharmaceutical therapies and thereby appealing to current pressures on pharmaceutical companies to generate novel therapies. The idea of the magic bullet enabled by nanotechnologies is a powerful image. There are further expectations of the application of nanotechnologies which link up with issues in the drug delivery sector as discussed in section 4.2.1., in particular the challenge of sustaining pharmaceutical business: (1) creating new drugs or extension of patent life of existing drugs by providing new and improved formulations with respect to therapeutical effectiveness and safety; (2) enabling formulations for API's which are difficult to develop pharmaceutically, including promising new biopharmaceutical therapies such as those based on genes.

[14] Also visible in a literature search including non-nano terms. Personal communication with Professor Porter, Search Technology, Inc. 30-05-2010.
[15] Source: Observations by the author during the Euronanomedicine Conference in 2009.
[16] Source: Personal communication Porter, Search Technology, Inc. 30-05-2010.

In table 1 an overview of specific expectations of the applications of NDDS is presented.

Pharmaceutical challenges	Expected solutions from NDDS
Difficult or unacceptable pharmaceutical format due to poor solubility or toxicities linked to particular excipients.	Enhancing drug solubility, e.g. by micelles and liposomes providing hydrophilic and –phobic environments.
Undesirable side-effects caused by extravasation (e.g. by leakage) of drugs from diseased to surrounding tissues.	Regulated drug release can reduce or prevent tissue damage by extravasation.
Loss of activity of drugs due to rapid breakdown in the body.	NDDS protect drugs from premature degradation and may enable use of lower doses.
Loss of activity due to too rapid clearance of drugs.	NDDS can reduce clearance and may enable use of lower doses.
Undesirable side-effects due to too widespread distribution in the body affecting healthy tissues.	Particulate character of NDDS lowers distribution and helps to reduce side-effects.
Suboptimal therapeutic effects due to use of low concentration of drugs to reduce side-effects.	NDDS can increase drug concentrations by passive and active targeting (EPR-effect, targeting ligands).
Insufficient drug absorption and intracellular penetration.	NDDS can improve absorption through epithelium and improve intracellular penetration and distribution.
Difficult or unacceptable excipients to stimulate immune responses in case of vaccines.	NDDS can be engineered to stimulate immune response, e.g. virosomes and virus-like particles.

Table 1: Expectations of nanotechnology enabled drug delivery systems[17]

While promises of nanotechnologies created openings for change within the drug delivery sector, institutional entrepreneurs of nanotechnologies need to cope with significant challenges in resource mobilization for legitimating their introduction, such as waiting strategies and reimbursement pressures. What has happened in terms of institutional entrepreneurship initiatives in the drug delivery sector?

[17] Sources: Modified and expanded from Allen and Cullis (2004) with items from Couvreur and Vauthier (2006).

4.3 The evolving patchwork of embedding nanotechnologies in the drug delivery sector

For my analysis into the evolution of distributed institutional entrepreneurship I focused on developments within Europe. Europe has a strong tradition of interaction and co-ordination and therefore I would expect to find also a broad variety of actors involved, i.e. a rich collection of distributed institutional entrepreneurship activities. In particular I focused on initiatives with a transnational character. These initiatives need to take into account international aspects and will be less shaped by national circumstances. Identified initiatives with a translational character will be relevant for the drug delivery sector as a whole because they address general, non-country specific, issues. I will map initiatives and construct a narrative of the evolution of their initiatives in order to understand what is happening.

4.3.1 Overview of distributed institutional entrepreneurship

Instances of institutional entrepreneurs were identified through conducting interviews with experts involved in the world of nano drug delivery and my moving about in the world of nanomedicine & drug delivery through attending conferences. I attended meetings of the Netherlands Platform for Targeted Nanomedicine in 2008 (Groningen) and 2009 (Utrecht); Investing in Medical Nanotechnologies II in 2007 (London); Nanotechnology and the law: The legal nitty gritty for nano foods, nanocosmetics and nanomedicine in 2008 (Leuven, Belgium); Euronanomedicine in 2009 (Bled, Slovenia). In my interviews and moving about I looked for sites and actors where new conditions for developing and embedding nano drug delivery technologies were developed and promoted. In addition I examined an overview of networks & initiatives at the nanowerk.com website (launched in December 2005) and scanned trade press articles at their website from September 2006 till May 2010. To check whether my inventory was complete I examined additional stakeholders' activities (potential institutional entrepreneurs) such as patient organizations and pharmaceutical branch organizations at a European level.

In table 2 an overview of all identified institutional entrepreneurship initiatives operating at a European level is presented. [18]

Institutional entrepreneurs & spaces	Period	Characterization of activities	Illustrative quotes
European Technology Platform Nanomedicine (ETP Nanomedicine)	2004-ongoing	Promoting combination of nanotechnologies and medical, including drug delivery, technologies. Promoting adoption of translational research (emphasis on link with industry).	"Nanomedicine, the application of nanotechnology in healthcare, offers numerous very promising possibilities to significantly improve medical diagnosis and therapy, leading to an affordable higher quality of life for everyone. At the same time nanomedicine is a strategic issue for the sustainable competitiveness of Europe. In order to avoid that this young and very fast growing discipline suffers from fragmentation and a lack of coordination, industry and academia – together with the European Commission – have identified the need for a European initiative to intermesh the several strands of nanomedicine into a firm strategy for advancement." (ETP Nanomedicine 2006, p. 6)
European Foundation for Clinical Nanomedicine (CLINAM)	2007-ongoing	Promoting combination of nanotechnologies and medical, including drug delivery technologies. Promotion adoption of translational research (emphasis on link with clinical medicine).	"The European Foundation for Clinical Nanomedicine is a non-profit institution aiming at advancing medicine to the benefit of individuals and society through the application of nanoscience. Aiming at prevention, diagnosis, and therapy through nanomedicine as well as at exploration of its implications, the Foundation reaches its goals through support of clinically focussed research and of interaction and information flow between clinicians, researchers, the public, and other stakeholders." (CLINAM 2010b)
European Society for Nanomedicine (ESNAM)	2007-ongoing	Promoting combination of nanotechnologies and medical, including drug delivery technologies. Promotion adoption of translational research (emphasis on link with clinical medicine).	"Since the success in the clinical application of nanomedicine depends both on an orientation of basic research towards clinical relevance and on the broad clinical application of the tools and methods arising from this research, a strong link between clinical medicine and nanosciences research is of utmost importance. To fill this gap, the European Society for Nanomedicine (ESNAM) was founded in 2007. [..] The European Society of Nanomedicine aims to promote the research and the application of nanomedicine and its implication for humanity and for the environment, keeping always in view the welfare of individuals and society." (ESNAM 2010)
MediTrans	2007 - 2010	Promoting application of nanotechnologies for (targeted) drug delivery technologies. Promoting adoption of translational research (emphasis on link with industry).	"The overall aim is to advance health care via the development of innovative targeted drug / imaging agent delivery [..] The MEDITRANS project has clear potential to forward targeted nanomedicines to the clinic, and will contribute to improved structural collaboration between industry and academia." (MEDITRANS 2010a)
Responsible Nanocode Working Group	2007-2008	Promoting a pro-active approach from companies towards assessing and mitigating possible risks of nanotechnologies, including pro-active involvement of stakeholders.	"Organisations will be encouraged to adopt the Seven Principles of the Responsible Nano Code. [..] The Code and the benchmarking process are intended to stimulate these organizations to consider and continuously improve all aspects of their involvement with nanotechnologies – including governance, risk assessment, broader social and ethical issues and to take into account the views of their stakeholders." (Responsible NanoCode 2008)

Table 2: Overview and characterization of institutional entrepreneurs & spaces in drug delivery sector

Salient in this overview are the type of initiatives that unfolded and their overlap. The identified initiatives are carried by new organizations and spaces for interaction, rather than incumbent actors in the drug delivery sector. Except

[18] I did identify additional (local) initiatives related to nanomedicine which may provide a venue for institutional entrepreneurship activities, such as the Spanish Nanomedicine Platform, the Netherlands Platform for Targeted Nanomedicine, the French Technology Platform on Nanomedicine, the American Academy of Nanomedicine, the American Society for Nanomedicine, the Alliance for Nanohealth.

in the case of MediTrans, all initiatives focus on nanomedicine, or nanotechnologies in general (as in the case of the Nanocode), rather than taking drug delivery as their exclusive topic.[19] As expected, broader societal aspects do not appear as a main subject for institutional entrepreneurship activities, except for the Responsible Nanocode working party. Further, the ongoing initiatives are overlapping in terms of activities with a focus on the promotion of translational research practices, a form of anticipatory co-ordination. As it turns out, there is also overlapping membership. The emergence of new actors, agenda-building, and attempts to co-ordinate interactions are indications of an emerging world of nanomedicine.

Examining what these initiatives do and how they contribute to changes in the drug delivery sector then results in slightly moving away from nanotechnology enabled drug delivery technologies. Initiatives focus on broader themes such as nanomedicine (and nanotechnology) of which drug delivery is part of. Here, I am interested in the emergence of institutional entrepreneurs in the drug delivery sector rather than in developments associated with nanomedicine more generally. Then, I need to broaden my research question to examine what is happening in this world, relevant for developments in the drug delivery sector.

4.3.2 Promoting the combination of nanotechnologies and drug delivery

Institutional entrepreneurship initiatives emerged during a period in which there was increasing interest in the combination of nanotechnology and drug delivery. Around 2000 there was a strong increase in patents and scientific publications related to these technologies, as already mentioned in section 2.2. Some nanotechnology enabled drug delivery technologies were already on the market such as Doxil (Caelyx outside US), Ambisome, and DaunoXome (Bawa 2008). It was also a period in which public funding into nanotechnologies increased and these governmental initiatives were highly visible, particularly the U.S. National Nanotechnology Initiative. The application of nanotechnologies in medicine, ‘nanomedicine’, including drug delivery, would

[19] MediTrans focuses on targeted drug delivery technologies and imaging probes.

become increasingly prominent in funding from the 2000s on (Murday et al. 2009, 2008).

There were also notes of caution. Promises of nano-enabled drug delivery technologies were picked up by industry analysts such as NanoMarkets who added some reservations related to general developments in the pharmaceutical world (as discussed in the previous section) and related to debates on nanotechnologies. While their study noted that "the market is heating up" (Moradi 2004, p. 4) it also referred to uncertainties of nanotechnologies related to health, environmental and safety concerns, consumer perceptions and broader developments such as calls for increased oversight of the pharmaceutical industry. In particular, the report observed structural challenges related to uptake of new technologies in the sector such as reluctance within public capital markets to invest; it further noted that drug delivery firms historically had not been valued very much by the drug discovery firms. The report concluded that new entrants would need to cope with a 'difficult environment'.

So, the overall situation in the drug delivery sector was fertile ground for potential institutional entrepreneurs. Institutional entrepreneurship initiatives that emerged, however, would not exclusively focus on the promotion of the combination of nano and drug delivery. Instead they promoted nanomedicine, an umbrella term for the application of nanotechnologies for medicine under which drug delivery was only one of the themes.

By the mid 2000s, nanomedicine was considered to be an emerging field by drug delivery researchers such as Prof. Kostarelos at the Centre for Drug Delivery Research in London who is a senior editor of the new journal nanomedicine (Kostarelos 2006).[20] By then, nanomedicine had become a separate theme for funding in the US, but not (yet) in Europe (Moran 2006). A report by the European Science Foundation actually called for more dedicated funding into nanomedicine. The report discussed the application of nanotechnologies in the domain of drug delivery, but also within other domains such as imaging technologies. The ambivalent situation of optimism

[20] In addition to *Nanomedicine,* other journals focused on nanomedicine were launched mid 2000s: *Nanomedicine: Nanotechnology, Biology, and Medicine* (launched in 2005); *International Journal of Nanomedicine* (launched in 2006).

and cautiousness observed by NanoMarkets was also visible within the ESF report. In the report's executive summary it referred to "increasing optimism that nanotechnology applied to medicine will bring significant advances in the diagnosis treatment and prevention of disease." It also noted that "many challenges must be overcome" for the realization of these advances (European Science Foundation 2005, p. 7). The ESF report not only called for more dedicated funding, but also for initiatives to develop linkages between disciplines and across actors in the sector. Promises of nanomedicine and ESF's call for funding and development of linkages across actors in this area opened up spaces for interaction for actors who wanted to explore and exploit nanomedicine.

The first institutional entrepreneurship initiative to promote nanomedicine and the development of linkages between stakeholders was the European Technology Platform Nanomedicine. In 2004 a group of actors considered the ETP as a possible venue for promoting nanomedicine and explored "the need for an ETP in Nanomedicine, to identify the most important strategic topics, and to initiate drafting of a first vision."(CORDIS 2009) The ETP Nanomedicine was chaired by medical imaging companies Philips and Siemens.[21] Within the platform a number of working groups were established on themes such as diagnostics, regenerative medicine, drug delivery, ethical and social issues, and intellectual property rights. The drug delivery working group was chaired by Mike Eaton from biopharmaceutical company UCB Celltech, who had also participated in the ESF workshops. While promises of nanomedicine opened up this space, its emergence was also linked with broader developments. European Technology Platforms were a general instrument set up by the European Commission in 2004 (European Commission 2004).

In a communication on a European strategy for nanotechnology the European Commission referred to new instruments such as Integrated Projects (to which I will return later) and Networks of Excellence and European Technology Platforms to tackle "the problem of dispersion, duplication and fragmentation" (p. 10). The idea behind ETPs was "to bring together all interested stakeholders to develop a long-term shared vision, create roadmaps, secure long-term financing and realize a coherent approach to governance. This concept might

[21] Philips is very visible in the world of nanomedicine and also interested in targeted delivery of pharmaceuticals. See also the Sonodrugs project (www.sonodrugs.eu).

be appropriate in response to the need for more synergy and coordination between various stakeholders in a specific technological area." ETPs were considered by the EC as a way to 'foster public-private partnerships' and to articulate strategic research agendas which could be supported by the EC with existing instruments or by the creation of 'joint technology initiatives' (Commission 2004). The ETP's, then, were set up to support governance of a domain, and could therefore act as a vehicle for the development of rules and practices. What did the ETP Nanomedicine do, in particular with respect to drug delivery?

The first activities of the ETP Nanomedicine were the construction of a vision paper and building of a strategic research agenda for nanomedicine, promoting among others the combination of nanotechnologies and drug delivery, and mobilizing actors to participate in or support the forum activities. I will offer some details in order to be able to trace changes in ETP's activities as visible in their publications. Over time, ETP's articulation of nanotechnologies and medicine (and how to bring them about) would become increasingly specific and changed in focus.

In 2005 the ETP Nanomedicine published their vision paper which put nanomedicine and its promises on the agenda of EU policy makers, the drug delivery sector and other domains of nanomedicine applications. In their vision paper, nano enabled systems were seen as contributing to important challenges in the sector such as patient acceptability, reduction of health care costs, and delivery of (difficult to deliver) novel classes of drugs. In the vision paper general promises and the idea of the 'magic bullet' were mobilized to support the promoted combination of nanotechnologies and drug delivery:

> "The long-term objective of drug delivery systems is the ability to target selected cells and/or receptors within the body. At present, the development of new drug delivery techniques is driven by the need on the one hand to more effectively target drugs to the site of disease, to increase patient acceptability and reduce healthcare costs; and on the other hand, to identify novel ways to deliver new classes of pharmaceuticals that cannot be effectively delivered by conventional means. Nanotechnology is critical in reaching these goals." (p. 8)

> "Nanotechnology has a trump card to play when applied to medicine. [..] The properties of nanoparticles, such as increased chemical activity and the ability to cross tissue barriers, are leading to new drug targeting and delivery techniques. In the future, a nanoparticle or a set of nanoparticles may be designed to search for, find and destroy a single diseased cell, taking us even closer to realising the ultimate goal of disease prevention."(p. 35)

The vision paper articulated which actors should play a role and on what kind of activities they should be working. By doing so, the ETP Nanomedicine was working towards the creation of an emerging world of nanomedicine, cf. Van Lente and Rip (1998) on the emerging world of membrane technology. To realize the promoted combination of, among others, nanotechnologies and drug delivery, the vision paper called for close collaboration in research activities:

> "At present Europe has a strong position in the emerging field of NanoMedicine that has a high potential for technological and conceptual breakthroughs, innovation and creation of employment. NanoMedicine is an area that would benefit from coordination at European level. Thus, close cooperation between industry, research centres, academia, hospitals, regulatory bodies, funding agencies, patient organisations, investors and other stakeholders could dramatically boost this promising field. In response to these challenges, scientific experts from industry, research centres and academia convened to prepare the present vision document regarding future research priorities in NanoMedicine." (p.5)

One year later, as part of the general approach of ETPs, the platform published its strategic research agenda. In its opening pages, the ETP explicitly positioned itself as a vehicle for co-ordination of developments in the field of Nanomedicine. Whereas the vision paper advocated the application of nanotechnologies for health in general, the strategic research agenda emphasized how nanotechnologies would contribute to addressing clinical needs. The articulation of nanotechnologies and applications, and how to realize them, became more specific. This move would continue during the following years.

The focus on clinical needs returned in the ETP's suggestions for co-ordinating nanomedicine research between industrial, academic and clinical actors.

> "Research on nanomedicine is unusually spread across industrial, clinical and academic sectors. For real clinical progress improved communication is required between all three parties; as ultimately only those teams able to manage clinical studies through phases 1-3, regulatory submissions and marketing will be able to provide benefits for patients. Depending on the stage of the research, it will be advisable for proposals to show that collaborators are really capable of transitioning their work through the clinic." (p. 30)

The actual establishment of linkages across the drug delivery sector proved to be a challenge. In Europe, the ETP Nanomedicine had put the application of nanotechnologies for drug delivery on the agenda, but the creation and shaping of an arena to implement the agenda, including their own platform, was not straightforward. Key actors such as big pharmaceutical companies were not involved. Whereas the vision paper was signed by high-level managers of companies such as GlaxoSmithKline and Schering, no large pharmaceutical companies were present within the drug delivery working group of the ETP Nanomedicine. Large pharmaceutical companies did not appear to be interested in being involved - at least not through participation in working groups - in European wide attempts to further the development of nanotechnology engineered drug delivery technologies via concerted action.22 This was in contrast to another European Technology Platform called Innovative Medicines. This platform was co-ordinated by the European Federation of Pharmaceutical Industries and Associations and eventually developed into a Joint Technology Initiative in which there was strong participation by large pharmaceutical companies (Innovative Medicines Initiative 2008). [23]

The lack of interest on the part of large pharmaceutical companies in ETP Nanomedicine is part of a broader phenomenon. In their review of technological and commercial developments Couvreur and Vauthier (2006) pointed out that on the one hand there is a 'confident climate' for new nanosystems to be developed as there are already positive experiences (both clinically and in regulatory terms) of such systems. On the other hand, they also observed reluctance of large pharmaceutical companies towards nano drug

[22] Source: interview with Professor Molema, University of Groningen, July 2009

[23] For pharmaceutical branch organizations such as the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) nanotechnology was not an important topic. Source: Correspondence by the author with IFPMA, July 2009.

delivery: "Today, most developments are carried on by small entrepreneurial firms including many spin-ups that cannot support themselves as yet on current revenues, whereas big pharmaceutical companies seem still awaiting for more successes."[24] Wagner, Hüsing et al. (2006) speculated that firms were waiting for the first nano blockbuster before they would initiate heavy investments in this area. A widespread expectation is that if nanotechnologies would prove their clinical value, they would then be acquired by big pharma.[25]

Uncertainties of nanotechnologies and structural features of the drug delivery sector (see section 2) supported a situation of a waiting game. Big pharma was interested, but waited for reduction of uncertainties. Firms and knowledge centers waited for funding of investors such as big pharma to continue research and development activities in this area, cf. Kostarelos (2006). Apart from waiting strategies and general cautiousness with respect to investments in pharmaceutical technologies, reluctance is likely to be related to uncertainties around intellectual property rights. At a conference on medical nanotechnologies in 2007, a principle scientist from AstraZeneca argued that patents for drug delivery were hard to defend and that many 'colloidal' patents existed (Washington 2007). Uncertainties about what can and what cannot be protected made large pharmaceutical companies act carefully with respect to these technologies.[26] IP experts warned of uncertainties around patents complicating protection of new products related to overlapping patents and 'patent land grab' (Bawa 2007; Harris et al. 2004).

Some of the promises of nanotechnology enabled drug delivery systems were not overly attractive for large pharmaceutical companies, which will have contributed to further reluctance. The improvement of existing medicines by increasing bioavailability and improving of dosing regime might not have been

[24] Also within research communities skeptical sounds were voiced. Delegates at conferences voiced fundamental uncertainties around understanding of nanotechnology enabled drug delivery technologies as well as to the added therapeutic value and safety of these technologies. Researchers expressed concerns that if the added value in these technologies would not be demonstrated relatively soon, attention and funding would dry up. The promise of targeting or 'the magic bullet' was still elusive, see also Ruenraroengsak et al. (2010).

[25] Source: interview with Crommelin, ibid; interview with Storm, ibid. Observations by the author during the conference Investing in Medical Nanotechnologies II, London 2007

[26] Source: interview with Mr. Von Bonhorst, independent consultant, 04-11-2009.

attractive, because therapeutical gains were expected to be limited and nanotechnologies needed to compete with well-developed conventional means. Delivery of new active compounds such as biopharmaceutical entities and disease targeting were considered to be relatively more promising (Boyd 2008; Keller 2007; Wagner et al. 2006).[27] Separations between drug discovery and development - big pharma's focus on drugs, i.e. active compounds rather than formulations and or delivery systems - also ran through discussions on the application of nanotechnologies. Big pharmaceutical companies such as Glaxosmithkline and AstraZeneca preferred to co-operate with other parties rather than developing nano drug delivery technologies themselves (Keller 2007; Washington 2007). Director Keller from GlaxoSmithKline remarked during the conference on Medical Nanotechnologies that they 'recently had shut down their department as it was not the time to create a nano department'.[28]

4.3.3 A further round of initiatives

Legitimation of nanomedicine, including the application of nanotechnologies to drug delivery technologies, was beset with difficulties. However, around the same period that the ETP Nanomedicine emerged, other initiatives emerged which, taken together, would further support legitimation of nanomedicine. Strikingly, these initiatives emerged from different positions in the chain and overlapped in terms of focus and objective. These new initiatives, as well as the ETP Nanomedicine's later activities, would take a broader approach than simply promoting the combination of nanotechnologies and drug delivery. While the promotion of nanotechnologies remained important, these initiatives emphasized anticipatory co-ordination between academics, industrial actors and clinicians via translational research practices. The overlapping initiatives by actors with an academic, industrial and clinical background reinforced the overall effect of building an emerging world by creating linkages between these positions in the chain. So, these institutional entrepreneurs contributed to the creation and filling in – 'furbishing' - of an emerging world, predicated on

[27] Sources: interview with Crommelin, ibid; observations by the author during targeted drug delivery workshop.
[28] Source: Observations by the author during the conference Investing in Medical Nanotechnologies II, London 2007. See also Earl (2007).

promises of nanomedicine, but now with a strong emphasis on clinical application.

The MediTrans project launched in 2007 can be characterized as an institutional entrepreneurship initiative which worked from the position of researchers in the world of drug delivery research and contributed to the furbishing of the emerging world of nanomedicine by emphasizing translational research. With its academic orientation, it supplemented the industry driven ETP Nanomedicine. The MediTrans Integrated Projected consisted of 30 partners in which knowledge institutes were well represented and also included SMEs and large pharmaceutical companies such as Bayer Schering Pharma, Merck Serono and Organon (which would later become part of Merck). As one of its specific challenges, MediTrans aimed to "Promote entry of targeted nanomedicines into industrial exploitation and clinical proof-of-principle studies" and expected to achieve "Improved structural collaboration between industry and academia" (MEDITRANS 2007b) To realize this objective the project included lab studies and toxicity assessments, but also industrial exploitation studies, to be lead by Bayer Schering Pharma. So, the entrepreneurial forces behind MediTrans appeared to have been successful in overcoming waiting games by mobilizing big pharmaceutical companies.

As with the ETP Nanomedicine, the occasion for the emergence of MediTrans was provided by the EU Framework Programme. The MediTrans project was an EU funded Integrated Project, which was, as European Technology Platforms are, a general instrument of the European Commission to improve co-ordination. Integrated projects were meant to be multidisciplinary and involve actors across the value chain in order to facilitate knowledge transfer between academic and industrial partners; see European Commission (2004). As such, they could provide a relevant venue for institutional entrepreneurs promoting new rules and practices across the value chain.

The entrepreneurial driver behind the development of the MediTrans project, Gert Storm, Professor Targeted Nanomedicine at Utrecht University, was one such institutional entrepreneur. Storm had the ambition to bring new nanotechnology enabled drug delivery technologies to the clinic. To realize this objective it was important, according to Storm, to further the 'field of targeted nanomedicines' in such a way that products would be taken up by industry. In

order to stimulate uptake it was essential that academia and industry co-operated. Integrated Projects were well suited for such purposes according to Storm (Wentzel 2006).

As an institutional entrepreneurship initiative, MediTrans took the building of an emerging world of nanomedicine one step further by promoting 'bench-to-clinic'- 'translational' – approaches. The legitimacy of targeted drug delivery and its combination with nanotechnology approaches was assumed to be in place. Collaboration between academia and industry was considered to be essential and insufficient until now, and the key problem to be overcome by translational practices.

> "It is now well known that a reliable targeting system is essential for successful drug delivery in many serious disease situations. It is becoming increasingly recognised that a major limitation, impeding the entry of targeted delivery systems into the clinic, is that new concepts and innovative research ideas within academia are not being developed and exploited in collaboration with the pharmaceutical industry. Thus, an integrated 'bench-to-clinic' approach realised within a structural collaboration between industry and academia, is required to safeguard and promote the progression of targeted nanomedicines towards clinical application." (MEDITRANS 2007a)

In MediTrans, clinicians were not much involved, despite promotion of translational research practices. Still, the involvement of clinicians was seen as vital for the further development of nano drug delivery and nanomedicine according to Storm.[29] The limited involvement of clinicians was not unique to MediTrans, however. Also within the ETP Nanomedicine, clinicians had not been involved very much.[30] Clinicians appeared to be the 'forgotten people in nanomedicine'[31] and were at best moderately involved within dedicated initiatives. But this was about to change.

In 2007, the foundation for clinical nanomedicine (CLINAM) and the European society for nanomedicine (ESNAM) were launched. These institutional

[29] Source: interview with Storm, ibid.
[30] Source: Observations by the author during Nanomedicine Conference (Slovenia, 2009); Interview with Löffler, CLINAM/ESNAM, 13-08-2009
[31] Source: Observations by the author during conference 'Investing in Medical Nanotechnologies II' in London, 2007.

entrepreneurship initiatives promoted nanomedicine from a clinical perspective. The entrepreneurial forces behind these initiatives were prof. Hunziker, a clinician working at the University Hospital in Basel, and Beat Löffler, a concept engineering and program development consultant. The initiators explicitly built upon earlier initiatives linked to nanomedicine. Hunziker and Löffler themselves positioned their initiative as complimentary to what was happening already in the field; that is initiatives such as European technology platforms and European Framework Programmes (ESNAM 2010; Neis-Beeckmann 2008). They positioned their initiatives as having different targets than the ETP Nanomedicine: emphasizing medical problems instead of pushing nanomedicine technologies.[32] They argued that the interests of medical doctors into nanomedicine had recently increased, but that clinicians had a different perspective and approach than current initiatives led by industry and researchers. The CLINAM foundation was created "with a view to involving medical clinicians into the debates, since they had not been present at so many nanomedicine meetings previously."(Löffler 2009, p. 705)

CLINAM and ESNAM supplemented attempts by MediTrans and ETP Nanomedicine to build and orchestrate an emerging world of nanomedicine. While the initiators did refer to broad promises of the application of nanotechnologies in the domain of health including drug delivery technologies, cf. Neis-Beeckmann (2008), CLINAM and ESNAM promoted collaboration between stakeholders with an eye on clinical application. With their call for clinically oriented activities and organization of interactions across the sector, i.e. academia, industry and clinicians, they implicitly drew upon notions of 'translational research'.

> "The European Foundation for Clinical Nanomedicine is a non-profit institution aiming at advancing medicine to the benefit of individuals and society through the application of nanoscience. [..] the Foundation reaches its goals through support of clinically focussed research and of interaction and information flow between clinicians, researchers, the public, and other stakeholders. The recognition of the large future impact of nanoscience on medicine and the observed rapid advance of medical applications of nanoscience have been the main reasons for the creation of the Foundation." (CLINAM 2010a)

[32] Source: Interview with Löffler, ibid.

> "Since the success in the clinical application of nanomedicine depends both on an orientation of basic research towards clinical relevance and on the broad clinical application of the tools and methods arising from this research, a strong link between clinical medicine and nanosciences research is of utmost importance. To fill this gap, the European Society for Nanomedicine (ESNAM) was founded in April of 2007."(ESNAM 2010)

The initiators themselves thought in terms of building a world of nanomedicine through supporting interactions. They wanted "to make sure that nanomedicine will not suffer because of ineffective communication" (Neis-Beeckmann 2008). Major activities of CLINAM (and ESNAM) were acquisition of research funding, the creation of a European research lab, organizing conferences and a 'clinically oriented nanomedicine community'.[33] Later, around 2009, the notion of 'translational' would be explicitly used in activities undertaken by CLINAM. In the call for universities to participate in their annual conference in 2010 they mobilized the universities by stating "CLINAM 2010 calls for translation of Nanomedicine for the benefit of the patient."[34] Furthermore, CLINAM would be initializing activities to establish the "International Laboratory for Translational Nanomedicine." [35] Earlier, the plans to develop a laboratory had been labelled as a "European Research Lab Space for Clinical Nanomedicine" (CLINAM 2009). So, as in MediTrans, translational research was a key theme in the institutional entrepreneurship activities of CLINAM/ESNAM. Not all institutional entrepreneurship initiatives which emerged would take translational research as a key theme, however.

The Responsible Nanocode, whose activities also started in 2007, was a different type of institutional entrepreneurship initiative. Here, the construction of an emerging world of nanomedicine and or co-ordination of interactions via translational research was not put up front. The drug delivery sector was, in a sense, involved through the membership of Johnson & Johnson in the working party of the Responsible Nanocode initiative. The firm was represented by Mr. Gannon, Executive Director Government Affairs and Policy (Europe). Johnson & Johnson is owner of ALZA Corporation which introduced one of the first nanotechnology enabled drug delivery products, Doxil (Caelyx

[33] Sources: www.clinam.org'; www.esnam.org.; interview with Löffler, ibid.
[34] Source: Personal communication from Löffler to the author, 17-12-2009
[35] Source: Interview with Löffler, ibid.

in Europe). Johnson & Johnson's interest in nanotechnologies is not limited to drug delivery as it is a large diversified company involved in diagnostics, medical devices, personal care products including cosmetics, and pharmaceuticals.

