NANOTECHNOLOGY AND INSTITUTIONAL CHANGE

THE CO-INDUSTRIAL AND INSTITUTIONAL EMERGENCE OF NANOTECHNOLOGY AS A DEMONSTRATIVE CASE OF A NEW FORM OF INSTITUTIONAL ENTREPRENEURSHIP

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ABSTRACT

This study provides a conceptual framework of the combined actions of various groups of stakeholders to account for a new field of institutional emergence: technology-centred institutional emergence. The aim is to gain better understanding of the process of the co-institutional and industrial emergence of a new technology. Rather than focusing on a particular group of stakeholders, the institutional entrepreneurial 'heroes', the chosen perspective is to provide evidence that institutional entrepreneurship is a complex process which results from a multifaceted web of interactions. By focusing on the particular empirical case of the co-industrial and institutional emergence of nanotechnology, it reveals some of the characteristics of this process.

The empirical field of nanotechnology is the nexus of a whole range of technical, economic and social activities and is at the core of much debate relating to ethics, regulation, economics and politics. Therefore it constitutes an excellent domain of research to enable the replicability of the findings. The scope of the study is global, with a particular focus on Europe and the United States.

In this research, I draw mainly from the theoretical frameworks of new institutionalism and entrepreneurship. New institutionalism claims that institutions operate in an environment consisting of other institutions which influence them and that to survive in such an environment, organisations need to establish legitimacy within the world of institutions. The establishment of legitimacy is at the heart of this research and I show that in the field of nanotechnology ventures, institutional legitimacy arises from close interactions between entrepreneurship and institutional entrepreneurship. Building on this conceptual framework I show that:

- The process of nanotechnology institutional emergence is co-evolutionary with that of industrial emergence.
- Institutional emergence in nanotechnologies results from a specific web of interactions where increasing awareness of the importance of sustainable

development constitutes an overlapping area of the distinct visions of each group of stakeholders and may be seen as the connecting element which keeps otherwise potentially diverging agendas together.

My demonstration rests on a model which postulates that nanotechnology institutional emergence results from the combined interactions of mainly five groups of stakeholders: entrepreneurs, commentators, end users, scientists and policy makers.

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This study could only see the light thanks to a large number of people. Firstly, I would like to thank my supervisors, Nelson Phillips and Namrata Malhotra, for their tremendous support and guidance. Namrata Malhotra showed great generosity with her time and with her spirit, and her encouragements and constructive criticism have been essential to lead this project to completion. Nelson Phillips guided my exploration of institutional entrepreneurship even before I started working under his supervision, because his writings were a real source of enlightenment for me. In particular, his paper (Lawrence et al., 2002) gave new meaning to my previous research into the role of NGOs in the institutionalisation of international organisations and it gave me the incentive to launch into a new exploration of institutional emergence. I am fully indebted to his theoretical guidance all along the various stages of my research. I add my warmest thanks for his rare combination of drive, energy and constant good humour which render working under his supervision such an unforgettable experience. Nicos Nicolaou played a very important role in introducing me to entrepreneurship research. As a specialist of entrepreneurship in high technology ventures he steered me through the understanding of some of its specific mechanisms and our discussions were extremely helpful. My initial acquaintance with the environmental issues linked to the development of nanotechnologies took place at the Center for Biological and Environmental Nanotechnology (CBEN) in Houston, and I am particularly grateful to its Executive Director Kristen Kulinowski for her early support, as well as for her help in the constitution of part of my database.

Then, such a study would never have seen the light without the raw material I collected, and for this I am eternally thankful to the numerous people who kindly provided me with information, whether in the form of interviews, documents, or advice for further encounters. From nanotechnology research facilities at Rice University (Wade Adams) to the arcane structure of the European Commission in Brussels (Renzo Tomellini), to the functioning of an

NGO in Winnipeg (Pat Mooney) or to the understanding of the motivations of early nanotechnology enterprises in Lyon (Patrick Valade, Babolat), I owe the ‘feel’ of my research to these people, to the time they spared for me, and to the openness of our discussions. I cannot list them all here, but I would like to express my deepest gratitude to them for their time and support.

I received very helpful feedback on this work in the course of several conference presentations. I would like to thank in particular the participants of the conference 'Perspectives on Entrepreneurship: Cultures and Contexts?’ run jointly by CERVEPAS (centre d’études et de recherches sur la vie économique des pays anglo-saxons), and Charles P. Skene Centre for Entrepreneurship in Aberdeen in 2007, of the EURAM conference in Oslo in 2006, of the EGOS conference in Vienna in 2007, of the Cambridge Conference on Regulation, Inspection & Improvement in Cambridge UK in 2007, and of the Nanotechnology and Occupational Health and Safety Conference in Santa Barbara in 2007. I was extremely fortunate to discuss particular points of my research with specialists of very different fields like Alain Fayolle, Richard B. Freeman, Michael Lounsbury, Scott Shane, Mark Welland or Lynne Zucker among others. I would like to extend my deepest thanks to all for their contributions, some of which have been pivotal. My students at Sciences Po also deserve credit for adding new perspectives, particularly on environmental issues, and I thank them a lot for their insightful comments.

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The last word of thanks will be for my dearest ones… this undertaking was also theirs.

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INTRODUCTION

Introduction

The aim of this study is to offer an interpretation of a specific form of institutional emergence: institutional emergence around the development of a new technology. To do so, the chosen approach is to look at institutional emergence in nanotechnologies. The study of institutional emergence is a new discipline. It found its roots in new institutional theory, itself a fairly new field of research, as the literature review will indicate. As Greenwood et al. explain (Greenwood and Hinings, 1996; Greenwood et al., 2008), the conceptual foundations of modern organizational institutionalism were established in the works of Meyer and Rowan (1977), Zucker (1977), DiMaggio and Powell (1983, 1991) and Meyer and Scott (1983). The birth of new institutions, the way they take shape, and the shape they take are fascinating topics of research, even if the complexity of the interactions at play may be sometimes rather dispiriting.

My exploration of institutional emergence is grounded in the empirical field of nanotechnologies. The development of nanotechnology constitutes an excellent domain of research to find clues about the processes through which institutions become constructed. Indeed, the technology is the nexus of a whole range of technical, economic and social activities as well as the source of much debate relating to ethics, regulation, economics and politics. In this research, I build on the theoretical framework of new institutionalism. New institutionalism claims that institutions operate in an environment consisting of other institutions which influence them through institutional isomorphism (DiMaggio and Powell, 1983), and that to survive in such an environment, organizations need to establish legitimacy within the world of institutions. The establishment of legitimacy is at the core of this research.

In their work on institutional entrepreneurship, Lawrence et al. have analysed the process through which organized actors – institutional entrepreneurs – structure the institutional contexts in which they operate in order to create opportunities to generate new institutions (Lawrence et al., 2002). Maguire et al. (2004) have for their part tried to identify the specifics of institutional entrepreneurship in emerging fields. Building on extensive previous research e.g. (DiMaggio, 1988, Fligstein, 1997, Rao et al., 2000, Seo and Creed, 2002) they show that 'Central to institutional entrepreneurship is the relationship between interests, agency, and institutions', and that 'key to their success is the way in which institutional entrepreneurs connect their change projects to the activities and interests of other actors in a field, crafting their project to fit the conditions of the field itself' (Maguire et al., 2004). They show the importance of the relationship between interests, agencies and institutions for the success of institutional entrepreneurship. I build on the concurring conclusions of Maguire et al. and Lawrence et al. to provide the conceptual frame for this study of the development of nanotechnology, and postulate the following set of interactions as a model for nanotechnology institutional entrepreneurship (Fig 1).

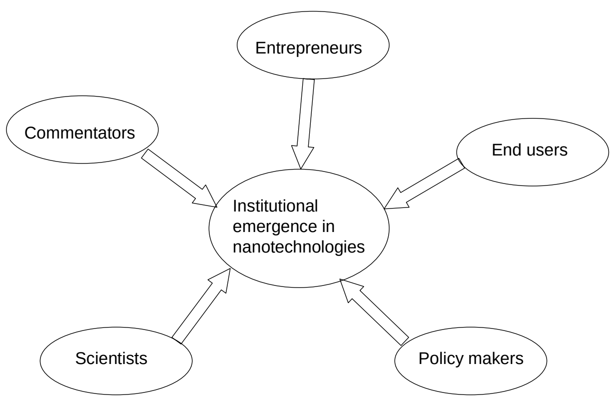


Fig 1

My contribution with this study is to provide an integrated analysis of these combined actions to show the specificity of institutional emergence in nanotechnologies. The study establishes that it is not one group of stakeholders, one set of actions alone which can bring it about, but a complex web of interactions. It also shows that the connecting element between all these interactions is an increasing awareness of the importance of sustainable development.

Background

In their groundbreaking work on the institutionalisation of science, Callon and Latour explained that the institutionalisation of science and technology rests on a temporal process which includes several steps (Latour, 1988, Callon et al., 1986). Science and technology firstly emerge as disconnected facts and gradually stabilise and acquire ontology through the settlement of controversies concerning their validity. For the researchers, it is not an intrinsic natural value but the settlement of *controversy* which lies at the root of scientific institutional emergence. Controversy is followed by *translation*, an operation which consists in creating a common language of reference so that previously unrelated entities can be connected and be seen in interaction. The process of translation gives unity and intelligibility to otherwise obscure and apparently disconnected entities. It allows the institutionalisation process to move into the domain of public understanding. It is also the lifeblood of the *network*, an ensemble of meta-organizations including human and non-human *actants* which interact together to form the new institutions.

Two new elements have emerged since Callon et al. developed their theory. One is a global awakening to the importance of sustainable development, and the other is the widespread use of information technology. The introduction of these parameters does not affect the overall validity of their model, which is one more confirmation of its encompassing value. Yet they bring interesting changes to the understanding of institutional emergence.

Sustainable development

One cannot hope to understand the notion of sustainable development without looking at the historical background. Development and sustainability are two terms which look incompatible on the face of it. They have spawned a huge literature that has produced so many theories and counter theories that one might safely say that they have come to underpin a large part of economic thinking today. The words themselves appeared for the first time in the outcomes of a study commissioned by the UN in 1972 (UN, 1972). The concept had emerged earlier, but it took some twenty years to emerge as a collective preoccupation. To understand the mechanism of its emergence, one has to go back in history.

Malthus noticed in his first *Essay on population* in 1798 that the "power of population" was far superior to the "power of the earth" to produce subsistence for man, and that it was only because there were epidemics, wars and various exogenous causes for population extermination that population could be kept in check at a sustainable level (Malthus, 1999). He then calculated what would happen if the earth's population was not decimated at regular intervals. His calculation led him to predict in 1798 that population would one day – which he situated in the middle of the 19th century – outrun food supplies. Although this prediction was proved wrong – essentially because of flaws in his methodology – his theory became extremely influential, and can be seen to have introduced the concept of the necessity for sustainability in human development.

In 1896 the Swedish scientist Svante Arrhenius, who received a Nobel Prize in 1903 for his work on electrolysis, calculated that if the volume of carbon dioxide present in the atmosphere were to double this would lead to a temperature rise of the planet of 4 degrees by the end of the twentieth century. He predicted that the intensive use of fossil fuels would warm the earth's climate. His study stayed untouched for many years because scientists lacked the tools to confirm or disconfirm his intuitions. It was only in the 1960s with the development of the first computers that people started collecting data to model airflows so as to improve weather forecasting. Until then, climate research could only rely on very basic observations and technologies, as people lacked the computering power necessary to analyse airflows. The first experiments led to the discovery of the thinning of the ozone layer, of the nature of acid rain, and of a fear of a general pollution of the higher atmosphere because of the growing number of supersonic planes. In 1965, three groups of American researchers (Geophysical Fluid Dynamics Laboratory, UCLA Department of Meteorology and the National Center for Atmospheric Research) began to draw the first lessons from their attempts to model airflows (Weart, 2003).

The next landmark contribution to the emergence of the concept of the environment not as an exogenous entity but as a component of the evolution of the human species came from the work of Donella Meadows, an American researcher who had started studying chemistry and biophysics at Harvard before joining Jay Forrester's team at the MIT (Massachusetts Institute of Technology). Forrester (1961) was at the origin of systems dynamics, and the research group developed a computer model, 'World3', which was a computer simulation of the interactions among population growth, industrial growth, food production and the limits to the earth's ecosystem. The book which followed this research, *The limits to growth* (Meadows and Meadows, 1972) used the computer model to show that over one century, unlimited growth would lead to a collapse of world resources and that if current trends were not modified, the world-system would collapse around 2000. The report was very controversial but it made it clear for the first time that there were physical limits to world resources, and that development might be limited by the fact that the earth resources were limited.

That time was also the beginning of space missions. The picture below (Fig 2), taken by the NASA in 1969 from the Appolo 13 orbiter, was the first view of the earth from outside.

It helped make people realise how small our planet was, and also how beautiful and fragile it looked in the immensity of space.

Fig 2

The above can be summarized by saying that it was technological progress which was at the origin of people's awareness of the complexity and vulnerability of the environment. This new awareness was double sided: on the one hand people realised that through their activities they were altering the conditions which made their life on earth possible. On the other hand, they discovered that the mechanisms of interactions between human activities and the environment were extremely complex and interconnected: Air pollution in Eastern Europe resulted in acid rain in Sweden (Oden, 1968); Individual problems of pollution such as the persistence and spread of DDT or oil spills in the oceans led to global changes (SCEP (Study of Critical Environmental Problems) and Matthews, 1970); Human activities could result in climate change (SMIC, 1971).

The rest of the story is well known: the phrase 'sustainable development' appeared for the first time in writing in 1980 in a report called *World Conservation Strategy: Living Resource Conservation for Sustainable Development* which was co produced by the IUCN (International Union for the Conservation of Nature), the UNEP (United Nations Environmental Program) and the WWF (World Wildlife Fund) (IUCN et al., 1980). Then, the

UNEP published in 1987 a report resulting from a three-year study: *Our Common Future* (Brundtland and World Commission on Environment and Development, 1987). The report, also called the Brundtland report, defined sustainable development as:

> “Development that meets the needs of the present without compromising the ability of future generations to meet their own needs.”(Brundtland and World Commission on Environment and Development, 1987) A42/427, Chap 2, p54.

In 1991, the successor to the World Conservation Strategy, IUCN, produced with UNEP and WWF a new report called *Caring for the earth: a strategy for sustainable living*. In the report, sustainable development received a new definition:

> “Improving the quality of human life while living within the carrying capacity of supporting ecosystems.” (IUCN et al., 1991) Chap 1, p 10

The report showed the need to implement new strategies to allow continuing development whilst preserving the world’s capacity to preserve and regenerate itself. This new definition integrated economic and social development with the preservation of the environment and of natural resources.

The notion of sustainable development has now become deeply engrained in society, and the reason it has done so in such a radical way is the widespread use of information technology. The last thirty to forty years, the period we are studying, saw first the generalisation of television, which allowed pictures like the one of ‘earth rise’ to be seen by the immense majority of people on earth. Besides, it so happened that the release of the Brundtland report *Our common future* coincided with a few human and environmental tragedies which were widely broadcast on the news. These made the planet appear smaller and the connections between technological progress and disaster scary for some people. The report itself drew a list of these disasters in the form of a chart which is reproduced here (Fig 3):

The World Commission on Environment and Development first met in October 1984. And published its Report 900 days later, in April 1987. Over those few days:

- The drought-triggered, environment-development crisis in Africa peaked, putting 36 million people at risk, killing perhaps a million.
- A leak from a pesticides factory in Bhopal, India, killed more than 2,000 people and blinded and injured over 200,000 more.
- Liquid gas tanks exploded in Mexico City, killing 1,000 and leaving thousands more homeless.
- The Chernobyl nuclear reactor explosion sent nuclear fallout across Europe, increasing the risks of future human cancers.
- Agricultural chemicals, solvents, and mercury flowed into the Rhine River during a warehouse fire in Switzerland, killing millions of fish and threatening drinking water in the Federal Republic of Germany and the Netherlands.
- An estimated 60 million people died of diarrhoeal diseases related to unsafe drinking water and malnutrition; most of the

Fig 3

(Brundtland and World Commission on Environment and Development, 1987) A 42/427, 1.2.13

This means that the increasing awareness of environmental issues went along that of the globalisation of information, and of citizens’ awareness of those issues.

Then, the development of the internet took the movement of information and the popularisation of science even further, to the stage we now know and take for granted. I will go back later in greater details to this important element in my study of the institutionalisation of nanotechnologies, but these introductory remarks are key to the development of the theory. Growing awareness of the importance of sustainable development underpins the whole analysis of the institutional emergence of nanotechnologies.

As I explain at length in later pages, nanotechnologies have arrived at a point in time when technological progress and social evolution reached a point of convergence with the awareness of the importance of sustainable development for the economy. A search of the literature shows that in fact, there has been a time gap for the awareness of the importance of sustainable development between social scientists and economists. Sustainable development became a concern for business only about ten years ago, whereas it was one for social scientists - and for a minority of concerned natural scientists - already over thirty years ago (Stiglitz, 1998) (Fig 4).

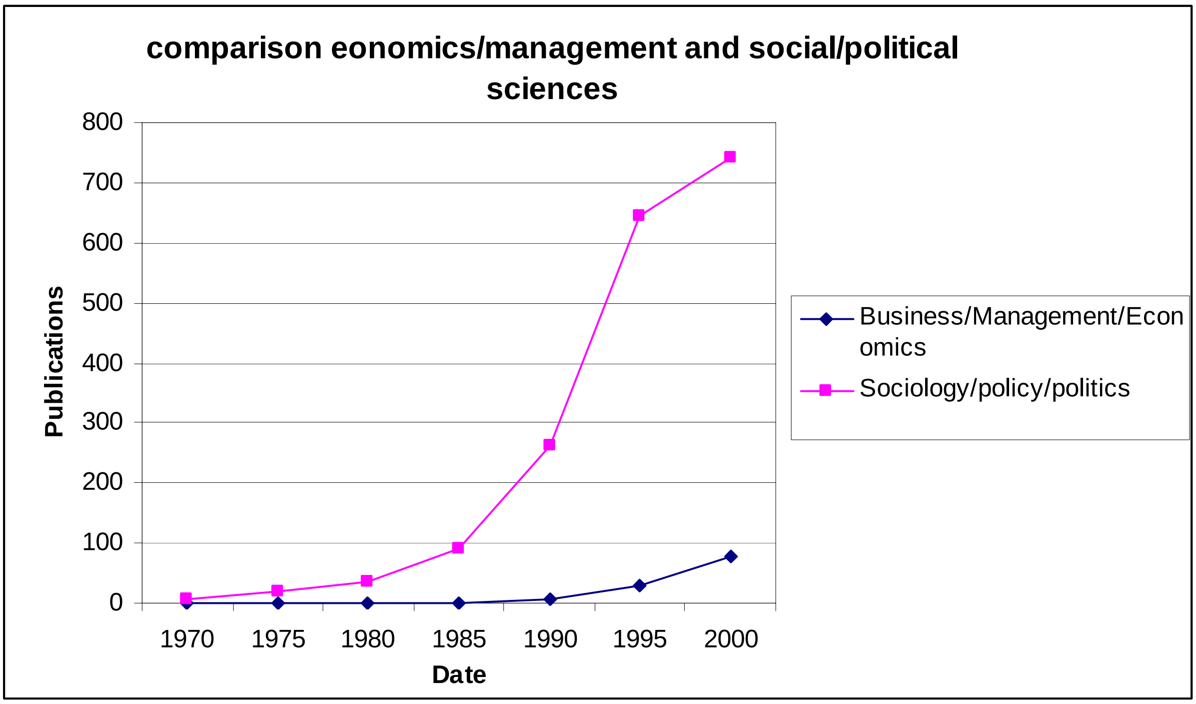


Fig 4

Number of publications in EBSCO, search terms: sustainable development environment

Date	Number
1970	0
1975	0
1980	0
1985	0
1990	8
1995	28
2000	77

Number of publications in JSTOR, Arts, social and political sciences.

Date	Number
1970	6
1975	19
1980	36
1985	91
1990	262
1995	646
2000	743

Some experts and scholars deny any real impact of the concept of sustainable development on business activity. Although a growing number of listed companies include a chapter on sustainable development in their business reports; although – as an example – companies listed on the French stock exchange are obliged by law to include social and environmental information in their annual reports (European Commission, 2007), these specialists highlight wide gaps between rhetoric and reality and they consider that sustainable development relates more to communication processes than to any deep change in business models (Veleva, 2007).

However, most recent research points to the contrary. It indicates that sustainable development is gradually changing the focal point of some segments of business activity, and that this is the premise of a more general change in business models (Jacquet and Tubiana, 2007). In 2008, the French consultancy RSE paradigm21 carried out a study to explore the operationalization of the sustainable development paradigm (Rios, 2008). It drew its conclusions from an empirical study bearing on some forty Multi National Companies

(MNCs) in sectors as diverse as food, telecommunications, retailing, electronics, cars, transport and banking. An important finding was that companies were now producing the second generation of sustainable development managers, and that this second generation was extremely different from the first one.

While the first generation might have been constituted of people coming from various backgrounds with sometimes no clear idea of their role and aims, the second one is often constituted of managers who have a specific agenda. The first generation was there mostly because there was a general feeling that integrating sustainable development in organisations was the thing to do since everyone else was doing the same. It took the form of adding paragraphs on sustainable development in business reports or creating positions of sustainable development managers. However, this first generation of sustainable development managers demonstrated through original initiatives that constraining environmental regulation could also bring about growth opportunities. At the same time, training in sustainable development became more widely available, starting with the most prestigious universities. So, far from considering sustainable development as a form of window dressing, the second generation of sustainable development managers often sees it as a source of new business developments. And therefore sustainable development is gradually bringing about shifts in business strategies.

The RSE Paradigm21 study reflected that there were differences in the way sustainable development was integrated in business models in different sectors. It highlighted two trends. The first trend consists in adding new functionalities to existing products or services so that they comply with sustainable development targets. This trend does not signal fundamental change in business models. However, the second trend is completely different and this is what is important for my study. By actively seeking to meet environmental targets, some companies reinvent the way they work. This involves strong and long-term support from the top management, with a new understanding of performance and new forms of interactions between business functions like R&D, resource acquisition, human resources, marketing or public relations. But it actually leads to shifts in R&D focus as well as development strategies.

A few examples will help see the change: while only 2 percent of the world wastewater is recycled, the Company Degrémont, a subsidiary of SUEZ environment specializing in water treatment launched a new program to build factories treating wastewater so that it can safely be used in agriculture. The first such factory – treating 4000 litres of wastewater per second – was built in Milan in Italy in 2004. The French national rail company SNCF (Société Nationale de Chemins de Fer) started publishing an 'eco-comparator' in 2006. The EcoComparateur® was designed in collaboration with ADEME (National Agency for environment and energy management). It enables people to compare different modes of transportation to a given destination thanks to an environmental index using CO2 kg as a unit. Its impact on customers was quick, the website receiving over 850 000 visits in two years. Now technical innovation and management innovation have become two major drives to improve the score of the train as a means of transport on the EcoComparateur. This means that the publication of the EcoComparateur has led to changes in the SNCF business strategy. It signed in 2008 a framework agreement with ADEME to improve its environmental practices. This includes among other things change in the management of refuse (quantity and type of refuse left onboard trains) and therefore change in the type of food and packaging used by train restaurants. It also involves changes to improve energy efficiency (lighter components for lighter trains, experiments with alternative fuels, different rail systems etc.).

Another sector which is undergoing big changes because of the awareness of sustainable development is the sector of the built environment. According to Lafarge, a world leader in building materials, the challenges of sustainable construction concern all players in the building sector. Lafarge works closely with industrial associations, energy suppliers and architects to identify building methods which are cleaner and more environmentally friendly. In 2006, within the framework of the World Business Council for Sustainable Development (WBCSD), the company initiated the Energy Efficiency in Buildings (EEB) project in partnership with United Technologies Corp., the world's leading supplier of capital goods. One of the major targets of the EEB project is to construct buildings which are self-sufficient in terms of energy and do not emit any CO2. In just a few months, nine multinational companies including DuPont, Gaz de France, Cemex, Tokyo Electric Power Company and ITT joined the project. These examples illustrate that the concept of sustainable development brings deep strategic changes not only inside companies, but also in the way they relate to others and work together on shared projects. Change affects companies internally and externally, in R&D orientations as well as in business strategies. I infer from this context that sustainable development is gradually becoming a full component of economic activity, and that time has come to explore its interactions with organisations and management.

Nanotechnologies

What about nanotechnologies? How do they connect to sustainable development issues? If we continue with the examples above, among the many promises of nanotechnologies are the ability to eliminate waste and toxins from production processes, to remove contaminants from water and to improve fuel efficiency. Besides, the report of the 2007 Workshop on Nanotechnology for Cement and Concrete sponsored by The National Concrete Pavement Technology Center and the National Science Foundation showed how nanotechnology applications could have extremely important outcomes with cement and concrete for the built environment in particular, and for the environment in general (Taylor et al., 2007). So nanotechnology appears like a cross-sector technology which may bring new solutions to all the areas I chose as examples to highlight how sustainable development related to important areas of business development and was beginning to bring about strategic change. In a way, nanotechnologies can be seen as the crux of these changes. At the same time, researchers and environmentalists have long cautioned that working with molecular-scale materials offers unforeseen threats to humans, animals and the planet. So nanotechnologies themselves can be seen either as a solution to sustainable development issues, or as a source of problems to come. In September 2008 the US National Science Foundation and the Environmental Protection Agency established two new research centres with a total budget of $39 million to study the environmental implications of nanotechnologies. The Center for the Environmental Implications of NanoTechnology (CEINT) is dedicated to elucidating the relationship between nanomaterials and their potential environmental exposure, biological effects, and ecological consequences. A distinctive element of the research centre is that it will transfer the synthesis of environmental information about nanoparticles to policy makers and society at large. This example shows how intricate the connections between nanotechnologies, sustainable development and economic development are. The emergence of nanotechnologies epitomizes the important changes which are affecting both the economic paradigm and society at large.

Research questions

With this background in mind, the focal research question of this study is:

What are the links between a new technology and institutional emergence?

This broad research question covers several sub questions.

- What makes the nanotechnology context a propitious one to study institutional emergence?
- How do various stakeholders acting as institutional entrepreneurs collectively shape the institutional emergence of nanotechnologies? In particular, how does entrepreneurship relate to institutional entrepreneurship?
- What are the characteristics of this institutional field emergence? What does it reveal?

Motivations for the study and contributions

There are several motivations for the study. At the empirical level, nanotechnology is being hailed as one of the most promising sectors of socio and economic development, whether by public institutions (European Commission Research and Nordmann, 2004, White House, 2000), by academic researchers (Roco and Bainbridge, 2001, ten Wolde, 1998) or by analysts and investors (Lux Research et al., 2004, Paull et al., 2003). Calculations predict that it will become a trillion euro industry within a decade or so and that it will affect the economy in a way that has not been seen before (MRG Multimedia Research Group Inc and Fuji-Keizei, 2004, Paull et al., 2003, Gillis and Krim, 2004). Pundits claim that nanotechnology can bring a revolution of at least the same magnitude as the industrial revolution, because of all the changes in our life-styles that it can bring about. At the same time, many specialists draw attention to the challenges it brings, and again these are seen at various levels from the scientific (Drexler and Smalley, 2003) to the socio-economic (Mazzola, 2003, Huw Arnall, 2003, Mnyusiwalla et al., 2003) and to the regulatory levels (Reynolds, 2002).

There is great interest in trying to unpack the complexity of this empirical context, because it connects directly to exciting theoretical challenges. Indeed, (Walsh et al., 2006) believe that the field of organisation theory is adrift, and that in the last twenty years, theories have not assimilated the fundamental changes in organisations, organisational contexts and the accompanying management practices that have occurred. To address these failings, they expect emerging theory to evolve so as to grapple with fundamental questions. Among these, one is the necessity to understand today's organisations in view of transnational emergence as it produces novel social structures and systems. Another one is the necessity to account for the increasing impacts of organisations on humans' social and material lives and on the ecosystem of the planet. Walsh et al. consider that these challenges will lead researchers to reconceptualise organisations as social constructions, and to reconceptualise organising as a social technology to achieve desired outcomes, rather than as an immutable fact of economic and social life. One motivation for my study is to show that the co-industrial and institutional emergence of nanotechnology connects to a new form of institutional entrepreneurship, where institutional entrepreneurs aim to either create new institutions or modify existing ones, so that organisations respond to their expectations, one of them being the necessity to take sustainable development into account.

One of the routes I take to do so is to build on both entrepreneurship theory and institutional entrepreneurship theory. Recent research indicates that both theoretical streams have a lot to tell each other, whether as entrepreneurship theory informing institutional entrepreneurship theory (Phillips and Tracey, 2007) or conversely, as institutional entrepreneurship theory informing entrepreneurship theory (Veciana and Urbano, 2008). At the time of the beginning of this research, (Busenitz et al., 2003) recalled that entrepreneurship research was an emergent discipline, and they proposed directions for its pursuit of distinctive boundaries and legitimacy. They explained that the distinctive domain of entrepreneurship research was the nexus of business opportunities, individuals and teams, and modes of organizing within the overall context of market environments. One motivation for my own exploration is precisely to see how nanotechnology constitutes such a nexus, and how the components they identify relate to one another. I want to show that with nanotechnologies, the creation of business opportunities is tightly connected to a process during which new institutions are created and existing ones are modified, to meet the expectations of stakeholders. Other researchers like (Moray and Clarysse, 2005) have drawn from institutional theory and especially neo-institutional theory to explore new modes of organising, and they have showed the relevance of this theoretical approach for the exploration of new practices linked to the development of scientific and technological innovation.

Finally, a strong motivation for this study is to add to the emerging literature between sustainable development and the economy (Bansal and Roth, 2000, Jaffe et al., 2005, Potoski and Prakash, 2004). I hope, with my analysis, to shed new lights on the relations between environmental awareness and technological development (Wiesner et al., 2006, Wiesner and Bottero, 2007).

The study makes several types of contribution. It augments empirical knowledge of the development of nanotechnologies. By examining successively the interactions of several groups of stakeholders, I provide information not only about the technology itself, but also about its various constituencies. In particular, my exploration of the role of civil society organisations introduces a novel approach to understand the co-industrial and institutional emergence of nanotechnologies. It supports previous studies which show that society plays an important regulatory role in innovation (Chataway et al., 2006). My choice of a global approach, with a focus on the US and the EU contributes to fill the gap identified by Walsh et al. in the necessity to understand today's organisations in view of transnational emergence. Also, in studying the relations between technological innovation and the shaping of institutional structures, I offer new insights into the emergence of institutions (Latour, 1988). In particular, by placing the construct of a new form of risk management based on the awareness of the concept of sustainable development at the core of institutional emergence, I provide a fresh approach of institutional theory (Phillips et al., 2004, Romanelli, 1991, Zucker, 1977). Finally, by assessing the relative importance of the characteristics of nanotechnologies in the design of an institutional framework for their development – particularly in the areas of risk assessment and management – I shed new light on the links between institutions and technology (Wiesner et al., 2006, Wiesner and Bottero, 2007).

Roadmap

In this study, my aim is to provide a conceptual frame of the emergence of nanotechnologies by studying the co-evolution of the technological field and of the institutional field. To do so, I have articulated my research around the intersection of two transversal themes with five units of analysis. The units of analysis are the five groups of stakeholders previously mentioned: entrepreneurs, commentators, scientists, policy makers, end users. The two transversal themes are entrepreneurship and institutional entrepreneurship. I call them transversal themes because they intersect with the five groups of stakeholders as well as with the other theme.

The study is built around representative cases which illustrate emblematic trends situated at the cross-sections of the units of analysis and of the transversal themes. The first one explores some aspects of nanotechnology entrepreneurship through the analysis of a few selected indicators. The second one relates nanotechnology entrepreneurship and regulatory practices. The third one studies institutional entrepreneurship through the lens of the particular role played by a civil society group. The fourth one focuses on new dynamics in risk management as an illustration of institutional change. The synthesis of these cases allows me to draw conclusions concerning the co-industrial and institutional emergence of nanotechnology.

LITERATURE REVIEW

The purpose of this literature review is to provide a theoretical foundation for my arguments. It delineates the theoretical context in which I anchor my discussion. As the title of my thesis suggests, my work is empirically grounded in the development of new technologies, and it explores a phenomenon that connects the two fields of entrepreneurship and institutional entrepreneurship. Therefore, I draw mainly from these three theoretical streams to shape my own contribution, which is to demonstrate why and how institutional emergence in nanotechnologies constitutes a particular form of institutional emergence.

New institutional theory

My quest is part of the well-known desire of many scholars to understand how and why organisations behave as they do, and with what consequences. In the management literature, institutional theory has become a dominant approach to decipher the behaviour and functioning of organisations. People seem to have wondered about the way institutions frame society at least since the Antiquity, and Greek philosophers already wrote about various forms of political organisation, and what institutions they were embedded in, be they monarchy, tyranny, aristocracy, oligarchy or democracy (Aristotle, 1981, Plato, 1992). Yet, although scholars have been studying institutions for centuries, and although there had been research about institutions and organisations before the 1980s (Hirsch, 2008), it is usually agreed that what has come to be known as new institutionalism found its origins in two papers first published in 1977: (Meyer and Rowan, 1977, Zucker, 1977). At that time organisations were traditionally seen as entities shaped to respond to situational circumstances, to exogenous parameters. Research explored the relationships between organisations and their environment as it was understood that they were modelled to try and achieve the best fit with it. But researchers soon puzzled over why organisational arrangements did not always correspond to rational explanations based on the notion of best environmental fit.

Meyer and Rowan's (1977) and Zucker's (1977) papers introduced the idea that organisations were influenced by their institutional context. They defined the institutional context as a set of commonly understood rules and societal norms which determined what was appropriate and meaningful behaviour, 'the rationalized myths' that characterise a context. So the literature of the 1970s and 1980s tried to account for the relations between organisations and their institutional contexts. There was a new turning point at the beginning of the 1980s with the publication of DiMaggio and Powell (1983). This period also corresponded to a transitional period when some researchers turned their attention to the links between institutions and agency (Bourdieu, 1977, Scott, 1987). In their 1983 paper DiMaggio and Powell tried to explain why there was such surprising homogeneity of organisational forms and practices in spite of the diversity of the situational contexts. This quest led them to explore the forces which drove organisations to become similar to one another, and therefore to the process of institutionalisation itself. The concept of institutional entrepreneurship emerged as a means of understanding how new institutions arise (DiMaggio, 1988). So it is only in the past thirty years that researchers have been focusing on the dynamics of the creation and modifications of institutions (Holm, 1995, Lounsbury, 2003, Zucker and Tolbert, 1996).

Institutional entrepreneurship is still an emerging area of research. Although growing very rapidly, the literature is still not very developed and there are many areas that remain unexplored. Lawrence and Suddaby's (2006) authoritative synthesis of contemporary research shows that it is only in the past 10-15 years that various research efforts – still not aggregated – have started exploring the deeds of actors who leverage resources to create new institutions or to transform existing ones, which is what my own contribution is about.

As Lawrence and Suddaby (2006) state, the literature is replete with definitions of institutions. Within the tradition of new institutional theory, scholars have given their own definitions of institutions. To them, the concept of an institution is at the heart of all institutional approaches of organisational research. Their theory is that there are enduring elements in social life – institutions – that have a profound effect on the thoughts, feelings and behaviour of individual and collective actors. This is the core of the analyses of organisational phenomena that adopt an institutionalist perspective, whether these are based on a theoretical or an empirical approach. Most definitions encompass the vision that institutions are ensembles of structured conventional social practices that have acquired a taken-for-granted ontological status which allows them to set conditions on action (Barley and Tolbert, 1997, DiMaggio and Powell, 1991, Jepperson, 1991, Copay et al., 1991, Meyer and Rowan, 1977, Zucker, 1977, Phillips et al., 2004). The work of neo institutionalists is very helpful because it provides templates by which to assess the pattern of interactions which surrounds the emergence of nanotechnologies. More precisely, the theoretical frame of institutional entrepreneurship provides keys to analyse how the pattern of interactions in which the various stakeholders act collectively as institutional entrepreneurs and shape nanotechnology institutional emergence follows a logic of its own.

Theories of institutional creation, maintenance, disruption

Building on the modern definitions of institutions they use to frame their thinking, Lawrence and Suddaby aim to understand what they call institutional work, i.e. ‘the purposive action of individuals and organizations aimed at creating, maintaining, and disrupting institutions’ (Lawrence and Suddaby, 2006) : 215. During the theorisation process, they pay tribute to generations of predecessors, like Bourdieu (1977) or de Saussure (1995) who, in their own fields and with their own references to previous research, contributed to piece together some parts of the puzzle. As an introduction to their study Lawrence and Suddaby explain that before they launched into their own synthesis, research on institutional work had been largely unconnected. Although some semi-coherent research streams had emerged around institutional entrepreneurship and deinstitutionalisation, the overall focus had remained largely unarticulated. They show how varied the approaches are, from qualitative to quantitative, from discourse analysis, ethnography or the study of oral history, to statistical analyses of event histories or social networks etc. Their work points to the many areas which institutional research has explored or is exploring, and they look at organisational journals in which institutional research appears in order to outline what is understood and not understood in institutional work. Their exhaustive analysis of institutional research papers published in *Administrative Science Quarterly*, *Academy of Management Journal*, and *Organizations Studies* leads them to identify the following foci: creating institutions, maintaining institutions, disrupting institutions. It also shows that there is a clear lead in terms of number of publications of the literature dealing with the creation of institutions.

A careful examination of the extensive references they provide leads us to qualify some of their findings. They claim in their introduction (p2) that there has over the past 10-15 years emerged a new emphasis on understanding the role of actors in effecting, transforming, and maintaining institutions and fields. They also stress the importance in terms of number of institutional studies documenting the ability of actors to have significant impacts on the evolution of institutions and fields. In fact, this literature is minimal. On the whole, the references have two foci, the role of *collective actions*, which is not really that of actors as such, and the *process* of institutional change.

Collective actions

In these references it is not so much the role of particular actors which is examined, as that of social groups and/or of collective action. Let us take some of the examples given:

In Clemens (1993), the author looks at the role of women's groups in the transformation of US politics between 1890 and 1920. His conclusion is that:

> "Women's groups were a source of political change because they were marginal to the existing electoral system, but not so marginal that they were ignored by other political actors (…) the potential of a challenging group to produce changes in existing institutions is a joint product of the incentives to innovate produced by relative marginality *and* its visibility within the political arena, as well as the acceptability of those innovations to other political actors".(Clemens, 1993) :792

Similarly, Lawrence and Suddaby mention Greenwood et al. (2002). This study examines the role of professional associations in a changing, highly institutionalised organisational field and suggests that they play a significant role in legitimating change. A model of institutional change is outlined, of which a key stage is "theorisation," the process whereby organisational failings are conceptualised and linked to potential solutions. Regulatory agencies, such as professional associations, play an important role in theorising change, endorsing local innovations and shaping their diffusion. But once again, the focus of the study is the mechanisms of the influence of *collective* action in the transformation of institutionalised fields (Greenwood et al., 2002).

The next example they give, Holm's analyses of the transformation processes and particularly of the issue of the preservation of the price of herrings in Norwegian fisheries, also illustrates the *collective* role and actions of fishermen in the dynamics of institutionalisation (Holm, 1995).

Process

If we put aside these studies of collective action the other references do not focus so much on the role of actors in effecting, transforming, and maintaining institutions and fields or on their ability to have significant impacts on the evolution of institutions and fields, as on the process of institutional change or on the conditions which lead to it. This constitutes the second focus of research on institutional work. For instance, Ahmadjian & Robinson's study, which examines the role of downsizing in the deinstitutionalisation of permanent employment among publicly listed companies in Japan between 1990 and 1997, shows the impact of the combination of external pressures and internal sources of resistance on organisational change (Ahmadjian and Robinson, 2001).

In Oliver's study, which determines the likelihood of institutional organisational behaviour to rejection over time, the purpose is to identify the factors – internal or external – that are likely to predict deinstitutionalisation, defined as the process by which the legitimacy of an established or institutionalised organisational practice erodes or discontinues (Oliver, 1992). We are fairly far from the role of actors here and it becomes apparent that research in institutional entrepreneurship focuses more on the 'process' by which interested actors work to influence their institutional contexts through such strategies as technical and market leadership, lobbying for regulatory change, or discursive action (Fligstein, 1997, Garud et al., 2002, Hoffman, 1999, Maguire et al., 2004, Suchman, 1995) than on the actors themselves. There remains a challenge to explore the motivations, characteristics, specific features which institutional entrepreneurs possess and which are key to the success of institutional entrepreneurship. One step in this direction comes from studies like Oakes, Townley and Cooper's. They apply the theoretical framework provided by Bourdieu's theory of fields and capital to the introduction of business plans in museums in Alberta. Here we have a study which explores the role of language and control in a changing institutional field. (Oakes et al., 1998). Further work in this direction comes from the study of the role of discourse analysis in institutional change (Maguire, 2004, Phillips et al., 2004)

Interpretation

To summarize the above findings, it is helpful to see things in a chronological way. Some researchers started looking at the reasons which prompted the creations of new institutions with the argument that social life is only possible because and to the extent that individuals in interaction create common frameworks and understandings that support collective action (Berger and Luckmann, 1967). Other researchers then focused on the institutions themselves, as a means to try and understand why they came into existence. Institutions were defined as conventions that are self-policing (Douglas, 1986), and as cognitive, normative, and regulative structures and activities that provide stability and meaning to social behaviour (Scott, 1995). North characterised them as humanly devised constraints that structured political, economic and social interaction and consisted of both informal restrictions and formal rules (North, 1990). For Jepperson, institutions were an organised, established procedure reflecting a set of standardised interaction sequences (Jepperson, 1991). Within the tradition of new institutional theory, scholars later defined institutions more specifically as historical accretions of past practices and understandings that set conditions on action through the way in which they gradually acquired the moral and ontological status of taken-for-granted facts which, in turn, shaped future interactions and negotiations.

Starting from there, it became possible to investigate institutionalisation itself, that is, the process by which actions were repeated and given similar meaning by self and others, the process by which social reality was constructed. The next stage was initiated by researchers like Scott (1987) who realised that very little was known about the constituent elements that go into forming institutions, or about the actual steps by which this process takes place. They pointed out that most institutional research had focused on the effect of institutions as dependent variables, at the expense of an examination of the determinants and components of institutions, and that the process by which institutions became constructed remained a 'black box' (Zucker, 1991). More recent studies like those of Greenwood and Suddaby (2006); Maguire (2004); Phillips & Hardy(2002); Phillips et al.(2004) show that understanding how institutional change occurs has become a central challenge to institutionalists' accounts of organisational behaviour as well as to institutional entrepreneurship theorists.

Towards new perspectives

As mentioned before, I argue in my study that the pattern of interactions of the various stakeholders acting collectively as institutional entrepreneurs and shaping nanotechnology institutional emergence follows a logic of its own. In order to analyse this phenomenon, I focus particularly on two features: rules and discourse. Indeed, rules are a very important aspect of both the development of nanotechnologies and the creation of new institutions. The work of Perrow (1986) on how rules bundle together all the technological and social aspects of organisations and constitute means of preserving group autonomy and freedom may thus be integrated into the broader perspectives of institutional theory. It can be reconciled in this perspective with the theory that institutions reflect cognitive, normative, and regulative structures and activities that provide stability and meaning to social behaviour (Scott, 1995).

Greenwood et al. (2008) explain that the fact that Meyer and Rowan omitted to provide a formal definition of 'institutional context' other than that it contained rationalised myths in their landmark paper of 1977 led to confusion over the actual meaning of 'institutional context' for the next couple of decades. They consider that the term was used to cover two very different ideas: on the one hand 'institutional context' referred to a set of symbolic and/or cultural differences, and on the other hand it referred to the regulatory framework of state and professional agencies, an approach that is closer to institutional economists. So Greenwood et al. (2008) insist that works that expose how regulatory agencies (institutions) shape organisational behaviour are incomplete institutional explanations unless they show how regulatory frameworks embody, enact or transmit societal norms and values. Otherwise, they estimate that referring to regulatory frameworks as 'the institutional context' risks confusing institutional theory with resource-dependence or political-economy explanations (Greenwood et al., 2008:4). In my work, it is precisely my purpose to show that new societal norms and values are embodied in the regulatory frameworks which delineate nanotechnology institutional emergence. I demonstrate that by taking into account the concept of sustainable development, norm creation in nanotechnology contributes to shape the emergence of a new institutional field.

Discourse is another component of my analysis of nanotechnology institutional emergence. Greenwood et al. (2008) suggest eight directions for future research in institutional dynamics. In their fourth proposition, they explain that to date most studies have portrayed institutional processes as fully formed (Aldrich, 1999) and they point toward new directions taken to address this gap. One such direction is precisely to look at rhetoric and discourses as parameters of institutional change (Phillips et al., 2004, Suddaby and Greenwood, 2005). Indeed, most recent institutional work bears on the role of discourse in the emergence, maintenance or disruption of institutions. It shows how new discourses do not suddenly supplant legacy discourses but, instead, are made to overlap and interact with them through the authorial agency of actors. It is out of this discursive struggle that new institutions emerge, momentarily stabilising meanings and thus resulting in particular institutional outcomes (Maguire and Hardy, 2006). I draw from this novel and constructive approach to analyse the process of the institutional emergence of nanotechnology (see particularly chapter 7).

Greenwood et al. suggest two other directions of research which I find of particular relevance to my own analysis. One is to look at social movement theory. They note that for the most part, institutional work has remained silent on issues of social power. Their remark is particularly appropriate and it underlines the lack of communication between scientists. Indeed, European researchers like Friedberg and Crozier (1997), Bourdieu (1977, 1992) or Giddens (1986) in his recent research are not classified as institutional theorists. Yet their analyses of social structures based on agency and power have a lot to bring to management research. They are also very helpful to account for nanotechnology institutional emergence as I show in my last chapters. Finally, Greenwood et al. (2008) signal the importance of combining institutional theory with other theories, and particularly strategy theories. They note with some surprise that the literature has witnessed almost no attempts to combine comprehensively a strategy theory with institutional theory. Although there has been a pronounced growth in the application of institutional theory to mainstream strategy topics, this has not been accompanied – a few exceptions aside – by the explicit juxtaposition of institutional theory and specific strategy theories. Chapter 5 in particular seeks to analyse the links between strategy and institutional emergence in the exploration of nanotechnology entrepreneurship.

Entrepreneurship literature

Several authors have documented the historical development of entrepreneurship and helped established identifiable foci of the literature (Gartner, 1988, Hisrich, 1986, Livesay, 1982, McMullan and Long, 1983). Even though the boundaries between the different orientations of research are not always perfectly tight and there are overlaps, there are still strong nuclei of research (Sharma and Chrisman, 1999, Salgado-Banda, 2005). In my analysis of institutional emergence, I draw from the entrepreneurship literature for two major reasons. The first one is that in order to shed light on a particular empirical phenomenon which is the institutional emergence of nanotechnologies, I look at the close connections between industrial emergence and regulatory frameworks. My purpose is to show that, around the development of nanotechnologies, the evolution of regulatory frameworks embodies new societal norms and values. On the one hand these frameworks are the result of the particular characteristics of nano-based products. On the other hand, they shape the development of the technology. I consider that the best way to analyse this sort of see-saw movement between regulatory frameworks and industrial emergence is to look at nanotechnology entrepreneurship, as is made clear in Chapter 5 in particular.

The second reason to draw from the entrepreneurship literature is that, in line with Greenwood et al. (2008) who suggest that institutional theory may benefit from being confronted or juxtaposed with other theories, I believe that entrepreneurship theory has a lot to tell institutional entrepreneurship theory about the process of institutional emergence (see chapter 7).

In his comprehensive overview of entrepreneurship, Shane (2003) explained that although entrepreneurship is one of the most popular aspects of business, it is also one of the least understood. Starting from the premise that the academic field of entrepreneurship does not have a well-established and coherent conceptual framework to integrate it, he proposed to create one. He placed the individual-opportunity nexus at the core of his conceptual framework, and studied the following areas: the characteristics of opportunities, the individuals who discover and exploit them, the processes of resource acquisition and organising and finally the strategies used to exploit and protect the profits from those efforts. In order to build his conceptual framework of the individual-opportunity nexus he devoted the chapters of his book to the different dimensions of the entrepreneurial process which he had identified. In doing so he provided an extensive overview of the areas covered by the entrepreneurship literature.

Schumpeter (1934, 1939 and 1947) and Knight (1967) were at the forefront of the research on the essence of entrepreneurship. Schumpeter found that entrepreneurship involved a combination of creation and destruction, as the creation of new products and business models went along with the elimination of others, and that this ‘creative destruction’ was largely responsible for the dynamism of industries and long-run economic growth. For Knight and later Drucker (1970) entrepreneurship is about taking risk. The entrepreneur is the kind of person that is willing to put his career and financial security at stake, to spend his time and capital for an uncertain venture. Among the various schools of thought concerning the definitions of entrepreneurship and the ways to assess it, most circle around the ability to identify and exploit opportunities to create new business activities. It is generally agreed that entrepreneurship occurs when an individual or a group of individuals, in association with an existing organisation, mobilise resources to create a new organisation or instigate renewal or innovation within that organisation with the view to generate new businesses (Collins and Moore, 1970, Sharma and Chrisman, 1999, von Hippel, 1977).

But whereas earlier research focused essentially on the traits of individuals, what characteristics are needed to be an entrepreneur (Busenitz and Barney, 1997, Cole, 1946, Collins and Moore, 1970, Hartman, 1959), there has since been an evolution to challenge this approach, (Gartner, 1988) and the research has gradually moved towards studying entrepreneurship more from an organisational perspective. For instance, Yli-Renko and Autio (1998) studied the systemic evolution model of new, technology-based firms in relation to their network environment. This has also given rise to a number of studies exploring corporate entrepreneurship, corporate venturing and intrapreneurship. Covin and Slevin (1989) looked at the performance of small firms in hostile and in benign environments to identify the necessary conditions for success in each type of environment. Pinchot (1985), who coined the word ‘intrapreneurship’, theorised how to foster, support and enhance creativity and innovation within the workplace; Zahra (1993) examined the interrelations between corporate entrepreneurship, the external environment and a firm’s financial performance. In their attempt to reconcile definitional issues in the field of corporate entrepreneurship, Sharma and Chrisman (1999) drew a panorama of existing research on all the efforts to understand and explain entrepreneurial activities within existing organisations. All these research strands describe entrepreneurial activities within organisations and relate to organisational processes that contribute to firms’ survival and performance. More recently, research has been carried out into the relationships between entrepreneurship and economic growth, and this may be seen as the beginning of a new interest for the relative place of entrepreneurship in society (Schramm, 2006). Finally, a small minority of scientists is exploring the relations between education in entrepreneurship and entrepreneurial cognition. Their work underlines that institutional teaching has an impact on entrepreneurship, and also opens up new avenues of research into some connections between institutions and entrepreneurship (Wright et al., 2007, Fayolle et al., 2006).

However, the relations between the institutional environment and entrepreneurship are an area which has remained understudied. One explanation may be that the entrepreneurship literature has until recently tended to assume a positivist approach by focusing on the individual-opportunity nexus in entrepreneurship without much attention to contingencies. Campbell already pointed years ago that entrepreneurship was not a purely psychological phenomenon, and that policy makers could influence the level of entrepreneurship (Campbell, 1992). Shane did notice that there was still today a paucity of theoretical or empirical research discussing the relationship between the institutional environment and the discovery of opportunity (Shane, 2003). However, in his review of his *General Theory of Entrepreneurship*, Casson (2005) noted that he had disappointingly not attempted to explore this area. He suggested that this could be explained by the fact that Shane largely confined himself to the contents of recent issues of mainstream journals on small business and entrepreneurship, in which the main focus is on evidence relating to individual firms. As a result, Casson noted that very little was said about the macroeconomic implications of entrepreneurship, and pointed that the cognitive processes underlying the identification of opportunities was one of the areas in urgent need of further work.

It is no easy task to assess with accuracy the relative importance of the number of studies devoted to each area. What is clear is that at the strong end of the spectrum are all the studies concerning the psychological, innate/non innate characteristics of the entrepreneur, as well as the relations between entrepreneurship and the economy. At the lower end are the studies concerning the environment of entrepreneurship, as well as the *process* of entrepreneurship. Baron is one of the few researchers who are interested in the connections between the business environment and entrepreneurial cognition (Baron, 2005, Baron et al., 2004). The work of (North, 1990, 1991 and 1993) spearheaded studies into the relations between entrepreneurship, organisations and institutions. His exploration of societal change based on the analysis of transaction costs lead him to the conclusion that entrepreneurs and what he gathers under the generic term of ‘members of organisations’ invest in the skills and knowledge which lead to revised evaluations of opportunities, and that this in turn induces alteration of institutions (North, 1993). For him, it is essential to differentiate organisations from institutions, for he sees organisations – and the entrepreneurs and decision makers within organisations – as the agents of institutional change.

