#### Tentative governance for new markets by creating market infrastructures

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### Section 1. Setting the issue

This paper explores the conditions under which radical innovations find their way into society. It more specifically focuses on the multiplicity of strategies that actors deploy to structure future markets for their innovations. We could talk of tentative governance work.

In the classical view, the "innovation journey" (Van de Ven et al., 1999) comprises two main phases, a fluid one focused on exploration (March, 1991), and a retention one focused on exploitation and organized around a dominant design (Abernathy and Clark, 1985; Tushman and Anderson, 1986) which facilitates cumulative evolutions that generalize its use. Much work has been done on how exploration is nurtured, which has been well synthesized by Rip and Kemp (1998) in their notion of "protected spaces". These authors highlight the

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importance of governance mechanisms associated with the creation and preservation of these protected spaces. In previous work we have linked their creation with the development of communities of practice, and have shown how specific policy interventions can nurture their development (Delemarle and Laredo, 2008).

However, the literature is far more sparse and inconclusive about exploitation, and the generalization of radical innovations i.e. moving out of "protected space", as we will show. Sociologists such as Latour and Callon argue that innovations move out of protected spaces when innovation networks become stabilized. They see an innovation being proved as mature when the enrolment of new actors in the network does not entail other actors leaving, and does not require a redefinition of the attributes of the innovation. Management researchers speak of the move toward the exploitation phase as a 'narrowing process' (Cheng and van de Ven, 1996). Evolutionary economists underline the importance of the selection environment (Nelson and Winter, 1982), and emphasize the institutional and organizational conditions, which enable a learning process to take place (Nelson, 2001; Metcalfe, 1994). They also focus mostly on the ability of producing firms to change routines in order to incorporate the knowledge associated with the new design. Some studies have discussed differences between competence enhancing and competence destroying of new designs (Tushman and Anderson, 1986), while others have highlighted the changes in consumption/use patterns, the role of lead users (von Hippel, 1986) and the importance of user learning in diffusion (Cooper, 2000). Mixing both aspects – production and consumption – Abernathy and Clark (1985) speak of 'architectural innovations'.

These studies have provided very important insights in categorizing and characterizing the types of changes associated with radical/breakthrough innovations, but they say little about the dynamics of change and the underlying governance structures. This is explicitly the objective of the transition theories developed by Geels (2002, 2005). Geels (2011:31)

describes the socio-technical regime as "intangible and underlying deep structures (such as engineering beliefs, heuristics, rules of thumb, routines, standardized ways of doing things, policy paradigms, visions, promises, social expectations and norms" and mobilize classical aspects of the sociology of innovation (actor alignment) to explain how momentum is gained and so how innovations get out of their niches and enter society. However, Geels and his colleagues (Geels and Schot, 2007, Geels and Kemp, 2012) still face a the same problem as previous developments, and are unable to progress beyond developing typologies of 'transition pathways' built on a number of case studies (Geels and Schot, 2007) that the authors themselves consider as 'helicopter views' (Geels and Kemp, 2012: 59). How then radical innovations break through their protected space?

Our hypothesis is that this inability to conceptualize transition lies in overstating the dynamics of market construction, which Fligstein (2001) calls 'market infrastructures'. Market infrastructures are the basis for the structuring of future markets. They are thus part of the governance of future markets. For us, unfolding and operationalizing this concept is the key to analyze how intended radical innovations move from the exploration to the exploitation phase and get out of their 'protected spaces' so that they can emerge and be tested in general market-places. We argue that the move from exploration to exploitation implies work from actors to develop market infrastructure pieces and to test them outside of the "protected space". We could thus talk of tentative governance work.

The article unfolds as follows: we first analyze the literature on markets and derive from it a framework that considers markets in their collective dimension; we link successful market development i.e. the move outside of a protected space, to the shaping of new governance mechanisms, which promote a specific architecture combining pre-existing with new or transformed infrastructures. In section 3 we test this approach on the on-going case of nanotechnologies, explaining why we prefer a situation which is "in the making" for such a

test. We consider the analysis of six different, partly competing, partly complementary attempts; their features build an interesting and illuminating demonstration, if only by illustrating the variety of actors involved and the extent of their tentative efforts to create a governance for future markets. It also underlines the unique institutional change we believe may be taking place, which we discuss in section 4. The last section concludes by linking the present paper more clearly to the overall discussions on the governance mechanisms of emerging technologies.

### Section 2. Market building and market infrastructures

This section starts from the limits of the existing literature on radical innovation as outlined above, which requires that we reconsider our knowledge about market building. This reconsideration enables us to propose a framework to analyze how want-to-be innovations can quit their protected spaces, and to redefine 'niches' as spaces where the institutional conditions needed for this shift can be elaborated.

Economists do not consider that markets can be created, but rather that they are naturally generated - as Williamson argues: "in the beginning there were markets" (Williamson, 1975: 20). But this view has been questioned, notably by sociologists (for instance, Callon, 1998), who hold that markets are socially constructed entities, and there is more to the notion of 'markets' than that they just spontaneously unfold as a result of exchange activity between buyers and sellers. There are "institutional arrangements: (...) rules, roles and relationships (...) [which] make market exchange possible" (Abolafia, 1996), and which must exist for market exchanges to take place. In order to differentiate these elements from the market per se, we call them "market infrastructures". They are the focus of this paper, and we begin by examining this notion in more depth by using the concept of "frame".

Fligstein (2001) argues that market building results from a political process in which the State

plays a particularly important role. He defines four necessary rules that are embedded in society and which underlie any exchange, which he labels "market infrastructures": property rights, governance structures, rules of exchange, and concepts of control. However, these four rules are macro elements, and do not explain how specific innovations can be diffused. Extensive work on such questions has been done at the micro level - of protected spaces or niches – and we build on this work to consider these matters at the intermediary, "meso" level.