A key force behind the development of the Responsible Nanocode had been concerns of companies regarding their low involvement in issues of regulation and risk assessment. As the drug delivery sector is well regulated, issues of regulation and risks appear to be somewhat less of a concern, even while they are debated. Carbon nanotubes, which had been considered as a possible delivery system for drugs (Couvreur and Vauthier 2006), became a topic in debates on risks and were put on the shelf for safety reasons.[36] The debates on risk issues of these technologies might have contributed to an (even more) cautious attitude among large pharmaceutical companies.[37] De Jong and Borm (2008) argued that risks of nanotechnology enabled drug delivery systems in general have only recently started to receive attention. They suggested that current regulatory requirements seemed sufficient to characterize risks of nano drug delivery systems, but also pointed out that new testing procedures might be required to find out about nanoparticle toxicology. For authorities such as the European Medicines Agency (EMEA), not all nano-sized products implied novelty and evaluations were based on risk/benefit considerations rather than the technologies as such.[38] Existing methodologies were considered to be sufficient for most of the potential hazards, although new methods might need to be developed (Papaluca Amati 2008; Committee For Medicinal Products for Human Use 2006). In 2006 the US Food and Drug Administration (FDA) adopted a similar position; that nano drug delivery did not require particular regulatory and or testing requirements. Still, it was expected by some actors involved in the development of nanotechnologies and drug delivery systems that new requirements (linked to nanotechnologies) would appear in the future; see Couvreur and Vauthier (2006).[39]

[36] Source: Observations by the author during targeted drug delivery workshop in Utrecht, January 2010. See also Eaton in Moran (2006) who questioned the use of carbon nanotubes for drug delivery purposes.
[37] Source: Interview with Von Bonhorst, independent consultant, 04-11-2009.
[38] There are debates on the application of drugs or medical devices regulatory regimes (Committee For Medicinal Products for Human Use 2006).
[39] Expectations about future regulation of nanotechnology enabled pharmaceutical technologies were expressed during my targeted drug delivery workshop.

In 2008 the working party published a draft code of conduct (see further Fiedeler et al. (2010) about the draft status of the code). The code was meant for a 'transitional period' until more certainty on implementation of regulatory frameworks existed. It promoted a pro-active approach from companies toward assessing and mitigating possible risks of nanotechnologies, including the involvement of stakeholders (Responsible NanoCode 2008).

There appeared to be no clear-cut relevance, let alone necessity, of codes of conduct such as the Responsible Nanocode for the drug delivery sector, but they could not simply be neglected either. Codes of conduct were a topic for discussion during a conference on medical nanotechnologies in 2007. A delegate from GlaxoSmithKline, director Keller, was critical about the added value of such codes. [40] According to Keller, the pharmaceutical sector was already very concerned with regulation, health and safety issues. In a direct discussion, Tomellini, then head of the Unit nano-and converging sciences and technologies of the European Commission and a key figure in promoting the code of conduct developed by the European Commission, replied 'that big pharma might not need a code as you are already very responsible.' [41] Still, in a public position statement about nanotechnologies in 2009 GlaxoSmithKline emphasized that, while current regulatory frameworks were sufficient, they were willing to contribute to further revisions of regulations. They pointed out that GlaxoSmithKline actively participated in the development of the Responsible Nanocode (GlaxoSmithKline 2009). So, whatever the reason, they still felt that they needed to do something with a code of conduct. The Responsible Nanocode Initiative promoting a code of conduct appeared to be a different type of initiative compared to the other institutional entrepreneurship initiatives and played a different role in embedding processes of nanotechnologies in the drug delivery sector. It appears to have lost its momentum after 2008.[42]

[40] GlaxoSmithKline is involved in the EU funded Integrated Project 'NanoBioPharmaceutics'.

[41] Source: Observations by the author during conference Investing in Medical Nanotechnologies II, London, 2007.

[42] In 2010 new activities were initiated. Researchers at Cranfield University undertook a benchmarking study with the aim of further developing the Responsible Nanocode "to a point where it will be adopted by businesses across the supply chain" (Collinson et al. 2010).

The 'furbishing' of an emerging world of nanomedicine with translational research practices would receive a further push when the ETP Nanomedicine took this up as a central theme in their activities, thereby overlapping activities of MediTrans and CLINAM/ESNAM. While overlapping actor networks were not a topic for systematic research, I learned from my interviews that actors from MediTrans were also involved in activities of ESNAM, and actors from ESNAM were involved in activities of the ETP Nanomedicine. There was overlap among the initiatives, therefore, not only in terms of substance but also in terms of actor networks.

Within the ETP Nanomedicine, the establishment of translational research practices was particularly pushed by Eaton, who used the ETP Nanomedicine as a venue and vehicle for his institutional entrepreneurship activities. In 2007 in a paper in Nature Materials he questioned whether then-developed nano delivery systems would pass regulatory processes and argued that academia and industry should be more aligned (Eaton 2007). He positioned the ETP as a forum supporting such alignment processes and as having the ambition to "publish guidance on how industry routinely evaluates new drugs in the development process." (Eaton 2007, p.252) During meetings of the ETP nanomedicine, and through publications (Eaton 2007, 2009) he advocated improved communication and novel patterns in interactions between industry and academia.

By 2009, ETP was firmly committed to promoting the establishment of translational research practices in the emerging world of nanomedicine as visible in their roadmap document. It shared the diagnosis of MediTrans, and CLINAM/ESNAM regarding the lack of co-operation between stakeholders as a key challenge to overcome. Compared to earlier publications of the ETP Nanomedicine, the roadmap document was less open-ended, to an extent that it had become more 'prescriptive'.[43] The roadmap document (ETP Nanomedicine 2009) signaled that the ETP needed to become more pro-active to shape development and prospects for future introduction of nanomedicine technologies.

[43] Source: Interview with Eaton, ibid.

> "The Strategic Research Agenda of the ETP Nanomedicine was drafted in 2006 with a broad range of options highlighted. Over the intervening years it has become increasingly clear to the industrial sector that an academic driven or *laissez-faire* approach to Nanomedicines will be an inefficient process. It is recognized that it is now time to make more detailed specific recommendations [..] Successful translation of research results from academia into products has been identified to be one of the major challenges in this innovative science based area. Strategies to foster and initiate this translatability must be developed and implemented to help European research and industries remain competitive in the global market." (p.4)

From the roadmap document it appeared that involvement of large pharmaceutical actors in the emerging world of nanomedicine was not yet secured. The ETP Nanomedicine, through the roadmap document, emphasized the importance of co-ordination between industry and academia through translational practices and, relatedly, of mobilizing actors from the pharmaceutical sector to participate in the world of nanomedicine.[44] According to the roadmap document:

> "The initial enthusiasm for nanomedicines research has led to significant funding for non-translatable research and manufacturing, which we can no longer afford and which unsurprisingly has not attracted industrial involvement. It is hoped that aligning research programmes with real industrial priorities will encourage the pharmaceutical sector to participate. It will be argued that this will detract from more radical nanomedicines on the longer term, but it should be born in mind that even these shorter term objectives will take over 10 years to get to patients." (p.21)

What occured anyway, and what may be important for institutional entrepreneurs' attempts to mobilize large pharmaceutical companies and legitimize nanomedicine, were changes in the drug delivery sector. The structure of the sector in terms of distribution in number and size of firms changed through a number of mergers & acquisitions. Schering-Plough acquired Organon in 2007 and Merck and Schering-Plough merged in 2009. These mergers already had consequences for interactions in the MediTrans project in which these firms were involved. Positions were taken over by new people who had less affinity with the subject and the workpackage on

[44] Also the term "open innovation" is mobilized in the roadmap document.

industrial exploitation was no longer co-ordinated by a big pharmaceutical company.[45] According to an industry observer, the consolidation process contributed to uncertainties about future research directions, which would make large pharmaceutical companies reluctant to invest in new projects such as nanotechnology enabled drug delivery technologies.[46] While large pharmaceutical companies are aware of an emerging world of nanomedicine, they appear to be observers of, rather than active players in, this world.

By 2010, the focus on translational aspects within the ETP nanomedicine started to eclipse focus on nanotechnologies and acquisition of research funding (a key driver in ETP's activities). An opinion paper by the ETP Nanomedicine, co-authored by Eaton, emphasized the importance of 'open innovation' and translational research to improve the competitive position of Europe and contribute to health care (Eaton and Weltring 2010). This forms a contrast to the ETP's vision paper which emphasized nanotechnology and nanomedicine as a way to improve the competitive position and to contribute to health care. Not only did the opinion paper place more emphasis on the process (rather than products) of innovation, but nanotechnologies were put in brackets in the title of the opinion piece. According to the opinion piece:

> "With the advent of Open Innovation the gulf between the two stakeholders [industry and academia] will become more evident and this lack of knowledge flow will seriously handicap the European science base with respect to its competitors. In fact, the lack of translatability of publicly funded European and national applied healthcare research becomes a more important issue than the level of funding itself!" (p.1)

The evolution of institutional entrepreneurship activities in, and relevant for, the drug delivery sector was shaped by attempts at constructing an emerging world of nanomedicine and orchestration of interactions via translational research practices. While I focused on the development of European institutional entrepreneurship initiatives, there are strong indications that in the United States as well initiatives emerged which promoted nanomedicine and translational research. As in Europe, these initiatives were carried out by newly organized platforms, consortia and societies.

[45] Sources: (MEDITRANS 2007b, 2010b); interview with Storm, ibid.
[46] Source: Interview with Bonhorst, ibid.

One such initiative in the US was the creation of the Alliance for Nanohealth. The Alliance claimed to be the "first collaborative research endeavor aimed solely at bridging the gaps between medicine, biology, materials science, public policy, and nanotechnology. [...] Here, the wet truly does meet the dry, where nanomaterials from the dry world are used to solve medical problems in the most important wet environment of all: the human body." (Alliance for Nanohealth 2004)

Also in the US, nanomedicine societies were launched, including the American Academy of Nanomedicine initiated by dr. Chiming Wei in 2005. According to Wei, the "association will provide the link between the academic research community and the business community in the field of nanomedicine, and help foster better global communication." (Collins 2005) However, this society did not survive. The association collapsed in 2008 when board members resigned and initiated the American Society for Nanomedicine. The president of the Academy of Nanomedicine, dr. Wei, was accused of mismanaging the association. Dr. Wei apparently also used fake credentials positioning him as a leader in the field, and incorrectly referred to nanomedicine experts as being involved in his enterprise (Johnson 2009; Zielinska 2009).

As in Europe, the notion of translation was prominent within dedicated initiatives to shape nanomedicine developments in the US. By 2006 the Consortium for Translational Research in Advanced Imaging and Nanomedicine (C-TRAIN) had adopted the term translational in its name (C-TRAIN 2010). Furthermore, in 2008 a National Science Foundation workshop was held on 'Re-Engineering Basic and Clinical Research to Catalyze Translational Nanoscience' and recommended more focus on translational aspects (Murday et al. 2009, 2008).

While the promotion of nanomedicine and translational research is similar across the Atlantic, there appear to be differences in terms of timing and involvement of actors. Clinicians appeared to have been involved in dedicated initiatives more rapidly than in Europe as they have been involved in the NanoHealth Alliance and C-TRAIN consortia since their inception in 2004 and 2006. Furthermore, at face value, the US Food and Drug Administration appeared to be more pro-active than its European counterpart, which takes a

more distantiated position.[47] Since 2008, the FDA has collaborated with the Alliance for NanoHealth (ANH) within a public-private partnership, the FDA-ANH Nanotechnology Initiative (FANTI). Also within the FANTI consortium we find a strong focus on translational research (Alliance for Nanohealth 2010).

> "The overarching goal of FANTI is to develop a framework of collaboration – that will include stakeholders from industry (pharmaceutical, biotech and devices), non-profit organizations, government and others – to work pre-competitively in identifying high priority scientific and translational gaps in moving nanoengineered medical products from preclinical stages of development through clinical stages and then to commercialization."

4.3.4 Future developments in distributed institutional entrepreneurship

What could be further developments in terms of ongoing and emerging institutional entrepreneurship initiatives shaping development and embedding of nano delivery systems? Would such initiatives reinforce the existing initiatives, further articulating an emerging world of nanomedicine by adding additional actor perspectives, mobilizing resources to overcome reluctance and waiting games, or focus on more specific rules and practices related to nanotechnology enabled drug delivery technologies? To explore this I constructed three scenarios on future developments in distributed institutional entrepreneurship linked to targeted drug delivery technologies and conducted a stakeholder workshop to assess future developments.

Each of the scenarios had a different starting point for institutional entrepreneurship activities: a group of actors promoting incremental

[47] EMEA was actively monitoring what was happening, but did not employ institutional entrepreneurship initiatives. EMEA had started several activities in the field of nanotechnology enabled delivery systems and drugs, such as collaboration with the FDA since 2006, interactions with OECD and ISO and the creation of an own nanomedicine expert group. Still, it had not pursued particular initiatives other than this expert group, meetings and conferences in order to create new rules or practices. Source: interview (together with N. Chowdhury, University of Twente) with dr. Papaluca-Amati and Boucamont, Pharm D., European Medicines Agency, 17-07-2009

developments and short term advances and a group promoting breakthrough technology developments; a platform promoting generic platform technologies; and an alliance between a knowledge institute and a set of patient organizations and foundations. Without going into too much detail, a common thread in all three scenarios was that there was no across the board uptake of nanotechnologies in the drug delivery sector. Initiatives within each of the three scenarios promoted rules and practices related to either specific types of technologies, disease areas or general requirements for translatable research. The substance of the promoted rules and practices shifted from what initiators initially planned, predominantly due to changing situations in the drug delivery sector.

The workshop participants (knowledge institutes, SMEs, and a public health organization) recognized the situation of reluctance and waiting games and appreciated the scenarios and their overall approach in terms of bringing about sector level changes. The development and stabilization of patterns linking different disciplines and actors across the sector, in particularly the connection between disease, biology and delivery systems, was considered highly important for the further development of targeted drug delivery technologies. In that sense, the establishment of translational practices in actions and interactions was regarded as a challenge in itself.

To further developments in the field of nano drug delivery it was felt important by participants to show the added value of nano drug delivery in order to convince the sector of the value of nanotechnologies. The dedicated creation of a system which could act as an exemplar in the field, demonstrating the value of nano and how this value was created, was considered to be a promising tactic to convince the sector. A contest between established drug delivery concepts was discussed as a possible strategy. The contest would stretch over a number of years in order to cover different phases of development and ending in a Phase 2 clinical trial after which large pharmaceutical companies ideally should take over. The contest would not only demonstrate the clinical value, but also be used as a way to profit from the learning experience, including passing and overcoming technical, safety and regulatory hurdles.

While a knowledge institute from the drug delivery sector could act as a co-ordinator, it would most likely need to ally or cooperate with governmental

authorities in order to mobilize sufficient resources to conduct development activities and clinical trials. The participants expected that big pharma would not be easily convinced to invest in such an endeavor. Thus, future institutional entrepreneurship initiatives would draw upon some actors in the drug delivery sector and upon others, such as governmental actors, who have broader interests and responsibilities than only drug delivery technologies. Then, also other actors must be considered, as governments are not the only source of funding; patient foundations and private capital are further possibilities. On the one hand, broadening of actors would contribute to building and filling an emerging world of nanomedicine with additional actors and actor perspectives. On the other hand it might induce more specific developments, niches within an emerging world, as additional actors will articulate which combinations of technologies and diseases should be stimulated at all. Such niches will be faced with specific challenges around concrete products, but - taken together - may go beyond the focus on general promises and translational research practices. Then, more specific institutional entrepreneurship initiatives might emerge, linked with uncertainties around sets of concrete nanotechnology enabled drug delivery systems and their future embedding.

4.4 Conclusions and discussion

What did we see in terms of institutional entrepreneurship initiatives? Initiatives were carried by newly institutionalized actors linked to the emergence of the field of nanomedicine: European Society for Nanomedicine (ESNAM) and European Foundation for Clinical Nanomedicine (CLINAM), European Technology Platform Nanomedicine and research consortium MediTrans, embedded within the European Framework programmes. [48] This is already an indication that something different is happening here than in the food packaging sector. The difference becomes clear if we examine what these initiatives actually do. Institutional entrepreneurs in the drug delivery sector foregrounded the general promise of the application of nanotechnologies to

[48] The Responsible Nanocode initiative was an instance of institutional entrepreneurship relevant for both sectors, considering the involvement of actors from both sectors. So, not al initiatives were different.

medicine rather than rules and practices associated with concrete applications of nanotechnologies as with food packaging. Drug delivery often appeared as a promising application area within nanomedicine, rather than a topic of itself – except for Meditrans. While broader debates on nanotechnologies (such as potential risks) also touched upon the world of nanomedicine and drug delivery, they did not have a strong impact on institutional entrepreneurship activities.

What is characteristic for the examined initiatives (even to some extent the Responsible Nanocode Initiative), is that they are mobilizing resources for, as well as legitimating, research and development activities linked to nanomedicine, including but not limited to drug delivery. The initiatives came from different positions in the sector (academia, industry, clinicians) and contributed, albeit indirectly, to co-ordination of nanomedicine related activities via a shared promise and identification of relevant actors; such mechanisms have been shown by Van Lente and Rip (1998) on the emerging world of membrane technology. The net effect of these overlapping initiatives is that they contributed to the creation of an emerging world of nanomedicine with drug delivery as a particular application area. It was a world they were filling in, already by the perception that they were inhabitants sharing a world, and by their institutional entrepreneurship.

Salient were attempts at establishing translational research practices, as a form of anticipatory co-ordination. Promotion of translational research contributed to building and furbishing an emerging world at the same time. It contributed to building by articulating who should be (at least) involved in this world – in this case academia, industry and clinicians. It contributed to filling in the world by articulating dependencies between these actors, and between these actors and emerging technologies' promises. What is interesting for my theme of societal embedding is that the filling in of this world went beyond immediate issues for co-ordination. It included anticipations of future societal embedding, albeit unspecified and short-circuited, as it predominantly focused on integration of nanotechnologies in business and clinical practices.

In the construction process of an emerging world of nanomedicine, sectoral dynamics relatively independent of nanotechnologies played a key role. As in my food packaging study, promises of nanotechnologies for drug delivery alone

were not sufficient to ensure embedding of nanotechnologies in ongoing research and development practices. Institutional entrepreneurs faced reluctance and waiting games, in which waiting strategies by large pharmaceutical companies, independent of nanotechnologies, played a prominent role. Institutional entrepreneurs mobilized the umbrella term 'translational research', which has become an important theme throughout the world of pharma, as a symbolic resource for overcoming reluctance and waiting games. Translational research practices were positioned as a way to bridge gaps between research in the lab and clinical application. ETP Nanomedicine, MediTrans and CLINAM/ESNAM justified their promotion of 'translational' on the basis of diagnoses of developments which were independent of, though relevant for, nanotechnologies and played at the level of the drug delivery sector. So, while sectoral circumstances such as waiting games have constrained attempts at mobilization of resources for building a new world, the umbrella term 'translational research' enabled such attempts.

The main conclusion is that, until now, the evolution was mainly carried by attempts at building and orchestrating interactions in an emerging world of nanomedicine, partly embedded in and overlapping with the drug delivery sector. The basic dynamics of building and filling in a new world were articulated through the promotion of general promises of nanomedicine and translational research practices, instead of reductions of uncertainties about embedding as in the food packaging sector. Interestingly, even if initiatives were not focused on shaping embedding of nanotechnology enabled drug delivery technologies directly, the promoted rules and practices in the emerging world of nanomedicine will affect societal embedding processes of such technologies once they are tried out and used. By then, translational research practices will have become established as a form of anticipatory co-ordination, contributing to the articulation of mutual dependencies between a variety of actors while taking into account future introduction of nanotechnology enabled products.

My analysis of institutional entrepreneurs building and filling an emerging world of nanomedicine with translational research practices identifies interesting dynamics. It shows a move towards broadening anticipation of societal embedding of nanotechnologies at a collective level. In the drug delivery sector this move is not exclusively linked to nanotechnologies as the

promoted practices apply to emerging pharmaceutical technologies in general. Still, it is significant, presently and in the future if more activities (including by institutional entrepreneurs) are undertaken. If the push toward translational research practices continues, as suggested by my workshop, future development of nano drug delivery technologies will take place in a world in which there is pressure on actors to adopt translational research practices. Translational research practices then may become a nexus between enactors and selectors of (research on) nanotechnology enabled drug delivery technologies.

The focus on general promises and anticipatory co-ordination we see in this case raises the question of whether the specific sequence of institutional entrepreneurship initiatives found in my food packaging study is indeed a general pattern. If it is, we can say that compared to food packaging, institutional entrepreneurship in the drug delivery sector is still in the first wave of promising. At the moment, further waves are postponed. Broader discourse and developments around nanotechnologies such as debates about risks and responsible innovation do not appear up front as considerations within the examined initiatives. That is, at least for now: expectations are voiced that risk debates will affect, eventually, also regulatory discussions in the world of nanotechnology engineered drug delivery technologies. Time will show whether future initiatives (if any) will be shaped by attempts to further build and fill an emerging world of nanomedicine taking into account broader debates or not.

The generic, and diffuse, character of translational research with the emerging world of nanomedicine allows me to take a further, speculative, step. As an umbrella term, here associated with the umbrella term of nanotechnologies, the notion of translational research may be transferred to other domains of nanotechnology. Actors involved in debates over responsible innovation of nanotechnologies might take up the notion of translational research and consider it as a way to fill in attempts at articulating responsible innovation of nanotechnologies. Then, translational research practices can become a general pattern in reflexive co-evolution of nanotechnology and society.

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PART 3

The following two chapters address my research question regarding dynamics in interactions in CTA workshops. Some of the data generated by the workshops were already used for my studies on institutional entrepreneurship in part 2. As another modality of anticipatory intervention (constructing a window on the world, cf. Chapter 1, Section 1.2) it deserves to be described and analyzed in detail.

I will start (in Chapter 5) by highlighting a particular part of the methodology, here called 'pre-engagement'. Preparation of CTA workshops supported by socio-technical scenarios is about more than organizing. There is 'moving about' in the domain, becoming knowledgeable about it. This enabled the analyst to develop the scenarios himself. They are input in the 'engagement' (i.e. the workshop) to support actors' assessment of ongoing developments and articulation of strategies for embedding. An important element in constructing the scenarios is the use of anticipatory intervention (including institutional entrepreneurs) as a starting point for a scenario to unfold. In each of the three scenarios the intervention starts at a different level, and the story takes into account sectoral circumstances and broader nanotechnology developments.

In chapter 6 I will discuss interactions in the workshops (the actual engagement of CTA agents in the world of the stakeholders. CTA agents do more than analysis and organization; to emphasize this, I use the terminology of (CTA) agents). Process dynamics are set in motion, with the aim, broadly formulated, of stimulating reflexivity in co-evolutionary processes. Examining workshop interactions provide insights in dynamics in actors' assessment of, and anticipation of societal embedding of nanotechnologies within the context of a CTA-type anticipatory intervention. I will also ask whether there are emerging patterns.

Chapter 5

Constructing productive engagement: Pre-engagement tools for emerging technologies *

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Constructing productive engagement: Pre-engagement tools for emerging technologies

Haico te Kulve & Arie Rip[1]

Abstract. Engagement with stakeholders and civil society is increasingly important for new scientific and technological developments. Preparation of such engagements sets the stage for engagement activities and thus contributes to their outcomes. Preparation is a demanding task, particularly if the facilitating agent aims for timely engagement related to emerging technologies. After identifying requirements for such preparation we present two complementary tools: multi-level analysis and socio-technical scenarios, and indicate their basis in the literature. We use the case of nanotechnologies in the food packaging sector to demonstrate (in outline) how these tools work. In the conclusion we reflect on the role of organizers of engagement activities, especially in light of recent policy demands for responsible innovation.

Keywords: engagement, pre-engagement, multi-level dynamics, anticipatory co-ordination, nanotechnology, scenarios

Introduction

Engagements between promoters of new science & technology and other stakeholders and civil society actors so as to broaden decision and policy making processes have attracted considerable attention both inside and outside academia. Such attempts have been criticized for inadequate timing [1, 2]. Engagement is often organized only after a particular issue has emerged, when it may be too late to make a difference. However, engagements in early stages of technology developments need to grapple with uncertainty or even ignorance about possible impacts of new technologies [3].Whatever the timing

[1] An earlier version of this paper was presented at the annual meeting of the Society for Social Study of Science (4S) in Montreal, Quebec in October 2007.

of the engagement, it requires pre-engagement activities to help mitigate the dilemma between early engagement, which is full of unknowns, and late engagement, when socio-technical developments are already entrenched. A key point is that merely organizing and moderating stakeholder interactions is not enough. Engagements must be about substance, which requires preparation. This is a challenge in its own right: pre-engagement.

Pre-engagement activities include of course an organizational component such as inviting people and setting up a location. But they have to enable anticipation in a situation which is full of uncertainties: whether expectations for new technologies will materialize, how they might be integrated into value chains, which regulatory measures may obtain, and the nature of broader societal acceptance. To support such anticipation, analysis of ongoing societal and technological developments is necessary—drawing on science and technology studies and innovation studies. Also, some reduction of the complexity posed by uncertainties and ignorance is necessary to facilitate deliberations between stakeholders. A further point is then that reduction of complexity needs to be open-ended to take the fluidity of the situation into account and to avoid biases regarding (selection of) particular options. This is where socio-technical scenarios play an important role.[2] Such pre-engagement activities will improve the quality of the actual engagement: interactions can be more productive, participants can be enabled to articulate strategies, and reflexivity can be enhanced. This sets the scene for better outcomes. And it can be adapted to the nature of the situation and the timing of the engagement. While the challenge of intervening at a moment when it is still possible to modify the course of developments remains, it can be addressed concretely.

Requirements for pre-engagement

A recent evaluation of nanotechnology engagement projects in the UK suggests that pre-engagements have an important role in early-stage engagement

[2] The first *Yearbook of Nanotechnology in Society*, chapters of which we refer to in [4] and [5], discusses a variety of scenario approaches. See also [6] on preparation for engagement workshops and the importance of linking up - though not to identify - with perspectives of nanotechnology advocates.

activities [7]. In the UK, the idea of upstream (public) engagement has been developed as a response to the issue of timely engagement [1] and nanotechnologies, whose future shape and societal embedment are quite uncertain, are an obvious target. The evaluation argued that the upstream engagement projects contributed to improved mutual understanding between scientists and members of the public. One criticism was the lack of clear links with nanotechnology policy and decision making processes. The report authors argued that this was related to the lack of a clear strategy (of the UK government) about what to do with the public engagement activities and they offered several recommendations to overcome this problem, including more focus on purpose and outcomes of engagement activities and more involvement of decision-makers.

While the UK evaluation recommended requirements for public upstream engagement projects in order to improve their outcomes, it glossed over how to realize such requirements. The diagnosis was that the upstream projects were non-committal exercises, and this was linked to a relatively low degree of structuring of engagements in terms of objectives, issues at stake, and involvement of actors with sufficient agency to make a difference. We add that there is a role here for engagement agents, i.e. individuals and organizations orchestrating engagement activities, who are not immediate stakeholders or otherwise seen as partial. Such engagement agents have to prepare, as we do, and develop tools to do so, when organizing Constructive Technology Assessment (CTA) workshops [4, 6]. In general, a key point is the degree to which socio-technical developments have become articulated and are embedded in actors' activities, because this defines how much structuring of engagement activities is embedded in the situation already and how much must be constructed by engagement agents.

A further point is that timely engagement with emerging technologies and their development and embedding in society entails an action perspective for the engagement agents. For CTA, this has been formulated as CTA agents having a second-order goal: not the first-order goal of realizing or criticizing technology X (which is what they enable actors to do), but to enhance reflexivity of the overall development [8]. This prepares the ground for an outline of requirements for pre-engagement activities, i.e. "timely" analysis and structuration of actor's interactions.

First, understanding is required of the emerging science & technology and its dynamics, especially the various expectations and emerging/partial path dependencies which can be seen as 'endogenous futures' [4]. Tools to do this are by now available—see for instance [9]. We note that such tools are particularly suited for midstream engagement [2, 10], where some articulation has occurred already, but where developments are still open-ended and relatively malleable.

A second requirement is to assess actor's propensities to anticipate future societal embedding of new technologies [11], and to coordinate their activities with those of other actors. There are clear differences, for example between Monsanto's refusal to interact with civil society groups about their genetically modified product development, and DuPont's willingness to cooperate with Environmental Defense to formulate a risk framework for nanomaterials. There are also differences in willingness to engage in anticipatory coordination. The semi-conductor sector practices the long-standing and authoritative tradition of the International Technology Roadmap for Semi-Conductors and is now making attempts to address new developments "beyond Moore's Law." In contrast, in the food and food packaging sector (which we discuss in some detail below), the opportunities and risks of emerging nanotechnologies are only incidentally taken up in consultation and concertation activities. It is thus clear that, although important, more is at stake than willingness to enter into a dialogue (or multilogue) with other actors. The propensities to be assessed play a role in the further development and societal embedding of the technologies.

A third set of requirements concern how to select and locate actors, which is linked to the envisaged orchestration of interactions during the engagement. Participants can be chosen on the basis of demographic or professional characteristics, but also on the basis of their role – or for that matter, lack of a role – in the socio-technical dynamics. For example in food packaging, retailers have a powerful position in the market introduction of new products, so they must be included in engagement activities.

Fourthly, broader developments that may not always be visible to the various actors have to be taken into account. Consider the role of parties which are not directly involved in technological developments and their embedding in society, but which may still exert influence. Insurance companies are a good

example: they are driven by financial interests, but their requirements for offering insurance coverage can include requirements on the technology. And they can become pro-active, as when Swiss Re in 2004 issued its report on risks of nano-particles, which transformed an earlier contested issue into a legitimate concern [12]. Another example is how articulation and integration of ethical, legal and societal aspects (ELSA) in technological development trajectories (first introduced in the Human Genome Project (since the early 1990s, as a separate funding line in the budget but not really integrated in the Human Genome Project), is becoming a real concern, especially for nanotechnology. Incipient institutionalization is visible in articulation of codes of conduct fostering responsible innovation, and the engagement of big firms in dialogues with stakeholders.

We shall discuss nanotechnologies for food packaging applications to illustrate how these requirements can be addressed in a particular case. The first step, however, is general: the importance of analysing multi-level dynamics, where actors and their practices interact with sectoral dynamics including evolving industry structures, and how these dynamics co-evolve with more global developments. By now, this type of analysis is well-established in science, technology and innovation studies [13, 14], and it can be extended to cover societal embedding of emerging technologies [9]. Also, on this basis socio-technical scenarios can be constructed.

Multi-level dynamics in societal embedding processes

Engagements aim to gather a heterogeneous set of actors with different socio-cognitive perspectives (as Garud and Ahlstrom [15] emphasized) and to elicit, and deliberate on, views and activities related to developments in a particular domain of science & technology. The broader goal of such engagements is to improve processes of societal embedding and their outcomes. Thus, some (anticipatory) co-ordination of current and future activities is in order, and pre-engagement should stimulate and support that. To do so, we take a closer look at what we call alignment between actors and activities.[3]

[3] Fujimura's [16] analysis of how researchers construct 'do-able problems' through alignment work (articulation tasks) is interesting for us, because it takes the multi-level nature of the situation into account and takes alignment as alignment across levels. Her

In their analysis of societal embedding and product creation management Deuten *et. al* [11] first characterize societal embedment of new technologies by three dimensions: "integration' in relevant industries and markets, 'admissibility' according to regulation, and 'some degree of acceptance' by the public [11, p.131]. Then they point out that there is a structural problem in the development of alignments related to new technologies and products, which derives from the way technology developers and managers adopt a concentric view on their environment (cf. [12]): first comes the business environment, then regulation environment, and lastly, wider society. These environments are then addressed sequentially rather than simultaneously, so alignments with the wider society are developed at a late stage. When problems for example with public acceptance become manifest they will be difficult to resolve. Deuten *et al.* [11] make the general claim that ongoing anticipation on societal embedding is required in addition to product development, whether such anticipation includes public engagement or not.