> “Deliberate institutional change will come about therefore as a result of the demands of entrepreneurs in the context of the perceived costs of altering the institutional framework at various margins. The entrepreneur will assess the gains to be derived from recontracting within the existing institutional framework compared to the gains from devoting resources to altering that framework”. North (1976): 37.

North acknowledged in his autobiography that Schumpeter had had a strong influence upon him (North, 1997). His theoretical quest led him through an evolution. From introducing the idea of applying economic theory and quantitative methods to history, he came to the realisation that the tools of neo-classical economic theory were not up to the task of explaining the kind of fundamental societal change that had characterised European economies from medieval times onward. This led him to search for a framework that would provide new tools of analysis, and thus to new institutional economics.

It appears from the above that the study of the environment and of the *process* of entrepreneurship constitute gaps in the literature. Both of these areas are central to my analysis. Indeed, I consider that the mechanism of nanotechnology entrepreneurship – how the process works, how it relates to its environment – is a key to analyse nanotechnology institutional emergence. This is because nanotechnology institutional emergence *rests* on nanotechnology entrepreneurship. The above could be summarised by saying that my research points towards the process of entrepreneurs who become institutional entrepreneurs on the one hand and towards the relations between opportunity recognition and the institutional environment on the other hand. It is this particular area which is at the core of the specificity of nanotechnology institutional emergence, as will be shown later in this study.

Theories of science and technology

As mentioned in the introduction, one of the research questions for this study is: 'What makes the nanotechnology context a propitious one to study institutional emergence?' The science and technology literature offers highly interesting clues to build an explanatory theory to answer this question. The first one comes from Popper (2002). For him, scientific theories, and human knowledge in general, are generated by the human mind in order to solve problems that have arisen in specific historic cultural settings. He rejects the approach of science which is at the core of classical empiricism: inducting theory from observations. He considers that scientific theories are abstract in nature, that they can only be tested indirectly, in reference to their implications. Best known for his falsifiability criterion, he argues that falsifiability is indeed a criterion to differentiate what is genuinely scientific from what is not because although no number of positive outcomes at the level of experimental testing can confirm a scientific theory, one single counterexample is enough to invalidate it. Therefore, a theory should be considered scientific if and only if it is falsifiable. In Popper's view, the advance of scientific knowledge corresponds to an evolutionary process: in response to a given problem, a number of competing conjectures or tentative theories are systematically subjected to attempts at falsification. This process of error elimination is akin to the process of natural selection which Darwin (2003) analysed to explain biological evolution. Theories that better survive the process of 'refutation' are not more true, but rather, more 'fit', or in other words, more adapted to the problem considered. For Popper, the way scientific knowledge advances is by continuous interaction between tentative theories (conjectures) and error elimination (refutation). This process, which is very similar to the process of natural selection and genetic evolution, explains both the progress of human knowledge and why scientific knowledge advances toward solving more and more complex problems.

Kuhn (1962) has also written extensively on the history and philosophy of science. A contemporary of Popper, he has a completely different interpretation of the development of science. Whereas Popper's theory suggests that progress follows a linear evolution, Kuhn's own work shows that the major developments in science are mostly revolutionary. His most important insight, as far as my study goes, is that scientific progress is not a linear accumulation of new knowledge, but is instead the result of revolutions in which the nature of scientific inquiry within a particular field is abruptly transformed. For Kuhn, generally speaking, science emerges through three distinct stages. The first stage is 'prescience'. At this stage, the various components of knowledge to come are still scattered around without a central core, or 'paradigm'. Then comes the second stage, 'normal science'. At this stage, a consensus has emerged to accept the new paradigm, and subsequent research consists in applying known methods to solve the new types of problems raised. This is the stage which Kuhn calls 'puzzle-solving'. Just as puzzles generally have predetermined solutions, in doing 'normal' research scientists aim to discover something that is known in advance. At this stage, if results do not conform to the central paradigm it does not mean that the paradigm must be refuted, but rather that the researcher has made mistakes in his analysis. Yet, if too many anomalous results build up, then science reaches a crisis, and a new paradigm arises, which supersedes the old results and accounts for the anomalous results. This is what Kuhn terms revolutionary science. Kuhn's theory challenges the prevailing positivistic concept of science as a unitary and unidirectional process of accumulating facts about a pre-existing world.

Building on Kuhn's work, various scholars have had their own approach and interpretation of what came to be known as the theory of paradigm shifts. Callon and Latour explore the sociological dimension of the process of the institutionalisation of science. When analysing the chronological steps of the emergence of science and technology they show that the process of stabilisation and ontology acquisition has little to do with the intrinsic qualities of a given theory, but rests rather on the strength and breadth of the scientists' social network. The scientists' social network is what facilitates the 'translation' stage (Callon et al., 1986, Latour, 1988). As mentioned in the introduction, for Callon et al., scientific knowledge emerges from disconnected facts through the settlement of a controversy concerning their validity. The settlement of the controversy itself results from the success of the translation phase, during which a common language of reference is created so that previously unrelated entities can be connected and be seen in interaction. The process of translation gives unity and intelligibility to otherwise obscure and apparently disconnected entities. It allows the institutionalisation process to move into the domain of public understanding. It rests on the strength of the scientists' network, which Callon et al. define as an ensemble of meta-organisations including human and non-human 'actants' interacting together.

Drexler (1986) pays tributes to Popper's and Kuhn's evolutionary theories in his own account of the evolution of matter itself in his groundbreaking analysis of the emergence of nanotechnologies. For Drexler, the evolution of species, the evolution of the human environment and the evolution of our understanding of the world all reflect the evolution of matter, which follows a similar pattern as the one first described by Darwin (2003). His book puts forward several new concepts. One such concept is that the common point of all sciences from different fields is matter itself, and that the way the emerging laws of physics account for the evolution of matter connects directly to the evolution of all sciences. This theory has been given particular visibility with the focus placed on converging technologies, or NBIC (Nanotechnology, Biotechnology, Information technology and Cognitive science).

In 2001, the US National Science Foundation and Department of Commerce sponsored a workshop that resulted in an extended report, in which convergent technologies were defined as:

> “ the synergistic combination of four major ‘NBIC’ (nano-bio-info-cogno) provinces of science and technology, each of which is progressing at a rapid rate” (Roco and Bainbridge, 2003): ix.

The report explained that the four technologies – nanotechnology, biotechnology, information technology, and cognitive science – have undergone significant changes and expansion over the last fifty years, and that their respective paths of development are more and more closely interwoven. More, thanks to the convergence of NBIC, one can for the first time in human history envisage:

> “a comprehensive understanding of the structure and behaviour of matter from the nanoscale up to the most complex system yet discovered, the human brain” (Roco and Bainbridge, 2003): 1.

So this new generation of science and technology authors, whom some have criticized as being more akin to science fiction writers than to reliable scientists, consider that science and technology have reached a stage when we are beginning to understand the scope and the possibility to modify matter by acting on its basic components, its atomic structure. For them, it is only a lack of adequate tools which prevents us from doing so and –

as some like to phrase it – to have Godlike powers over human beings and their environment.

Conclusion

The concept that science and technology have reached a stage where people can envisage the complete mastery of matter through work on its most basic components definitely constitutes an answer to the question of what makes the nanotechnology context a propitious one to study institutional emergence. If nanotechnologies are the tools that can enable man to modify matter at will by acting on its basic components, then their emergence has the potential to bring radical change to our understanding of the world, as well as to our own existence and evolution. So it constitutes an ideal context to study the combined effects of a new technology and of a new institutional logic.

The task which I set myself for the rest of this work is to build on these three theoretical fields – institutional entrepreneurship, entrepreneurship and science and technology – to provide an integrated analysis of nanotechnology institutional emergence within the analytical frame I have chosen: What is specific about nanotechnology institutional emergence? How does nanotechnology entrepreneurship relate to nanotechnology institutional entrepreneurship? What role does the concept of sustainable development play in this form of institutional emergence? It is hoped that by doing so, I will contribute to fill some of the theoretical gaps I have highlighted in the course of the literature review.

THEORETICAL CONTEXT AND PERSPECTIVES

Outlining the general philosophy of the research

In the literature review, I highlighted the inputs of various schools of thought in my analysis of nanotechnology institutional emergence. I draw more precisely on institutional theory to analyse how the pattern of interactions in which the various stakeholders act collectively as institutional entrepreneurs and shape nanotechnology institutional emergence follows a logic of its own. It is now time to define what I mean by the institutionalisation of nanotechnologies. Building on the work of Meyer and Rowan (1977), DiMaggio and Powell, (1983), Tolbert and Zucker (1983), and Greenwood et al. (2008) I will start by giving my own interpretation of the notion of institutions. Institutions are ensembles of structured conventional social practices which have acquired a taken-for-granted ontological status which allows them to set conditions on action. Two very important aspects of institutions are that they are 'permanent' and 'universally acknowledged' social structures.

'Permanent' does not mean that institutions are everlasting. Otherwise it would be impossible to have new institutions, and the notion of institutional change would not mean anything. By 'permanent', I consider that institution have a relative persistence in time, a persistence which outlasts fads and trends. Bureaucracy has been and still is to a certain extent an institution. It corresponds to a norm, a standard of behaviour, a set of practices which is widely understood (meaning that everyone understands what it corresponds to) and accepted. It was one of the most widespread organisational forms in the western world of the twentieth century (Weber and Gerth, 1958) (Weber, 1997). Yet organisational structures are changing, and even if bureaucracy still appears as a set of organised practices fitting a well defined social, legal and economic framework, bureaucracy is no longer the dominant model that it used to be, and it has undergone change (Lounsbury, 2005, Beck, 1992, Kallinikos, 2003).

'Universally acknowledged' does not mean either that everyone on earth places a given institution on the same value scale. Yet by 'universally acknowledged', I mean that institutions have a form of *cultural identity* which makes people recognise what they are whatever the various organised forms they take. In French, Armed Forces come under one generic word: L'armée. It makes the symbolic meaning stronger than the somewhat hazy term of 'Armed Forces'. However, whatever the name, whatever people think of their value, when they read or hear about 'Armed Forces', or 'l'Armée' in French, they immediately identify what this refers to (with symbols like uniforms, discipline, national identity…). Armed forces constitute an ensemble of structured conventional social practices. They have a taken-for-granted ontological status which allows them to set conditions on action: apart from the few nations which were forbidden to keep armed forces at the end of the Second World War, it is a universally accepted fact that nations keep armed forces. Armed Forces constitute an institution whose cultural identity is probably one of the most widely shared on earth. Yet the US army is quite different in its organisational from, say, the Ugandan armed forces. The family, (in French 'la famille') is also an institution, but the outlines of this institution are not the same everywhere. According to different cultures, family laws are different, family structures are different, family organisations are different. In western societies, the family institution has undergone huge changes. Yet, the cultural nature of this organised form of social links is universally known, it is an institution.

Can nanotechnologies delineate an institution then? To be able to answer this crucial question, it is necessary to start by outlining the field of nanotechnologies.

Outlining the field

Nanotechnology is a generic word that refers to science, technologies, products and processes involving the manipulation of matter at the level of atoms and molecules, at the scale of the nanometer (nm), i.e. of a billionth of a meter (10^{-9} m), in order to obtain new and unique properties not found in the bulk forms of the particles. It was the lecture that the American Nobel Physics Prize Richard Feynman gave in 1959 which made people realise that people could change the characteristics of matter by acting on its constituent atoms. The transcript of the talk that he gave on December 29th 1959 at the annual meeting of the American Physical Society at the California Institute of Technology (Caltech) was first published in the February 1960 issue of Caltech's Engineering and Science. In this lecture *There is plenty of space at the bottom,* he envisaged for the first time what this could mean:

> "But I am not afraid to consider the final question as to whether, ultimately – in the great future – we can arrange the atoms the way we want; the very *atoms*, all the way down! What would happen if we could arrange the atoms one by one the way we want them". [1]

The word itself was used for the first time in 1974 by Norio Taniguchi, a scientist from Tokyo University (Taniguchi, 1974). The concept of nanotechnology refers to working on matter at the atomic and molecular scale: by modifying the ways atoms are placed or grouped together, people can either obtain known products with new characteristics, or completely create new matter, whether living or inert. Although not everyone agrees on this as a criterion, nanotechnology tends to refer as a rule to structures which have at least one dimension which is smaller than 100 nm. Even if people started conceiving the immense potential of manipulating matter by acting on its basic components in the 1950s, one had to wait until the 1990s to see on the market the first tools that enabled scientists first to see, and

[1] Feynman, R. (1959) (Ed, Annual Meeting of the American Physical Society at the California Institute of Technology (Caltech)) Engineering and Science, Caltech, Pasadena, CA.

then to work at such a small scale. Today, nanotechnologies cover very diverse fields, which can be gathered under two major areas of development. Firstly all the computing and optical tools making it possible to visualise nanometric components and to work at the nanoscopic scale. Secondly, all the fabrication processes involving nanoparticles.

To manipulate the atoms which constitute any form of matter, there are two opposite approaches: one can either start from the bottom or from the top.

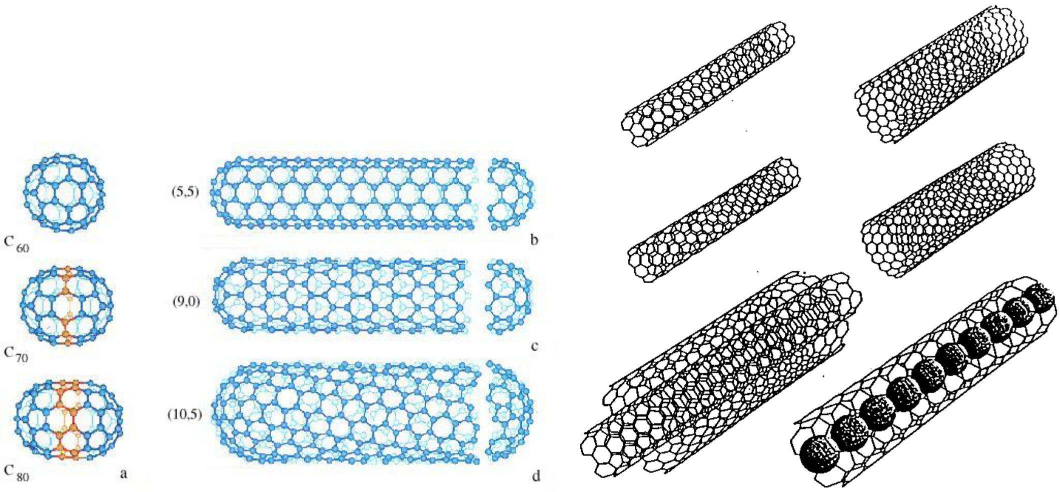
Starting from the bottom. With this method, the idea is to start from the atoms themselves, and to assemble them or make them assemble according to a very specific design, in a way that could remind one of children using Lego blocks to make their own constructions. In 1989, scientists from the IBM lab in Almaden Research Center in San José, California, placed 35 xenon atoms on the surface of a nickel crystal to form the letters IBM. To do so they used a scanning tunneling microscope (STM), which allowed them to see and manipulate the atoms one by one. The microscope had been invented in the IBM Zurich lab and brought its inventors' a Nobel Prize in physics in 1986[2]. However, to this day, manipulating individual atoms remains in the domain of lab science. One reason is the price of the equipment, essentially very sophisticated microscopes: some of them exceed 1 million euros. The other reason is that the time necessary to manipulate the atoms makes it absolutely impossible to assemble enough molecules to create matter in a sizeable way. Richard Smalley made a quick calculation based on the fact that making a mole of something of about one ounce (30 grams) would require at least 6×10^{23} bonds, one for each atom. He explained that at the frenzied rate of creating 10^9 bonds per second it would take 19 million years to do so! (Smalley, 2001).

Manipulating matter from the bottom seems to be more promising using molecular self-assembly. Eric Drexler championed this technique in his book *Engines of creation: the coming era of nanotechnology* (Drexler, 1986). He proposed to use nanoscopical self-

[2] Two Swiss researchers, Gerd Binning and Heinrich Roher.

reproducing robots, which he called ‘assemblers’ to build matter starting from atoms. He based his vision on the fact that this is precisely what happens with biological reactions in nature. When cells are created or biological actions take place, matter is being created or modified according to pre-determined designs. Living cells, for example, are nanoscale devices that are constantly assembling complex structures one or two molecules at a time. For instance, cells construct proteins by putting a chain of amino acids together in the right order, following the ‘construction manual’ provided by the DNA. In Drexler’s vision, assemblers would guide chemical reactions leading to the construction of new matter by moving reactive molecules in the right places. This technique blurs the divide between biology, chemistry and physics, and is progressing extremely fast in spite of the early criticisms which Drexler had to face. The major criticism addressed to Drexler was that he presented his vision as if it could come true in the near future, which created a hype close to marketing techniques, whereas scientists knew that the current advancement of science made it a dream for a great number of decades and possibly centuries. However, it did make people understand and realize what modifying matter could mean in practical terms, and did boost research in this direction. (Drexler and Smalley, 2003)

Nanotechnology from the top: the second approach to create nanostructures is to manipulate matter starting from the top, i.e. to modify the atomic composition of existing matter through a succession of various operations, usually chemical reactions. Whereas in the bottom up approach scientists start from atoms and try to force them to assemble in given ways to obtain molecules with specific characteristics which have not been found in nature, in the top down approach, scientists start from existing matter and attempt to modify its molecular structure to obtain new structures and products. For instance, carbon is a well-known natural element, which is found in abundance on earth, and which is present in everything we eat, as well as as a component of our bodies. By submitting carbon to chemical and thermal reactions scientists are able today to create varieties of carbon nanotubes which have never been found in a natural state[3]. These molecules, containing only carbon atoms, have a tubular form and very interesting properties: they are 100 times stronger and six times lighter than steel. Some have a diameter which does not exceed one nanometer, and can reach a length of 100 000 nm. Depending on their structure, they can look like sausages, or rolls or wrapping paper if their ends are chopped (Fig 5). They can be utilized as electric conductors, or conversely as semi-conductors, which makes them extremely interesting in electronics.



Examples of carbon nanotube structures, including singlewalled, multiwalled and metal-atom-filled nanotubes.
Sources: virag.elte.hu/kurti/science.html and
http://www.wtec.org/loyola/nano/fh04_06.gif

Fig 5

After more than a decade of promise and speculation created by their unique properties, nanotubes are establishing a presence beyond university laboratories and corporate research and development (R&D) centres. Current commercial applications include motor vehicle fuel system components and specialized sports equipment. In the short term, world demand for nanotubes is expected to expand rapidly from this small base to more than $200 million in 2009 and $1070 million in 2014 (Source: http://www.azonano.com, accessed on 22 October 2008). However, a number of issues, including high costs,

[3] The discovery of fullerenes, molecules of carbon atoms assembled in the shape of a cage, led to the Nobel Prize in Chemistry for Harold Kroto, Robert Curl and Richard Smalley in 1996, and to the elaboration of carbon nanotubes.

inadequate purity levels, and insufficient product yields in manufacturing, still need to be addressed.

Can nanotechnologies delineate an institution?

The straight answer to this question is ‘no’, and I will explain why. The social practices which delineate institutions are usually organised around a certain technology, or set of technologies, which has a specific purpose. This may be weapons in the case of the armed forces, reproduction in the case of the family, or the tools of organised rationalisation (accountancy books, various types of records or reports, ranking tools etc.) in the case of bureaucracy. Until 2003, there was a consensus to present nanotechnologies as a single technology. An archival search of 192 papers written between 2001 and 2003 – which covers the majority of the papers written during that period – shows that the word nanotechnology was almost always used in the singular at that time. The most widely accepted explanation for this is that the first stakeholders (essentially scientists and politicians) voluntarily created hype around ‘nanotechnology’. The reasons for this will be debated at a later stage. Yet one of the means to create the hype was to use a word in the singular as a way to give existence to an otherwise completely immaterial concept. ‘Nanotechnology’ started as a visionary programme, *defined by the effects it would produce*. The first official documents about it were released by the US, and they served to describe a vision of a unifying technology which would bring a revolution. This revolution was presented as the latest in a succession of revolutions: the industrial revolution had lasted 200 years, it was followed by the electronics revolution which had a likely working life of 75 years, and then by the biotechnology revolution which, although hardly yet on its feet, was already prophesied to be supplanted by (or perhaps to morph into) the nanotechnology revolution.

A few quotations illustrate this mechanism:

> “Nanotechnology’s relevance is underlined by the importance of controlling matter at the nanoscale for healthcare, the environment, sustainability, and almost every industry. There is little doubt that the broader implications of this nanoscience and nanotechnology revolution for society at large will be profound”.(Roco and Bainbridge, 2001) :9

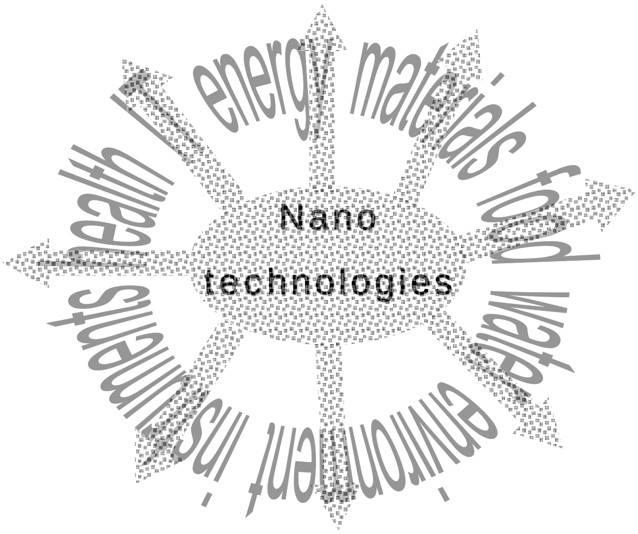
> “Those who participate in the “nano revolution” stand to become very wealthy”(Roco and Bainbridge, 2001): 19

> “The promise of nanotechnology to remake our world seems virtually infinite. So the first thing to say is that if — as is variously claimed — nanotechnology is going to revolutionize manufacturing, health care, travel, energy supply, food supply, and warfare, then it is going, as well, to transform labor and the workplace, the medical system, the transportation and power infrastructure, the agricultural enterprise, and the military. » (Roco and Bainbridge, 2001) : 57

In 2001, the US created a single program centralizing the major research efforts relating to ‘nanotechnology’. This was the NNI: National Nanotechnology Initiative. Before this decision, nanotechnology R&D was a haphazard smattering of various unconnected initiatives, in the US and everywhere else. The creation of the NNI was followed by the publication of the S 189 Act, the full title of which was: 21st Century Nanotechnology Research and Development Act (US Congress, 2003). Tellingly, both landmarks documents referred to nanotechnology in the singular. In the wake of the US, other countries, and regional powers like the EU, saw the importance of coordinating nanotechnology research and establishing it as a field. The first such document produced by the EU was ‘Towards a European Strategy for Nanotechnology’. COM(2004) 338, produced by the European Commission in May 2004 (European Commission, 2004c). There again, the word ‘nanotechnology’ was in the singular.

So it can be said that the birth of nanotechnology was orchestrated by politicians and scientists firstly in the US as a way to create a nanotechnology institution. The vision of this institution was that it would be a global institution and that it would revolutionize society for the better… by acting on the structure of matter. This was the way to create a new ensemble of structured conventional social practices that would set conditions on action.

But as more and more research was carried out and the field began to emerge, it became clear that nanotechnology as a singular word did not mean anything: the modification of matter at the atomic scale took so many different forms, rested on so many different approaches, and led to so many different outcomes that it could not be assimilated to one single technology. As Alfred Nordmann explained, the era of nanotechnologies is rather like the advent of plastic. Plastic was the first non-natural material. Now it is everywhere around us, and even within some of us (after some surgical operations) (Nordmann, 2007). Plastic has diffused across most of the sectors of activity and become ubiquitous. With nanotechnologies, things look very similar, with an even greater extent of diffusion. Based on a list of sectors directly affected by the development of nanotechnologies compiled by Nicholas Deliyanakis, from the European Commission DG Research - G4 : Nano S&T and Converging Science and Technologies, here is my own illustration of the pervasiveness of nanotechnologies in 2007 (Fig 6):



The field of nanotechnologies: a pervasive diffusion (fig. 6)

Although plastic is all pervasive, although a lot of our social practices have changed with its arrival on the market under various forms, one cannot say that plastic is an institution. It has *changed* our practices, but it does not correspond to an ensemble of practices. The same can be said of nanotechnologies. In spite of the initial thrust which presented them as a unified technology, they are now referred to as nanotechnologies in the plural. Only one year after the EU released its first landmark document entitled 'Towards a European Strategy for Nanotechnology', it produced a second report called: 'Nanosciences and nanotechnologies: An action plan for Europe 2005-2009'(European Commission, 2005). It was only one example of the complete change that was taking place. Today, hardly any document refers to nanotechnology in the singular, and just as plastic is not an institution, nanotechnology, or even nanotechnologies, do not correspond to an ensemble of social practices, and do not constitute an institution. We might go further and say that only common point to all nano technologies – and it is a major one – is that they deal with the most basic components of matter. But if we wanted to stretch it a bit, we might say that all living and inert substances of the universe are made of atoms anyway, so why consider that something special is happening? Is there anything to write about?

My argument is that there *is* something to write about, because something special *is* happening with nanotechnologies. Scientists are modifying the structure of matter, and in so doing, they are completely changing the human paradigm. Nanotechnologies are revolutionary, in the strongest sense of the term. They may not correspond to an institution but they are shaping a new transversal field which is going to spread until it affects most human activities one way or another. This emergence is at the core of my study, because it brings about a whole new ensemble of structured social practices which I intend to study in detail.

Institutional emergence around the development of nanotechnologies

I explained in the introduction that the aim of this study is to offer an interpretation of a specific form of institutional emergence: institutional emergence around the development of a new technology. To do so, I ground my exploration of institutional emergence in the empirical field of nanotechnologies. I have just explained how nanotechnologies do not constitute an institution. I will show how the emergence of the field of nanotechnologies coincides with the emergence of new types of institutions. This is what I mean by institutional emergence.
DiMaggio and Powell defined fields as:

> “sets of organizations that, in the aggregate, constitute an area of institutional life; key suppliers, resource and product consumers, regulatory agencies, and other organizations that produce similar services or products.” DiMaggio (1983) : 148-149.

Scott later defined an organizational field as:

> “a community of organizations that partakes of a common meaning system and whose participants interact more frequently and fatefully with one another than with actors outside the field”. Scott (1995): 56

For Hoffman (1999), organisational fields may include constituents such as the government, critical exchange partners, sources of funding, professional and trade associations, special interest groups, and the general public, in fact, any constituent which imposes a coercive, normative or cognitive influence on the organization. Seeking to understand how organisational fields and institutions co-evolve, he suggests that fields form around central issues, not around markets or technologies.

> "The notion that the field forms around a central issue – such as the protection of the natural environment – rather than a central technology or market introduces the idea that fields become centres of debate, where competing interests negotiate over issue interpretation. As a result, competing institutions may lie within individual populations (or classes of constituencies) that inhabit that field, what I define as "situated" institutions" (Hoffman, 1999: 353).

This is precisely what I want to show in the rest of my work: that the field of nanotechnologies is shaping around a central issue: 'the realisation of the importance of sustainable development'. Nanotechnologies are indeed centres of debate where competing interests negotiate over issue interpretation. Scientists, entrepreneurs, commentators, end users and policy makers – the five groups I have identified for my study – are constituents whose actions impose competing 'coercive, normative and cognitive influences'. They act as institutional entrepreneurs because they mobilise resources to modify existing institutions or to create new ones to suit their purposes. So when I speak of the institutionalisation of nanotechnologies – or nanotechnology institutional emergence – I refer to the emergence of new types of institutions around the development of a new field: the field of nanotechnologies. My purpose is to clarify the complex set of interactions which shapes the emergence of the field by shedding light on the role of each group as institutional entrepreneurs.

METHOD

Introduction

This research raises several important methodological challenges. To explain these, I will first recapitulate what I intend to do, starting with my research questions again:

How do various stakeholders acting as institutional entrepreneurs collectively shape the institutional emergence of nanotechnologies? In particular, how does entrepreneurship relate to institutional entrepreneurship? What are the characteristics of this institutional field emergence? What does it reveal?

I have explained that I call nanotechnology institutional emergence the emergence of new types of institutions around the development of the field of nanotechnologies. I have clarified that I do not see nanotechnologies as an institution but as a field, and that the field of nanotechnologies can be seen as both a set of organisations which in the aggregate constitutes an area of institutional life (DiMaggio, 1983) and a network of social relations, within which struggles or manoeuvres take place over resources, stakes, and access to establish legitimacy and survive (Bourdieu, 1992, Latour, 1988). I have emphasised that the establishment of legitimacy is at the core of this research. My analysis bears on the role of organised actors to structure the institutional contexts in which they operate in order to establish legitimacy for the field of nanotechnologies. I analyse the way in which these actors – the institutional entrepreneurs – connect to the activities and interests of other actors to give legitimacy to the new field. I explore the relationships between interests, agencies and existing institutions in this process, and how they relate to the emergence of new types of institutions or the modification of existing ones – two manifestations of institutional entrepreneurship (Maguire et al., 2004). My aim is to provide a conceptual frame to interpret a specific form of institutional emergence: institutional emergence around the development of a new technology.

Methodological options usually reflect a trade-off between the researcher's resources and the requirements of the set task. I have chosen a qualitative study as the most satisfactory course to unpack the complexity of institutional emergence in an integrated way. To capture the essence of the specifics of institutional emergence around the development of nanotechnologies, I have opted to develop a few case studies which illustrate relevant parameters of this institutional emergence. The interplay between case study material and theory development is based on personal interpretation. The replicability and generalizability of my findings will be the test of the validity of the method (Yin, 2002). For each case study, I rely on the triangulation method described by Jick (1979). According to him, triangulation is a good way of capturing a complete, holistic and contextual portrayal of the units under study, because the weaknesses in each single method are compensated by the counter-balancing strengths of another. The idea is that every method has assets and liabilities, and that triangulation exploits the assets and neutralizes the liabilities because multiple and independent measures do not share the same weaknesses or potential for bias. Besides, examining the same phenomenon from multiple perspectives allows for new and deeper dimensions to emerge. The triangulating investigation allows the researcher to find the emergence of a logical pattern by organising materials within a plausible network. So the researcher becomes a builder and a creator who draws on the firsthand knowledge of multiple observation points, and uses intuition to interpret the data and piece together the various pieces of a complex puzzle into a coherent whole. (Glaser and Strauss, 1965).

Data collection has spread over four years and I have focused on the geographic areas of the US and the EU. The US has produced the first institutional documents about nanotechnologies. I call institutional documents either documents emanating from existing institutions, or written performative statements (Austin, 1975, 2nd edition) which give birth to institutions. For example the National Nanotechnology Initiative (NNI) set up the first framework to aggregate hitherto disparate initiatives. The NNI has now become an institution, which speaks in its own voice. It consists of the individual and cooperative nanotechnology-related activities of 25 US Federal agencies with a range of research and regulatory roles and responsibilities. Thirteen of the participating agencies have R&D budgets that relate to nanotechnology, with the reported NNI budget representing the collective sum of these. The document which gave birth to this institution was the report following the President's request for year 2001 Budget (White House, 2000). As it produced the first nanotechnology institutional documents, US data constitutes an essential source to understand the process of nanotechnology institutional emergence. Besides, the US started as the global leader in all nanotechnology activities, both in R&D and in production. In 2004, when the first reliable and comprehensive comparative quantitative data on nanotechnologies were published, the US led the way globally in the number of patent applications and publications, as well as in public and private spending on nanotechnology. While US-based entities accounted for 56 percent of total issued patents at the US Patent and Trademark Office, they were assigned 69 percent of the nanotech patents. More, the European Patent Office data showed that the U.S. filed nearly three times as many nanotechnology patent applications as the EU in 2004 (President's Council of Advisors on Science and Technology, 2005; European Commission, 2004c).

As to R&D spending, data analysis shows that whether one speaks of corporate R&D or more generally on R&D funding, the US also started as the global leader. Lux Research estimated that while corporations worldwide spent about €3.8 billion on nanotechnology R&D in 2004, corporations based in the U.S. spent €1.7 billion or so, which means nearly half the global investment, and was far more than any other country (Lux Research et al., 2004, Lux Research and Nordan, 2005).

I also look at EU data, because the EU was at the time of writing the other major protagonist in the process of the institutionalisation of nanotechnologies. I analyse in detail in the course of the study the various forces at play and how they relate to equivalent forces in the US. Ideally, I would have liked to look at Asian data in detail as well, as Japan, Korea and China play a very important part in the story. However, because of resource limitations, I have not been able to integrate this angle of approach. This is one of the limitations of my theory building. I try to account for this gap in my interpretation of data whenever possible in order to reduce the bias which unavoidably results from this partial approach.

Data about nanotechnologies is plentiful, but this abundance does not always reflect quality and data mining can be a very frustrating exercise. The major problem consists in inconsistencies between various sources. For this project, I have relied heavily on institutional statistics mostly coming from the European Commission's various directorates, the US National Science Foundation, the NNI but also organisations providing macro economic data like the World Bank or the IMF among others. Surprisingly, the data coming from these sources is far from consistent. As an example of this problem, here is a simple comparison of three rankings of the 20 countries which had the highest GDP in 2007 (Fig 7). The GDP estimates in billion US dollars came from three different organisations, the International Monetary Fund (IMF), the World Bank and the CIA World Factbook My compilation shows the variances between the estimates, and these variances sometimes exceed 10 percent.

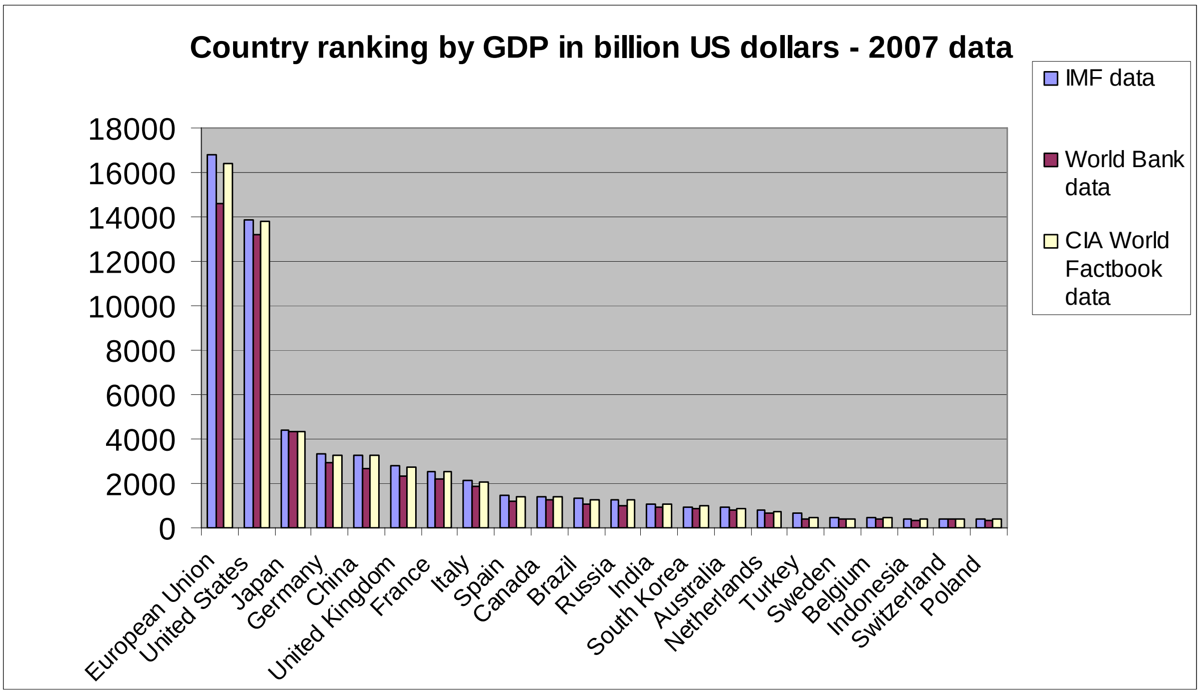


Fig 7

The same inconsistencies were found all along the way, notably in data concerning nanotechnology funding. Apart from inconsistencies in various data sources, another problem comes from the confusions that are sometimes made by the users of primary data. There are several reasons for these confusions. One is the mixture between dollars and euros. As most of the data analysed in this study concerns the period 2004-2006, the confusion means at least 15 percent uncertainty. Another one is the mixture between various ways of writing numbers, especially large numbers, when these are sometimes written with a comma separating every group of three digits whereas for other systems, a comma is used as a decimal separator. Finally, there are confusions between billions and trillions as these may still mean different powers of tens in different countries. Long scale is the English translation of the French term ‘échelle longue’. It refers to a system of numeric names in which every new term greater than million is 1,000,000 times greater than the previous term: "billion" means "a million millions" (10^{12}), "trillion" means "a million billions" (10^{18}), and so on. The short scale where a billion is a thousand million (10^{9}) is used in most English speaking countries and Brazil, whereas the long scale is used in the rest of the world. A British billion also used to mean a million million (10^{12}) yet because of the influence of banking systems the US thousand million (10^9) rule has now generally taken over. In the data used for my study it is sometimes very difficult to be sure of the system which is used. This time, the range of error is 10^3!

Research setting

I postulated in the introduction that the following set of interactions (Fig 8) serves as a model for nanotechnology institutional entrepreneurship.

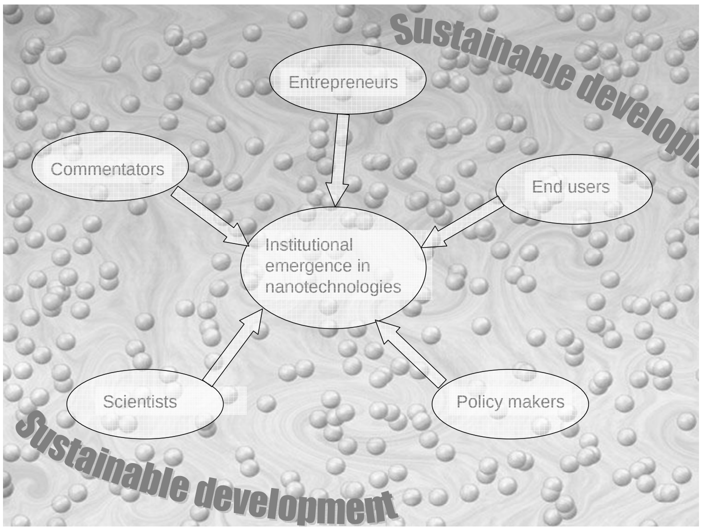


Fig 8

What I mean is that each group of stakeholders acts as an institutional entrepreneur and contributes to the creation of new institutions or the modifications of existing ones around the emergence of the field of nanotechnologies. In the introduction I also claimed that the new awareness of the concept of sustainable development constituted a connecting factor among the different groups of institutional entrepreneurs .

In order to build the cases which illustrate my hypotheses, one first challenge is to determine which units of analysis to use (Kenny, 1996, Robinson, 1950). The problem I face is that the analysis must follow a linear pattern because reading and writing follow such a pattern. Just as one cannot describe a phenomenon in writing without following the linear structure of written sentences, of words which are read one after the other, I have to follow this linear structure to describe each moment of the institutionalisation process, one after the other (Fig 9). However, institutional emergence follows an entirely different design: out of separate and seemingly unrelated elements, a new, unified, recognisable entity which has acquired ontology arises. This emergence has duration in time, but the elements aggregate concomitantly over this period of time, and this is impossible to translate in writing. This means that I have to follow a more or less arbitrary order to analyse one after the other how each group of stakeholders contributes to the institutionalisation process, and THEN provide a synthesis of the integration of all the separate elements. The cases I develop are the products of this two-stage synthesis.

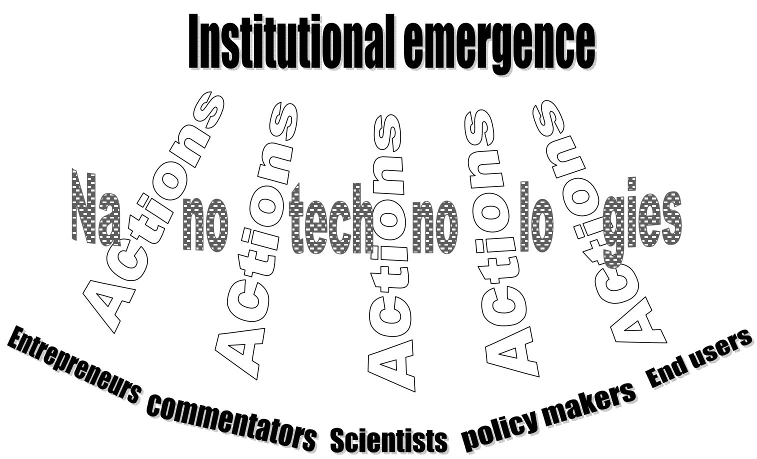


Fig 9

So I take groups of stakeholders as units of analysis, and progress towards identifying particular types of actions relevant to the process of institutional emergence. The black boxes I need to decipher, to take Zucker et al.'s terminology (Zucker and Tolbert, 1996) are the boxes of actions which lead to institutional change. The meaning Zucker and a large number of scholars give to 'black box' rests on the comparison with a device whose workings are not understood by or accessible to its user. A black box is something you do not understand and cannot explain at first sight. So you look into the black box, open it, sort all its elements, and give an interpretation of the issue. My task consists in finding what is inside the black boxes of actions of each group of stakeholder. My prediction is that the concept of sustainable development is the linking element which gives purport to the ‘sum’ of all the actions.

In his work, Latour has clarified the meaning he gives to the expression black box and then taken it to another level. He explains that cyberneticians use the term black box whenever a piece of machinery or a set of commands is too complex. In its place, they draw a little box because what is inside is not important in the discussion and would make the drawing too complex, as they are only interested in the input and output of the apparatus. In other words, the black box is a device or system which is considered mainly in terms of its input and output characteristics. What is inside is not what matters. He illustrates this with the example of computer chips: people do not care about what is inside a computer’s chips if the computer works well (Latour, 1988). Latour then demonstrates that there is a social process which consists in ‘blackboxing’ issues. When science is successful, no-one cares any longer about what is inside a black box. People are only interested in its input and output. So he defines blackboxing as:

> "the way scientific and technical work is made invisible by its own success. When a machine runs efficiently, when a matter of fact is settled, one need focus only on its inputs and outputs and not on its internal complexity. Thus, paradoxically, the more science and technology succeed the more opaque and obscure they become." (Latour, 1999: 304).

We will see in the course of the study that this interpretation of blackboxing is very helpful to develop a new theory of institutional emergence. It is central to the understanding of some phases of the institutionalisation process.

I need now to clarify what I mean by ‘institutional emergence’ in figure 9. In the empirical context I have chosen, the term refers collectively to the emergence of new institutions and the modifications of existing ones around the development of nanotechnologies. My purpose is to show the specificity of this process, to explore how the emergence of a new institutional field relates to the emergence of a new technological field, and what is specific about the case of nanotechnologies.

Sources of data

To build my case studies I have followed a classic combination of archival analysis and focused interviews. (Denzin and Lincoln, 2000, Glaser and Strauss, 1967, Saunders et al., 2003). I have added to these the field notes taken from a large number of conferences and workshops I attended during the period of data collection. The advantages of field notes of focused workshops and conferences are numerous. Firstly, they are efficient because one gets a large amount of data in a short time. Most importantly, these notes provide an excellent solution to correct potential bias. Indeed, one of the most noted side-effects of interviews is the tendency for the interviewee to adjust his or her comments to his perception of the interviewers’ designs (Kvale, 1996, Rubin and Rubin, 1995). In this sense, field notes of conference presentations provide more objective contents. Firstly, the data has been in a way filtered through a peer-reviewing process before the presenter could make his or her presentation. Then, when questions are asked the answers are public, which gives them a more authoritative value. Being a participant to these conferences and workshops, I could ask the questions that I wanted to see addressed in the light of my quest.

Early writings – press articles

The collection of archival data has lasted four years. The first step was to set up an archive which was as comprehensive as possible of early writings in English language about nanotechnology, in the general press as well as in academic or practitioners’ publications.

This task was relatively easy for the years up to 2003, as the number of publications was still manageable. The data base was set up in actual time in collaboration with the CBEN centre at Rice University (Center for Biological and Environmental Nanotechnology). It constitutes the starting point of the evolution of nanotechnology as a field. It contains nearly 200 documents written before 2003. The identification of references was done through LexisNexis and day to day press reviewing.

I used this database to obtain a first validation of my hypothesis that the awareness of sustainable development is a key to understand nanotechnology institutional emergence and constitutes a connecting element between the various groups of institutional entrepreneurs. To do so, I selected from the pool of documents all the newspaper articles written in 2003. I chose this sample for several reasons. Firstly, I focused on newspaper articles because they are a reliable indicator of the societal importance of a given issue at a given time. Secondly, I selected the year 2003 as the most representative year to depict the starting point of the emergence of nanotechnologies: before that year, events and facts were too scattered to outline meaning. Thirdly, 2003 was the year of the passing of the American '21st Century Nanotechnology Research and Development Act' (US Congress, 2003), followed closely after by the European 'Towards a European Strategy for Nanotechnology' (European Commission, 2004c) which were the first institutional texts outlining each nation's respective vision of the development of the field. Removing all the duplicates (same or near identical articles appearing in different papers), I obtained a sample of 144 articles. I coded them to measure the relative importance of the concept of sustainable development in them. I opted for two indicators, A and B.

The A coding corresponded to references to health and environmental risks. It could be seen as an indicator of the concept of sustainable development because if an article mentioned health and environmental risks in relation to nanotechnologies, then it credited the idea of potential liabilities which could make the next generations less able to enjoy the benefits of innovation than their predecessors. One of the core ideas of the concept of sustainable development is indeed that opportunities stemming from innovation must not endanger those of future generations.

The B coding corresponded to references to economic risks. Usually, the articles envisaged economic risks through comparisons with previous innovations like DDT, asbestos, genetic engineering or nuclear technology. The B coding reflected the idea that if the development of nanotechnologies leads to situations where in terms of capital cash flows positive conventional cash flows turn out to be less important than expected, and negative conventional cash flows turn out to be more important than expected, again, this will create a situation where the future generations will be in a worse position than the existing one. Again, one of the core ideas underlying the concept of sustainable development is that future generations may not be worse off than the current one because of the technological choices (among others) made today. The result of this simple study was that 70.8 percent of the documents received an A or B coding, with 40.2 percent having both. So it appears clearly that, from the start, at the beginning of the emergence of the field, although the phrase 'sustainable development' was hardly ever mentioned, the majority of newspaper articles published reflected a strong preoccupation with this issue.

Institutional data bank

A second step of my archival data collection was to set up an exhaustive bank of all institutional texts relating to nanotechnology, in the US and in the EU. This databank is organised under three headings: EU data, US data and others. The heading 'others' contains institutional texts relating to individual US states and EU countries which produced a particular piece of documentation standing out as especially important, as well as institutional texts coming from other nations which also have a distinctive relevance. To understand the specific features of each subgroup of the databank, it is important to clarify the mechanisms of governance of the EU and the US, and how they relate to international regulation.

EU data bank

The European Union has a unique system of governance. It is not a federal state like the U.S. because its member countries remain independent sovereign nations. It is not a purely intergovernmental organisation like the United Nations either, because it can produce joint decisions of member countries pooling some of their sovereignty together. They do so through shared institutions like the European Parliament which is elected by the EU citizens, or the Council of the European Union which represents national governments.

The three main decision-making institutions of the European Union are:

1. The **European Parliament**. It represents the citizens of the EU and is directly elected by them. Elections are held every five years, and every EU citizen is entitled to vote and to stand as a candidate, wherever they live in the EU. Parliament has 785 members from all 27 EU countries (in 2008). Members of the European Parliament (MEPs) do not sit in national blocks, but in EU-wide political groups, which represent all views on political issues and European integration, from the strongly pro-federalist to the openly Eurosceptic.
2. The **Council of the European Union**. It represents the individual member states. It is composed of twenty-seven national ministers (one per state). The ministers change with the topic being discussed. For example, if the topic is the agricultural policy the Council is formed of the twenty-seven national agriculture ministers. The Council does not have a single president in the traditional sense. Each EU country has the presidency in turn for a six-month period. When an EU country has the presidency, it takes charge of the Council agenda and chairs all the meetings during that period of time.
3. The **European Commission**. It represents the interests of the Union as a whole and is independent of national governments. It drafts proposals for new European laws,

which it presents to the European Parliament and the Council. It is also the EU's executive arm and is responsible for implementing the decisions of Parliament and the Council. The Commission operates like a cabinet government, with 27 Commissioners, one Commissioner per member state. Commissioners represent the interests of the EU as a whole, not those of their home state. The term 'Commission' can mean either the college of the 27 Commissioners – each of them appointed by his or her national government – or the larger institution of about 23 000 European civil servants. These are divided into departments called Directorates-General. The European Commission is also the voice of the EU on the international stage, whether in international forums such as the World Trade Organisation or in international negotiations like the Kyoto Protocol to the United Nations Framework Convention on Climate Change. The EC speaks and negotiates on behalf of the EU in areas where the member states have pooled sovereignty. This is done on the basis of agreements reached in advance with the states.

This 'institutional triangle' produces the policies and laws that apply throughout the EU. The rules and procedures for EU decision-making are laid down in the treaties and every European law is based on a specific treaty article. The Treaties are agreed by the presidents and prime ministers of all the EU countries (27 countries in 2008) and then ratified by their parliaments. In principle, it is the Commission that proposes new laws. These proposals must aim to defend the interests of the Union and its citizens, not those of specific countries or industries. Every proposal for a new European law must be based on a specific Treaty article, referred to as the 'legal basis' of the proposal. Then, it is the Parliament and Council that adopt them, and the Commission and the member states then implement them. The Court of Justice is the final arbiter in disputes about European law or when an EU country is not applying an EU law. It has the power to impose penalties and its judgements are binding on the member states and the EU institutions.

A number of other bodies also have key roles in making the EU work. They need to be mentioned to give a complete overview of the institutional framework of the EU.

- The **European Economic and Social Committee.** It represents economic and social players in organised civil society such as employers and employees, trade unions and consumer organisations;
- The **Committee of the Regions.** It represents regional and local authorities;
- The **European Investment Bank.** It finances investment in economic development projects within and outside the EU, and helps small businesses via the European Investment Fund;
- The **European Central Bank.** It is responsible for the European monetary policy;
- The **European Ombudsman.** It investigates complaints about maladministration by EU institutions and bodies;
- The **European Data Protection Supervisor.** It safeguards the privacy of personal data. This is an important element in the governance of the EU. The position of European Data Protection Supervisor (EDPS) was created in 2001. Its responsibilities are to protect personal data processed by the EU institutions, i.e. to make sure that when EU institutions and bodies process personal data about an identifiable person, they respect that person's right to privacy. 'Processing' covers activities such as collecting data, recording and storing them, retrieving them for consultation, sending them or making them available to other people, and also blocking, erasing or destroying them. There are strict privacy rules governing these activities. For example EU institutions and bodies are in general not allowed to process personal data that reveal racial or ethnic origins, political opinions, religious or philosophical beliefs or trade-union membership.

The EU also works with the help of **specialised agencies**. Agencies are not EU institutions, but they are bodies set up by a specific piece of EU legislation to carry out a particular task. My data bank lists the EU agencies which are concerned with nanotechnologies, even if they do not contain the word in their title or in the list of their activities. The complete list of EU specialised agencies is available in the appendix. Here is the list of the EU agencies including nanotechnologies in their activities in 2008.