We start by considering Callon's notion of the "framing and overflowing" of markets (1998), which has three benefits: first it introduces a dynamic dimension into the discussion of markets, which otherwise is rather static. Second, it includes the notions of actors and of their strategies. Third, it brings in the notion of "framing" of markets, which we can better understand in relation to Goffman's (1974) definition of a frame as a "schemata of interpretation". Mobilizing this schemata, individuals or groups can "locate, perceive, identify, and label occurrences within their life space and world at large. By rendering events or occurrences meaningful, frames function to organize experiences, and guiding actions, whether individual or collective." (Snow et al., 1986:464). Callon sees the notion of a frame as setting the boundaries for a market. The frame defines what is important and what should be the focus of actions, what and who should be in the frame and what and who should not. But this is also a dynamic concept: whenever new issues arise in markets – that is when 'externalities' generate issues that cannot be dealt within the existing frame - an 'overflowing' happens, which results in the emergence of a new arena that takes these externalities into consideration. Negotiations within the arena lead to a robust compromise (Rip, 1986) which sees a new frame created that internalizes – at least partly – what was previously external. Callon argues that market frames are constantly overflowing and so changing: static frames cannot deal with all possible issues and need to be periodically

updated.

We develop this notion by discussing Goffman's two illustrations, which take the picture and the theatre as examples of frames. Trevino (2003) recalls how Goffman uses the image of photos or paintings to illustrate the concept: "the picture frame concept illustrates how people use the frame (which represents structure) to hold together their picture (which represents the context) of what they are experiencing in their life" (2003:39). And Callon (1998) mobilizes Goffman use of the theatre as another illustration, highlighting the rules that all persons involved must follow for a performance to happen: cashiers sell tickets, usherettes place spectators and sell programs. When the bell rings the audience must take their seats - the performance is about to start - the curtain is raised, the stage lights come on and the actors perform. All this activity is focused on the theatre auditorium - and of course the stage itself – the specialized physical setting, which is itself embedded in a larger institutional framework including author's rights, safety regulations etc.

In sum, markets need framing, which we call infrastructures, as a set of rules (what actors are allowed to do), of norms (what they ought to do) and of values (what they want to do)<sup>2</sup>. While some are intangible (embodied in the way actors behave), most are embedded in physical equipment (like Goffman's theatre, communication networks or transport networks and their support systems, e.g. containers for shipping); in formalized processes that build on specialized certification and validation bodies; or/and in legal obligations (with corresponding legislative and enforcement structures). Such a definition assumes that there is not one infrastructure to frame one market, but a set of them that build an infrastructure set or what

 $<sup>^2</sup>$  In sociology (social) norms are defined as "a kind of grammar of social interactions. Like a grammar, as system of norms specifies what is acceptable and what is not in a society or group" (Bicchieri, 2006). Norms convey a society or group's main values and ideals. Norms can be formal and written (they become rules, the law or directives) or can be informal (Demeulenaere, 2003). In the case of radical innovations that are characterized by social and technical uncertainties, it is important to make the distinction between the three elements : rules, norms and values. Controversies illustrate the fact that in specific situations actors do not agree on what to do because they have different values and norms. Thus rules cannot be defined.

Abernathy de facto called an "architecture". Some elements of a given architecture may be shared between markets, and some are specific to given markets. So each market will have its own architecture, and the origins and shapes of the different infrastructures composing it may differ from one market to another. Once the infrastructures of a given market have been stabilized, they become "naturalized" - to use Latour's term - or (as a recent EU report puts it) they come to resemble plumbing "vital, but unglamorous and forgotten until something goes wrong" (EU Commission, 2012), that is, to follow Callon, when externalities lead to an 'overflowing' and the subsequent redesign of the preexisting architecture.

The deliberate creation of a new market is then the process of identifying the 'list and architecture of rules, norms and values' relevant to the new products/services involved, comparing it with existing ones and defining the type and extent of the transformations required<sup>3</sup>.

In considering how the construction of markets unfolds, we can equate the problem of radical innovations getting out of their protected spaces with the identification of the market infrastructures that need to be created or transformed and of the activities associated with such shifts. These are specific activities that take place mostly within the innovations' protected spaces, and can be seen as attempts to enroll existing infrastructures and their operators in the new world promoted by the radical innovation. An interesting example is Apple's creation of its *I-Tunes* service. Convincing music producers that it could be an interesting channel, persuading them to accept a rule based on song selling and not record selling, and building a new financial model<sup>4</sup> was neither easy nor quick. Moving on from the initial experimental stage took a number of years: it is only nearly a decade later that we see the extent of the

<sup>&</sup>lt;sup>3</sup> This is, in a way, a classical definition of an innovation process applied to this specific stage of that process, and does not take place just within the firm or a set of promoters of innovations, but requires interactions with the broader society, thus linking with other stakeholders and arenas (Kuhlmann, 1999). Those arenas are not always explicitly political (as it is mostly the case with the construction of new policies) but can remain within the "civil" society so that a de facto governance is built (Rip, 2003).

<sup>&</sup>lt;sup>4</sup> In which song are all sold at the same price (regardless of their intrinsic quality)

resultant economic transformation of the music industry (which has had a lot of unexpected effects, such as the rebirth of independent labels). We give this example to illustrate the embedding in physical infrastructures (i.e. the I-pod device, the internet infrastructure, the I-tunes software etc.) and to have a broader view than one limited to situations requiring direct state intervention. It is also suggests that a radical innovation may not require changing all the elements of the extant infrastructure set. We hypothesize that, in most cases, radical innovations require only a major transformation in one infrastructure of the pre-existing market architecture, and can even be diffused in parallel with the established one. Last, this example calls attention to another important aspect: the attempt to create or change an existing market infrastructure depends on the uncertainty about the expected market at the time a radical innovation is proposed. Here, Apple provided a protected space in which to experiment and started enrolling both producers and users, but anticipated little about its future extension beyond I-Pod users.

### Section 3. Case study: testing our proposals using nanotechnologies

### 3.1 Selection of case study and methods

The paper aims at better understanding the diffusion of radical innovations, which (as explained above) we assume is linked to the emergence of adapted market infrastructures and their stabilization over time. This section aims to show, by studying one case, the variety of actors involved and of attempts made to shape these new infrastructures. These activities illustrate the tentative governance that actors are trying to shape: in practice we anticipate that actors will try to embed their visions and organizational/institutional preferences in selected market infrastructures. We consider an on-going case study the most relevant method to demonstrate our theoretical proposal (Eisenhardt, 1989). In comparison, a historical case study would have had three disadvantages: first, edited materials do not always cover all

attempts to change/create markets (and, particularly, failures); second, existing case studies are written with a specific purpose which makes them difficult to re-use when aiming to test a new framework; third it is difficult in a historical case to evaluate the effects of ex-post rationalizations of those actors involved in the study. We thus decided on a test based on an on-going case study.