Societal embedding of technologies requires alignment work anyhow. The outcomes of such alignment processes may be unintended. Alignment refers to the eventual entanglement of actors and activities so that there are mutual dependencies; they cannot move completely independently. Alignment also implies that there is some mutual accommodation, like parts fitting together, creating a configuration that works – which *de facto* steers actors' activities and interactions in certain directions. Anticipatory co-ordination can now be positioned as (1) the development of linkages, up to alignments, between levels of activities that (2) take into account the prospective development and introduction of new technologies.

Alignment processes across different levels of activities are visible in the world of nanotechnologies. Entrepreneurs mobilize resources for novel research and product development activities and draw upon expectations about wonderful benefits in order to legitimize such investments. When entrepreneurs mobilize allies and financial resources, they create novel linkages between envisioned outcomes of research activities as well as expected contributions to societal

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approach is concentric, however, focusing on the research actor making her research doable by aligning the experiment, lab, and wider social world.

issues or problems.[4] Entrepreneurs may themselves be constrained by linkages they created during their mobilization activities. In their study of the development of a nanotechnology research cluster Mangematin *et al.* [18] argued that entrepreneurs create momentum, and when achieved, it carries them on.

Alignment across levels is of interest because it introduces a particular form of stabilization: if actors appear to move in other directions and might actually be able to do so on their own level, they will now be constrained by the links to another level with its own dynamics. A simple example would be research practices constrained by rules of funding agencies and programmes to be conservative and/or follow certain directions. In other words, activities at a particular level are shaped by dynamics at that level, but also through alignments with, and thus dynamics of, other levels.

Actors who can work at more than one level are important for eventual alignment. They act as 'linking pins' between levels of activities. A venue for inter-level interaction which will be visible in our case study, are forums and in general, spaces in which actors active at different levels can interact and try out new linkages up to alignments. Dedicated alignment actors include promise champions circulating expectations and building agendas [19]; network builders enrolling new actors [20]; and institutional entrepreneurs establishing new rules such as standards [21]; meanings, and practices related to new technologies [22]. We will use these entrepreneurial activities as one entrance point to map multi-level dynamics in our case of nanotechnology and food packaging.

Entrepreneurial activities will also form the entrance point for the second pre-engagement tool: socio-technical scenarios. Scenarios fulfill a double role. Firstly, they are useful to facilitate deliberations between stakeholders and to assess future developments in multi-level dynamics and possible developments in (attempts at) anticipatory co-ordination. Not as a mere extrapolation of trends, but in terms of shifts and branching of developments starting from the present situation and its dynamics [23]. Scenarios can foreground alternative

[4] Abernathy and Clark similarly emphasize how the advent of an innovation entails obsolescence of earlier technological capabilities and customer linkages, and the need to create new capabilities and linkages [17].

futures as such, but for pre-engagement it is more important to explore what may happen when actors at one level, or across levels, get involved in *de facto* alignment activities.

Secondly, scenarios of future developments show possible worlds. Thus, they can be used to identify actors and dynamics that were not very visible in the mapping exercise. They also highlight what might be at stake in a particular domain and what are possible societal and ethical dilemmas. During engagement activities, the scenarios themselves can be offered as playgrounds where (anticipatory) co-ordination and alignment can be explored virtually by the participants.

Nanotechnologies for food packaging: three scenarios

An interesting case for the approach we have sketched is the food sector, where high expectations regarding the application of nanotechnologies abound, but firms are nervous about possible backfiring of such applications. Within the sector, food packaging is expected to take the lead in the application of nanotechnologies. At first sight, the application of nanotechnologies for packaging applications appears as less controversial compared to food ingredients designed and developed with nanotechnologies. However, concerns are already voiced on issues such as environmental impacts of (silver) nanoparticles and reliability of sensors indicating food spoilage.

In our mapping we draw upon European and North-American sources and do not focus on possible regional differences. To demonstrate our approach, an overall picture of the uptake of nanotechnologies in the food packaging sector is sufficient. For specific engagement exercises more contextualization is necessary to account for regional differences and local circumstances.

Packaging is an omnipresent technology where a wide variety of materials are used in different forms and shapes from basic material such as wood, plastics, textiles, paper and paperboard as well as additional materials such as inks and glues [24]. The value of the production of packaging materials alone is estimated at 400 billion euros: food packaging itself accounts for 35% [25].

The food packaging sector is an intersection of food and packaging filières [26], with several additional actors including research institutes, regulatory agencies and NGOs (see also [27]).

There is ongoing research on the development of nanotechnologies for packaging applications. For example on nanocomposites such as on kaolinite clays [28] and bio-nanocomposites [29] to improve barrier properties, antimicrobial properties of nanosilver particles [30], sensors that can detect food spoilage or existence of pathogens [31, 32] and nano barcodes to authenticate sources of products [33]. A few nano enabled food packaging technologies are being introduced on the market such as nanocomposites for plastic packaging [34] and food containers containing antimicrobial nano particles [35]. Actors believe there are many unexplored possibilities.

Mapping multi-level dynamics

Development of nano food packaging discourse

Expectation dynamics are an important aspect of emerging technologies [36] and are visible in articulations of potential benefits and uptake of new technologies. In the case of food packaging, industry observers expect that "nanotechnology will change 25 per cent of the food packaging market [..] in the decade to follow." [37] Nanotechnologies are expected to contribute to the preservation of food through enhanced packaging technologies.

Roadmaps are a way to articulate and specify expectations, and are often used. The roadmap initiative of the Dutch quasi branch association for micro- and nanotechnologies MinacNed [40] in its context functioned as a temporary space, a forum which facilitated the development of linkages through the articulation of necessary alignments between macro-level discourse on benefits of future technologies and micro-level research activities. At the same time, the drawing up of such a roadmap is an attempt to mobilize resources and co-ordinate future activities. The presentation of the roadmap at a seminar was accompanied by a call from the organizers to form consortia to implement the roadmap.

A second aspect of the discourse derives from the general phenomenon that the development of new technologies is subject to proponent- opponent controversies [38] and expectations of future benefits are accompanied by expectations of possible risks. Actually, such controversies are now expected by proponents and can lead to fear of possible fears, in some cases up to 'nanophobia phobia' [39]. In the case of nanotechnologies for food applications: "The food industry is hooked on nano-tech's promises, but it is also very nervous" [40]. Indeed, some concerns are now voiced, for example by Friends of the Earth about the use of nanosilver particles for antimicrobial packaging [41].[5] The MinacNed roadmap [42] and food packaging experts interviewed within the Nanologue project [43] also voiced scepticism regarding the profitability of investments in nanotechnologies for food packaging related to the costs of new nanomaterials.

Research and development of nanotechnologies does not appear as a high priority on the food packaging sector's agenda. Early attempts by linking-pin entrepreneurs, such as Kraft who initiated the Nanotek Consortium in 2000, have shifted to the background. Kraft has reduced its visible involvement with nanotechnologies through relabeling the consortium and its replacement by a new sponsor, Philip Morris USA [44]. Sustainability is the buzzword now in general packaging conferences such as the Packaging Summit Europe 2007 and Intertech-Pira's Sustainability in Packaging 2007. Consortia such as Sustainpack have been formed that foreground sustainability aspects of new packaging technologies. They do formulate expectations of future nano enabled packaging technologies which reduce packaging waste and improve useful packaging properties [45, 46]. Thus, if nano R&D and product development will be stimulated, it will be through this detour, rather than dedicated alignment.

Development of rules and regulations

Rules and regulations are important for development and uptake of new packaging technologies. In addition to explicit, formal regulation there is also

[5] The concerns of Friends of the Earth are part of a broader controversy on the use of nanosilver particles in consumer products. For instance the use of nanosilver in washing machines and the decision of the US Environmental Protection Agency to limit regulation of nanosilver particles to washing machines have stirred debate (see also [41]).

de facto regulation on the level of the sector, as when retailers stipulate requirements [27]. At this moment, specific regulation of nanotechnologies and food (packaging) is still in an early phase [47] and opinions differ whether existing regulation is sufficient [48, 49]. One of the attempts to bridge the gap was the launch of a voluntary reporting scheme by the UK government [50]. Interviews with researchers and companies by Nanologue pointed out that large retail chains are considered to play a decisive role. They are seen to "determine the diffusion of NT-based applications for food packaging on the market" [43, p. 25]. Thus, in food packaging, a waiting game occurs: regulators wait for firms to introduce nanotechnology enabled products and firms wait for regulators to clarify regulations for nanotechnologies before they allocate resources to research and product development activities.

Development of socio-technical networks

In food packaging, co-ordination of actors' interests in product development activities is a challenge as there is no single end user. Brand owners, retailers, distributors, consumers, waste managers may all set different requirements to packaging technologies.

The development of collaborations between actors at different locations, and hence novel linkages between levels, is made difficult by the fragmentation of the sector and by competition. With exception of paper and cardboard based packaging technologies, food packaging has a relatively low degree of vertical integration and downstream signals may not always reach upstream players [25]. Moreover, the development of nano food packaging "requires collaboration between the different organizations involved, which is somewhat of a new concept for an industry that is highly competitive and consequently has the tendency to be very secretive" [51]. Thus, because of the sectoral structure, the propensity of actors to invest in anticipatory co-ordination and the emergence of actors that act as linking pins, will be low. Collaboration in the case of nanotechnologies is even more challenging because nanotechnologies add an additional domain of knowledge and skills to the development and production of packaging technologies [42]. New networks to develop nanotechnologies for food appear to be still at an emerging stage according to an analyst of Pira International [34].

This brief mapping demonstrates the first pre-engagement tool. The mapping shows the challenges for (linking pin) entrepreneurs and fora when attempting to develop new linkages between activities. The mapping provides the pre-engagement agent with a baseline and insight in dynamics from which scenarios can be developed.

Three scenarios of future developments in anticipatory co-ordination

The starting point for the scenarios is the current situation in which research on nano food packaging applications occurs in a few places, predominantly research institutes and big firms. Articulation of regulatory aspects as well as possible benefits and risks for both firms and consumers is still relatively underdeveloped. Based on our overall diagnosis of how alignment occurs, we distinguish three possibilities and develop each in a separate scenario: (1) no cross-level activities and attempts at anticipatory coordination; (2) top-down activities by government, reducing strategic uncertainty by introducing some regulation; (3) meso-level activities of linking-pin entrepreneurs animating platforms.[6] Our scenarios show that the development and subsequent embedding of nanotechnology in food packaging increases from the first to the third. Of course, in the real world, all three dynamics might occur to some extent and create a patchwork outcome. The scenarios should not be seen as mutually exclusive alternatives.

Scenario 1: "Little Nano" (limited development of nano food packaging). Research institutes recognize the apparent impasse in the development of nano food packaging, but are not pro-active in trying to change this situation as they do not consider it as one of their tasks. Individual researchers as well as institutes anticipate on being increasingly held accountable of valorisation of research in the context of international economic competition, and on the dissatisfaction among policy makers and industrialists about short term valorisation of research. They attempt to meet such requirements by shifting their research, and do not focus on the often highly uncertain long term promises of nanotechnologies, especially for active and intelligent packaging purposes. By orienting research objectives this way, fewer resources are left to

[6] These scenarios were presented already in [4]. In the meantime, they have been developed further in preparation for a scenario workshop.

allocate to investigations of more long term nano food packaging. Big promises of nano enabled food packaging fade, and discussions of their possible impacts seem irrelevant. Firms appear to be content with this situation.

Scenario 2: "Regulation Helps" (regulation supports development of nano food packaging). Societal debates on the desirability and risks of nanoparticles continue, relatively independent of ongoing research and development activities of nano-technologies for food packaging and attempts to mobilize resources. Food regulatory agencies are under pressure from policy and NGOs and initiate actions to assess and regulate nano-related health, environmental and safety risks. Existence of regulatory schemes is expected to influence consumer (and thus retailer) confidence, which lowers barriers to develop nano food packaging including the effort to meet regulatory requirements. For SMEs and start ups regulation is an additional burden, however, and because of their narrow product portfolio they are more vulnerable to an eventual controversy over risks and side-effects. The big firms welcome their new competitive advantage, and proceed – cautiously – with the development of nano food packaging products.

Scenario 3: "Thresholds are passed" (broad platforms support development of nano food packaging). Nanotechnology research entrepreneurs and some industrialists act as champions and 'linking pins' for nano food packaging and are able to create a few nano-platforms, despite residual reluctance because of concerns of risks and negative consumer perceptions. The big step is that some critical NGOs were persuaded to participate, with the argument that this allows them to make a difference in shaping future technologies. Firms expect that participation of NGOs, taken as spokespersons for civil society, will help legitimize future products. Then, with additional involvement of, and support by, governmental agencies, a broad platform for the development and introduction of novel food packaging products is created which acts as a forum linking activities at different levels. Pharmaceutical companies, linked because of the blurring of boundaries between the food and health sector, join the platform when promising results of improved packaging properties become visible. The involvement of pharmaceutical packaging suppliers adds to the momentum of the development of novel nano enabled packaging materials by creating economies of scale.

We have reduced the three scenarios to their outlines, which is sufficient to indicate the approach. To prepare for a concrete engagement activity, more detail is necessary, including reference to actual actors and activities. Such detailed scenarios have been made for other cases, and used in engagement workshops.[7] The detailed versions of the three scenarios for nano food packaging will be used in an engagement workshop planned for early 2009.

Discussion

Our case of food packaging demonstrates how engagements can be prepared for through multi-level analysis and scenarios. The multi-level mapping adds to understanding of dynamics in the domain such as how dependencies between activities at different levels are shaped by rules of the game in the food packaging sector, but also by expectations of new nano enabled applications and attention for sustainability issues of packaging. Through mapping ongoing activities an overview of (emerging) networks attempting to co-ordinate development of nano-enabled packaging is created. More importantly, dynamics that enable and constrain such attempts at co-ordination can be mapped, including the present waiting game. This mapping is employed to select and position participants and orchestrate interactions in a workshop. It is important to select participants from different positions in the food packaging chain as well as from different levels of activities, in our case material suppliers, brand owners, research institutes, regulators, NGOs and in particular retailers which are expected to act as gatekeepers. In addition, one can identify presently invisible actors, and that is where detailed scenarios play a role, because they sensitize us to which further actors might get entangled and make a difference. The trend towards convergence of food and health is a case in point which we discussed in scenario 3 through the involvement of pharmaceutical packaging suppliers. In addition the scenarios can be used to explore when broader societal aspects are likely to be articulated. In the case of food packaging we speculated that broader issues are more likely to be

[7] See for instance engagement workshops including scenarios/imaginaries in TA Nanoned projects [4, 6], in NanoSoc [5], NanoBioRaise [52] and in a project on genomics [53].

articulated when a broad platform is constructed. An overview of how the case study fulfills pre-engagement requirements is given in Table 1.

Pre-engagement requirements	**Items considered in the case of food packaging**
Understanding of socio-technical dynamics in the domain	• Focus on development of immediately useful technologies such as nanocomposites. • Expectations of beneficial packaging properties, but also of unprofitability and public backlashes • Nanotechnologies no high priority on food packaging sector's agenda, sustainability as buzzword
Estimation of actors' propensity for anticipatory co-ordination	• Waiting games • Emerging consortia and networks • Anticipation on customers' preference for sustainable packaging, cf. Sustainpack program
Selection and location of actors	• Retailers as gatekeepers • Importance of co-operation across the chain
Assessment of broader dynamics	• Linkages between food and health sector: involvement pharmaceutical packaging suppliers • Attention for health, environmental & safety aspects, less for issues like reliability and social inequality

Table 1: Pre-engagement requirements in the case of food packaging

There is more to say. The scenarios will also function as support for deliberations, making the discussion more concrete. In such discussions the scenarios may be modified so that actors recognize themselves and the issues at stake for them – and others. A next step in such a workshop would be to collectively design linkages between various levels of activities. The workshop then becomes a temporary forum, a space in which prospective alignments can be explored and tried out. The composition of the workshop participants is then an important aspect, but also how the workshop is located, for example in relation to an existing network or branch organisation. And of course, whether there is something at stake in the domain, already visible for most of the participants, or recognized by them when following the scenarios and/or listening to the contributions in the workshop.

Engagement activities can be organized with different goals, depending on actors' perceptions of what is at stake. Governmental agencies and firms may organize engagements in the context of roadmapping which is focused on emerging technological paths rather than their embedding in society. Such roadmapping exercises benefit from adding multi-level analysis and scenarios as this broadens anticipation through taking explicitly into account what might happen during societal embedding of new technologies.

In CTA, the general goal of engagement activities is to stimulate learning and to broaden decision and policy making processes. Engagement workshops are only one element in such processes, but evaluation of the workshops that have been held shows that some broadening and use of new insights occurs [6]. The goal of broadening is also visible in the responsibility of the engagement agent. Our scenarios started with a situation where actors waited for each other to make the first step. The objective of an engagement project could then be seen as to break through the waiting game, and this is definitely how promoters see it. We add that this should be done in a responsible way: by anticipating on broader societal aspects as these products are introduced, such as environmental assessments of disposal of packaging products and reliability of improved shelf dates. The engagement agent thus has the task to make sure that such broadening is part of the scenarios.

It is clear that through engagement activities, the organizers may help to set things in motion or solidify ongoing developments - effects which themselves require critical examination, for example by considering tensions, conflicts, and what (and) who may be excluded.

Van Oudheusden (this issue [54]) formulates a general call for more attention to power dynamics as engagement outcomes may reflect dominant positions and frames rather than stimulate genuine mutual engagement and learning. While the sentiment is fine, the formulation is too simple. Framing and dominance occur anyway as group dynamics partly shape what actors say and are prepared to say during engagement events. In a reflexive vein, we note that engagement agents, like the participants, are embedded in a broader world of actions and interactions and are limited in what they can do. They need to negotiate with sponsors of the exercise about the substance of the activities, but also with participants. Engagement agents are one among many actors

attempting to shape interactions and to create and orchestrate temporary forums for (heterogeneous) interactions.[8]

Being a player in the games, who happens to be also the organizer of an engagement exercise, introduces further complexities. When organizers carefully analyze and position various ongoing dynamics in order to stimulate debate and reflexivity among participants, they might also include themselves and their strategies in the analysis and scenarios. In this way, the organizers at least reveal their agenda and strategies, which can, like the roles of the other actors, be discussed during the workshop.

Generally, scenarios can be used to 'play' with conflicts and tensions and see how they may work out. Tensions are linked to views and dependencies, and embedded in overall dynamics. Making them visible to participants will foreground a patchwork of power gradients — that is how the call from Van Oudheusden can be addressed productively.

Clearly, engagement agents should not get away with positioning themselves as 'mere facilitators' who are focused only on improving their analyses and approaches. The CTA goals of broadening and increasing reflexivity require facilitating, but with some own pro-active role. Our earlier remark about facilitating further developments, but in a responsible way, was an example. For engagement exercises about nanotechnology it links up with the present emphasis, at least in policy documents, on responsible development of nanotechnology. This creates recognition for the importance of broadening, and in that sense makes life easier for us. There is also an analytical responsibility, however, to position this trend of responsible innovation in dynamics and face value. This may lead to the identification of relevant but up till now invisible actors, and invite them as participants to the exercise. Such a pro-active role can be characterized, in terms of our multi-level analysis, as organisers become linking-pin entrepreneurs themselves, with their own socio-political agenda.

[8] One of our anonymous reviewers suggested this reflexive point.

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Chapter 6

CTA workshops for the domains of food packaging & targeted drug delivery

6.1 Introduction

CTA workshops act as probes into force fields in a domain of technology. They provide an occasion for the analyst to learn about ongoing and future dynamics in embedding processes in a particular domain of technology. I already used data generated from the workshops for a prospective analysis of future interventions (in Chapters 3 and 4). At the same time, the workshops are part of 'anticipatory interventions' by CTA agents who aim to support actors' reflexivity with respect to societal embedding. In this chapter I will offer details and analysis of dynamics in actors' anticipations on societal embedding of nanotechnologies within the setting of a CTA workshop.

The CTA workshop is a micro cosmos which reflects parts of the macro cosmos, in this case a sector of industry, through participants' interactions and their assessments of the force fields in which they find themselves. The workshops provide a space in which actors with different socio-cognitive positions, summarized as enactors and comparative selectors, can interact. Thus, the temporary space is a bridging event, and is designed as a bridging event. Within this general framing, my CTA workshops are tailored towards stimulating actors' anticipation of embedding through broadening and enriching actors' assessments of ongoing dynamics, and actors' articulation of possible embedding strategies. Facilitating interactions, especially mutual 'probing', between enactors and selectors is one of the mechanisms. At the same time, interactions between enactors and selectors offer insights into what is happening in a domain.[1] Supported by careful preparation – pre-engagement – CTA workshops then provide a 'window on the world' to the participants; their world as it is, and might be in the future.

Analysis of interactions in the workshops provides building blocks for an assessment of current and emerging patterns in embedding processes at the meso level, at a particular stage of the development of the technologies. A proviso needs to be made. Patterns as apparent in interactions may to some extent be an artifact of the workshop, as actors' articulations of nanotechnologies and societal embedding will be stimulated during the

[1] That is, of course, also dependent on what participants can and are willing to say.

workshop. On the one hand, the articulations in this micro cosmos will offer a view of potential developments in the domain. On the other hand, the temporary (and protected) space of the workshop will not fully reflect the force fields in the macro cosmos. Still, the patterns that are found in actors' articulations and their assessments of force fields affording actions, offer good indications. One reason is that participants probe into or comment on each other's positions and considerations.[2]

The main research questions in this chapter are: (1) which dynamics do participants in a CTA workshop take into account when articulating nanotechnologies and societal embedding? (2) What do we learn about participants' positioning in terms of enactor and selector perspectives on anticipation of societal embedding in the domains of food packaging and drug delivery? I will begin by discussing the set-up of the workshops, including preparations and analysis. As I argued in my chapter on pre-engagement, to achieve the aims of a CTA workshop, preparation through detailed analysis of ongoing dynamics and the development of scenarios is important. Such preparations then provide a point of departure for the design of the engagement activities and help to understand interactions during the workshops.

6.2 Workshop design and methods

6.2.1 Workshop set-up

To elicit actors' perspectives on societal embedding and to stimulate broadening of anticipations of embedding, the workshops were designed with the aim of discussing two themes: (1) identification of challenges, opportunities and directions for development of nanotechnologies in the sector; (2) identification of ways to cope with challenges and opportunities of

[2] Clearly, anticipatory competences of actors and their assessment of force fields are not fully dependent on the workshops, even if workshop interactions will contribute to further development of anticipatory competences and their knowledge about the domain.

nanotechnologies. The workshops were set up as two rounds of discussions on these themes in which participants were invited to respond to these themes and to react on, and ask questions to, the other participants.

The workshop themes had an open-ended character in order to simulate actors to articulate linkages between nanotechnologies and aspects of societal embedding. This was partly intentional and partly unavoidable considering the emergent character of the application of nanotechnologies in the food packaging and drug delivery sectors. It was intentionally open-ended in order to allow for open discussion and prevent too early lock-in to particular options or strategies. This is congruent with a general CTA objective to foster 'open-ended learning'.

Some reduction of the open-ended character of the two discussion themes was important in order to have a productive meeting and attract participants. The participants received a preparatory document which justified and framed the meeting. While the set-up of the workshop as an assessment of force fields in a domain of technology may stimulate actors to think and talk about broader aspects, it is also challenging for both actor and analysts. For actors it may be neither a common, nor interesting, perspective. For analysts such as myself, conducting CTA workshops is a balancing act between pursuing research objectives and placing oneself in potential participants' shoes. To some extent it is required to link up with enactor/selector perspectives, although analysts should not identify themselves with these perspectives. To link up with enactor/selector perspectives, the document identified challenges in societal embedding of promising nanotechnology enabled technologies and elaborated the two themes of the workshop. The document assumed that the exploration and possible exploitation of the application of nanotechnologies, including development of possible strategies, was of interest to the participants.

The document contained: (1) a program of the meeting; (2) a short introduction into and justification of the topic of the meeting; (3) a brief analysis of the current situation of development and embedding of nanotechnologies for food packaging or drug delivery; (4) the presentation of multi-level scenarios; and (5) a list of identified dilemmas when strategic choices about development and societal embedding of nanotechnology enabled technologies have to be made. The document aimed to create common ground

for participants, and offer ideas for discussion. In particular the scenarios and dilemmas were offered as ways to think about future developments and strategies. We emphasized that the scenarios were controlled speculations. Participants were invited to modify and add to the scenarios.

In the design of the workshop not only the substance of the deliberations was important, but also the setting and composition, such as type of actors involved; see also Van Merkerk (2007). I organized the workshops in co-operation with branch organizations. Branch organizations operate at the sectoral level and could thus contribute arguments and interests that occur at this level. Their involvement reinforced the sectoral-level focus of the workshop. Co-operation with branch organizations was expected to be – and in my experience indeed was – also helpful in organizational issues such as inviting, and then convincing, actors to participate.

Finally, to stimulate an open discussion and overcome possible concerns regarding confidentiality, the workshops were held under the 'Chatham House rule'. This rule is as follows: "When a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed" (Chatham House 2010). By adopting this workshop rule, we aimed to create an informal atmosphere and stimulate an open discussion. The quotations in this document are anonymized, and used with permission of the participants.[3]

6.2.2 Workshop preparations

The preparation consisted of two components: (1) activities in order to fulfill pre-engagement requirements such as through conducting research into the domain and developing scenarios; (2) preparation of the overall workshop process, including before and after activities such as collaborations with branch organizations, preparing input documents for the workshops themselves, and interactions with participants and actors potentially interested in participating in the workshop.

[3] As the workshop language was Dutch, the quotations were translated into English.

Mapping of dynamics linked to nanotechnologies and the food packaging and drug delivery sectors was completed by analyzing relevant reports, papers, conducting interviews and attending conferences. Interviews were conducted with experts in the field in order to map opportunities, challenges and dynamics. In addition, interviews were used to find out about existing activities to develop new framing conditions, rules and practices and attempts at co-ordination with respect to nanotechnologies. Also, questions about institutional entrepreneurship were pursued; see chapters 3 and 4 on institutional entrepreneurship in the food packaging and drug delivery sectors.

The preparatory document including the scenarios was written in collaboration with the workshop moderator, Arie Rip, and with input from the branch organizations. The scenarios were based on the multi level approach outlined in chapter 5. We also aimed to make the document attractive to read for the participants. It had to be read by the participants if a common ground were to be obtained.

The workshops themselves were moderated by Arie Rip, an experienced moderator of CTA workshops. In addition to myself, in each of the workshops an observer was present to observe interactions and non-verbal communication. The workshop discussions took about three and a half hours and were recorded and transcribed.

I also held two rounds of short interviews by phone in order to familiarize myself and the moderator with the participants and, afterwards, evaluate the workshop with the participants.

6.2.3 Analysis of the workshop

Compared to other forms of data collection, workshops, like focus groups, have as their distinguishing feature the opportunity to analyze interaction. For focus group discussions, Kitzinger argued for the “overt exploitation and exploration of interactions” to highlight participants’ “attitudes, priorities, language and framework of understanding”, to “provide insight into the operation of group/social processes in the articulation of knowledge (e.g. through the

examination of what information is censured or muted within the group)" and to "explore the arguments people use against each other" (1994, p. 116)

To analyze the workshop I focused on stretches of interactions during the workshop; see also analysis of workshops in the dissertation of Douglas Robinson (2010). l examined two types of interactions: (1) sequences in which actors' were probing each others' worlds; and (2) sequences in which arguments of a participant were further articulated by providing additional aspects or actor perspectives.

In the analyzed stretches of interaction I am interested in what participants take into account when articulating nanotechnologies and aspects of societal embedding. That is, what is left out; does the workshop work as a bridging event; do we see in the interactions typical enactor/selector patterns, or are there indications of more reflexive positioning? For a bridging event, it is important that interactions occur between enactors and selectors which can be characterized as 'probing each other's worlds'. While occurrences of probing are interesting in terms of 'bridging', they also provide further insights into actors' orientations (in terms of substance and style). Probing, such as during sequences of commenting and responding to each other's statements, provides a challenge for actors to justify and elaborate on their positions and perspectives.

I will pay attention to factors such as the composition and background of participants, and patterns in the discussion, such as whether or not consensus emerges. In addition, I will briefly discuss the pre-engagement phase, which is important in itself. During pre-engagement activities, when interacting with branch organizations as co-organizers and with potential workshop participants, the analyst gains insights into dynamics in the sector and nanotechnologies. By 'visiting' a field (see also chapter 2) when preparing and organizing a workshop, through articulating and positioning workshop objectives and asking questions, the analyst learns about dynamics in the field. These insights will be building blocks for the scenarios in the preparatory document for the meeting, but are also relevant for understanding how participants may position themselves and interact with other participants during the meeting.

6.3 Food packaging workshop

After discussing the pre-engagement phase I will provide an overview of the workshop by discussing how participants articulated nanotechnologies and societal embedding issues. This overview provides the overall context in which the interactions took place, which will then be discussed in more detail in the final part of this section.

6.3.1 Pre-engagement

As has been described in the pre-engagement chapter, I addressed general pre-engagement requirements. These are specified in table 1, reproduced from my pre-engagement chapter.

Pre-engagement requirements	**Items considered in the case of food packaging**
Understanding of socio-technical dynamics in the domain	• Focus on development of immediately useful technologies such as nanocomposites. • Expectations of beneficial packaging properties, but also of unprofitability and public backlashes • Nanotechnologies no high priority on food packaging sector's agenda, sustainability as buzzword
Estimation of actors' propensity for anticipatory co-ordination	• Waiting games • Emerging consortia and networks • Anticipation on customers' preference for sustainable packaging, cf. Sustainpack program
Selection and location of actors	• Retailers as gatekeepers • Importance of co-operation across the chain
Assessment of broader dynamics	• Linkages between food and health sector: involvement pharmaceutical packaging suppliers • Attention for health, environmental & safety aspects, less for issues like reliability and social inequality

Table 1: Pre-engagement requirements food packaging workshop

For the preparation of the food packaging workshop I co-operated with the Netherlands Packaging Centre (Nederlands Verpakkingscentrum, NVC). NVC positions itself as a chain association for packaging and emphasizes the

importance of thinking in packaging chains and the relation between packaging and packaged product. Accordingly, NVC emphasized the importance of involving a variety of actors across the chain for the organization of this workshop. The focus on involving actors along the food packaging chain fitted with my analysis of pre-engagement requirements and more general CTA considerations.

I expected that attracting workshop participants from across the chain would be difficult. Recruiting workshop participants is difficult for all kinds of contingent reasons, however based on my pre-engagement analysis I could see more specific reasons. Waiting games, relatively low priority of nanotechnologies in the food packaging sector, and uncertain risk-benefit trade-offs would make actors reluctant to participate in a stakeholder workshop.

However, it appeared to be relatively easy for the NVC and myself to find interested workshop participants. We actually had to refuse some interested actors to avoid the number of people in the workshop becoming too large for in-depth discussion. Involvement of retailers, a key actor according to my pre-engagement analysis, appeared to be difficult however. A respondent from a retailer pointed out that within their organization the application of nanotechnologies for food packaging was considered as too futuristic and thus received little attention. Firms at other positions in the chain did show interest to participate. Also, NGOs and governmental organizations were interested in discussions on the theme of nanotechnologies and food packaging, yet some of them had to excuse themselves.