- **European Agency for Safety and Health at Work** (OSHA). Location: Bilbao, Spain; osha.europa.eu. This agency pools and raises awareness of knowledge and information on health and safety at work, with an emphasis on creating a culture of effective prevention. The agency mentioned in its 2007 annual report that it was working through its European Risk Observatory on compiling existing documentation on potential risks coming from nanotechnologies, particularly in the workplace. It mentioned in particular a report examining skin exposure in the workplace.
- **European Centre for the Development of Vocational Training** (CEDEFOP). Location: Thessaloniki, Greece; cedefop.europa.eu.efop. One of the oldest European agencies, CEDEFOP is the European Agency that promotes the development of vocational education and training (VET) in the European Union. It provides advice, research, analysis, information, and stimulates European cooperation and mutual learning. CEDEFOP works closely with the European Commission, governments, representatives of employers and trade unions, as well as with researchers and practitioners. It provides information and forums for policy debate. CEDEFOP is regularly involved in activities relating to the development of nanotechnologies. It runs workshops and conferences, with a focus on the identification of skill needs in nanotechnology and nanobiotechnology (Abicht, 2006) (http://www2.trainingvillage.gr/etv/publication/download/panorama/5170_en.pdf).
- **European Chemicals Agency.** (ECHA). Location: Helsinki, Finland; ec.europa.eu/echa. The agency manages the technical, scientific and administrative aspects of REACH, the EU registration system for chemicals. Obviously, it deals with nanotechnologies, but interestingly, the word never appears on its website. The website search engine does not have any return for any combination around the term nano-, and the list of keywords it provides does not include any word related to

nanotechnologies. One of the sectors of activities of ECHA is to deal with 'substances of very high concern'. The organisation produces a candidate list of substances that have been identified as Substances of Very High Concern (SVHC). These substances may have very serious and often irreversible effects on humans and the environment and the website states that they may subsequently become subject to authorisation by decision of the European Commission. On 28 October 2008, ECHA produced a list of 18 Substances of Very High Concern, but the list did not contain any reference to nanoparticles, or to increased concern coming from nanometric components of certain chemicals (retrieved from http://echa.europa.eu/chem_data/candidate_list_table_en.asp, 05 November 2008).

On 07 November 2008, ECHA published an updated intermediate list of pre-registered substances. The list contained over 50,000 substances which had to be pre-registered by the deadline of 1 December 2008 to meet the REACH deadline of registration of chemical substances. The purpose of the intermediate list was to gradually implement the process of Downstream Use of chemicals within the REACH framework. Out of the 50,000 substances, 98 contained the term 'nano' in their denomination.

- **European Defence Agency (EDA).** Location: Brussels, Belgium; eda.europa.eu. The EDA helps promote coherence in Europe's defence and security capabilities, including in armaments and equipment, research and operations. European governments agreed in May 2008 to establish a joint investment program for research into emerging technologies which might have a disruptive effect on the battlefield. This was the second such program and it had a lifetime of two years. Eleven European countries contributed to this initiative, which was funded by a common budget of €15.58 million[4]. Among the 4 Research and Technology (R&T) goals which were identified for joint research was one which was specifically on nanotechnologies

[4] The eleven contributing members were in November 2008: Cyprus, France, Germany, Greece, Hungary, Italy, Norway, Poland, Slovakia, Slovenia, Spain.

(applied to armour and intelligent clothing); but the other 3 goals of the research program contained areas of research which also related to nanotechnologies, for instance in health monitoring or integrated navigation architecture.

- **European Environment Agency** (EEA). Location: Copenhagen, Denmark; eea.europa.eu. The EEA has a double mandate: to help the Community and member countries make informed decisions about improving the environment, integrating environmental considerations into economic policies and moving towards sustainability, and to coordinate the European environment information and observation network. In other words, it provides policymakers and the public with information to help promote sustainable development and improvements in Europe's environment. The EEA came into force in 1993 and, with 169 staff, is one of the large European Agencies. Among its various activities, it has recently developed an interest in the development of nanotechnologies. The focus is on the exploration of 'nanotechnology solutions for a sustainable future'.
- **European Food Safety Authority** (EFSA). Location: Parma, Italy; efsa.europa.eu. The European Food Safety Authority (EFSA) considers itself as the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides scientific advice and communication on existing and emerging risks. Its most recent involvement in nanotechnology issues is the launch of a public consultation on nanotechnologies and food and feed safety in October 2008. The draft opinion focuses on engineered nano materials that could be deliberately introduced into the food chain and elaborates on approaches to risk assessment in this field.
- **European Medicines Agency** (EMEA). Location: London, United Kingdom; emea.europa.eu. The EMEA advises the European Commission when human and veterinary medicines are ready to be put on the EU market. It monitors adverse effects, and provides scientific advice. Currently, there are no specific guidance

documents on nanomedicinal products. In order to assist applicants developing nanomedicinal products, the EMEA has established a dedicated 'nano group' within its Innovation Task Force (ITF). Its goal is to interact with potential applicants developing nanomedicinal products to discuss informally about bottlenecks in the development of nanomedicinal products, and to explore possible scientific and regulatory solutions.

US data bank

The US system of governance has grown much more organically than the EU one, simply because the EU was an ad hoc structure created as recently as 1952 when the Treaty establishing the European Coal and Steel Community (ECSC), the ancestor of the EU, came into force, whereas the US was an accretion of territories which gradually merged into a nation over a period of nearly two centuries, from 1607, the first successful English settlement in Jamestown, Virginia, to 1959 when Hawaii became the 50th state of the US. As a result, the US system of governance is much more complex than the EU one, and it clearly lacks integration. The federal government of the United States is the centralised United States governmental body established by the Constitution. It has three branches: the legislative, executive, and judicial, which work through a system of “checks and balances”, where each of the branches has some authority to act on its own, some authority to regulate the other two branches, and has some of its own authority, in turn, regulated by the other branches. In addition, the powers of the federal government as a whole are limited by the Constitution, which leaves a great deal of authority to the individual states.

The US also has independent agencies. Most of them are part of the executive branch although a few are part of the legislative branch under Congress (like the Government Accountability Office, formerly called the General Accounting Office; the Library of Congress; the Congressional Research Service or the Government Printing Office). Independent agencies are not part of a specific executive or legislative department. They have been established through separate statutes passed by the U.S. Congress. Each respective statutory grant of authority defines the goals the agencies must work towards, as well as the areas of their rulemaking power. While the agencies are in force, their rules or regulations have the power of federal law. The nature and purpose of independent agencies vary widely. Some are regulatory groups with powers to supervise certain sectors of the economy. Others provide special services either to the government or to the people. In 1970, for example, Congress established the United States Environmental Protection Agency (EPA) to coordinate governmental action to protect the environment. The list of the major US independent agencies (2008 data) can be found in the appendix. Here is the list of the major US independent agencies covering nanotechnology issues:

- The United States **Environmental Protection Agency** (EPA) works with state and local governments throughout the United States to control and reduce pollution in the air and water and to deal with problems related to solid waste, pesticides, radiation, and toxic substances. EPA sets and enforces standards for air and water quality, evaluates the impact of pesticides and chemical substances, and manages a program for cleaning toxic waste sites. As EPA's mission is to protect human health and the environment, it considers that understanding the consequences of nanomaterials and how they may impact human health and ecosystems is of critical importance to the Agency. EPA's Office of Research and Development has launched a Nanomaterial Research Strategy to guide nanomaterial research. It aims to address data needs for risk assessment and management and it has identified four key research themes: Sources, fate, transport, and exposure; Human health and ecological research to inform risk assessment and test methods; Risk assessment methods and case studies; Preventing and mitigating risks. Generally speaking EPA acts as an observatory of the development of nanotechnologies.
- The **National Aeronautics and Space Administration** (NASA) was established in 1958 to run the U.S. space program. It placed the first American satellites and astronauts in orbit, and it launched the Apollo spacecraft that landed men on the

moon in 1969. Today, NASA conducts research aboard earth-orbiting satellites and interplanetary probes, explores new concepts in advanced aerospace technology, and operates the U.S. fleet of manned space shuttle orbiters. Its research programs include nanotechnologies, and it has a centre especially devoted to nanotechnology research: the Ames Research Center. The centre has about 55 scientists working on the development of novel concepts in nanotechnology for NASA's future needs in electronics, computing, sensors, and advanced miniaturization of all systems.

- The **National Science Foundation** (NSF) supports basic research and education in science and engineering in the United States through grants, contracts, and other agreements awarded to universities, colleges, and non-profit and small business institutions. The NSF encourages cooperation among universities, industry, and government, and it promotes international cooperation through science and engineering. With a yearly budget of nearly 400 million dollars earmarked for nanotechnologies (2008 figure) it is a major channel of funds for nanotechnology research under the coordination of the National Nanotechnology Initiative.
- The **United States Agency for International Development** (USAID) administers U.S. foreign economic and humanitarian assistance programs in the developing world, as well as in Central and Eastern Europe and the New Independent States of the former Soviet Union. The agency supports programs in four areas — population and health, broad-based economic growth, environment, and democracy. Since 2001, it has showed an interest for nanotechnologies as a source of innovative solutions for both development and sustainable agriculture. It has sponsored several types of activities like workshops or the writing of reports to explore the potential of nanotechnologies for agriculture and natural resources management (USAID, 2005).
- The **United States International Trade Commission** (USITC) provides trade expertise to both the legislative and executive branches of government, determines the impact of imports on U.S. industries, and directs actions against certain unfair trade practices, such as patent, trademark, and copyright infringement. Its interest in

nanotechnologies relates to issues of intellectual property and protection of innovation and competitive advantage. See for example (USITC, 2007).

Texts of reference

In this part, I list the 'texts' which shape the emergence of nanotechnologies, in the US and the EU. I add a small section for texts coming under the heading 'others' which correspond to either texts of international bearing or texts coming from other sources than the EU or the US but which have a strong impact on the emergence of the field. I call 'texts' all the official public documents – i.e. coming from public institutions – which participate in the institutionalisation of nanotechnologies. These may be legislative documents (statutes, laws, rulings…) as well as reports, hearings, speeches etc. Scores of documents have been published by the major European and American institutions dealing with nanotechnologies in the last twenty years, but not all of them have a function in the institutional emergence of the field. To be included in my list, they must meet the following criteria:

- Be in the public domain *and*
- Have a regulatory function *or*
- Have a strong impact on the shaping of the emergence of nanotechnologies

In the US, federal regulation is gathered in the *United States Code (*Government Printing Office*)*, the register of all US Federal regulation. The United States Code is the codification by subject matter of the general and permanent laws of the United States. It is divided by broad subjects into 50 titles and published by the Office of the Law Revision Counsel (LRC) of the U.S. House of Representatives. Since 1926, the United States Code has been published every six years. In between editions, annual cumulative supplements are published in order to present the most current information. The electronic version may be as much as 18 months behind current legislation, but it is the most up to date official version. Because of the codification approach, a single named statute may appear in different places in the Code. For example, a bill providing relief for family farms might affect items in Title 7 (Agriculture), Title 26 (Tax), and Title 43 (Public Lands). When the bill is codified, its various provisions might well be placed in different parts of those various Titles. Traces of this process are generally found in the Notes accompanying the 'lead section' associated with the popular name, and in cross-reference tables that identify Code sections corresponding to particular Acts of Congress.

US Federal Laws.
Source: United States Code, 2008

- General provisions
- The Congress
- The President
- Flag and seal, seat of government, and the states
- Government organisation and employees
- Domestic security
- Agriculture
- Aliens and nationality
- Arbitration
- Armed forces
- Bankruptcy
- Bank and banking
- Census
- Coast guard
- Commerce and trade
- Conservation
- Copyrights
- Crime and criminal procedure
- Customs duties
- Education
- Food and drugs
- Foreign relations and intercourse
- Highways
- Hospitals and asylums
- Indians
- Internal revenue code
- Intoxicating liquors
- Judiciary and judicial procedure
- Labour
- Mineral lands and mining
- Money and finance
- National guard
- Navigation and navigable waters
- Patents
- Patriotic and national observances, ceremonies & organisations
- Pay and allowances of the uniformed services
- Veterans' benefits
- Postal service
- Public buildings, property and works
- Public contracts
- The public health and welfare
- Public lands
- Public printing and documents
- Railroads
- Shipping
- Telegraphs, telephones and radiotelegraphs
- Territories and insular possessions
- Transportation
- War and national defence

Fig 10

A reading of the table above (Fig 10) indicates how complex this system is. The overlapping areas are numerous. It also shows the difference of foci from the EU approach (Fig 11). In Europe, community regulation is gathered in the *Directory of Community Legislation* (European Communities). It includes 20 chapters with divisions into further sub-sections as necessary.

EU Community laws.

Source: Directory of Community legislation, 2008

- General, financial and institutional matters
- Customs Union and free movement of goods
- Agriculture
- Fisheries
- Freedom of movement for workers and social policy
- Right of establishment and freedom to provide services
- Transport policy
- Competition policy
- Taxation
- Economic and monetary policy and free movement of capital
- External relations
- Energy
- Industrial policy and internal market
- Regional policy and coordination of structural instruments
- Environment, consumers and health protection
- Science, information, education and culture
- Law relating to undertakings
- Common foreign and security policy
- Area of freedom, security and justice
- People's Europe

Fig 11

US federal laws, like EU community laws, constitute the minimum requirement which must be respected by all the parties (the states in the US, and the various EU members in the EU). This means that individual states in the US, and individual EU members in the EU *may* have additional regulations if they wish, but *must* comply with the existing regulation. In the EU, the acceding member states (in 2008, the EU consisted of 27 Member states) have the obligation to fully and correctly transpose and implement the 'acquis communautaire' by the date of accession so as to guarantee equivalent rights and obligations to all citizens of the enlarged European Union. The 'acquis communautaire' amounts to some 1,600 directives. As from the date of accession the acceding countries are monitored in the same way as the previous Member States and a regular publication reports the monitoring and compliance issues (European Commission, 2004b). Eur-Lex, the portal to European Union law (http://europa.eu.int/eur-lex/en/index.html) also provides studies and statistics concerning the application of community law in member states. In the US, individual states must follow Federal regulation more or less in the same way, and on the whole, both systems work in a fairly similar manner.

At the end of 2008, there were five texts relating to nanotechnology published in the *United States Code*. They all appeared in Title 15, 'Commerce and Trade', under three headings:

- Title 15, 7501. 'National Nanotechnology Program' and 'Triennial external review of the National Nanotechnology Program'.
- Title 15, Chapter 101. 'Nanotechnology research and development'

The *Directory of Community Legislation* counted four texts relating to nanotechnologies.

- Opinion of the European Economic and Social Committee on the 'Communication from the Commission: Towards a European strategy for nanotechnology'(COM(2004) 338 final)
- Communication from the Commission - Towards a European strategy for nanotechnology (COM/2004/0338 final)
- Written question P-2248/03 by Caroline Lucas (Verts/ALE) to the Commission. ***Official Journal C 051 E , 26/02/2004 P. 0231 - 0231***
- Commission Recommendation of 7 February 2008 on a code of conduct for responsible nanosciences and nanotechnologies research (notified under document number C(2008) 424).

My lists of texts of references (Fig 12, 13, 14) include these, of course, but they also gather other documents which participate in the institutional emergence of nanotechnologies. Some of these texts do not mention nanotechnologies either in their title or even in their lists of contents, and yet they all have a direct bearing on the emergence of the field.

US REGULATION					
DATE	TITLE	ABBREVIATION/ REFERENCE CODE	FROM	URL	COMMENTS
13/02/2008	Strategy for nanotechnology-related environmental health and safety research		National Science and Technology Council (NSTC), Subcommittee on Nanoscale Science, Engineering and Technology (NSET), Committee on Technology (CT)	http://www.nano.gov/NNI_EHS_Research_Strategy.pdf	A road map of **Environnemental, Health and Safety research orientations**, when they relate to nano
24/01/2008	Nanomaterial Research Strategy (NRS) Draft	EPA 600/S-08/002 Document ID: EPA-HQ-ORD-2008-0114-0002	EPA	http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=09000064803af39f	docked as 'draft nanomaterials research strategy, non rulemaking'.
23/01/2008	Toxic Substances Control Act (TSCA) Inventory Status of Nanoscale Substances – General Approach		EPA	http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf	a document defining nanoscale substances - inventory not available freely online
21/09/2007	Pesticide Registration; Clarification for Ion-Generating Equipment	Federal Register: September 21, 2007 (Volume 72, Number 183)] [Page 54039-54041] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr21se07-91] [EPA-HQ-OPP-2007-0949; FRL-8149-4]	EPA	http://www.epa.gov/fedrgstr/EPA-PEST/2007/September/Day-21/p18591.htm	Nearly a year after EPA reversed itself on whether the Samsung SILVERWASH ™ washing machine was regulated as a pesticide under FIFRA, the clarification sets forth EPA's position that machines that produce silver ions for pesticidal purposes are "pesticides" subject to registration under FIFRA, and not "devices". Therefore they are not addressed as nanomaterials.
16/08/2007	Prioritization of environmental, health and safety research needs for engineered nanoscale materials - an interim document for public comment		National Science and Technology Council (NSTC), subcommittee on Nanoscale Science, Engineering, and Technology (NSET), Nanotechnology Environmental and Health Implications Working Group, Committee on Technology (CT)	http://www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf	an exploration of Environmental, Health and Safety (EHS) issues relating to the development of nanotechnologies
12/07/2007	NMSP: Nanoscale Materials Stewardship Program and Inventory Status of Nanoscale Substances under the Toxic Substances Control Act; Notice of Availability	Federal Register: July 12, 2007 (Volume 72, Number 133)] [Page 38083-38085] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr12jy07-60] [EPA-HQ-OPPT-2004-0122; FRL-8139-2]	EPA	http://www.epa.gov/fedrgstr/EPA-TOX/2007/July/Day-12/t13558.htm	Voluntary reporting Scheme. Comments received until September 2007
March 2007	Nanotechnology: The Future is Coming Sooner Than You Think		Joint Economic Committee United States Congress	http://www.house.gov/jec/publications/110/nanotechnology_03-22-07.pdf	a document reviewing government nanotechnology policy
February 2007	US Environmental Protection Agency Nanotechnology White Paper	EPA 100/B-07/001	Prepared for the U.S. Environmental Protection Agency by members of the Nanotechnology Workgroup, a group of EPA's Science Policy Council	http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf	A report discussing describing key science issues EPA should consider to ensure that society accrues the benefits to environmental protection that nanotechnology may offer, as well as to better understand potential risks from exposure to nanomaterials in the environment. 'This document does not and should not be construed to create any legal rights or requirements' (quoted from first page)
28/11/06	Approaches to safe nanotechnology: an information exchange with NIOSH		NIOSH (National Institute for Occupational Safety and Health)	http://www.cdc.gov/niosh/topics/nanotech/safenano/pdfs/approaches_to_safe_nanotechnology_28november2006_updated.pdf	Draft for comments
3/12/03	Nanotechnology: Societal implications - Maximizing benefits for humanity		Prepared for the National Science and Technology Council (NSTC), Subcommittee on Nanoscale Science, Engineering and Technology (NSET) by the National Science Foundation	http://www.nano.gov/nni_societal_implications.pdf	Report of a workshop exploring potential societal impacts of nanotechnology and identifying key areas for related research
18/11/2003	21st Century Nanotechnology Research and Development Act	S 189	US Congress	http://www.govtrack.us/data/us/bills.text/108/s189.pdf	An act
March 2001	Societal implications of nanotechnology		Prepared for the National Science and Technology Council (NSTC), Subcommittee on Nanoscale Science, Engineering and Technology (NSET) by the National Science Foundation	http://www.wtec.org/loyola/nano/NSET.Societal.Implications/nanosi.pdf	A report outlining societal issues
21/01/2000	National Nanotechnology Initiative: Leading to the next industrial revolution		The White House, Office of the Press secretary	http://clinton4.nara.gov/WH/New/html/20000121_4.html	a document with performative value, as the statement, by being proferred, initiates the NNI
1976, revised several times since	TSCA (Toxic Substances Control Act)		EPA		Not available freely online. Exemptions for up to ten tons a year, and products with low environmental impact: Code of Federal Regulations, Title 40, Ch 1, part 723.5 http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2820e18ba272a3e29bab5c83935bc661&rgn=div5&view=text&node=40:30.0.1.1.11&idno=40#40:30.0.1.1.11.2.1.1
1970, amended several times since	Occupational Safety and Health Act (OSHAct)		Department of Labour, Department of Health and Human Services (formerly Health, Education and Welfare		the basis of legislation framing the development of nanotechnologies in the workplace

Fig 12

EU REGULATION					
DATE	TITLE	ABBREVIATION	FROM	URL	COMMENTS
17/06/2008	Regulatory aspects of nanomaterials	COM(2008) 366 final	COMMISSION OF THE EUROPEAN COMMUNITIES	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF	Outline of all EU regulation under which nanotechnologies may fall
07/02/2008	Commission recommendation on a code of conduct for responsible nanosciences and nanotechnologies research	C 2008 424 (final)	COMMISSION OF THE EUROPEAN COMMUNITIES	ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanocode-recommendation-pe0894c08424_en.pdf	A voluntary code aiming to 'facilitate and underpin the regulatory and non-regulatory approaches outlined in the 2005-2009 N&N Action Plan for Europe'. Also aims to serve as a European basis for dialogue with third countries and international organisations.
30/06/2007	Council resolution on a new Community strategy on health and safety at work (2007-2012)	2007/C 145/01	EUROPEAN COMMISSION	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2007:145:0001:0004:EN:PDF	A report on health and safety issues
06/09/2007	Nanosciences and Nanotechnologies: an action plan for Europe 2005-2009. First Implementation Report 2005-2007	COM 2007 (505) final	EUROPEAN COMMISSION	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0505:FIN:EN:PDF	An update of the Outline of European strategy for the development of nanotechnologies
18/12/2006	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency,amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC	EC 1907/2006	EUROPEAN PARLIAMENT AND COUNCIL OF THE EUROPEAN UNION	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF	The European piece of regulation for chemicals. Out of 849 pages, not one reference to nanoparticles, nanoscience or nanotechnologies, although most nanoparticles come under its jurisdiction.
08/08/2006	Opinion of the European Economic and Social Committee on the Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee — Nanosciences and nanotechnologies: An action plan for Europe 2005-2009	2006/C 185/01	ECOSOC	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:185:0001:0009:EN:PDF	Outlining European strategy for the development of nanotechnologies
28/06/2005	Opinion of the European Economic and Social Committee on the 'Communication from the Commission: Towards a European strategy for nanotechnology'	2005/C 157/03	ECOSOC	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2005:157:0022:0033:EN:PDF	Comments on the report outlining European strategy for the development of nanotechnologies
07/06/2005	Nanosciences and Nanotechnologies: an action plan for Europe 2005-2009.	COM 2005 (243) final	EUROPEAN COMMISSION	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0243:FIN:EN:PDF	A Road map for the European development of nanotechnologies
12/05/2004	Towards a European Strategy for Nanotechnology	COM 2004 (338) final	EUROPEAN COMMISSION	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0338:FIN:EN:PDF	Devising a European strategy for the development of nanotechnologies
26/02/2004	WRITTEN QUESTION P-2248/03 by Caroline Lucas (Verts/ALE) to the Commission	Official Journal C 051 E; P. 0231 - 0231	Caroline Lucas, question asked on 1st July 2003	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:92003E2248:EN:HTML	One question concerning the environmental impact of nanotechnologies, included in the Directory of Community Legislation
24/10/1995	Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data	Directive 95/46/EC. Official Journal L 281 , 23/11/1995 P. 0031 - 0050	EUROPEAN PARLIAMENT AND COUNCIL OF THE EUROPEAN UNION	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML	Although this text does not mention the term 'nanotechnology', it constitutes the legislative framework that regulates the development of nano-devices allowing the processing of personal data and the free movement of such data. It integrates the work of the ANNA (European Integrated Activity of Excellence and Networking for Nano and Micro-Electronics Analysis) set up in 2007

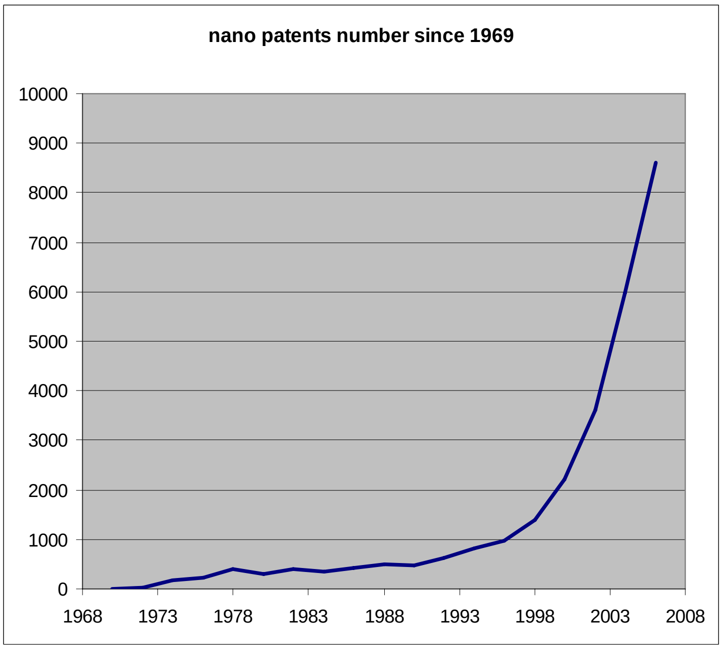
Fig 13

OTHERS				
DATE	TITLE	FROM	URL	COMMENTS
30/09/2008	1. ISO/TS 27687:2008 2. ISO/TR 12885:2008	International Organization for Standardization (ISO)	http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=52093	First international standards (ISO) for the development of nanotechnologies, one to define nano-objects, one to frame health and safety practices in occupational settings relevant to nanotechnologies
03/01/2008	Nanotechnology recent developments, risks and opportunities	Lloyds . (Lloyds' emerging risks team)	http://www.lloyds.com/NR/rdonlyres/7C1D8222-A3E8-4781-8C80-7FFABFC3F59E/0/Nanotechnology_Report.pdf	First comprehensive and critical analysis of the implications of nano-scale technologies in terms of emerging risks for financial investments
June 2007	Nano Risk Framework	Environmental Defense and DuPont	http://www.edf.org/documents/6496_Nano%20Risk%20Framework.pdf	First partnership between business and civil society to frame the developement of nanotechnologies
01/04/2005	list of seven national standards for nanomaterial	Standardization Administration of PR China	http://english.peopledaily.com.cn/200503/02/eng20050302_175299.html	First national standards for nano material in the world
29/07/2004	Nanoscience and nanotechnologies: Opportunities and uncertainties	Royal Society and Royal Academy of Engineering	http://www.nanotec.org.uk/finalReport.htm	First comprehensive and critical analysis of the implications of nano-scale technologies by scientists
May 2004	Nanotechnology: Small matter, many unknowns	Swiss Re	http://www.swissre.com/INTERNET/pwsfilpr.nsf/vwFilebyIDKEYLu/ULUR-5YNGET/$FILE/Publ04_Nanotech_en.pdf	First comprehensive and critical analysis of the implications of nano-scale technologies by the insurance sector
January 2003	The Big Down: from Genomes to Atoms - Technologies converging at the nano-scale	ETC Group	http://www.etcgroup.org/upload/publication/171/01/thebigdown.pdf	First comprehensive and critical analysis of the implications of nano-scale technologies by civil society

Fig 14

Patents

A third step of the archival data collection has been to compile nanotechnology patent data. To do so, I have used Delphion services, as well as Nanobank. Nanobank is a project funded by the US National Science Foundation (Grant SES-0304727). This project uses econometric methods to estimate the impact of nanoscale science and technology (NST) research as well as associated interdisciplinary research. The patent data collection covers the years 1970 to 2006. As with written papers, it was very easy to track the patents during the first few years, as the number of yearly patent grants did not exceed a few hundred. However, it became impossible to keep track of individual patents after 1990, as there were more than 500 patents granted, and very rapidly more than thousands (Fig 15).



1970	1
1972	34
1974	164
1976	234
1978	392
1980	288
1982	386
1984	351
1986	418
1988	486
1990	477
1992	613
1994	809
1996	961
1998	1385
2000	2218
2002	3597
2004	5979
2006	8597

Fig 15. Source of data: Delphion, patents number worldwide, compilation by author

To collect patent data, I have used EU, US and WIPO PCT (World Intellectual Property Organization – Patent Cooperation Treaty) *granted* patents, by slices of two years. As the chart above shows, after 1990, there were above 500 patents granted, which made it impossible to track them individually. So I used the Delphion relevancy scoring. The relevancy scoring is based on algorithms built into Delphion search engine which factor in the density of the search terms found in the document. Density is calculated in proportion to overall document text as well as proximity operators i.e. the nearness of terms within the document. Thanks to the relevancy scoring, I get representative samples of 500 patents, which remain manageable.

Interviews and field notes

Finally, I have constituted archives relating to each of the stakeholder groups which I postulate are the key institutional entrepreneurs in the institutional emergence of nanotechnologies: entrepreneurs, scientists, commentators, policy makers and end users. To do so, I have used interviews and field notes to extend information coming from written documents and internet searches. I have conducted 37 focused interviews (Wengraf, 2001, Kvale, 1996). Interviewees were representative of the five groups of stakeholders and interviews were conducted in very different settings and circumstances. 58% were conducted in the E.U (France, the UK and Belgium), 34% were conducted in the U.S., and the rest took place in Canada and over the phone. My research question was the common quest underpinned each meeting but the interviews were tailor-made to suit the individual specificities of each interviewee. In general, the interviews contained two parts: a structured part destined to collect specific data pertaining to the field of the interviewee and a non-structured informal part to determine his or her perceptions of various aspects of the development of nanotechnologies in his or her own field. Data collection was mainly in the form of notes and recordings of the interviews. After the interviews all the conversations were critically analysed in the light of the literature review (Rubin and Rubin, 1995). To select the interviewees, I built on archival research to identify the most relevant representatives of each stakeholder group and approached them for interviews. I also used snowball sampling in order to broaden my panel of interviewees (Patton, 1990). Finally, I also used what I call 'chance meetings', as I consider allowing space for fortuitousness an essential component of research.

The history of scientific discoveries is replete with instances of breakthroughs due to chance events. A well-known one is that of Penicillin. In 1928 The Scottish bacteriologist Alexander Fleming had left a pile of dirty Petri dishes in his lab while he went on holiday with his family. On his return, he found that one of the dishes was dotted with bacterial growth, apart from one area where a patch of mould was growing. The mould produced a substance which inhibited bacterial growth. This substance was what he named penicillin. It was later found to be effective against a wide range of harmful bacteria… and led to the manufacturing of antibiotics.

In the field of nanotechnologies, one of the major breakthroughs also happened by chance. Michael A. Duncan, Franklin professor of chemistry at the University of Georgia in the U.S. explained that he worked at Rice University with Professor Richard Smalley as a graduate student in 1982. At that time lasers had been around for a while but they were not usually used in the study of nanoparticles. Michael Duncan and a fellow graduate student were working on a molecular beam experiment when they accidentally misaligned the laser and vaporized part of the apparatus. Checking the damage, they realized they had found a way to produce metallic compounds, large regular molecules which are also called metal clusters and mostly exist for milliseconds. So what began as a lab accident led to an entirely new idea: shooting laser beams at metals and then studying the gaseous metal clusters that were blasted off. The Smalley group at Rice later used the same equipment and repeated the experiments on carbon and discovered a form of the element called carbon-60. Shaped in panels like the geodesic dome invented by architect Buckminster Fuller, the C60 forms were named “buckeyballs,” and the team that discovered them was awarded the Nobel Prize for Chemistry in 1996.

In both examples, the decisive moment brought about by chance would not have led to anything if some components of the context had not been there. More recently, in 2007, Danish researchers also discovered fortuitously a new nanostructure with a lot of potential for energy solutions in solar cells: nano flakes. And again, it was because the persons in charge were able to understand that something important had happened that the chance event could turn into a discovery. If a cleaning lady had found the dishes in Flemming’s lab, she would simply have thrown them away or washed them with a sigh at his untidiness, without thinking more about it. If the two students in Smalley's lab had not been able to check what they had done with a mass spectrometer, they would not have been able to understand the possibilities they had sparked. However, it was indeed because of a chance event that there could be a step forward in science.

I therefore argue that it is important to leave space for the unexpected when attempting to construct a theory. There has been an emphasis in recent years on leaving as little space as possible to chance in scientific research. This can be seen in the growing emphasis on quantitative analysis as well as in the development of quantitative approaches of qualitative analyses – like discourse analysis software for example. These developments allow forms of research that could not be done otherwise, and they are an essential component of the progress of scientific research in general. Yet concentrating exclusively on pre-determined quantitative sets of data and shunning the unexpected as a distraction from the main pursuit of results may lead to miss important points. Even though research which steers clear of the unexpected may appear more focused, it risks becoming too process-focused to allow for innovative diagnoses. So I argue that it is important to leave a part to chance in the data collection in order to allow for the possibility of unexpected findings. I tried to do this by giving unplanned interviews to people I met in the course of the study who related to the topic in one way or the other, but whom I had not anticipated to meet. Although I was not too sure of their contribution, I wanted to record it to be in a position to add new perspectives to my findings.

Field notes of conferences or workshops also cover a period of four years. I attended 16 conferences and workshops relating directly to some aspects of the development of nanotechnologies. Each of these events allowed me to gather field notes of an average of six presentations which were of particular relevance, giving me access to a total of 72 sets of data. The conferences and workshops took place in the EU and the US. Again, the foci of the presentations which I considered particularly relevant to my research concerned the five groups of stakeholders mentioned in the introduction.

Data analysis and design

Drawing from these sources of data, my aim is to provide a conceptual frame of nanotechnology institutional emergence, showing how the emergence of the technological field relates to the emergence of the institutional field. To do so, I have articulated my research around the intersection of two transversal themes with my units of analysis. The units of analysis are the five groups of stakeholders previously mentioned: entrepreneurs, commentators, scientists, policy makers, end users. The two transversal themes are entrepreneurship and institutional entrepreneurship. The rest of this study is an account of the cases which I have built to illustrate emblematic trends situated at the cross-sections of the units of analysis and of the transversal themes. The first one explores nanotechnology entrepreneurship through the analysis of a few selected indicators. The second one relates nanotechnology entrepreneurship to regulatory practices. The third one studies institutional entrepreneurship through the lens of the particular role played by a civil society group. The fourth one focuses on new dynamics in risk management as an illustration of institutional change. It is the synthesis of these four cases which allows me to draw my conclusions concerning the co-industrial and institutional emergence of nanotechnology.

Data analysis has been different according to the different cases, and I expand on the methodology I used in each of the corresponding chapters. I have used my databases differently depending on the chapters. In chapter 4, Indicators of nanotechnology entrepreneurship, I drew mostly from two sections: my institutional data bank and patents. In chapter 5, entrepreneurship and regulatory practices, I used the same data sources, but added another data base: texts of references. In chapter 6, I drew mostly from the data bases of field notes and interviews, as well as texts of references. The data of Chapter 7 also came mostly from interviews and texts of references. In all these cases, I crossed the information I obtained from archival sources with focused interviews and field notes. I had made transcripts of most of the interviews I conducted, and summaries of the other ones, with transcripts of the parts I considered particularly relevant. Consistent with the constructivist approaches, I examined all these texts both from the insider perspective and, in line with structuration theory, in relation to other data I had gathered. I did not 'code' data strictly along the lines of the traditional grounded approach, but used computer capacity to create sub files containing all the data pertaining to what I had identified as recurring patterns. To identify these 'recurring patterns', I started from a holistic approach usually coming from key ideas mentioned by interviewees, or from the executive summaries of official documents, and then I sought confirmation of what I intended to discuss with the use of word searches as well as relevance scores. I validated my findings by interview follow ups whenever possible. Theory building rested on a personal interpretation of the empirical cases and again, each chapter has a slightly different approach according to the data sources and the desired outcome. Chapters 5 and 6 rely less on the strength of interviews because of the importance of official data, and it is the reverse in chapters 7 and 8. Traditional metrics could not apply in such a constructivist analysis, and even indicators of structures such as recurrence could not give a full account of the hierarchy of concepts. So whenever possible, I used a triangulation method and examined the same phenomenon from multiple perspectives to reach my conclusions (Jick (1979), Glaser and Strauss (1967)).

SOME INDICATORS OF NANOTECHNOLOGY ENTREPRENEURSHIP

Introduction

As a first step in the study of the emergence of the nanotechnology field, this chapter provides a snapshot of salient features of nanotechnology entrepreneurship until 2008. It will serve in later chapters to explore connections with institutional emergence and build the main argument of the research: that a key element to understand the relation between the emergence of the nanotechnology field and the creation of new institutions or modification of existing ones is the awareness of the importance of the concept of sustainable development.
I started clarifying my understanding of the term entrepreneurship in the literature review. Since the term entrepreneur was used for the first time in an economic context in 1755, supposedly by Cantillon (1952), the concept of entrepreneurship has attracted a growing amount of literature, a lot of it trying to define what entrepreneurship really is. Schumpeter was the one to introduce in the 1930s the notion that entrepreneurship is the process of carrying out new combinations, which may take the form of new products, processes, markets, organisational forms, or sources of supply.

> "Whatever the type, everyone is an entrepreneur only when he actually carries out new combinations and loses that character as soon as he has built up his business, when he settles down to running it as other people run their business" (Schumpeter, 1934) p. 78.

Entrepreneurship has since been described as occurring when an individual or a group of individuals, in association with an existing organisation, create a new organisation or instigate renewal or innovation within that organisation with the view to generate new businesses (Collins and Moore, 1970, Gartner, 1988, Sharma and Chrisman, 1999, von Hippel, 1977). Building on the work of these scholars, and on Scott Shane's general theory of entrepreneurship (Shane, 2003), I use the classic definition of the word, as *the creation of new products and services out of the identification, evaluation and exploitation of either new resources or the combination of existing ones, in order to make a profit*. Definitions of entrepreneurship vary, tend to apply to more and more forms of human activity, and do not always consider profit making as a discriminating feature. For example, in their exploration of social entrepreneurship (Dorado, 2006, Wei-Skillern et al., 2007), some researchers disconnect profit making from the engine that drives the mobilisation or recombination of resources. I deliberately place myself in an economic context of tangible value creation and my understanding of entrepreneurship is based on the notion of profit seeking. This positioning may be debatable, but it allows me to outline a form of emergence of nanotechnologies which can be clearly defined as it is based on quantifiable values. Besides, nanotechnology is recognised as a promising new growth innovator for the decades to come (Knol, 2004, Paull et al., 2003, Rocco, 2001, ten Wolde, 1998), and the studies reaching these conclusions are all based on the creation of new profit making markets.

Building on the aforementioned definition, I focus on the following form of entrepreneurship: *when organised actors (like university spin outs, start ups) use collaborative relationships with existing institutions (like business angels, institutional funding agencies) to generate new organisations creating future goods and services around the emerging technological field of nanotechnologies*. This definition serves as the frame for my study of nanotechnology entrepreneurship, and it is on this form of entrepreneurship that I build my exploration of institutional emergence around the development of nanotechnologies.

Just as there is a large amount of literature trying to define exactly what entrepreneurship is, the attempts to measure entrepreneurship have led to many projects and theoretical models (Blanchflower and Oswald, 1998, GEM and Bosma et al., 2007, OECD, 1998, OECD and Davis, 2007). Among these, some models account for entrepreneurship by combining R&D expenditure and patent numbers with other variables (Aghion and Howitt, 1997, Darby et al., 2004a, Shane, 2003). In this study, I build on this theoretical approach for several reasons: nanotechnology is an emerging field which is based on technological innovation and whose growth relies heavily on R&D and patents. Besides, nanotechnology entrepreneurship also connects closely to university research, as appears with the importance of university spinoffs and partnerships between business and universities (Institute of Nanotechnology, 2004). Therefore, I base my outline of entrepreneurship as defined above on three indicators: an analysis of nanotechnology R&D funding, a mapping of nanotechnology research centers and infrastructure and finally a study of nano-related patent activity. I conclude the chapter by looking at how these three indicators relate to nano-products reaching the market.

Global outline of nanotechnology R&D

Public and private R&D

Nanotechnology R&D funding started being documented on a systematic basis in the early 1990s. Before that time, although there were programs focusing on atomic manipulation, nanotechnology R&D as such was too small to be significant. In a period of about ten years, the total global investment in nanotechnology R&D, public and private, reached around 15 billion euros in 2006 (sources: Lux research, European Commission and NNI). This amounted to nearly 0.05 percent of the World GDP (Some 32.6 trillion euros in 2006, based on the Gross World Product combined data of the CIA World Factbook, IMF and World Bank). Different sources like the National Science Foundation and the National Nanotechnology Initiative predict that the market for nanotechnology-based products will be worth at least a trillion euros in 2015, the highest prediction being €1.6 trillion for 2015.(Lux Research et al., 2004). Based on a projected annual growth rate of the World Gross Product of about 5 percent in 2006-2007 (World Bank and National Bureau of Economic Research figures), the nanotechnology industry which was still negligible in terms of marketed products in 2000 will then contribute about 3.5 percent of the World Gross Product.

There has been a lot of hype around the projected trillion euro industry, and analysts rate nanotechnology as a very promising sector (MRG Multimedia Research Group Inc and Fuji-Keizei, 2004, Paull et al., 2003, Gillis and Krim, 2004). The simple calculation above shows how promising the sector is indeed. However, it signals something else: the technology is likely to be very disruptive. A sector which – from hardly any marketed outcomes in 2000 – is projected to affect 3.5 percent of the World Gross Product fifteen years later inevitably brings about extremely important changes on its way. The short time period during which this change is due to come about is another new element. (Drexler, 1991) and other scientists have noted the acceleration of the eras which have marked the evolution of mankind, from the agricultural era lasting several thousand years to the industrial era lasting a few hundred years, to what has been called the new industrial revolution, the information age, which has to this date lasted a few decades, and is giving now way to the nanotechnology era.

It is no easy task to obtain accurate data concerning nanotechnology R&D funding, particularly private funding. When assessing R&D funding in general, analysts usually consider that the total amount of public funding is matched by private funding. In nanotechnologies as we will see, there are some important differences between public and private funding of nanotechnology R&D depending on the countries. Public funding of nanotechnology R&D has been monitored on a fairly systematic basis since the early 2000s. Yet, the comparison of the various available data sources reveals important differences, indicating that figures are to be taken more as indications of tendencies than at their face value. With this word of caution in mind, here is a panorama of nanotechnology R&D public funding (Fig 16). The data used in the following analysis comes from the following sources:

CIA World Fact book, European Commission, OECD, International Monetary Fund (IMF) and World Bank.

Global R&D spending in percentage of GDP - 2005

Americas	2,3
Asia	1,8
Europe	1,8
World	2

Source: R&D magazine, Batelle, OECD, World Bank

Chart A

Percentage of the total global R&D in 2005 and 2007

	2005	2007
Americas	37,7	36,8
Asia	34,9	36,5
Europe	24,1	23,2
Other	3,3	3,5
World	100	100

Source: R&D magazine, Batelle, OECD, World Bank

Chart B

Fig 16

The two charts above show that *on the whole* countries spend some 2 percent of their GDP on R&D in general. They also show that globally, Europe lags somewhat behind Asia and the Americas in terms of global R&D funding. In 2007, it contributed less than 25 percent of the overall R&D funding, whereas Asia contributes over a third and the Americas even more, with nearly 40 percent of the world effort.

This permits a comparison with nanotechnology R&D funding as illustrated by the two other charts below. Chart C refines the results of Fig 16, and gives an outline of R&D spending per country in percentage of GDP including all R&D (not only nanotechnology) and combining public and private funding. It does not show a combined entry for EU data.

R&D percentage of GDP - 2005

Israel	4,5
Japan	3,2
South Korea	2,6
U S	2,6
Germany	2,5
France	2,2
Taiwan	2,2
Canada	2,0
Belgium	1,9

Netherlands	1,9
United Kingdom	1,9
Australia	1,7
China	1,4
Ireland	1,1
Italy	1,1

Source: R&D Magazine, Batelle, OECD, World Bank

Chart C Fig 17

Public nano R&D expenditure in percentage of GDP - 2004

Israel	0,066
South Korea	0,042
Taiwan	0,034
Ireland	0,030
Belgium	0,028
Japan	0,027
France	0,018
Germany	0,018
U S (states + fed)	0,018
EU (states + EC)	0,017
Australia	0,016
Netherlands	0,012
United Kingdom	0,010
China	0,007
Canada	0,006
Italy	0,006

source: European Commission, World Bank, IMF

Chart D Fig 18

Chart D gives the same outline but simply for *public* investment in *nanotechnology* R&D (about half the total investment in nanotechnology R&D as was mentioned before). The figures show that this is a very small fraction of R&D in general. As a reminder, we saw that in 2006 nanotechnology R&D (public and private) amounted in total to some 0.05 percent of the world GDP. Again, the charts below give refined data of nanotechnology public R&D funding.

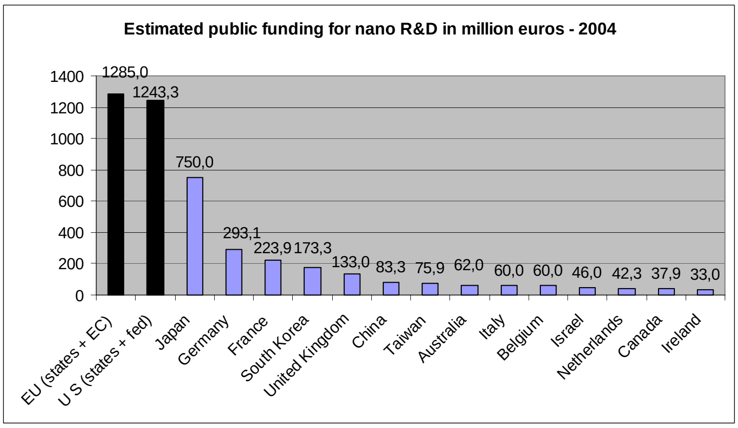


Fig 19
Absolute world public expenditure (not ppp corrected) in million euros in 2004. Source of data: European Commission (European Commission Research DG and Monk, 2005).

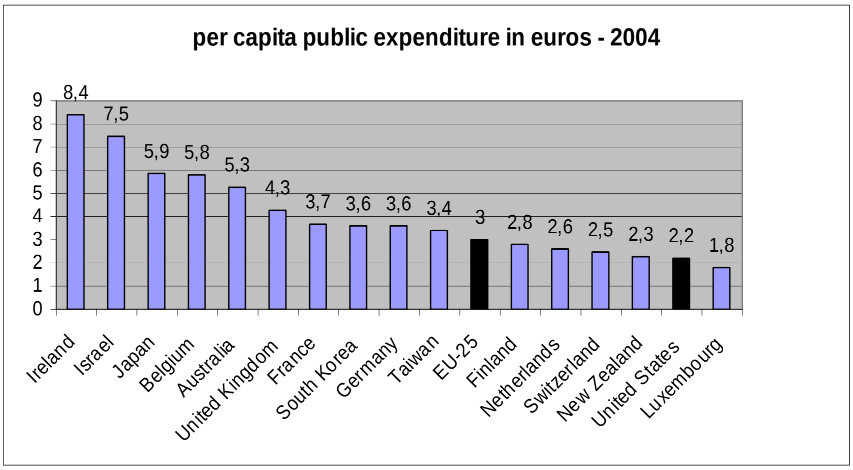


Fig 20
World per capita public expenditure in euros in 2004 (not ppp corrected). Source: European Commission. (European Commission Research DG and Monk, 2005)

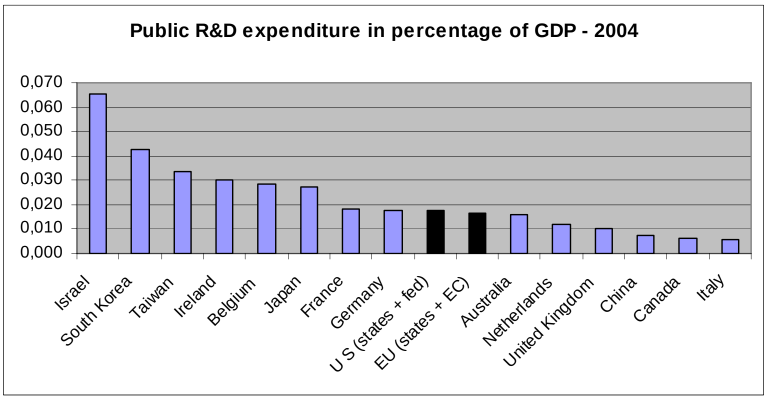


Fig 21. Sources of data: European Commission and Eurostat.

The above charts (Fig 19, 20, 21) show the relative value which different countries place on nanotechnologies. Here again, one must insist on the difficulty to obtain reliable and consistent data, and look at these charts as general indicators of trends. One first comment is that nanotechnologies have mobilised *a very small part* of the world's assets so far. In other words, there is a discrepancy between the hype surrounding the potential of nanotechnologies and the actual sums that have been invested in them. Secondly, and unsurprisingly, countries investing most in nanotechnology public R&D are highly developed countries in terms of new technologies. The charts give interesting information about two rather small countries, Ireland (ranked 120th country in the world in terms of geographical area) and Israel (ranked 152nd).

Ireland's GDP is 32nd in the world and Israel's 45th in the world. Both of these countries have decided to spend a relatively very important share of their GDP on nanotechnology research. Indeed, Israel comes first in terms of national R&D spending (general R&D) with a budget reaching 4.6 percent of GDP in 2004 (source: http://www.nanoisrael.org/player_govt.asp, accessed 07 June 2008) and it also comes top of the list in terms of national public nanotechnology R&D funding as a share of GDP (0.066 percent in 2004, see chart above). The Israel National Nanotechnology Initiative (INNI) was established in 2001. It explained the heavy R&D nanotechnology funding by the fact that Israel was recognised the world over as a leading source of knowledge and innovation in advanced research and technology, particularly in the fields of communications, electronics, computer software, networking, defence, security and life sciences industries. Besides, it stated that Israel's workforce was highly educated, with 20 percent of Israel's working population holding academic degrees. For each 10 000 employees, 140 were scientists or technicians and 135 were engineers, a much better ratio than in the US, Japan or Europe. Israel's academic, business and government leaders recognised nanotech as a key platform for ensuring Israel's continued R&D excellence for decades to come, and the INNI considered that nanotechnology was a natural enabler for Israel, with the small size of the country an advantage because it meant sharper focus, more efficient use of funds, fewer commercial obstacles, rapid prototyping and testing, higher quality standards(source: http://www.nanoisrael.org/player_govt.asp, accessed 07 June 2008). An article from the International Herald Tribune added another explanation for Israel's important participation: the role of Shimon Peres, the incumbent president of Israel since 2007. Simon Peres was born in 1923 and had helped develop Israel's nuclear option around the fifties. He then wanted Israel to invest in nanotechnology because he was convinced that it was key to Israel's economic future. "Nuclear power is destructive but nanotechnology is all about constructing the world anew", Peres said in a telephone interview. "It gives us the opportunity to change everything: to make computers the size of a head of a pin, material hundreds of times stronger than steel, robots the size of a single hair on your head that can travel inside your body and attack cells like those that cause cancer." (Schenker, 2003)

In spite of historical and geographical differences, Ireland's position as regards nanotechnologies is rather similar to that of Israel. Its focus on nanotechnology R&D results from two major factors. Firstly, it had a strong university research network in high tech. This network spawned indigenous start-ups which emerged from university based research groups and these attracted international venture capital as early as the mid nineties. Nanotechnology quickly became a key enabling technology in industrial settings that were very promising: electronics, pharmaceuticals, energy, chemicals and consumer products. Besides, Ireland was in 2004 one of the most competitive economies in the world, with a GDP of 34000 euros per capita, just behind the US. Its attractive tax incentive of 12.5 percent for corporate tax combined with a well-educated skilled workforce attracted strong Foreign Direct Investment (FDI) and a number of multi-national corporations set up their European headquarters in Ireland. Out of 1200 companies based there, 1000 were in the IT sector. Besides, 9 of the top 10 pharmaceutical companies and 13 of the top 20 medical devices companies were located in Ireland. This combination created an environment which was particularly adapted to the pursuit of high tech ventures, and nanotechnology was identified as the key area to support. (Sources: Irish Council for Science, Technology and Innovation ICSTI, and FORFAS)

I mentioned before that it is generally admitted that *on the whole* private funding matches public funding. The following figure shows the share of public and private funding for nanotechnology R&D, and it illustrates some discrepancies.

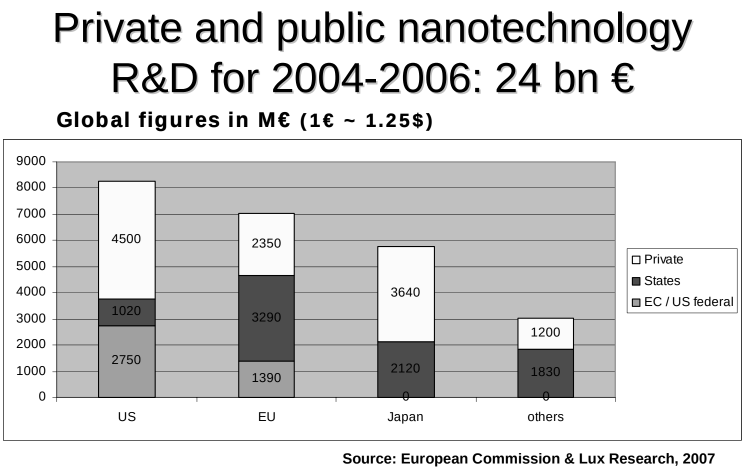


Fig 22

The integration of all public funding (federal and states for the US, EC-wide and states for the EU) shows that public funding tends to be more important in the EU than in the rest of the world (Fig 22 and 23): over the period 2004-2006, public funding amounted to 66.6 percent of nanotechnology R&D funding in the EU, whereas it was 45.6 percent in the US and 36.8 percent in Japan.