We focus on nanotechnologies, which are generally considered to represent a radical technological shift. Working at the nanoscale enables scientists to harvest new properties that do not exist at larger scales, so as either to add new functions to existing products (like waterrepellent glass to keep windows always clean) or to build completely new products (like complex high speed chips in which transistors are only nanometers in size). Today, nanotechnologies are present in multiple markets (from leisure, to electronics, food and pharmaceuticals) mostly to add new functionalities to existing products, but they also open up radically new avenues to address numerous prevailing issues (from boosting energy conversion for solar panels, to drug delivery and new structural materials). In terms of governance issues, this case is interesting from a variety of perspectives. First, nanotechnologies have generated a great deal of hype, so that most countries have developed their own nanotechnology public programs, investing billions in R&D (Larédo et al., 2010). The largest is the US National Nanotechnology Initiative: created in 2001, it has led to a cumulated investment of almost \$1.8 billion (NNI<sup>5</sup>, 2013): since 2008 the European Union and Japan have invested approximately \$1.7 billion and \$950 million respectively, while Roco et al. (2010) estimate that the governments of China, Korea, and Taiwan have invested \$430 million, \$310 million, and \$110 million respectively. This is the first time countries outside the Triadic group have made such massive R&D investments, and the phenomenon has had two consequences: it has generated very high rates of growth in the production of

<sup>&</sup>lt;sup>5</sup> NNI 2013 budget supplement. <u>http://www.nano.gov/node/748</u> Last accessed, March 4th, 2013

knowledge (for instance Delemarle et al., 2009, calculated that nanotech publications registered by the Web of Science have grown by 14% annually over the last decade); and it has led to the creation of multiple S&T niches in which national programs have developed and tested new technological demonstrators/prototypes. Second, this hype has also driven private sector activity, with most of the largest world firms now owning nanotechnology patents from chemicals and materials, to health care and pharmaceutical industry, and to electronics and telecommunications, to cite just a few application fields (Larédo et al. 2010). Nanotechnologies are indeed considered as "general purpose technology" (Bresnahan and Trajtenberg, 1995), which promise to impact all fields in a pervasive manner.

Last but not least, civil society at large also participates in this movement: NGOs have drawn attention to uncertainties about the environmental and health effects of nanomaterials – and indeed, we know little about their long term effects on human beings or the environment, as matter at the nanoscale does not always have the same physical, chemical, electronic or structural properties as it does at the microscale (Royal Society, 2004; Aitken et al., 2009). Science fiction movies and books - such as Michael Crichton's The Prey (2002) – have also generated public concerns and rekindled fears about techno-sciences, and social movements have led governments to try out various forms of interactions between science, politics and society via direct/participative or technical democracy (Callon et al., 2001). The case is thus rich in terms of the multiplicity of actors involved, the variety of spaces in which they can act and the diversity of concerns they may want to advance.

In order to select attempts at developing new infrastructures, we have chosen to follow engagements of active actors: policymakers, a consumer NGO (who invited us to record some of their attempts, in particular the framing of new standards, see below), and actors from firms. One individual in particular, employed by Arkema, a large French chemical company, is illustrative of the variety of activities, actors have engaged in. He was the founder and head

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of the French nanotechnology standardization committee (AFNOR X457) and has been, since their creation, the head of the French delegations to two international standardization committees (CEN TC352 and ISO TC229): thus standardization is the first attempt we follow (section 3.2). He is a member of the executive committee of the French chemical industry association (UIC) and the French representative at the European chemical industry association (CEFIC), which led him to get involved in the REACH negotiations, and is currently part of the discussions about how REACH is going to cope with nanotechnologies (via what is called nano-REACH): this is another attempt we study (section 3.6). His position at CEFIC also drove him to participate actively in the EC development of a voluntary European code of conduct for responsible nanotechnology R&D. The attempt of developing a "soft law" approach is thus another focus for our analysis (section 3.5). We have already noted the considerable uncertainty linked to safety and environmental issues related to nanotechnologies, and OECD has been active (within its chemical remit), in trying to address them through creating a working party on nanomaterials (WPN). This group has gathered interest from several governments, which encouraged our focal actor to get involved in those developments that have taken place. So this is yet another attempt at shaping and adapting regulations for nanotechnology that we follow (section 3.4). Concerns to gain better knowledge about human and environmental safety has also led to the formation of a number of EC-supported collective projects dedicated to producing a safe ecosystem for nanomaterials, with members including toxicologists (ex: Nanosafe project<sup>6</sup>) but also jurists (ex: Nanonorma project<sup>7</sup>). Another visible French actor, active in safety issues in other fields, is a representative of L'Oreal, which early on faced an important controversy in the US about a new face cream, which it had to remove from the market. As a result of this experience, L'Oreal chose to be active, together with academics, NGOs and other firms, in the creation of