My expectation regarding the low priority of nanotechnologies and uncertain risk benefit evaluations of nanotechnologies in the food packaging sector was visible in two ways during preparations for the workshop. The low priority of nanotechnologies and uncertainties involved functioned as an argument for potential participants not to participate. On the other hand this argument could be picked up, together with associated promises (and risks), as an interesting occasion to learn what was happening with nanotechnologies and food packaging. Many of the participants in the workshop considered nanotechnologies a promising opportunity, and indeed an interesting theme to learn more about.

The results of the pre-engagement activities formed the departure point for the eventual set-up of the workshop. Table 2 provides the main characteristics of the set-up of the workshop.

Characteristics workshop set-up	**Food packaging workshop**
Composition of attendees	11 participants 1 representative of the Netherlands Packaging Centre 3 analysts/moderator
Organizational background of attendees	1 - *non-governmental organization* involved with nanotechnologies 1 - *research institute* involved with food, packaging and nanotechnologies 1 – company/consultant involved with product innovation, including packaging 2 - *governmental organization* involved with food products 1 - *brand owner of food products* 2 - *packaging material suppliers* 1 - *packaging manufacturer* 1 – *wholesaler in packaging* 1 - *company* offering industrial services including testing
Overall diagnosis in the preparatory document	Uncertainties about promises and risks of application of nanotechnologies contribute to reluctance to explore promises of nanotechnologies by risk aversive actors in the food packaging sector.
Dedicated initiatives and outcomes in the scenarios	(1) Knowledge institutes and nanotechnology associations push promise of nano packaging for a sustainable and healthy society. Few new products are developed and introduced on the market. (2) Governmental organizations introduce regulation to reduce uncertainties about risks. New products are launched but meet strong criticisms from civil society. (3) A broad platform is established which induces successful product launches. The platform expands with other participation from other sectors, but collapses due to internal conflicts of interests.

Table 2: Characteristics of the food packaging workshop set-up

6.3.2 Articulation of nanotechnologies and societal embedding

The food packaging workshop was held on 23rd February 2009 at the office of the Dutch Packaging Centre in Gouda, The Netherlands. The discussion took place in an informal atmosphere with space for voicing one's own views and considerations, and for interventions.

The workshop interactions consisted of an open-ended discussion on a variety of themes linked to the generation and possible introduction of new food packaging technologies. The themes discussed reflected the preparatory document of the workshop, and this was not the result of strong shaping by the moderator. The interactions during the workshop gave their own twist and particular focus to themes. In addition, participants discussed topics such as challenges of upscaling nanotechnologies and new packaging technologies in general; uncertainties around demand for new packaging materials across the chain; and broader societal changes related to coping with risks of new technologies.

In the interactions unfolding between enactors and selectors and the manner in which they discussed aspects of societal embedding, the variety in discussed topics is interesting in itself. Clearly, there was not yet a lock-in into a particular set of technologies to be developed, or a dominant reverse salient to be addressed in overall development and embedding processes. The open-ended character was also visible in the manner in which participants articulated nanotechnologies and issues of embedding and how the workshop discussions unfolded (see also section 6.3.3).

When confronted with nanotechnologies, either in participants' assessment of desirable future developments and challenges therein, as well as possible strategies for exploring and exploiting novel products, participants often referred to dynamics and issues which were relatively independent of, but relevant for, nanotechnologies. If more specific aspects of nanotechnologies were discussed, it was often in the context of uncertainties regarding performance, and health, environmental and safety risks.

Salient were considerations at the level of the food packaging sector. Sectoral issues were already highlighted in the preparatory document, but the fact that

they were discussed suggests that they are relevant and important for participant's assessment and strategy articulation. Sectoral challenges such as issues of co-ordination across the chain, but also waiting games and expectations about relevant issues for embedding packaging technologies in general were important items. These observations support the idea that dynamics for embedding new technologies play, for an important part, at the meso-level. I offer some quotes from my workshop to demonstrate this point.

During the discussion the question was raised of which 'crying need, or societal need' would be addressed by nanotechnology enabled food packaging materials. One participant from a knowledge institute responded to this question by pointing out general themes in society for which nanotechnology engineered packaging materials were among the possible solutions. The response has the characteristics of an umbrella promise in which general societal challenges are linked with expectations of contributions by nanotechnology enabled applications.

> Knowledge institute 1: I think that a number of large societal problems are advancing on us, which can be solved, among others, by packaging materials. The dilemma between fresh, fresher, but still convenient and long shelf life, are topics in that context. Food safety, the safety of the packed product [...], these are needs that are very present in society. And which can be solved with this type of developments. But again, as I always point out, nanotechnology is only one of the technologies that can contribute to these [needs]."

While promises of nanotechnologies were generally appreciated, some participants were skeptical about the performance of nanotechnology enabled packaging. In order to be taken up in manufacturing practices it was seen as important that existing production equipment could be used. Changing production infrastructures was considered to be a more long term development, whereas packaging manufacturers were often more focused on short term developments.

> Material supplier 2: We [material suppliers / packaging manufacturers] are more focused on short term successes with products produced by present equipment, than on fundamental assessments of technologies of the future.

Participants from the packaging industry also discussed uncertainties regarding possible risks of application of nanotechnologies, issues of sustainability and how regulatory regimes would deal with nanotechnology enabled packaging. These uncertainties made it difficult to take further steps. This prompted a participant from a knowledge institute to intervene in the discussion and observed the existance of a waiting game between regulating authorities and industry.

> Knowledge institute 1: But that is a matter of uncertainty for you [material suppliers / packaging manufacturers]. That has to do with the fact that nothing has been developed yet. Also the consumer is looking at the government, and the government tells that there is nothing. There is no objective authority that guards my safety through regulation. And the industry says that there is not yet an objective authority that has developed regulation to which they can refer. That is a very tricky issue.

Participants identified further challenges relating to interactions between actors in the packaging sector, such as problems of co-ordination across firms in the packaging chain (see also 6.3.3). While sectoral issues, independent of nanotechnologies, often returned in discussions, participants also referred to general approaches in their organization such as internal rules for selecting emerging technologies and their introduction, and strategies for co-operating with other firms. Occasionally, also diagnoses of broader, macro-level developments were discussed, such as changes in how businesses were dealing with risks. In that sense, participants' articulation of visions of further developments of nanotechnologies and their embedding draw upon a general repertoire of aspects of societal embedding. Sectoral considerations are salient in this repertoire.

Themes such as how to cope with societal embedding of future nanotechnologies received only limited attention. While the participants appreciated the idea of developing a platform regarding packaging technologies, including nanotechnologies, discussions focused on who might take initiative rather than discussing the substance of activities of such a platform. Participants were knowledgeable about aspects of societal embedding of nanotechnologies; most of them had some experience with the application of nanotechnologies, either directly through research activities or by monitoring

developments in this area. But clearly, articulation of future strategies was not seen as a topic for discussion in this group.

Discussions on future strategies were limited, despite attempts by the moderator and occasionally by participants to focus the conversation on strategies. My pre-engagement experiences, as well as how actors presented themselves during the workshop, showed that actors attending the workshop were mainly interested in learning about what was happening around nanotechnologies. Thus, they would not focus on articulating strategies for introducing and embedding novel packaging technologies. The discussions did provide insights into what was foregrounded by a number of actors in the food packaging sector during a particular moment in processes of development and embedding processes of nanotechnologies.

6.3.3 Interactions during the workshop

Actors provided further development of themes under discussion via a series of interactions: through probing each others' worlds, commenting on what was said, by giving an exposition on a particular topic and, occasionally, by persuading other actors to think differently. New items were put on the table and unfolded as (yet) 'another important item to take into account'. This contributed to rich assessments of the situation in which actors in the food packaging sector faced with emerging nanotechnologies found themselves.

Probing each other's worlds

Probing happened during the workshop. These interactions highlighted the broader orientations of enactors, and occasionally of selectors. These orientations often took into account generic themes or issues in the food packaging sector, rather than items specific for nanotechnologies.

During the workshop participants involved in the development of new packaging technologies (enactors) and actors evaluating introduction of new materials, such as governmental organizations (selectors) were probing into other participants' worlds. One instance of probing occurred when a workshop participant, a material supplier, was discussing his doubts as to whether to continue with a promising nanotechnology development project. This project

was positioned as a novel material replacing a packaging material which was considered to be controversial and undesirable from a societal point of view. However, the material supplier argued that the new nanomaterial might not be sustainable and implicitly referred to societal debates on risks of nanomaterials. This prompted a participant working for a governmental organization and interested in risks of new nanotechnology engineered products, to confirm the participants' considerations – apparently somewhat surprised:

> Governmental organization: So, the assessment is then really about the costs of, societal resistance and the turnaround time for creating new products?
>
> Material supplier 1: Yes, eventually a consideration is that [also in innovation] you can only spend money once. [...] The second point is that we do not know all the hazards [of nano]. Nano in combination with packaging might not be very clever. [...] We do not know which kinds of hazards are associated with nanotechnologies. We do know fairly precisely which dangers are associated with [the existing and to be replaced packaging material]. Fear for the unknown.[4]

For the material supplier, uncertainty regarding sustainability was not just an obstacle to be overcome, but an important evaluation criterion. The firm explicitly expressed concerns regarding lack of sustainability as a reason to dismiss the product, which was welcomed by an NGO present at the workshop. In that respect, the material supplier did not act as a typical enactor emphasizing benefits and downplaying considerations of risks. Instead, this actor also included considerations that link up with positions of 'comparative selectors' or 'outsiders'. Clearly, issues of sustainability in general have become an important theme throughout the packaging sector and compliance with sustainability issues are considered to be important to gain acceptance. For example, later in the discussion, a participant emphasized that criticisms of lack of sustainability associated with packaging should not be overestimated as food wastage may outweigh concerns about sustainability associated with disposed materials. Then again, as yet another participant remarked, gains in

[4] When checking the quotes, the participant offered further arguments for the statements. According to the participant, one has to choose for the most viable option when spending money. Unknown hazards of nanotechnologies, in combination with the absence of rules that the participants' firm can adapt and will safeguard in the case of litigation, might make the combination nano & packaging not a clever option for the firm.

both areas would be wonderful – a notion which was welcomed by the participants.

For the participant from the governmental organization, packaging firms' considerations of potential risks were relevant in order to understand how firms were coping with emerging nanotechnologies. This participant was also interested in firms' assessments of when to expect introduction of new packaging products. Further probing occurred in that area, albeit indirectly, such as when following a discussion about new packaging materials remaining in laboratory environments, this participant concluded that packaging suppliers were not introducing many new materials (without explicit reference to nanotechnologies). This prompted a response by a packaging manufacturer who emphasized that there were promising developments and that nanotechnologies offered 'countless possibilities'. These comments are characteristic of a typical 'enactor' as characterized by Garud and Ahlstrom (1997): a promise champion emphasizing benefits.

Further probing occurred in which more downstream actors were active. In the second half of the meeting, the discussion was oriented towards finding ways to further development and embedding of the application of nanotechnologies. At one point the moderator asked whether the brand owner present at the workshop would consider becoming more pro-active, considering promises of nanotechnologies for sensoring applications. Earlier in the discussion, the brand owner commented that they had not witnessed any significant innovations in packaging materials recently. The brand owner saw the combination of packaging and sensors as an opportunity, but doubted whether the company would be large enough to initiate (and fund) packaging developments in a consortium or lead a platform. This prompted a participant from a research institute to probe into the background for the brand owners' considerations. The brand owner responded that there were further reasons not to take the lead. They didn't see themselves in a position to initiate such developments as nanotechnologies were still in a research phase. The participant considered that research institutes would be in a better position as they were 'more scientific' than the brand owner or many packaging suppliers.

The brand owners' reference to R&D capacities of packaging suppliers was linked to an extensive, and at times heated, discussion about the role of

material suppliers, packaging suppliers and brand owners in bringing about new packaging innovations. That discussion revolved around actors' preferences for co-operation with particular actors in the packaging chain and included concerns about distribution of costs and profits of innovations. While this discussion is not specific – though relevant - for the development of nanotechnologies, it was recognized by other participants as an important and relevant phenomenon in the packaging sector and complicating packaging innovations.

Responding to each other's statements

A striking pattern in the workshop was the broadening of articulation processes of nanotechnology and embedding with further items to be taken into account. This was visible when participants commented on earlier statements of actors, tried to persuade participants to share a view or when they discussed a theme or position.

Broadening of participants' perspective by offering further considerations often had as effect the introduction of a new topic in the workshop discussions, but occasionally also offered further articulations of a theme in the workshop. At one point in the discussion initiated by the reflections of the material supplier on whether or not to proceed with a nanotechnology development, a participant from a knowledge institute offered further considerations. The suggestions took into account the criteria and considerations emphasized by the material supplier. In that respect, the knowledge institute did not act as a promise champion who was mainly emphasizing possible benefits of nanotechnology application, but anticipated broader selection criteria.

> Company/Consultant: You talked about disposable packaging. Would you see more opportunities, if you would take a broader perspective? For example, re-usable packaging, or secondary packaging for transport purposes requiring a low weight? Would that not be a domain for you? Something which is longer used, for example for one year or for two years?
>
> Material supplier 1: That could be interesting. Then you talk predominantly about secondary packaging. [...] I have not thought about it.

> Company/Consultant: Then you can link up with sustainability themes. The hazards remain, are unknown, but it is a domain in which you might be successful earlier and receive a return on your investment.
>
> Material supplier 1: Yes, that is a good suggestion.

In a workshop on emerging nanotechnologies one would expect that some participants present narratives of promise, whether they were champions of nanotechnologies or not. This was indeed the case as I already indicated during my discussion of instances of probing. The most striking appearance of promise narratives, introducing not only new topics in the discussions, but also presenting broad horizons of future nanotechnology applications, were within the statements and expert comments of a participant from a knowledge institute. This participant was a well-known expert on nanotechnologies and often appeared as an invited speaker at conferences and other official meetings.

Interestingly, this participant promoted nanotechnologies as a possible alternative, rather than the single or most important option, to address consumer demands. These demands were not considered to be fixed and clear-cut. This participant presented themselves as a reflexive enactor. In response to a discussion on the risks of nanotechnologies for packaging for human health and the environment, the participant mentioned that the knowledge institute considered it their responsibility to develop research on unknown risks of the application of new materials. As a reflexive enactor, this participant promoted not only the application of nanotechnologies, but also the development of knowledge to assess potential risks of these applications. The participant expected that development of applications and knowledge of risks would evolve in parallel. At the same time, the participant warned not to overestimate risks of nanotechnologies and not to consider nanoparticles as a fully new phenomenon.

The suggestion of a parallel strategy could provide an opening for the further articulation of strategies for embedding nano packaging. However, the idea was met with skeptical comments. Both material suppliers pointed out that uncertainties about risks were problematic for firms as they would be held accountable in the end. On the other hand, it was later pointed out that risks also could act as an opportunity. If one firm was more skilled at minimizing

risks with new materials or sensors than another firm, this would create a competitive advantage.

A participant from an NGO followed with interest the exchanges between participants regarding risks of nanotechnologies and packaging in general. Considering overall critical perspectives of NGOs with respect to the application of nanotechnologies to food packaging, one might expect to see this also in responses of the NGO present at the workshop. Interestingly, this participant also took into account considerations of enactors of nanotechnologies and appreciated the potential benefits of the application of nanotechnologies. In a follow up comment on a firms' discussion of financial obstacles for developing new packaging materials for firms in the packaging sector, the NGO remarked that consumer packaging might not be an interesting application domain for nanotechnologies at all. Why take considerable risks in an area where potential profits appear to be marginal, the participant wondered. The NGO placed itself in a packaging firms' shoes and argued that packaging for non-consumer products in the area of hospitals or the hotel and catering industry might be more interesting.

The NGO's position was interesting in itself. It demonstrates that actors traditionally associated with a selector role need not exclusively position themselves as typical selectors. Instead, selectors can take up a constructive role by taking into account enactor perspectives. In this particular case, the positioning might be an effect of the workshop set-up and interactions, rather than necessarily reflecting a position also taken up outside the workshop. As pointed out by this participant, the involvement of NGOs critically contributing to discussions in a sector-wide platform on packaging was not likely to emerge as NGOs had limited human resources. The limited resources would most likely be devoted to involvement in high level discussion groups at the level of the central government, and specific packaging issues might not be a high priority. In addition, resources would most likely be devoted to polarizing debates. Only when NGOs would have sufficient capacity might they be able to constructively contribute to discussions.

Toward the end of the meeting the moderator asked whether important themes had been left out. A participant then introduced a new theme which led to a series of interactions. One of the material suppliers emphasized that they

worked from the principle that they would not develop a new material unless there was a customer willing to buy it when the development process was successful. The participant felt that needs and demands had not been sufficiently considered during the workshop.[5]

While the remarks are interesting in themselves, from a downstream actor who would normally be associated with the position of an enactor of new technologies, the interactions that followed also provided insights into waiting games between firms in the sector. During the discussions, participants working at a brand owner and at a packaging manufacturer said that they were waiting for their suppliers to come up with new products. Both material suppliers and further upstream actors were waiting on each other to take the first step, then.

The call for considering demand led to interactions in which actors articulated general considerations at a sectoral level (cf. 6.3.2). From the interactions it became clear that participants disagreed about who would benefit at all and who would benefit most, but also about the nature of demand.

> Knowledge institute 1: Food safety, the safety of the packed product [..] these are needs that are very present in society [..]. In the context of convenience also packaging technologies are included that can be used for preparing a product. This will also lead to functional requirements which somehow need to be addressed by some form of smart technologies.
>
> Company/Consultant: But these are all themes which will not be at the top of the list of consumers. One finds it obvious that food quality is preserved, that food is easy to be consumed and prepared, that packaging is easily opened. These are basic requirements.
>
> Knowledge institute 1: I believe that these items are on top of consumers' lists.

[5] The participant pointed out that this theme was not taken up until now as it would be a discussion concerning content, but that it was desirable to conduct this discussion. Between the lines this suggests that there are further, more specific considerations which were not visible in the workshop. While there are always constraints on what can be discussed because of reasons of space or what actors are willing to say, it does imply that the findings should be interpreted with some caution in terms of what is considered to be important by participants

Company/Consultant: I do not. I believe that people are more concerned with impacts of materials and packaging on the environment. That is an important theme. People will not put on the head of their list: yes, I want to preserve my meat products longer. That is an accepted fundamental principle for all packaging. If you were a consumer you would not accept that you would have to dispose of your meat products after one day.

Material supplier 1: But something like a roasting bag for example, that is a huge market.

Company/Consultant: That is convenience, but not so much a theme for discussion.

Material supplier 1: It is fairly high tech.

[..]

Knowledge institute 1: To come back in the discussion; I often open the refrigerator, and then everything is packed, but still perished. And then I think, if this would have been preserved for one more week, that would have been an advantage.

Wholesaler: I believe that the advantage is not there [with the consumer], but a step back in the chain, with distribution.

Knowledge institute 1: Ah, no doubt that they will also enjoy huge advantages [of novel packaging] [...] But in the end, the proof of the pudding will be if the consumer sees sufficient advantages.

Wholesaler: Perhaps. But ask a retailer about their benefit from a product which has one extra day of shelf life. That is huge. They no longer need to do a lot of things.

Material supplier 1: But they do not want to pay much for it.

Wholesaler: No, never.

The selected interactions showed a pattern of broader orientations compared to ideal typical enactor/selector positions. Actors introduced broader considerations and themes, but sometimes at the expense of tying up loose ends or rounding off a particular theme. In that respect the discussions were not oriented at consensus, or for that matter, dissensus. Instead, the flow of interactions contributed to creating a rich picture of participants'

considerations and assessments of dynamics and issues linked to technologies in the world of food packaging.

6.4 Targeted drug delivery workshop

For the discussion of the workshop on nanotechnologies and targeted drug delivery I will follow the same approach as for food packaging. I will start with my pre-engagement analysis and experiences, continue with discussing how participants articulated nanotechnologies and societal embedding, and end with examination of interactions during the workshop.

6.4.1 Pre-engagement

General pre-engagement requirements, such as assessing dynamics in the drug delivery sector and developments linked to nanotechnologies, were mapped and described in my drug delivery chapter. These are specified in Table 3.

For the organization of the drug delivery workshop I co-operated with branch organizations Nefarma and Niaba. Nefarma is an association of companies, including large pharmaceutical companies, who develop new pharmaceutical products. Niaba is an association of companies and organizations involved in biotechnology, including pharmaceutical applications. For Nefarma, nanotechnology is not a central topic as it is not (yet) an important theme for its members. Nefarma's members are relatively little involved in R&D activities; i.e. their subsidiaries in the Netherlands, and therefore activities in this area are limited almost by definition as many nanotechnologies are still in a pre-clinical stage. For Niaba the situation is somewhat different. Biopharmaceutical companies are likely to be interested in nanotechnologies considering the promises for (difficult) delivery of macromolecules such as siRNA.

I expected that attracting workshop participants would be difficult. Large pharmaceutical companies might not be interested due to waiting games and the low priority for nanotechnologies. Clinicians might not be interested, due to their limited involvement until now.

Pre-engagement requirements	Items considered in the case of drug delivery
Understanding of socio-technical dynamics in the domain	• Focus on targeting applications and promises, but also on other promises such as longer circulation time of drugs. • Long history of development and few products on the market which are labelled as nanotechnology engineered delivery systems. • Nanotechnologies not high priority on drug delivery sector's agenda, translational research as buzzword
Estimation of actors' propensity for anticipatory co-ordination	• Waiting games, independent of nanotechnologies as a general phenomenon in the world of pharmaceuticals • Emerging consortia and platforms for drug delivery researchers and for more heterogeneous actors interested in drug delivery (often linked to broader theme of nanomedicine). • Uptake of notion of 'translational research'
Selection and location of actors	• Big pharma as gatekeepers • Importance of co-operation across the chain, including involvement of clinicians
Assessment of broader dynamics	• Linkages between drug delivery and imaging sector; between drug delivery and food sector. • Attention to regulatory and clinical aspects, less on broader issues such as patient involvement. • Overall developments in the pharmaceutical landscape: reimbursement pressures; mergers and job cuts within large pharmaceutical companies

Table 3: Pre-engagement requirements drug delivery workshop

It indeed proved difficult to attract participants from large pharmaceutical companies and, for that matter, biopharmaceutical companies, to attend the workshop on drug delivery - despite efforts by co-organizers Nefarma and Niaba. Nanotechnologies were not a high priority for potential participants and caution in discusing R&D developments were provided as important reasons for not attending the workshop. Attracting clinicians also proved to be difficult, albeit for different reasons. While some clinicians were interested in the phenomenon of nanotechnologies, but not able to attend for practical

reasons, others were sceptical about the value of nanotechnologies and not interested in participating in the workshop.

While no clinicians or participants from large pharmaceutical companies attended, participants from different parts of the chain were present at the workshop: knowledge institutes, suppliers of delivery systems, and a drug development firm. In addition, a firm involved with micro system technologies and a governmental organization involved with nanotechnologies were present. In table 4 I have sketched the main characteristics of the set-up of the workshop.

Characteristics of the workshop set-up	**Targeted drug delivery 20th January 2010**
Composition of attendees	7 participants 1 representative from Niaba 3 analysts/moderator
Organizational background of attendees	3 - *research institutes* involved in drug delivery research and nanotechnologies 1 - *governmental organization* involved with pharmaceuticals and nanotechnologies 1 - *firm* involved in delivery systems 1 –*firm* involved with drug development, including drug delivery systems 1 –*firm* involved with micro system technologies.
Overall diagnosis in the preparatory document	Waiting games, independent of nanotechnologies, and uncertainties about performance contribute to reluctance to explore promises of nanotechnologies in the drug delivery sector.
Dedicated initiatives and outcomes in the scenarios	(1) Two consortia with different foci create development paths. One consortium survives, but as an effect limits exploration of other promising possibilities. (2) A broad platform is setup for co-ordination. Internal dynamics create a particular (limited) perspective which is met by opposition from the outside world. (3) An alliance between patient organizations, clinicians and knowledge institutes creates a powerful general demand for cancer therapies. When research projects cannot meet the high expectations, patient organizations are disappointed.

Table 4: Characteristics of the targeted drug delivery workshop set-up

6.4.2 Articulation of nanotechnologies and societal embedding

The targeted drug delivery workshop was held on 20th January 2010 in the Jaarbeurs building in Utrecht. The discussion took place in an informal atmosphere with space for voicing one's own views and considerations and for interventions.

The workshop interactions were less open-ended compared to the discussion in the food packaging workshop. Also in the drug delivery workshop, themes discussed reflected the preparatory document, without being encouraged by the moderator. The workshop interactions gave them a particular twist, however. While the workshop discussions covered a variety of themes, there was a strong focus on the clinical value of nano drug delivery technologies. Sectoral issues of co-ordination between disciplines and across positions in the chain emerged as the most important challenges to be overcome. They were recognized and were actually highlighted by some participants in the workshops as being a key factor holding back embedding processes of nano drug delivery technologies. The lack of clinical evidence of (significant) therapeutical effectiveness was positioned as the reverse salient for furthering developments in the field. In that sense, the workshops' interactions turned out to be more concentric (from the point of view of drug delivery researchers) than what happened in the food packaging workshop.

From the composition of the workshop participants one could expect that more concentric discussions would occur, considering the relatively homogenous group (compared to the composition of participants in the food packaging workshop). According to Van Merkerk (2007) heterogeneous actor compositions contribute to more productive discussions in terms of broadening and enriching actors' perspectives than discussions dominated by insiders (nanotechnology enactors). Issues of manufacturing, as discussed in the food packaging workshop and a well-known challenge for emerging technologies, were not discussed. Issues of intellectual property rights were mentioned in passing, but were not a subject of discussion. Neither was demand articulation, although there were general discussions about the importance of clarifying demand via involvement of clinicians. The absence of discussions about the aforementioned issues may very well have to do with the fact that no large

pharmaceutical companies, clinicians or patient organizations attended the workshop.

While concentric, broader items relevant for embedding were discussed, participants often articulated dynamics and issues of embedding which were independent of nanotechnologies' application to drug delivery systems. This was actually observed by one of the participants (see also 6.4.3):

> Governmental organization: When listening to the discussion, I sometimes also ask myself: What is specific for nanotechnologies, here? Listening to clinicians is something which one should always do. Assessing whether one can introduce [new technologies] in the market should always be done. Whether one manufactures a nanomaterial, or another a chemical entity, these routings are the same in my opinion.

Salient were considerations evident at the level of the drug delivery sector. Issues of co-ordination across disciplines/positions in the chain and waiting games were important items. I will give two quotes to demonstrate this.

During the discussion the point was made that the development of linkages between research on drug delivery materials and specific diseases was difficult. A participant from a knowledge institute suggested that research programmes should stimulate the improvement of interfaces within a chain of activities involved in developing these linkages. At the same time, this participant observed that developing linkages would not be straightforward, for different reasons.

> Knowledge institute 1: There are also groups that only focus on researching their own chemical entities and do not develop them further. While, clearly, further development of these substances should be considered. In which area do you want to have an application? Then you also need a partner to do this. We, as material developers, are all confronted with the problem that we have difficulties in reaching those people, particularly the industrial actors which are interested in these materials.

According to a participant from another knowledge institute, the difficulty in bringing the field of nanotechnology enabled targeted drug delivery further was rooted in the lack of clinical evidence, as I mentioned earlier. This would make it difficult for researchers and drug delivery firms to link up with large

pharmaceutical companies. Later, the participant commented that big pharmaceutical companies were to some extent dependent on these new technologies. So, this was a waiting game, considering that researchers and firms are to some extent dependent on large pharmaceutical companies for funding and further exploitation of nanotechnology enabled delivery systems.

> Knowledge institute 2: There is still too little on the market that convinces large companies to put effort in this area. There is very little data on the clinical benefits. Real, concrete proof. And that is what the industry is waiting for [..] but big pharmaceutical companies are not inactive altogether. On the one hand there is a development which forces them to pay attention to these type of products, eventually. Because there are increasingly less blockbusters. [..] Big pharmaceutical companies do have interest in these [nano drug delivery] type of systems. Watch it carefully.

The relatively focused discussion created time and space for discussion and articulation of strategies. Discussions focused on the question of how to further develop nanotechnologies in the drug delivery sector. Overcoming what was seen as the reverse salient in the overall development, the lack of clinical evidence, was a central theme in that part of the discussion. Participants explored possible strategies of co-ordinating developments in the sector, including the creation of a nano drug delivery exemplar which – if successful – might convince the field of drug delivery of the value of the application of nanotechnologies. Further issues of how to mobilize resources to actually implement these strategies were discussed as well.

The lock-in to particular themes and focus on concrete strategies may very well have to do with the background of invited actors and their interest in attending the meeting. During pre-engagement and the actual workshop, it became clear that participants appreciated and recognized the themes as they resonated with their own interests. One participant was actually involved in institutional entrepreneurship activities where issues of translational research were important. For this participant, the workshop provided a venue for entrepreneurship.

Toward the end of the workshop participants expressed interest and enthusiasm in adopting the discussed strategies in order to try to actually

implement them.[6] In that respect the workshops unfolded in quite different ways. In the food packaging workshop articulation of further actor perspectives and aspects to be addressed were highlighted, rather than strategies of further developments in the field. While unfolding of workshop interactions to some extent are contingent, differences in reductions of complexity of assessments will definitely play a role.

6.4.3 Interactions during the workshop

Interactions during the targeted drug delivery workshop are characterized as a series of exchanges on diagnosing the key challenges in furthering developments in the field of nanotechnologies and drug delivery, and on the best methods to cope with those challenges. While there was no explicit consensus on which strategies should be pursued in the future, the emphasis on problems of co-ordination and lack of clinical evidence effectively constituted a lock-in in the discussion.

Probing each other's worlds

Probing occurred within interactions during the workshop, although less prominent than in the food packaging workshop. The homogenous composition of the workshop participants' background contributed to limited probing between enactors and selectors.

Puzzles about the unique character, if any, of nanotechnology engineered drug delivery technologies set the stage for probing. The discussion was initiated by a participant (see 4.2) wondering about specificities of the application of nanotechnologies and how these contributed to reluctance in uptake and development of nano drug delivery technologies. A participant from a drug development company replied by pointing out uncertainties about the unknown safety profile of nanoparticles. Whether this meant that there was a lack of testing methodologies and knowledge about distribution and effects of

[6] This is one way of how CTA workshops can act as an intervention in ongoing developments. The creation of networks through assembling workshop participants, stimulating learning through interactive articulation of relevant aspects to be taken into account during development and embedding processes, are other intervention effects of CTA workshops.

nanoparticles in the body – which would suggest the existence of specific nanotechnology related challenges - or required more efforts during testing was unclear.

This question regarding safety of nano drug delivery technologies prompted a participant, working for a company supplying drug delivery systems, to frame the question differently by asking about the status of knowledge and methodologies for assessing 'conventional' pharmaceutical materials. This participant considered questions regarding safety to be the responsibility of their customers and not a topic for his firm. However, by asking about evaluation criteria for their customers' products, his understanding of broader developments increased.[7] In that respect, this participant did consider broader developments rather than only customer-supplier exchanges.

> Delivery systems supplier: May I ask a simple question? We discussed that we cannot observe where nanoparticles are travelling to, but this is also unknown for pharmaceutical substances, molecules. Also in these cases one doesn't analyze in detail whether particles travel to the liver, or to..
>
> Knowledge institute 2: Well, well
>
> Delivery systems supplier: They do?
>
> Knowledge institute 2: There is pre-clinical pharmacokinetics, tissue distribution; this should all be done.
>
> Governmental organization: But that is not different for what needs to be done already for pharmaceutical substances.
>
> Delivery systems supplier: Hence, my question. If this is already being done for small molecules, why would this be problematic for nanoparticles?
>
> Governmental organization: Because for non-nanoparticles, let's call them that way, for other chemical substances, not necessarily pharmaceutical compounds, already a number of patterns are known.