Global nanotechnology R&D funding, in million euros, 2004-2006

	Private	Public	percentage public money
JAPAN	3640	2120	36,8
US	4500	3770	45,6
RoW	1200	1830	60,4
EU	2350	4680	66,6

Fig 23

The above chart confirms that while the US has a fair balance between private and public funding, private investment is lagging behind public funding in Europe. This trend is not specific to the development of nanotechnologies, but is part of a general pattern where Europe has a tradition of greater public funding for research in new technologies (European Commission and Hullmann, 2006). According to this report, whether public funding brings better quality of research than private funding is not clear but private funding research tends to have more short term objectives of profitability than public research. The report states that the high level of public funding of nanotechnology research is likely to have a positive impact on European excellence in science and technology, but has not direct correlation with successful technological implementation and the translation into commercially successful products, as these depend on the integration of industry in these projects. A greater share of *private* funding in R&D means greater industrial integration, and this combination is more conducive to entrepreneurship. The European commission also notes in the same report that the importance of public funding in relation to private funding has an additional effect: the share of research into the societal implications of nanotechnologies is more important in Europe than in the US.

This may have important repercussions on the economic development of nanotechnologies, as it is felt that nanotechnologies will be accepted by the general public if they are seen as providers of new solutions, but not of new problems. One great advantage of publicly funded research is that it can steer research politically – notably by the definition of priority areas – to stay in line with public expectations. By influencing the direction of nanotechnology research towards areas such as the safety aspects of nanotechnology, new environmental solutions or new medical devices it can correspond better to societal expectations. Whether this is conducive to positive economic impact is not entirely clear, but it is certainly more likely to avoid potential backlashes due to public rejection of a new technology.

Another important feature of nanotechnology public funding is that the EC, as a body, accounts for only a third of the general EU budget of nanotechnology public R&D funding, whereas the US federal agencies account for about 60 percent of all public nanotechnology R&D funding. This reversed positioning confirms the fact that the EU is still in a phase of integration where nation states have more power than the global entity, whereas the US acts as an integrated body with an overpowering federal power.

Looking now specifically at *public* R&D funding, there is a very important difference between the US and the EU: it is the way the NNI and the European Framework Programs are financed. I will start with the NNI to explain the difference. Twenty-six agencies contributed to the NNI in 2007. However, their participation was not at all evenly shared. Indeed the Department of Defense (DoD) was the major contributor, with 33.5 percent of the overall budget, followed by the National Science Foundation (NSF) with 26.4 percent, the Department of Energy (DoE) with 15.8 percent and the National Institutes of Health (NIH) with 13.2 percent. Together, these agencies accounted for 88.9 percent of the NNI budget.
With the EU, the system is quite different. The EU is an association of independent member states (27 in 2008). This association finances common policies throughout the Union with an agreed budget which is financed directly by member states and which has been set at about 1 percent of the EU's GDP (€116 billion for the year 2007). Within this budget, the funding of research amounts to 5 percent of the total, while the largest single expenditure item on the EU budget is the Common Agricultural Policy (CAP) at around 45 percent of the total.

Because of their relative economic health, countries do not all contribute the same percentage of their GDP to the EU, yet it is their pool of contributions which funds the Framework Programs, and not the budgets of specific agencies like in the US. This totally different form of funding has a direct consequence: Public R&D funding in the EU has no direct connection with particular disciplines as it does in the US with the overwhelming participation of the departments of Defence (33 percent), Energy (16 percent) and Health (13 percent).

Given the different approaches to funding, what are the foci of public R&D?

The European Framework Programs

As has already been mentioned, the European Commission funds about a third of all European public research, the other two thirds coming from individual states' funding agencies. The Framework Programs for Research and Technological Development, also called Framework Programs (FP) are funding programs created by the European Union in order to support and encourage research at the European level. The detailed objectives and actions vary from one funding period to another. Nanotechnology research started appearing in framework programs with FP4, in 1996. Since then, the European Community has released three more Framework Programs, FP 5, 6 and 7, each of them lasting between three and four years. FP7, the program with the longest life so far, is running from 2007 to 2013. As we see with the following chart (Fig 24), nanotechnology funding really started taking off in 2004.

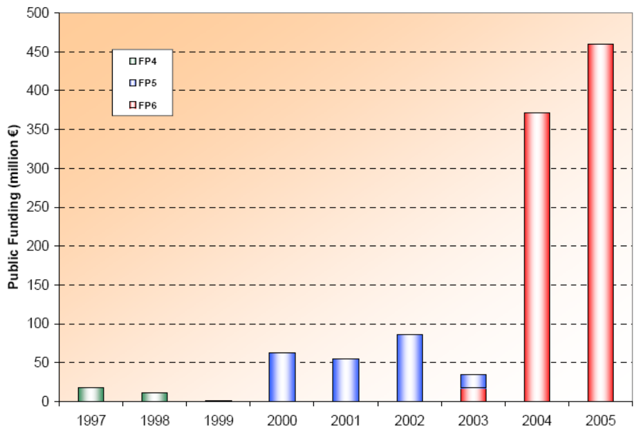


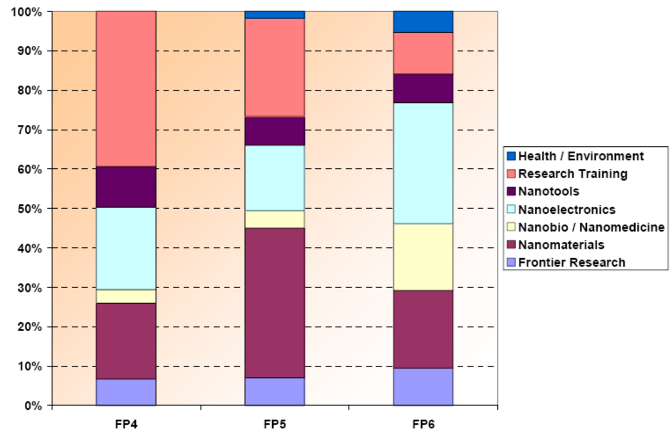
Fig 24
Evolution of EU Framework Programmes (FP) funding devoted to nanotechnology R&D. Source : Unit G4 *Nanosciences and Nanotechnologies*
European Commission, Research DG, Version: 8 December 2005.

The total budget of FP6 (from 2003/4 to 2006) for nanoscience and nanotechnologies (N&N) was nearly 1.4 billion euros, shared over 550 projects.

The NNI programs

For the same period of time (2004-2006), the budget of the US National Nanotechnology Initiative was 3.5 billion dollars, i.e. 2.7 billion euros (1€~1.30$; Souce: NNI budget history by agency, http://www.nano.gov/html/about/funding.html, accessed 17/06/08). While the European Community funds about a third of EU public nanotechnology research, the NNI accounts for about 70 percent of all US public nanotechnology research funding. The NNI is an interagency program that coordinates Federal nanoscale research and development activities and related efforts among various participating entities. It was launched in 2001 and its activities were defined two years later in the 21st century nanotechnology research and development act of 2003 (US Congress, 2003). Six agencies developed the original 2001 proposal. They were the Department of Defense (DOD), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), the National Institutes of Health (NIH), the National Institute of Standards and Technology (NIST) and the National Science Foundation (NSF). In 2006, the NNI gathered a total of 23 agencies (26 in 2008).

Comparing nanotechnology public R&D funding orientations in the US and the EU



Evolution of nanotechnology R&D areas as supported by successive framework programs. Source: European Commission

Fig 25

Nanotechnology public R&D funding by the NNI

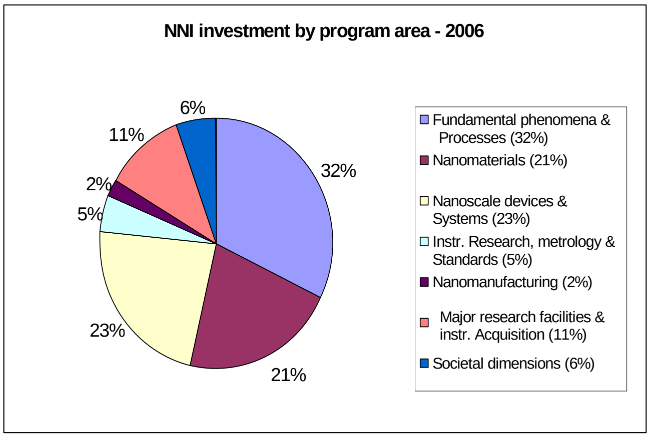


Fig 26. Own compilation based on NNI data

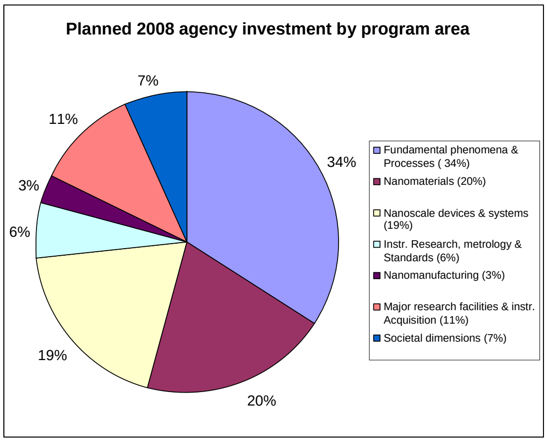


Fig 27. Own compilation based on NNI data

The comparison of the above charts (Fig 25, 26, 27) shows that the EC and the NNI have different orientations. Both of them identify seven major program areas, but the foci are different. Eleven percent of the NNI budget goes to infrastructures and equipment acquisition, to which may be added 5 percent going to research into metrology and standards. In monetary terms, this means that the US spends some 200 million euros on these aspects of the development of nanotechnologies, while the EU FP programs do not mention infrastructures in their program areas. So the US chooses to focus on setting the frame for nanotechnologies, not only by building important infrastructure, but also by giving itself the means to set up the international standards which will then be used globally. These are two very important steps in the institutionalization of new technologies (Garud et al., 2002).

At the same time, the EC still devotes about 10 percent of its budget to research training. Even if this share of the budget is gradually decreasing, showing that the goal is nearly attained, several EU reports still insist on the necessity to harmonize the standard of nanotechnology research in the EU. Indeed, EU enlargement goes with the objective of bringing all the EU countries to a similar technological advancement. The European Commission calculated that there were on average 30 percent fewer researchers for every active 1000 persons in the EU than in the US (European Commission, 2003). This meant that some countries had a lot of catching up to do, which explains the importance of spending adequate means to achieve European technological integration. The fact that the NNI charts do not mention research training seems to indicate that the US is already past the stage of technological unification.

The NNI charts on investment by program area show great consistency over time, while the EC charts reflect a constant refocusing. This is another illustration of the fact that technologically speaking, the US is much better integrated than the EU, where the construction and integration processes are still going on. An example of refocusing of the EU program areas was the appearance in 2000 (FP5) of a new area called Health/environment. It grew fast and more than 6 percent of the FP6 budget was devoted to it. It confirmed the European strategy as expressed in its founding document to:

> ‘address any potential public health, safety, environmental and consumer risks upfront by generating the data needed for risk assessment, integrating risk assessment into every step of the life cycle of nanotechnology-based products, and adapting existing methodologies and, as necessary, developing novel ones.’ (European Commission, 2004c) p 3

Nanotechnology research centres and infrastructure

Academic studies have shown the importance of research as a trigger of entrepreneurship in high technology ventures (Wright et al., 2007, Zucker and Darby, 1998). In the following part, I attempt to map nanotechnology research centers, with their respective foci and features. The following charts have been compiled from various data sources, mainly from the EU and the US.

In 2005, the European Nanoforum (nanoforum.org) released a survey of European nanostructure and networks (Nanoforum, 2005). This report detailed the numbers of Nanotechnology and Nanoscience (N&N) infrastructure centres and networks within the EU and associated states. Centres and/or networks were found in all EU and associated states apart from Croatia, Cyprus, Iceland, Liechtenstein, Malta, and Slovakia. Based on this report, the following map (Fig 28) is a personal compilation showing the major EU research centres, in terms of budgets and investments.

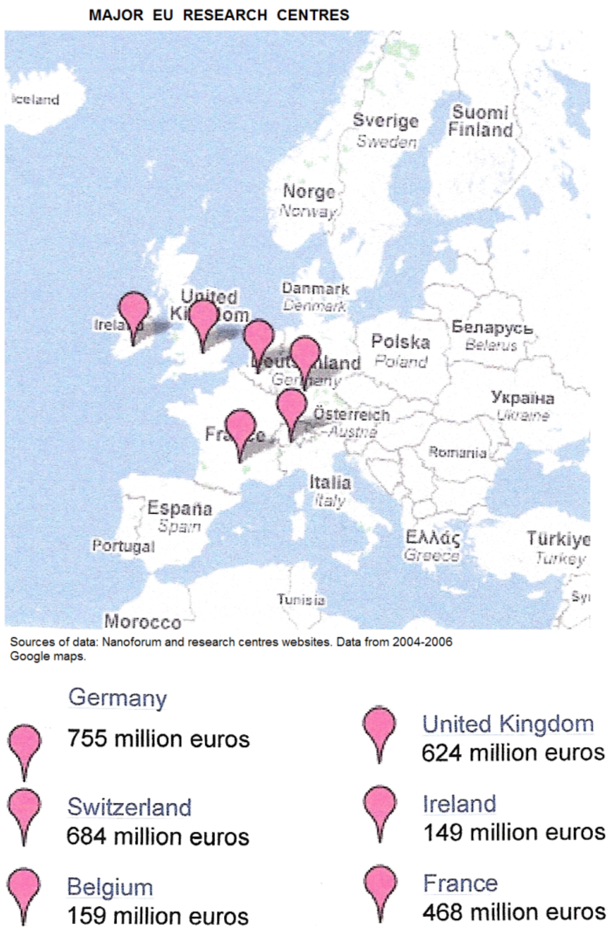


Fig 28

The Nanoforum report identified a total of 143 networks which offered support for collaboration and information exchange between members across 23 EU and associated states (Fig 29). Seventy-nine of these were national networks and 64 were involved in international cooperation.

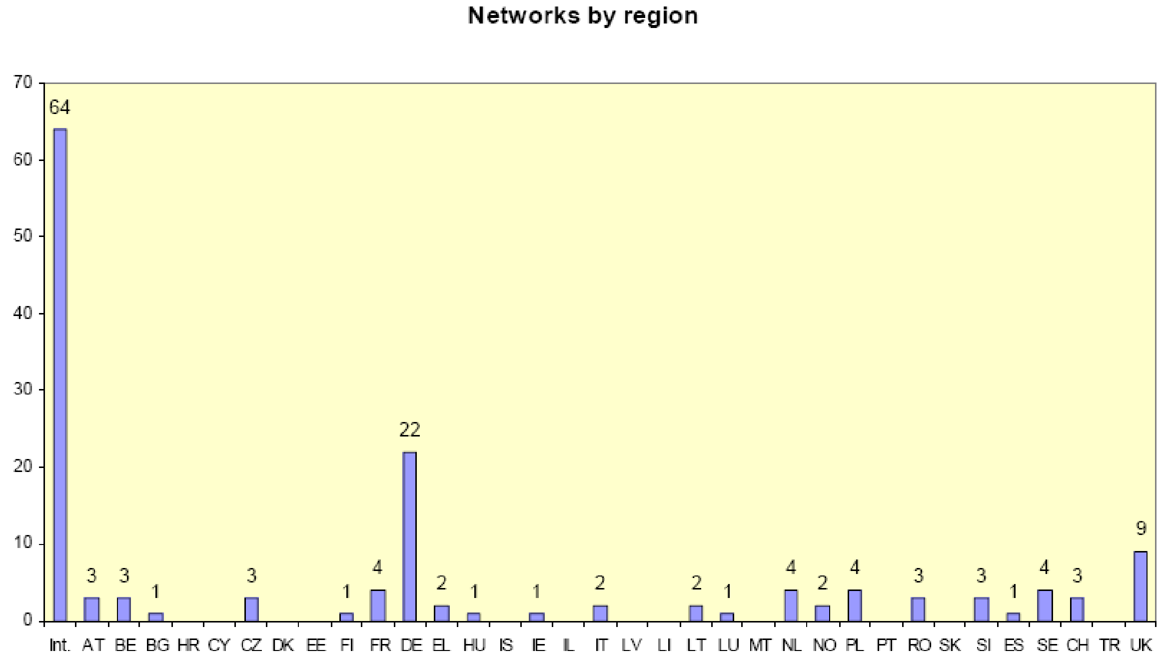


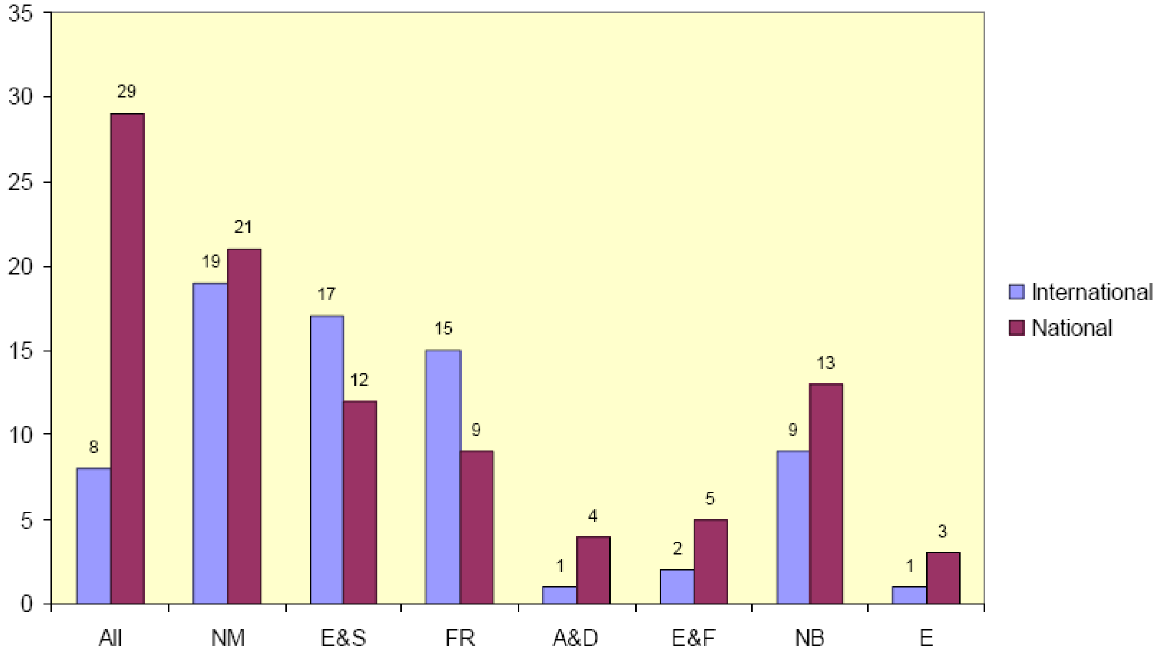
Fig 29. Source: Nanoforum, *European nanotechnology infrastructure and networks*, 2005

The report used the following 7 broad categories to assess infrastructures and networks: all technologies; nanomaterials; electronics and systems; fundamental research; nanobiotechnology; analytical and diagnostics; engineering and fabrication; energy. Thirty seven networks supported all N&N activities, and 40 specialised in nanomaterials. There was variation in the distribution of disciplines covered by international and national networks, with over a third of national networks supporting all disciplines while international networks were more specialised. Of the national networks most (22) were coordinated from Germany, with 9 from the UK, and 4 from each of France, the Netherlands, and Poland.

Most networks involved several disciplines, and some covered them all (Fig 30). Thirty-seven (about a quarter) of all N&N networks in the EU and associated states covered all disciplines. The most common type of thematic network focused on nanomaterials (28 percent). This was followed by electronics (20.3 percent), fundamental research - mainly physics and chemistry (16.8 percent), nanobiotechnology (15.4 percent), engineering and fabrication (4.9 percent), analytical and diagnostic tools (3.5 percent), and energy (2.8 percent).

International networks tended to be more specialised (36.7 percent of national networks supported all disciplines compared with 12.5 percent of international networks). However in two areas (Analytical and Diagnostics, and Energy) most of the relevant networks were national.

Breakdown of the 143 EU N&N networks based on areas covered with splitting of international and national networks



Key: NM nanomaterials, **E&S** electronics and systems, **FR** fundamental research, **A&D** analytical and diagnostics, **E&F** engineering and fabrication, **NB** nanobiotechnology, **E** energy.
Source: Nanoforum, *European nanotechnology infrastructure and networks*, 2005
Fig 30

To attempt a mapping of US nanotechnology research centres, I compiled data from the NNI and various US organisations like the Department of Energy of the Department of Defence (Fig 31 and 32), as well as from the Nanobank, a large scale multiyear project funded by the NSF to build a public digital integrated database of nanotechnology research (see Nanobank.org)

NNI centers and networks – 2007

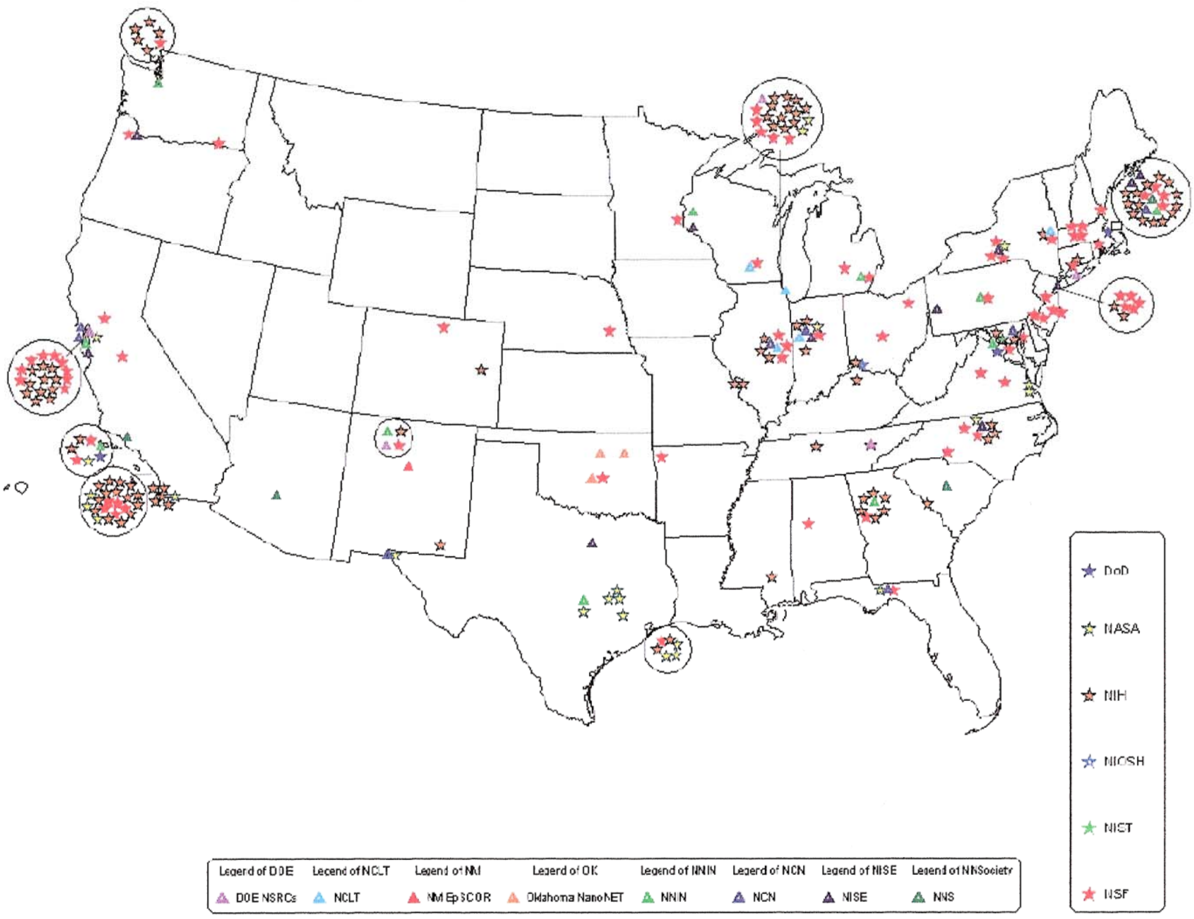


Fig 31. Source: NNI, A.H. Carim, NSET subcommittee of NSTC, adapted.

Acronyms:

DOD – Department of Defence
DOE – Department of Energy
NASA – National Aeronautics and Space Administration
NCLT – National Center for Learning
and Teaching in Nanoscale
NCN – Network for Computational Nanotechnology
NIH – National Institutes of Health
NIOSH – National Institute for Occupational Safety and Health
NISE – Nanoscale Informal Science Education Network
NIST – National Institute of Standards and Technology
NM EPSCOR – New Mexico Experimental Program to Stimulate Competitive Research (Nanoscience)
NNN – National Nanomanufacturing Network
NNS – National Nanotechnology Society
NSF – National Science Foundation
NSRCS – Nanoscale Science Research Centers

Nanoscale science research centers funded by the US Department of Energy (2007)

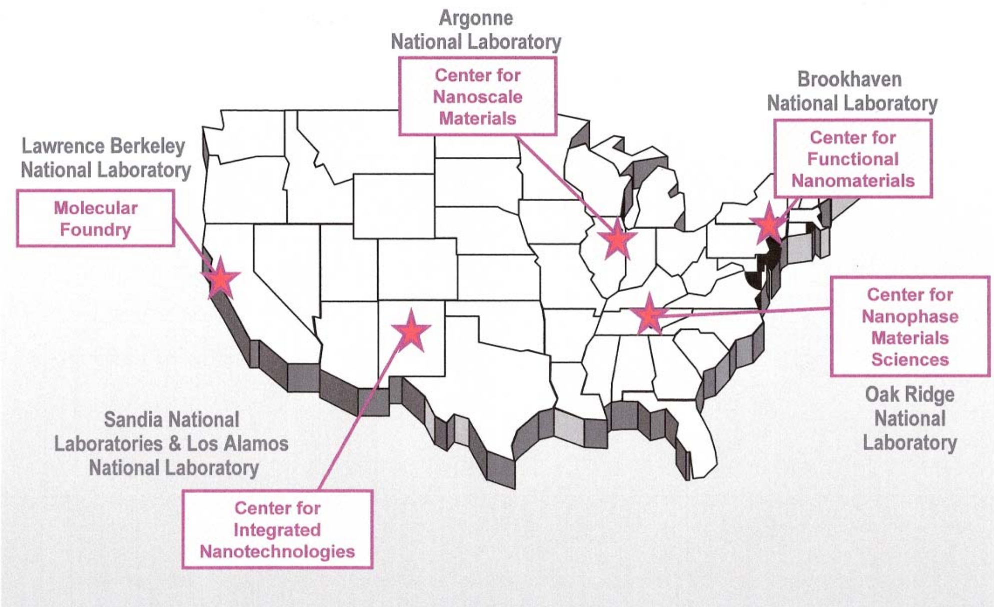


Fig 32. Source: NNI, A.H. Carim, NSET subcommittee of NSTC, adapted.

NNI Agency Contributions to Selected Nanotechnology Application Areas

● – Central Role ○ – Supporting Role

Application Area \ Agency	CPSC	CSREES	DOD	DOE	DHS	DOJ	DOL	DOT	EPA	FDA	FS	IARPA	ITC	NASA	NIH	NIOSH	NIST	NSF
Aerospace			●	○	○			○				○	○	●			○	○
Agriculture & Food		●	○	○	○	○			○	●	○							○
National Defense & Homeland Security		○	●	○	●	○			○	○		●	○	○	○	○	○	○
Energy		○	●	●	○				○		○	○	○	○			○	○
Environmental Applications	○	○	○	○	○		●		●	○	○				○	○	○	●
Information Technologies			●	○	○							○	○	○	○		○	●
Medicine & Health	○	○	○	○			●		●	●				○	●	○	○	○
Transportation & Civil Infrastructure			○	○	○			●	○		○						○	○

Fig 33. Source: NNI Strategic plan 2007, Science and Technology Council, subcommittee on nanoscale science, engineering and technology (NSET), adapted.

Acronyms:

CPSC - Consumer Product Safety Commission
CSREES - Cooperative State Research, Education and Extension Service (U.S. Dept of Agriculture)
DHS - Department of Homeland Security
DOD - Department of Defence
DOE - Department of Energy
DOJ - Department of Justice
DOL - Department of Labour
DOT - Department of Transportation
EPA - Environmental Protection Agency
FDA - Food and Drug Administration
FS - Forest Service (Dept of Agriculture)
IARPA - Intelligence Advanced Research Projects Activity (representing the Intelligence Community)
ITC - International Trade Commission
NASA - National Aeronautics and Space Administration
NIH - National Institutes of Health
NIOSH - National Institute for Occupational Safety and Health
NIST - National Institute of Standards and Technology
NSF - National Science Foundation

The above chart (Fig 33) outlines a vision of research which is quite different from the EU one. As was mentioned before, in the EU, the public funding of research comes from a pool of contributions emanating from all the member states. The chart below (fig 34) shows the contributions of the four major EU contributors (Germany, France, Italy and the United-Kingdom). For the sake of comparison, I added two other countries, Belgium and Ireland.

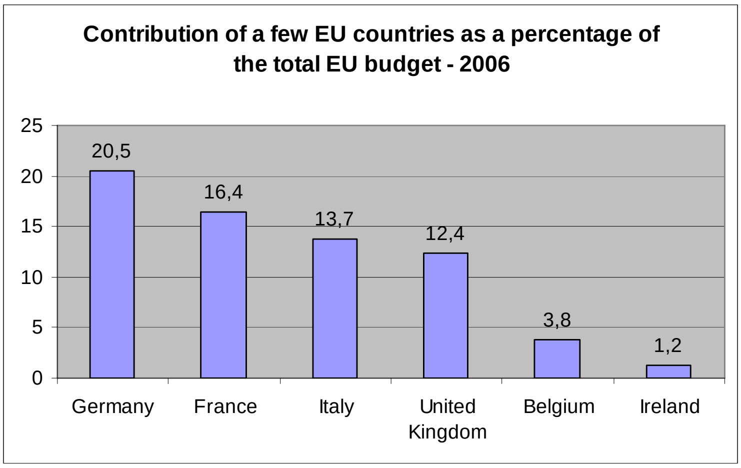


Fig 34. Source of data: European Parliament, 2006 budget. Own compilation.

The four major EU contributors are called net contributors (with Sweden and the Netherlands) because they contribute more to the EU budget than they receive in various financing. Conversely, Belgium and Ireland are two countries which receive more from the EU budget than what they contribute. Fig 28 (major EU research centres) shows that although the financing of public research in the EU comes from the contributions of countries, public research is not structured along the national lines of participating countries in relation to their involvement. Ireland and Belgium are among the six most important EU nano research centres and structures, yet they are not at all among the top contributors of EU funding.

In the US the situation is very different as public research is structured along the lines of *agencies.* The agencies which are willing to give more funding to nanotechnology research have a greater say in the orientation of research, as is illustrated by fig. 33 and 35.

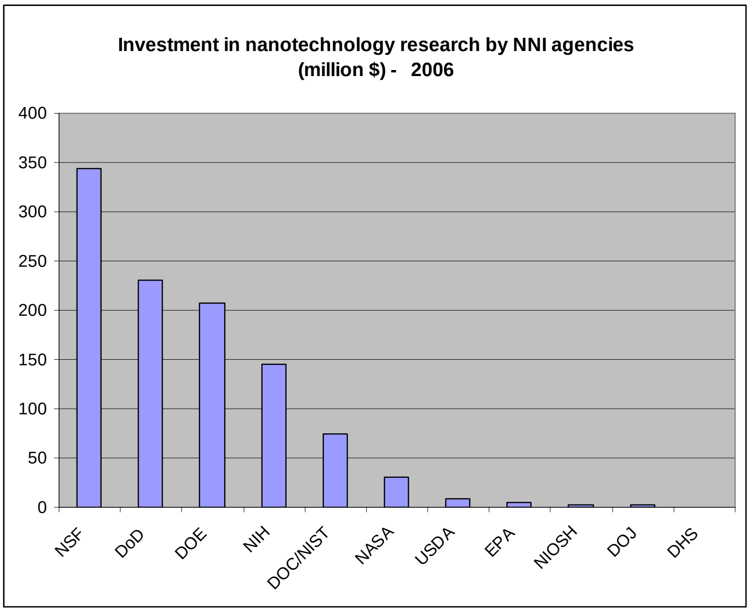
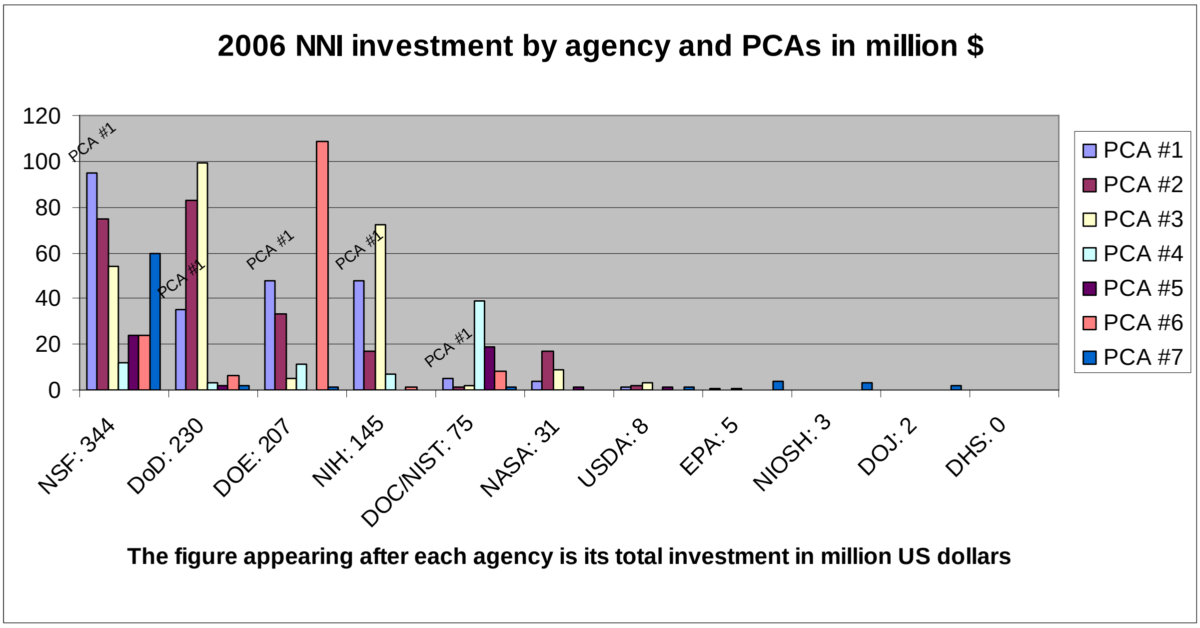


Fig 35. Source of data, DoD, 2006. Own compilation and chart.

The agencies fund the areas of research which are most likely to strengthen their position altogether. This is made clear in the chart below (Fig 36) which shows how each of the NNI participating agencies splits its funding for nanotechnology research along the 7 major Program Component Areas (PCAs) which the NNI identified for years 2004-2006. The differences between the ways each agency finances the various PCAs are quite important. For example, the National Institute of Standards and Technology (NIST) focuses on instrumentation research, metrology and standards, the major involvement of the Department of Energy is on research facilities and instrumentation acquisition and the Department of Defence focuses heavily on PCAs 2 and 3, namely nanomaterials and nanoscale devices and systems.



PCA #1: Fundamental Nanoscale Phenomena and Processes

PCA #2: Nanomaterials
PCA #3: Nanoscale Devices and Systems
PCA #4: Instrumentation Research, Metrology, and Standards for Nanotechnology

PCA #5: Nanomanufacturing
PCA #6: Major Research Facilities and Instrumentation Acquisition

PCA #7: Societal Dimensions
Fig 36. Compilation based on NNI data

One of the major consequences of this structural difference of approach between the US and the EU is that US funding (backed by agencies) is more focused on problem solving than EU funding (backed by a pool of country funding).

Nano-related patent activity

Several researchers link patent analysis with entrepreneurship, particularly in new technologies (Darby et al., 2004b, Akrich et al., 2006, Bonaccorsi and Grid, 2005, Lemley, 2005). According to Hullman (European Commission and Hullmann, 2006), patents reflect the ability of transferring scientific results into technological applications. Patents are also a prerequisite for the economic exploitation of research results. In the following part, I analyse patent activity in the field of nanotechnologies, starting with a general outline, and then scrutinising data coming from several patenting offices more finely. For this research I have worked mainly with the Nanobank and the Delphion database. Delphion is part of the Thomson Corporation and provides access to Intellectual Property Networks for the searching and analysis of patent data collections worldwide (see www.delphion.com). The lack of uniform definitions for nanotechnology means that it is difficult to identify the number of nanotech-related patents. In 2004, the US PTO (United States Patent and Tradesmark Office) created a new classification for nanotechnology patents – Class 977 – precisely to address this problem. Class 977 defined nanotechnology patents narrowly by including only patents:

1) Whose subject matter is in the scale of approximately 1-100 nanometers in at least one dimension;
2) Which involve materials, structures, devices or systems that have novel properties and functions because of their nanoscale size.

However, in May 2005 Class 977 included only 726 patents issued by the US PTO for the period 1980-2005. So Class 977 does not give a comprehensive picture of nano-patenting in the US, let alone in the world, which is why the Delphion database is preferable. This is currently the best available databank of patenting activity for the regions of the EU and the US, although it is still far from being exhaustive. For example, Delphion lists under 'US granted patents' *all* the patents issued by the US Patent and Trademark Office, and under 'EU granted patents' only the *European* patents issued by European Patent Office. The database I use for this research comprises patents from the USPTO (United States Patent and Tradesmark Office), EPO (European Patenting Organisation), and WIPO PCT (World Intellectual Property Organization – Patent Cooperation Treaty). To search through patents, I use the generic search term 'nano'. Some critics argue that this can lead to exaggerated counts, but it is on the other hand probably the most efficient one, particularly since the term nano has no other use than the ones relating to nanotechnologies. To take this concern into account, I use the search term not only in the title but also within the complete text of patents.

As an introduction to my panorama of patenting activity in nano-related fields, here is an outline of the evolution of the relative importance of the USPTO and the EPO as patenting organisations (Fig 37).

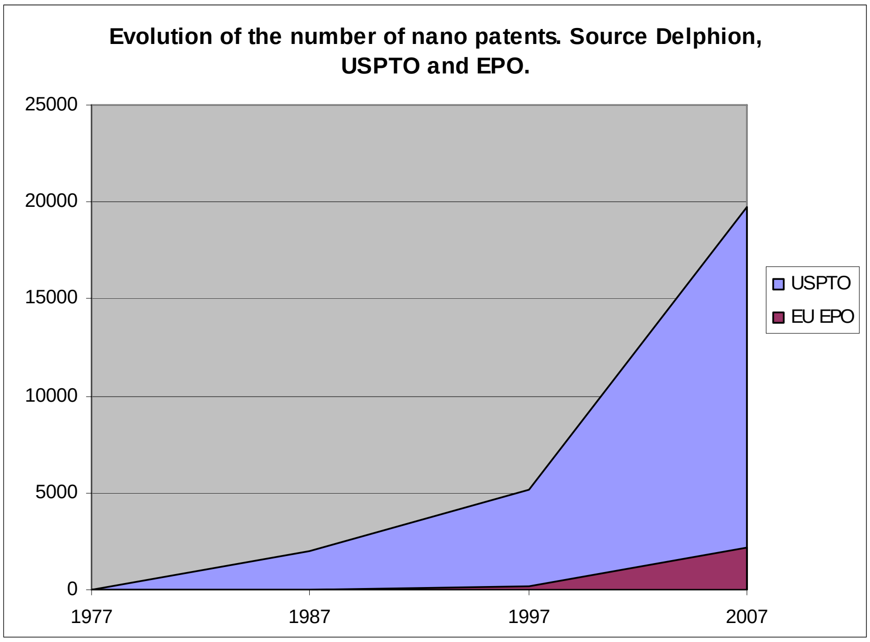


Fig 37. Source of data: Delphion (USPTO and EPO). Own compilation

This chart shows that the USPTO was still by far the agency of reference when it came to registering patents in 2007-08. Indeed, in July 2008, the number of patents falling under the heading ‘EU granted patents’ was just above a tenth of the number of patents under the heading ‘US granted patents’ (2394 vs 22028 patents). In his indicator-based study of the economic development of nanotechnology (European Commission and Hullmann, 2006) Hullmann looked at the evolution nanopatenting in terms of the regions from which the patents originated. In 2003, he found that Europe was not only lagging behind the Americas (mainly the US and Canada) but also behind Asia (mainly Japan and South Korea). His analysis bore on the country from which the application for a patent was made and not on the nationality of the applicants. The chart below therefore reflects the dynamism of each region in terms of nanotechnology patenting.

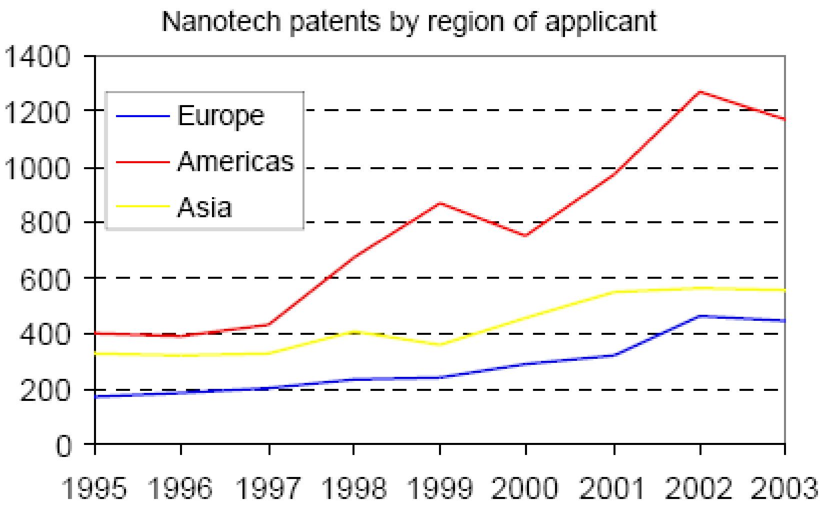


Figure 38: Patents worldwide according to applicant countries.

Source: EPO, 2006 and Hullman's calculations (Indicators based Cordis).

Figure 38 shows the evolution until 2003 and indicates a trend towards more balance between the three regions as the number of patents granted to American applicants started declining in 2002 while the other two regions were catching up. In their study of nanotechnology, (Lux Research and Nordan, 2005) confirmed that although the US was still enjoying a leading overall position in terms of nanotechnology patenting, this position was being challenged in certain areas. They explained that in many specific promising application domains, researchers in other countries had begun to outpace the US. For instance, of the 70 patents for carbon nanotube display applications (potentially useful for large flat-panel monitors that could outperform LCD and plasma) issued by the USPTO through February 2005, only 17 percent were issued to entities based in the US compared with 29 percent in Japan and 31 percent in South Korea. Another study on intellectual property in the nanotechnology economy coming from the UK-based 'Institute of Nanotechnology' (Singh and Morrison, 2007) showed that in 2005-2006 Japan was the most active country in nanoelectronics patenting. Of the top thirty patent applications worldwide which they had surveyed, 18 had been filed by organisations based in the Far East, 10 by organisations based in the US and 2 by organisations based in Europe. The main companies involved in the Far East were Fujitsu with 62 nanoelectronic patent families and Samsung with 56 patent families. Other organisations active in this sector were Hewlett Packard, Hitachi, Japan Science and Technology agency, Infineon Technologies and Philips.

These studies confirm that the core of nanotechnology patenting happens within the Americas, South East Asia and Europe, leaving the other regions of the world as outsiders. There is fierce competition and much reorganisation going on as patenting offices are striving towards more harmonisation of data and Delphion now also provides data from JAPIO (Japan Patent Information Organisation). Asia is rising very fast while Europe is somewhat lagging behind the other two regions in terms of patent activity.

For a more detailed outline of nanotechnology patenting, I have looked at the evolution of nano-related patenting since the beginning of nanotechnology patenting in the 1970s. I have combined data from the USPTO, the EPO and the WIPO PCT (World Intellectual Property Organisation – Patent Cooperation Treaty). The WIPO PCT covers patent publications from over 175 countries including the US. Since the first patent was granted in 1969, there has been an exponential rise in the number of patents relating to nanotechnologies. A Delphion search of the combined data bases of the USPTO (United States Patent and Tradesmark Office), the EPO (European Patenting Organisation) and the WIPO (World Intellectual Property Organisation) showed that there was in July 2008 a total of 7 201 129 granted patents and that out of these 45 510 related to nanotechnologies. In order to facilitate patent researching within such large numbers of patents, I use the Delphion relevancy score. The score is based on algorithms built into Delphion's search engine which factor in the density of the search terms found in the document. Density is calculated in proportion to overall document text. When proximity operators are used, the nearness of terms within the document is also a factor. The exact details of the scoring algorithm are proprietary but the relevancy score enables me to narrow each quest to a sample of the 500 most relevant results for my query, which is then manageable.

The next chart (Fig 39) shows the average number of patents granted per assignee. If we put aside the early times of nanotechnology patenting in the 1970s, there is a regular average of 1.5 to 2 patents per assignee. This crude figure hides the fact that about a third of all assignees obtains between 3 and 12 patents, while the others have only one, as is illustrated by a parallel study done by the USPTO.

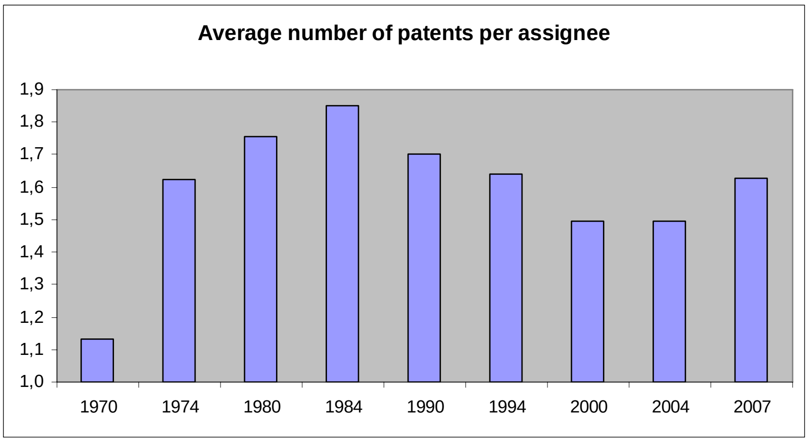


Fig 39. Source of data: Delphion (USPTO, EPO, WIPO – PCT). Own compilation

The USPTO looked at the top patent assignees in its 977 Classification, and found the following repartition in 2005 (Fig 40).

List of the Top Patent Assignees Under the US PTO's Class 977 as of May 25, 2005 (726 patents)

Company/Institution	Headquarters	Patents issued
Canon Kabushiki Kaisha	Japan	49
IBM	USA	47
Silverbrook Research	Australia	28
The United States of America	USA	16
Hitachi	Japan	16
Seagate Technology	USA	16
Micron Technology	USA	14
Eastman Kodak Company	USA	13
Olympus Optical Co., Ltd	Japan	10
University of California	USA	9
Rohm and Haas Company	Germany	9

Polaroid Corporation	USA	9
Sony Corporation	Japan	8
Molecular Imaging Corporation	USA	8

Fig 40. Source: Azonano.com, accessed 18 June 2008

This confirms the fact that the number of assignees which patent a lot is really small. My own analysis of nano patenting activity over the last thirty shows that the vast majority of assignees patent between 2 and 5 patents.

For a more comprehensive analysis of who patents most, I have looked at the evolution of patent assignees over the last thirty years under 5 categories: business firms, universities, government agencies, individual claims and others. The 'others' category gathers foundations which are not universities or research institutions per se, as well as patents which have no assignees (4 patents came under 'unknown' in the column 'assignees' in 2007).

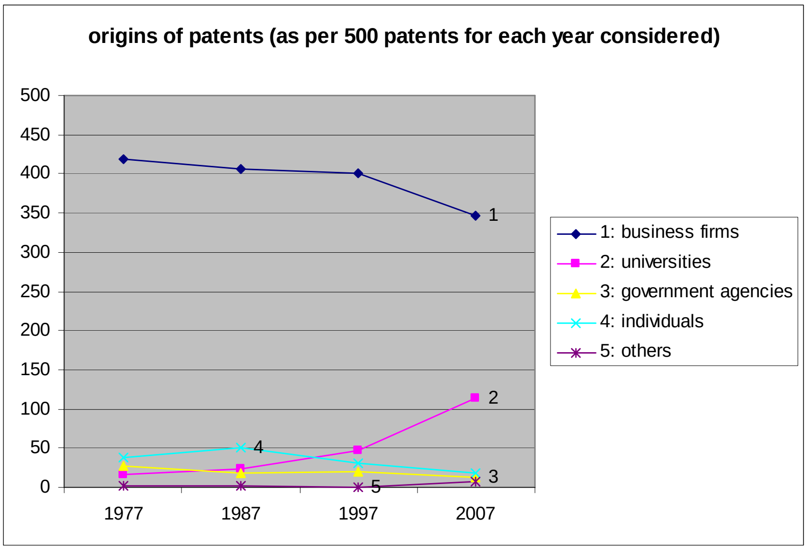


Fig 41. Source : Delphion (US PTO, EPO, WIPO). Own calculation

The chart on Figure 41 shows interesting trends. Firstly, it appears that fewer and fewer patents are granted to individuals. The number of patents being granted to government agencies remains more or less stable, at about 4 percent of the total. These appear in headings like: 'The Secretary of State for Defence in Her Britannic Majesty's Government of the United Kingdom and Northern Ireland' or 'The United States of America as represented by the Department of Health, Education and Welfare'. Some law analysts have raised concerns about the treatment of the potential liabilities of these patents, asking who would be responsible in case of litigations. Finally, the most important trend is the steady decline of patents granted to business firms, compensated by the steady increase of patents granted to universities and other research organisations. The increase of the share of patenting taken by universities reflects the fact that nano patenting is more and more the result of group work. Individuals are not in a position to compete with whole teams. Besides, universities have gradually moved towards a research policy where their researchers surrender their patenting rights to them. The gradual decline of the number of business firms as assignees of nano patents has another explanation. Firms more and more consider universities as subcontractors for R&D. They prefer to fund university research departments than to carry in-house research. Again, the important resources which are necessary to obtain results may explain that it is more efficient for them to do so. The other reason is that by doing so they disconnect their activities from R&D. If new products or processes prove harmful, they will not be associated with them but the universities giving birth to them will.