<sup>&</sup>lt;sup>6</sup> www.nanosafe.org

<sup>&</sup>lt;sup>7</sup> www.nanonorma.org

ICoN - a new NGO dedicated to gathering all existing toxicological knowledge and making it accessible to all stakeholders: this development is the fifth infrastructure development attempt we study (section 3.3). Last but not least, both our two actors have been involved in the different public debates that have taken place in France and in different TV programmes on the topic, in particular the very visible French/German documentary produced by Arte (2012). Public debates thus constitute the sixth attempt at framing markets we analyse (section 3.7). We present these six attempts in more details below. We rely on different data sources for each of them. Public debate on nanotechnologies has attracted a lot of attention from STS scholars and many initiatives have been analyzed throughout Europe (Scholl and Petschow 2009; Stilgoe 2007; Randles, 2010). Though both authors have been involved in the French debates, we mostly rely on work done by our colleagues cited above. REACH developments have also been well documented in Henri Boullier's work (2010), we mobilize it as well as notes from the numerous standardization meetings where firms discussed issues pertaining to the implementation of REACH. The other attempts to develop market infrastructures were less documented for two reasons. The first is the failure (or relative failure) of these attempts - this applies to both the ICoN and the European Code of Conduct initiatives. The second reason is the difficulty of accessing the process at work in private organizations, such as standardization committees. We have addressed the latter by the long-term involvement (since 2008) of one author in the French and international standardization committees, both as an observer but also as an expert on two of the ISO TC229 task groups, and on several projects run by the French, European and international standardization committees. This allowed us to follow the debates, evolutions and processes within these organizations in detail. The methods used in each of the six situations are explained as we present them. We have investigated each situation in terms of what it intended to produce, and focus our presentations on the characterization of the expected infrastructure, its building process and the efforts deployed to make it sustainable over the long-term. A summary of the six situations is presented in table 7.

### 3.2 Attempts at shaping a new approach to standards – ISO Technical Committee 229 "nanotechnologies"

The first attempt we follow is the building of a standards infrastructure through the work of the ISO nanotechnologies technical committee. We focus especially on the committee's dynamics as mirrored in its successive work programs, which were collectively defined and evolved as countries proposed new work items.

The International Organization for Standardization (ISO) creates standards in all fields. "ISO is the world largest standards developing organization. Between 1947 and the present day, ISO has published more than 18,500 International Standards, ranging from standards for activities such as agriculture and construction, through mechanical engineering, to medical devices, to the newest information technology developments" (ISO website, 2011). Standards are usually produced when products are already on the market with the objectives of safety for the workers and the users, and of making trade and exchange easier between countries based on interoperability. ISO is organized in technical committees (TC) that are created by ISO Technical Management Board. In 2005, the latter requested an investigation on the relevance of having a nanotechnologies committee at an early stage of development of nanotechnology markets' development: at that time, very few countries had set up national standardization committees on nanotechnologies and no standards had been published on the subject. Created the same year (2005), the TC229 "nanotechnologies" brought together a heteroclite group of people with various interests. Some are high-level scientists with management positions in industry or scientific agencies who felt that something needed to be done to support the development of nanotechnologies, while others, in contrast, are specialists

in standards but had, at the start of the Committee, no knowledge of nanotechnologies. The first meeting of the committee then aimed at defining the scope of the TC i.e. what it should work on. The first task was to define what nanotechnologies were, as no shared definition existed on the subject<sup>8</sup>, and the second was to define how to proceed, since nanotechnologies are transversal - should they be handled by a new committee or dealt with in the various relevant technical committees that already existed. Issues of redundancy of activities and coordination were central: to solve these, TC229 members decided not to focus on applications, which could be handled elsewhere later<sup>9</sup>, but to develop high-level standards that can be used in all applications. In a later version of its strategic document, TC229's mission was defined in very generic terms as "to develop science-based standards for the field of nanotechnology in order to promote its commercial applications in a secure manner" (General assembly, June 12th 2009).

At its first meeting, members defined the committee's work-program around three themes and three 'working groups', as proposed by the UK delegation and easily agreed. They were convinced that without shared definitions no standards could be written in the long run, and also wanted to avoid the mistake that had happened in biotechnologies. Thus WG1 "Terminology and nomenclature<sup>10</sup>" was created to fill that gap<sup>11</sup>. WG2 "Measurement and characterization" was tightly related to WG1 – that things would be named when they could

<sup>&</sup>lt;sup>8</sup> The group produced this first definition of its activities in 2005: "Title: Nanotechnologies; Scope: "Standardization in the field of nanotechnologies that includes either or both of the following: (i) Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometers in one or more dimensions where the onset of size- dependent phenomena usually enables novel applications; (ii) Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties". Source: ISO TC229 archives – N41

<sup>&</sup>lt;sup>9</sup> They did not state where, whether in another industrial committee or in another standard setting organization.

<sup>&</sup>lt;sup>10</sup> WG1 aims at creating "a common language for scientific, technical, commercial and regulatory processes" (TC229 Business Plan, 2007).

<sup>&</sup>lt;sup>11</sup> Abe stated in 2006 that "many new terms have been introduced independently, each by a small group of researchers in a particular field, without considering consistency with existing terms. As a result, it is not easy to see relationship between technical terms even for experts."

be seen and measured<sup>12</sup>. Finally, WG3 was set up to focus on health, safety and environment<sup>13</sup> because members considered these the most important issues to deal with to support future products development.

TC229 then discussed its structure. While most ISO committees are organized in subcommittees, after discussion and on the recommendation of the ISO technical management board, the members agreed on a flat structure, based only on the working groups. The chairman "was more favorable to a flat structure for newly established committees as this would ensure co-ordination of work among its working groups, would obviate a level of bureaucracy and would be more flexible in the management of its program of work than a Sub-Committee structure (since SCs tend to be more independent from each other).(...) if the intention of the TC was to commence work on new work item proposals in the near future, a WG structure seemed to be more suitable. He explained that setting up SCs required TC approval by resolution and then further approval by ISO Technical Management Board (approximately 4 months), which could cause an unnecessary delay" (London meeting, 2005, minutes, T. Hancox, N41). This structure pointed to the need for transversality, for transparency and to take into consideration that no specific work had been defined and that no clear vision yet existed within the committee.

In 2007, TC229 proposed its first business plan, a mandatory step for each new committee: indeed the ISO Technical Management Board (TMB) assesses the relevance and work of all new committees after their first 18 months. To start work quickly (and avoid the "blank page

<sup>&</sup>lt;sup>12</sup> WG2 aimed to develop measurement standards that would be "internationally accepted for quantitative scientific, commercial and regulatory activities" (TC229 Business Plan, 2007).