[7] During my post-workshop interviews this participant expressed that understanding in this area helped the firm to assess their business plan forecasts as uncertainties in this area might slow down introductions of their customers' products, and therefore the participants' sales volume.

> [...] The case of nanoparticles is becoming a totally different story for us.

The series of discussions on the unique character of nanotechnologies resulted in participants' reflecting on general patterns in development and introduction of pharmaceutical technologies. The question concerning the unique character was unresolved, although participants commented on possible specific risk aspects of nano drug delivery technologies.

Still, participants from research institutes emphasized that the application of nanotechnologies provide important (and unique) targeting functionalities – promising development of targeted drugs. What is interesting is that these participants, enactors, anticipated discussions about risks and registration procedures of new pharmaceutical technologies. One participant from a research institute explained that their drug delivery research activities had shifted towards biodegradable systems. They expected that regulation procedures would be unfavorable to non-degradable delivery systems with which they had worked before. Thus, this participant took broader aspects into account than an ideal-typical enactor.

The emphasis on promises of nanotechnologies led the moderator to return to the question regarding factors contributing to reluctance in the field. This provided the occasion for further probing. According to participants from research institutes, big pharmaceutical industries were reluctant. This led the participant from the governmental organization to probe into big pharma's considerations. While no participant from big pharma was present, participants replied by referring to big pharma's waiting strategy, which was considered to be independent of nanotechnologies. A participant from a drug development company pointed out that, among other commercial considerations, clinical proof established in Phase II studies was required to demonstrate the added value of a new pharmaceutical technology. The participant from the governmental organization challenged this claim. The participant probed whether clinical studies were really required in order to convince pharmaceutical companies to invest in nanotechnologies. This was confirmed by a number of participants and not questioned by others, effectively contributing to a lock-in in the discussion.

Focus on convincing large pharmaceutical companies by acquiring – hopefully – significant clinical data (for a specific drug – delivery systems – disease combination) was an important topic in the workshop. The consideration of evaluation criteria from pharmaceutical companies (acting as future selectors of concepts generated by research institutes) by participants from research institutes and firms implies that these actors did take into account broader aspects. Still, the discussion was focused on pushing forward nanotechnologies (from the world of research). The overall strategy itself is predicated on the assumption that convincing firms and health insurers that clinical evidence is 'out there' and that expected benefits only need to be harvested – after which new drug delivery technologies will enter into the clinics. This type of reasoning resembles a typical enactor perspective.

This observation about the focus on promoting technologies points to a further overall observation about enactor/selector perspectives visible in the drug delivery workshop, but for that matter also in the food packaging workshop. Participants think in terms of furthering new technologies rather than societal embedding. Interestingly, this is the case for enactors and selectors. In both workshops governmental organizations, NGOs and downstream actors (if present) were open to the idea of introducing nanotechnology engineered products and contributed with articulating arguments and aspects which needed to be taken into account or considered. Aspects of societal embedding such as integration in industry, admission according to regulations, and broader societal acceptance (Deuten et al. 1997) were put forward as items to be taken into account rather than as objectives in themselves.

While participants in the drug delivery workshop did discuss how to involve pharmaceutical firms by creating a drug delivery exemplar, and the creation of platforms for co-ordination was discussed in the food packaging workshop, both workshops did not focus on articulating strategies for societal embedding. Participants did not articulate strategies, as institutional entrepreneurs, to shape particular aspects of societal embedding processes. The aforementioned discussions could be interpreted as part of such institutional entrepreneurship, however. While participants did consider sectoral developments, they did not discuss whether if and how institutions should be changed, or created, in order to support societal embedding processes of nanotechnologies.

Responding to each other's statements

Salient within the interactions in the workshop was the emergence of a lock-in on the idea that acquisition of clinical data was key for furthering drug delivery technologies towards clinical application. This theme was pushed by some participants and returned in discussions on strategies for further developments. Still, broader considerations were voiced and alternative strategies were discussed. The interactions that followed reveal actors' assessments of relevant force fields in the sector and their impact on application of nanotechnologies.

Early in the discussion, participants discussed the umbrella term nanotechnology and associations with the term. Participants from research institutes and a drug development firm pointed out that the associations of targeted drug delivery with the umbrella term also, albeit incorrectly, implied connections with discussions of 'disadvantages or risks' linked to nanotechnologies in the public domain. According to these participants, such associations could provide nuisances for nano drug delivery technologies. This type of reasoning shows that these enactors take broader aspects into account, yet in a way which resembles other patterns which have been called by Rip (2006) as 'folk theories': taken for granted patterns, which have not systematically been checked. In this case, the expectation that association with debates on risks of a broad collection of technologies will provide obstacles for specific technologies.

A series of interactions followed in which a participant from a governmental organization questioned this implicit pattern. This participant pointed out that specificities of the drug delivery sector would limit possible risks of nanotechnologies. Exposure to nanotechnologies through pharmaceutical therapies would be well controlled and registration procedures would check, among other things, toxicity. In addition, access to consumers – patients – would be regulated through intervention of clinicians. Furthermore, authorities had already considerable experience with delivery systems such as liposomes, suggesting that registration procedures should not pose particular difficulties. However, the participant acknowledged, patients might think differently about risks than experts do.

The point about regulatory expertise was contested by one of the participants who had experience with regulatory authorities, puzzling over whether existing

evaluations were sufficient – even for liposomal formulations. The participant speculated that more knowledge about risks of nanotechnologies might lead to re-evaluating existing registration procedures. This prompted a reflective comment from the participant of the governmental organization, noting that there were tendencies in society to reduce and solve all uncertainties and problems linked to nanomaterials. While such an objective might be laudable, the participant warned that one should not increase risk assessment criteria for nanotechnologies beyond what was presently accepted.

While broader themes such as risks of the application of nanotechnologies for drug delivery created openings for broadening the discussion, they shifted to the background. Participants raised further points to open up the discussion, thereby moving away from the lock-in on clinical value of drug delivery technologies, which was pushed by a number of participants. One of the participants challenged the idea of initiating technology development trajectories from a disease oriented point of view.

> Knowledge institute 3: I would like to react to your comment to take diseases as a starting point. There are of course many material research groups which start to think from their technology. [...] If you assert that one needs to start to think from the clinical picture, this means that you actually need to involve all groups in that discussion. [...] For each disease there are then several delivery systems. Whereas one could also say that one should start thinking from delivery systems and whether they are toxic or not.
>
> Knowledge institute 2: Yes, but eventually we develop, we produce [...] not things that are safe. No, we produce things that have to work effectively and which have to help patients [...] Look, it is a bit like, disease searches for a device, or device searches for a disease.
>
> Microtechnology firm: It is an interaction.
>
> Knowledge institute 2: It is an interaction. And actually I am also in favor of broad academic research. But, if one takes the step to, let's call it, valorization, then one needs to make a small value chain and this should be done by spin-offs.
>
> [..]

> Knowledge institute 1: You need them both, of course. You need to have a lot of knowledge about particles in order to know how and for what you can use them. [..] So, there is a disease and there is a material, and these should be brought together. How would you like to improve this? Then one would say, for these connections, these points, there should be programs that support them.

The conclusion that interfaces between actors needed to be improved (cf. 6.4.2) can be interpreted as a call for translational research, although the term itself was not employed. The conclusion shows a non-typical enactor perspective; enactment of new technologies is guided by a diagnosis of what happens at the level of a sector and what should be improved upon.

Assessments of sector level developments were very visible throughout the workshop and were also mobilized by participants to discuss alternative analyses and approaches of what is happening with drug delivery. Sometimes these ideas were directly refuted by other participants, sometimes they were not followed by responses directly. The latter happened when one of the participants discussed the role of insurance agencies in innovation processes, thereby potentially enriching the discussion with a further actor perspective, although the actors themselves were not present during the meeting. At first this topic was not picked up, but later it returned in the context of costs of new pharmaceutical treatments and their reimbursement when participants were discussing reluctance of pharmaceutical firms.

One of the participants pointed out further sectoral dynamics. The participant argued that big pharma had a strong focus on blockbuster drugs and that novel nanotechnology enabled drug delivery technologies would not likely fall under that class of drugs. This then led to a series of interactions regarding structural features in the drug delivery sector constraining development of new pharmaceutical technologies in general. During this set of interactions one participant, who emphasized clinical proof, suggested that if the clinical value would be convincing, actors (which were left unspecified) could not dismiss these technologies. The emphasis on benefits, which would overcome all barriers, is a typical enactor perspective. But this was not left unchallenged. One participant remarked that patients then probably needed to take action as health insurers might be reluctant to pay for new (costly) therapies. Here, we see a typical selector argument, pointing out that benefits alone might not be

sufficient, as issues of costs were known to limit introduction of new pharmaceutical therapies.

Considerations regarding sector level developments also returned in discussions on future strategies. In the second half of the meeting, actors discussed how to further the field. One of the ideas was to develop a program, organized as a contest, which would further develop promising pre-clinically developed combinations of drug delivery technologies and drugs until Phase II clinical trials.

Other strategies were articulated as well. One is particularly interesting as it appealed to the promise of reducing undesirable side-effects. In the interactions that followed, not only researchers, enactors, of drug delivery technologies were articulating this strategy, but also the participant of the governmental organization.[8] One of the participants rebutted this strategy by referring to negative experiences with large pharmaceutical companies. According to this participant, the strategy of re-evaluating problematic drugs did not fit with big pharma's practices. By providing an account of those experiences, the participant also provided further insights into the world of large pharmaceutical companies:

> Knowledge institute 1: There is also an opportunity in which one could make up for some costs. There are of course many pharmaceuticals which in the end have not made it due to side-effects. Targeted delivery offers an opportunity to avoid such toxic side-effects. The therapeutic effect will probably already have been demonstrated very clearly, but in the end they have not made it due to the side-effects. In that respect one may skip some developments, or at least short-cut them and focus on whether one can reduce these side-effects through targeting.
>
> Knowledge institute 2: Yes, yes, but you can also evoke them [side-effects] via targeting. That automatically appears, safety, you can not eliminate that, because through linking…
>
> […]

[8] Cf. the 'two hands' of the government in innovation processes: one hand stimulating development of new socio-technical options, the other hand controlling development and embedding of new options.

> Knowledge institute 3: Big pharmaceutical companies have many pharmaceuticals on the shelves [which cannot be used due to drug delivery problems].
>
> Governmental organization: Yes, [...] one should also have a look at the deleted products.
>
> Knowledge institute 2: We have already tried that many times in the past. [...] And eventually it works, pre-clinically, and they [big pharmaceutical companies] do not do anything with it. Because it doesn't fit with their block buster model eventually, and it is too laborious, costs too much money and finally they pull out. We had spoken already with a number of big pharmaceutical firms in the past about creating a better life for interesting pharmaceuticals, problem medicine. And, that is, … well, yes, big pharma does not think that way.

During the discussion of strategies to further the field, also the question of mobilizing resources for such strategies was put forward for consideration. Toward the end of the meeting the moderator pointed to one of the scenarios in which patient foundations and organizations were involved and asked whether that would be a feasible option. Patient organizations can be involved for financial but also symbolic (moral) support. Participants from research institutes and the governmental organization were hesitant and argued that it might be too early to involve them for funding and moral support. Too-high expectations based on too little evidence and uncertainties over risks were mentioned as reasons (without making explicit the expected effects). Between the lines, the analyst can see a folk theory of a hype-disappointment cycle at work.

Interestingly, one of the participants from a firm not directly involved with drug delivery technologies responded to this discussion by pointing out that little involvement of patient organizations might induce a pattern reminiscent of the biotech discussions. A pattern, argued the participant, in which little information by enactors of new technologies is distributed, leaving civil society organizations to guess what is happening and perhaps leading to a rejection of new technologies. This was acknowledged by one of the participants from a research institute as something for which an answer should be developed, but not as something directly important for the question of furthering the field.

This participant considered this theme as off topic and (again) emphasized the importance of clinical evaluation of new delivery technologies.

These interactions regarding whether or not to involve civil society actors provided a further indication that participants thought in terms of technologies to be developed, rather than in terms of societal embedding. It also demonstrates that, while enactors do think about broader aspects, these orientations can be short-cut by focusing on a particular - though relevant - theme and leaving aside, possibly postponing, further considerations. Such reductions of complexity may be inevitable, but could itself be a topic of discussion. That would, however, require actors to take a broader view; i.e. thinking in terms of societal embedding and what would be important for embedding.

6.5 Conclusions

Both workshops generated rich data regarding dynamics and functioned as a probe into force fields in a domain of technology during a particular moment in processes of development and embedding of emerging nanotechnologies. Participants recognized dynamics identified during pre-engagement and further elaborated on these dynamics. Through probing each others' worlds and responding to statements by adding further considerations or articulating broader perspectives, these interactions provided insights into processes of development and embedding. For the analyst, the insights generated are robust, as interactions between participants provided checks on (each others') statements. How then, did participants articulate nanotechnologies and societal embedding, and which dynamics did they take into account? What do the workshops tell us about participants' orientations in terms of enactor/selector perspectives?

What was salient in both workshops was that participants' assessments of nanotechnologies in relation to their sector of industry often took into account what was happening at the level of the sector. Participants did discuss nanotechnology specific aspects, often in the context of uncertainties about

performance, risk and demand for nanotechnology engineered products. Still, during interactions and positioning of actors, broader considerations about sectoral dynamics and circumstances came to the foreground. Participants took into account patterns of interaction between actors in the chain and developments at the level of the sector that were independent of, but relevant for, nanotechnologies. Occasionally, participants also discussed issues transcending sectoral aspects such as reflections on overall changes toward dealing with risks of (new) technologies and nanotechnology as an umbrella term.

Anticipation on societal embedding was visible. Participants involved in technology development (enactors) and those involved in selecting or evaluating new socio-technical options (comparative selectors), took societal aspects into account in their positioning. Which aspects of embedding were taken into account and how, differed between the food packaging and drug delivery workshop. Whereas the food packaging workshop was relatively open-ended as to the themes discussed, in the drug delivery workshop there was a lock-in on a few dominant themes: interfaces between research disciplines and actors across the chain, and the demand for clinical evidence of nano drug delivery technologies. The differences in composition of the workshops may have contributed to these differences in articulation processes, but the differences do reflect similar findings in my chapters on institutional entrepreneurship in these domains. So, at this moment, articulation processes of nanotechnologies and societal embedding appear to be more heterogeneous in the food packaging sector than in the drug delivery sector.

The data from interactions in the workshops suggests that actors' anticipations on embedding, i.e. what they take into account, at this stage of development of emerging nanotechnologies predominantly focus on the level of a sector. A word of caution applies here. The setup of the workshop, guided by my interest in meso-level dynamics, may to some extent have induced such responses from participants. However, present uncertainties of performance of emerging technologies make concrete anticipation of societal embedding difficult. Understanding of sector-level patterns linked to food packaging and drug delivery technologies in general then offers clues as to what will be important. Macro-level developments will offer further, though non-specific clues, such as general pressures to take into account risks (of nanotechnologies). Then,

considerations about sectoral conditions and patterns of interactions between actors in the sector are likely to be foregrounded. In this way, participants will draw upon a general repertoire of embedding issues in their sector, independent of specific emerging technologies, as part of their anticipatory competences.

While the workshop participants did take into account dimensions of societal embedding, they predominantly thought (as appears from the interactions) in terms of technologies which should be developed or pursued, rather than considering embedding as an objective in itself. This was visible in participants' general positioning as enactors or comparative selectors. However, we also find more typical enactor (or selector) perspectives – sometimes voiced by the same participant. Participants' orientations cannot simply be categorized as enactor or selector perspectives. Instead, enactors co-opt some aspects of selectors' perspectives (and selectors some aspects of enactors' perspectives). While analytically one can still distinguish between the two positions, they are blurred in the workshops. This is significant as it indicates that actors in the two sectors recognize mutual dependencies (at a sectoral level) and can engage in strategic interactions, which, if they occur, will contribute to reflexive co-evolutionary processes.

However, blurring boundaries between enactor and selector perspectives in sectors of industry does not necessarily imply that patterns in reflexive co-evolutionary processes will emerge. There were discussions whether to invest or not to invest in nanotechnology developments during the food packaging workshop. Both workshop discussions showed reluctance, and waiting games at the sectoral level. Meso-level dynamics, therefore, may constrain anticipatory strategies.

For the participants, the workshop interactions provided insight into dynamics at the sectoral level. The workshop supported participants' anticipatory competences, and perhaps improved them. At least, the workshop supported their recognition of what plays at the collective level and their ability to position their strategies in a broader context.

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PART 4

Chapter 7

In conclusion: A forward look

7.1 Introduction

Anticipatory interventions will have effects on the co-evolution of nanotechnology and society, even if they can not be fully assessed at this stage. Effects on the generation and selection of socio-technical options are still difficult to trace. What can be assessed, however, is whether anticipatory interventions are adding up to patterns in how actors in our society are, and will be, coping with emerging nanotechnologies in the present and nearby future. How are the spheres of 'nanotechnology' and 'society' bridged? Are patterns in reflexive co-evolution emerging, and if so, what type of patterns?

This was the background question for my dissertation research and it is fitting to come back to it in this concluding chapter. Now, to look forward. This will entail an element of speculation, but it is 'controlled speculation' if the analyst focuses on an analysis of dynamics in context as a starting point. By analyzing dynamics in ongoing processes the analyst gains an understanding of what Rip and Te Kulve (2007) have called 'endogenous futures': future developments are predicated on patterns in the present situation. These are domain specific, as was visible in my analyses of anticipatory interventions in the drug delivery and food packaging sectors. However, I want to consider them now as instances of reflexive co-evolutionary processes, and thus offer an 'analytical generalization' (Yin 2003, p. 32-33) of my analyses. While the extent to which my analysis is replicated across sectors will differ, the reference to overall reflexive and multi-level co-evolutionary dynamics will provide a shared background. So, when discussing emerging patterns across domains, I must take into account domain specificities.

For a forward look I can draw upon my insights into meso level dynamics, however I have to include a diagnosis of macro-level developments. Knowledge of macro-level developments informed my earlier chapters, but was not articulated because of my focus on sector level dynamics. In this chapter I will therefore start by discussing macro-level developments and the role they played in my two domains as they constitute part of the 'endogenous futures'. Given that I am interested in the evolution of anticipation of embedding and the sort of interventions which have occurred, I must look at macro developments associated with societal embedding of nanotechnologies.

Actually, there has been a cumulation of developments at this level during which, over time, an agenda of societal embedding of nanotechnologies has emerged.

Actors take into account what is happening at the macro level (in particular developments in the public domain), which provides directions for anticipatory actions and interactions. Societal debates, also visible in media coverage of nanotechnologies, are one important aspect of macro level developments. The second key aspect is 'de facto governance' (Kearnes and Rip 2009) of nanotechnologies, including both stimulation of research and innovation as well as regulation of the introduction of future products.[1] So, for a diagnosis of macro-level developments I will definitely have to pay attention to societal agenda building and emerging overall institutional arrangements which provide directions for actors' anticipatory actions and interactions.

For my discussion of specific developments at the macro level related to societal embedding of nanotechnologies, I take 'anticipatory interventions', now at the macro level, as an entrance point.[2] These will include the recent interest in 'responsible development' of nanoscience and nanotechnologies. 'Responsible development' is now a key theme in policy debates about nanotechnologies (Ferrari 2010; Kearnes and Rip 2009) and, possibly, an important aspect in patterns in co-evolutionary processes of nanotechnology and society. I will examine what has happened until now and where macro level developments are heading. Having done this, I will return to my background question about emerging patterns in reflexive co-evolution.

[1] Rip (2010b) uses the notion of de facto governance to emphasize the bottom-up character of governance arrangements. That is, governance arrangements which emerge through actions and interactions rather than designed and implemented by (distributed) authorities.

[2] Some of the entrepreneurial initiatives at the macro level have already been referred to or discussed in the previous chapters.

7.2 An evolving nanotechnology landscape

There are methodological and substantial problems when addressing the role of macro level developments, because these cannot be identified as such, but must be inferred. A good entrance point is to think of a socio-technical landscape which guides actors' actions and interactions through 'affordances'. "Affordances are functional and relational aspects which frame, while not determining, the possibilities for agentic action in relation to an object."(Hutchby 2001, p. 444) The notion of affordances allows room for maneuver by actors. That said, affordances may be more or less constraining, and therefore differ in the way they guide actions and interactions. To examine future affordances provided by the macro level, including 'responsible development', I will discuss, at some length, salient shifts in articulation processes of nanotechnologies and societal embedding at the macro-level. While some of the items are not new, as they have already been referred to in the previous chapters (in which case I only briefly mention them here), they are now discussed as part of a longer term development. This allows me to position, among others, the emergence of 'responsible development' in a broader set of landscape changes relevant for societal embedding of nanotechnologies. Finally, I will look at the role these macro-level developments have played in my two domains.

Over time, macro-level developments have cumulated in the sense that an agenda of societal embedding of nanotechnologies has emerged. Presently, societal embedding is not only part of the discourse surrounding nanotechnologies, but also a topic in concrete actions and interactions to actually do something about embedding. Within overall macro-level developments one can distinguish a number of phases in agenda-building and emerging overall institutional arrangements.[3] An overview of macro-level developments and their phasing, which will be discussed further in some detail, is provided in table 1.

[3] Rip & Van Amerom (2009) have distinguished phases in the evolution of a nanotechnology landscape in their discussion of utopian and dystopian visions linked with 'Eric Drexler', and the emergence of risk debates. In a similar fashion I was able to distinguish phases in the evolution of newspaper coverage of nanotechnologies in the Netherlands, see appendix.

Period	Characteristic features
Pre 2000s	• Utopian ('molecular manufacturing') and dystopian views ('grey goo') • Some nanotechnology research funding programmes
Early 2000s	• Steep rise in funding and media interest in nanotechnologies. • Establishment of 'nanotechnology' as a socio-political entity • Inclusion of Ethical, Legal, Social Aspects (ELSA) research in nanotechnology research programmes
± 2003-2006	• Emergence of a debate on Health, Environmental and Safety (HES) risks • Emergence of 'responsible development' discourse • Early initiatives to identify and manage risks
Post 2006	• HES risks of nanotechnologies accepted and firmly on the agenda • Responsible development key theme in policy circles • Launch of various codes of conduct

Table 1: Timeline evolution nanotechnology landscape

I will begin by discussing macro-level developments in 2000. At that time, nanotechnology was established as a socio-political entity which could be discussed as such and referred to - an 'ideograph' (McGee 1980). The creation of the US National Nanotechnology Initiative (NNI) was a landmark event as it firmly established nanotechnology on the political agenda around 2000. In fact, by then it was on the societal agenda as well. A key, often referred to, event was Sun Microsystems' founder Bill Joy's publication, '*Why the future doesn't need us*' where he made a plea to limit development of converging technologies, including nanotechnologies. In his essay, Joy expressed his concerns for the possibility of self-replicating nanobots (and other technologies) which could become out of control. The scenario of self-replicating molecular assemblers, turning Earth into 'grey goo' was already introduced by Drexler in the 1990s, a early key figure in nanotechnology, but Joy's essay made 'grey goo' part of societal debates on possible drawbacks of nanotechnology (Rip and Van Amerom 2009). Joy's article received broad coverage across media in the US and, as it was published only months after the launch of the NNI, must have been 'galling' to NNI's advocates (Bennett and Sarewitz 2006).

Around 2000, funding and media attention for nanotechnologies sharply increased (Bennett and Sarewitz 2006; McCray 2005; Schmidt Kjærgaard 2010; Te Kulve 2006). [4] A 'funding race' between countries emerged. Governments across the globe steadily increased funding into nanotechnologies from 432 million US$ in 1997 to 3,739 million US$ in 2004 (Roco 2005). During this growing interest in nanotechnologies, societal embedding as a theme worthy of attention was put on the agenda with the US National Nanotechnology Initiative.

Behind the emergence of the NNI and the promotion of inclusion of ELSA studies were the entrepreneurial activities of Mihail Roco, special adviser to the US National Science Foundation for nanotechnology (see McCray (2005)). The activities of Roco and others contributed to putting nanotechnology research (including ELSA research), on the agenda. In September 2000, the US National Science and Technology Council sponsored a workshop about (future) research into societal implications of nanotechnologies. The workshop was co-chaired by Mihail Roco and was organized in order to identify areas for research to be included within the NNI. Future societal embedding was recognized as a challenge, and Roco and others wanted to do something about it. The inclusion of ELSA-type research was seen as an opportunity to 'get nanotechnology right from the beginning', cf. chapter 1.

In the report on the social implications workshop, the importance of research into societal aspects was legitimized by references to nanotechnology's claimed promises about economic and broader societal benefits, and the need to support realization of such promises. In that respect, ELSA research was positioned as instrumental for realizing nanotechnology's promises. The discourse on societal aspects of nanotechnologies was predicated on promises of nanotechnologies. According to the executive summary of the workshop report (Roco and Bainbridge 2001, iii):

[4] In his analysis of responses of research councils to nanotechnologies, Van der Most (2009) describes the existence of funding initiatives before 2000. Interestingly, in the UK, already in the mid 1980s a national initiative on nanotechnology was launched and was followed by funding schemes until 1995/1996. In the period until 2002 no new funding programmes were launched by the research councils. The UK Department of Trade and Industry did not invest in new programmes, because industry did not appear to be very much interested at that time.

> "Advances in nanoscience and nanotechnology promise to have major implications for health, wealth, and peace in the upcoming decades. Knowledge in this field is growing worldwide, leading to fundamental scientific advances. In turn, this will lead to dramatic changes in the ways that materials, devices, and systems are understood and created. [..] Research on societal implications will boost the chances for NNI's success and help the nation take advantage of new technology sooner, better, and with greater confidence. Moreover, sober, technically competent research on the interactions between nanotechnology and society will help mute speculative hype and dispel some of the unfounded fears that sometimes accompany dramatic advances in scientific understanding."

The phrasing of the last sentence in the quote is interesting for a number of reasons. It specifies the kind of ELSA research which should be done, 'sober and technically competent'. Speculative hype and unfounded fears were seen as undermining the realization of promises and should be 'muted' and 'dispelled'. Bill Joy's essay provided a concrete occasion for this attention to 'hype and unbounded fears' and was actually discussed during the workshop (Roco and Bainbridge 2001). Important for my sketch of macro level developments is that the quote provides an idea of what was then considered to be at stake by nanotechnology enactors; i.e. hypes and fears, and where anticipatory efforts should focus.

While the entrepreneurial drive behind funding programmes, and, as it happens, the inclusion of ELSA studies, can be attributed to individuals, they themselves drew upon elements already present in the socio-technical landscape. Expectations regarding nanotechnologies had been circulating for some time, pushed by promise champions such as Drexler, but also supported by advances in imaging tools such as scanning tunneling microscopy (McCray 2005) and the discovery of new nano-entities such as bucky balls (buckminsterfullerenes) and carbon nanotubes. Nanotechnologies were positioned as being part of strategic science. At the time when the proposal for the NNI was prepared, the US House Committee on Science emphasized the importance of science and technology for economic competitiveness. In attempts to convince the US Congress to fund a major initiative for nanotechnology, promises of nanotechnologies and notions of strategic science were mobilized, cf. McCray (2005).

The idea to include ELSA was not new, as the Human Genome Project had already included an ELSI research component. Fisher (2005) in his analysis of the Nanotechnology Research and Development Act of 2003, pointed out that the inclusion of ELSI research was explicitly considered a model for societal research activities with the US nanotechnology program by a US House Science Committee. However, earlier ELSI research was criticized for being irrelevant for policy. The US House Science Committee's report accompanying the Nanotechnology Research and Development Act of 2003 stressed the importance of integrating ELSI research with nanotechnology research in order to ensure that ELSI studies influenced the direction of ongoing development of research and commercial applications (Fisher 2005). [5]

While the inclusion of ELSI research was available as a model to be adopted, there were also the beliefs of nanotechnology enactors about the importance of anticipating future introduction in society. The reference to avoiding an impasse in nanotechnologies akin to agro-food genetically modified technologies and 'let's do it right from the beginning' is a prominent one. Enactors of nanotechnologies had 'folk theories' (Rip 2006), in particular about expected negative public reactions. The key point here is that such folk theories became part of 'cultural repertoires' (Swidler 1986) on which actors draw. The Royal Society and Royal Academy of Engineering report (2004) did so when it referred to public backlashes about genetic modification and argued for the importance of a broad public dialogue regarding nanotechnologies. Such folk theories then, like strategic science and the inclusion of ELSA-type research as a model, offer affordances for anticipatory actions of enactors of nanotechnologies. The landscape around nanotechnology also offers opportunities for actions by selectors, and thus further articulation of nanotechnologies and societal embedding.

With promises of nanotechnologies in abundance, nanotechnology enactors had also expected criticisms of nanotechnologies and their application; for example Vicky Colvin (Rice University) presenting the 'wow to yuck' trajectory in a Congressional Hearing about the new Nanotechnology Bill (Rip 2006). While these are folk theories, their wide uptake reflects a salient pattern around new

[5] Fisher (2005) also critically discussed ELSI research and offered suggestions for how ELSI research could be integrated in ongoing nanotechnology research and development.

and emerging technologies: a proponent-opponent dichotomy which often casts debates abound new technologies 'in an antagonistic mould' (Rip and Talma 1998). In that sense, independent of the substance of nanotechnology developments, the socio-technical landscape around nanotechnologies afforded the emergence of a(nta)gonistic discussions, which were anticipated by enactors. From a reflexive point of view, involvement of broader actor perspectives is important as it may contribute to broadening enactors' anticipatory competences, cf. evolving newspaper repertoires as a form of technology assessment (Te Kulve 2006).

Debates regarding nanotechnologies shifted in focus. Early debates concerning nanotechnologies included discussions of high expectations and utopian views, as well as dystopian visions such as 'grey goo' in which nano-robots would overrun the world. The 'runaway nanobot' narrative is an instance of a general pattern associated with new and emerging technologies: recall the 'runaway nuclear reactor' and the 'runaway genetically modified organism' (Rip and Talma 1998). Scientists were concerned about negative public reactions to nanotechnology, because of critical stories such as dystopian visions of grey goo. Concerns over public concerns, or 'nano phobia phobia' has actually become a pattern in itself, a folk theory residing with nanotechnology enactors (Rip 2006). Nano phobia phobia was fueled by concerns of possible effects of media uptake of dystopian visions of nanotechnologies. The grey goo vision was popularized in the novel *Prey* by Michael Crichton (2002). The announcement of a possible movie led a scientist being interviewed in a newspaper to be concerned about possible negative public opinions (Te Kulve 2006). Interestingly, a study by Cobb and Macoubrie (2004) found the opposite to be the case. While subject for debate for some time, 'grey goo' eventually disappeared from debates on nanotechnologies after 2004 (Rip and Van Amerom 2009). Both nanotechnology promoters and critics would dismiss 'grey goo' scenarios. Concerns about media framing contributing to negative public receptions also appear to be out of place. Newspaper coverage of nanotechnologies would pay attention to benefits and possible risks, however the extent to which promises and critical views were covered differs between regions, preventing an easy conclusion about an overall dominant framing

(Kjolberg 2009; Schmidt Kjærgaard 2010; Te Kulve 2006).[6] Risk issues, however, would become a dominant frame, and one that was here to stay.