Lastly, I have looked at the evolution of the areas which have attracted patents over the last thirty years or so. This allows me to give a panorama of the areas which are most likely to become areas of entrepreneurial activity. To define these areas, I have used IPC codes. The International Patent Classification (IPC) is currently used by over 70 patent authorities to classify and index the subject matter of published patent specifications. The IPC is maintained and is administered by the World Intellectual Property Organisation and was first published in 1968. The most recent edition was published in mid 2005 and came into force in January 2006. The IPC divides patentable technology into 8 key areas:

A: Human Necessities

B: Performing Operations, Transporting

C: Chemistry, Metallurgy

D: Textiles, Paper

E: Fixed Constructions

F: Mechanical Engineering, Lighting, Heating, Weapons

G: Physics

H: Electricity

Within these areas technology is divided and subdivided to a detailed level, which allows the subject matter of a patent specification to be very thoroughly classified as follows:

A SECTION A — HUMAN NECESSITIES (16 child classes)
A01 AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING (12 child classes)
A21 BAKING; EQUIPMENT FOR MAKING OR PROCESSING DOUGHS; DOUGHS FOR BAKING (3 child classes)
A22 BUTCHERING; MEAT TREATMENT; PROCESSING POULTRY OR FISH (2 child classes)
A23 FOODS OR FOODSTUFFS; THEIR TREATMENT, NOT COVERED BY OTHER CLASSES (10 child classes)
A24 TOBACCO; CIGARS; CIGARETTES; SMOKERS' REQUISITES (4 child classes)
A41 WEARING APPAREL (6 child classes)
A42 HEADWEAR (2 child classes)
A43 FOOTWEAR (3 child classes)
A44 HABERDASHERY; JEWELLERY (2 child classes)
A45 HAND OR TRAVELLING ARTICLES (4 child classes)
A46 BRUSHWARE (2 child classes)
A47 FURNITURE (arrangements of seats for, or adaptation of seats to, vehicles B60N; DOMESTIC ARTICLES OR APPLIANCES; COFFEE MILLS; SPICE MILLS; SUCTION CLEANERS IN GENERAL; ladders E06C) (9 child classes)
A61 MEDICAL OR VETERINARY SCIENCE; HYGIENE (13 child classes)
A62 LIFE-SAVING; FIRE-FIGHTING (ladders E06C) (3 child classes)
A63 SPORTS; GAMES; AMUSEMENTS (8 child classes)
A99 SUBJECT MATTER NOT OTHERWISE PROVIDED FOR IN THIS SECTION (1 child class)

B SECTION B — PERFORMING OPERATIONS; TRANSPORTING (37 child classes)
B01 PHYSICAL OR CHEMICAL PROCESSES OR APPARATUS IN GENERAL (furnaces, kilns, ovens, retorts, in general F27) (5 child classes)
B02 CRUSHING, PULVERISING, OR DISINTEGRATING; PREPARATORY TREATMENT OF GRAIN FOR MILLING (2 child classes)
B03 SEPARATION OF SOLID MATERIALS USING LIQUIDS OR USING PNEUMATIC TABLES OR JIGS; MAGNETIC OR ELECTROSTATIC SEPARATION OF SOLID MATERIALS FROM SOLID MATERIALS OR FLUIDS; SEPARATION BY HIGH-VOLTAGE ELECTRIC FIELDS (separating isotopes B01D 05900; crushing or disintegrating B02C; centrifuges or vortex apparatus for carrying out physical processes B04) (3 child classes)
B04 CENTRIFUGAL APPARATUS OR MACHINES FOR CARRYING-OUT PHYSICAL OR CHEMICAL PROCESSES (2 child classes)
B05 SPRAYING OR ATOMISING IN GENERAL; APPLYING LIQUIDS OR OTHER FLUENT MATERIALS TO SURFACES, IN GENERAL (domestic cleaning A47L; cleaning in general by methods essentially involving the use or presence of liquid B08B 00300; sand-blasting B24C; coating of articles during shaping of substances in a plastic state B29C 03910, B29C 03900, B29C 04102, B29C 04100, B29C 04318, B29C 04322, B29C 04514, B29C

04702; for further classification of forming layered products, seeB32B; printing, copying B41; conveying articles or workpieces through baths of liquid B65G, e.g. B65G 04900; handling webs or filaments in general B65H; surface treatment of glass by coating C03C 01700, C03C 02510; coating or impregnation of mortars, concrete, stone or ceramics C04B 04145, C04B 04160, C04B 04181; paints, varnishes, lacquers C09D; enamelling of metals, applying a vitreous layer to metals, chemical cleaning or de-greasing of metallic objects C23; electroplating C25D; treating of textile materials by liquids, gases or vapours D06B; laundering D06F; treating roads E01C; apparatus or processes for the preparation or treatment of photosensitive materials G03; apparatus or processes, restricted to a purpose fully provided for in a single other class, see the relevant class covering the purpose) (3 child classes)

B06 GENERATING OR TRANSMITTING MECHANICAL VIBRATIONS IN GENERAL (1 child class)

B07 SEPARATING SOLIDS FROM SOLIDS; SORTING (separation in general B01D; wet separating processes, sorting by processes using fluent material in the same way as liquid B03; using liquids B03B, B03D; sorting by magnetic or electrostatic separation of solid materials from solid materials or fluids, separation by high voltage electric fields B03C; centrifuges or vortex apparatus for carrying out physical processes B04; sorting peculiar to particular materials or articles and provided for in other classes, see the relevant classes) (2 child classes)

B08 CLEANING (1 child class)

B09 DISPOSAL OF SOLID WASTE; RECLAMATION OF CONTAMINATED SOIL (treatment of waste water, sewage or sludge C02F; treating radioactively contaminated solids G21F 00928) (2 child classes)

B21 MECHANICAL METAL-WORKING WITHOUT ESSENTIALLY REMOVING MATERIAL; PUNCHING METAL (casting, powder metallurgy B22; shearing B23D; working of metal by the action of a high concentration of electric current B23H; soldering, welding, flame-cutting B23K; other working of metal B23P; punching sheet material in general B26F; processes for changing of physical properties of metals C21D, C22F; electroforming C25D 00100) (9 child classes)

B22 CASTING; POWDER METALLURGY (3 child classes)

B23 MACHINE TOOLS; METAL-WORKING NOT OTHERWISE PROVIDED FOR (punching, perforating, making articles by processing sheet metal, tubes, or profiles B21D; wire-working B21F; making pins, needles, or nails B21G; making chains B21L; grinding B24) (9 child classes)

B24 GRINDING; POLISHING (3 child classes)

B25 HAND TOOLS; PORTABLE POWER-DRIVEN TOOLS; HANDLES FOR HAND IMPLEMENTS; WORKSHOP EQUIPMENT; MANIPULATORS (7 child classes)

B26 HAND CUTTING TOOLS; CUTTING; SEVERING (3 child classes)

B27 WORKING OR PRESERVING WOOD OR SIMILAR MATERIAL; NAILING OR STAPLING MACHINES IN GENERAL (11 child classes)

B28 WORKING CEMENT, CLAY, OR STONE (3 child classes)

B29 WORKING OF PLASTICS; WORKING OF SUBSTANCES IN A PLASTIC STATE IN GENERAL (processing doughs A21C; working chocolate A23G; casting of metals B22; working cement, clay B28; chemical aspects, see section C, particularly C08; working glass C03B; candle making C11C 00500; making soap C11D 01300; manufacture of artificial filaments, threads, fibres, bristles or ribbons D01D, D01F; manufacture of articles from cellulosic fibrous suspensions or from papier-mâché D21J) (5 child classes)

B30 PRESSES (1 child class)

B31 MAKING PAPER ARTICLES; WORKING PAPER (making layered products not composed wholly of paper or cardboard B32B; handling thin material, e.g. sheets, webs, B65H) (4 child classes)

B32 LAYERED PRODUCTS (1 child class)

B41 PRINTING; LINING MACHINES; TYPEWRITERS; STAMPS (reproduction or duplication of pictures or patterns by scanning and converting into electrical signals H04N) (10 child classes)
B42 BOOKBINDING; ALBUMS; FILES; SPECIAL PRINTED MATTER (4 child classes)
B43 WRITING OR DRAWING IMPLEMENTS; BUREAU ACCESSORIES (3 child classes)
B44 DECORATIVE ARTS (4 child classes)
B60 VEHICLES IN GENERAL (18 child classes)
B61 RAILWAYS (9 child classes)
B62 LAND VEHICLES FOR TRAVELLING OTHERWISE THAN ON RAILS (8 child classes)
B63 SHIPS OR OTHER WATERBORNE VESSELS; RELATED EQUIPMENT (5 child classes)
B64 AIRCRAFT; AVIATION; COSMONAUTICS (5 child classes)
B65 CONVEYING; PACKING; STORING; HANDLING THIN OR FILAMENTARY MATERIAL (6 child classes)
B66 HOISTING; LIFTING; HAULING (4 child classes)
B67 OPENING OR CLOSING BOTTLES, JARS OR SIMILAR CONTAINERS; LIQUID HANDLING (nozzles in general B05B; packaging liquids B65B, e.g. B65B 00300; pumps in general F04; siphons F04F 01000; valves F16K; handling liquefied gases F17C) (3 child classes)
B68 SADDLERY; UPHOLSTERY (4 child classes)
B81 MICRO-STRUCTURAL TECHNOLOGY (2 child classes)
B82 NANO-TECHNOLOGY (1 child class)
B99 SUBJECT MATTER NOT OTHERWISE PROVIDED FOR IN THIS SECTION (1 child class)

C SECTION C — CHEMISTRY; METALLURGY (21 child classes)
C01 INORGANIC CHEMISTRY (processing powders of inorganic compounds preparatory to the manufacturing of ceramic products C04B 03500; fermentation or enzyme-using processes for the preparation of elements or inorganic compounds except carbon dioxide C12P 00300; obtaining metal compounds from mixtures, e.g. ores, which are intermediate compounds in a metallurgical process for obtaining a free metal C21B, C22B; production of non-metallic elements or inorganic compounds by electrolysis or electrophoresis C25B) (5 child classes)
C02 TREATMENT OF WATER, WASTE WATER, SEWAGE, OR SLUDGE (settling tanks, filtering, e.g. sand filters or screening devices, B01D) (1 child class)
C03 GLASS; MINERAL OR SLAG WOOL (2 child classes)
C04 CEMENTS; CONCRETE; ARTIFICIAL STONE; CERAMICS; REFRACTORIES (alloys based on refractory metals C22C) (1 child class)
C05 FERTILISERS; MANUFACTURE THEREOF (processes or devices for granulating materials, in general B01J 00200; soil-conditioning or soil-stabilising materials C09K 01700) (5 child classes)
C06 EXPLOSIVES; MATCHES (4 child classes)
C07 ORGANIC CHEMISTRY (such compounds as the oxides, sulfides, or oxysulfides of carbon, cyanogen, phosgene, hydrocyanic acid or salts thereof C01; products obtained from layered base-exchange silicates by ion-exchange with organic compounds such as ammonium, phosphonium or sulfonium compounds or by intercalation of organic compounds C01B 03300; macromolecular compounds C08; dyes C09; fermentation products C12; fermentation or enzyme-using processes to synthesise a desired chemical compound or composition or to separate optical isomers from a racemic mixture C12P; production of organic compounds by electrolysis or electrophoresis C25B 00300, C25B 00700) (8 child classes)
C08 ORGANIC MACROMOLECULAR COMPOUNDS; THEIR PREPARATION OR CHEMICAL WORKING-UP; COMPOSITIONS BASED THEREON (manufacture or treatment of artificial threads, fibres, bristles or ribbons D01) (8 child classes)

C09 DYES; PAINTS; POLISHES; NATURAL RESINS; ADHESIVES; COMPOSITIONS NOT OTHERWISE PROVIDED FOR; APPLICATIONS OF MATERIALS NOT OTHERWISE PROVIDED FOR (8 child classes)
C10 PETROLEUM, GAS OR COKE INDUSTRIES; TECHNICAL GASES CONTAINING CARBON MONOXIDE; FUELS; LUBRICANTS; PEAT (10 child classes)
C11 ANIMAL OR VEGETABLE OILS, FATS, FATTY SUBSTANCES OR WAXES; FATTY ACIDS THEREFROM; DETERGENTS; CANDLES (edible oil or fat compositions A23) (3 child classes)
C12 BIOCHEMISTRY; BEER; SPIRITS; WINE; VINEGAR; MICROBIOLOGY; ENZYMOLOGY; MUTATION OR GENETIC ENGINEERING (12 child classes)
C13 SUGAR INDUSTRY (polysaccharides, e.g. starch, derivatives thereof C08B; malt C12C) (7 child classes)
C14 SKINS; HIDES; PELTS; LEATHER (2 child classes)
C21 METALLURGY OF IRON (3 child classes)
C22 METALLURGY (of iron C21; FERROUS OR NON-FERROUS ALLOYS; TREATMENT OF ALLOYS OR NON-FERROUS METALS; general methods or devices for heat treatment of ferrous or non-ferrous metals or alloys C21D; production of metals by electrolysis or electrophoresis C25) (3 child classes)
C23 COATING METALLIC MATERIAL; COATING MATERIAL WITH METALLIC MATERIAL (by metallising textiles D06M 01100; decorating textiles by locally metallising D06Q 00100; CHEMICAL SURFACE TREATMENT; DIFFUSION TREATMENT OF METALLIC MATERIAL; COATING BY VACUUM EVAPORATION, BY SPUTTERING, BY ION IMPLANTATION OR BY CHEMICAL VAPOUR DEPOSITION, IN GENERAL; for specific applications, see the relevant places, e.g. for manufacturing resistors H01C 01706; INHIBITING CORROSION OF METALLIC MATERIAL OR INCRUSTATION IN GENERAL; treating metal surfaces or coating of metals by electrolysis or electrophoresis C25D, C25F) (4 child classes)
C25 ELECTROLYTIC OR ELECTROPHORETIC PROCESSES; APPARATUS THEREFOR (electrodialysis, electro-osmosis, separation of liquids by electricity B01D; working of metal by the action of a high concentration of electric current B23H; treatment of water, waste water or sewage by electrochemical methods C02F 00146; surface treatment of metallic material or coating involving at least one process provided for in class C23 and at least one process covered by this class C23C 02800, C23F 01700; anodic or cathodic protection C23F; single-crystal growth C30B; metallising textiles D06M 01100; decorating textiles by locally metallising D06Q 00100; electrochemical methods of analysis G01N; electrochemical measuring, indicating or recording devices G01R; electrolytic circuit elements, e.g. capacitors, H01G; electrochemical current or voltage generators H01M) (4 child classes)
C30 CRYSTAL GROWTH (separation by crystallisation in general B01D 00900) (1 child class)
C40 COMBINATORIAL TECHNOLOGY (1 child class)
C99 SUBJECT MATTER NOT OTHERWISE PROVIDED FOR IN THIS SECTION (1 child class)

D SECTION D — TEXTILES; PAPER (9 child classes)
D01 NATURAL OR ARTIFICIAL THREADS OR FIBRES; SPINNING (metal threads B21; fibres or filaments of softened glass, minerals, or slag C03B 03700; yarns D02) (6 child classes)
D02 YARNS; MECHANICAL FINISHING OF YARNS OR ROPES; WARPING OR BEAMING (3 child classes)
D03 WEAVING (3 child classes)
D04 BRAIDING; LACE-MAKING; KNITTING; TRIMMINGS; NON-WOVEN FABRICS (5 child classes)
D05 SEWING; EMBROIDERING; TUFTING (2 child classes)

D06 TREATMENT OF TEXTILES OR THE LIKE; LAUNDERING; FLEXIBLE MATERIALS NOT OTHERWISE PROVIDED FOR (11 child classes)
D07 ROPES; CABLES OTHER THAN ELECTRIC (1 child class)
D21 PAPER-MAKING; PRODUCTION OF CELLULOSE (7 child classes)
D99 SUBJECT MATTER NOT OTHERWISE PROVIDED FOR IN THIS SECTION (1 child class)

E SECTION E — FIXED CONSTRUCTIONS (8 child classes)
E01 CONSTRUCTION OF ROADS, RAILWAYS, OR BRIDGES (of tunnels E21D) (5 child classes)
E02 HYDRAULIC ENGINEERING; FOUNDATIONS; SOIL-SHIFTING (4 child classes)
E03 WATER SUPPLY; SEWERAGE (4 child classes)
E04 BUILDING (layered materials, layered products in general B32B) (6 child classes)
E05 LOCKS; KEYS; WINDOW OR DOOR FITTINGS; SAFES (5 child classes)
E06 DOORS, WINDOWS, SHUTTERS, OR ROLLER BLINDS, IN GENERAL; LADDERS (2 child classes)
E21 EARTH OR ROCK DRILLING; MINING (4 child classes)
E99 SUBJECT MATTER NOT OTHERWISE PROVIDED FOR IN THIS SECTION (1 child class)

F SECTION F — MECHANICAL ENGINEERING; LIGHTING; HEATING; WEAPONS; BLASTING (18 child classes)
F01 MACHINES OR ENGINES IN GENERAL (combustion engines F02; machines for liquids F03, F04; ENGINE PLANTS IN GENERAL; STEAM ENGINES) (8 child classes)
F02 COMBUSTION ENGINES (cyclically operating valves therefor, lubricating, exhausting, or silencing engines F01; HOT-GAS OR COMBUSTION-PRODUCT ENGINE PLANTS) (9 child classes)
F03 MACHINES OR ENGINES FOR LIQUIDS (for liquids and elastic fluids F01; positive-displacement machines for liquids F04; WIND, SPRING, OR WEIGHT MOTORS; PRODUCING MECHANICAL POWER OR A REACTIVE PROPULSIVE THRUST, NOT OTHERWISE PROVIDED FOR) (5 child classes)
F04 POSITIVE-DISPLACEMENT MACHINES FOR LIQUIDS; PUMPS FOR LIQUIDS OR ELASTIC FLUIDS (portable fire extinguishers with manually-operated pumps A62C 01100, with power-driven pumps A62C 02500; charging or scavenging combustion engines by pumps F02B; engine fuel-injection pumps F02M; ion pumps H01J 04100; electrodynamic pumps H02K 04400) (4 child classes)
F15 FLUID-PRESSURE ACTUATORS; HYDRAULICS OR PNEUMATICS IN GENERAL (3 child classes)
F16 ENGINEERING ELEMENTS OR UNITS; GENERAL MEASURES FOR PRODUCING AND MAINTAINING EFFECTIVE FUNCTIONING OF MACHINES OR INSTALLATIONS; THERMAL INSULATION IN GENERAL (14 child classes)
F17 STORING OR DISTRIBUTING GASES OR LIQUIDS (water supply E03B) (3 child classes)
F21 LIGHTING (electric aspects or elements, see section H, e.g. electric light sources H01J, H01K, H05B) (7 child classes)
F22 STEAM GENERATION (chemical or physical apparatus for generating gases B01J; chemical generation of gas, e.g. under pressure, Section C; removal of combustion products or residues, e.g. cleaning of the combustion contaminated surfaces of tubes of boilers, F23J; generating combustion products of high pressure or high velocity F23R; water heaters not for steam generation F24H, F28; cleaning of internal or external surfaces of heat-transfer conduits, e.g. water tubes of boilers, F28G) (3 child classes)
F23 COMBUSTION APPARATUS; COMBUSTION PROCESSES (12 child classes)

F24 HEATING; RANGES; VENTILATING (protecting plants by heating in gardens, orchards, or forests A01G 01306; baking ovens and apparatus A21B; cooking devices other than ranges A47J; forging B21J, B21K; specially adapted for vehicles, see the relevant subclasses of classes B60-B64; combustion apparatus in general F23; drying F26B; ovens in general F27; electric heating elements or arrangements H05B) (6 child classes)
F25 REFRIGERATION OR COOLING; COMBINED HEATING AND REFRIGERATION SYSTEMS; HEAT PUMP SYSTEMS; MANUFACTURE OR STORAGE OF ICE; LIQUEFACTION OR SOLIDIFICATION OF GASES (4 child classes)
F26 DRYING (1 child class)
F27 FURNACES; KILNS; OVENS; RETORTS (specially adapted for a purpose covered by a single other class and specifically mentioned in that class, see the class in question, e.g. bakery ovens A21B, glass melting furnaces C03B, coke or gas-making apparatus C10B, C10J, apparatus for cracking hydrocarbons C10G, blast furnaces C21B, converters for making steel C21C, furnaces for heat treatment of metal C21D; furnaces for electroslag or arc remelting of metals C22B 00900; enamelling ovens C23D; combustion apparatus F23; electric heating H05B) (2 child classes)
F28 HEAT EXCHANGE IN GENERAL (heat-transfer, heat-exchange or heat-storage materials C09K 00500; arrangement or mounting of heat-exchangers in air-conditioning, air-humidification or ventilation F24F 01300) (5 child classes)
F41 WEAPONS (7 child classes)
F42 AMMUNITION; BLASTING (3 child classes)
F99 SUBJECT MATTER NOT OTHERWISE PROVIDED FOR IN THIS SECTION (1 child class)

G SECTION G — PHYSICS (14 child classes)
G01 MEASURING (counting G06M; TESTING) (17 child classes)
G02 OPTICS (making optical elements or apparatus B24B, B29D 01100, C03, or other appropriate subclasses or classes; materials per se, see the relevant places, e.g. C03B, C03C) (3 child classes)
G03 PHOTOGRAPHY; CINEMATOGRAPHY; ANALOGOUS TECHNIQUES USING WAVES OTHER THAN OPTICAL WAVES; ELECTROGRAPHY; HOLOGRAPHY (reproduction of pictures or patterns by scanning and converting into electrical signals H04N) (6 child classes)
G04 HOROLOGY (5 child classes)
G05 CONTROLLING; REGULATING (4 child classes)
G06 COMPUTING; CALCULATING; COUNTING (score computers for games A63B 07106, A63D 01500, A63F 00100; combinations of writing implements with computing devices B43K 02900) (11 child classes)
G07 CHECKING-DEVICES (5 child classes)
G08 SIGNALLING (indicating or display devices per seG09F; transmission of pictures H04N) (3 child classes)
G09 EDUCATING; CRYPTOGRAPHY; DISPLAY; ADVERTISING; SEALS (5 child classes)
G10 MUSICAL INSTRUMENTS; ACOUSTICS (8 child classes)
G11 INFORMATION STORAGE (2 child classes)
G12 INSTRUMENT DETAILS (1 child class)
G21 NUCLEAR PHYSICS; NUCLEAR ENGINEERING (8 child classes)
G99 SUBJECT MATTER NOT OTHERWISE PROVIDED FOR IN THIS SECTION (1 child class)

H SECTION H — ELECTRICITY (6 child classes)
H01 BASIC ELECTRIC ELEMENTS (14 child classes)
H02 GENERATION, CONVERSION, OR DISTRIBUTION OF ELECTRIC POWER (8 child classes)

H03 BASIC ELECTRONIC CIRCUITRY (10 child classes)
H04 ELECTRIC COMMUNICATION TECHNIQUE (10 child classes)
H05 ELECTRIC TECHNIQUES NOT OTHERWISE PROVIDED FOR (6 child classes)
H99 SUBJECT MATTER NOT OTHERWISE PROVIDED FOR IN THIS SECTION (1 child class)

The classification shows that there are some overlapping areas and that some patents may fall under several headings. The IPC contains one section devoted to nanotechnology. It is section B82, NANO-TECHNOLOGY B82. However, this section faces the same shortcomings as the USPTO classification 977: most of the nano patents do not go under this heading while the heading contains only few of the nano patents which have been granted since the first one in 1969.

In the following chart, I used the Delphion relevancy score to calculate, for each period considered, the number of patents relating to each of the 8 categories.

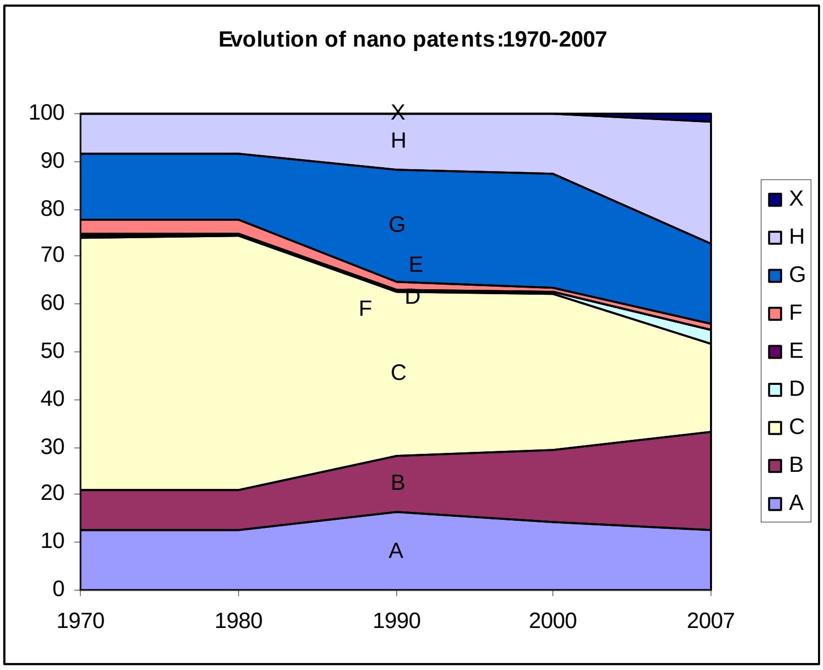


Fig 42. Source of data: Delphion (USPTO, EPO, WIPO – PCT). Own compilation.

The chart (Fig 42) shows that nano patenting started overwhelmingly in the area of chemistry and metallurgy (classification C) in the 1970s. At that time, it accounted for nearly 53 percent of all nano-related patents. In 2007-2008, the patenting activity had become fairly evenly spread out among the 5 categories A-Human necessities (12.6 percent), B-

Performing Operations, Transporting (20.8 percent), C-Chemistry, Metallurgy (18.4 percent), G-Physics (16.8 percent) and H-Electricity (25.8 percent). The great ‘winners’ were sections B (Performing Operations, Transporting) and H (Electricity) which had moved respectively from 8.3 to 20.8 percent and from 8.3 to 25.8 percent. Another interesting phenomenon was the appearance of what I classified as X, that is, patents without any classification code. These did not exist in the 1970s, but in 2008 they amounted to 1.6 percent of all the nano-patents, which is not really negligible. One section has remained remarkably unaffected by nano-patenting; it is section E (Fixed constructions). This may reflect the fact that nanotechnologies are still a long way away from the application stage in this domain. Applications seem more readily accessible in Textiles as is illustrated by the fact that section D started taking off around 2000.

Nano-products reaching the market

A lot of speculation is going on to predict what nanotechnology entrepreneurship will look like in the near future. Several conclusions may be drawn from the preceding analysis. One is that nanotechnology R&D is a global activity which involves three teams of players: the Americas, Asia and Europe. Apart from them, the other regions of the world are for the moment only outsiders in the development of nanotechnologies. In the group of three, globalisation is felt not only in the exchanges of researchers coming from various parts of the world, but maybe even more so in the fact that each one monitors carefully what the others are doing and responds accordingly in order to enhance their position. So although there are still important structural differences between their approaches, there is an evolution towards a global integration of priorities and to a certain extent of roadmaps. This points to a globalisation of the major areas of development for nanotechnology entrepreneurship.

Secondly, in spite of all the research that is going on to assess nanotechnology R&D, it is very difficult to obtain an accurate picture of the situation. As different regions or organisations use different methodologies and classifications, comparisons are not easy. There is also a growing tendency to include in classifications categories like ‘NEC’ (not elsewhere classified), or ‘unknown’, in which up to 10 percent of the data is stored, which leads to further difficulties in interpretation especially when differences are small. Bearing this in mind, what do the recent studies of nano-products reaching the market tell us?

In its report ‘Sizing nanotechnology’s value chain’ (Lux Research Inc., 2004) tried to forecast the commercial evolution of the technology. The researchers interviewed more than 100 executives, researchers and academics working to commercialise nanotechnology, and integrated macroeconomic data from the World Bank and the US Bureau of Economic Analysis among others, in order to build models for 42 product segments connecting with nanotechnologies. They found that sales of products incorporating nanotechnologies would rise from nearly nothing in 2004 to 15 percent of the total global manufacturing output in 2014. This value approached the size of the combined information technology and telecom industries, and was ten times larger than the revenues from biotechnologies. The report showed that the economic impact of nanotechnologies would not come from the sale of staple products like carbon nanotubes, but rather from very diverse products and goods from different industrial sectors which would integrate the technology at some point. Their projection was that in 2014 four percent of general manufactured goods, 50 percent of electronics and IT products, and 16 percent of goods in healthcare and life sciences by revenue would incorporate nanotechnologies. Lux Research modelled nanotechnology growth as a three-phase process: after an initial phase where nanotechnology was incorporated selectively into a few high-end products, the second stage would see an explosion in the sector of electronics and IT applications when microprocessors and memory chips using new nanoscale processes reached the market. This analysis was in line with my own analysis of the evolution of patenting areas (fig 42). Then, towards 2010 according to the same report, there would be a third stage with the generalisation of manufactured goods including nanotechnologies and the beginning of nano-enabled pharmaceuticals and medical devices, as trial times would be over for healthcare and life sciences applications (Fig 43).

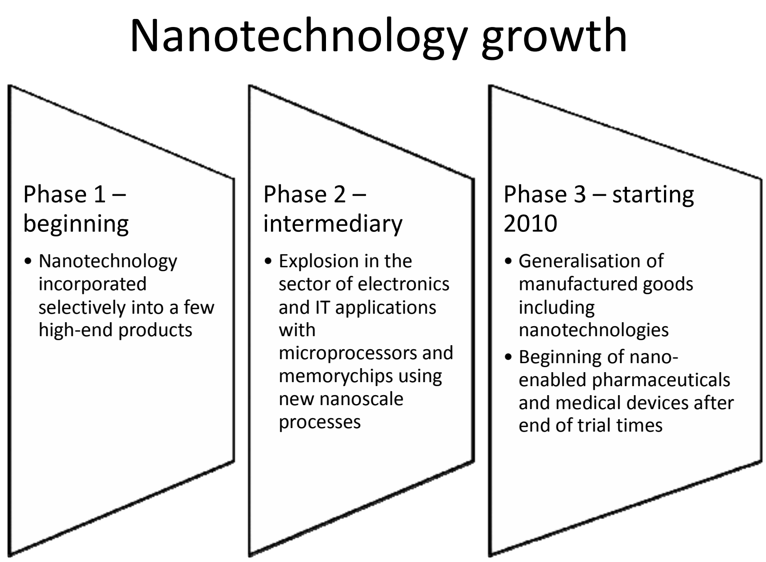


Fig 43. Source of data, Lux Research

Another study of the types of nano-products reaching the market came from Credit Suisse, one of the world leaders in financial services. The study was intended to offer guidance to investors and its conclusions were presented at the Nanotech Northern Europe 2008 conference which took place in Denmark in September 2008 (http://www.nanotech.net). Crédit Suisse identified five major areas of nanotechnology development: nano tools, nano materials, nano energy and others, nano information technology and nano healthcare (Fig 44).

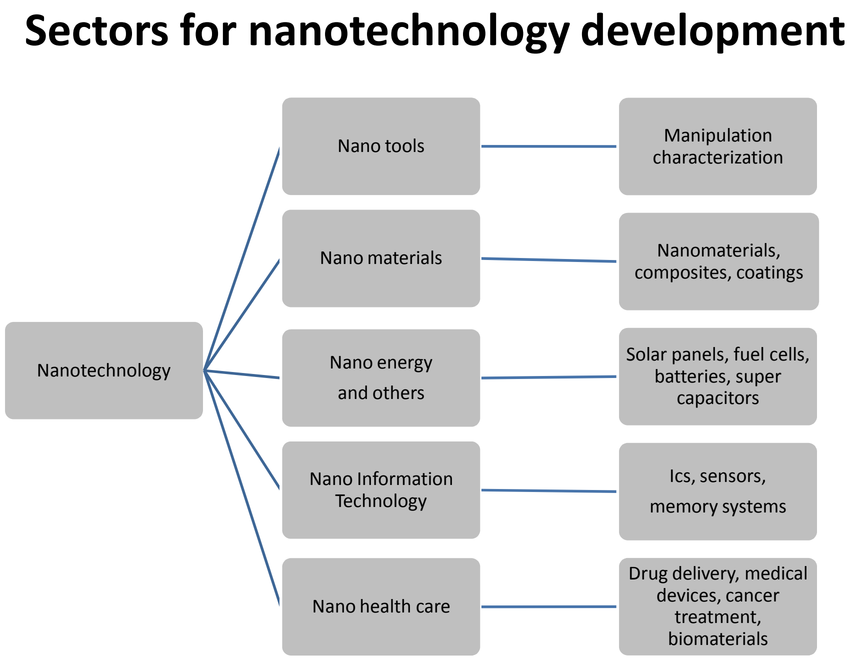


Fig 44. Source: Credit Suisse - 2008

Credit Suisse identified 'population growth, better life quality and rising energy and water and security needs' as the main drivers of nanotechnology. This finding supports my hypothesis that awareness of the concept of sustainable development plays a major role in the development of nanotechnologies. Indeed, the drivers identified by Credit Suisse relate directly to a pattern of resource use that aims to meet human needs while preserving the environment on the sustainable development model. They also tie concern for the carrying capacity of natural systems with the social challenges of today. In other words, they reflect a preoccupation for environmental preservation and sustainable development.

What does this mean in terms of products actually on the market? The Pew Charitable Trusts, in collaboration with the Woodrow Wilson Research Center produced an inventory of nano-based products present on the market worldwide in 2008 (see: http://www.nanotechproject.org/inventories/consumer/analysis/). The inventory contained over 800 nano-based products, split along eight categories: health and fitness, home and garden, electronics and computers, food and beverage, cross cutting, automotive, appliances and goods for children.

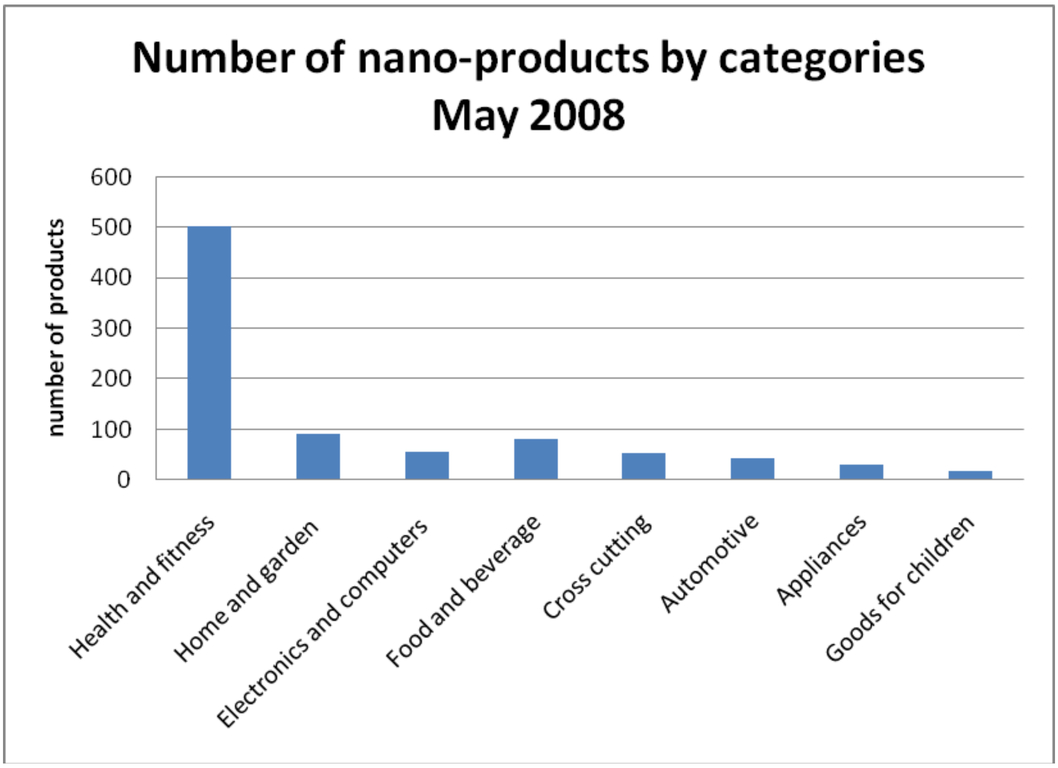


Fig 45. Source of the data, Project on Emerging Nanotechnologies (PEN), Woodrow Wilson International Center for Scholars and Pew.

The chart (Fig 45) shows how important the category health and fitness is in relation to the others. This category contains several sub-categories, in which cosmetics, clothing and personal care dominate.

Finally several recent studies, including (Zhu, 2008), identified construction as an extremely promising sector for nanotechnology applications. Zhu explained that construction industry was among the earliest – in the 1990s – in categorizing nanotechnology as a promising emerging technology. Yet, because of a tradition of low R&D investment in construction and of an absence of communication between scientific circles and the construction industry, the rate of application stayed very low until 2002-2003. Since then, research on cement and concrete has received much attention, with environmental and sustainability concerns identified as major drivers of progress. Although nanotechnology applications in construction still lag behind other industries, commercial activities have started to emerge in the high performance and functional materials sectors, and show an enormous potential of development.

Conclusion

In this chapter, I have used mainly archival data to give an interpretative analysis of the salient aspects of nanotechnology entrepreneurship. My purpose was to establish the context from which I draw my observations of the nanotechnology field and of its relation to institutional emergence in later chapters. At the time of writing, nanotechnology research mobilized only a *very* small fraction of the world's GDP. This means that whatever findings my study could produce could only be inductive in essence. In a way it vindicates my methodological approach of building theory from the observation of a few illustrative cases. In this particular chapter, the fact that the early development of nanotechnology corresponded to the creation of ad hoc coordinating structures like the American NNI or the European Nanoforum shows the importance of policy making in the institutional emergence of the field. So does the fact that the 6th and 7th European Framework programs (those when European nanotechnology R&D funding really took off) were the largest ever funding programmes for research and technological development (RTD). The shift in the patenting model towards the domination of university patenting for nanotechnology discoveries also goes in the same direction since university research tends to correlate to institutional funding by research councils. The analysis of the categories of nanoproducts reaching the market as well as of the areas of growth for the technology illustrates the growing importance of sustainable development issues in the development of the field.

ENTREPRENEURSHIP AND REGULATORY PRACTICES

In the previous chapter, I started my exploration of the emergence of the field of nanotechnologies with an outline of some salient features of nanotechnology entrepreneurship. It was based on three indicators: nanotechnology R&D, nanotechnology research centres and infrastructures and finally nano-related patent activity. Among other findings, I showed that institutional funding and R&D orientations play an important role in nanotechnology entrepreneurship, and that sustainable development was one of the drives of nanotechnology entrepreneurship. In this part, I focus on regulatory practices. My objective in the next pages is to demonstrate that regulatory practices play a vital role on nanotechnology entrepreneurship. My longer term goal in the study is to build on this intermediary finding to show that change in regulatory practices signals change in institutional emergence: on the one hand, nanotechnologies are creating a context which is conducive to regulatory change, and at the same time, change in regulatory practices influences the shaping of the field through its impact on nanotechnology entrepreneurship.

With this double objective in mind, I analyse how the regulatory contexts of the nanotech sector in the US and in Europe initially influenced entrepreneurship differently. The study is based on an interpretative comparative content analysis of the emergence of the biotechnology sector and the nanotechnology sector in the US and in Europe. In the US, the data relates essentially to federal regulation, and in Europe, to Community regulation. I take regulation as the whole of the texts and official decisions taken by the governing structures in relation to the development of biotechnologies and nanotechnologies. This data is complemented by focused interviews with officials working in regulatory agencies, and by business reports concerning the evolution of the biotechnology and nanotechnology sectors.

The analysis is structured as follows: I first recall the major areas of development of nanotechnologies. I then describe the specifics of the evolution of regulations designed to accompany the development of technological discoveries and their impact on society. Next I discuss the robustness of the different regulatory frameworks to exogenous factors. Drawing on a comparison with a longitudinal analysis of the biotechnology case, I discuss the influence of regulatory contexts on entrepreneurship. I conclude that over the period of the early emergence of the nanotechnology field (2001 – 2006), in spite of a perceivable trend towards globalisation and harmonisation of regulatory frameworks in general, Europe and the US were not aligned when it came to nanotechnology regulation, because each regulatory framework created its own competitive advantage for entrepreneurship.

Areas of nanotechnology entrepreneurship

As has already been mentioned, nanotechnology is a holdall word that refers to products and technologies involving the manipulation of the matter at the level of the atoms, at the scale of the nanometre (nm), i.e. of a millionth of a millimetre. Over the last ten years, there have been countless arguments over the exact definition of nanotechnology, particularly since particles of the nanometre size have existed since the beginning of the world. For example, there have been carbon nanoparticles in soot and volcano exhausts since the beginning of times. It is now agreed that the field of nanotechnology concerns man-made particles of a nano size which present properties that were not present in a natural state before. Again, to be counted as a particle of nano size, it is generally agreed that a particle must have at least one of its dimensions which is inferior or equal to 100 nanometres. Manipulating the matter at such a scale, by acting directly on the atomic structure of particles, seems to open up endless possibilities. Today, nanoproducts which are on the market, i.e. products which contain specific man-made nanoparticles, include self-cleaning glass or textiles, reinforced tyres or bumpers, plasters or refrigerators containing nanosilver particles to kill bacteria, cosmetics, toothpaste, cements or paints with specific properties, food, beverages, wrappings, fuel additives etc. In terms of the products of research, nanotechnology is at least as full of promises for entrepreneurs as biotechnology was in the seventies. There are currently three major identified fields of development for all the products and techniques obtained by working on nanoparticles: the health sector, military applications and sustainable development through the development of new or better products in electronics, fuel additives or industrial materials.

The health sector is the best known sector of development and entrepreneurship involving nanotechnology applications. It is amply documented, particularly since most developments of nanotechnology research in the health sector intersect with biotechnology research. (See for example ‘Nanotechnology and the Health of the EU Citizen in 2020’, on www.nano.org.uk or reports like the Ernst & Young Biotech Report (Ernst & Young, 2003) or the US Department of Commerce’s Survey of the Use of Biotechnology in US Industry (US Department of Commerce, 2003).

Nanotechnology and human health applications

Here is a brief summary of the most promising applications of the use of nanotechnologies for human health:

DNA-based

Gene probes, DNA markers, Bioinformatics, Genomics, pharmacogenetics

DNA sequencing/synthesis/amplification, genetic engineering.

Biochemistry/Immunology

Vaccines/immune stimulants, Drug design & delivery, Diagnostic tests, antibiotics

Synthesis/sequencing of proteins and peptides, Cell receptors/signaling,

structural biology, Combinatorial chemistry, 3-D molecular modelling

Biomaterials, Microbiology, virology, microbial ecology

Bioprocessing-based

Culturing/manipulation of cells, tissues, embryos

Extractions, purifications, separations

Fermentation, bioprocessing, Biotransformation

Environmental

Bioleaching, biopulping, biobleaching, biodesulfurization

Bioremediation, biofiltration

Other

Source: U.S. Department of Commerce Technology Administration, Bureau of Industry and Security.

Nanotechnology and the military sector

It is more difficult to find comprehensive statistical data concerning the development of nanotechnologies in the military sector. The Department of Defense accounted for about a third of the yearly budget that the US Congress had appropriated for FY 2003-2005 for nanotechnology R&D across all the agencies participating in the NNI (National Nanotechnology Initiative). For the period 2004-2006, the NNI changed its budget presentation around the notion of Program Component Areas (PCAs). This made it more difficult to single out how much of the general budget the US Congress appropriated to Defense for nanotechnology R&D, but the Department of Defense (DoD) appeared to count for about a quarter of the investment in nanotechnology research in the NNI in 2006 (US Department of Defense, 2005, NNI, 2007). Several new institutes focused on military applications, e.g. the Institute for Soldiering Nanotechnology at the Massachusetts Institute of Technology, the Center for Nanoscience Innovation for Defense at the University of California, Santa Barbara, and the Nanoscience Research Laboratory of the Naval Research Laboratory, which is funded with Military Construction (MILCON) funds. (Source NNI Budget

Documents, NNI, http://www.whitehouse.gov/omb/budget/fy2004/pdf/spec.pdf ; http://www.ostp.gov/html/budget/2005/FY05NNI1-pager.pdf)

In Europe, MINATEC was in 2008 the leading European nanotechnology research centre. It was based in Grenoble in France, but came from the association of several partners. Among the major partners were the French DGA (Délégation Générale à l'Armement) and CEA (Commissariat à l'Energie Atomique), and according to a report published by CROCIS (Centre Régional d'Observation du Commerce, de l'Industrie et des Services) in 2003, nanotechnology public research investments in France focused more on the military and energy sectors than on the health sector (Rigaud, 2003). Finally, the first plant dedicated to the production of nanoparticles in the UK was inaugurated in 2003 in Farnborough in Hampshire, and belonged to the QinetiQ Group. QinetiQ was created in 2001 as a Public-Private Partnership (PPP) takeover of part of the UK Ministry of Defence (the Defence Evaluation and Research Agency - DERA), and the Ministry of Defence was its largest customer. It became one of the world's leading defence technology and security companies. QinetiQ Nanomaterials Ltd, one of its spinout companies, became the largest nanometric materials and nanotechnology group in Europe (Source: www.qinetiq.com, accessed 10 August 2008). The proceedings from a workshop on nanoscience for the soldier sponsored by the US Army research Office summarise the dimensions explored to develop new products and services in this area (North Carolina Biotechnology Center, 2001).

Materials and Fabric

High strength, ultra light weight material, adaptive multifunctional materials (to make soldiers invisible, or for interactive clothing)

Power, Energy distribution and cooling

Revolutionary power sources to enable soldiers to operate autonomously for up to 144 hours i.e. six days; warrior body cooling devices to enable sustained performance under incapacitating environmental conditions (extreme heat, extreme cold, pollution or poisoned atmosphere).

Soldier status monitoring and modelling

Soldier status monitoring (operational capability, NBC detection (Nuclear, Biological and Chemical warfare), casualty monitoring), soldier performance prediction and enhancement, soldier casualty minimization.

Displays, detectors and antennas

Communications between "suit" and helmet/soldier, information management, security of soldier system.

Source: US Army Research Office

Nanotechnology and sustainable development

As to the field of sustainable development, it may become the leading entrepreneurial sector as the necessity to find new energy sources and to preserve the environment becomes more and more a priority. The United Nations Environmental Program (UNEP) published in 2007 a special section devoted to nanotechnologies in its yearly Global Environmental Outlook (GEO) (UNEP, 2007). A Canadian study released in April 2005 (Salamanca-Buentello F et al., 2005) focused on the potential use of nanotechnology to address some of the world's most critical development problems, and identified the ten applications of nanotechnology most likely to benefit developing countries, while demonstrating that these applications could contribute to the attainment of the United Nations Millennium Development Goals (MDGs). The study also showed that developing countries were already harnessing nanotechnology to address some of their most pressing needs. Although the study was done to account for the needs and development potential of developing countries, it could also apply to developed countries faced with sustainability issues. The ten applications of nanotechnology most likely to benefit developing countries were as follows:

1 Energy storage, production, and conversion

2 Agricultural productivity enhancement

3 Water treatment and remediation

4 Disease diagnosis and screening

5 Drug delivery systems

6 Food processing and storage

7 Air pollution and remediation

8 Construction

9 Health monitoring

10 Vector and pest detection and control

Source: www.utoronto.ca/jcb/home/documents/PLoS_nanotech.pdf

The study included references to the health sector, which shows how closely interconnected the potential developments of nanotechnology applications are.

Initial positive regulation

To discuss the influence of regulatory contexts on entrepreneurship in the nanotech sector I draw on a comparative analysis of the biotechnology case. I take as the origin of my study (like the origin of a graph) the discovery of the three-dimensional double helix structure of DNA by James Watson and Francis Crick in 1953. Although research is a continuing process and this discovery could not have happened without previous research leading to it, it is generally considered as the starting point of the emerging field of biotechnology. At this point of origin, the stakeholders were the scientists involved in the discovery, and their supporting institutions. Watson was American and Crick was British, but the discovery was made in England, at Cambridge University. When Watson and Crick discovered the double helix structure of DNA, they were not entrepreneurs, they were scientists. However, they quickly became entrepreneurs (as opposed to other scientists working in labs who did not take the same course of action) because they moved to work in new structures that would connect them to the market. As it happened, they both found these structures in the US:

Crick did brain research at the Salk Institute for Biological Studies in La Jolla, California, and Watson became director of the molecular-biology lab at Cold Spring Harbor, N.Y., and served as the head of the Human Genome Project.

The two most enabling features to attract them to their new institutions were regulation and funding, the two being very closely related. Firstly, American institutions clearly favoured an absence of restrictive regulation. In 1977, although sixteen bills had been introduced in the American Congress to regulate recombinant DNA research, particularly to prevent escapes of the developed products from the laboratory environment, no bill was passed. At the same time, the UK was one of the first countries to introduce regulation concerning research on genetic modifications: in 1976, the UK Medical Research Council set up the Genetic Manipulation Advisory Group (GMAG), and The Health and Safety (Genetic Manipulation) Regulations 1978 asked for the notification of any activity involving genetic manipulation.

The second stage was 'positive regulation'. Conversely to 'restrictive regulation', which is often seen as putting restraints on the development of technological innovation, 'positive regulation' is to be understood as regulation encouraging the development of an emerging field. Positive regulation took several forms in the US. For example, in 1980 the US Supreme Court ruled that genetically altered life forms can be patented, and granted scientist Ananda Chakrabarty a patent for oil-eating bacteria. This ruling opened up enormous possibilities for commercially exploiting genetic engineering, as patents enabled companies to begin cashing in on laboratory discoveries. This was positive regulation. Another piece of positive regulation came with the Bayh-Dole Act, enacted in 1980, which gave universities and non-profit institutions control of the inventions that arose from research supported by federal funding.

This was where regulation and funding closely interrelated: more than 60 percent of the Salk Institute for Biological Studies' research was funded by U.S. government grants. Thanks to the Bay-Dole Act, and with the help of the Salk's Office of Technology Management (OTM), which was created in the late 1960s to maximize patent protection and to facilitate the transfer of the Institute's technology to the market, technology management at the Salk Institute resulted in over 350 U.S. patents and more than 250 license agreements with pharmaceutical, biotechnology, and reagent supply companies. In addition, seventeen start-up companies were founded to develop Institute technology. With such enabling environment, the Salk Institute was an ideal place to foster academic technology transfer and this is one example among many successful ones: it led to advances in the medical and biotechnology industries thus creating hundreds of companies and tens of thousands of jobs in the San Diego region alone. Finally, regulatory support was boosted by political publicity: In 1981, Congressman Al Gore held a series of hearings on the relationship between academia and commercialisation in the arena of biomedical research. He focused on the effect that the potential for huge profits from intellectual property and patent rights could have on the research environment at universities.

Although Jonathan King, a professor at MIT speaking at the Gore hearings, reminded the biotech industry that "the most important long-term goal of biomedical research is to discover the causes of disease in order to prevent disease", from the early start, the prospect of huge economic returns was a key motivation for entrepreneurship. For example that same year, Hoechst AG, the West German chemical company, gave Massachusetts General Hospital, a teaching facility of Harvard Medical School, $70 million to build a new Department of Molecular Biology in return for exclusive rights to any patent licenses that might emerge from the facility. The Human Genome Project was another example of how the combination of regulation and funding led to entrepreneurship. It began formally in 1990, as an effort coordinated by the U.S. Department of Energy (DOE) and the National Institutes of Health (NIH) to map the position of every human gene and to read and decipher every message encoded in the twisted double helix of human DNA. It was originally planned to last 15 years, but rapid technological advances accelerated the completion date to 2003. The project later became truly international, but it nevertheless benefited from several hundred million dollars coming from the US DOE and NIH[5]. This huge investment of public money went along an enormous amount of knowledge transfer and business creation. In the genomics sub field alone, dozens of small companies sprung up to sell information, technologies, and services to facilitate basic research into genes and their functions.

To encourage the early development of nanotechnologies, the US followed the same model mixing funding and positive regulation. It added a new step to this strategy: integration. In 2001, the government created a single program centralising the major research efforts relating to nanotechnology: the NNI (National Nanotechnology Initiative). The NNI's website states that the National Nanotechnology Initiative (NNI) is a federal R&D program established to coordinate the multi-agency efforts in nanoscale science, engineering, and technology with the following aims:

1. Maintain a world-class research and development program aimed at realizing the full potential of nanotechnology
2. Facilitate transfer of new technologies into products for economic growth, jobs, and other public benefit
3. Develop educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology
4. Support responsible development of nanotechnology

Source: www.nano.gov, accessed July 2007.

[5] The often quoted figure of $3billion over a thirteen-year period covers a wide range of scientific activities related to genomics, of which the Human genome sequencing represents only a small fraction. For more detailed information concerning the Human Genome Project, see http://www.ornl.gov/sci/techresources/Human_Genome/project/budget.shtml

In 2001 at its birth, the NNI gathered six federal agencies. They were the Department of Defense (DOD), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), the National Institute of Health (NIH), the National Institute of Standards and Technology (NIST) and the National Science Foundation (NSF). In six years, this number rose to 25 federal agencies, among which 13 had a special nanotechnology R&D budget. During the same period, spending nearly tripled, from an estimated $464 million in 2001 to $1.4 billion FY 2007. The US centralisation promoted by the central government was instrumental in making the whole sector more efficient, and in promoting entrepreneurship. The report published in May 2005 by the US President's Council of Advisors on Science and Technology (PCAST, 2005) found that the U.S. was the world leader in nanotechnology as well as the acknowledged leader in nanotechnology research and development. The approximately $1 billion the Federal government would spend on nanotechnology R&D in 2005 was roughly one-quarter of the current global investment by all nations. Total annual U.S. R&D spending (Federal, State, and private) stood at approximately $3 billion, or one-third of the estimated $9 billion in total worldwide spending by the public and private sectors combined. In addition, the United States led in the number of start-up companies based on nanotechnology, and in research output as measured by patents and publications. The report concluded that the NNI appeared well positioned to maintain United States leadership going forward thanks to its coordinated interagency approach to planning and implementing a Federal R&D program. Therefore, PCAST recommended continued robust funding for the NNI.