<sup>&</sup>lt;sup>13</sup> WG3's objective was to ensure "occupational safety, and consumer and environmental protection, promoting good practice in the production, use and disposal of nanomaterials, nanotechnology products and nanotechnology-enabled systems and products" (TC229 Business Plan, 2007). It was the largest group and involved in the most projects.

syndrome"), TC229 agreed it should meet twice a year<sup>14</sup>, which is unusually often for an ISO TC. Normally, plenary TC meetings are only informative meetings where working group conveners report to the TC - the actual work happens in between meetings via email exchanges or teleconferences. But, since the start, TC229 meetings have been strategic meetings, where members build a shared view about the development of the field as a whole, aiming to convince other delegations to support new work projects, and to develop trust relationships. They attract between 120 and 200 participants - again, very unusual high numbers.

| Date             | Place of<br>Meeting | Number<br>of<br>permanent<br>countries<br>members | Number of<br>projects<br>discussed | Number<br>of internal<br>liaisons | Number of<br>external<br>liaisons | Comments  |
|------------------|---------------------|---|------------------------------------|-----------------------------------|-----------------------------------|---|
| November<br>2005 | London              | 23  | 0                                  | 6                                 | 0                                 | Definition of scope and organization  |
| June 2006        | Tokyo               | 27  | 1                                  | 7                                 | 2                                 | Discussion on internal WG<br>roadmaps<br>Liaisons with EU (CEN) and OECD  |
| December<br>2006 | Seoul               | 28  |                                    | 15                                | 4                                 | First draft for Business Plan   |
| June 2007        | Berlin              | 29  | 10                                 | 18                                | 4                                 | "Nanoscale" definition  |
| December<br>2007 | Singapore           |   |                                    |                                   |                                   |   |
| May 2008         | Bordeaux            | 30  | 29                                 | 21 (incl<br>IEC)                  | 4                                 | 1 <sup>st</sup> meeting WG4<br>First business plan  |
| Nov 2008         | Shanghai            | 32  | 33                                 | 19                                | 4                                 | 1 <sup>st</sup> Meeting TG "sustainable<br>Development and nano"  |
| June 2009        |                     | 32  | 40 (2<br>published)                | 25                                | 7                                 | 1 <sup>st</sup> meeting TG "consumer and<br>societal dimensions of<br>nanotechnologies"<br>1 <sup>st</sup> meeting WG1 PG10<br>"nanomedecine" |
| Oct 2009         | Tel Aviv            | 32  | 41 (2<br>published)                | 25                                | 8                                 |   |
| May 2010         | Maastricht          | 33  | 44 (2<br>published)                | 26                                | 8                                 |   |
| December<br>2010 | Kuala Lumpur        | 36  | 39 (7<br>published)                | 26                                | 9                                 |   |

Table 1 - list of TC229 meetings and activities

<sup>&</sup>lt;sup>14</sup> "The Chairman mentioned the need for TC229 to meet at six-month intervals during its early stages and until the structure was established and its programme of work progressing. He felt that TC229 could meet twice in 2006 and then hold one single plenary meeting from 2007 onwards." (London minutes, 2005, N41).

| May 2011  | St Petersburg | 24 | 34 (11      | 27 | 9 |  |
|-----------|---------------|----|-------------|----|---|--|
| -         |               |    | published)  |    |   |  |
| November  | Johannesburg  | 34 | 32 (15      | 27 | 9 |  |
| 2011      |               |    | published)  |    |   |  |
| June 2012 | Stresa        | 34 | 24 (23      | 29 | 9 | New chairmanship                               |
|           |               |    | published)  |    |   | 1 <sup>st</sup> meeting WG1 – PG13 "indicators |
|           |               |    |             |    |   | for nanoeconomics"                             |
| March     | Queretaro     | 34 | Unavailable | 30 | 9 | 1 <sup>st</sup> meeting WG 1 – PG14            |
| 2013      |               |    | information |    |   | "terminology – nanotechnology in               |
|           |               |    |             |    |   | plain English"                                 |

Note: when a project is accepted, ISO's rules state that it should produce an outcome within 36 months. Projects then last in general 3 years.

TC229 has evolved over time. It first grew in terms of participants: it attracted only 40 delegates at its first meeting. An important point to note is that it has considerably extended its geographic breadth over time, so it now includes permanent members from Latin America, Africa, the Middle East, India and South East Asia<sup>15</sup>, and experts from these countries lead both projects and working groups. The scope of TC229's activities has also grown: annex 1 shows the number of projects it has developed over time and their outputs. And in 2008 the committee developed a roadmap that integrated its various working groups' internal roadmaps<sup>16</sup>. The same year, a fourth working group on material specifications was added after considerable debate. This move resulted from pressures from the Chinese standardization committee, which published the first standards on nanomaterials, causing much debate about the relevance of the metrics and characterizations used. This revived the debate on the role of TC229: should it deal with product by product material specifications (e.g. nanoTiO2 for suncreams) or material specification in a generic manner (e.g. nanoTiO2 in general)? Although the answer was not straightforward at the time, today TC229 is considered as the

<sup>&</sup>lt;sup>15</sup> In 2012, TC229 had the following membership: 34 participating countries (P) members 11 observing countries (O) while these were 28 P and 6 O in 2006.

<sup>16</sup> A planning and coordination task group as well as a strategic task group were created to ensure the coherence of such work and the relevance of new work item proposals (NWIP) within the overall TC's strategy. In its first two years, all NWIP were accepted because the TC needed to engage in activity, whatever it was – and national delegations were reluctant to vote against other countries' proposal even if they had neither interest nor experts in those topics.

coordinating TC for nanotechnologies<sup>17</sup>; specific work on applications is carried out by existing industrial TCs, even if this involves working outside the ISO structure. In 2011 for example, TAPPI, the worldwide Technical Association for Pulp, Paper and related Industries, which is in charge of standardization in those fields, contacted ISO TC229 to coordinate the standardization activities in relation to nanocellulose materials, and it was agreed that ISO TC229 WG1 would work on definition related to nanocellulose and that WG2 would work on their characterization and measurement. To give another example: in 2007, ISO TC229 and the IEC (the International Electrotechnical Commission - in charge of standardization activities in electrotechnology) decided to avoid redundancy by creating joint working groups to manage their nanotechnology-related activities<sup>18</sup>. The TC's scope of activities was also enlarged to include themes that are not specifically technical, with the creation in 2007 and 2008 of two task groups on "sustainable development and nanotechnologies" and "consumer and societal dimensions of nanotechnologies" that report to the TC as a whole. In 2012, the first projects that are not directly technical were proposed in WG1 (with the support of the OCDE) covering "economic indicators for nanotechnologies" and "terminology nanotechnologies in plain English".