The rise of a risk debate and the promotion of institutional arrangements managing risks definitely meant a key step in articulation processes of nanotechnologies and societal embedding at the macro-level. 2003 can be marked as the beginning of a new phase in landscape developments around nanotechnologies (Rip and Van Amerom 2009). A discourse on health, environmental and safety (HES) risks emerged, and one can trace its emergence in newspaper coverage regarding nanotechnologies (Te Kulve 2006). Risks of nanotechnologies were picked up by a variety of actors who wanted to do something about it. Institutional entrepreneurs and spaces emerged which intervened in these macro level debates and promoted the adoption of general practices identifying and controlling risks. The emphasis on risks and the emergence of governance arrangements associated with risks offers directions for actors' anticipations of embedding. As with the idea of 'inclusion of ELSA research', risk debates and generic governance arrangements to manage risks are a form of second order anticipation. That is, they provide actors with directions for anticipation (in this case HES risks) rather than specifications of concrete anticipations.

At first, concerns regarding risks of emerging nanotechnologies were dismissed. In 2003 the Action Group on Erosion, Technology and Concentration (ETC Group), a civil society expert group, put the topic of regulation and control over nanotechnologies on the agenda and pushed for regulations. Given the uncertainties of risks of nanoparticles, the ETC group proposed (as early as 2002) a moratorium on the production and introduction of products containing nanoparticles. Scientists in nanotechnology research labs dismissed the fears and wondered "what all the fuss is about."(Brumfiel 2003, p. 246) Still, the risk debate was 'gathering pace' with nanotechnology and science policy experts discussing safety issues, and industrial and environmental actors discussing possible environmental hazards (Brumfiel 2003).

[6] Even common assumptions about a critical Europe towards new technologies versus an uncritical US do not seem to hold according to Schmidt Kjærgaard (2010).

While previously risks could be dismissed as not (yet) relevant, this changed irreversibly with the appearance of a third party: reinsurance company Swiss Re (Rip 2010b). In 2004, Swiss Re published a report arguing that nanotechnology engineered materials such as carbon nanotubes could generate risks similar to asbestos. In 2006, Swiss Re organized a meeting, together with the International Risk Governance Council, a not-for-profit foundation established in Geneva. The publication of the Swiss Re report, the 2006 meeting and its report are part of de facto agenda building processes. Actions and interactions emphasizing the importance of articulating and regulating risks of nanotechnologies solidify such processes, which in turn may further shape actions and interactions.

Rather than a single coherent system of regulating nanotechnologies, a patchwork of arrangements emerged which coped with regulating risks of nanotechnologies. Various schemes were launched by institutional entrepreneurs, some of which were already discussed in some detail in the previous chapters. While linking up with more specific sectoral developments, the promoted governance arrangements often had a general character and institutional entrepreneurs were active at meso and macro levels. The development of the nano risk framework by Dupont & Environmental Defense, UK DEFRA's voluntary reporting scheme, EPA's Nanoscale Materials Stewardship Program (also voluntary reporting) have in common that they aim to support and promote risk assessment of nanotechnology engineered materials and products via particular practices. Through promoting these practices, they contributed to the construction of a patchwork of governance arrangements regarding nanotechnology risks.

The importance attributed to risks of nanotechnologies can be traced in the allocation of nanotechnology research budgets and discussions surrounding them. In their discussion of the NNI budget, Fiedeler et al. (2009) noted that ELSA-type research and HES research has been treated separately since 2005. Since then, funding of ELSA and in particular HES research has increased, but not without controversy. Fiedeler et al. noted that funding of ELSA research had been institutionalized in the form of fixed budget percentage, following the model of the Human Genome project, but that things were changing. Following criticisms on how funds for HES research were spent, debates in the US about a fixed percentage shifted to discussions regarding the actual substance and

objectives of such research activities. Still, calls, such as by the Nanobusiness Alliance, were made to allocate a fixed percentage of the budget for nanotechnology R&D on research on environmental, health and safety risks (Sargent 2010).[7] In any case, the inclusion of risk research in nanotechnology research programmes appears to be institutionalizing.

Risks of nanotechnologies, in particular nanoparticles, have become a central theme in debates (Ferrari 2010; Rip and Van Amerom 2009). According to Ferrari (2010), there is a "strong tendency to see risk as the sole issue emerging from nanotechnological applications".(p. 31) Further items were put on the agenda, but risks would dominate discussions on societal aspects of nanotechnologies. In Dutch newspaper coverage we can see discussions of the legitimacy of nanotechnology research (as opposed to other domains of research) and the type of research pursued (basic or more applied forms of research). The ETC Group put broader geo-political aspects on the agenda, such as growing divides between countries on the Northern and Southern hemisphere. These themes are, however, in the margins of overall debates on nanotechnologies.

A further turning point in articulation processes of nanotechnologies and societal embedding at the macro-level was the emergence of the notion of 'responsible development'. According to Ferrari (2010) it has become a substantial part of policy debates in the European Union and the USA. While the idea of responsible development is pushed in policy documents, there is also de facto agenda building in the form of the promotion of schemes fostering responsible behaviour practices, 'codes of conduct'. So, the patchwork of emerging (de facto) governance arrangements witnessed a further expansion. As with the theme of risks, the notion of 'responsible development' provided actors with direction, but in principle opened up the inclusion of broader themes than risk alone. In this way, responsible innovation may contribute to further broadening of actors' anticipations of societal embedding of nanotechnologies, which is an interesting development from the perspective of reflexive co-evolution.

[7] In their call for a collaborative effort to 'get nanotech right' Krupp and Holliday (2005) suggested a fixed budget percentage on risks of about 10% and consider this as a "wise insurance policy on such a high-potential investment".

The notion of responsible development can be characterized as an emerging 'ideograph' (McGee 1980) through which it provides affordances for action. Ideographs exert pressure on actors which cannot be easily ignored and can act as a symbolic resource to mobilize actors for particular actions. According to Van Lente (1993) ideographs are flexible, enabling actors to make linkages, and can provide actors with an 'end point' which does not require further support. Umbrella promises of nanotechnologies and 'sustainability' are examples. In the food packaging workshop there was a clear example of the ideographic role of the notion of 'sustainability'. A participant defended his consideration not to further explore nanotechnologies for consumer packaging, because of the concern that these technologies were not 'sustainable'. This argument was taken for granted by the other participants, i.e. was not challenged or considered to require further elaboration. Ideographs then provide affordances which, when adopted, contribute to 'opening up and closing down' (Stirling 2008) processes of articulation, depending on how they are mobilized by actors.

Compared to debates on risks of nanotechnologies, and attempts to articulate and manage risks, discussions on 'responsible development' and 'responsible innovation' are (even) more open-ended (Rip 2010b). Responsible development, and also 'codes of conduct', are forms of second order anticipation, providing directions for anticipation rather than specifications of concrete anticipation. The following quote from the US National Research Council attempts to define the term responsible development:

> "Responsible development of nanotechnology can be characterized as the balancing of efforts to maximize the technology's positive contributions and minimize its negative consequences. Thus, responsible development involves an examination both of applications and of potential implications. 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." (National Research Council 2006, p. 73)

Note the difference in style compared to the quote from the societal implications report from 2000, which I presented earlier. While still technology-centric and emphasizing further development of nanotechnologies, anticipation now encompasses, in principle, a much broader range of aspects.

Anticipation no longer needs to be about 'muting hype' and 'dispelling unfounded fears', but about 'maximizing benefits and minimizing negative consequences'.

The notion of responsible development was pushed and promoted by a number of actors. In 2004, Mihail Roco and Renzo Tomellini established the International Dialogue on Responsible Development of Nanoscience and Nanotechnology. Their position provided them with authority and enabled them to move at the macro level. The first meetings took place in 2004 (Alexandria, US) with later meetings in 2006 (Tokyo) and 2008 (Brussels). The emergence of and focus of this space for interaction is interesting in itself as it offers informal opportunities to exchange ideas on responsible development across the globe. The 2004 meeting "highlighted that there is the need and opportunity to address the possible societal, health and environmental impact of nanotechnology at an international level." (Tomellini 2004) When stabilized, the international dialogue could act as a forum, as a macro alignment actor promoting reflexivity, rather than an institutional entrepreneur with specific interests, cross-sections of embedding processes.

The idea of codes of conduct was linked with responsible development early on. The International Dialogue meeting already referred to codes of conduct. During the meeting the idea of a declaration was discussed which might have elements of a code of conduct (Tomellini 2004). The development of codes of conduct by a broad variety of actors is an indication that responsible development has become a significant topic. Both governmental actors and private actors were involved in the development of a number of codes, at various levels.[8] A 'code of conduct for responsible nanosciences and nanotechnologies research' was published by the European Commission in 2008 (Commission of the European Communities 2008). A 'Responsible Nanotechnologies Code' was under development in 2008 by the UK Royal Society, Insight Investment, Nanotechnology Industries Association and the

[8] Codes were developed at a national level: Swiss retail association IG-DHS in 2008 and the German NanoKommission in 2008 (NanoKommission 2008 2009); and at an organizational level: chemical firms BASF (BASF 2010) and BAYER (BAYER 2007). For an overview of codes of conduct, voluntary reporting schemes, see Mantovani et al. (2010).

UK's Nanotechnology Knowledge Transfer Network (Responsible NanoCode 2008).

There are further initiatives at the macro level which are important for de facto agenda building processes and institutionalization of 'responsible innovation'. Work on definitions and standards of nanotechnologies by the International Standards Organization (ISO) and the Organisation for Economic Co-operation and Development (OECD). The OECD has established a working party on nanotechnology (WPN) which has as its objective "to advise on emerging policy-relevant issues in science, technology and innovation related to the responsible development and use of nanotechnology" (OECD Working Party on Nanotechnology (WPN) 2010). For this, the WPN collaborates with other organizations, including HES aspects of manufactured nanomaterials.

The involvement of ISO and OECD is part of a broader development: the emergence of a 'world of responsible innovation of nanotechnology'. This emerging world is populated by a broad variety of actors who aim to articulate and shape embedding of nanotechnologies. Renzo Tomellini often included a slide in his presentations showing an overview of this emerging world, and updated it (Rip 2010b). On this slide, societal aspects linked to nanotechnology play a central role.[9] The fact that he showed this slide, and the substance of this slide itself, is interesting, as it shows which actors are considered relevant and how they are connected. This is an acknowledgment of an emerging world.

In this history of macro-level developments I showed that over time a nanotechnology landscape evolved as relations between nanotechnologies and societal embedding at the macro-level became more articulated and shifted in focus. The move toward responsible development and innovation of nanotechnologies plays a key role and may contribute to more reflexive co-evolutionary processes. Of course, this is not the whole story of what is happening in the domain of nanotechnologies. This was already clear in my discussion on drug delivery, where a further macro level development such as the emergence of 'translational research' was important. While 'translational research' is not about societal embedding of nanotechnologies, it is relevant for embedding. Still, in the world of nanotechnology there is an interest in

[9] Slide is published on Cordis: see ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/a-interactions-global.pdf

challenges of societal embedding and how to deal with them. Therefore, it is worthwhile to explore what has happened at the macro level. What then, does this move toward responsible development and innovation at the macro-level mean for actors' anticipation of embedding?

The emergence of debates on risks of nanotechnologies as such (rather than specific risks) provided affordances for action in the sense that actors can take into account possible risks of nanotechnologies (and actor perspectives thereof) in their actions and interactions. When actors began to take into account risks in anticipation oriented actions, articulation processes of nanotechnologies and embedding opened up, i.e. were extended with broader considerations. On the other hand, considerations of risks also closed down the scope of interventions and anticipations as risks appeared to have become a dominant issue, eclipsing other considerations and constraining further articulation. For actors involved, there appears to be no escape from consideration of risks. Part of the force of the notion of risks is that, in general, there is strong attention for risks of emerging technologies. When no actors are willing to risk their neck, a waiting game then easily emerges in which actors (risk authorities and product manufacturers) wait for each other to take the first step.

When actors take up the notion of responsible development, articulation processes may open up as they move away from a dominant focus on risks. This is not straightforward, however. One (speculative) reason why the notion may not be effective as an affordance lies in its character. Discourse and arrangements associated with 'responsible development' provide general direction for actors' anticipations as to the kind of things which should be taken into account, but leave open how they could be filled in. Concrete anticipations are left to actors who face difficulties of anticipations, see further Deuten et al. (1997) about the wicked problems of anticipation. Then, landscape affordances around HES risks may be relatively easier to be adopted.

Future macro level developments may contribute to easier uptake of affordances of the landscape, however. One possible development is that 'nanotechnology' as a socio-political entity dissolves and instead discourse and arrangements around nanotechnologies become more differentiated with respect to application domains. Debates about HES risks and responsible

innovation, then, will be linked with more specific developments, which facilitates uptake of landscape affordances.

In any case, macro level developments act as a backdrop to strategic actions and interactions in the here-and-now and offer directions for future action. Uptake of affordance provided by the landscape will be different though. Which role do these macro level developments play in my two domains?

Salient is that in the domain of food packaging, institutional entrepreneurship initiatives follow overall developments at a macro level, whereas this does not happen in the drug delivery sector – at least not yet. Expectations regarding the application of nanotechnologies for packaging emerged in the 1990s, but received further momentum around 2000 with the launch of Kraft's Nanotek. This coincided with a general increasing attention for nanotechnologies and their promises, as visible in newspaper reporting and with the launch of the US National Nanotechnology Initiative in 2000. The emergence of the risk debate and attempts to do something about it are also reflected in initiatives in the food packaging sector. Clearly, this is not surprising, as some of the initiatives (Dupont & Enviromental Defense, UK DEFRA) play at both levels. Risk debates on emerging nanotechnologies will have contributed to reluctance and waiting games within a sector such as food, which is already cautious with new technologies. A further key macro level development, discourse regarding responsible innovation, is not very visible, though codes of conduct, in various forms, are. Again, we see an initiative, the Responsible Nanocode working party, active at both levels. Other initiatives such as the EU code of conduct are mainly visible at the macro level, while the code of conduct by the Swiss retailer association IG DHS predominantly acts at the level of sectors, including the food packaging sector. So, there is some alignment between macro-level and meso level activities in the food packaging domain.

This is less so for ongoing actions and interactions, as apparent from my food packaging workshop. Themes such as responsible innovation and codes of conduct were not visible within the workshop, however discourses on risks in general and on sustainability were referred to and discussed. General expectations regarding nanotechnologies and risks were recognized, often in the context of uncertainties. Risks of nanotechnologies, and anticipation thereof, were positioned as a significant challenge for firms. One participant

remarked that risks could also be an opportunity, if one firm would be more able to manage risks than others. Uncertainties about performance and risks of nanotechnologies made actors reluctant to engage in embedding processes. Discourse on responsible innovation is not taken up in actors' actions and interactions yet as anticipations of more concrete items are already challenging enough and put up front.

For drug delivery we saw a different picture. There, institutional entrepreneurship initiatives emerged in the second half of the 2000s. Initiatives focused on legitimizing the application of nanotechnologies and participation in the construction of a world of nanomedicine. No initiatives emerged which focused on risks of nanotechnologies. Risk debates were not taken up in the form of waiting strategies and waiting games (but may have contributed to them), even if waiting games occurred. Anticipatory interventions were oriented toward broadening and co-ordinating research activities, especially regarding the need for translational research in an emerging world of nanomedicine. So, while there is some anticipation of embedding, albeit via a detour and with a specific focus, macro level debates on challenges of embedding were out of the picture. Broader themes regarding responsible innovation were not prominent, although large pharmaceutical companies had been involved in an early stage of the development of the Responsible Nanocode.

Even if risks were not much of a theme for institutional entrepreneurship in the drug delivery sector, they were discussed during the targeted drug delivery workshop. Participants were concerned that the risk discourse would spill over to the domain of drug delivery and would contribute to negative public reactions and new regulation.[10] Other participants referred to domain characteristics and argued that risk management in the domain of drug delivery was well organized compared to other domains. These discussions of macro-level developments demonstrate the relevance of landscape developments for anticipation oriented actions and interaction, even if the perception of action possibilities varies across my two workshops. In the drug delivery workshop, as in the food packaging workshop, much attention was paid to sectoral issues and challenges. Whereas responsible innovation and

[10] One participant remarked that new regulation might not necessarily be a bad thing though.

codes of conduct were not discussed, macro developments specific for medical and pharmaceutical technologies such as translational discourse were referred to and discussed, in the context of improving co-ordination across the sector and overcoming present impasses.

Thus, sector dynamics refracted affordances offered by macro level developments related to societal embedding. If friction between different levels can induce openings for change (see chapter 2), a lack of friction will let meso level developments continue as they are. The limited uptake of debates concerning risks and responsible innovation in the domain of drug delivery illustrates this point.

One general feature is how the enabling character of nanotechnologies creates difficulties for concrete anticipation. Nanotechnologies go into intermediate products (nanomaterials, platform technologies) which can be used in different sectors of industry. The implication is that attempts at anticipation of nanotechnologies without an explicit link with a domain of application can only be generic. This is reflected in the generic character of 'responsible development' discourse. While this makes it difficult for actors to translate to concrete anticipations, and while it can be refracted by sectoral dynamics, it will also be difficult to neglect. First, because of its generic character it appeals, in principle, to a variety of sectors. Second, there is an overall credibility pressure on nanotechnology enactors to act 'responsibly'. Firms' willingness to engage in stakeholder dialogues are indications that this pressure is felt and leads to prudent action. Responsible development can become an important concept guiding actors' anticipatory actions and interactions when actors leave their waiting strategies and move toward exploration and exploitation of nanotechnologies. Prior to that, anticipatory interventions aiming to overcome waiting games in a sector can contribute to opening up toward anticipation of embedding.

7.3 Anticipatory interventions in the food packaging and drug delivery sectors

Different modalities of anticipatory interventions were distinguished. Institutional entrepreneurs can emerge who take pro-active action with respect to societal embedding, either out of prudential considerations or with a vision of societal embedding of emerging technologies in a particular field. While these types can be analytically distinguished as different modalities, in practice they will be mixed. Another modality is formed by anticipatory interventions which aim to promote reflexivity: 'reflexivity entrepreneurs'.[11] A whole range of such reflexivity entrepreneurs can be identified, beginning with commentators wanting to push reflexivity and 'soft' change agents such as CTA agents who organize workshops. One can actually think of a third category of anticipatory interventions: actors, who, because of their authoritative position, are able to modulate ongoing developments. These actors can modulate out of prudence or with a vision of societal embedding, up to stimulating reflexivity in embedding processes. My empirical studies examined two modalities of anticipatory interventions at the level of sectors. Here, I will discuss overall findings and conclusions of my studies in the domains of food packaging and drug delivery, to provide domain specific input for my forward look.

In both domains there are interventions by institutional entrepreneurs which anticipate embedding, however they evolve in different ways. In food packaging, interventions contribute to an emerging patchwork of rules and practices at the sectoral level, whereas in drug delivery interventions link up with the broader area of nanomedicine and create a world overlapping with the drug delivery sector. Within this emerging world of nanomedicine, actors from different positions in the sector intervene to push anticipatory co-ordination, in particular by promoting translational research. It is a patchwork of overlapping initiatives. While anticipations are linked to ongoing research activities rather than to the embedding of products, they are relevant for embedding as they link up worlds of academia, pharmaceutical companies and clinicians. This differs from developments in the food packaging sector, which are more product oriented rather than research oriented.

[11] The term 'reflexivity entrepreneur' was coined by Arie Rip.

The dynamics in the evolution of institutional entrepreneurship in the drug delivery sector provides an interesting contrast with the food packaging sector. Institutional entrepreneurs were driven by attempts at building a world rather than reducing uncertainties related to challenges of embedding. Risks were not considered an important topic as regulation was seen to be in place (although practitioners in the sector expected that general debates on risks of nanotechnologies could spill over to drug delivery). More so than in the food packaging sector, sector dynamics refracted or even backgrounded pressures from the evolving nanotechnology landscape I sketched in section 7.2. The type of actors which emerged as institutional entrepreneurs or within fora, and dynamics in the sort of interventions, are therefore different between the food packaging and drug delivery sectors.

These findings are significant as they make our understanding of enabling conditions for institutional entrepreneurship more complex than existing propositions within the literature on institutional entrepreneurs. The link with macro -level developments, and the point that actors operate on both levels, imply that enabling conditions are related to landscape developments, rather than only sectoral or field level developments. Landscape developments such as the emergence of themes of risks and responsible innovation provide affordances for institutional entrepreneurship. However, as noted, macro level affordances will be refracted by sectoral level dynamics. Further adding to the complexity is the fact of changes at the macro- and meso-levels, and their co-evolution. Even if the food packaging and drug delivery sectors are similar with respect to structural conditions in terms of their composition as intersecting product-value chains and of their facing uncertainties and challenges of nanotechnologies, dynamics in institutional entrepreneurship differ.

Interactions between participants in the CTA workshops, the other main anticipatory intervention modality, indicated further dynamics in embedding processes. In particular, waiting games, as salient conditions enabling and constraining actors, and thus also the institutional entrepreneurship, were evident. Uncertainties regarding performance and risks of nanotechnologies were discussed in the food packaging workshop and uncertainties concerning performance and translational research were visible themes in the drug delivery workshop. Further topics emerged. In the drug delivery workshop uncertainties regarding risks of drug delivery technologies were discussed, even

if they were not considered to be a topic for future action. In the food packaging workshop, the idea of a platform for anticipatory co-ordination was discussed and appreciated, although participants were reluctant to take the initiative. All of these topics have to do with reduction of uncertainties in embedding, through building and orchestration of a newly emerging world where (forms of) anticipatory co-ordination are important, and accepted as important, by most actors.

Participants in the workshops identified further items to be taken into account during embedding processes (which can be expected from a workshop aiming to stimulate actors' reflexivity). In the food packaging workshop a range of concrete items linked to challenges of embedding were discussed, such as whether nanotechnology-engineered materials will fit with existing production equipment and whether customers were willing to pay (extra) for these products. In the drug delivery workshop participants discussed the extent to which nanotechnology-engineered drug delivery systems would pose new challenges for research methodologies in pre-clinical and clinical studies, and how to link different disciplines in the chain of research and development activities. This shows that more 'patches' are relevant, and required in the patchwork of new rules and practices than are now promoted by anticipatory interventions. Stabilization of emerging patchworks of rules and practices, then, will co-depend on broader articulation processes of nanotechnologies and embedding.

What is striking across all my studies is that institutional entrepreneurship initiatives and actors' considerations of societal embedding cannot be simply categorized anymore as enactor or selector perspectives. [12] The initiatives by researchers and firms started out, in the early 2000s, as attempts to legitimate the combination of nanotechnologies and food packaging or drug delivery. At that point the coupling of socio-cognitive positions of actors and type of initiatives was pronounced, but this changed over time.

Workshop participants usually associated with an enactor perspective co-opted some aspects of selectors' perspectives, and selectors some aspects of the

[12] This finding nuances the proposition that the "identity of the institutional entrepreneur distinctly impacts the legitimacy building initiatives undertaken" (Jain and George 2007, p. 538).

enactor's perspective. This is an early indication of changes in a division of promotion and control labour with respect to emerging technologies. Even if actors did not consider societal embedding as an objective they should pursue, they did take into account other's positions. This is significant as it indicates that actors recognize mutual dependencies and engage in strategic interactions, which, if continuing, will contribute to reflexivity in co-evolutionary processes.

7.4 Emerging patterns in reflexive co-evolution of nanotechnology and society

To consider emerging patterns I will begin by discussing patterns in the here-and-now. There is 'embedding work' of various actors who are involved in actual and anticipated societal embedding of nanotechnologies. And there are also mutual dependencies and strategic interactions which add up to 'games of embedding'. From there I can speculate (in a controlled manner) about future patterns.

Division of embedding work

Within the nanoworld, the historically grown division of promotion and control labour (Rip et al. 1995) is bridged, at least partially. The division itself is recognized and accepted by the various actors. In terms of Rip and Shelley-Egan (2010) there is a division of moral labour with respect to nanotechnologies. This is visible in how actors work with standard repertoires, including a perception of their 'mandate'. This then justifies their views and strategies: for NGOs, the need for concern and precautionary measures; for scientists, their work towards 'progress'; and for chemical companies, their concerns regarding lack of trust in industry.

The institutionalization of ELSA research components (and now also risk research programs) in nanotechnology R&D programs is an instance of dedicated bridging – yet implemented as a division of work on societal embedding. Independent of the question of whether ELSA research acts as a 'lubricant' for research on, and future introduction of, nanotechnology (or not)

the institutionalization of ELSA research represents a division of (anticipatory) embedding work.

The emerging ELSA 'industry' (Rip 2009) and an emerging 'world of responsible development' is a further indication of a division of embedding work. Work towards societal embedding, including anticipation of future developments, is outsourced, or left, to ELSA scholars. In a world of 'responsible innovation' some actors specialize in 'innovation', others in 'responsible'. Outsourcing of embedding work will always be partial: some embedding activities, such as selling products, and integration of new technologies in business practices, will remain the responsibility of enactors.

Embedding work at the level of a sector (or across sectors due to the enabling character of nanotechnologies), is taken up by a limited number of actors and in specific spaces for interaction. Actors and fora which promote anticipation-of-embedding oriented actions have by now become legitimate intermediaries in co-evolutionary processes – and therefore a further element in the *de facto* division of embedding work. Their 'anticipatory interventions' can have different modalities. They can focus on particular themes as institutional entrepreneurs do. Or, they can focus on stimulating reflexivity as 'reflexivity entrepreneurs' do, ranging from macro level actors such as Roco and Tomellini promoting responsible innovation of nanotechnologies, to soft interventions in the form of 'laboratory engagement' (Schuurbiers and Fisher 2009) and Constructive Technology Assessment workshops. While the substance of such anticipations will differ across sectors, the promotion of anticipatory co-ordination and the reduction of uncertainties through promotion of rules are general, and recognized, routes for anticipatory interventions.

The legitimacy of such intermediaries is not automatic, as is apparent in the critical responses to the creation of a risk framework by Dupont and Environmental Defense (see chapter 3) and in the reluctance of actors to participate in CTA workshops organized by myself and some of my fellow PhD students (see Robinson 2010). Still, Dupont and Environmental Defense's ability to mobilize support indicates that they are considered by some actors to be a legitimate initiative, at least one worthy to consider. In my own engagement activities and that of fellow PhD students in the TA NanoNed program, we did have the experience of being accepted 'visitors' in the

nanoworld.[13] Thus, such modalities of anticipatory intervention have become part of the world of nanotechnology.

Games of embedding

Pro-active embedding strategies, highlighted in the slogan 'Let's do it right from the very beginning' (see Section 7.2) can be part of, and shaped by, games of embedding - as I argued in Section 2.3.3. They always occur as processes of embedding depend on interactions between various actors, however they are now recognized as such even when actors do not use the terminology of strategic games. Actors recognize mutual dependencies and take other actor's perspectives into account. The interactions in my workshops showed that actors reflected on what was happening at the level of a sector and considered other actor's perspectives on nanotechnologies.

A number of different games were visible in the domains I studied. Salient were waiting games in the food packaging and drug delivery sectors, and how anticipatory interventions were attempted to overcome the waiting game. One can find waiting games in other sectors as well, such as in the area of Organic Large Area Electronics (Parandian et al. 2010). Another game, primarily at the level of public authorities deciding to invest in nanotechnology development, is the funding race between countries comparing their expenditure with that of other countries (the USA, now also China) and funding nanotechnologies in order to not lag behind (see 7.2.1).

A further game of embedding, very visible in the nanoworld, is the 'public engagement' game (Rip 2010a). For nanotechnology enactors there is a pressure to engage with citizens in order to avoid being seen as not transparent, not 'responsible'. Citizens are willing to engage with enactors, or pressed to do so, because nanotechnologies are positioned as important. It is almost a moral appeal: 'you can't refuse to engage, nanotechnology is coming'. A net effect of the game character of public engagement is that outcomes of public engagement on agendas and decision making are less important than the ability to say "See, we have engaged".

[13] Actual uptake of anticipation on embedding-oriented considerations in ongoing actions and interactions (and their effects) is another question and beyond the scope of this thesis. For analysis of actual uptake of interventions see Robinson (2010).

Games of embedding are one of the patterns in how actors in society are coping with challenges of societal embedding of newly emerging science and technology. However, a word of caution applies. Waiting games and public engagement games may be not so strong in other sectors of industry. The domain of nano-electronics, and specific application areas, will be less sensitive to public engagement games as public acceptance is not a prominent issue there. For semi-conductors the main game is an innovation race where Moore's law is the rule of a strategic game involving firms and governments investing in new chip developments (Rip 2010a). Actors stay in the race for superior chips and expect others to do the same, and so do not want to risk falling behind.

Future developments and patterns

For the future development I will highlight two scenarios. One scenario is the institutionalization of anticipation of embedding in ongoing technology developments. The other scenario is the opposite, where attempts to make anticipation of embedding more concrete, backfired.

The first scenario assumes that situations of waiting games and reluctance to explore nanotechnologies are overcome and 'responsible development' gets through. At present actors do consider anticipation of embedding important, but do not want to risk their neck. The stagnation in exploration and exploitation of nanotechnology opportunities implies that there is no concrete "peg" to hang consideration of future embedding on. This scenario assumes that present and future attempts to overcome waiting games and reluctance will be successful, at least in a number of domains of nanotechnology. Anticipation then becomes real, particularly so when the discourse on responsible development and associated governance arrangements are taken up in practice. This will require further articulation at the level of ongoing technology development and embedding processes. For example, the availability of benchmarks with respect to 'compliance with codes of conducts', such as currently under development for the Responsible Nanocode, implies pressure on organizations to do something about it. The emerging responsible innovation 'industry' of social scientists and consultancies who offer their

services with reference to the ideograph of 'responsible development' becomes an established part of the newly emerging world of nanotechnology.[14]

In this situation, a 'natural trajectory' (Nelson and Winter 1977) emerges in which anticipation of embedding is an integral part of technology development; see further Rip (2010b). Just as the natural trajectories of mechanization (since the 19th century) and automation (since at least the 1950s), this trajectory has a general character and need not be equally visible in all domains. Empirically, it can only be recognized with the benefit of hindsight. This new natural trajectory can be labelled as one of 'socio-technical robustness'. Technologists' mandate to develop technologies is now broadened with anticipation of embedding.

To be able to speak of a trajectory, it must not only be a promising way, but also an emerging irreversible way; i.e. it will be increasingly difficult to deviate from this way of coping with emerging technologies. Indicators for the emergence of such a natural trajectory can already be found: translational research in the world of nanomedicine, second order anticipations in the form of responsible innovation, and general risk debates. These approaches can be applied to other emerging technologies, and nanotechnology will be the leading domain for such approaches. A proxy indicator for the irreversibility (which cannot be fully assessed at this stage) is actors' evaluation of such attempts as passing 'a point of no return'. Recent discussions on institutionalization of risk research in nanotechnology research programmes may be an example.

Such an institutionalization process will make technology development more societally robust, but there may be a price to pay. The lock-in that goes with it can have disadvantages as well, because certain aspects and issues will be excluded. One can see this happen already in the strong focus on risk aspects (Rip and Van Amerom 2009). Debates surrounding emerging technologies, with their (ant)agnostic pattern (Rip and Talma 1998), and projections of opponents versus proponents, will often focus on benefit-risk trade-offs. When this is internalized in technological development as the operational form of the

[14] Voss (2007) has analyzed a similar phenomenon, the emergence of a so-called carbon industry' of economists, consultants, and banks supporting emission permit trading of CO_2.

natural trajectory of socio-technical robustness, there are good reasons to try to open up the natural trajectory once again.