In Europe nanotechnology only took off in the European Framework Programs covering all European research in 2004, with Framework Program 6 (FP6). Before that, the European Commission had launched in 2000 the European nanotechnology network Phantoms (see http://dbs.cordis.lu/fep-cgi/srchidadb?ACTION=D&CALLER=PROJ_IST-&QM_EP_RCN_A=53682 and http://www.phantomsnet.net). In 2004 the network included 237 partners from 32 countries, and gathered approximately 2100 researchers. However the partners did not all come from Europe. Eight partners were from the US, 2 from Canada, 1 from Argentina, 1 from Australia, 1 from Cuba, 1 from India, 1 from Israel,1 from Japan and 1 from Venezuela. Besides, the network was essentially a virtual structure of coordination and exchange or information.

In February 2004, the European Commission started a new structure, based in Grenoble in France and called Nano2Life (see http://www.nano2life.org), whose objective was to merge existing European expertise and knowledge in the field of nanobiotechnology. Nano2Life was tackling the fragmentation of European nanobiotechnology by joining 23 previously unconnected, highly specialised regions and centres with experience in initiating and running nanobiotech programmes. A pool of 41 high-tech companies was associated to the network. Nano2Life aimed at setting the basis for a virtual European Nanobiotech Institute, focused on the understanding of the nanoscale interface between biological and non-biological entities, and its possible application in the area of complex and integrated novel sensor technologies for health care, pharmaceuticals, environment, security, food safety, etc. However, there was still in 2008 no strict equivalent to the US NNI, even if coordination was well under way.

The overall structure coordinating European nanotechnology was Nanoforum, the European Nanotechnology Gateway (see www.nanoforum.org). Nanoforum is a virtual network which provides a comprehensive source of information on all areas of Nanotechnology. It was originally funded by the European Commission through FP5 in 2003. Since July 2007 it has been operating as a European Economic Interest Grouping (EEIG), giving it legal status and the ability to enter into contracts with other parties, including tenders and new EU-funded projects. In the early development of the nanotechnology sector, it is clear that the European lack of coordination was detrimental to entrepreneurship. According to a survey carried out by NanoForum (Nanoforum et al., 2004), North America was perceived to be the world leader both in nanosciences (76 percent of the respondents) and the transfer of nanotechnology to industry (77 percent of the respondents), with Europe and Asia falling far behind. The lagging behind was mainly attributed to a lack of a coherent system of infrastructure and the majority of respondents highlighted the need for a new large infrastructure at European (64 percent) level.

One may summarize the above by saying that just as it had played a key role in favouring entrepreneurship in the biotech sector, positive regulation was instrumental in giving the US a head start in the early emergence of the nanotechnology sector. The two most important features of this positive regulation were that it was about allocating money (and vast sums of it) to an emerging sector, and that it immediately aimed for the integration of the sector with the creation of a dedicated program, the NNI. The creation of this centralised institution preceded the writing of an act defining what was going to be done. This was done thanks to two texts. The first one, *National Nanotechnology Initiative: Leading to the next industrial revolution,* emanated from the US White House on 21 Jan 2000 and was a four-page press release with the following introduction:

> "President Clinton's FY 2001 budget request includes a $227 million (84 percent) increase in the government's investment in nanotechnology research and development. The Administration is making this major new initiative, called the National Nanotechnology Initiative (NNI), a top priority". (White House, 2000)

Then followed a brief summary of the potential breakthroughs nanotechnology might lead to, and an outline of the funding strategy. The second text, *21st Century Nanotechnology Research and Development Act - Act S 189*, was a Congress Act of ten pages explaining the functioning of a national nanotechnology program, which in other words was the functioning of the NNI, with a clearly dated and budgeted roadmap (US Congress, 2003).

In Europe, the process was in a way reversed; in 2005 two major defining texts had been written: *Towards a European Strategy for Nanotechnology* and *Nanosciences and Nanotechnologies: an Action Plan for Europe 2005-2009* (European Commission, 2004c, European Commission, 2005). Yet Nano2life (set up in February 2004) was still only the preparatory structure of a future European Institute of NanoBiotechnologies, and there was no single integrated European nanotechnology program. The tables of contents of the two European reports summarize the differences from the US approach (Fig 46 and 47). They show that the EU texts are much longer than the US ones. Contrary to the US texts, the European ones have no performative value in the sense that they do not *create* institutions, but they describe and define what is to become the field of nanotechnologies as conceived by the EU, with specific parts on safety, the third world, and the necessity to integrate energies.

Towards a European Strategy for nanotechnologies (28 pages)

Fig 46. Source: (European Commission, 2004c)

Nanosciences and Nanotechnologies:
an action plan for Europe 2005-2009 (12 pages)

Fig 47. Source: (European Commission, 2004c, European Commission, 2005)

Here is a summary of what differentiates the two approaches (Fig 48):

Two different visions of nanotechnology positive regulation

US: an act setting up an integrated structure

- *National Nanotechnology Initiative: Leading to the next industrial revolution*. US White House, 21 Jan 2000
- *21st Century Nanotechnology Research and Development Act*. S. 189. 108th Congress, 1st Session, 18 Nov 2003

EU: a strategic plan framing a field

- *Towards a European Strategy for Nanotechnology.* COM(2004) 338, European Commission, 12th May 2004
- *Nanosciences and nanotechnologies: An action plan for Europe 2005-2009.* COM (2005) 243, European Commission, 7th June 2005

Fig 48.

Initial restrictive regulation

At the end of 2006, the period considered for this analysis, US Federal regulation was gathered in the *United States Code* (Fig 49), the register of all US Federal regulation. In Europe, community regulation was gathered in the *Directory of Community Legislation* (Fig 50).

US Federal Laws.

Source: United States Code, last updated 2003

- General provisions
- The Congress
- The President
- Flag and seal, seat of government, and the states
- Government organisation and employees
- Agriculture
- Aliens and nationality
- Arbitration
- Armed forces
- Bankruptcy
- Bank and banking
- Census
- Coast guard
- Commerce and trade
- Conservation
- Copyrights
- Crime and criminal procedure
- Customs duties
- Education
- Food and drugs
- Foreign relations and intercourse
- Highways
- Hospitals and asylums
- Indians
- Internal revenue code
- Intoxicating liquors
- Judiciary and judicial procedure
- Labour
- Mineral lands and mining
- Money and finance
- National guard
- Navigation and navigable waters
- Patents
- Patriotic and national observances, ceremonies & organisations
- Pay and allowances of the uniformed services
- Veterans' benefits
- Postal service
- Public buildings, property and works
- Public contracts
- The public health and welfare
- Public lands
- Public printing and documents
- Railroads
- Shipping
- Telegraphs, telephones and radiotelegraphs
- Territories and insular possessions
- Transportation
- War and national defence

Fig 49

EU Community laws.

Source: Directory of Community legislation, 2005

- General, financial and institutional matters
- Customs Union and free movement of goods
- Agriculture
- Fisheries
- Freedom of movement for workers and social policy
- Right of establishment and freedom to provide services
- Transport policy
- Competition policy
- Taxation
- Economic and monetary policy and free movement of capital
- External relations
- Energy
- Industrial policy and internal market
- Regional policy and coordination of structural instruments
- Environment, consumers and health protection
- Science, information, education and culture
- Law relating to undertakings
- Common foreign and security policy
- Area of freedom, security and justice
- People's Europe

Fig 50

In the US as in Europe, this regulation constituted the minimum requirement which must be respected by all the parties (the states in the US, and the various EU members in the EU). This meant that individual states in the US, and individual EU members in the EU *might* have additional regulations if they wished, but *must* comply with the existing regulation. In the EU, the acceding member states (in 2006, the EU consisted of 25 Member states) had the obligation to fully and correctly transpose and implement the 'acquis communautaire' by the date of accession so as to guarantee equivalent rights and obligations to all citizens of the enlarged European Union. The ‘acquis communautaire’ amounted to some 1,600 directives. As from the date of accession the acceding countries were monitored in the same way as the previous member states and a regular publication reported the monitoring and compliance issues (European Commission, 2004b). Eur-Lex, the portal to European Union law (http://europa.eu.int/eur-lex/en/index.html) also provided studies and statistics concerning the application of community law in member states. In the US, individual states must follow Federal regulation more or less in the same way, and on the whole, both systems worked in a fairly similar manner.

However, the contents of regulation were quite dissimilar. The first EU mention of the ‘Precautionary Principle’ was in the environment title of the Treaty of Maastricht establishing the European Community in 1992 (European Community, 1992). At that stage the notion was mentioned in the context of marine pollution and only referred to, not defined:

> 2. Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay…
>
> Source: *The Maastricht Treaty*, Title XV1, Environment, Article 130r, 2, p.37.

In 2000 the EU wrote a complete text of reference concerning the precautionary principle called the “*Communication from the Commission on the precautionary principle, COM (2000) 1*”(Commission of the European Communities, 2000). This then served as a basis for all EU regulation, and there was no counterpart in the US legislation. The most important area of disagreement with US law circled around the following statement:

“The absence of scientific proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure should not be used to justify inaction.”

Source: Communication from the Commission on the precautionary principle, COM (2000) 1: p17.

In essence, what this rather confusing statement meant was that decisions could be taken against some specific products, even in the absence of *proof* that they were dangerous. The US rejected the precautionary principle, considering that until something was proved harmful, it was not to be considered so. The US chamber of commerce specifically stated that it opposed the adoption of the precautionary principle as the basis for regulation.

U.S. Chamber Strategy:

- Support a science-based approach to risk management, where risk is assessed based on scientifically sound and technically rigorous standards.
- Oppose the domestic and international adoption of the precautionary principle as a basis for regulatory decision making.
- Educate consumers, businesses, and federal policymakers about the implications of the precautionary principle.

Source: US Chamber of Commerce, Regulatory Reform Issues, Precautionary Principle (US Chamber of Commerce, 2005), update 5th September 2005. See also (U.S. submission to the April 10-14 Codex Alimentarius meeting in Paris addressing U.S. concerns over EU communication to the Codex on "precautionary principle.", 2000).

Regulatory frameworks and exogenous factors

Trying to explain why there are different economic or political patterns has been at the heart of a lot of scholarly research at least since the 19th century and de Tocqueville's *De la démocratie en Amérique (1835)* (Kagan, 2004, Tocqueville, 1999, Kotkin, 1994). Most comparative studies have drawn from cultural factors to explain differences observed in various economic systems or, more recently, to account for dissimilarities between national attitudes towards economic power, freedom of trade or regulatory matters (Kohler, 2008, Pape, 1999). According to Pape, in spite of differences between various countries, Europe has on the whole traditionally supplemented market economy with a social component, while the American form of anglo-saxon capitalism is marked by a strong Darwinist pioneer spirit, as well as by a high level of antagonism between the private and public spheres in general.

This leads to substantial differences between US and European law. These differences appear clearly in the way exogenous factors are taken into account in rule making and the emergence of regulatory frameworks. I will start by defining what I mean by exogenous factors. Regulation usually results from the actions of official bodies working according to a democratically accepted procedure. I call external stakeholders individuals or groups of individuals who do not connect to the area of rule making by any lucrative activity. Scientists, policy makers, regulatory bodies are all 'inside stakeholders' because at least part of their revenues come from their involvement with the area covered by the regulatory framework. The connection between exterior stakeholders and the area is a non profit one. They have no commercial connection with the area. The forces they represent may take the forms of lobbies, pressure groups, community representatives and so on. I call their actions 'exogenous factors'.

There is a wide difference between the US and the EU in the robustness of regulation to exogenous factors. Exogenous factors were increasingly part of the law making process in EU regulation, and their 'voice' was heard at an initial stage: when, in 1978, the United Kingdom was the first country in the world to pass legislation controlling genetic modification, the initial thrust had come from scientists themselves (Berg, 1975). These were inside stakeholders. But the restrictions they obtained were quickly eased and research carried on. However, when in October 1990 all the European Union (EU) nations adopted two European Council Directives governing the "contained use" and "deliberate release" of genetically-modified organisms (GMOs)[6] into the environment, the regulations came as answers to growing public concern initiated and relayed by NGOs.

We find the same permeability to exogenous factors in the early talks about the regulation of the nanotechnology sector. In June 2003 in Brussels, a seminar discussing the current state of nanotechnology, examining its risks and promises and proposing steps towards regulating the technology was jointly sponsored by the Greens/EFA in the European Parliament and by several NGOs (ETC Group, Greenpeace, Dag Hammarskjold Foundation, Genewatch UK, Clean Production Action). The report from the European parliament, '*Nanotechnologies: a Preliminary Risk Analysis on the Basis of a Workshop Organized in Brussels on 1-2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission*' (European Commission, 2004a) was based on a consultation which involved about 20 nanotechnology specialists, mostly scientists, but also the Chief scientist of Greenpeace UK, an environmental group. The report concluded that the behaviour of nanoparticles deviated from the matter at the macroscale, with sometimes diverse effects on environment and health, and that the existing regulations did not cater for the differences. It stated that there might be a need for new regulation, and that 'the Precautionary Principle suggested avoiding the release of nanoparticles in the environment.

[6] Contained use: Directive 90/219/EEC, later replaced by Directive 98/81/EC.
Deliberate release: Directive 90/220/EEC, later replaced by Directive 2001/18/EC.

In the last couple of decades, the US has eschewed exterior stakeholders' views, and aimed for *voluntary* nanotechnology regulation (Forrest, 1989, Reynolds, 2001, Reynolds, 2002, Wardak, 2003, Wardak, 2004). This was confirmed by an article from *The Scientist* of June 2005 (Pitman, 2005):

> 'The Environmental Protection Agency (EPA) is spearheading moves to voluntarily regulate the introduction of nanoscale materials in a variety of applications, including the cosmetics and toiletries market'.
>
> Source: S. Pitman, 'US authorities aim for voluntary nanotechnology regulation', *The Scientist*, 9 August 2005.

Essentially, in the areas of the environment and public health, there are four major regulatory agencies in the US: the Consumer Product Safety Commission (CPSC), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHIA). There might be other agencies that can impact the environment and public health, like Federal Communications Commission and Department of Agriculture, but they do not have an immediately foreseeable role in nanotechnology. The four agencies above have direct regulatory or standards development power. They have the authority to prohibit substances, food, drugs, products, and/or workplace practices. These regulatory agencies (CPSC, EPA, FDA, and OSHA) all provide "notice(s) of proposed rulemaking." The rulemaking is the regulatory action to be undertaken on a product, and it is printed in *The Federal Register*. The notice is an advance warning. In a span of approximately sixty days, any concerned party outside of the regulatory agency can seek input into the decision. If enough public comment is given or for other reasons, it precipitates a public hearing on the proposed rulemaking. Once the 60-day period has passed, the rulemaking is again published in *The Federal Register* and this determines the final rule. The rulings can be found in either *The Federal Register* or the *Code of Federal Regulations* (CFR).

These regulatory bodies are quite impervious to exterior stakeholders, as is illustrated by the case of titanium dioxide. As sunscreens' active ingredients have evolved, the regulations have changed in kind, and there have been numerous issues with sunscreens for the last 26 years. One of the most significant rulings was recent. In 1999, the FDA ruled that micronized titanium dioxide was not a new substance relative to its larger particle size counterpart.[7] With this ruling, the FDA denied the existence of nanomaterials as distinct from their macroparticle equivalents. This meant that in spite of the different properties of the molecules at the Nanoscale or at the micro scale, the companies which marketed the products using nanoscale titanium dioxide did not need to proceed to any specific toxicity test because the molecules were not considered as new chemicals. Although it received a public comment in support of considering micronized titanium dioxide as a new ingredient, the FDA, "[did] not consider micronized titanium dioxide to be a new ingredient but consider[ed] it a specific grade of the titanium dioxide originally reviewed by the Panel."[8]

Another sign of the robustness of the US regulatory system to exterior stakeholders was a resolution which was introduced in the US Senate in March 2005:

> Expressing the sense of the Senate that judicial determinations regarding the meaning of the Constitution of the United States should not be based on judgments, laws, or pronouncements of foreign institutions… (109th Congress, 1st Session, 20 March 2005. S. RES. 92)

This statement clearly indicated that the US did not intend to modify its regulatory system to integrate a foreign perspective – another form of exterior stakeholders.

[7] 64 F.R. 22671-22672 (21 May 1999).

[8] 64 F.R. 22671 (21 May 1999).

Impact on entrepreneurship

In a paper exploring the variation in rates of entrepreneurship in the United States from 1899 to 1988 (Shane, 1996) Scott Shane expanded on the work of Schumpeter (Schumpeter, 1939, Schumpeter, 1947) to explain that entrepreneurs, rather than managers in established firms, are the ones who see the opportunity for most of the new production functions. His reasoning was that new technological developments are often so different from the way in which existing technology works that they cannot be incorporated into the technological framework of existing firms. The conflict between the demands of the new technology and the production function of the established firm means that managers in established firms are less likely than entrepreneurs (who are not reliant on the existing production function) to accept the new technology. With new technologies like nanotechnologies, because of the importance of research and initial investments, entrepreneurship tends to happen at the level of institutions or organisations with university spin outs or corporate start-ups, but it follows the same model: entrepreneurs are not reliant on existing production functions. So when biotech or nanotech entrepreneurs want to use the opportunities created by scientific inventions to produce new combinations of factors of production, they look for the most favourable environment to transform these opportunities into profitable business activities.

This explains why the US had a head start in entrepreneurship in the biotech and nanotech sectors. Entrepreneurs go where the terrain is most favourable and initially, US regulation made the terrain more favourable. From the outset with the biotech sector, and then with the emergence of the nanotech sector, the US provided a mixture of positive regulation and absence of a regulatory framework which fostered entrepreneurship in these sectors. However, entrepreneurship in new technologies is volatile. Entrepreneurs adapt very quickly to try and always find themselves in the most favourable environment to generate new institutions creating future goods and services around an emerging technological field.

The EC laws about the development of genetic engineering had rapid effect on the sector. In October 1990 when all the EU nations adopted two European Council Directives governing the "contained use" and "deliberate release" of genetically-modified organisms (GMOs) into the environment, this restrictive piece of legislation led to a shift in entrepreneurship. Between 1998 and 2004, no new GMOs were authorised for planting or use in the EU until the issues of traceability and labelling were resolved. In April 2004, new European directives[9] allowed the trade of some approved GM products, but the new rules from Brussels stated that – above a threshold of 0.9 percent – all ingredients that contained or consisted of genetically modified organisms, or contained ingredients produced from GMOs, must be labelled and traceable. The rules also set up a centralised procedure to consider applications to grow and market GMOs in the European Union. According to a 2003 European Commission survey of private biotech companies and public research institutes (European Science and Technology Observatory, 2003), 39 percent of the respondents cancelled research projects on GMOs during the years 1999-2003, and in the private sector alone, 61 percent of respondents cancelled research projects in this field. Between 1998 and 2001, the number of notifications for GMOs' field trials in the EU decreased by 76 percent.

The figures showed that Foreign Direct Investment (FDI) was also affected by up to 50 percent between the first term of 2003 and the first term of 2004. This trend reached far beyond Europe, and the biotechnology sector was affected worldwide. For example, in 2003, Uganda refused to grow a disease-resistant GM banana out of fears it would lose its European market. The Company Bayer Cropscience India announced in November 2004 that it had stopped all its work on creating new GM crops in India, and would concentrate on

[9] (EC) 1830/2003 on the Traceability and Labelling of GMOs and (EC) 1829/2003 on Genetically Modified (GM) Food and Feed.

conventional plant breeding. It also stopped all trials of GM Oilseed Rape in Australia. In effect this entailed that entrepreneurship was changing to accommodate EU regulation. If we look at R&D as an indicator of entrepreneurship, we find that the decline was stronger in the US than in Europe. Research from Ernst & Young's European Investment Monitor (Ernst & Young, 2003) showed a decline of 11 percent in R&D in the European biotechnology industry between 2002 and 2003, and a decline of 17 percent in R&D in the US biotechnology industry for the same period.

Conclusion

In *The Competitive Advantage of Nations* (Porter, 1990) explained that it was by understanding the reasons for the ability of a nation's firms to create and sustain competitive advantage in particular industries that one could find clues to the competitive advantage of nations. In the ten years that elapsed since the first publication of the book, globalisation changed much of the facts and data, and the rise of the EU as an economic entity means that the notion of the competitive advantage of nations has shifted towards that of blocs (China, the EU, the US…). At the same time, entrepreneurship in emerging fields, and particularly in the biotech and nanotech sectors, has become one of the drives of the competitive advantage of the economic blocs. One conclusion of this chapter is that to uphold the competitive advantage that nanotechnologies may create the US and the EU regulatory systems provide each their own way of encouraging entrepreneurship in this field. The case of biotechnologies suggested that while the US regulatory system initially fostered entrepreneurship by providing a favourable environment to entrepreneurs, the constraints of EU regulation led to shifts in entrepreneurship alongside wealth destruction (Auplat, 2006). In other words, entrepreneurs who complied with the EU regulatory environment may have found themselves in a better position than those who did not in the long run.

What does it mean for my study? My empirical analysis of archival sources and patenting activity allowed me to conclude in the previous chapter that although there were still important structural differences between the approaches of the three major players – the US, the EU and Asia – there was a move towards an alignment of the major areas of development of nanotechnologies. Another finding was that sustainable development was increasingly perceived as a driver for nanotechnology entrepreneurship. In this part, I focused on regulatory practices to illustrate how they accompany and to a certain extent shape entrepreneurship. One of the provisional conclusions of the two chapters is therefore that institutional emergence – the creation of new institutions or the modification of existing ones – reflects the two distinctive features of nanotechnology entrepreneurship: the importance of sustainable development and the progressive alignment of areas of entrepreneurship. In the next chapter, I will probe a particular case of nanotechnology institutional emergence to continue my analysis of its mechanism.

INNOVATIVE PRACTICES AND NANOTECHNOLOGY INSTITUTIONAL EMERGENCE

Introducing the case of the ETC Group, one of the first NGOs to have brought nanotechnology to public attention

At this point of the study it might be necessary to recapitulate where we stand and where we are aiming. I established in the introduction that the development of nanotechnologies signalled important changes affecting the economic paradigm as well as a deep societal transformation. I explained in chapter 3 that nanotechnologies could not be considered as an institution as such, but were shaping a new transversal field which was spreading progressively and was likely to affect most human activities one way or another. I stressed that understanding how this field emerged was at the core of my study because the development of the field was bringing about a whole new ensemble of structured social practices including new institutions – what I called nanotechnology institutional emergence. I postulated that nanotechnology institutional emergence was the result of the interactions of some groups of actors or stakeholders along the following model:

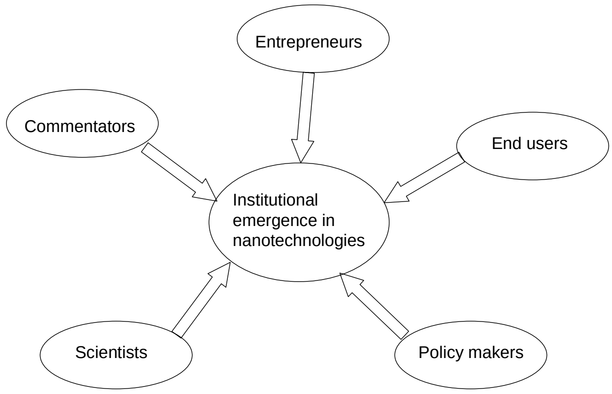


Fig 1

In chapter 4, I clarified the design of my study: articulate research around the intersection of five units of analysis with two transversal themes in order to show the specificity of nanotechnology institutional emergence. The units of analysis are the entrepreneurs, commentators, scientists, policy makers and end users and the two transversal themes are entrepreneurship and institutional entrepreneurship. I focused on the actions of *scientists* in Chapter 3 and Chapter 6. I looked at the actions of *entrepreneurs* in chapter 5 and at those *policy makers* in Chapter 6. At this point in the study, I start integrating the parameters that have emerged to analyse how they combine together. To do so, I look at one particular aspect of institutional entrepreneurship dynamics: the integration of civil society in the process of institutional emergence. I focus on one case study: the ETC Group. The ETC Group – usually regarded as the first NGO to have brought nanotechnology to public attention – was virtually unknown a decade ago. Through a longitudinal analysis over a five year period, I examine its role and that of its leader in the early design of new regulatory frameworks and institutions around the development of nanotechnologies. I show that a combination of innovative practices, the use of an entrepreneurial toolbox and bricolage allowed it to become an OPP – Obligatory Passage Point as developed by Callon and Latour (Akrich et al., 2006) – in the process of institutional emergence, thereby giving birth to a new form of institutional dynamics where decision making is becoming a complex, multi-stakeholder process.

A large body of literature has emerged through the last two decades to consider how new forms of organisation arise and become established in the organisational community. The literature represents a very wide array of theoretical perspectives, and various streams of research have sought to explicate the nature of contexts and processes that may generate new organisational forms. This analysis situates itself in the theoretical perspective of an emergent social systems view which considers variations in organisational forms to be the products of embedded social-organisational interactions (Romanelli, 1991). I consider the rise to prominence of the ETC group as part of a social movement acting outside of institutional channels to promote change in society, what (Gamson, 1995) defined as a challenging group. Considering that in the case of the ETC group, success means being accepted by institutions as a legitimate organisation addressing valid concerns, I build on Gamson's work to assess the different variables that may have contributed to the group's success in achieving its goal (Gamson, 1990).

As mentioned earlier, the development of nanotechnologies is recent, but it diffuses very fast and very broadly, and it is likely to bring deep and radical changes to society. It constitutes an ideal empirical field to analyse the emergence of new institutions in real time because it raises questions linked not only to entrepreneurship and innovation, but also to risk management and to ethics. Risk management may well be the cornerstone of institutional entrepreneurship in nanotechnologies. It may be *the* explanation to the interactions of the different groups of stakeholders which I mentioned in my model. The development of any new technology raises issues relating to risk management, i.e. to the process of measuring or assessing risk and developing strategies to manage it (Johnson and Covello, 1987, Cothern, 1995, Vogel, 2003, Singh, 2006). The difficulty with nanotechnologies is that it is at the present time extremely difficult to measure or assess the risks linked with the development of nanostructures. There are three major reasons for this. Firstly, the majority of the nano effort is still at the research stage, which means that the risks that may or may not exist concern essentially the scientists themselves. They are only really beginning to develop nanostructures in a stable and measurable way and toxicity assessment standards and protocols are largely non-existent (Wiesner et al., 2006). Secondly, because nanoparticles are so small, it is very difficult to trace them and to assess their inherent risks. At present, people lack the tools to trace and measure the potential risks induced by these particles. One speaks here of monitors as well as of modeling capacities. The only certainties are that nanoparticles are so small that they can cross most barriers and filters including cell barriers within living organisms, and that due to quantum effects it is still difficult to predict their behaviour in many cases. There is an increasing number of safety related studies concerning the use and development of nanotechnologies, but the results diverge hugely (Lam et al., 2004, Warheit et al., 2004, Oberdörster G et al., 2002). As Roure and Dupuy, the two co-authors of a French report on nanotechnology industrial prospective put it:

> 'We stumble collectively against the lack of results of impact studies, against the absence of risks characterization, against the difficulty to assess their nature and financial valuation in terms of insurance liabilities and against the obvious shortage of adequate conceptualisation.' Source (Dupuy and Roure, 2004):39

Finally, a third source of risk comes from uncertainties surrounding what will be produced: at the current stage of knowledge, no one knows how much will be produced, and how the nanomaterials will be used.

It was in this context that Pat Mooney and his NGO, the ETC Group (pronounced etcetera), the Action Group on Erosion, Technology and Concentration came to prominence in the nanotechnology debate, with a twofold position on nanotechnology:

1. Requesting the establishment of a moratorium on the commercialisation of new products containing novel, engineered nanoparticles until lab protocols are established to protect workers, and until regulations are in place to protect consumers and the environment.
2. Requesting the creation of an International Convention for the Evaluation of New Technologies (ICENT), 'a new body dedicated to track, evaluate and accept or reject new technologies and their products'.

The first public reference to nanotechnology coming from the ETC Group dates from 2001, with a report called *the ETC Century* (Mooney, 2001). The NGO had started its activities a few years before by focusing on seeds, genetic erosion, corporate concentration in the fields of pesticides and seeds and intellectual property monopolies over life forms and biotechnology issues. Pat Roy Mooney, the co-founder and executive director of the ETC Group, was born in Brandon, Manitoba, Canada, in 1947. What is commonly known about him is that he is a father of five and is legally blind, and that he did not receive university training. He is also known to have lived most of his life on the Canadian prairies. Yet, to take the terminology of (Callon, 1986) the NGO and its executive director had become in 2006 an OPP - an Obligatory Passage Point - in the nanotechnology debate. How did this come about and what roles did the man and his organisation play in this debate? What was their part in the emergence of new institutions around the development of nanotechnologies? Could the answers to these questions provide an outline of a theory of a new form of institutional emergence around specific knowledge structures?

Theoretical background

Institutional theory provides a theoretical model of analysis for the process of institutional construction which fits well with the development of nanotechnologies as a field

(Lawrence et al., 2002, de-Holan et al., 2004, Phillips et al., 2004). However, the exploration of the impact of Pat Mooney's innovative practices on the emergence of new institutions leads to revisit some of its conclusions in organisational analysis, notably about embeddedness and institutional isomorphism (DiMaggio and Powell, 1983, DiMaggio, 1988, Jepperson, 1991). Indeed, the findings of this chapter illustrate two important phenomena. Firstly, they show that the extent of Pat Mooney's influence on the institutionalisation of nanotechnology is directly linked to his innovative practices. The importance of innovative practices in explaining the success of institutional entrepreneurship is an area which has not received a great deal of attention until recently (Clemens, 1993). Secondly the study corroborates the findings of other works showing that innovation processes themselves are more like bricolage than the traditional linear model of innovation would suggest (von Hippel, 1977, Garud and Karnoe, 2003, Baker and Nelson, 2005). The exploration of the haphazard nature of innovation processes is an important and under-researched field, particularly in institutional entrepreneurship. The study shows that in Pat Mooney's case, although the succession of events and decisions bringing them to their particular place on the nanotechnology scene appeared to follow a clear strategy, it was also a combination of chance opportunities. It also demonstrates that it was because of the 'un-embedded' nature of its strategy that the NGO received sufficient support to emerge as an Obligatory Passage Point in the nanotechnology debate.

The notion of OPP was initiated by the work of Callon, Latour et al. on Actor Network Theory (ANT) and on the sociology of translation in the 1980s (Callon et al., 1986, Akrich et al., 2006). This work focuses on the institutionalisation of science and technology, without a particular emphasis on nanotechnologies. However I consider that the model they developed is quite useful in our case. According to them the institutionalisation of science and technology rests on a chronological process which includes several steps. The time sequence of this process is as follows: firstly, there is the appearance of a series of apparently disconnected facts. These facts give rise to *a controversy* over their value and validity. Controversy is followed by *translation*, an operation which consists in creating a common language of reference so that the previously unrelated entities can be connected and seen in interaction. The process of translation gives unity and intelligibility to things which would otherwise have remained obscure and disconnected. It also allows the institutionalisation process to move into the domain of public understanding. This process happens through the *network*, an ensemble of meta-organisations including human and non-human *actants* which interact together.

For Callon, Latour et al., and as they illustrate with various cases, it is not an intrinsic value which lies at the root of scientific institutional emergence, but the *settlement of a controversy* over the validity of new facts through the interactions of the various actants of a network. In other words, science and technology firstly emerge as disconnected facts and gradually stabilise and acquire ontology through the settlement of controversies concerning their validity. This analysis has led them to propose a method in ten steps to account for institutional emergence or change. The initial step is the situational analysis of the context in order to identify all the actants. The final one concerns the spreading of the network and the necessity of transparency to keep the actants' trust. The turning point of the institutionalisation process is what they call the OPP, the Obligatory Passage Point. Although Callon-Latour have not specifically explained it, they probably borrow the expression Obligatory Passage Point (in French: '*Point de Passage Obligé*', or PPO) from the French maritime vocabulary, where it referred to a particular place which sailing boats had to go through if they wanted to reach a certain destination. For example, the Cape of Good Hope was an OPP for Portuguese sailors wanting to reach the Far East. Even if they knew it was a dangerous place, they could not ignore it, and they could not take another route. They had to go through it. In the ANT context, the obligatory passage point may refer to a physical or virtual location i.e. to a geographical place but also to a specific situation gathering certain actors, or to a type of discourse. It is the place (geographical, physical or institutional) or the discourse that cannot be ignored or done without during the institutionalisation process.

In Callon's empirical case study of the domestication of the scallops of the bay of St Brieuc (Callon, 1986), three researchers had tried to farm scallops in Brittany. These three men were institutional entrepreneurs because they wanted to modify the institutional context in which they operated in order to create a new institution: scallop farming. They also constituted an OPP because their discourse gave its orientation to the venture which they had initiated. They had become the 'head' of several populations – experts, fishermen and crustaceans – and all the stakeholders of the debate over scallop farming in France knew about their experience, referred to it, and acted according to it (whether to agree with it or to reject it). Likewise, in 2006, the ETC Group and its executive director had become in 2006 an OPP in the nanotechnology debate. They could be seen as institutional entrepreneurs because they were trying to modify the institutional context in which they operated, either with the creation of a new institution (the ICENT - International Convention for the Evaluation of New Technologies) or with the modification of existing ones (changing regulation to request the establishment of a nanotechnology moratorium). They became an OPP because the other stakeholders could not ignore them. Whether they thought the ETC Group created a danger or not, whether they liked it or not, they could not do as if it did not exist.

One of the contributions of this study is to illustrate that it is by integrating the findings of both the institutional entrepreneurship literature and the entrepreneurship literature that one can find the best interpretation as to why Pat Mooney and his NGO had become an Obligatory Passage Point in the institutionalisation of nanotechnologies in 2006. The two strands of literature have gradually been moving closer to each other, institutional entrepreneurship towards entrepreneurship notably with writings on the mobilisation of resources (Dorado, 2005) or on new practice creation (Lounsbury, 2007) and entrepreneurship towards institutional entrepreneurship with work on entrepreneurship in the non-profit sector or in criminal activity among others (Tone, 2000, Friman, 2001, Tracey, 2005). In this chapter, I build on some findings of the entrepreneurship literature to interpret the success of an institutional entrepreneurship venture. To the tantalizing question of how to account for successful entrepreneurship, the entrepreneurship literature has produced interesting insights which I put to the test of institutional entrepreneurship in this study. Among the salient features is the importance of innovation, technological innovation as well as resource management innovation (von Hippel, 1977, Aldrich and Zimmer, 1986, Zucker and Darby, 1998, Pinchot and Pellman, 1999, Gaglio, 2004). I find that this, in combination with a first mover advantage (Lieberman and Montgomery, 1998, Lieberman and Montgomery, 1988), constitutes the most valid explanation to account for the success of the institutional entrepreneurship venture of Pat Mooney.

Methodology

The methodology rests on extensive archival research, complemented by in-depth interviews (Foddy, 1993, Rubin and Rubin, 1995, Denzin and Lincoln, 2000, Wengraf, 2001). Archival research included regulatory archives, media archives as well as industrial archives and the archives of the ETC Group. In their discussion about structuration and institutionalisation, (Barley and Tolbert, 1997) stressed that the investigation of how patterns of interactions lead to the emergence of a new institution was a difficult task and that to account for the links between actions and the emergence of new institutions, it was important to have a dynamic model rendering structuration through time. In my case, the interviews were conducted over a period of four years, between 2003 and 2007. I met the NGO leader several times, and crossed the information coming from these interviews with interviews of key stakeholders in the nanotechnology debate: researchers, entrepreneurs, journalists and nanotechnology officials of various national and intergovernmental institutions. The interviews took place in Belgium, Canada, France, the UK and the US (see appendix for a chronology of nanotechnology involvement by the ETC Group). A template for the analysis was drawn from DiMaggio's statement that institutional changes 'arise when organised actors with sufficient resources (the institutional entrepreneurs) see in them an opportunity to realize an interest that they value highly' (DiMaggio, 1988):14. So I started my study of the ETC Group as an institutional entrepreneur by identifying the actors and looking at how they were organised. Then I looked at what resources they used and how they mobilised them, and finally, I analysed how they 'realised an interest that they value highly'.

According to a study released by the Centre for Applied Studies in International Negotiations in 2006 there were about 60 non-governmental organisations involved in nanotechnology advocacy globally in 2006 (Lee and Rwanda, 2006). The authors' classification was rather loose, involving Trade Unions and Consumer associations, or regional chapters of the same NGOs. It also listed without discrimination organisations seeking to enhance the development of nanotechnologies as well as organisations aiming to restrict it. This list was helpful but only to a certain extent as it included entities that were either too dissimilar to draw any conclusion, or on the contrary too close together (regional chapters of the same NGO). In order to find answers to my research question of why had the ETC Group and its executive director become an OPP in the nanotechnology debate in 2006, I needed to compare the NGO with other similar ones. So to make comparisons relevant, I focused on NGOs with a similar mission statement to that of the ETC Group. As it happened, for all these NGOs, the focus on nanotechnology was only *a part* of their activities on a broader scale. None of these NGOs had been started in an ad hoc way simply to discuss the case of the development of nanotechnologies. Their common denominator was that one of their stated objectives was *to preserve the environment and encourage sustainable development*. This pool produced a list of a dozen NGOs. To assess their relative importance I checked the number of internet occurrences of their name in association with the term nanotechnology with a search engine. Although it is a rather crude way of estimating the importance of non-governmental organisations in the nanotechnology debate, it clearly shows a group of five NGOs standing out with a number of occurrences over about 200 000, with a sharp drop to fewer than 60 000 hits for all the others (Fig 51). The drop is so important that it validates this rather simplistic approach.

NAME	**Number of occurrences**
ETC Group	1.000.000
Friends of the Earth	991.000
Environmental Defense	829.000
Greenpeace	295.000
Sierra Club	185.000
OXFAM	63.000
WWF	47.400

Fig 51. Compilation dated 27 February 2007

Since my purpose was to understand the innovative practices which had enabled the ETC Group to reach prominence, I decided to consider only the first five NGOs in my study.

Actors

The following table (Fig 52) summarises key data relating to the five NGOs.

Name	Mission statement	Date of creation	Membership
ETC GROUP	Dedicated to the conservation and sustainable advancement of cultural and ecological diversity and human rights. To support socially responsible developments of technologies useful to the poor and marginalized. To address international governance issues and corporate power.	1984 in Canada under the name of RAFI. Took its current name in 2001	No members
FRIENDS OF THE EARTH	To challenge the current model of economic and corporate globalization To promote solutions that will help to create environmentally sustainable and socially just societies	1969 in the United States Became an international network in 1971	The world's largest grassroots environmental network Approximately 1.5 million members and supporters around the world
ENVIRONMENTAL DEFENSE	To link science, economics and law to create innovative, equitable and cost-effective solutions to society's most urgent environmental problems. To pay special attention to U.S. environmental problems and to America's role in causing and solving global problems, and to share approaches internationally.	1967 in the United States	Speaks for 500 000 members
GREENPEACE	To expose global environmental problems, and to force solutions for a green and peaceful future, using non-violent, creative confrontation. To ensure the ability of the earth to nurture life in all its diversity.	1969 in Vancouver, Canada Became the Greenpeace Foundation in 1972	An estimated 2.8 million financial supporters
SIERRA CLUB	To explore, enjoy and protect the wild places of the earth. To practice and promote the responsible use of the earth's ecosystems and resources. To educate and enlist humanity to protect and restore the quality of the natural and human environment. To use all lawful means to carry out these objectives.	1892 in the United States	America's oldest and largest grassroots environmental organization Over 750 000 members

Fig 52. Data sources: NGO websites and annual reports. Own compilation of data, 2007.

The first two features that stand out when comparing the ETC Group with the four other NGOs are its size and its management model. The ETC Group is extremely small in size. It has eight permanent staff who do not all work full time. Accountancy services are outsourced to a consultant. The Board of Trustees which oversees the organisation comprises a President, a Secretary-Treasurer and six other members (this number can vary a little). Then, the ETC Group is the only organisation without members. Its management does not want it to grow and considers that if it grows, it will be by accident, not by intent. This raises the following questions: How can such a small structure have reached such prominence in the nanotechnology debate? What innovative processes have enabled it to compensate its lack of human capital? Is the small number itself part of the efficiency process? How?

Resources

When talking about resources, one common starting point is financial resources (Fig 53 and 54). The following table (Fig 54) compares the budgets of the five NGOs and the origins of their funding. One word of caution here: it is a fact that NGOs have greatly improved the transparency of their accounts, simply by having them audited and made public, very recently in some cases. As an example, it was only in August 2005 that Greenpeace international had 100% of its accounts audited (Greenpeace, 2005). However, the arcane nature of NGO funding still makes it quite difficult to interpret. For the sake of clarity, the table below only mentions the financial data relating to the *international* NGOs cited. But, for instance, Greenpeace international is an NGO with affiliates in over 40 countries worldwide, each being run independently. The major source of funding of Greenpeace international comes from contributions from the regional offices. But there is a large gap between the budget of Greenpeace international and the total of the budgets of the regional offices. In 2005, the total net unrestricted assets of Greenpeace international amounted to 45.7 million euros, but the total of all the unrestricted assets of the Greenpeace groups globally was 129.4 million euros. Similarly, when NGOs give the sources of their funding, it is not easy to interpret the statements. For instance, some say they do not accept money coming from corporations or governments, yet they are subsidised by foundations which are themselves directly funded by corporations.

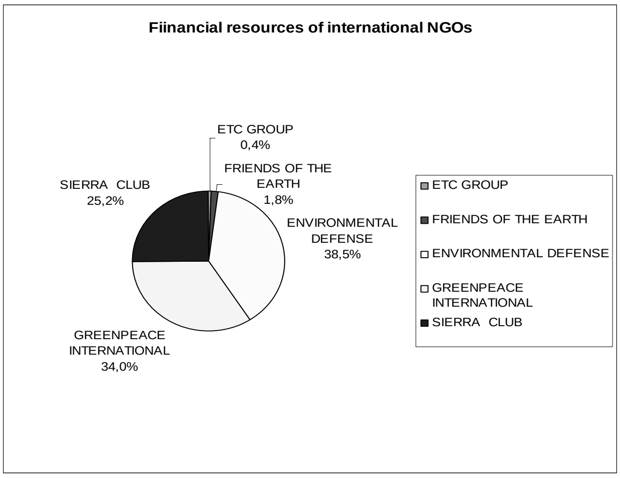


Fig 53.

Financial resources of international NGOs

ALL DATA: 2005

Name	**Financing: total net unrestricted assets**	**Sources of finance**	**Place of registration of the international NGO**	**Headquarters**
ETC GROUP	587,200 euros	100% coming from grants from various foundations.	the Netherlands	Ottawa, Canada Winnipeg, Canada, until 2004
FRIENDS OF THE EARTH INTERNATIONAL	2.38 million euros	90% coming from individual members and supporters	the Netherlands	Amsterdam, the Netherlands
ENVIRONMENTAL DEFENSE	51.7 million euros	59% coming from members, 32% coming from grants from foundations, 1% coming from government and other grants, the rest from bequests from members of the Osprey Society,investment income and other revenue	the US	New York, the US
GREENPEACE INTERNATIONAL	45.7 million euros	Income of Greeenpeace International**:** Over 95% coming from grants and donations from individuals or charitable foundations, the rest from merchandising and investment. Does not accept funding from governments or corporations.	the Netherlands	Amsterdam, the Netherlands
SIERRA CLUB	33.9 million euros.	Income of Sierra Club Foundation: Mostly coming from private funds and individual contributors. Accepts funding from corporations.	the US	San Fransico, CA the US

Fig 54. Sources of data: annual and financial reports of the NGOs. Own compilations, February 2007.

Until 2005, the ETC Group relied only on funding coming from governments or foundations. This meant that the very small staff did not need to spend time resources on securing funding. This is itself an important element in explaining their efficiency in relation to their small size. The NGO also went against the usual idea (at least in the US) that the best way to achieve efficient lobbying was to set up offices at the foot of Capitol Hill. Its headquarters were until 2004 in Winnipeg, a small town of Manitoba in Canada, quite remote from both political and scientific central spheres.

ETC Group Revenue in euros - 2005

Swedbio	195 190
CS Fund	62 418
Canadian International Development Agency	96 853
IDRC	67 012
Lillian Goldman Charitable Trust	46 425
Ford Foundation	39 664
Educational Foundation of America	40 346
CBDC	17 137
Other	22 787
Total	**587 832**

American source	
Canadian source	
Swedish source	
Other	

Fig 55. Source: ETC Financial report, 2005

The table above (Fig 55) shows that approximately a third of the ETC Group's funding came from organisations supported by the Canadian government, another third from organisations supported by the Swedish government, and the rest from American private foundations. Clearly, the financial resources of the NGO were small. This was in itself a reason for showing innovation in their management. Financial efficiency was a leitmotif of the NGO and finding solutions to have the most cost efficient clout was part of its essence. But this also meant that the prominence achieved by the NGO could not be ascribed to its financial resources. So we have to look elsewhere to understand what brought the ETC Group to the front in the nanotechnology debate. We can also renew the questions asked after the description of the actors: How could a structure with so few financial means have reached such prominence in the nanotechnology debate? What innovative processes enabled it to compensate its lack of capital?

Resource management

In this chapter, the focus is on an early-stage process of institutional creation. There was in 2006 no 'nanotechnology industry', or 'nanotechnology sector'. Regulation has often been described as a pillar of institutionalisation (Scott, 1995); there was at that time no specific regulation pertaining to nanotechnologies. Scientists even argued whether there was such a thing as 'nanotechnology research'. It is at this early stage, indeed, that one can observe the work of institutional entrepreneurs: Pat Mooney and his NGO took part in many of the debates and their voice was heard. Between 2003 and 2006, 421 articles were written in English language about the ETC Group and his executive director, in publications as varied as the Taipei Times, the Washington Post, Forbes or the St Petersbourg Times. Pat Mooney spoke about nanotechnologies at the European Parliament in Brussels, as well as at various hearings and testimonies worldwide. His name and that of his NGO appeared alongside those of top scientists in conference proceedings. It is impossible to say that they were responsible for a particular orientation in the debate, for example that they contributed to the cancellation of some specific nano-projects or to the introduction of particular pieces of legislation. Neither their demand for a moratorium on the commercialisation of engineered nanoparticles or their request for the creation of an International Convention for the Evaluation of New Technologies (ICENT) was successful. Yet they achieved, in spite of their minuscule size and lack of financial means, the position of OPP (Obligatory Passage Point) in the debates: they participated in the major discussions, and references to the position of civil society invariably included allusions to them. In the following part, I analyse how their innovative practices allowed them to make up for their lack of human and financial capital.

Rhetoric

Institutional researchers have begun to explore the importance of rhetoric and discourse in the institutional process (Phillips et al., 2004, Suddaby and Greenwood, 2005, Maguire and Hardy, 2006, Phillips and Malhotra, 2008). In this study, I show that rhetoric is a tool which enables the ETC Group to aggregate a particular community which in turns provides access to various institutional levies (science, policy, regulation…). As has been mentioned before, Pat Mooney, the NGO leader, had no university training. He acknowledged that his Research Director, Hope Shand, played an instrumental role in putting together the reports which contributed greatly to the recognition of the NGO, thanks to her technical writing and research skills. One thing he did not say was that he was himself extremely articulate, with a particular gift for finding catchy formulas. The rhetoric of the ETC Group had some very distinguishable features.

Firstly, it introduced neologisms. The ETC Group regularly introduced new terms or concepts. Not all remained, far from it, but a few did, and they contributed to strengthen the identity of the NGO. Two neologisms that have remained were biopiracy (introduced in 1993), and terminator seeds (introduced in 1998). Both terms were coined when the main involvement of the NGO was the loss of agricultural genetic resources and the erosion of biodiversity, with a desire to protect small farmers against the overriding force of big agribusinesses. Pat Mooney explained that in the order of things, they identified the technology, gave it a name, and then went to get support to ban it. In their newest reports, the ETC group continued to introduce neologisms. Some examples were: atomtechnology, BANGS (bits, atoms, neurons and genes), or ICENT (International Convention for the Evaluation of New Technologies). Only time will tell whether these will remain, but the NGO leader stated clearly that finding good names was an important part of the success of ‘projects’ as he called them.

Secondly, it combined detailed – mostly accurate – scientific facts with anecdotes that tended to be unexpected. Several scientists pointed out the somewhat bizarre rhetoric of the NGO, where “Ninety percent is real material and then they came up with something that is disconnected” (Stuart, 2003). This technique may irritate scientists, but it attracted the attention of the general public. It contained a lot of puns which drew the reader’s notice and kept him entertained or at least alert. The language itself was a mixture of very topical and sometimes colloquial references with articulate notions requiring some academic culture spelled out in a rather elaborate style. A few examples will illustrate this point; A report on the increasing concentration of the world’s resources in the hands of a few started with the heading “**the Equity Erosion E=TC2**” and went on to explain:

> ‘It does not require an Einstein to recognize the new equation of power: The exponential erosion of our biosphere – coupled with the erosion or our ability to understand the biosphere – coincides with a similarly exponential expansion of our technical ability to manipulate large living systems, safely or otherwise. What remains of diversity, and the technologies thrust upon diversity, are falling into the hands of corporate oligopolies’. (Mooney, 2001):18)

A recent report on attempts to alter the earth's climate stated that:

> 'Paul Crutzen returned to the debate, stirring up a real tempest in a teapot in August 2006 when he wrote an "editorial essay" in Climatic Change magazine calling for active research into the use of "sub-micrometer"-sized sulfate-based aerosols to reflect sunlight in the stratosphere in order to cool the earth. Crutzen, a professor at the Max-Planck-Institute for Chemistry in Mainz, Germany, opines that high-altitude balloons and artillery cannons could be used to blast sulfur dioxide into the stratosphere, in effect, simulating a volcanic eruption.' (Mooney, 2007):6)

These examples illustrate the combination of plays on words, disconnection between the seriousness of the subject and the tone used, and rather sophisticated technical references.

Thirdly, the ETC Group rhetoric involved regular historical comparisons and references. These were carefully chosen to appeal to the largest possible audience, spanning regional cultural differences. They tickled the reader's brain and called on his general culture, creating what could be called a 'spirit of connivance': the reader's understanding of the reference rested on a shared cultural heritage, and the rhetoric therefore created a sentiment of belonging, belonging to an international cultural elite. They also gave the demonstrations a 'common sense' feel. Being put into an historical perspective, the NGO statements acquired a timeless value. Here is an example of a very common rhetoric practice:

> '"The main reason for productivity gains [during the Renaissance] was technological progress…," historian Carlo Cipolla insists, looking back on the explosion of wealth during that period. The productivity of Italian weavers doubled and then tripled—even without the textile machinery that became the trademark of Britain's Industrial Revolution centuries later. Gutenberg's first printers churned out three hundred pages a

day. By the end of the Renaissance, a printer could produce four times that amount. Between 1350 and 1550, English iron production rose seven or eightfold. Many of the Renaissance advances came in the areas of shipping and trade. Before Columbus, the crew-to-cargo ratio was one sailor for every five or six tons. The Dutch achieved a ratio of one man per ten tons by the end of the Renaissance. Five hundred fifty years later: info, nano, and bio' (Mooney, 2003): 7).

Fourthly, the ETC Group used cartoons and drawings in its reports and publications. They followed the same pattern as the word rhetoric, relying on a mixture of humour, call on the reader's general culture, and clash between technical accuracy and incongruity (Fig 56).

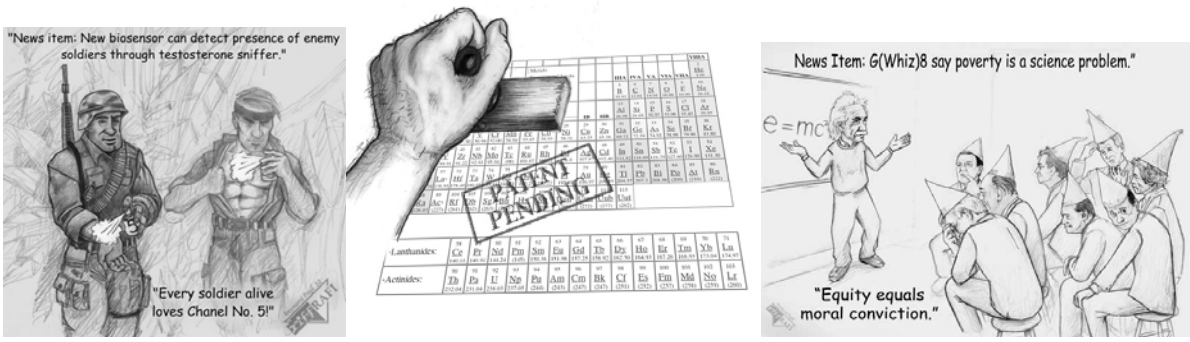


Fig 56: Some examples of ETC cartoons. Source : http://www.etcgroup.org/en/materials/cartoons.html
drooker(at)drooker.com ; reypage(at)shaw(dot)ca; s(at)shtig(dot)net; www.shtig.net .; http://www.drooker.com/

This analysis complements the work of researchers like (Suddaby and Greenwood, 2005, Maguire and Hardy, 2006) who show the importance of rhetorical strategies in aggregating a community around a common theme – an essential step towards institutional change. Indeed, it is by rallying a large enough number of people who showed interest for the issues relating to nanotechnology that the ETC Group could start the process of bringing the topic on public tables of discussion.