TC229's development pattern thus shows the progressive enrolment of new actors and the enlargement of its scope of activities. It has succeeded in attracting other international standardization bodies to follow its approach and coordinate their activities. It has also attracted policy actors that have driven to an enlargement of its remit, to environmental and societal issues. And, a critical point to note, all these activities take place 'upstream', before national standards are developed and promulgated, raising the issue of a potential reversal of classical standardisation processes.

<sup>&</sup>lt;sup>17</sup> So TC229 is transversal across many industries – in 2013, its members come from multiple industries and application committees: biotechnologies, forestry, textiles, electronics, materials etc.

<sup>&</sup>lt;sup>18</sup> ISO TC229 WG1 and WG2 are actually now Joint WGs between ISO and IEC, bringing together experts from both organizations and producing documents that are published jointly by ISO and IEC.

## 3.3 - Attempts at creating a new knowledge infrastructure on toxicology: the International Council on Nanotechnologies (ICoN)

As we look for outcomes and the ability of actors to shape new governance mechanisms, we have chosen to follow the unfolding of the ICoN toxicology database. ICoN is a NGO, and defines itself as "an international, multi-stakeholder organization whose mission is to develop and communicate information regarding potential environmental and health risks of nanotechnology, thereby fostering risk reduction while maximizing societal benefit" (ICoN Fact sheet, 2010)<sup>19</sup>.

ICoN was "founded in 2004 as an extension of the US National Science Foundation Center for Biological and Environmental Nanotechnology (CBEN) at Rice University in Houston, Texas. ICON is a knowledge-driven organization [that] does not engage in advocacy or commercial activities [...]. It is composed of members from academia, industry, government and non-governmental organizations<sup>20</sup> from France, Japan, the Netherlands, Switzerland, Taiwan, the United Kingdom and the United States" (ICON Fact sheet, 2010). Icon is supported by a NBER grant and by Rice University, as well as by industrial sponsorship from DuPont, Intel, Lockheed Martin, L'Oreal, Mitsubishi Corporation, Procter & Gamble and Swiss Re insurance<sup>21</sup>.

As its website notes, ICoN aims at providing transparent and high quality technical information on health and environmental risk issues in nanotechnologies. Initially, it created a

 <sup>&</sup>lt;sup>19</sup> Downloaded July 1st. 2010 is the date of the last update of the document .
 <sup>20</sup> Evolution of ICoN executive board 2004/6-2012 (based on ICoN website).

|                      | 2004-2006 | 2012 |  |  |  |
|----------------------|-----------|------|--|--|--|
| pub admin./govt. lab | 7         | 9    |  |  |  |
| university           | 3         | 4    |  |  |  |
| company              | 11        | 10   |  |  |  |
| other                | 3         | 4    |  |  |  |

The most recent changes in the executive board occurred in 2009 when 5 new members joined (2 companies, 2 public administrations and 1 other). Since then, there has been no change in the membership: both individual and organizational members have been very stable over the years.

<sup>&</sup>lt;sup>21</sup> membership costs \$50,000 per year.

database - the ICON Environmental, Health and Safety (EHS) database - to collect as much data as possible on these issues. The database has since been upgraded into a virtual journal, which contained March 8, 2013, 7014 summaries (abstracts) and citations of research papers related to the EHS implications of nanoscale materials covering the period 1962-2013. Anyone can propose on line the inclusion of a new summary provided the paper has already been published in a scientific journal (called source-journal). The database/virtual journal can be searched on 9 specific criteria: Method of study, Particle type, paper type, risk exposure group, production method, exposure pathway, exposure of hazard target, content emphasis and target audience. So for instance, if one wants to know all the research about "carbon" as a particle type with "inhalation" as an exposure pathway, the search engine will deliver 201 hits; and a search for "nanotube" in a document title over the period will show 653 hits. It is also possible to search for the best-ranked publications from 1 to 5 stars, but only 73 journals are ranked.

Has the virtual journal succeeded in becoming a widely shared resource? Apart from the database/journal, the website has not been updated since 2010, and carries no data on its use. Nor have the database organizers answered our emails, so it is difficult to assess the extent to which the virtual journal/database is used. We asked the members of the standardization committees ISO TC229 in 2009 (see section 3.2) and were struck by the fact that (apart from one sponsor who is a French standardization committee participant) no one knew about the database or had used it as a source of information. This drives us to conclude that this attempt to create a new worldwide knowledge reference had not succeeded yet in its objective beginning of 2013, even though OECD (see below) refers to it with the NIST database as central sources of knowledge on toxicology.

# 3.4 – OECD (WPMN)<sup>22</sup>: an international public attempt to build a knowledge infrastructure on nano particles

Not being involved in the OECD working group, we followed their work in two ways: we first investigated the WPMN website and collected all the documents produced until mid 2013 (Table 4). We then followed its work through the internal liaison it developed since 2006 with the ISO TC229 (14 documents from 2005 to 2012): OECD WPMN and ISO agreed to be complementary to each other, to coordinate their activities and OECD gave mandate to ISO TC229 "to develop and normalise definition, nomenclature and terminology, (...) to develop and normalise sampling and measurement methodologies for exposure & characterisation, and (...) to develop and normalise testing methodologies for the physical and chemical properties identified above"(OECD 2006)<sup>23</sup>.