The second scenario is set in motion when waiting games and reluctance continue and result in a situation where actors no longer pursue exploration and exploitation of nanotechnologies. Nanotechnology's 'house of cards' is built on promises and might collapse if eventual performance is disappointing for actors. Enactors' concerns about a possible collapse of nano have been voiced in the domain of drug delivery. We find indications of a possible collapse in the food packaging sector as well. Firms are sceptical about performances of nanomaterials, or have taken a step back, such as Kraft has done.

Compared with biotechnology, where resistance to agro-biotechnology applications created debate and an impasse (for enactors), it is now reluctance and disappointment creating the impasse (for promoters of nanotechnology). The slogan "Let's do it right this time from the very beginning" was followed, but it did not work. Thus, actors will now also be disappointed about pro-active action and anticipatory efforts, and this spills over to emerging technologies in general. Anticipating societal embedding at an early stage will then be perceived as overkill, and contributing to stirring up too many concerns. Enactors will return to their usual approach of putting effort into reducing uncertainties about performance first (the sequential approach, cf. Deuten et al. 1997). For firms, this implies a trial-and-error strategy: put product options on a market and see which ones survive. Researchers and research sponsors may continue with their promising game and the associated funding race, but will be more vulnerable to critical questions regarding actual benefits.

Selectors of emerging technologies will have a different interpretation of the collapse and the role of anticipatory actions and interactions. For them, nanotechnology enabled products are only one possible socio-technical option, sometimes welcomed, sometimes seen as irrelevant. They will continue to value early anticipation, but as a defense against the unbridled introduction of new technology. This is already visible in the insistence of NGOs for precautionary measures and transparency with respect to development and introduction of emerging technologies.

In the present situation of nanotechnology (and of emerging technologies more generally) one sees elements of both scenarios. It is too early to see whether (and how) one or the other scenario will prevail, or whether a muddling-through scenario obtains - a patchwork of different elements not adding up to an overall thrust.

7.5 Final comments

I sketched two scenarios of patterns in how our societies will cope with the co-evolution of nanotechnology and society, and considered the possibility of a patchwork of elements of each of them. Such exercises broaden anticipatory activities by shifting from a technology-centric perspective to a societal-pattern perspective. Whatever happens, recognition of such scenarios, and how they build on tendencies already present, will enhance reflexivity in the co-evolution of technology and society.

My study of two modalities of anticipatory intervention (by institutional entrepreneurs and by CTA agents) and the patterns that evolve, is set against the backdrop of the general question about reflexive co-evolution. In these final comments, I offer some reflections on my findings.

Successful outcomes of anticipatory interventions (whatever is considered exactly as 'successful') cannot be attributed to a single actor working from a particular context. Anticipatory interventions are always embedded. Institutional entrepreneurs, CTA agents, are one among many actors attempting to shape interactions, or just doing their own thing, which still has repercussions on interactions and outcomes. This is a general observation, but it explains why I had, most often, to characterize what I found as 'patchworks'.

Anticipatory interventions are not only attempts to achieve the goals of the interventionists (whether concrete goals of actors or reflexivity goals of CTA agents). They are also attempts to figure out how to cope with embedding of emerging technologies, and can be studied in those terms so that others can learn and try to do 'better'. Anticipatory interventions contribute to an

emerging patchwork of increased reflexivity in co-evolutionary processes. Taking a leaf out of the 'book' of the literature on learning organizations, one can see this also as a learning experience at the interorganisational and macro-levels.

Patterns in the reflexive co-evolution of nanotechnology and society are still emerging, and it is not clear what form they will take. Still, my analyses of anticipatory interventions provided strong indications that reflexive co-evolution of nanotechnology and society is here to stay, even if the form and the concrete activities are still open-ended.

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Appendix 1

Evolving Repertoires: Nanotechnology in Daily Newspapers in the Netherlands *

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Evolving Repertoires: Nanotechnology in Daily Newspapers in the Netherlands

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In new and emerging science and technology, such as nanoscience and nanotechnologies, newspaper coverage is important in a number of ways.[1] Newspapers can act as a 'catalyst' when reporting on controversial issues, exacerbating the degrees of opposition between actors. However, newspapers may also have a mediating function through the creation of an arena in which proponents and opponents can interact (Rip, 1986). Proponents of the development of new technologies are often concerned about the ways in which new science and technology are represented in the media—and by the results of negative perceptions. Typically, the concern is that print and audio-visual media have the power to form public perceptions. This concern is often overstated. For example, Nisbet and Huge (2006) suggest that in media debates about the regulation of plant biotechnology other national news received more media attention. They argue that in the end, media coverage of plant biotechnology had little effect on public concern.

Still, newspaper coverage does frame issues and contributes to agenda building (Nisbet *et al.*, 2003). In this view, recipients of newspaper coverage are not considered to be merely passive, but actively take up issues covered by media. This supports Swidler's (1986, p. 273) concept of 'repertoires' which views culture as providing actors with a '"tool kit" of symbols, stories, rituals, and world-views' from which they can select different elements to shape their action and solve problems. In this perspective, newspaper coverage can be viewed as an expression of a 'newspaper repertoire' which can be used by actors to engage in public dialogues on new and emerging science and technology.

There is no simple one-to-one relation between the presentation of media coverage and subsequent effects on public attitudes (Ten Eyck, 2005). However, such coverage is still important because newspapers are publicly available and enable readers to become aware of new scientific and technological developments and, more specifically, engage in dialogues about nanotechnology. Especially when most people have little experience of a new technology, media coverage can provide heuristics for understanding and assessment (Scheufele and Lewenstein, 2005). Because of this wider relevance, newspaper coverage of nanotechnology is an important domain to study, not only as a potential catalyst and

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mediator of controversies, but also as a medium that supports the development of broader dialogues on nanotechnology. With this support for public dialogues as a backdrop, it is not only important to analyse what is reported, but also the dynamics of any coverage, for example, if and when changes in the repertoire occur, such as the introduction of new perspectives and arguments or the emergence of controversies. Key questions then become: (1) how do newspapers represent nanotechnology; and (2) how does this coverage evolve over time?

Media coverage of nanotechnology has recently been examined in a number of studies (Anderson *et al.*, 2005; Faber, 2006; Stephens, 2005). One of these studies concluded that there were significant differences in reporting between US and non-US media (Stephens, 2005). Non-US newspapers are more likely to argue that risks and benefits need to be balanced than US newspapers. US newspapers appear to emphasize the promise of nanotechnology and represent it as a technology that offers solutions for key social issues (Faber, 2006). The political and scientific culture in the US appears to be markedly different from that which predominates in Europe, as far as the ways in which new science and technology is reported. Instead of an emphasis on the promise of nanotechnology one would find more modest expectations in European newspaper coverage. With the exception of the UK (Anderson *et al.*, 2005), no recent studies appear to be available that analyse in detail how nanotechnology is reported in Europe.

In this paper I will analyse Dutch newspapers' coverage of nanotechnology since 1992. This coverage is divided into three periods in which new issues or perspectives on nanotechnology emerged. This historical account also reveals shifts in reporting patterns, particularly changes in the reporting pattern as competing views are increasingly contrasted. Such a shift, introducing not only arguments but also counter arguments, may be a further contribution to the improvement of the public understanding of nanotechnology.

The importance of public attitudes and their possible effects on the further development of nanotechnology has been noted in several studies. For example Wood *et al.* (2003, p. 1) observed that 'diverging views on nanotechnology and the increasingly public debate, involving civil society, non-governmental organizations and the media, have led to concerns that there will be a backlash against nanotechnology akin to that over genetic modification'. This reference to earlier experiences with genetic modification is also reflected in a report from a working group of The Royal Society and The Royal Academy of Engineering that argued that public attitudes play an important role in realizing the potential of new and emerging technologies. Subsequently, that report emphasized the importance of a broad dialogue on nanotechnology involving actors other than scientists and engineers (The Royal Society and The Royal Academy of Engineering, 2004). Understanding and discussing the risks and benefits of nanotechnology is a public good and is an essential prerequisite to realizing the potential of nanotechnology.

Repertoires

The concept of repertoire is employed to analyse and understand how newspaper coverage of nanotechnology enables attentive readers to engage in public dialogue through the provision of a (newspaper) repertoire. The concept is introduced by Swidler (1986) and has also been taken up in science and technology studies.[2] For example, Mulkay (1996) referred to cultural repertoires to argue that images from science fiction are used in

debates over experiments on human embryos in Britain. Rip and Talma (1998) employ the concept of cultural repertoires to argue that there are patterns that are reproduced in debates around new and emerging technologies.

Swidler (1986) introduced the idea of repertoires as an alternative to existing views on culture as formulated by Max Weber and Talcott Parsons. She argued that culture does not shape actors' actions by providing them with 'ultimate ends or values' but with a 'tool kit' of possible lines of action. The role of the repertoire and how it may shape action may differ between more or less established modes of life and 'unsettled periods'. During 'settled periods' culture shapes action by limiting the available range of strategies of action. In unsettled times, cultural meanings are more articulated and shape action more directly because they provide lines of action that people are not familiar with. In this respect, repertoires are especially important in the case of a new and emerging field such as nanotechnology (cf. Scheufele and Lewenstein, 2005).

Newspaper coverage of nanotechnology is conceptualized as contributing to, as well as solidifying, an evolving repertoire about science, technology and society. It is possible to conceive of newspaper coverage—here in relation to nanotechnology—as a repertoire itself, because after an initial period of intermittent reporting there tends to emerge a common and recurring set of framings of particular issues. The newspaper repertoire may itself reflect broader repertoires (on nanotechnology, but also concerning science, technology and society in general), which in turn introduce further framing. The journalists writing the articles (or sometimes just selecting from press releases) contribute towards the evolution of the repertoire—sometimes consciously so—when they selectively seek out actors and give them voice in the texts.

The evolution of the newspaper repertoire is important in the sense that it can contribute to further understanding how to handle new and emerging science and technology. In Western culture, patterns exist that influence the construction of repertoires around particular technologies; patterns that are often of an antagonistic nature (Rip and Talma, 1998). This means that responses to and discussions about novel technologies are often 'cast in an antagonistic mould'. Antagonistic is in this case a more extreme variant of a range of agonistic interactions such as struggles and tensions.[3] For example, actors can be identified to be either 'proponents' or 'opponents' of a new technology. Actually, actors who introduce new technologies also expect that there may be opponents who are opposed to the introduction and watch out for them. These antagonistic patterns may structure a repertoire associated with a certain technology and can be regarded as a characteristic feature of the internal structure of such a repertoire.[4]

What is of special interest here is Rip and Talma's suggestion that antagonistic patterns can lead to an impasse when only 'proponents' and 'opponents' are identified, but on the other hand may also provide opportunities for learning how to deal with a specific technology. Actors may be forced to search for arguments and counter-arguments and eventually a better understanding of the issues at hand may occur. Similarly, Rip (1986) argues that scientific controversies (as informal technology assessment) may support this type of learning, provided that there is interaction between contending parties and between problem definitions. This links up with the backdrop of this paper of how newspaper coverage may support broader dialogues. Therefore, the evolving internal structure of the newspaper repertoire is important and will be the main focus for the empirical analysis of the newspaper articles.

I will analyse the newspaper repertoire empirically through analysing its articulation and the extent to which views are explicitly related to each other: the emergence of agonistic and antagonistic patterns. The concept of 'articulation' expresses the way in which perspectives and arguments associated with nanotechnology are clarified through the formation of new or more substantial links (Rip, 1986). For example, articulation occurs when nanotechnology is framed in a new way and this frame remains a stable element in the repertoire—for example discussion of nanotechnology in the context of innovation agendas. In this article I refer to this particular type of framing as an additional segment in the newspaper repertoire. Of course, further articulation can also occur within a segment. For example, when new perspectives, arguments, or better defined versions of existing arguments are introduced in the context (segment) of how and to what extent nanotechnology will or will not contribute to innovation.

Overall Newspaper Coverage of Nanotechnology

To study how newspapers discuss nanotechnology, all 'nanotechnology' related documents in the main (quality) Dutch daily newspapers were retrieved from the Lexis-Nexis Academic database. For this purpose the terms 'nanotechnologie' (nanotechnology), 'nano-technologie', and combinations of 'nano' and 'technologie' or 'nano' and 'wetenschap' (science) were used as keywords. The time period was 1992, when the first article appeared, up until the end of 2005. The sample contained 237 articles from the Dutch newspapers: *NRC Handelsblad*, *de Volkskrant*, *Trouw*, *Het Parool* and *Algemeen Dagblad*. These newspapers are distributed nationally, except for *Het Parool*, which is distributed in Amsterdam, which as the capital city of the Netherlands is where many opinion leaders live. In addition, items referring to nanotechnology in the financial newspaper *Het Financieele Dagblad* were also retrieved, mainly comprising press releases, a calendar of upcoming events but also a variety of opinion pieces, which will be discussed below.

Figure 1 gives an overview of the data, showing the increasing attention paid to nanotechnology from 1999 onwards. What is also striking is the large increase in articles that mention nanotechnology in passing, or as an item in the discussion of another topic (for example innovation) compared with articles that focus solely on nanotechnology. The latter does not show a sustained upward trend after the main shift that occurred from 1997 to 1999. Rather, articles about nanotechnology begin to appear in other places, for example in the *Staatscourant*, the official government magazine announcing new laws, regulations and measures, which regularly also features a background article (Van Kasteren, 2004).

The increasing number of articles that mention nanotechnology is partly a consequence of the fact that there are an increasing number of events to report. It also derives from 'nanotechnology' becoming more recognized as a regular part of scientific and technological discourse. This is visible in how the term 'nanotechnology' is taken up in other contexts. Some examples are how a composer, Paap, in an interview in 2000, referred to nanotechnology when discussing his dreams of a digital future, speculating about lettuce transported through fibre cables and the possibility of connecting his brain to a computer network in order to 'think' music (Carvalho, 2000). Another article in 2001 discussed new developments in radiation therapy and noted that medicals called their invention fashionably, 'nano generators' (Becker, 2001).

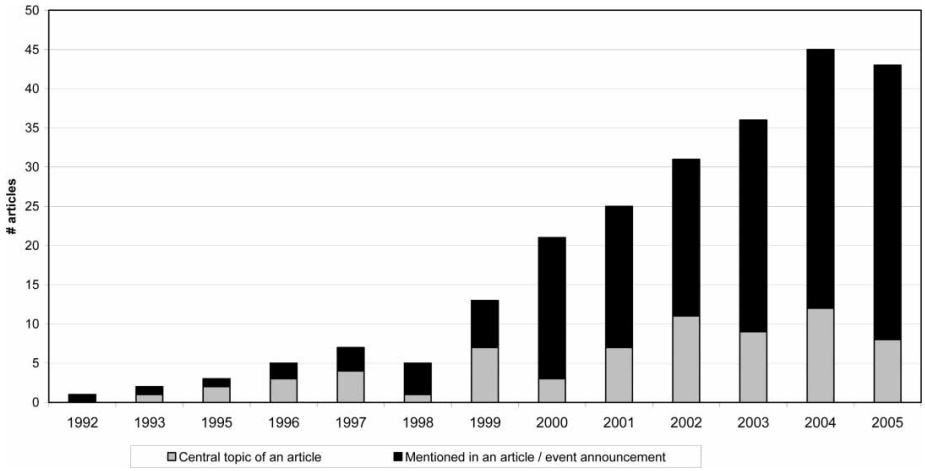

Figure 1. 'Nanotechnology' articles in five general Dutch daily newspapers 1992–2005

To analyse the evolution of the repertoire, a simple classification of subjects of the articles was created, focusing on the context in which 'nanotechnology' appears. Figure 2 shows that in addition to an increase in numbers, there is also an increase in different contexts in which 'nanotechnology' appears.[5] From 1999 onward there are articles discussing the visions of Eric Drexler, often referring to the dystopian depicture of possible nanotechnology future scenarios, including Bill Joy's well known article 'Why the Future Doesn't Need Us' (Joy, 2000b). From 2002/2003 a focus of the role of nanotechnology in innovation is strongly represented. This shows that the newspaper repertoire evolved and that more contexts or segments were included. I consider this as one aspect of articulation. The other aspect is the articulation of the segments themselves.

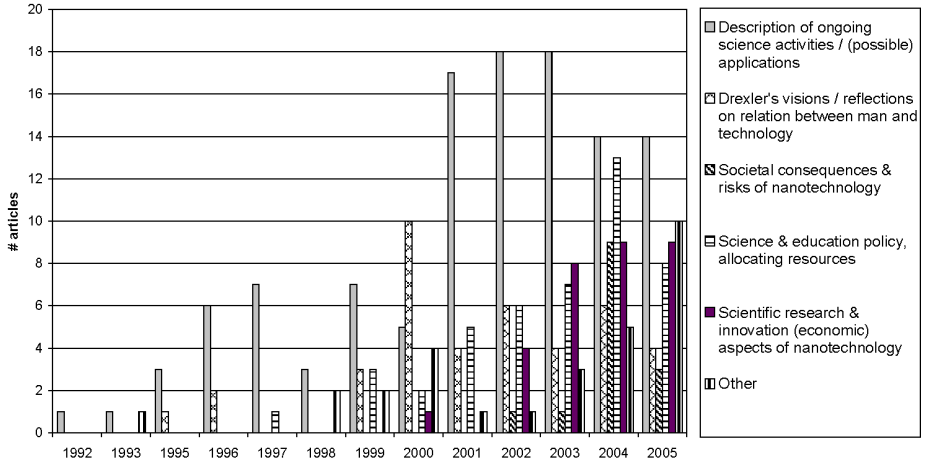

Figure 2. Articulation of 'nanotechnology' in daily newspapers 1992–2005

First Period: The Rising 'Star' of Nanotechnology (1992–99)

In 1992, the 'nanotechnology wave' drifted ashore, at least according to the newspapers concerned. In contrast to the US, it was not surrounded exclusively with high expectations, but instead tended to present both favourable and more sceptical versions throughout the period. Already at this stage an apparently unproblematic repertoire of contradictory associations is visible in the newspaper coverage. On the one hand, nanotechnology is presented as a new technology providing great opportunities for the benefit of mankind. On the other hand, representations can be found that picture nanotechnology simply as ongoing research and that expectations of results are exaggerated. These contradictory associations are not confronted with each other explicitly and appear to exist side by side. I will refer to this characteristic of the internal structure of the repertoire as a 'dual repertoire' or a repertoire having 'dual patterns'. In this period nanotechnology was chiefly covered from the viewpoint of ongoing scientific research and less so in terms of its broader cultural and social articulations (see Figure 3).[6]

The first newspaper article that mentioned nanotechnology represented this emerging field in a scientific context: as building upon discoveries on the micro scale and suggested that nanoscale research is driven by scientists' quest to construct motors on a molecular scale (Den Hond, 1992). The first indication that newspapers picked up nanotechnology explicitly as a rising star can be found in an article in 1993 that signalled that nanotechnology was gaining a lot of attention and that engineers were aiming for the fabrication of mechanical structures on an increasingly smaller scale (Van den Berg, 1993).

It would take some time before visions of the possible applications of nanotechnology, including reflections on future relations between man and (nano)technology, would appear as a context for nanotechnology in newspapers. Even though *Engines of Creation* was published in 1986, it was not until 1995 that the ideas of Eric Drexler were discussed in the daily newspapers in the Netherlands. The first article that discussed Drexler's utopian (molecular machines) and dystopian ('grey goo' in which nano-robots dominate mankind) visions speculated that 'sober-minded Europe' will not warm to his ideas (Van den Berg, 1995).[7] While scientists in the Netherlands may not warm to Drexler's visions, they were warming to nanotechnology as an emerging science domain. Several

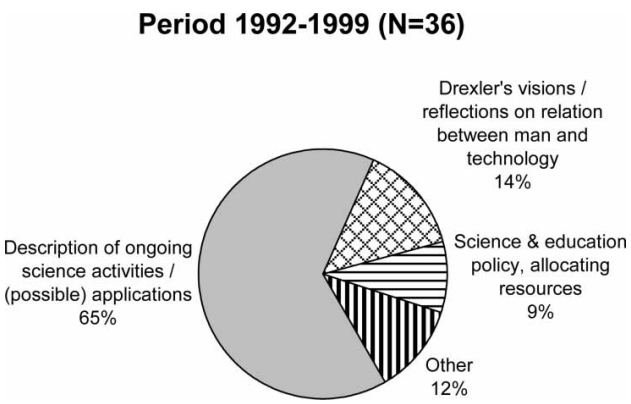

Figure 3. Repertoire segments in the period 1992–99

articles observed the growing interest in nanotechnology. For example, an article concluded that in the light of the increasing popularity of the term, one should 'at least' use the prefix 'nano' nowadays (Van den Berg, 1996). Nanotechnology was also picked up in the context of science policy and research funding: an article signalled that it 'is good' to include the term in project proposals (Engels, 1996). It also remarked on several studies from the Ministry of Education, Culture and Science and the European Parliament suggesting that 'we' (The Netherlands and the European Union) were in danger of falling behind the United States and Japan. At the same time the article concluded that nanotechnology research was not so different from research a decade before. New technologies (like Scanning Tunnelling Microscopy) may have enabled new research methods, but the focus of research was still the same: making increasingly smaller structures. In addition, scientists were quoted who foresaw many problems in the development of Drexler's molecular machines.

The sceptical reflections articulated by scientists to Drexler's vision of molecular machines gradually developed into warnings against making extravagant promises about nanotechnology. Newspapers quoted scientists who claimed that the possibilities of nanotechnology are overestimated (Akinci, 1999; Anonymous, 1999; Van Calmthout, 1999) and who disassociated themselves explicitly from Drexler not least since it impacted negatively on the credibility of nanotechnology research (Akinci, 1999).

While the rising popularity of nanotechnology was noted in newspapers, the newspaper discourse positioned itself as sceptical of the high expectations associated with nanotechnology. On the other hand, nanotechnology seemed to have become a domain of strategic science, in which nations competed internationally and where individual nations did not want 'to lag behind'. This dynamic introduced another element in the repertoire with a rhetorical force that was linked to national competitive advantage. Although advocating modest expectations, the mentioning of 'nanotechnology' was seen as of apparent importance for acquiring funding. These different views were not explicitly contrasted in newspapers. At this stage, newspaper coverage can be characterized as having a dual pattern with both optimistic and more modest interpretations of the potential applications of nanotechnology.

Second Period: The Consolidation of Nanotechnology Research (2000–02)

During this period new contexts (segments) appeared in the newspaper repertoire and existing segments became more articulate (see Figure 4). Key features of this period included Bill Joy's dystopic 'Why the Future Doesn't Need Us', the rapid increase of media commentary on nanotechnology, and the mobilization of more substantial research monies by Dutch actors. This period can be characterized as one of further consolidation and articulation of the dual nanotechnology repertoire from the previous period, because the new segments' 'societal consequences' and 'innovation' received limited attention and in general arguments and perspectives were not contrasted.

In this period, the segment of the repertoire addressing wide ranging questions of the relation between man and technology was further articulated. Several articles discussed these issues (Ormel, 2000; Starink, 2000; Stein, 2000; Van Delft, 2000) and referred to the article of Joy (2000b), which was also translated and published in a Dutch newspaper (Joy, 2000a). The articles set out both utopian and dystopian scenarios. Nanotechnology was also picked up by a broadcasting station that made a documentary called 'Technocalyps' about human enhancement and the role that nanotechnology could play in such

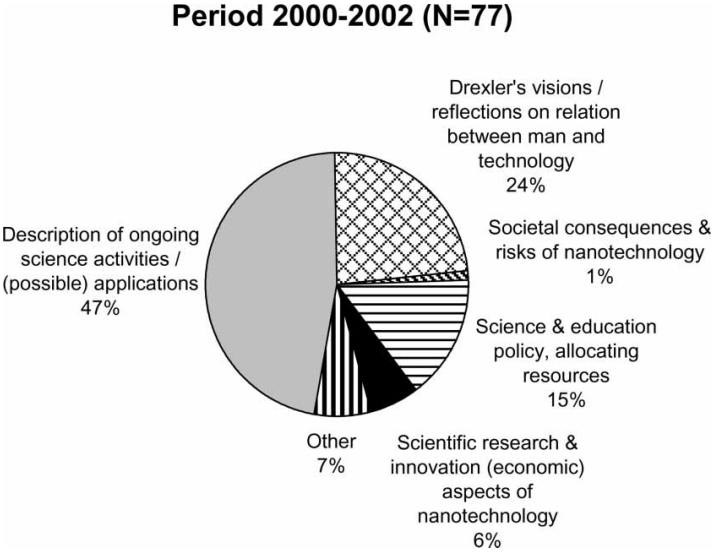

Figure 4. Repertoire segments in the period 2000–02

developments (Oosterbaan, 2000). Also the Arts sector was impacted by nanotechnology according to a newspaper that quoted artists who described robotics, genetics and nanotechnology as becoming dominating factors in life that required new perspectives on mankind (Van der Jagt, 2000).

Descriptions in the context of ongoing science remained a dominant feature in newspaper coverage. Articles discussed for instance the coupling between electronics and nerve cells (Van Delft, 2000) and lab-on-a-chip developments (Voormolen, 2000). Significant attention was paid to the Dutch physicist Dekker who conducted research on nanotubes (Anonymous, 2002; Van Calmthout, 2001; Van den Berg, 2001). Scientists quoted in newspapers continued to be sceptical about grandiose promises and expectations of nanotechnology, tending to discard claims as extravagant. For instance, Professor Kouwenhoven at the University of Delft argued that the promise of manipulating individual atoms was in practice more complex than envisaged by the nano-enthusiasts. Similarly, Professor Knol at the University of Bielefeld claimed that the 'grey goo' scenario was highly improbable, not least because malicious robots would have to act quickly to rebel successfully against humanity, and that their batteries are usually flat within half an hour (Van Delft, 2000).

During this period central actors in Dutch nanoscience and nanotechnologies began to coordinate their actions in order to mobilize funding for large scale projects (see Mangematin *et al.*, 2005). In general these activities were not reported in the media—limiting the further articulation of the segment on science policy—with the exception of the funding of a new nanotechnology research institute in Groningen (Joustra, 1999). It would take some time before nanotechnology research was taken up on the national level. In 2001, the Dutch Research Council NWO selected nanotechnology as one of the themes eligible for extra funding (Van Delft, 2001). The logic behind this mobilization of resources was not questioned in the newspaper articles and the 'invest in order not to lag behind' argument still played a dominant role (Anonymous, 2000, 2001).

Although one could argue that agonistic positions in the sense of 'promotion' and 'control' can be found in newspaper articles, they were not explicitly contrasted. Newspapers continued to have a dual nanotechnology repertoire consisting of, sometimes implicit, references to great promises and utopian visions as well as more modest expectations and dystopian visions. Scientists probably profited from the nanotechnology hype, as indicated by newspaper articles about the importance of the label nanotechnology for funding, which indicated how actors can draw upon a repertoire (although not necessarily the newspapers' repertoire) and their success in getting these funds reinforced the hype. At the same time they acted strategically through presenting themselves as realistic, probably in order to anticipate possible disappointments at a later stage.

Third Period: The Confrontation of Nanotechnology and Society (2003–05)

From 2002 onwards two major changes occurred in the internal structure of the repertoire. First, new issues in the context of innovation, science policy and social consequences of nanotechnology were introduced. Second, these new perspectives and arguments were increasingly contrasted. The prior dual pattern, which was a characteristic feature of the newspaper repertoire until 2002, made way for more (ant)agonistic patterns. For example, optimistic views with respect to profitable societal and economical returns became increasingly questioned. The repertoire not only became more articulate and internally contrasted with respect to the previous period, its internal structure also became more balanced in the sense of more evenly distributed (see Figure 5).

The increasing sociotechnical critique seems to spring from the broad, more or less philosophical discussions covered in the second period. For instance, an article in 2002 signalled that Dutch nanotechnology scientists had started to worry about public fears associated with nanotechnology (Van Calmthout, 2002).[8] The article quoted physicist Professor Mooij at the Technical University of Delft who considered the disruptive effects of a possible movie based on Crichton's novel *Prey!* on public opinion about nanotechnology. Professor Mooij argued that scientists cannot neglect the possible images of fear associated with nanotechnology and should explore how to prevent public distrust against nanotechnology. This is interesting, because it introduced a perspective in the newspaper repertoire which was until then not very visible in not only the newspaper repertoire, but also not in public debates. For example, the article quoted scientists in the Netherlands who claimed that the wider public debate with respect to risks and benefits of nanotechnology had been hitherto comparatively 'quiet' in the Netherlands.

From 2002 onwards more agonistic patterns emerged in the newspaper repertoire. The contexts of innovation and science policy became more articulated and contrasted in the nanotechnology repertoire. For example, a number of articles discussed the declining strength of innovation in the Netherlands and started to question the assumption of the role of nanotechnology as an engine for future innovation. According to economics professors Van den Bosch and Volberda at the Erasmus University Rotterdam, it was not necessary for the Netherlands to prioritize research funding on nanotechnology and biotechnology to help assure future economic growth. Priority instead should be given to strengthening organizational innovation, as well as building up existing domains of Dutch competence, such as the exploitation of knowledge on tulips (De Vre, 2003; Jorritsma, 2003).

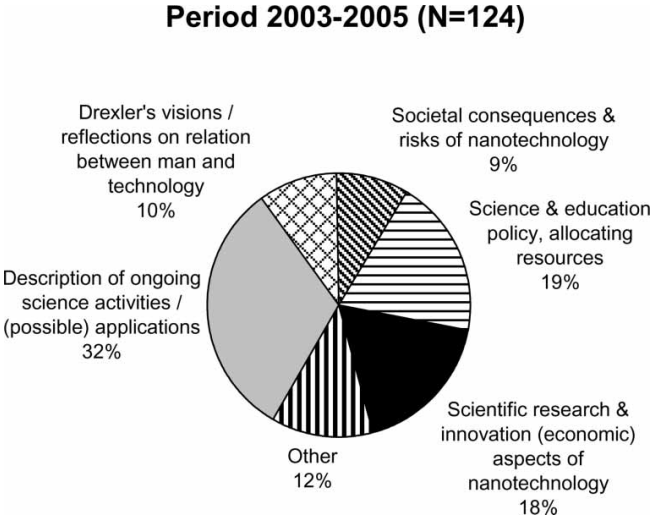

Figure 5. Repertoire segments in the period 2003–05

In December 2003 the government of the Netherlands made the final allocation of the knowledge infrastructure budget of €800 million, including a €95 million allocation for the research programme NanoNed (Anonymous, 2003). Several months later, members of parliament questioned the government priorities for research: genomics, ICT and nanotechnology. It was suggested, by government and opposition parties, that the government was promoting the exact sciences disproportionately and emphasizing economic benefits too strongly (Anonymous, 2004). A report from the Innovation Platform in October 2004, an initiative of the Dutch government to strengthen the innovation power of the Netherlands, suggested that the Netherlands should concentrate on flowers and food, advanced technology (including nanotechnology), shipbuilding and hydraulic engineering, and the creative industries (Persson, 2004). Not only was the national science priority setting discussed during this period, the specific motivations of ongoing nanotechnology research were also questioned. For example, it was argued that current research in the Netherlands was too scientific and that a more explicit focus on applications—as in the United States and Japan—was preferable (Aan de Brugh, 2004).