IT

Internet Technology was at the core of both the innovative practices and the management of the NGO. Not surprisingly, the ETC Group had close relationships with Sweden, one of the pioneering and most advanced nations in terms of Internet use. This gave it an edge and the NGO relied on IT from the start. In terms of management, Pat Mooney explained that the three major assets of IT use for them were that the technology was very cheap compared to usual means of communication, that it enabled them to overcome time differences easily and to stay in touch permanently, and finally that it allowed them to act fast, one of the critical factors of success according to the NGO leader.

The early use of IT was also part of the NGO's innovative practices. It enabled them to spread their work quickly and broadly. Contrary to a lot of organisations who sell their reports, from the start, the NGO made everything it produced freely available on the Internet. This gave them an advantage as they were precursors in doing so and it strengthened the initial recognition of their work. Finally, IT was from the start a cheap and easy source of information for them. They were innovative in that they understood this sooner than others.

A lot has been written on IT use in the entrepreneurship literature. A search of academic journals based on the terms Internet or IT and Entrepreneurship returned 30 500 hits in May 2007, showing the interest of researchers for this area. Yet not much has been written on the importance of IT use in institutional entrepreneurship. One interesting conclusion of this study is that successful institutional entrepreneurship may be explained by similar patterns of behaviour as successful entrepreneurship. IT use is a case in point.

Language outreach

The NGO may have been a precursor in its early widespread use of IT. Its outreach would not have been the same if it had not been coupled with the vision of giving output in

Spanish and Portuguese as well as English. It had started with its work on seeds, and the credibility it acquired with this issue gave it a strong advantage at the beginning of the nano issue (Hardon et al., 2005). From the start the ETC Group communicated in English and Spanish, and constant efforts were made to further increase the number of languages in which publications or statements were released, in French, Portuguese, Swedish and German among other languages. The initial will to reach both the Spanish and English speaking communities globally had an enormous influence on the visibility of the NGO. Besides, at the beginning of the IT revolution, most of the data circulating on the internet was restricted to the English speaking constituency, so data coming from the English speaking world but made accessible in Spanish had great appeal to Spanish speaking people, particularly in South America. As a result, Pat Mooney and his team were able to gain global recognition – and in a way some sympathy – quickly. In 2005, out of the ten countries which most frequently accessed the ETC website, 5 were Spanish speaking.

Networks

The entrepreneurship literature is extremely clear that social ties are of vital importance for the success of new business ventures (Aldrich and Zimmer, 1986, Dubini and Aldrich, 1991, Uzzi, 1997, Hoang and Antoncic, 2003, Yli-Renko et al., 2001, Clarysse et al., 2005). This study shows that social ties also constitute an element of paramount importance to explain *institutional* entrepreneurship. It confirms previous findings of the entrepreneurship literature on the necessity of a combination of weak and strong ties to guarantee both innovation and stability. These are key features of successful business ventures (Lawrence et al., 2005, Karra, 2006). They are also essential in the success of *institutional* entrepreneurship ventures. The ETC Group is in fact run by a very small group of people who have known each other for thirty years, have evolved together and have followed the same ideals, although not always the same paths. The core of the group was constituted by three persons: Pat Mooney, Cary Fowler and Hope Shand, who began working together in the mid 1970s, at that time on seeds issues and the preservation of agricultural biodiversity.

In 2007, the ETC Group staff was based in four locations: three persons in Canada (Ottawa), two in the US (North Carolina), two in Mexico (Mexico City) and one in the UK (Oxford). Pat Mooney and his staff considered that the small size was an important way of achieving efficiency because the chains of communication were simple and because personnel problems could be solved very easily, or prevented from happening. Decision making could be very fast. To optimize this, the NGO made the best use of IT to remain in constant contact in different locations and time zones.

One explanation to the incredible efficiency of the NGO in relation to its small structure and lack of human capital comes from what Latour et al. called 'actants' to denote the human and non-human actors giving shape to a network by their interactions (Latour et al., 1986). In the ETC Group case a key actant was the Dag Hammarskjöld Foundation. The stories of the NGO and of the foundation were closely intertwined. The Swede Dag Hammarskjöld was the second Secretary-General of the United Nations, from 1953 to 1961. The Foundation which bears his name was set up in his memory in 1962 in Uppsala, Sweden.

The ETC Group was built on the same model as this organization in terms of human resources: the Dag Hammarskjöld Foundation has an extremely small staff of only two professionals and three secretaries, one of them part-time. It also has a very long-lasting structure with hardly any turnover: the current Director, Olle Nordberg, took over from his predecessor Sven Hamrell in 1994. Sven Hamrell had been the foundation's director since 1967 and had been working with Olle Nordberg since 1969. The beginning of the collaboration between the Dag Hammarskjöld Foundation and the ETC Group dated back to 1981. Sven Hamrell was the first president of RAFI, the ancestor of the ETC Group, and Olle Nordberg had been on the ETC Board since its creation. Both organizations had the same model of management, and both had the same strategic vision: identifying causes and fighting for them. They both very much dealt in foresight. They also both aimed at altering institutions. The Dag Hammarskjöld foundation constituted a key actant in shaping a network of interactions that might fashion the nanotechnology debate because it provided the ETC Group with resources. The resources were not strictly financial ones. The Dag Hammarskjöld foundation was not on the list of the funding agencies of the NGO. However, it had been instrumental in publishing the first reports of the ETC Group and co hosting conferences with it. According to a study by the California Institute of Public Affairs, the success of the Dag Hammarskjöld foundation itself, in relation to its extremely small size and budget, rested a lot on 'mystery, loyalty and democracy' and on 'having a lot of friends and drinking together'. (Trzyna, 1990). This operating mode was also what can explain the success of the ETC Group.

These very strong ties, involving a very close knit community, were what held the NGO together, what gave it its stability. Other strong ties existed with the funding agencies, and with the governments of Canada and Sweden. Apart from these, the other ties were on the contrary rather weak. For example, although the ETC Group worked closely with the NGO Environmental Defence on some issues, it did not hesitate to lambaste it for its proposed collaboration with Dupont on nanotechnology in early 2007. These weak ties connected the ETC Group to the fringes of other organisations, and corroborated the findings of institutional researchers that Powell and DiMaggio's analysis of embeddedness had to be somewhat qualified: neither isomorphism nor embeddedness can give a full account of institutional change, and it is by looking at the fringes of organisations that one can find the origins of institutional change (Greenwood and Suddaby, 2006).

The ETC Group was at the centre of a network of interactions which was progressively giving ontological coherence to the institutionalisation process. The following chart (Fig 57) outlines the main ties which constituted this network of interactions.

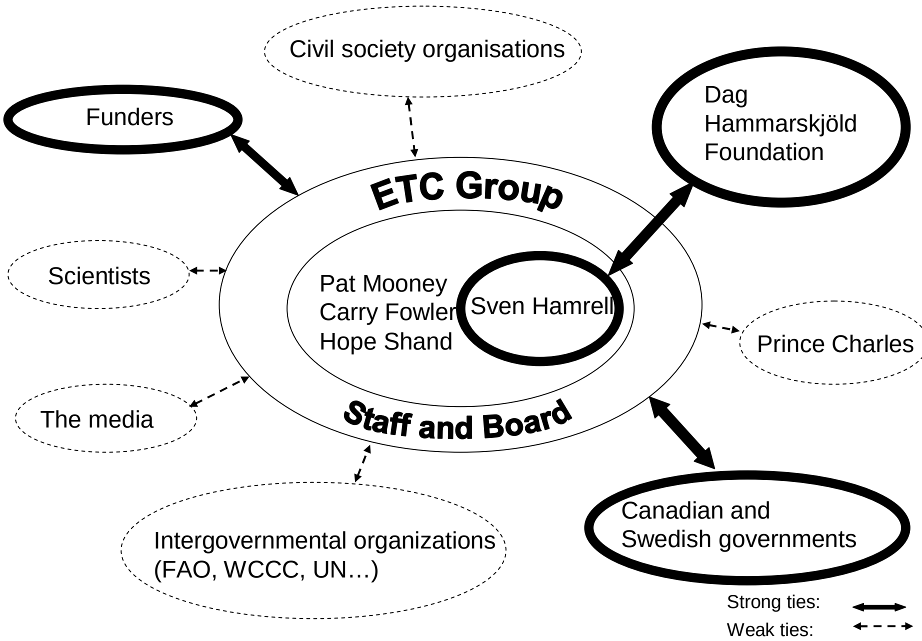


Fig 57. Summary of the network of interactions around the ETC Group

In this chart, embeddedness is illustrated with the ties with the Dag Hammarskjöld foundation, funders, possibly the governmental ties, and those with civil society organisations. A distinctive feature of the ETC Group was that most of its offices were shared with other, larger NGOs. This was an efficient way of reducing costs, of course, but not only. On the one hand, the close proximity of the other NGOs boosted the knowledge capacity of the ETC Group, but more importantly, it also provided a multiplier effect which increased diffusion and impact. Fringe relations cover all the other ties. It was because the discourse of the ETC Group was new to the world of Prince Charles that he was intrigued enough to invite some of its members to tea to debate nanotechnology issues with representatives of the Royal Society. Although the ETC Group staff members were clearly not scientists, or *because* they were not scientists, eminent researchers like Professor Vyvyan Howard, who was until 2004 President of the Royal Microscopical Society, agreed to co-author a report with them (ETC Group, 2003). The same can be said of the ties with the UN and other intergovernmental agencies. Pat Mooney made it clear in his interviews that he wanted to stay on the periphery of these organisations, that he did not seek to be too closely connected to any of them. Combining weak and strong ties, embeddedness and fringe relations was part of his strategy.

Chance, first mover advantage and life-cycle issues

I already mentioned that the success of Pat Mooney's venture can be explained in part by the theory of the first mover advantage (Lieberman and Montgomery, 1988, Porter, 1998). Indeed, the NGO was the first one to voice public concern about the risks associated with nanotechnologies. In an interview he gave me in May 2004, the NGO leader elaborated on the NGO move to the issue of nanotechnologies. He explained that they had first spotted the issue more or less by chance in the eighties as part of their routine of scouring the scientific press. They had thought the issue was fascinating and had started building a thin file on it. At that time, the hot issue was biotechnologies and the NGO's major activity was to rally other NGOs to the cause of biotechnologies. They had looked at biotechnologies long before the other NGOs did and spent years trying to tell other NGOs that they should take this seriously, looking at the implications… They found that by the late nineties they were successful in the sense that a wide range of NGOs had taken on the issue of biotech, and as a very small organisation they were faced with the choice of staying involved in that issue or getting involved in a new cause, which is what they did. Although retroactively people said that there was a connection between nanotech and biotech, this was not the way things had happened for the NGO. This analysis provides empirical support to Romanelli's analysis of emergent social systems (Romanelli, 1991). It corroborates the theory that technological innovation is a dynamic social process which, as it unfolds, creates the resource space that will support the new firms reflecting new organisational forms. It also supports the theory of life-cycles. Organisations compete for resources, and appropriability, and have to move on to new targets once they have reached the peak of their efficiency at their own level (Noymer, 2002).

Findings

Assessing the relative success of the institutional entrepreneurship venture of Pat Mooney and his NGO was no easy task, especially since the process was not complete when the field research ended. In 2007, there had not been a moratorium on nanotechnology research, and there had not been a creation of an ICENT (International Convention for the Evaluation of New Technologies). However, what the NGO had achieved was:

- Stirring up a controversy
- Being part of the debates about the creation of new institutions, mainly regulatory institutions, but also ethics groups overseeing technological developments.

What it could claim to have achieved is:

- Contributing to putting nanotechnology regulation on the agenda
- Contributing to a slow down of research in some areas
- Contributing to a new societal approach of technological progress

Interestingly, and this was definitely part of the NGO strategy, the ETC Group was very modest about its role. It did not boast about its participation in influential meetings, and the lists of key events relating to the various milestones of the development of an institutional framework around the development of nanotechnologies tended to overlook its own involvement. (See for example Mooney, 2005). Yet it can definitely be said that Pat Mooney could be considered an institutional entrepreneur. He played an active part in the emergence of an institutional framework around the development of nanotechnologies. What is of particular interest is that he had apparently everything against him in this venture: He is a person with a handicap (functionally blind), with no university training, no particular scientific background, living in a remote place in Canada and with quantitatively very few human or financial assets. It was by using the entrepreneurial toolbox of business entrepreneurs that he achieved what he did. The important elements of his success were:

- his character, personal dynamism,
- capacity to motivate
- strong ties and network
- vision
- use of IT

Using these tools in an innovative way including language outreach, the ETC Group aggregated a community of supporters who provided access to decision makers. Most observers agree that one of the main differences between the early development of nanotechnologies and that of biologies which took part thirty years before was that civil society was involved in the discussions from a much earlier stage, with, therefore, a different institutionalisation process. The ETC Group was the first NGO to bring civil society into nanotechnology discussions, and it can be said that one of its roles was to give some legitimacy and recognition to the voice of NGOs in institutionalisation processes.

Where does this take us in relation to the model of nanotechnology institutional emergence presented in Figure 1? Clearly, this chapter deals with what I called **commentators**. The term commentator was meant to have a very generic meaning. A commentator can have several roles. It may be someone who observes and comments on something, but also someone who reports and analyses events. The ETC Group belongs to this group of stakeholders because of its self-described role: The NGO’s mission statement is to address international governance issues and corporate powers in order to support socially responsible developments of technologies useful to the poor and the marginalised (see Fig 52). The advocacy role of the NGO consists in commenting on the development of nanotechnologies, and reporting its own analyses of the situation. Several conclusions can be drawn there. I explained in chapter 4 that in order to capture the specifics of institutional emergence around the development of nanotechnologies, I had chosen to develop a few case studies illustrating relevant parameters, considering that the replicability and generalizability of my findings would be the test of the validity of the method. In this section, I have drawn from interviews and archival analysis to establish the influence of one group of stakeholders, the commentators, on nanotechnology institutional emergence. Within my general objective to provide a conceptual framework of nanotechnology institutional emergence I have focused with this particular case on the integration of civil society in the process as one sign of the specificity of nanotechnology institutional emergence. A first contribution of this study is to initiate a theoretical debate on the changes taking place in institutional dynamics.

In this chapter, I offer some explanations to understand the role of civil society in nanotechnology institutional emergence. One set of explanations relates to the means used by NGOs to become part of the institutionalisation process: they act like business entrepreneurs. In other words, NGOs become institutional entrepreneurs by using the same toolboxes as entrepreneurs. Although the term ‘business plan’ never came up in discussions, it was obvious that the ETC Group followed clear internal guidelines with specific ‘customer’ (audience) targets, ‘product/services’ (what Pat Mooney called projects) identification and launch timelines, resource mobilisation and risks and exit strategies. Like business entrepreneurs, Pat Mooney identified and exploited opportunities for new ventures and he combined existing resources and used new ones in order to do so.

One major difference between him and a business entrepreneur was that his venture was clearly not about making money. Generally speaking, entrepreneurs explicitly seek to make profit, this is their unequivocal motivation. With institutional entrepreneurs the case is more difficult because their common motivation is not so straightforward. Put simply, they aim to create new institutions or to alter existing ones, but there is no single obvious reason for doing so. DiMaggio referred to 'an interest that they value highly', but without details. Is it power? Is it social recognition? Is it something else? When the director of the Dag Hammarskjöld Foundation was asked how the foundation decided what to do next, how it identified the fields on which it focused, he replied that they basically worked on hunches and intuition (Trzyna, 1990). Asked the same question, Pat Mooney observed that they tended to go where their loves took them. Although these replies may not tell the whole truth, they do confirm the findings of Garud and Karnoe that there is always a certain amount of bricolage in path creation (Garud and Karnoe, 2001). They also lead to another set of explanations to account for the role of NGOs in institutional dynamics. This time, the findings do not relate to the *means* allowing institutional entrepreneurs to shape the process of nanotechnology institutional emergence. They shed light on the *reason why* this can happen.

I explained in the introduction that nanotechnologies had arrived at a point in time when technological progress and social evolution had reached a point of convergence with the awareness of the importance of sustainable development for the economy as well as for the general public. This global awakening to the importance of sustainable development, coupled with the widespread use of information technology, modified the model of institutional emergence known with previous new technologies as described by Callon et al. As I explained at the beginning of this chapter (*methodology*), the common denominator of all the NGOs involved in nanotechnology advocacy in 2006 was that one of their stated objectives was to preserve the environment and encourage sustainable development. So it may be inferred that the common 'interest which they valued highly' was precisely the defence of sustainable development. This was precisely what the general public was beginning to feel the need for. What happened between 2003 and 2006 was that an NGO like the ETC Group was the most visible structured group available to relay the public's concern for sustainable development in the field of nanotechnologies. It could comment on some of its aspects. One of the characteristics of institutional emergence in nanotechnologies is that for the first time the voice of civil society groups was heard from the start. This could happen for two reasons: the cause of sustainable development had acquired enough legitimacy (even if it was very little) to be impossible to bypass, and there was a structured organisation available and altogether acceptable by all parties to voice concerns.

NEW INSTITUTIONALISATION PROCESSES: RISK MANAGEMENT AND PUBLIC ENGAGEMENT

Introduction

In this chapter, I bring my exploration of the co-industrial and institutional emergence of nanotechnology to a close by focusing on end users. I give the phrase ‘end users’ a very broad meaning. The Pew Charitable Trusts and the Woodrow Wilson International Center for Scholars run a project called PEN (Project on Emerging Nanotechnologies) which was launched in 2005 (http://www.nanotechproject.org/inventories/consumer/). Part of this project is to provide an online inventory of all nanotechnology-based consumer products currently on the market. The most recent inventory, dated 21 August 2008, listed 807 different products produced by 420 companies located in 21 countries world-wide. The figure below (Fig 58) shows the broad categories under which these products fell.

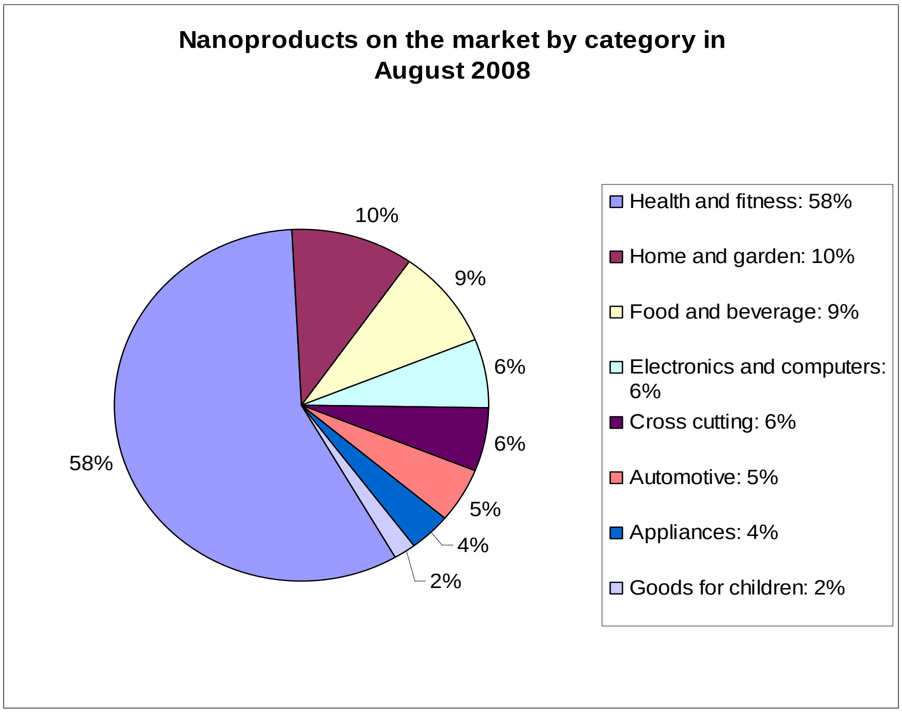


Fig 58. Source of the data: PEN project. Own chart.

The PEN project recalls that nanoproducts promise to change everything from the cars we drive to the clothes we wear, from the medical treatments our doctors can offer to our energy sources and workplaces. Its list of goods and services to come, from new cancer therapies to pollution-eating compounds, from more durable consumer products to detectors of biohazards like anthrax, from novel foods to more efficient solar cells, illustrates how nanotechnologies are changing the way people think about the future. However, in 2008 nanoproducts were used by only a *very small* proportion of the global population. So my use of the term ‘end-users’ refers to people who may not be current users of nanoproducts, but potential ones. It also refers to people who may end up being affected by nanoproducts although they did not choose to. As was explained earlier, nanotechnologies can in theory affect absolutely everything, since they correspond to modifications of matter at the atomic level. So they can potentially diffuse so much as to concern the whole of mankind under various forms, including those released incidentally in the environment or by-products. End-users in this sense refers to all those who will be affected willy-nilly by nanotechnologies as these start disseminating in our daily lives.

As the process of diffusion is spreading, numerous groups of stakeholders are affected by them. These stakeholder groups have their respective value systems to characterise the importance of various parameters. For example, start-up companies will focus on the great benefits of growing markets for their nano-based products. Insurance companies need to know how much to charge for premiums based on the risk they are taking on when insuring the nanotechnology industry. Users of products containing nanomaterials – notably in the health sector – want to enjoy the benefits of the new products but are very concerned about the safety of being exposed to them. It is the interactions of these different stakeholder groups, each managing nanotechnology-related risks with their varying value systems and priorities, which shape the institutionalisation of the field. In this chapter, I focus on end-users in order to assess their role in the process of institutional emergence. To do so, I study the case of public engagement experiments. Public engagement experiments probably constitute the most legible indicator of end-users' interactions with nanotechnologies. They also reflect their concerns and their perceptions of risk issues. My study shows that the current path of nanotechnology development gives rise to a new form of participatory risk management which includes a mechanism of aggregation of the expectations of the various stakeholders in the risk management process. This constitutes a change in risk management and this form of risk management is one of the characteristics of nanotechnology institutional emergence.

A chronology of institutional emergence

Once again, this chapter is firmly anchored in institutional theory. It integrates the findings of institutional economics which establish relations between the performance of economies and institutions and institutional change (North, 1990). Institutional theory also provides the theoretical model of analysis for the process of institutional construction around the development of nanotechnologies which I examine below (de-Holan et al., 2004, Lawrence et al., 2002, Lawrence and Suddaby, 2006, Lounsbury, 2007, Phillips and Brown, 1993, Phillips et al., 2004, Tracey, 2005). My objective here is to contribute my own interpretation of the institutionalisation process by focusing on risk management dynamics. After showing how risk was gradually institutionally integrated in the development of nanotechnologies, I analyse some of the characteristics of the new form of risk management that is emerging. I find that the development of nanotechnologies signals a new form of institutional emergence.

In his landmark study of institutions and organisations, (Scott, 1995), aiming to organise an hitherto somewhat nebulous field of research, devised a classification scheme which could encompass the numerous existing conceptions of institutions. He set up a typology around three types of analytical elements which could be found in various institutional carriers: regulative, normative and cognitive. He called these institutional pillars, meaning that they were at the heart of institutions. Much discussion has taken place about the validity of this typology, and Scott himself considered that the three pillars were on the whole interdependent and mutually reinforcing. Yet even though some critics later argued that some elements might be placed in more than one section and that the borders between the three pillars were hazy, by considering these independently he was able to shed light on the essence of institutions in a way that had not been done before (Dacin, 1997). In this study, I follow Scott's route in that I look at sets of analytical elements which are found in the various institutional processes accompanying the emergence of nanotechnologies as a field. But I depart from his work in that my aim is not to categorize various forms of institutions. Instead, I seek to unpack a particular process of institutional emergence. So my typology is not about the sets of elements which constitute institutions. It is about sets of elements which are at the heart of the institutionalisation process. I call these pillars 'pillars of the institutionalisation of nanotechnology'.

Chronologically, it seems that it was North America and the UK who produced the first bases of two pillars of the institutionalisation of nanotechnology as I define them. These were an institutional pillar-base and a non-governmental pillar base.

Institutional pillar-base, phase one

In 2001, the US created a single program centralizing the major research efforts relating to nanotechnology, the NNI (National Nanotechnology Initiative). Before this decision, nanotechnology R&D was a haphazard smattering of various unconnected initiatives, in the US and everywhere else. The NNI pursued the following aims:

- Maintain a world-class research and development program aimed at realizing the full potential of nanotechnology
- Facilitate transfer of new technologies into products for economic growth, jobs, and other public benefit
- Develop educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology
- Support responsible development of nanotechnology

(souce: www.nni.org, accessed July 2006).

The report published in May 2005 by the US President’s Council of Advisors on Science and Technology (PCAST, 2005) found that the U.S. was the world leader in nanotechnology as well as the acknowledged leader in nanotechnology research and development. It concluded that the NNI appeared well positioned to maintain United States leadership going forward thanks to its coordinated interagency approach to planning and implementing a Federal R&D program and recommended continued robust funding for the NNI.

The creation of the NNI was followed by the publication of the S 189 Act which defined the program in section 2, as:

(10) Ensuring that ethical, legal, environmental, and other appropriate societal concerns, including the potential use of nanotechnology in enhancing human intelligence and in developing artificial intelligence which exceeds human capacity, are considered during the development of nanotechnology by:

(A) Establishing a research program to identify ethical, legal, environmental, and other appropriate societal concerns related to nanotechnology, and ensuring that the results of such research are widely disseminated;

(B) Requiring that interdisciplinary nanotechnology research centres established under paragraph (4) include activities that address societal, ethical, and environmental concerns;

(C) Insofar as possible, integrating research on societal, ethical, and environmental concerns with nanotechnology research and development, and ensuring that advances in nanotechnology bring about improvements in quality of life for all Americans; and

(D) Providing, through the National Nanotechnology Coordination Office established in section 3, for public input and outreach to be integrated into the program by the convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events, as appropriate (US Congress, 2003).

With the creation of the NNI and the following S 189 Act, the US set a double trend: the need to coordinate all nanotechnology research, and the necessity to assess and address societal implications all along the way of the development of nanotechnologies. This was the first basis of the institutional pillar of the institutionalisation of nanotechnologies. In the wake of the American launch most nations and regional powers like the EU saw the importance of coordinating nanotechnology research and giving it some guidelines. Nowhere did the word 'risk' appear in these US texts institutionalising nanotechnology as a coordinated national enterprise. Yet, the first texts already mentioned the necessity to engage the public in the development of the new technology.

Non-governmental pillar-base, phase one

Just as these important institutional steps were taken, on the non-governmental level, in 2002, the Canadian-based NGO, the Action-Group on Erosion, Technology and Concentration asked for a moratorium on the commercialization of new products containing novel, engineered nanoparticles until lab protocols were established to protect workers, and until regulations were in place to protect consumers and the environment (ETC Group, 2002). This could be seen as the source of the non-governmental pillar base. The ETC Group was indeed the first NGO to draw attention to potential problems linked with the development of nanotechnologies. Interestingly, the word 'risk' did not appear once in this first text either.

Institutional pillar-base, phase 2

After North America, the UK government commissioned in 2003 the Royal Society and the Royal Academy of Engineering to study potential applications of nanotechnology and their possible environmental, health and safety, social and ethical implications. The report was published in 2004. It referred to the call for a moratorium by the ETC Group (chapter 8, paragraph 51) and included questions about some risks posed by manufactured nanoparticles and arguments on the need to review chemical regulations to ensure that they encompassed nanotechnologies.

> "Under current UK chemical regulation (NONS) and its proposed replacement under negotiation at European level (REACH), the production of an existing substance in nanoparticulate form does not trigger additional testing. We have recommended that this regulatory gap be addressed by treating nanoparticulates as new substances, thus requiring additional testing, under both NONS and REACH." (Dowling, 2004): 82

In its final chapter, recommendations, the word 'risk' appeared four times and in chapter 8, the chapter dealing with regulatory issues, the word appeared 29 times.

The report did not find any justification for imposing a ban on the production of nanoparticles. However, as a precautionary measure it recommended that releases to the environment be minimised until effects were better understood. It also mentioned the importance of public and stakeholder dialogue. It recommended that the UK Government initiate a properly funded public dialogue around the development of nanotechnologies at a stage when such discussions could inform key decisions about their development and before deeply entrenched or polarised positions appeared.

Non-governmental pillar-base, phase 2

In 2003, the NGO the ETC Group published a new report in collaboration with a renowned toxicologist, Dr Vyvyan Howard (ETC Group, 2003). The report included a literature search relating to the effects of nano-sized particles on human health and the routes by which nanoparticles can enter the body, and mentioned the word ‘risk’ 14 times. Another report published earlier that year, *the Big Down*, showed 30 mentions of the term (Mooney, 2003).

This chronology of events extends previous research on the increasing importance of risk management in society (Beck, 1992, Bennett and Calman, 1999) in that it highlights how the awareness of its importance has become *part* of institutional emergence. This in itself marks a rupture from other technological developments, where risk management issues appeared *after* the development of new technologies, as was illustrated by cases as varied as nuclear research (Campbell et al., 2004), DDT (Maguire, 2004) or asbestos (White, 2004). It also highlights that civil society gained admission in the process of institutional emergence. On the one hand, official structures like the Royal Society acknowledged the input of non-governmental organisations. On the other hand, public structures explicitly mentioned the necessity to engage the public *from the earliest stages* of the development of the technology.

The objective of the case study is to analyse the public engagement process to understand how it relates to risk management.

Risk management and institutional emergence

The development of any new technology raises issues relating to the process of measuring or assessing risk and developing strategies to manage it (Cothern, 1995, Singh, 2006, Vogel, 2003, Johnson and Covello, 1987). From even the earliest times, humans have likely been aware of the benefits of group action in reducing risk. In forming a social structure, individuals that help others to recover from hardships (like a fire destroying their dwelling), understand that if needed, a similar benefit will be extended to them by other community members. While approaches to formal risk mitigation have become increasingly sophisticated over time, the numerous examples of early approaches to transferring or distributing risk include the practice by Chinese merchants as long ago as the 3rd millennium BC of distributing their wares across many vessels to limit the loss due to any single vessel's capsizing when traversing treacherous rivers.

Alongside these basic approaches to sharing risk emerged the notion of risk assessment, as people realised three things. First, the 'value' of goods or persons exposed to dangers was not identical, second, some perils were more dangerous than others, and third, some hazards were more likely to happen than others. Not surprisingly, the evolution of risk assessment closely paralleled the evolution of an insurance sector. Here again, historical examples include the establishment of such insurance organisations as Lloyds in the 17th century to insure cargo during sea transportation or Nicolas Barbon's insurance company insuring buildings against the fire in the aftermath of the Great London fire of 1666 (Hanson, 2002). Risk is now generally defined as being a function of both the expected losses which can be caused by an event and to the probability of this event. The harsher the loss and the more likely the event, the greater the overall risk. These two factors, loss and the probability of the loss, are typically treated as sequential, independent events so that, in simplified terms, quantification of risk is expressed as:

Risk= (probability of an accident) x (losses per accident)

Along with risk assessment goes the notion of risk management (Louisot and Gaultier-Gaillard, 2007). Risk research has developed as society has become increasingly aware of its capacity – or incapacity – to manage risk, particularly when new potential sources of risk are presented. One characteristic of risk management is that risk is always acknowledged and assessed *a posteriori*. Scientific proof can only be put forward when harm has already been done. This is the only way to obtain an estimation of an unobserved quantity on the basis of empirical data. It was only after the London fire destroyed 13 200 houses and left some 70 000 Londoners homeless that Nicolas Barbon's idea to insure buildings against fire could firstly germinate and secondly become successful (Wainwright, 1953). It was only in 2007, when hurricane Dean approached oil production facilities off the coast of Mexico that the oil market started focusing on the potential for weather-related supply disruptions (Tan and Evans, 2007).

The paradox is that risk can only be envisaged in the light of past events and yet bears on the probability of the occurring of future events. This paradox leads to three types of risk management.

1. **Managing the known knowns**. This type or risk management is usually well mastered. For example, the dangers of fire are known. It is well known that fires and their associated losses depend upon two distinct factors, the likelihood that a fire hazard exists and will produce a fire, and the exposure of a given value (represented by the people,

property, heritage, environment or disruption affected) to the fire. So risk management will be about reducing the likelihood of starting a fire, and increasing fire protection.

2. **Managing the known unknowns**. What is **known** about the H5N1 virus is that it is the only one of 16 varieties of bird flu to have the ability to jump from birds to humans, and then to pass directly from one human to the other. The human death rate due to bird flu increased from 60 percent in the years 2002-2005 to 70 percent in 2006 (161 deaths out of 267 confirmed cases in 2006). Although several million birds had been destroyed since 1997 in the hope of stopping the pandemic, the World Health Organization (WHO) warned in 2007 that as long as the virus continued to circulate among birds, the threat of a human pandemic would persist, and that the world was still years away from effectively controlling the illness. Influenza pandemics can be expected to occur three or four times each century, when new virus subtypes emerge and are readily transmitted from person to person. The last great pandemic occurred in 1918-19, when Spanish flu swept the world, killing 40-50 million people. Experts agree that another pandemic is inevitable and possibly imminent. (WHO, 2007).

What is **unknown** is when the pandemic will strike, and how deadly it will be. Here, risk management is about preparing oneself as best one can. This includes among other things trying to develop vaccines, finding operational solutions to keep vital business activities going if populations are decimated, developing logistics connected with mass fatality management and preventing panics. The main challenge of managing the known unknowns is to keep public trust. (Irwin et al., 2006)

3. **Managing the unknown unknowns**. By definition, it seems impossible to manage unknown unknowns, since no-one can have any insight of unknown risks linked with unknown hazards. However, this is what is of interest to us in this part. Incomplete information regarding nanomaterial properties and their potential impacts makes it

particularly difficult to measure or assess the risks linked with the development of nanotechnologies. The concept of risk associated with nanotechnologies was first put forward by Eric Drexler in 1986 when he described a “grey goo” scenario in which self-replicating “nanobots” might consume all the carbon on the planet while building more of themselves (Drexler, 1986). The feasibility of such a scenario has been debated at length and remains contentious. However, the more immediate question of whether or not nanomaterials might be possible contaminants, posing risk to human health and environment, was raised publicly for the first time in December 2000.

> “Let’s envisage a release in the environment of these molecules, because of an accident in the production plant, or simply at the end of the life cycle of the manufactured product. Will they become a health hazard like asbestos? What will be their impact on ecosystems?”
>
> (Wiesner, 2000)

Increasing concern over the possible risks presented by nanomaterials led to some of the first experiments in public engagement on the topic during the period 2002-2004. This particular form of institutional emergence was explained by various factors:

- There was a genuine desire of governments to ‘do things right’ from the start (European Commission and Nanoforum, 2004, European Union, 2003, US Congress, 2003).
- Previous academic studies had shown the importance of involving the public into policy making in the face of technological uncertainty (Auplat, 2006, Callon et al., 2001, Fiorino, 1990, Godard et al., 2002) .
- The industry was very wary not to repeat the same mistakes that had hampered the development of biotechnologies (Auplat, 2006, Chataway et al., 2006, Gaskell et al., 2004) and was cautious about the possibility of creating legacy issues that might return to haunt corporations as had occurred in the case of hazardous waste legislation and litigation in the US.

- Similarly, the insurance sector was very cautious and expressed concern at covering products that might turn into asbestos-like problems (Swiss Re and Hett, 2004).
- People are more and more inclined to be risk averse if they are not in control of the risk or if they do not trust the people who manage risk (Currall et al., 2006, Irwin et al., 2006).

A case study of public engagement

In order to explore the relations between risk management and public engagement experiments, the first step was to identify what had actually been done. A comprehensive analysis of existing archival sources revealed that two reports – one from France and one from the UK – have attempted to establish a panorama of existing experience with public engagement as undertaken between 2003 and 2007 in the nanotechnology field. The data presented concerns essentially European and American experiments, as there do not seem to have been many other instances of consequence elsewhere in the period concerned. I synthesise the various features of each type of experiments, checking my findings with focused interviews with key stakeholders of the public engagement experiments. Finally, I draw conclusions about new dynamics in risk management. These conclusions are twofold: they bear on the concerns of end-users with the development of nanotechnologies and on the change in institutional emergence which these new risk-management dynamics signal.

In 2005 the UK government published its Outline Programme for Public Engagement on Nanotechnologies (OPPEN) as a response to the Royal Society and Royal Academy of Engineering report (Dowling, 2004). One of the parts of this programme was to fund a study of public engagement initiatives and NEG (the Nanotechnology Engagement Group) was established for this purpose. NEG's objective was to document the learning from a series of attempts to involve members of the public in discussions about the development and governance of nanotechnologies, and it did so in its report published in 2007, *Democratic Technologies?* (Gavelin et al., 2007).

In France, the Department of Higher Education and Research and the Department of Industry commissioned in 2006 a report gathering the recommendations of the main nanotechnology stakeholders to get a picture of their positioning and recommendations towards nanotechnology (Cité des sciences et de l'industrie, 2007). The report – entitled *'cahiers d'acteurs*' – was composed of 14 chapters, each one an independent report issued by one group of stakeholders. The stated objective was to gather the analyses of 'the main stakeholders: industry, science and politicians'. Interestingly, no mention was made of the opinion of citizens. However, half of the reports involved public engagement experiments. One of the major differences between the *cahiers d'acteurs* and *Democratic Technologies* reports is that the former is a gathering of primary sources, as each of the 14 chapters comes directly from the stakeholders themselves, whereas the latter speaks through the voice of the NEG's authors, as it is a digest of the various experiments they studied.

According to the NEG's report there had been until 2007 some twenty public engagement initiatives on nanotechnologies internationally. The report may not have accessed all available information, but it did not mention any initiative in Asia or the Middle East. Out of 23 projects identified involving public engagement, 14 came from EU countries, 6 from North American countries, and 3 from Australia and New Zealand. Public engagement was defined as the different ways that institutions interact with the general public outside of formal democratic structures such as elections. The NEG study focused exclusively on forms of public engagement that involved dialogue between members of the public and scientists or decision-makers, and excluded purely one-way forms of public engagement such as information campaigns or public opinion polls. The scope of the projects varied a lot, from a one day workshop to five-year projects and they spread out in time from 2003 to 2006.

Sticking to NEG's definition of public engagement, out of the 14 initiatives documented in the '*Cahiers d'acteurs*', 7 focused on programmes involving public engagement. There were some overlaps between the two reports' studies, and I identified a total of 25 different experiments meeting NEG's definition of public engagement, from which I drew my empirical data and established a typology of the major public engagement initiatives in relation to nanotechnology from 2003 to 2007 (Fig 59 and 60).

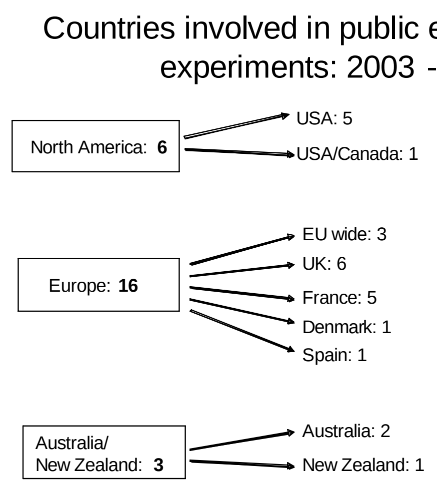


Fig 59. Data sources: NEG and Cité des Sciences & de l'industrie

Games and scenario playing

The first public engagement project – in 2003 – was in the form of a game called *Democs-nanotechnology.* It was commissioned by the EU sixth Framework programme and the Wellcome Trust. Participants are dealt a series of hands of cards to read, and are asked to pick the ones that they feel are most important for the discussion. At the end of the game participants state their preferred policy position on a subject by choosing from four pre-developed policy positions or developing one of their own. The games usually involve teams of six to nine people (See: www.neweconomics.org).

In another experiment in Australia, participants were divided into small working groups and were given a hypothetical scenario kit to stimulate discussions about the social, economic and environmental implications of nanotechnology. This experiment was supported by CSIRO, the Commonwealth Scientific and Industrial Research Organisation, Australia's national science agency. The participants selected included community members, CSIRO staff, nanotechnology specialists and government representatives (See www.minerals.csiro.au).

Nano juries

This experiment, run in 2005, resulted from a collaboration between Cambridge University Nanoscience Centre, Greenpeace UK, the Guardian and the Policy, Ethics and Life Sciences Research Centre (PEALS) at Newcastle University. Modelled on legal trial juries, the experiment brought together a group of sixteen participants from a West Yorkshire borough – the jurors – selected from the electoral register and via suggestions from youth and community workers. Before turning to nanotechnology, the jury addressed a topic of their choice over eight evening sessions of two and a half hours each. They decided to look at young people, exclusion and crime in the local community. They then discussed nanotechnologies in a further ten sessions of two and half hours each. Six witnesses selected by an oversight panel provided evidence and in the last few sessions the jurors wrote recommendations for the future development of nanotechnologies in the UK. The recommendations were presented to an audience of policy-makers, scientists, journalists and social researchers at an event in London in September 2005.

Deliberative public debates

The format is to have experts and specialists invited through organisers' networks come and give evidence on various aspects of nanotechnology, and then open discussions with the floor. The audience comes freely and most people attending have an interest or are involved in nanotechnologies. In the case of the French experiments, every meeting was about two and a half hour long and a report was released after each debate. A series of recommendations followed the debates, addressed specifically to policy makers, industry leaders and academics (see www.vivagora.org).

Online consultations and interactive assessment tools

This methodology for public engagement is more and more routinely used in conjunction with each of the other types of experiments. Websites offer information about nanotechnologies, as well as interactive more or less constructed spaces for chats or debates. Unfortunately at the time of writing this paper it had not received sufficient feedback to draw valid conclusions.

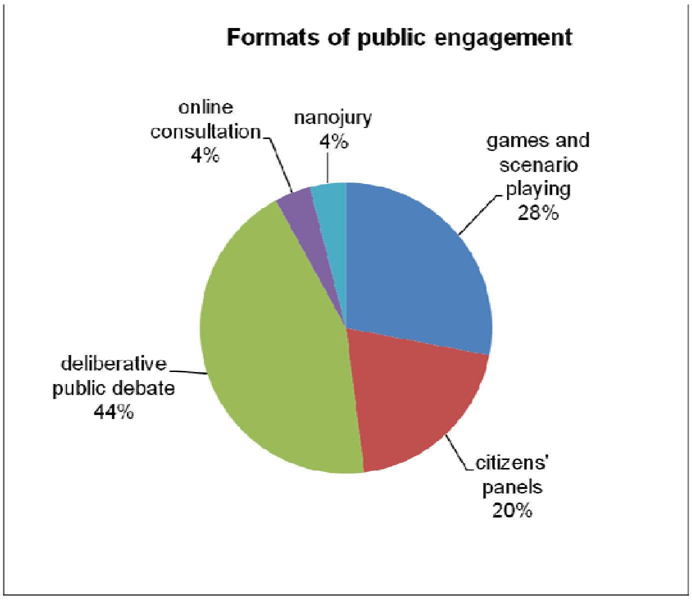


Fig 60

Interpretation

In the vast majority of cases, the public knew nothing about nanotechnologies before their involvement in the experiments (Fig 61). Only 4 percent of them concerned stakeholders who had a direct involvement in nanotechnologies, and then, the involvement was scientific rather than industrial or governmental. In most cases, participants engaged themselves on a voluntary base, although NEG documented experiments where the public were paid to participate or were enticed to do so by other means (for instance to talk about other subjects that deeply concerned them).

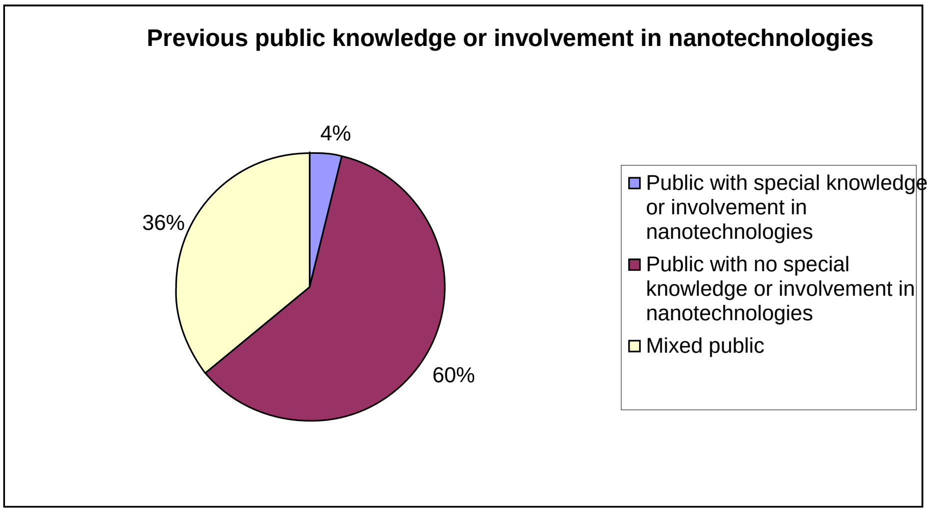


Fig 61

A big difference in the experiments was whether the thinking was directed or not. In the scenario-playing, games options, nano-juries and citizens' panels the participants had to choose solutions from various options that were presented to them. This meant that their contribution was in fact in the form of a reaction to ideas that were submitted to them. Conversely, in the deliberative public debates and to a certain extent online consultations and interactive assessment tools, their participation was allowed to be more open. This distinction between open and closed discussion is an important one. Indeed, history has shown that some of the societal issues of past technological innovation had not been anticipated by the scenarios of scientists or the early developers of these technologies. For instance, with biotechnologies, it was farmers' associations who first mentioned some of the risks associated with gene patenting like the loss of cultural heritage for some nations, or the issue of the ownership of the living. It was also non-specialists who drew attention to the risks coming from the cohabitation between genetically modified crops and non-genetically modified ones.

Finally, experiments fell into two categories. The vast majority (72 percent) originated from institutional sources (mainly government or science and research). The others came from civil society, usually local community groups or groups with environmental preoccupations, or partnerships between industry and local community groups or NGOs. A word must be said of an experiment of a unique nature, that of *Cahiers d'acteurs N°13.* This report came from a gathering of trade unions representing workers with nanotechnology-related activities. In this particular case, the stakeholders did have knowledge of nanotechnologies, and a particular involvement with the technology.

The outcomes of these various public engagement experiments could be summarised as follows:

Given the various differences outlined above (public engagement formats, locations, participants etc.) the outcomes were altogether rather homogeneous. The same types of preoccupations, although not phrased identically, emerged.

- On the whole, nanotechnology was perceived as a highly interesting area of innovation with a great potential for the improvement of society.
- Risk management was seen as one of the key issues of the development of nanotechnologies.
- There was consistent demand to accompany the development of nanotechnologies with societal assessments and public engagement.

Risk itself was defined differently by the various groups but with various salient points (Fig 62):

Most saw **risks in relation to the usage of nanomaterials**. Three subcategories emerged: health and especially human health risks, risks of a degradation of the environment, and finally risks of loss of freedom coming from the possibilities of miniaturization of monitoring devices. For most, the important thing about risk management was to assess the risk/benefit ratio, taking time into account, as well as *whom* risks and benefits were most likely to affect. In a lot of the reports there was a sentiment that risks might have more impact on less developed countries and more benefits for more developed countries. Participants stressed the necessity to make sure that risks/benefits were distributed equally among more and less developed countries. Although in some cases the debate was introduced especially in the form of 'how to improve *British* society', in all the experiments the answers were invariably of global purport.

The second understanding of risks was **risks in relation to policy making**. Many groups vented concern that the industry, politicians and regulators might not show enough transparency for various reasons in the processes leading to decision making. The major concerns were twofold:

- How to reconcile industry's understandable need to preserve some secrecy on some processes in order to maintain a competitive advantage with public expectations of information and transparency.
- How to make sure that policy makers and regulators really understood and controlled the various aspects of the development of nanotechnologies.

These preoccupations did not correspond to clear-cut groups of stakeholders and spanned various groups. Similarly, calls for more regulation or for a moratorium on nano-research did not correspond to any particular group. When calls for more regulation were made, they covered the following areas:

- Chemical classification and labelling of nanoparticles as well as regulation to monitor nanoparticles releases in the environment.
- Mechanisms of transparency in regulation and policy-making.
- Safeguarding of personal liberties.

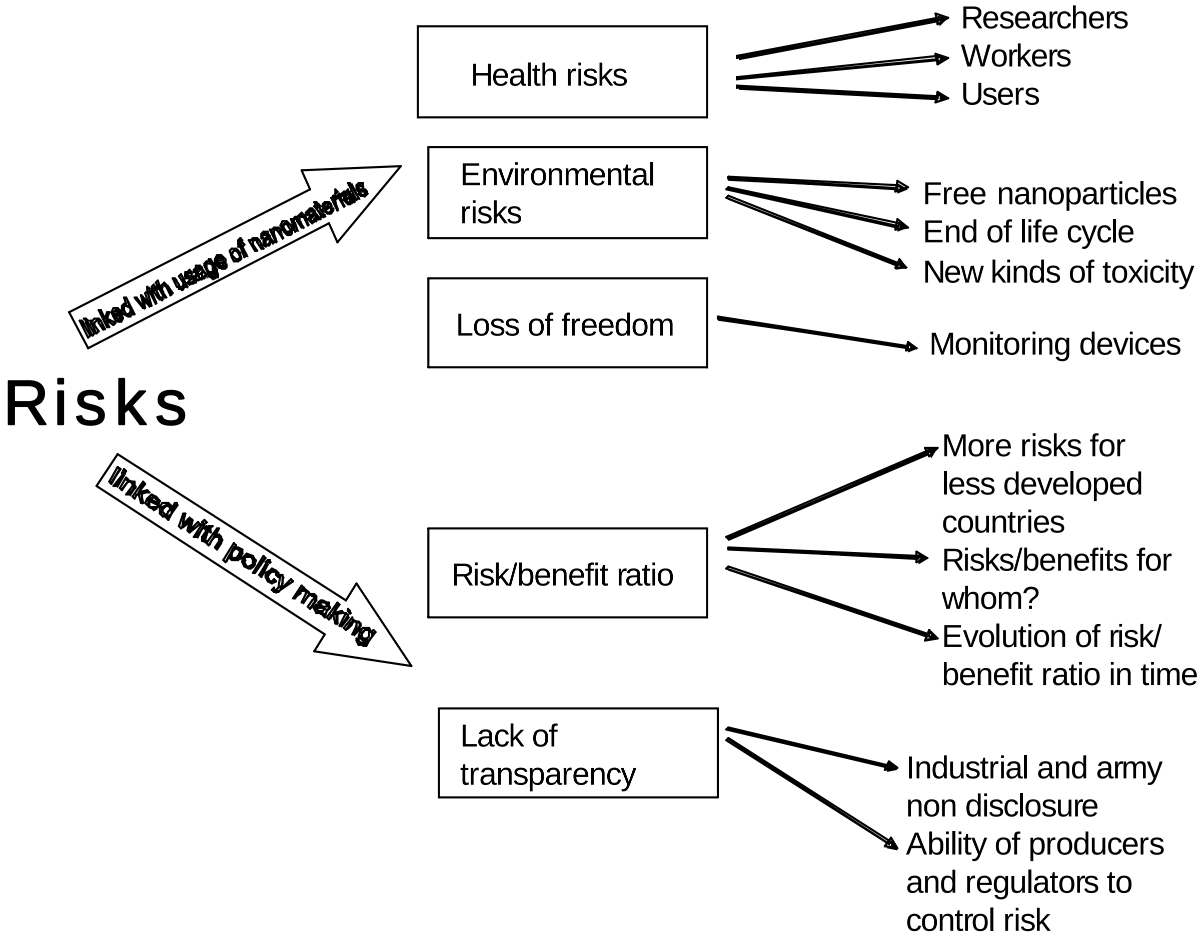


Fig 62: Summary of nanotechnology risk analysis based on the various public engagement experiments studied.