There is a long tradition by policymakers from developed countries of using OECD to discuss risks associated with chemical products<sup>24</sup>. They thus did the same to discuss health and safety issues about the risks associated with nanoparticles. Moreover, to avoid past political struggles in relation to GMO or biotechnologies for example, the chemical committee of OECD along with the Working Party on Chemicals, pesticides and Biotechnology, initiated in 2006 a Working Party on the safety of Manufactured Nanomaterials (WPMN) "to ensure that the approaches for hazard, exposure and risk assessment for manufactured nanomaterials are of a high quality, science-based and internationally harmonised"<sup>25</sup>. The terms of reference state 10 points among which the first is "to elaborate and implement a program of work (...) to promote international co-operation in the health and environmental safety related aspects of

<sup>&</sup>lt;sup>22</sup> OECD also discussed nanotechnologies in the Committee for Scientific and Technological Policy (CSTP). The work of the CSTP aims to enhance economic growth and social welfare by fostering science and innovation. We here only focus on OECD WPMN.

<sup>&</sup>lt;sup>23</sup> SUMMARY OF ISSUES FROM THE OECD CONFERENCE DECEMBER 2006. Reported to ISO – document N51

<sup>&</sup>lt;sup>24</sup> see for instance its "internet gateway providing direct free access to information on the properties of chemical as well as to hazard and risk assessments" http://www.oecd.org/chemicalsafety/

<sup>&</sup>lt;sup>25</sup> www.oecd.org, downloaded July 2013, 2.

manufactured nanomaterials ... The main topic areas to be included in the program of work will include: Definitions, nomenclature and characterisation (physicochemical properties, uses) where not otherwise available; Environmental fate and effects (hazard identification, hazard, exposure and risk assessment methods); Human exposure and health effects (hazard identification, hazard, exposure and risk assessment methods); Exchange of information on regulatory and risk management frameworks (limited mainly to the chemicals sector) as well as environmental benefits."<sup>26</sup>

The WPMN developed 9 projects to cope with its objectives. Table 3 gives a brief account of their content and development as they have been presented to the ISO technical committee 229.

| Project 1 - Development<br>of an OECD<br>nanotechnologies research<br>database on Human<br>Health and Environmental<br>Safety Research (EHS). | projects in<br>2006<br>launched | projects in june 2010<br>publicly launched in April 2009, and<br>now includes data on more than 803<br>research projects   | projects in nov 2011   |
|---|---------------------------------|--|--|
| Project 2 - Human Health<br>and Environmental Safety<br>(EHS) Research Strategies<br>on Manufactured<br>Nanomaterials                         | launched                        | split into project 1 and 9   |  |
| Project 3 – Safety Testing<br>of a Representative Set of<br>Nanoparticles   | launched                        | Sponsorship Programme launched in<br>2007. 13 nanomaterials listed. In nov<br>2011, programme in its 1st phase of<br>development; Guidance Manual for the<br>Testing of Manufactured<br>Nanomaterials: OECD's Sponsorship<br>Programme published   |  |
| Project 4 –Manufactured<br>Nanomaterials and Test<br>Guidelines   | launched                        | Preliminary Review of 115 OECD test<br>guidelines. "Preliminary Guidance<br>Notes on Sample Preparation and<br>Dosimetry for the Safety Testing of<br>Manufactured Nanomaterials" and<br>"Non-Inhalation Exposure Methods for<br>Studies on the Pulmonary Toxicology<br>of Nanoparticles" to be published. IT<br>collaborative platform in its pilot phase | Review of "Guidance Notes on Sample<br>Preparation and Dosimetry for the<br>Safety Testing of Manufactured<br>Nanomaterials" |

| Table 3 proje   | acts initiated by | OFCD   | WPMN in 2006 -    | 2000 and $2011$ |
|-----------------|-------------------|--------|-------------------|-----------------|
| 1 able 5 - plop | ects initiated by | Y UECD | WPININ III 2000 - | · 2009 and 2011 |

<sup>&</sup>lt;sup>26</sup> Terms of reference for the working party on manufactured nanomaterials, 2006

| Project 5 – Co-operation<br>on Voluntary Schemes/<br>Programmes                   | launched | report "Analysis of Information<br>Gathering Initiatives on Manufactured<br>Nanomaterials"  | report "Report of the Questionnaire on<br>Regulatory Regimes for Manufactured<br>Nanomaterials". Moving out of phase 1<br>(pilot) for the database containing the<br>info. |
|---|----------|---|--|
| Project 6 – Co-operation<br>on Risk Assessments                                   | launched | report of an OECD Workshop on Risk<br>Assessment of Manufactured<br>Nanomaterials in Regulatory Context<br>(September 2009)published. Document<br>on Critical Issues on Risk Assessment<br>of Manufactured Nanomaterials is to be<br>developed.                             | report "Risk Assessment of<br>Manufactured Nanomaterials – Critical<br>Issues – "  |
| Project 7 – The Role of<br>Alternative Test Methods<br>in Nanotoxicology          |          | Expert Consultation meeting   | third Expert Consultation Meeting  |
| Project 8 – Co-operation<br>on Exposure mitigation<br>and Exposure<br>measurement |          | potential projects on occupational,<br>consumer and environmental exposure<br>identified and prioritised by the<br>WPMN. Case studies on the exposure<br>assessment of manufactured<br>nanomaterials, organised through the<br>Sponsorship programme, will be<br>developed. | 3 projects under way. 2 case studies on<br>going : nano-silver and nano-gold   |
| Project 9 –<br>Environmentally<br>Sustainable Use of<br>Nanotechnology            |          | OECD Conference on the Potential<br>Environmental Benefits of<br>Nanotechnology: Fostering Innovation-<br>Led Growth, which was held on 15-17<br>July 2009 in OECD's Conference<br>Centre.  | report "National Activities on Life<br>Cycle Assessment of Nanomaterials"<br>and workshop on the Environmentally<br>Sustainable Use of Manufactured<br>Nanomaterials       |

Source: compiled by the authors based on OECD liaison reports to the ISO TC229

Table 4 further displays the outputs produced by the WPMN: we clearly see that no document directly addresses the safety of a given nanoparticle. Most of them are either the gathering of the opinions and activities of participating members (so called "tours de table") or reviews (including one list of 'regulated nanomaterials'). Out of the 37 public documents available only four are "guidance documents" which focus on approaches, methods and tests to characterize and measure the safety of manufactured nanomaterials.

| Type of document                | Number |
|---------------------------------|--------|
| "tour de table"                 | 11     |
| OECD work programme             | 7      |
| Reviews (including 2 workshops) | 14     |
| "Guidance" documents            | 4      |
| List of regulated nanomaterials | 1      |
| Total                           | 37     |