In addition to the relation between innovation, economic growth and scientific research, the risks of nanotechnology became a key issue as well. Especially, arguments relating to the health aspects of nanoparticles were both articulated and contrasted. For example, in an opinion piece in *Het Financieele Dagblad* the environmental sciences professor at the University of Amsterdam, Professor Reijnders, warned of the risks of nanoparticles and argued for a ban on non-degradable particles that may be released into the environment. According to Reijnders there had existed to date little or no interest in the assessment of nanoparticle risk during the development of nanotechnology in the Netherlands (Reijnders, 2004b). This opinion piece was also discussed by some participants at a workshop on 17 February 2004 organized by the Rathenau Institute on the health risks of nanoparticles, and a number of actors felt they had to respond.[9]

Several articles appeared in newspapers that referred to Reijnders' opinion piece. For example, the toxicology professor at the University of Düsseldorf (Germany), Professor Borm, responded with an opinion piece in *Het Financieele Dagblad.* He partially agreed with Reijnders' diagnosis of limited interest in risk assessment of nanotechnology in the Netherlands. He suggested that discussion was more recent in the Netherlands and that the starting point had been the Rathenau Institute workshop in February 2004. Instead of introducing a moratorium on nanoparticle research, he called for wider participation in an already ongoing international process in which nanotechnologists, toxicologists and biologists were discussing the possible undesirable effects of nanotechnology applications (Borm, 2004).

Similarly in an opinion piece in *Het Financieele Dagblad*, Nanoscience Professor Speller of the Radboud University Nijmegen declared the need for an open dialogue between scientists and the public that should be started as soon as possible (Speller, 2004). In an article in *de Volkskrant* she explained why she did not agree with a moratorium on nanoparticles. Professor Speller argued that many possible hazardous consequences of nanoparticles do not differ from those of traditional chemicals that are already in our environment. According to her the advantages outweighed the disadvantages. She compared the debate around nanotechnology with that of biotechnology:

> Especially in biotechnology things have been destroyed through exaggerated distrust and too much caution. In any case, this resulted in the disappearance of lots of research from the public domain and our sphere of influence. [. . .] The greatest danger is the disappearance of nanotech from the public sphere (Van Calmthout, 2004).[10]

By now, the reference to biotechnology, especially GM food, had become commonplace in newspaper articles. Physicist Professor Lagendijk of the Institute for Atomic and Molecular Physics discussed the emerging debate about health risks in his column in *de Volkskrant*:

> Scientific researchers regularly face negative publicity about their profession. Environmental activists seize every opportunity to put scientific and technological developments in a bad light. They have been very successful with their actions against genetically manipulated food in Europe. The new target of environmental activists is nanotechnology. Many health risks are expected to be linked with this technology. No physicist or chemist is able to define exactly what nanotechnology means, but the green can already devise doom scenarios if this technology should be introduced. [. . .] In order to avoid making the same mistake as with genetically manipulated food, scientists will take the grievances of the environmental movement very seriously. Or at least they will pretend to do so. They are scared to death of demonstrators near the entrance of their laboratory (Lagendijk, 2004).[11]

The emerging controversy regarding the possible risks of nanoparticles did not remain confined to debates between scientists. The repertoire became more articulate through the involvement of other actors linked with issues such as risks and more general social consequences of nanotechnology.[12] For example, several articles discussed reports from Swiss Re, the Rathenau Institute, the Royal Netherlands Academy of Arts and Sciences and the National Institute for Public Health and the Environment (Aan de Brugh, 2004; Becker, 2005; Van Calmthout, 2004; Van Nieuwstadt, 2004).

In contrast with earlier periods, the articulation of the repertoire, especially the contexts of science policy, innovation and societal consequences, was now also accompanied by newspaper pieces contrasting different views on nanotechnology. The dual pattern of hyped expectations, utopian visions, and more modest expectations, dystopian visions, was by now less prominent and more (ant)agonistic patterns were appearing in the repertoire. In the debate around nanoparticles, and also in discussions about science and innovation policy, we can recognize for the first time an emerging antagonistic pattern of proponents and opponents. This includes, for example, those who advocate nanotechnology as a priority area for research support due to anticipated economic benefits and actors who question these economic benefits and argue for emphasis on other priorities. Another example is the emerging controversy on the risks of nanoparticles where one can observe an emerging divide between those who promote nanotechnology and those who advocate control of nanotechnology.

This is an important shift in the repertoire pattern and prompts the question, what may have caused this shift in pattern? An explanation can only be partial and speculative, because the active role of journalists in developing the reporting repertoire and the wider environment including the (potential) newspaper audiences have not been systematically researched in this study. What is striking is that scientists played a prominent role in discussing the risks and benefits of nanotechnology rather than, for example, environmental or social activist groups. This is especially the case for the possible risks of nanoparticles which provoked considerable responses from the scientific community, either directly through opinion pieces or via interviews in newspaper articles.[13] The opinion piece by Reijnders on the risks of nanoparticles triggered scientists to respond. An explanation for the prominent role of scientists could be that they anticipated that environmental/health risks were sensitive topics and that they expected more opposition to emerge, cf. Rip and Talma (1998). In this context, scientists also explicitly referred to earlier experiences with biotechnology (Lagendijk, 2004; Van Calmthout, 2004). If a newspaper repertoire is a potential source of ideas, arguments and discourses that can be used to shape action, it is understandable that scientists responded to opinion pieces which might provide arguments that would lead to the strict regulation of nanotechnology or the reduction of research funding for nanoscience. Through the provision of other arguments, emphasizing the importance of continuity of research or other actions to control or contain the risks of nanotechnology, they provide alternative arguments, and thus lines of action, to (for instance) policy makers.

Conclusions

This paper has discussed Dutch newspaper coverage of nanotechnology in the period 1992–2005. With the public understanding of science and technology and its potential in shaping new technologies as a backdrop, it focused on two key questions: (1) how did newspapers represent nanotechnology; and (2) how did this coverage evolve over time?

To address these questions and their backdrop, the newspaper coverage was conceptualized as contributing to, as well as solidifying, a particular repertoire about science, technology and society in general, and a specific newspaper repertoire in particular. As a repertoire, representations of nanotechnology in newspaper coverage became a set of symbolic resources that readers can draw upon to help them to engage in public dialogue.

The empirical analysis of newspaper articles showed that the newspaper repertoire has evolved and became richer through the articulation of additional contexts, and through the further articulation of both arguments and perspectives within these contexts. The representations of nanotechnology gradually included not only scientific contexts, but also broader sociotechnical views such as utopian and dystopian visions, views regarding the possible contribution of nanotechnology to economic growth, as well as discussions about risks inherent in this new and emerging field of science and technology.

With respect to the representation of nanotechnology in newspaper articles, one can ask the question to what extent such representation corresponded to other sources—that is, whether they represented a credible and 'complete' picture. Interestingly, the identified segments of the repertoire and their contents have appeared not only in the newspapers studied in this research, but also in other media (Van Kasteren, 2004) and in two reports on societal consequences of nanotechnology that appeared in the Netherlands (Koninklijke Nederlandse Academie van Wetenschappen, 2004; Van Est *et al.*, 2004). A brief comparison between these reports and the newspaper coverage reveals that although they discuss nanotechnology more systematically, these reports reflect many similar themes and arguments of the newspaper articles.

What was perhaps one of the most striking features in this evolving repertoire was a shift in reporting patterns. Initially, diverging views on nanotechnology were not contrasted and the repertoire could be characterized as having a dual pattern of high expectations on the one hand and more modest expectations on the other. This is different from US coverage which is more positive and places more emphasis on the benefits of nanotechnology. What is especially interesting in this dual pattern is how scientists are represented dealing with the challenges presented by nanotechnology. Although scientists benefit from the excitement generated by high expectations of future applications, they themselves are often modest in their expectations. I suggest that these scientists acted strategically through voicing modest expectations while anticipating possible disappointments in the future.

Interestingly, this dual pattern shifted to a more antagonistic pattern at a later stage. Views became increasingly contrasted, and actors—especially scientists—began to refer to other actors and provided not only arguments in support of their own views, but also counter-arguments. It is especially in the debate on nanoparticles that one can recognize the emergence of an antagonistic pattern. This raises the question whether in our late modern society, debates on new and emerging science and technology will—in the end—always be cast in 'an antagonistic mould'. This will also depend on the positions actors take. For example, in the discussion related to nanoparticles, one can read between the lines that actors who promote nanotechnology may also advocate public dialogue in order to ensure public appreciation of nanotechnology research and as a way of avoiding potential concerns and antagonism. More critical actors may want to develop a more transparent analysis and articulation of risks and benefits, and stimulate antagonistic interaction.

The articulation of this evolving newspaper repertoire shares similarities with sociotechnical criticism (equivalent to literary criticism) which are considered, along with anticipation and feedback, to be key components of technology assessment (Rip *et al.*, 1995; Schot and Rip, 1997). In this paper, only one element of technology assessment was discussed, namely the increasing articulation of the repertoire. It is at the intermediate level of the newspaper repertoire, namely the addition and elaboration of new and existing

segments and the described shift within the internal structure from dual to more antagonistic patterns, that I suggest that the repertoire itself could be viewed as some form of technology assessment.[14]

In my opinion, through the steadily evolving newspaper repertoire that emerged in and through newspaper coverage, this coverage in Dutch newspapers increasingly improved newspapers' potential to support their readers to engage in dialogue about the risks and benefits of nanotechnology. Agonistic and antagonistic patterns in repertoires may further improve the ability of readers to engage in public dialogue, provided that the articulation of arguments and counter-arguments is continued in newspaper coverage. This enables newspaper readerships to appreciate the risks and benefits of nanotechnology in a more balanced way and contribute more constructively in discussions about the direction of developments of this new and emerging science and technology.

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Notes

[1]In this article both nanoscience and nanotechnology are covered under the umbrella term nanotechnology.
[2]For later work, see Swidler (2001, 2002).
[3]Cf. a battle or a military exercise (Rip and Talma, 1998, p. 302).
[4]See also Silber's (2003) discussion of the 'internal logic' of repertoires where she argues that this is an important, but not always articulated thread within 'repertoire theory'.
[5]Totals do not match with Figure 1 because articles can belong to more than one category.
[6]In Figures 3–5 '*N*' refers to the number of articles in that period.
[7]For a discussion of some of Drexler's ideas and the 'radical' nature of these ideas, see for instance Bueno (2004).
[8]The year 2002 could be viewed, like the year 1999, as a period of transition between the distinguished phases. The borders that are drawn are used to emphasize the observed evolution in the repertoire.
[9]Personal communication, Arie Rip, February 2006.
[10]Translation by the author.
[11]Translation by the author.
[12]For a recent discussion of risks and media, see Pidgeon *et al*. (2003).
[13]Other examples of direct responses are pieces by scientists who corrected 'errors' or mis-representations of science that appeared in newspapers, cf. Kluytmans (2001), Kooijman (2004) and Reijnders (2004a).
[14]The idea of media as some form of technology assessment has also been addressed elsewhere in the literature, cf. Oudshoorn (1999) and Sassower (1990).

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Samenvatting

In vergelijking met eerdere nieuw-opkomende technologieën is vroegtijdige anticipatie op maatschappelijke inbedding in het geval van nanotechnologie zeer zichtbaar. Actores zijn proactief met betrekking tot maatschappelijke inbedding in verschillende contexten en toepassingsdomeinen van nanotechnologie. Deze proactieve activiteiten zijn te karakteriseren als interventies in voortgaande processen van technologieontwikkeling en maatschappelijke inbedding. Ze grijpen niet alleen in op processen in het hier en nu, maar geven ze ook richting aan toekomstige ontwikkelings- en inbeddingprocessen. Gezien het opkomende karakter van nanotechnologie kunnen effecten van deze 'anticiperende interventies' niet zonder meer worden ingeschat. Wel kan worden bestudeerd hoe interventies in processen eventueel optellen tot patronen in hoe onze maatschappij omgaat met de verdere ontwikkeling en inbedding van nanotechnologie. Patronen die zelf onderdeel zijn van een lange termijn ontwikkeling waarin actoren in onze maatschappij in toenemende mate reflexief omgaan met de co-evolutie van technologie en maatschappij. De algemene vraag over het ontstaan van patronen in reflexieve co-evolutie van nanotechnologie en maatschappij is de achtergrondvraag voor mijn meer specifieke vragen over 'anticiperende interventies'.

In dit proefschrift concentreer ik mij op het analyseren van dynamiek in 'anticiperende interventies' op het niveau van toepassingsdomeinen en het verkennen van opkomende patronen die zichtbaar worden. Methodologisch betekent 'anticiperende interventies' als ingang nemen dat de analist een 'venster op de wereld' opent en laat zien wat er gebeurt in termen van opkomende patronen in inbeddingprocessen. De eerste manier bestaat uit het bestuderen en volgen van anticiperende interventies. Daarbij maak ik met name gebruik van literatuur over institutionele entrepreneurs en fora in institutionaliseringprocessen. Een andere manier is om zelf te interveniëren (maar dan zonder specifiek veranderingsdoel) en te traceren wat reacties zijn. De interventie levert inzicht in dynamiek op het niveau van een toepassingsdomein. Hiervoor maak ik gebruik van de aanpak van Constructive Technology Assessment (CTA): interactieve strategie articulatie workshops

ondersteund met toekomstscenario's. De scenario's verkennen de lotgevallen van toekomstige institutionele entrepreneurship initiatieven.

In hoofdstuk 2 beschrijf ik mijn conceptueel kader dat als achtergrond dient voor mijn onderzoeksaanpak en mijn empirische studies. In mijn dwarsdoorsnede van relevante literatuur voor analyse van maatschappelijke inbeddingprocessen van technologie leg ik de nadruk op multi-actor, multi-level verschijnselen. Maatschappelijke inbeddingprocessen worden in dit proefschrift gezien als de ontwikkeling en stabilisatie van koppelingen tussen activiteiten van heterogene actoren, op verschillende niveaus, die te maken hebben met (opkomende) technologieën. In 'anticiperende interventies' worden actief nieuwe koppelingen bewerkstelligd of gestimuleerd. In dit proefschrift concentreer ik mij voornamelijk op het meso-niveau, het niveau van een sector of toepassingsdomein van nanotechnologie. Ik bestudeer 'anticiperende interventies' in twee contrasterende domeinen: de toepassing van nanotechnologie voor voedselverpakkingen en voor geneesmiddel-afgiftesystemen (drug delivery systems). Beide domeinen bestaan uit kruisende product-waarde ketens waarbij zowel generieke aspecten van nanotechnologie als domein specifieke dynamiek een rol spelen. In het slothoofdstuk kom ik terug op relevante ontwikkelingen en interventies op het macro-niveau.

In het eerste empirische deel van mijn proefschrift bestudeer ik dynamiek in 'anticiperende interventies' door institutionele entrepreneurs en fora. In hoofdstuk 3 breng ik institutionele entrepreneurship initiatieven in de voedselverpakkingssector in kaart en analyseer hun evolutie. Initiatieven ontwikkelden zich in opeenvolgende golven met als netto effect een lappendeken van opkomende regels en praktijken welke uiteindelijk vorm zullen geven aan maatschappelijke inbedding van nanotechnologie. De opeenvolgende initiatieven bouwden op elkaar voort en werden gedreven door pogingen tot het reduceren van onzekerheden. Aanvankelijk enthousiasme maakte plaats voor voorzichtigheid in de sector. Onzekerheden over prestaties en risico's van nanotechnologie droegen bij aan impasses ('waiting games') waar geen van de actoren investeert in nanotechnologie. Waar aanvankelijk initiatieven zich vooral richtten op het promoten van de legitimiteit van de combinatie van nanotechnologie en voedselverpakkingen, verschoof dit later naar het beschouwen van risico's en bredere maatschappelijke aspecten.

In hoofdstuk 4 bespreek ik de evolutie van institutionele entrepreneurship initiatieven in de geneesmiddelafgifte sector. Ik verwachtte dat door de sterke structurering van het medisch-farmaceutisch domein initiatieven een ander karakter zouden hebben dan in de voedselverpakkingssector en dat er (nog) geen golven zichtbaar zouden zijn. Initiatieven bleken gedragen te worden door veelal nieuwe organisaties en richtten zich met name op de toepassing van nanotechnologie voor geneeskunde in het algemeen in plaats van specifiek voor geneesmiddelafgiftesystemen. De evolutie van de initiatieven werd gedreven door pogingen tot het bouwen en orkestreren van een wereld van 'nanogeneeskunde' via het promoten van algemene beloftes en translationele werkwijzen.Hier speelde anticiperende co-ordinatie, teneinde de werelden van onderzoek, industrie en kliniek te overbruggen. Ook in dit domein waren er impasses, 'waiting games', tussen actoren zichtbaar.

In het tweede empirische deel van mijn proefschrift bestudeer ik dynamiek in een andere modaliteit van 'anticiperende interventies': workshops georganiseerd door CTA actoren. Ik begin (in hoofdstuk 5) met het uitwerken van een specifiek onderdeel van de aanpak van deze workshops, namelijk de voorbereiding van CTA workshops ondersteund met socio-technische scenario's. Eisen aan de voorbereiding worden geformuleerd en tools in de vorm van multi-level analyse en scenario's worden uitgewerkt voor de voedselverpakkingsector. Een belangrijk onderdeel in de bouw van de scenario's zijn de lotgevallen van 'anticiperende interventies' die als startpunt genomen worden van de verschillende scenario's. Zulke scenario's fungeren zowel als ondersteuning bij de voorbereiding als input voor de workshops zelf.

In hoofdstuk 6 analyseer ik interacties in de workshops over nanotechnologie voor voedselverpakkingen en geneesmiddelafgiftesystemen. Het gaat met name om waar deelnemers rekening mee houden en hoe zij zich positioneren in termen van hun perspectief op technologieontwikkeling en introductie. In de workshops verwezen deelnemers in hun analyses van de ontwikkeling en introductie van nanotechnologie vooral naar ontwikkelingen op het niveau van hun toepassingsdomein, die niet specifiek, maar wel relevant zijn voor nanotechnologie. Impasses, 'waiting games', tussen actoren werden herkend door de deelnemers als belangrijk onderdeel van sectordynamiek. Anticipatie op maatschappelijke inbedding was zichtbaar in interacties in de workshops. Waar de discussie bij voedselverpakkingen een breed scala aan aspecten

relevant voor inbeddingprocessen omvatte, richtte de discussie bij medicijnafgiftesystemen zich op een relatief beperkt aantal thema's. Wat verder opviel was dat actoren die normaliter vooral geassocieerd worden met een perspectief dat technologiepromotie benadrukt, ook een aantal aspecten van actor-perspectieven meenamen die meer gericht zijn op het beheersen en selecteren van verschillende technologische opties. Dit is interessant omdat dit een indicatie is dat actoren wederzijdse afhankelijkheden herkennen en hierop anticiperen, wat, als dit gebeurt, bijdraagt aan reflexieve co-evolutie van technologie en maatschappij.

In hoofdstuk 7 ga ik in op de achtergrondvraag van mijn proefschrift door middel van een terugblik en een vooruitblik op emergente patronen in reflexieve co-evolutie van nanotechnologie en maatschappij. Hiervoor maak ik gebruik van inzichten vergaard in mijn empirische studies van modaliteiten van 'anticiperende interventies'. Op macro-niveau is er een verschuiving zichtbaar in de vorm van de opkomst van een debat over risico's en (maatschappelijk) verantwoord ontwikkelen van nanotechnologie. Deze macro-ontwikkelingen waren deels zichtbaar in mijn domeinstudies. Sector dynamiek maakt sommige handelingsmogelijkheden die door de macro-ontwikkelingen geboden worden minder relevant. Dit is met name zichtbaar in de geneesmiddelafgifte sector, in de nadruk op translationeel onderzoek. Opvallend in alle studies is dat actoren rekening houden met bredere maatschappelijke inbedding aspecten dan men zou verwachten op basis van hun positie in de sector.

Voor mijn verkenning van opkomende patronen in reflexieve co-evolutie van nanotechnologie en maatschappij begin ik met een bespreking van patronen die nu al zichtbaar zijn. Er zijn expliciete pogingen om bruggen te slaan tussen het promoten en beheersen van nanotechnologie via proactieve activiteiten ('anticiperende interventies'). Deze pro-actieve activiteiten worden niet 'across the board' gepleegd, maar in een soort verdeling van arbeid om maatschappelijke inbedding van nanotechnologie vorm te geven. Pro-actieve acties is voorbehouden aan, of wordt overgelaten aan, een beperkte groep actoren en bepaalde modaliteiten van 'anticiperende interventies'. Hoewel de inhoud van anticipaties zal verschillen van domein tot domein, zijn de promotie van anticiperende co-ordinatie en de reductie van onzekerheden via het realiseren van regels, algemene en erkende routes voor interventies. Een

tweede patroon is het fenomeen wat ik karakteriseer als ‘spelen van maatschappelijke inbedding’. Actoren herkennen wederzijdse afhankelijkheden en anticiperen op elkaars reacties in inbeddingprocessen. Zogeheten ‘waiting games’ waren zeer zichtbaar in mijn domeinstudies. Er zijn ook andere strategische spelen te onderscheiden in de wereld van nanotechnologie zoals financieringswedlopen en innovatieraces.

Voor toekomstige ontwikkelingen schets ik twee scenario’s. Het eerste scenario beschrijft het geval waarin anticipatie op maatschappelijke inbedding geïnstitutionaliseerd raakt in technologieontwikkelingsprocessen. Het andere scenario laat een tegengestelde ontwikkeling zien waar technologiepromotoren teleurgesteld raken in pro-actieve activiteiten en zich eerst gaan richten op het aantonen van prestaties van toekomstige nieuwe producten alvorens met bredere aspecten rekening te houden. Elementen van beide scenario’s zijn zichtbaar in de huidige ontwikkelingen, maar het is nog onduidelijk of (en hoe) één van beide scenario’s, of een combinatie daarvan, zal doorzetten. Desalniettemin verschaffen mijn studies sterke indicaties dat reflexieve co-evolutie van nanotechnologie een blijvend verschijnsel zal zijn, ondanks het vooralsnog open-einde karakter van ‘anticiperende interventies’.

De appendix bevat een studie naar verslaglegging van nanotechnologie door kranten in Nederland en de resultaten hiervan zijn verwerkt in de bespreking van macro-ontwikkelingen in hoofdstuk 7. In deze studie laat ik zien hoe de rapportage over nanotechnologie evolueert naar een steeds rijker wordende bespreking van perspectieven op nanotechnologie. In toenemende mate worden verschillende gezichtspunten met elkaar geconfronteerd. Dit krantenrepertoire over nanotechnologie kan worden gezien als een vorm van technologisch aspectenonderzoek. Het contrasteren van perspectieven en articulatie van argumenten in kranten ondersteunt de competenties van lezers om (geïnformeerd) deel te nemen aan publieke debatten over nanotechnologie.

Summary

In contrast with earlier emerging technologies, in the case of nanotechnology there is a lot of anticipation surrounding how it might, or should, become embedded in society. Pro-active activities are widespread and are undertaken by academia, industry, government and civil society. These pro-active activities can be characterized as interventions in ongoing processes of technology development and societal embedding. These interventions not only affect ongoing processes in the present, but also provide directions for the future development and embedding of nanotechnologies. Effects of such 'anticipatory interventions' cannot be fully assessed yet as nanotechnologies are still emerging. However, through actions and interactions, these 'anticipatory interventions' can add up to patterns in the here-and-now of how our society is coping with the emergence and societal embedding of nanotechnologies. This move toward anticipation of embedding of nanotechnologies is itself part of a more general move toward 'reflexive co-evolution of science, technology and society'. The general question about the emergence of patterns in reflexive co-evolution of nanotechnology and society serves as the background question for my more specific research questions regarding 'anticipatory interventions'.

In this dissertation I focus on the analysis of dynamics in 'anticipatory interventions' at the level of domains of application. To analyze dynamics in 'anticipatory interventions' it is necessary to take a broader perspective than one single actor's concentric focus on embedding. Embedding processes involve a variety of issues which create openings for different actors to engage in strategic actions and interactions. The substance of actors' activities, including anticipation, becomes entangled with other actor's activities during interactions, and this may shape further actions and interactions. Important dynamics in anticipation of embedding, then, exist at the level of a domain or sector faced with emerging technologies. By taking interventions which occur at the sectoral level as the entrance point, the analyst can trace emerging structures as well as dynamics in attempts at creating them. Methodologically, I use interventions as 'windows on the world': they allow me to see what is happening in terms of emerging patterns in embedding processes at the sectoral level. One 'window' is opened by following 'anticipatory interventions' and

assessing what they add up to. For this I draw upon literature regarding institutional entrepreneurs and fora in institutionalization processes. Another 'window' is constituted by another modality of 'anticipatory interventions', where I personally intervene (without a specific change objective). For this I draw upon the approach of Constructive Technology Assessment: interactive strategy articulation workshops supported by scenarios. The scenarios explore future institutional entrepreneurship initiatives.

I begin (in chapter 2) by describing my conceptual framework, which serves as the background for my research approach and empirical studies. Societal embedding processes are conceptualized as the development and stabilization of linkages between activities of heterogeneous actors, at different levels, which are involved with newly emerging technologies. Anticipatory interventions attempt to establish or stimulate novel linkages. I examine 'anticipatory interventions' in two contrasting domains: the application of nanotechnologies for food packaging technologies and for drug delivery systems. The world of food is known to be conservative about emerging technologies and its promises, whereas the world of health & medical technologies is generally more positive about emerging technologies. Both domains consist of intersecting product-value chains in which generic nanotechnology related dynamics as well as domain specific dynamics will play a role. In the concluding chapter I return to relevant developments and interventions at the macro-level.

In chapters 3 and 4 I examine 'anticipatory interventions' by institutional entrepreneurs and fora in the domains of food packaging and drug delivery, respectively. Institutional entrepreneurship initiatives in the food packaging sector developed in waves and had as a net effect a patchwork of emerging rules and practices which will eventually shape societal embedding of nanotechnologies. The initiatives built on each other and were driven by attempts at reduction of uncertainties. Early enthusiasm shifted to caution. Uncertainties about performances and risks of nanotechnologies contributed to the emergence of 'waiting games' between firms across the product-value chain, and between firms and regulators. In these waiting games, interdependent actors were faced with promising technologies which could not easily be ignored, but had high levels of uncertainty around impacts and their uptake by other actors and eventual consumers. With few actors willing to take

a risk, all preferred waiting for the other to act, which resulted in impasses. Whereas early institutional entrepreneurship initiatives focused on promoting the legitimacy of the combination of nanotechnologies and food packaging, later initiatives considered risks and broader societal aspects.

I expected that initiatives in the drug delivery sector would have a different character than in the food packaging sector due to the strong structuration of the medical-pharmaceutical domain. Initiatives turned out to be carried predominantly by newly formed organizations and focused on the promotion of nanomedicine in general rather than on the application of nanotechnologies for drug delivery specifically. The evolution of initiatives was driven by attempts at building and orchestrating an emerging world of nanomedicine - initially through the promotion of promises and later also via promoting translational research practices. The promotion of anticipatory co-ordination was a prominent theme here, with the aim to bridge the worlds of research, industry and the clinic. Here, again waiting games were visible, in this case between large pharmaceutical companies and firms/researchers involved with the development of drug delivery technologies.

In the second empirical part of my dissertation I examine dynamics in another modality of 'anticipatory interventions': workshops organized by CTA agents. I begin (in chapter 5) by highlighting a specific part of the methodology, here called 'pre-engagement'. There is more than organizing to the preparation of CTA workshops supported by socio-technical scenarios. There is 'moving about' in the domain - becoming knowledgeable about it. Understanding of domain dynamics enables the analyst to develop scenarios. Scenarios are both preparation for, and input in, the workshop where actors are engaged to assess ongoing developments and articulate strategies for embedding. An important element in constructing the scenarios is the use of a possible anticipatory intervention as a starting point for the scenario to unfold. Pre-engagement requirements are formulated and tools in the form of multi-level analyses and scenarios are developed for the food packaging sector (as an illustration of the approach).

In chapter 6 I discuss interactions in the workshops (the actual engagement organized by CTA agents) concerning nanotechnologies for food packaging and drug delivery applications. Salient in both workshops was that participants'

assessments of nanotechnologies in relation to their sector of industry often took into account what was happening at the level of the sector, rather than focusing specifically on nanotechnologies. Impasses, 'waiting games' between actors were recognized as an important part of sector dynamics. Participants did discuss nanotechnology-specific aspects, often in the context of uncertainties about performance, risk and demand for nanotechnology-engineered products. Whereas the food packaging workshop was relatively open-ended as to the themes discussed, in the drug delivery workshop there was a lock-in on a few dominant themes. Present uncertainties regarding performance will make concrete anticipation of embedding difficult. Then, considerations regarding sectoral conditions and patterns of interactions between actors in the sector are likely to be foregrounded. While the workshop participants did take into account dimensions of societal embedding, they predominantly thought in terms of technologies which should be developed or pursued, rather than considering embedding as an objective in its own right. Participants usually associated with a technology promotion perspective did take into account some aspects of actor-perspectives oriented toward control and selection of technological options. This is significant, as it indicates that actors recognized mutual dependencies and can engage in strategic interactions, which, if they occur, will contribute to reflexive co-evolutionary processes.

In the concluding chapter I return to the background question of my dissertation - first by looking back and then by looking forward to emerging patterns in reflexive co-evolution of nanotechnology and society. At the macro-level a shift is visible in the form of the emergence of a risk debate regarding nanotechnologies and of a discourse on responsible innovation of nanotechnologies. These developments were partially visible in my domain studies of modalities of 'anticipatory interventions'. Sector dynamics may refract or background lines of action provided by these macro-developments concerning societal embedding of nanotechnologies. Striking across all of my studies is that actors take into account broader aspects of societal embedding than one would expect on the basis of their position in a sector.

For my exploration of emerging patterns in reflexive co-evolution of nanotechnology and society I begin with a discussion of patterns already visible in the present. Pro-active activities to bridge promotion and control of

nanotechnologies ('anticipatory interventions') do not occur 'across the board', but in a sort of division, or at least distribution of labour to shape societal embedding of nanotechnologies. They are reserved for, or left to, a limited group of actors. While the substance of anticipations will differ between domains, the reduction of uncertainties via emerging rules and the promotion of anticipatory co-ordination are general and acknowledged routes for interventions. A second pattern is the phenomenon of 'games of societal embedding'. Actors recognize mutual dependencies and engage in strategic interactions concerning societal embedding. Waiting games, very visible in my domain studies, are one example. However, there are further strategic games of embedding in the nanoworld, such as funding races and innovation races. One can imagine public engagement 'games' as well.

For the future development I highlight two scenarios. In the first scenario anticipation of embedding becomes an institutionalized element within technology development processes. The second scenario shows an opposite move, where technology promoters become disappointed with pro-active activities and give up on them to focus on demonstrating performance first, before considering broader aspects. In the present situation one sees elements of both scenarios. It is too early to see whether (and how) one or the other scenario might prevail, or whether a muddling-through scenario remains. Still, my studies provided strong indications that reflexive co-evolution of nanotechnology and society is here to stay, even if the 'anticipatory interventions' are still open-ended.

The appendix includes a study about newspaper coverage of nanotechnologies in the Netherlands, the results of which are used in the discussion of macro-developments in the concluding chapter. This study shows how newspaper coverage evolved into an increasingly rich discussion of perspectives regarding nanotechnologies. Diverging views on nanotechnology were initially not contrasted, but this occurred increasingly so at a later stage. The articulation of the evolving newspaper coverage can be seen as a form of technology assessment. The contrasting of perspectives and the articulation of arguments in newspaper coverage support the ability of readers to engage in public dialogues concerning nanotechnology.