Findings

The fact that these public engagement experiments take place, coupled with the development of the internet and its multiplier effect on the shaping of public opinion shows how different risk management has become from what it was only ten years ago. From the top down approach that was used in the development of previous innovative technologies (Irwin et al., 2006), regulators now move towards a more inclusive way of policy making which gives a new weighting to technological and societal parameters. A major finding of the chapter is that a traditional top down approach of risk management alone is no longer considered sufficient in addressing the concerns raised by emerging nanotechnologies. This translates into institutional emergence in the very fact that these public experiments take place with the support of existing institutions. In terms of my study, it means that one of the characteristics of nanotechnology institutional emergence is that it places the construct of a new form of risk management at the core of institutional emergence.

The case study also shows that in the area of risk management, the development of nanotechnologies appears to be generating a mechanism for aggregating the expectations of various stakeholders. The analysis of public engagement experiments reveals that what really made a consensus for the stakeholders whom I defined as end users was the need to weigh the risks and benefits of the new technologies for society before bringing them to the market. The other aspect was that end users wanted to make sure that the benefits really outweighed the risks for all in the long run. It appeared that what was at the root of public concern was not so much scientifically defined risks to human health or the environment as the need to know whether a new technology risk/benefit ratio would be clearly in favour of long term benefits for society in general. The public engagement experiments also showed that what the public expected from regulation was the capacity to anticipate and provide a frame of action to future potential consequences (the unknown unknowns). These preoccupations were perfectly aligned with the definitions of sustainable development given in the introduction, suggesting that sustainable development constitutes the aggregating element of otherwise very distinct expectations of the various stakeholders.

These observations support previous studies which show that society plays an important regulatory role in innovation (Chataway et al., 2006). More importantly, they add to the emerging literature on the connections between sustainable development and the economy (Bansal and Roth, 2000, Jaffe et al., 2005, Potoski and Prakash, 2004). Also, in studying the relations between technological innovation and the shaping of institutional structures, they offer new insights into the emergence of institutions (Latour, 1988). In particular, by placing the construct of a new form of risk management at the core of institutional emergence, they provide a fresh approach of institutional theory (Phillips et al., 2004, Romanelli, 1991, Zucker, 1977). Finally, by assessing the relative importance of the characteristics of nanotechnologies in the design of an institutional framework for their development – particularly in the areas of risk assessment and management – they shed new light on the links between institutions and technology (Wiesner et al., 2006, Wiesner and Bottero, 2007).

CONCLUSIONS

Looking back at the research questions

The purpose of this study was to provide a conceptual framework of the combined actions of various groups of stakeholders to account for nanotechnology institutional emergence. Rather than focusing on a particular group of stakeholders, the institutional entrepreneurial 'heroes', the chosen perspective was to provide evidence that institutional entrepreneurship is a complex process which results from a multifaceted web of interactions. By focusing on the particular empirical case of the co-industrial and institutional emergence of nanotechnologies, it revealed some of the characteristics of this process. One is that an increasing awareness of the importance of sustainable development constitutes an overlapping area of the distinct visions of each group of stakeholders, and may be seen as the connecting element which keeps otherwise potentially diverging agendas together.

The study also showed that the process of nanotechnology institutional emergence is co-evolutionary with that of industrial emergence, and that in the development of nanotechnologies, entrepreneurship and institutional entrepreneurship are intimately mingled. Indeed, there is a constant interplay of reciprocal influence between the two. The PEN project, a joint project of the Pew Charitable Trusts and the Woodrow Wilson International Center for Scholars, provides an inventory of nano products reaching the market (http://www.nanotechproject.org/inventories/consumer/). It offers an illustration of this phenomenon: products falling under the heading 'health and fitness' are by far the most numerous. In the absence of specific nanotechnology regulation, but aware of all the institutional risks mentioned at various stages of the study, entrepreneurs tend to favour the development of products which are the most likely to be accepted by people, such as products improving their health or increasing their well-being. Another example is standardization. Standardization is becoming a new transnational institution (Djelic and Sahlin-Andersson, 2006, Brunsson and Jacobsson, 2002). In the domain of the development of nanotechnologies, the shaping of this institution closely reflects, as well as it aims to guide, the development and arrival on the market of new nano-based products and services.

Several specific issues were raised during the study, and time has come to look again at the research questions which guided my work to see what answers were found.

What makes the nanotechnology context a propitious one to study institutional emergence?

Firstly, nanotechnology is a diffuse, cross-sector technology which can potentially affect the whole of society, both horizontally (geographically speaking) and vertically (from the poorest to the richest, from the youngest to the oldest).

Secondly, it arrives at a point in the history of mankind when internet technology and globalisation mean that concerns are more and more widely shared and that attempts to find solutions to emerging problems are more and more global.

Thirdly, its specific characteristics render it both extremely attractive because of all its promises to improve society and at the same time very worrisome because of the current inability to assess correctly the risks associated with its development. This paradox calls for new types of institutions which can cope with this duality.

What are the characteristics of this institutional field emergence? What does it reveal?

Firstly, there is an overall global alignment of R&D priorities. This alignment is accentuated by the fact that economic studies on the promises of the technology are carried out by research or consulting institutions which tend to analyse data on a global scale and to render global conclusions (see for example in Lux Research Inc. (2004) the methodology of the analysis of the nano value-chain). Alignment of R&D priorities contributes to the shaping of the field, and since entrepreneurship and institutional entrepreneurship are so closely related it means that institutional emergence also becomes a global affair. This marks a change from previous histories of technology emergence where national interests were more significant.

Secondly existing institutions put more weight in the shaping of the process than ever before. As one of the interviewees representing the European Commission stated, nanotechnology was the first case in history of a new technology getting such generalised and financially important institutional support for its development.

Thirdly, the precautionary principle is underlying the regulatory framework of the development of nanotechnology. This time again, it is simply a question of historical conjunction: the precautionary principle came to underly all European regulation in 2000, with *Communication from the Commission on the precautionary principle, COM (2000) 1,* (Commission of the European Communities, 2000). As this text serves as a basis for all EU regulation, it covered the development of nanotechnologies from the start. This marks a difference with biotechnologies, for instance, because these had started being developed *before* the adoption of COM (2000) 1. Although Com (2000)1 only applies at the European level, globalisation and alignment of R&D priorities suggest that its effect is likely to be felt globally.

Fourthly, civil society is integrated in the institutionalisation process. As was showed at various points in the study, civil society was part of policy making all along the initial phases of the development of nanotechnologies. This happened at two different levels. One was when existing institutions gave space to civil society in the institutionalisation process (see for example all the official initiatives to involve the public at various stages and in various circles). The other one was when civil society empowered itself to participate in the debates (see for example chapter 7).

How do various the stakeholders acting as institutional entrepreneurs collectively shape the institutional emergence of nanotechnologies?

The most visible effects are changes in policy making. The globalisation of the institutionalisation process means that priorities may be different from what they were in previous forms of institutional emergence. Indeed, whereas previous cases of technological emergence tended to be entirely driven by developed countries, developing countries are participating in the nanotechnology process at various levels. One is by hosting various nanotechnology conferences like the most recent ones: the *2nd Bangalore Nano* conference was held in India in December 2008 (see http://www.bangalorenano.in/); the *Iran-India joint conference in Nano-Technology (IIJCN)* was held in Iran in 2008 (see http://iijcn.tums.ac.ir/); the third *NanoAfrica Conference*, will be held in February 2009 in South Africa (http://www.uct.ac.za/usr/pgfo/notices/appstud/nano_africa_2009.pdf). By hosting these conferences, by giving a voice to the research of their own representatives, these different nations modify the process of institutional emergence: they provide a visible sign of the fact that it is being globalised. It is too soon to speculate about the actual changes that this new development will bring, but it does contribute to shape nanotechnology institutional emergence. Research on tournament rituals, which shows how a highly charged ceremonial form may attract collective attention to a field and serve as a medium to create legitimacy may be helpful to analyse its impact further (Anand, 2004).

Besides, chapter 7 shows that the development of nanotechnologies is giving birth to a new form of institutional dynamics where decision making is moving towards a complex, multi-stakeholder process. Here we are in the realm of 'likely' changes, because the process is still in the making. Change in institutional dynamics is a very important aspect of institutional emergence. It deserves more than a passing note and I will develop in the next paragraphs one of its other aspects: the loss of ownership of regulatory frameworks. Indeed, a study of regulatory frames and initiatives covering the development of nanotechnologies shows that regulatory procrastination is met with the emergence of a new form of regulation where international standards are taking precedence over national regulatory frameworks and are gradually acquiring new ontology. Once again, this can be explained by the fact that the flow of information is becoming more and more international, notably because of the internet technology. What happens is that national decisions or roadmaps about regulatory frameworks seem to be gradually superseded by new forms of international regulation based on international standards. These standards are being put into place whether individual nation states want them or not, as will be shown in the next part.

As the development of nanotechnologies is gathering speed, so is the awareness of the importance of managing the risks which are potentially associated with nanoproducts; risks for consumers, for the environment, for the industry or for insurers, to mention but a few (Wiesner and Bottero, 2007, Singh, 2006, Lloyd's, 2007). The phrase ‘nanotechnology risks’ covers three different forms of risks, risks coming from nanoparticles, risks coming from public perception and risks coming from regulation (Swiss Re and Hett, 2004, Raje, 2007). These risks are of very different types and affect different groups of constituents, as is made obvious if we ask the simple question: risks for whom?

Risks coming from nanoparticles mostly affect those that are exposed to them. This may mean human beings, animals, or the environment. In this case, risk assessment is based on a well-known model. It is a function of hazard and exposure. To assess risks with some accuracy, the difficulty is firstly to know what is dangerous about a certain nanoproduct (the ‘hazard’). This is what is keeping a lot of scientists busy at the moment, as the technology is so radically new that there is no past experience or conventional tools to measure with certainty how dangerous given nano-based products are (Oberdorster, 2004, Robichaud, 2005, National Institute for Occupational Safety and Health, 2006).

Risks coming from public perception have not been investigated fully, and no satisfactory formula has yet been found to account for them. In this case, we lack the model. It seems that it will probably look like a function of ‘perceived risk’ and ‘media exposure’, but this has yet to be substantiated. So far, researchers use the case of the development of biotechnologies as a sort of benchmark to evaluate nano risks coming from public perception (Gaskell et al., 2004, Einsiedel and Goldenberg, 2004). However, there are big differences between the developments of the two forms of technologies and this constitutes a limitation to this approach.

The last form of nanotechnology risks is risks coming from regulation, and it is what is of interest to us in this part. The regulatory framework of nanotechnologies is volatile. At the moment, there is no certainty about the future aspect of nanotechnology regulation. This uncertainty induces risks for nanotechnology entrepreneurs and for the nanotechnology emerging industry altogether. Indeed, the case of the development of biotechnologies showed that regulatory changes entailed shifts in entrepreneurial activity accompanied by wealth destruction (Auplat, 2006). If regulatory frameworks change, what was allowed at one point in time may not be so any longer, which means that investments may become useless if what they had been designed for cannot be developed. More, these regulatory changes may also induce risks for the institutions themselves. In their analysis of risk colonization (Rothstein et al., 2006) looked at the co-emergence of societal and institutional risks. They defined societal risks as threats to members of society and their environment, and institutional risks as threats to regulatory organisations and/or the legitimacy of rules and methods of regulation. They argued that pressures towards greater coherence, transparency, and accountability of the regulation of societal risks could create institutional risks by exposing the inevitable limitations of regulation. They concluded that because of this, the very process of regulating societal risks gave rise to institutional risks. I build upon these findings to analyse the emergence of regulatory frameworks around the development of nanotechnologies. I show that the current regulatory procrastination which is accompanying the development of nanotechnologies is met with the emergence of a new form of regulation where international standards are taking precedence over national regulatory frameworks and are gradually acquiring new ontology, thereby leading to a loss of ownership of regulatory frameworks.

The data comes from a 2008 study of Indicators of nano policy-making around the World (Laas and Weil, 2008) as well as from my own empirical research. I looked at all the regulatory data and initiatives that are in place and in the making around the development of nanotechnologies to explore options for nanotechnology regulation. Archival research was complemented by focused interviews with representatives of multinational corporations with a stake in nanotechnologies. The interviewees were – under various company-specific titles – in charge of sustainability and R&D, or consumer safety and R&D. In my analysis, I do not enter the debate whether *existing regulation* – like REACH in the EU or TSCA or FHSA in the US[10] – is sufficient or not to cover the development of nanotechnology. I focus on the development of *new* normative initiatives *explicitly devised to cover the development of nanotechnologies*. The comparative analysis of their development enables me to draw conclusions about change in the emergence of regulatory frameworks, and regulatory risks for institutions.

Institutionalisation and norm

There are currently a great number of initiatives concerning potential normative frameworks to cover the development of nanotechnologies. Laas and Weil's study explores

[10] REACH: Registration, Evaluation, Authorisation and restriction of Chemicals, EU
TSCA: Toxic Substances Control Act, US
FHSA: Federal Hazardous Substances Act, US

the nuances of each initiative (Laas and Weil, 2008). However, very little has actually been enacted in terms of regulation.

There is to date only **one case of compulsory regulation**. It is a municipal ordinance passed in December 2006 by the city council of Berkeley, California. This ordinance amended existing health and safety rules to demand a full toxological report from all facilities manufacturing nanoparticles.

> ‘ All facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases and mitigate such materials’. Source: The Manufactured Nanoscale Health and Safety Ordinance. Berkeley Municipal Code, Chapter 15.12 HAZARDOUS MATERIALS AND WASTES MANAGEMENT. Section 15.12.040 Filing of disclosure information (Berkeley City Council, 2006).

There were rumours that this initiative would spread to other city councils and the City of Cambridge, Mass. was reported to be next on the list. However, in July 2008 a report to the Cambridge City Manager, ‘*Recommendations for a Municipal Health & Safety Policy for Nanomaterials*’ concluded that in recognition of the limited health effects data and the absence of a clear consensus on best practices and standards for engineered nanomaterials, the Cambridge Public Health Department, in collaboration with the Cambridge Nanomaterials Advisory Committee, **did not recommend** that the City Council enact a new ordinance regulating nanotechnology at that time (Cambridge Nanomaterials Advisory Committee and Cambridge Public Health Department, 2008).

Apart from this sole example of compulsory nanotechnology regulation, all other existing forms of specific nanotechnology regulation are currently only voluntary schemes. They can be divided into three broad categories, voluntary reporting schemes, codes of conduct and standards. Voluntary reporting schemes emanate from institutions, while codes of conduct can be divided into two sub categories: codes of conduct coming from institutions, and those coming from industry.

Voluntary reporting schemes

The UK's **Voluntary Reporting Scheme** (VRS) for Manufactured Nanomaterials was set up in September 2006 as a temporary experiment with an expected life of two years. It is run by Defra, the Department for Environment, Food and Rural Affairs. The scheme aims to provide an indication of the kinds of nanomaterials currently in development and production to help inform policy-making decisions and *to focus efforts and funding on areas which are relevant to the UK's current nano manufacturing and research base* (my italics). The program asks for data that can be provided on manufactured nanomaterials from anyone involved in the manufacture or use of engineered nanomaterials, or anyone involved in nanoscience research or managing wastes consisting of engineered nanoscale materials. The program includes regular updates to assess its implementation (Department for Environment, 2008).

In 2008, the seventh such quarterly report indicated that after 22 months, a total of 11 submissions had been received since the scheme's launch in September 2006, nine from industry and 2 from academia. These results appear quite poor in view of the UK estimated nanotechnology production. For example, QinetiQ - believed to be the UK's first production facility dedicated to the volume production of specialist nanomaterials - stated on its website that it had two production rigs which were each capable of producing up to several kilos of material an hour, and that it was looking at over 25 key nanomaterial projects (retrieved from: http://www.qinetiq.com/home/newsroom/news_releases_homepage/2003/1st_quarter/nanomaterials0.html)

In January 2008 the United States Environmental Protection Agency (EPA) launched the **Nanoscale Materials Stewardship Program** (NMSP), a similar voluntary reporting scheme covering engineered nanoscale materials manufactured or imported for commercial purposes (Environmental Protection Agency, 2007). The NMSP program invited interested parties to participate in a “basic” program by submitting existing data on the engineered nanoscale materials they manufactured, imported, processed, or used. The EPA also invited interested parties to participate in an “in-depth” program to test engineered nanoscale materials they manufactured, imported, processed, or used. This scheme seems to meet the same fate as the UK Voluntary Reporting Scheme. When it launched the NMSP program, the EPA said it expected to receive 240 submissions from 180 companies under the basic program, and to attract 15 participants in the in-depth program. This projection was based on an estimate that in 2005 more than 600 companies were manufacturing and applying nanotechnology. However, in 2008, the EPA provided on its website a list of only 9 companies that had made submissions and 11 companies that intended to, and 2 more volunteering for the ‘in-depth’ program component.

So it appears that the voluntary reporting schemes do not meet the enthusiasm of industry. Interviews with industry representatives suggest that the major reason for this failure is that when a company attempts to give an earnest report of its nanoactivities, the very information it provides becomes a source of scrutiny – and sometimes criticism or concern. Companies feel that because of the current lack of data, the data *they* provide becomes the source of a benchmarking of nanotechnology risk evaluation for which they are accountable because they are the source of the data. So they consider that participation in voluntary reporting schemes in fact increases risks for them.

Codes of conduct

Codes of conduct coming from institutions

The EU ‘**Code of Conduct for Responsible Nanoscience and Nanotechnology Research**’ was approved in February of 2008 (European Commission, 2008). Based on precautionary principles, this voluntary code covers seven general principles, including sustainability, precaution, inclusiveness, and accountability. The main goal of this code of conduct is to help research institutes, universities, and companies in the EU ensure the safe development and use of nanotechnologies in the face of knowledge gaps and uncertainties about the future impact of these technologies on human health and the environment. It is too soon to assess the impact of this voluntary initiative.

Codes of conduct coming from industry

The ‘**Responsible NanoCode**’: In 2008, the UK Royal Society, Insight Investment and the Nanotechnology Industries Association (NIA) produced together a document called ‘The Responsible NanoCode’ (Royal Society et al., 2008). The project had started in 2006 and aimed to explore the societal and economic impact of the technical, social and commercial uncertainties related to nanotechnologies. The idea had come from corporate codes of conduct that started being put in place by industry. The Chemical Company BASF had developed the first example of a code of conduct in 2004, outlining the company’s duties to workers, investors and clients. The Responsible Nanocode has seven principles. (See: http://www.responsiblenanocode.org/documents/TheResponsibleNanoCodeUpdateAnnoucement.pdf).

The initiative aims to develop a voluntary, principles-based Code that could be adopted by businesses involved in developing, manufacturing and retailing products using nanotechnologies. The Code is designed to establish a consensus of what constitutes good practice in businesses across the nanotechnology value chain (i.e. from research and development to manufacturing, distribution and retailing) so that businesses could align their processes with emerging good practice and form the foundation for the development of indicators of compliance. The Responsible Nanocode illustrates expected behaviours and processes, not standards of performance. It does not aim to be an auditable standard.

In June 2005, the chemical company DuPont and the environmental group Environmental Defense began developing the ‘**Nano Risk Framework**’. This initiative aimed to help answer questions an organization should consider in developing applications using nanomaterials, including providing a way to address areas of incomplete or uncertain information using 'reasonable assumptions and appropriate risk management practices'(Environmental Defense and DuPont, 2007). The framework included guidance on how to communicate information and decisions to stakeholders. One year after its launch, the Nano Risk Framework was available in French, Mandarin and Spanish and DuPont made the framework mandatory for all its nanotechnology work.

Following suit, BASF introduced in 2007 a specific code of conduct for nanotechnologies. Based on principles of responsible management, the code had four commitments detailing the company's approach, and included strong commitments to safety and transparency, among which one could quote:

> "Economic considerations do not take priority over safety and health issues and environmental protection".
>
> "We disclose new findings to the authorities and the public immediately".
>
> Retrieved from http://corporate.basf.com/en/sustainability/dialog/politik/nanotechnologie/kodex/?id=mXz1wD0.gbcp*9S

The analysis of these voluntary codes shows that they deal more with management practices than with the technology risks themselves. It is therefore impossible to measure their efficiency in terms of regulation of the emergence of the nano industry.

Standards

At the same time as all the initiatives described above, there has been a lot of activity from standardization organisations working on nanotechnology standards.

It is commonly agreed that standards exist to:

- Support commercialisation and market development

- Provide a basis for procurement
- Support appropriate legislation/regulation

Source (Phelps, 2006)

There are two forms of initiatives, national initiatives and international ones. In terms of national initiatives with an interest in nanotechnologies, one can mention among others the American National Standards Institute (ANSI), the Chinese National Nanotechnology Standardization Committee, the French Standards Agency (AFNOR), the UK British Standards Institute (BSI), the Japanese Standards Association (JSA).

National standardization agencies share in common the view that standardization is a means to assert competitive advantage. For instance, the British Standards Institute (BSI) states that 'standardization has a key part to play in all innovative technologies and nanotechnology is no exception'. It considers that its nano project, the publication of nine documents for nanotechnology terminology and standardization guidance for UK industry, does not only support worker, public and environmental safety but also underpins commercialization and procurement, and is part of BSI's overall initiative to support the innovation agenda of the UK government. (Retrieved from http://www.bsi-global.com/en/About-BSI/News-Room/BSI-News-Content/Disciplines/Nanotechnology/Nanotech-launch/)

For the French AFNOR, standards are differentiation tools, and 'standardization is an excellent method of international penetration for our competitiveness clusters' (Retrieved from AFNOR Activity report 2007 (Association Française de Normalisation (AFNOR), 2007), http://portailgroupe.afnor.fr/v3/pdf/activity-report.pdf)

The American National Standards Institute's Nanotechnology Standards Panel (ANSI-NSP) serves as the cross-sector coordinating body for the purposes of facilitating the development of standards in the area of nanotechnology including nomenclature/terminology, materials properties and testing, measurement and characterization procedures. Its strategy is to establish a framework that can be used by all interested parties to 'advance trade issues in the global marketplace, enhance consumer health and safety, meet stakeholder needs and, as *appropriate, advance U.S. viewpoints in the regional and international arena'* (my italics).

(Retrieved from United States Standards Strategy,

http://www.ansi.org/standards_activities/nss/usss.aspx?menuid=3)

The above quotations clearly show that standards are perceived as playing a vital role in economic dynamism, and that national standards agencies see standardization ownership – the fact that it is their standards which are applied by most in a given industry – as a way to assert a position of leadership.

On 1st April 2005, PR China became the first country in the world to establish national standards for nano-scale materials. It was a list of seven items: four standards for nanoscale nickel powders, zinc oxide, titanium dioxide, and calcium carbonate; two standards for the testing of the specific surface area and pore size distribution of powdered or solid materials via gas adsorption; and one standard for the granularity of nano-sized powders. According to ACON AG, a leading science and business consultancy focusing on Asia, (http://www.hkc22.com/about.html) it gave China a competitive advantage as these standards were expected to lay a good foundation for market access, market regulation and proper application of nano materials globally.

Just after this, the International Organization for Standardization (ISO) launched a technical committee on nanotechnology, ISO TC-229, in May 2005. Keeping up with these movements, the Japanese Ministry of Economy, Trade and Industry (METI) launched a panel within the Japan Standards Association called the Nano-Standardization Panel. It developed into the Council on Nanotechnology Standards in Japan in September 2005 and hosted the second plenary meeting of the ISC TC-229 in June 2006.

In June 2005, PR China launched its own National Technical Committee on nanotechnology standardization, with the approval of SAC (Standardization Administration of the People's Republic of China): SAC/TC 279. By 2007, each of the projects of ISO TC 229 had been categorized into one of the Technical Committees' working groups: WG 1, Terminology and Nomenclature, WG 2, Measurement and Characterization, or WG 3, Health, Safety, and Environment. But in October 2007, PR China's national standards agency SAC submitted two new work item proposals addressing specifications for nanomaterials in terms of possible applications. In response to these newly identified needs, a new working group on Material Specifications (WG 4) was formed in early 2008, under the convenorship of China.

The following table illustrates how global the process of nanotechnology standardization is. Over four years, ISO meetings for Technical Committee TC 229 on nanotechnologies were convened in seven countries, and the sixth plenary session gathered over 125 representatives from thirty member countries (at the time of writing, the 7th plenary meeting had not taken place). The table also shows the importance of Asia in this process, since four of the seven meetings were held in Asia.

ISO TC229 MEETINGS		
Meeting	Date	Place
1st plenary	November 2005	United Kingdom
2nd plenary	June 2006	Japan
3rd plenary	December 2006	Republic of Korea
4th plenary	June 2007	Germany
5th plenary	December 2007	Singapore
6th plenary	May 2008	France
7th plenary	November 2008	PR China

According to the International Organization for Standardization (ISO), an International Standard is:

> 'the result of an agreement between the member bodies of ISO. It may be used as such, or may be implemented through incorporation in national standards of different countries'. Source: ISO

It is thus plain that ISO standards are meant to be the result of consensus between nations, without any particular leadership. Ownership of ISO standards is a tricky question, since they incorporate the national standards of different countries. Yet, although it is difficult to assess ownership of international standards, one thing is certain: globalization renders them more attractive than national standards. The Nanotechnology Consumer Products Inventory put together by the Woodrow Wilson International Center for Scholars shows that in economic terms the bulk of the nano industry is in the hands of multinational corporations. These are usually more attracted by laws that will be the same in all the countries where they have a presence, and therefore international standards have greater appeal to them than national standards which will often be included in the international ones.

So the question which must be answered is whether nano international standards can supersede traditional regulatory frameworks.

Generally speaking, standards are sets of criteria which can be used as an established norm or requirement. Their value comes from the possibility of direct comparison with a base of reference.

Specific tasks of ISO TC 229 include developing standards for:

- terminology and nomenclature
- metrology and instrumentation, including specifications for reference materials
- test methodologies

- modeling and simulation
- science-based health, safety, and environmental practices.

Source: Issue on TC 229 – ISO Focus, April 2007 (International Organization for Standardization, 2007)

The elaboration of ISO standards is of a fairly long process which includes six stages: proposal stage, preparatory stage, committee stage, enquiry stage, approval stage and publication stage. All standards are reviewed within three years after publication and every five years after the first review by all the ISO member bodies. Source: Standards development processes, ISO, retrieved from http://www.iso.org/iso/standards_development/processes_and_procedures/stages_description.htm

As of October 2008, there were 28 international standards under development by ISO TC 229, and 2 which had been published.

The two published standards were:

1. **ISO/TS 27687:2008. Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate** (published 11 August 2008)

   Abstract: ISO/TS 27687:2008 lists unambiguous terms and definitions related to particles in the field of nanotechnologies. It is intended to facilitate communications between organizations and individuals in industry and those who interact with them.

2. **ISO/TR 12885:2008. Nanotechnologies – Health and safety practices in occupational settings relevant to nanotechnologies** (published 30 September 2008)

   Abstract: ISO/TR 12885:2008 describes health and safety practices in occupational settings relevant to nanotechnologies.

> ISO/TR 12885:2008 focuses on the occupational manufacture and use of engineered nanomaterials. It does not address health and safety issues or practices associated with nanomaterials generated by natural processes, hot processes and other standard operations which unintentionally generate nanomaterials, or potential consumer exposures or uses, though some of the information in ISO/TR 12885:2008 might be relevant to those areas.
> Source: ISO Catalogue. (Retrieved from http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=52093)

According to the US Nanotechnology Law Report, the standards developed under WG4 will have a tremendous impact on manufacturers in a wide variety of industries worldwide because they can be used in a variety of industrial applications and consumer products (Monica, 2008). Besides, as a footnote to the publication of its second nanotechnology standard, the ISO states:

> 'Use of the information in ISO/TR 12885:2008 could help companies, researchers, workers and other people to prevent adverse health and safety consequences during the production, handling, use and disposal of manufactured nanomaterials. This advice is broadly applicable across a range of nanomaterials and applications'.

So the standard is clearly designed to help fill the existing gaps in nanotechnology regulation. Interviews with representatives of the nanotechnology industry and insurance highlight the desire of both sectors to avoid regulatory risks, i.e. risks linked with changes in regulation. It is clear that standards are helpful because they enable both sectors to act according to clear benchmarks. Their legitimacy comes from their global reach as much as from the fact that they introduce a workable framework in a regulatory void. This is why international standards are likely to supersede existing forms of regulation. As was shown in the course of the discussion, they also lead to a loss of ownership of regulation, and this is another specific feature of nanotechnology institutional emergence.

Implications and future research directions

The study makes several types of contribution. It expands empirical knowledge of the development of nanotechnologies. By synthesizing existing scientific data on nanotechnology R&D, patenting activity and products reaching the market through the prism of the theoretical framework, it highlights likely areas of development which have received little attention until now, like sustainable construction or the quest for products with special relevance for the needs of developing countries. By examining successively the interactions of several groups of stakeholders, it provides information not only about the technology itself, but also about its various constituencies. The exploration of the role of civil society organisations introduces a novel approach to understand the co-industrial and institutional emergence of nanotechnologies. It supports previous studies which show that society plays an important regulatory role in innovation (Chataway et al., 2006). It also highlights that technology and society run on a system of checks and balances: in the constant and parallel evolution of both technology and society, society ratchets-up technological innovation, using the latest technological developments – like Internet technology – to safeguard itself against other possible technological dangers.

Theoretical contributions happen at various levels. The choice of a global approach with a focus on the US and the EU contributes to fill the research gap identified by Walsh et al. (2006) to better understand organisations in view of transnational emergence. In studying the relations between technological innovation and the shaping of institutional structures, the study offers new insights into the emergence of institutions (Latour, 1988). By assessing the relative importance of the characteristics of nanotechnologies in the design of an institutional framework for their development – particularly in the areas of risk assessment and management – it sheds new light on the links between institutions and technology (Wiesner et al., 2006, Wiesner and Bottero, 2007). The contributions to institutional entrepreneurship theory take several forms. With the case study of the ETC Group (chapter entitled ‘Innovative practices and nanotechnology institutional entrepreneurship’), the study offers keys to understand the conditions which lead to institutional change and the emergence of new institutions, as well as to understand what may give some actors the ability to have significant impacts on the evolution of institutions and fields. With the case study of the influence of regulatory practices (chapter called ‘entrepreneurship and regulatory practices’), it gives insight into the institutional entrepreneurship process itself, with the example of the role of positive regulation on the shaping of a field. With the case of public engagement experiments (chapter entitled ‘new institutionalisation processes: risk management and public engagement’) it places the construct of a new form of risk management based on the awareness of the concept of sustainable development at the core of institutional emergence, and this provides a novel approach of institutional theory (Phillips et al., 2004, Romanelli, 1991, Zucker, 1977). Finally, contribution to institutional entrepreneurship theory is also seen in the analysis of norm and institutionalisation: the study of the rising importance of voluntary codes in institutional emergence is a field of research which has received little attention before.

The study also highlights needs for further research in several areas. Firstly, empirical knowledge of the development of nanotechnologies needs to be pursued further, notably in terms of economic impact and of risk analysis. As was mentioned at the beginning of this work, the development of nanotechnology was originally mostly an affair between the EU and the US, and until 2007 it concerned only highly developed countries. Whether the very recent development of nanotechnology R&D in developing countries is something that will change the co-industrial and institutional emergence of the technology is something that needs to be studied in greater depth. One important question to be addressed in this light is whether this empirical change will bring one or several new group(s) of stakeholders into the process. The gaps in the field of risk analysis are also extremely important and the routes to explore are numerous, from the assessment of risk in the nanotechnology value chain to the process of risk management and risk communication to name but a few.

On the theoretical level as well, there numerous areas for further research. One direction is the relations between institutional entrepreneurship and entrepreneurship, particularly the relations between opportunity recognition and the emergence of new institutions. Another one relates to an emerging field of entrepreneurship research, high-impact entrepreneurship. A few researchers have started exploring this phenomenon. Whether by looking at star scientists (Darby et al., 2004a, Zucker and Darby, 1998), or by looking at particular technologies (Autio, 2008), they seek to explain the fascinating process which leads to the emergence of high-impact companies, i.e. start-ups that grow to have a real economic impact. An interesting extension of this stream of research would be to study high-impact entrepreneurship by focusing on the relationships between the entrepreneurs and the technology itself. In institutional theory research, a direction for future work is a new exploration of the relations between norms and institutional emergence based on the rising role of voluntary codes. Finally, one area of particular importance because it has received little attention until now is the replicability of the research concerning the importance of the concept of sustainable development in institutional emergence. Is this study simply a testimony to a short-lived phenomenon in the history of mankind, or is it an illustrative case of a deep societal transformation? Further research will tell.

APPENDIX

List of the major EU specialised agencies in 2008

Community Fisheries Control Agency (CFCA). Location: Vigo, Spain (provisional headquarters: Brussels, Belgium), ec.europa.eu/cfca/index_en.htm

This agency promotes and coordinates effective and uniform compliance with the rules of the common fisheries policy, in particular the protection of fish stocks.

Community Plant Variety Office (CPVO). Location: Angers, France, www.cpvo.europa.eu

The CPVO administers a system of plant variety rights, equivalent to a patent for new plant varieties. These are protected for 25 or 30 years depending on the type of plant.

Education, Audiovisual and Culture Executive Agency (EACEA). Location: Brussels, Belgium; eacea.ec.europa.eu

This agency manages the practical aspects of the EU programmes which provide funding for youth, student and teacher programmes, and cultural and media activities.

Eurojust. Location: The Hague, Netherlands; eurojust.europa.eu

Eurojust helps investigators and prosecutors across the EU work together in fighting cross-border crime. It plays a key role in the exchange of information and extradition.

European Agency for the Management of Operational Coordination at the External Borders of the Member States of the EU (Frontex). Location: Warsaw, Poland; frontex.europa.eu

Frontex assists the EU countries in implementing EU rules on external border controls consistently and in returning illegal immigrants to their countries of origin.

European Agency for Reconstruction (EAR). Location: Thessaloniki, Greece; ear.europa.eu

The EAR manages EU programmes for providing assistance with reconstruction, and economic and social development, to war-damaged countries in the Balkan region.

European Agency for Safety and Health at Work (OSHA). Location: Bilbao, Spain; osha.europa.eu

This agency pools and raises awareness of knowledge and information on health and safety at work, with an emphasis on creating a culture of effective prevention.

European Aviation Safety Agency (EASA). Location: Cologne, Germany; easa.europa.eu

The EASA promotes the highest possible standards of safety and environmental protection in EU civil aviation, and provides certification for planes and components.

European Centre for the Development of Vocational Training (Cedefop). Location: Thessaloniki, Greece; cedefop.europa.eu

The centre promotes the development of vocational education and training. It is a centre of expertise for the dissemination of knowledge and support for policymaking.

European Centre for Disease Prevention and Control (ECDC). Location: Stockholm, Sweden; ecdc.europa.eu

ECDC identifies, assesses and provides information on current and emerging threats to human health from infectious diseases, such as influenza, SARS and HIV/AIDS.

European Chemicals Agency (ECHA). Location: Helsinki, Finland; ec.europa.eu/echa

The agency manages the technical, scientific and administrative aspects of REACH, the EU registration system for chemicals.

European Defence Agency (EDA). Location: Brussels, Belgium; eda.europa.eu

The EDA helps promote coherence in place of fragmentation in Europe's defence and security capabilities, including in armaments and equipment, research and operations.

European Environment Agency (EEA). Location: Copenhagen, Denmark; eea.europa.eu

The EEA provides policymakers and the public with information to help promote sustainable development and improvements in Europe's environment.

European Food Safety Authority (EFSA). Location: Parma, Italy; efsa.europa.eu

The authority provides the Commission and the public with independent scientific advice on food safety and risks in the food chain ‘from farm to fork’.

European Foundation for the Improvement of Living and Working Conditions (Eurofound). Location: Dublin, Ireland; eurofound.europa.eu

The foundation is a hub of information on social policy issues, including employment and living conditions, industrial relations and partnership, and social cohesion.

European Global Navigation Satellite System Supervisory Authority (GSA). Location: Brussels, Belgium (provisional headquarters); ec.europa.eu/transport/gsa

This agency manages Europe’s satellite navigation programmes (notably Galileo and EGNOS), which are giving Europe its own capability and the latest technology in this field.

European Institute for Gender Equality. Location: Vilnius, Lithuania

This new institute promotes gender equality, including gender mainstreaming, and supports the fight against discrimination.

European Maritime Safety Agency (EMSA). Location: Lisbon, Portugal; emsa.europa.eu

EMSA provides the Commission and the EU countries with technical and scientific advice on how to improve safety and security at sea and prevent marine pollution.

European Medicines Agency (EMEA). Location: London, United Kingdom; emea.europa.eu

EMEA advises the Commission when human and veterinary medicines are ready to be put on the EU market. It monitors adverse effects, and provides scientific advice.

European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Location: Lisbon, Portugal; emcdda.europa.eu

The centre is a source of objective, reliable and comparable information on drugs and drug addiction in order to help policymakers identify common problems and goals.

European Network and Information Security Agency (ENISA). Location: Heraklion (Crete), Greece; enisa.europa.eu

ENISA helps ensure that information networks and the data they carry are secure by collecting information, analysing risks, raising awareness and promoting best practice.

European Police College (CEPOL). Location: Bramshill, United Kingdom; cepol.net

The college trains senior EU police officials and prepares training programmes for middle-ranking officers, with a particular emphasis on combating cross-border crime.

European Police Office (Europol). Location: The Hague, Netherlands; www.europol.europa.eu

Europol aims at improving the effectiveness and cooperation of law enforcement authorities in the EU countries in their fight against international organised crime.

European Railway Agency (ERA). Location: Lille/Valenciennes, France; www.era.europa.eu

This agency works on common approaches to railway safety and common standards for interoperability of railways to pave the way for a fully integrated EU network.

European Training Foundation (ETF). Location: Turin, Italy; etf.europa.eu

The ETF helps improve vocational training in non-EU countries, mainly around the Mediterranean, in eastern Europe and in Russia.

European Union Agency for Fundamental Rights (FRA). Location: Vienna, Austria fra.europa.eu

This agency collects and disseminates objective, and comparable information on fundamental rights matters, and advises on how to promote these rights. This can be racism and xenophobia but also other fundamental rights.

European Union Institute for Security Studies (EUISS). Location: Paris, France; www.iss-eu.org

The institute aims to help create a common European security culture, to enrich the strategic debate, and systematically to promote the security interests of the Union.

European Union Satellite Centre (EUSC). Location: Torrejón de Ardoz, Spain; www.eusc.europa.eu/

The centre collects and analyses data and images from earth observation satellites in support of EU foreign and security policy priorities and humanitarian activities.

Executive Agency for the Public Health Programme (PHEA). Location: Luxembourg; ec.europa.eu/phea

PHEA manages the practicalities of EU funding programmes for public health projects, and feeds the results back to public-health stakeholders and policymakers.

Office for Harmonisation in the Internal Market (Trade Marks and Designs) (OHIM). Location: Alicante, Spain; www.oami.europa.eu

The office registers trade marks and designs. These are then valid across the EU. This system exists side-by-side with the individual EU countries' domestic registration systems.

Translation Centre for the Bodies of the European Union (CDT). Location: Luxembourg; cdt.europa.eu

The centre provides translation services for the specialised agencies of the EU.

List of the major US independent agencies in 2007

- **The Central Intelligence Agency** (CIA) coordinates the intelligence activities of certain government departments and agencies; collects, correlates, and evaluates intelligence information relating to national security; and makes recommendations to the National Security Council within the Office of the President.

- **The Commodity Futures Trading Commission** (CFTC) regulates commodity futures and option markets in the United States. The agency protects market participants against manipulation, abusive trade practices and fraud. Through effective oversight and regulation, the CFTC enables the markets to serve better their important functions in the nation's economy providing a mechanism for price discovery and a means of offsetting price risk.

- **The United States Environmental Protection Agency** (EPA) works with state and local governments throughout the United States to control and abate pollution in the air and water and to deal with problems related to solid waste, pesticides, radiation, and toxic substances. EPA sets and enforces standards for air and water quality, evaluates the impact of pesticides and chemical substances, and manages the "Superfund" program for cleaning toxic waste sites.

- **The Federal Communications Commission** (FCC) is charged with regulating interstate and international communications by radio, television, wire, satellite, and cable. It licenses radio and television broadcast stations, assigns radio frequencies, and enforces regulations designed to ensure that cable rates are reasonable. The FCC regulates common carriers, such as telephone and telegraph companies, as well as wireless telecommunications service providers.

- **The Board of Governors of the Federal Reserve System** (Fed board) is the governing body of the Federal Reserve System, the central bank of the United States. It conducts the nation's monetary policy by influencing the volume of credit and money in circulation. The Federal Reserve regulates private banking institutions, works to contain systemic risk in financial markets, and provides certain financial services to the U.S. government, the public, and financial institutions.

- **The Federal Trade Commission** (FTC) enforces federal antitrust and consumer protection laws by investigating complaints against individual companies initiated by consumers, businesses, congressional inquiries, or reports in the media. The commission seeks to ensure that the nation's markets function competitively by eliminating unfair or deceptive practices.

- **The General Services Administration** (GSA) is responsible for the purchase, supply, operation, and maintenance of federal property, buildings, and equipment, and for the sale of surplus items. GSA also manages the federal motor vehicle fleet and oversees telecommuting centers and child care centers.

- **The National Aeronautics and Space Administration** (NASA) was established in 1958 to run the U.S. space program. It placed the first American satellites and astronauts in orbit, and it launched the Apollo spacecraft that landed men on the moon in 1969. Today, NASA conducts research aboard earth-orbiting satellites and interplanetary probes, explores new concepts in advanced aerospace technology, and operates the U.S. fleet of manned space shuttle orbiters.

- **The National Archives and Records Administration** (NARA) preserves the nation's history by overseeing the management of all federal records. The holdings of the National Archives include original textual materials, motion picture films, sound and video recordings, maps, still pictures, and computer data. The Declaration of Independence, the U.S. Constitution, and the Bill of Rights are preserved and displayed at the National Archives building in Washington, D.C.

- **The National Labor Relations Board** (NLRB) administers the principal U.S. labor law, the National Labor Relations Act. The board is vested with the power to prevent or remedy unfair labor practices and to safeguard employees' rights to organize and determine through elections whether to have a union as their bargaining representative.

- **The National Science Foundation** (NSF) supports basic research and education in science and engineering in the United States through grants, contracts, and other agreements awarded to universities, colleges, and nonprofit and small business institutions. The NSF encourages cooperation among universities, industry, and government, and it promotes international cooperation through science and engineering.

- **The Office of Personnel Management** (OPM) is the federal government's human resources agency. It ensures that the nation's civil service remains free of political influence and that federal employees are selected and treated fairly and on the basis of merit. OPM supports agencies with personnel services and policy leadership, and it manages the federal retirement system and health insurance program.

- **The Peace Corps**, founded in 1961, trains and places volunteers to serve in foreign countries for two years. Peace Corps volunteers, now working in some 80 nations, assist in agricultural-rural development, small business, health, natural resources conservation, and education.

- **The Small Business Administration** (SBA) was created in 1953 to advise, assist, and protect the interests of small business concerns. The SBA guarantees loans to small businesses, aids victims of floods and other natural disasters, promotes the growth of minority-owned firms, and helps secure contracts for small businesses to supply goods and services to the federal government.

- **The Selective Service System** (SSS) is an independent federal agency operating with permanent authorization under the Military Selective Service Act (50 U.S.C. App. 451 et seq.). It is not part of the Department of Defense; however, it exists to serve the emergency manpower needs of the Military by conscripting untrained manpower, or personnel with professional health care skills, if directed by Congress and the President in a national crisis. Its statutory missions also include being ready to administer an alternative service program, in lieu of military service for men classified as conscientious objectors.

- **The Social Security Administration** (SSA) manages the nation's social insurance program, consisting of retirement, disability, and survivors benefits. To qualify for these benefits, most American workers pay Social Security taxes on their earnings; future benefits are based on the employees' contributions.

- **The Securities and Exchange Commission** (SEC) was established to protect investors who buy stocks and bonds. Federal laws require companies that plan to raise money by selling their own securities to file reports about their operations with the SEC, so that investors have access to all material information. The commission has powers to prevent or punish fraud in the sale of securities and is authorized to regulate stock exchanges.

- **The United States Agency for International Development** (USAID) administers U.S. foreign economic and humanitarian assistance programs in the developing world, as well as in Central and Eastern Europe and the New Independent States of the former Soviet Union. The agency supports programs in four areas — population and health, broad-based economic growth, environment, and democracy.

• **The United States International Trade Commission** (USITC) provides trade expertise to both the legislative and executive branches of government, determines the impact of imports on U.S. industries, and directs actions against certain unfair trade practices, such as patent, trademark, and copyright infringement.

• **The United States Postal Service** is operated by an autonomous public corporation that replaced the Post Office Department in 1971. The Postal Service is responsible for the collection, transportation, and delivery of the mails, and for the operation of thousands of local post offices across the country. It also provides international mail service through the Universal Postal Union and other agreements with foreign countries.

• An independent **Postal Rate Commission**, also created in 1971, helps the Postal Service set the rates for different classes of mail by holding hearings on rates proposed by the Postal Service, and recommending rates to the Postal Service Board of Governors, which in turn may accept or reject the rates. As of February 2006, legislation had passed both houses of Congress greatly increasing the regulatory powers of the Postal Rate Commission.

• **The Federal Retirement Thrift Investment Board** is one of the smaller Executive Branch agencies, with just over 100 employees. It was established to administer the Thrift Savings Plan (TSP), which provides Federal employees the opportunity to save for additional retirement security. The Thrift Savings Plan is a tax-deferred defined contribution plan similar to a private sector 401(k) plan.

Chronology of nanotechnology involvement by the ETC Group

DATE	EVENT	INSTITUTION	MEANS of OUTREACH	COMMENTS
January 2001	Publication of *The ETC Century* by Pat Mooney	Dag Hammarskjöld Foundation	Hard paper Internet	
June 2001	International seminar: *What Next? Technological Transformation: Addressing Nano-technology And Other Emerging Technologies in the ETC Century*	Dag Hammarskjöld Foundation	Venue in Europe Audience and coverage Internet	
September 2001	Regional Seminar, follow up of *What Next* International seminar	ETC	Venue in Asia (Thailand) Audience and coverage Internet	Event hosted by civil society partners in the region

December 2001	Regional Seminar, follow up of *What Next* International seminar	ETC	Venue in Latin America (Chile) Audience and coverage Internet	Event hosted by civil society partners in the region
June 2002	Report on health and safety impacts of nanotechnology: *No Small Matter! ASKS FOR A MORATORIUM ON ON ENGINEERED NANOPARTICLES*	ETC	Hard paper Internet	
December 2002	Regional Seminar, follow up of *What Next* International seminar	ETC	Venue in Africa (South Africa) Audience and coverage Internet	Event hosted by civil society partners in the region
January 2003	Report *The Big Down: from Genomes to Atoms: Technologies Converging at the Nano-scale* (80 page report)	ETC	Hard paper Internet	First comprehensive and critical analysis of the implications of nano-scale technologies by civil society
April 2003	Study explaining the case for a global moratorium on nanotech and including a scientific literature review: *Size Matters*	ETC Coauthored with Dr. Vyvyan Howard of the Developmental Toxico- Pathology unit of the University of Liverpool's Dept. of Human Anatomy and Cell Biology. In 1999, Dr. Howard, as president of the Royal Microscopy Society, co-edited the first collection of papers (1999) to examine the toxicity of nanoparticulates	Hard paper Internet Scientific community	
June 2003	ETC Group speaker at European Seminar on nanotechnology and converging technologies at the	Seminar co-hosted by the Greens/EFA	Access to policy makers	

	European Parliament, Brussels			
September 2003	ETC identifies first major environmental release of nanotechnology product in an Indian territory in New Mexico (SoilSET ™ soil binders, a revolutionary new nanotechnology product used for dust control, soil stabilization, re-vegetation, and erosion control caused by wind, rain or water runoff).	ETC	Media coverage Internet	Environmental release in New Mexico. Contacts with Indian War Chief.
March 2004	Dinner with Prince Charles and members of the Royal Society to offer advice on nanotechnology	ETC	Media coverage Internet	
November 2004	Report *Down on the Farm*, on the impact of nano-scale technologies on food and agriculture	ETC	Media coverage Internet	
January 2005	ETC Workshops on new technologies at Porto Alegre (Brazil) World Social Forum	ETC	Media coverage Internet	
June 2005	ETC Group hosted seminar series on nanoscale technologies in Geneva geared towards civil society representatives	ETC, World Council of Churches, UN, South Center, and representatives of 30 international NGOs	Civil society multiplier effect Media coverage Internet	
2005	Publication of three reports on nanotechnology and Intellectual Property at key dates, including the opening of the GlenEagles G8 summit	ETC	Media coverage Internet	
October 2006	ETC Group testifies at US Food & Drug Administration's public meeting on nanotechnology	ETC, US FDA	Media coverage Internet	
January	ETC launches Nano	ETC	Media	Interactive

2007	Hazard symbol contest. Winning symbol to be sent to major regulating agencies.		coverage (Winners of Nano-Hazard Symbol Contest Announced at World Social Forum, Nairobi, Kenya) Internet	action Reaches all sorts of stakeholders
April 2007	Open letter to the international nanotechnology community to reject proposed framework put forward by DuPont and environmental Defence	ETC and coalition of civil society and labour organizations	Media coverage Internet	

COMMISSION OF THE EUROPEAN COMMUNITIES
Brussels, 2.2.2000
COM(2000) 1 final

COMMUNICATION FROM THE COMMISSION
on the precautionary principle

SUMMARY

1. The issue of when and how to use the precautionary principle, both within the European Union and internationally, is giving rise to much debate, and to mixed, and sometimes contradictory views. Thus, decision-makers are constantly faced with the dilemma of balancing the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health. Therefore, finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent
actions can be taken, requires a structured decision-making process with detailed scientific and other objective information.

2. The Communication's fourfold aim is to:
· outline the Commission's approach to using the precautionary principle,
· establish Commission guidelines for applying it,
· build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully, and
· avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism.
It also seeks to provide an input to the ongoing debate on this issue, both within the Community and internationally.

3. The precautionary principle is not defined in the Treaty, which prescribes it only once - to protect the environment. But *in practice*, its scope is much wider, and specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the *environment*, *human, animal or plant health* may be inconsistent with the high level of protection chosen for the Community.
The Commission considers that the Community, like other WTO members, has the right to establish the level of protection - particularly of the environment, human, animal and plant health, - that it deems appropriate. Applying the precautionary principle is a key tenet of its policy, and the choices it makes to this end will continue to affect the views it defends internationally, on how this principle should be applied.

4. The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk.
The precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data.
Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and

that scientific evaluation does not allow the risk to be determined with sufficient certainty.

The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty**.**

5. Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information. Judging what is an "acceptable" level of risk for society is an eminently *political* responsibility.

Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers. Therefore, all these factors have to be taken into consideration.

In some cases, the right answer may be not to act or at least not to introduce a binding legal measure. A wide range of initiatives is available in the case of action, going from a legally binding measure to a research project or a recommendation.

The decision-making procedure should be transparent and should involve as early as possible and to the extent reasonably possible all interested parties.

6. Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

· *proportional* to the chosen level of protection,

· *non-discriminatory* in their application,

· *consistent* with similar measures already taken,

· *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),

· *subject to review,* in the light of new scientific data, and

· *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.

Proportionality means tailoring measures to the chosen level of protection. Risk can rarely be reduced to zero, but incomplete risk assessments may greatly reduce the range of options open to risk managers. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk.

Non-discrimination means that comparable situations should not be treated differently, and that different situations should not be treated in the same way, unless there are objective grounds for doing so.

Consistency means that measures should be of comparable scope and nature to those already taken in equivalent areas in which all scientific data are available.

Examining costs and benefits entails comparing the overall cost to the Community of action and lack of action, in both the short and long term. This is not simply an economic cost-benefit analysis: its scope is much broader, and includes non-economic considerations, such as the efficacy of possible options and their acceptability to the public. In the conduct of such an examination, account should be taken of the general principle and the case law of the Court that the protection of health takes precedence over economic considerations.

Subject to review in the light of new scientific data, means measures based on the precautionary principle should be maintained so long as scientific information is incomplete or inconclusive, and the risk is still considered too high to be imposed on society, in view of chosen level of protection. Measures should be periodically reviewed in the light of scientific progress, and amended as necessary.

Assigning responsibility for producing scientific evidence is already a common consequence of these measures. Countries that impose a prior approval (marketing authorisation) requirement on products that they deem dangerous *a priori* reverse the burden of proving injury, by treating them as dangerous unless and until businesses do the scientific work necessary to demonstrate that they are safe.

Where there is no prior authorisation procedure, it may be up to the user or to public authorities to demonstrate the nature of a danger and the level of risk of a product or process. In such cases, a specific precautionary measure might be taken to place the burden of proof upon the producer, manufacturer or importer, but this cannot be made a general rule.

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