Table 4 - OECD outputs (at July 2, 2013)

This shows how OECD and member states evolved over time from their initial statements. From an initial idea of building knowledge (and potential regulation) on individual manufactured nanomaterials, they have slowly switched to the production of methodological documents for organizing testing. Their other main product is a public database that complements ICoN (which it refers to), by maintaining a database of projects initiated by national Governments.<sup>27</sup> The overall conclusion of the WPMN as presented on the website<sup>28</sup>, and previously elaborated in a summative document on their activities<sup>29</sup>, considers that manufactured nanomaterials at large do not require more than classical materials (apart from local adaptations in testing procedures). They thus de facto consider that it is the role of existing dedicated institutional settings (and more specifically standardisation organizations, which they gave mandate to) to organize such processes. Moreover, the role of coordination of activities at the international that was at the core of OECD's role, based on the terms of references, was progressively transformed into a mere database that simply accounts for the work undertaken by national authorities individually or other collective spaces (such as the ISO).

# **3.5** Attempts at shaping practices through the design of the European Code of Conduct for responsible nanosciences and nanotechnologies research

Dealing with existing products when most actors and authorities consider that we are still in an exploration phase puts on the forefront the risks associated with research and developent

<sup>&</sup>lt;sup>27</sup> OECD Database on Research into Safety of Manufactured Nanomaterials, accessible at http://webnet.oecd.org/NanoMaterials

<sup>&</sup>lt;sup>28</sup> Looked at July 2, 2013, <u>http://www.oecd.org/science/nanosafety/</u> 'the first six years'. See also downloadable 4 pages brochure "Six years of OECD work on the safety of manufactured nanomaterials: achievements and future opportunities" (no date)

<sup>&</sup>lt;sup>29</sup> Nanosafety at OECD: the first five years, OECD January 2011, 15 pages.

activities. One of the most prominent collective attempts has been to reject 'hard' regulation and to foster 'soft' approaches based upon the voluntary involvement of stakeholders. This section thus follows the use of the European Code of Conduct for responsible nanosciences and nanotechnologies research<sup>30</sup> developed in 2007 by the European Commission.

Codes of Conduct are by no mean exclusive to nanotechnologies. In this case, the idea and first developments came from a joint initiative by the UK Royal Society, Insight investment, the Nanotechnology Industrial Association and the UK Nanotechnology Knowledge Transfer Network, who collectively argued on the risk on inaction of business as technical, social and commercial uncertainties were rising (Sutcliffe and Hodgson, 2006). They brought together members from 8 companies, 4 scientific organisations/universities and 3 NGOs to produce seven principles illustrated by examples and a benchmark after numerous public consultations. The targets of the Code of Conduct are companies' boards because they are said to be the ones able to impose change in companies. "The Code will be 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 can align their processes with emerging good practice and form the foundation for the development of indicators of compliance" (The Responsible NanoCode, 2008)<sup>31</sup>

The project, was implemented as such in the UK by the Government with very limited success (only less than ten companies volonteered to apply it). And it was used as a basis by the European Commission to produce the EU Code of responsible research in nanotechnology with the support of large European companies such as Arkema. Some of its principles were

<sup>&</sup>lt;sup>30</sup> Commission Recommendation of February 7th, 2008 on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, COM (2008) 424 Final, O.J. (L116) 46. In the rest of the text, we simply mention it as the EU Code of Conduct or CoC.

<sup>&</sup>lt;sup>31</sup> <u>www.responsiblenanocode.org/documents/theresponsiblenanocodeupdateannouncement.pdf</u>, last accessed, April 15th, 2013).

already part of European Directives and the focus of the EU Commission was to provide guidance for undertaking research - not for commercialising products, thus focusing on the areas of largest uncertainties, implicitly recognizing that the field was yet in its exploration phase. The code of conduct (see box 1) has been publicized in European countries in specific conferences organised by the EU Commission. The text of the CoC invites Member States to widely disseminate it, especially through the public research funding bodies. Members States are also requested to collaborate with the EU Commission to monitor the application of the CoC (CoC, 2008)

### Box 1 - The EU Code of conduct for responsible nanosciences and nanotechnologies research

The Code of Conduct encompasses seven general principles on which Member States are invited to take concrete action to ensure that nanotechnologies are developed in a safe manner. These are:

(i) Meaning: N&N research activities should be comprehensible to the public. They should respect fundamental rights and be conducted in the interest of the well-being of individuals and society in their design, implementation, dissemination and use;

(iii) Precaution: N&N research activities should be conducted in accordance with the precautionary principle, anticipating potential environmental, health and safety impacts of N&N outcomes and taking due precautions, proportional to the level of protection, while encouraging progress for the benefit of society and the environment;

(iv) Inclusiveness: Governance of N&N research activities should be guided by the principles of openness to all stakeholders, transparency and respect for the legitimate right of access to information. It should allow participation in the decision-making processes of all stakeholders involved in or concerned by N&N research activities;

(v) Excellence: N&N research activities should meet the best scientific standards, including integrity of research and good laboratory practices;

(vi) Innovation: Governance of N&N research activities should encourage maximum creativity, flexibility and planning ability for innovation and growth;

(vii) Accountability: Researchers and research organisations should remain accountable for the social, environmental and human health impacts of their work.

Source: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/193&format=HTML, last accessed April 18th, 2012

For the preparation of the strategic nanotechnology action plan (SNAP 2010-2015), the European Commission organised a public consultation. This consultation comprised one question about the CoC. Of the respondents 33% did not know the code, 30% knew about it but had not read it, 25% had read it but did not use it, while only 12% of the respondents said

<sup>(</sup>ii) Sustainability: N&N research activities should be safe, ethical and contribute to sustainable development. They should not harm or threaten people, animals, plants or the environment, at present or in the future;

they used it (NanoForum, 2009). In 2010, for the first revision of the EU CoC, the European Commission organised a specific survey and only 49 answers were submitted<sup>32</sup>. We take this very low number (especially compared with classical returns for similar consultations organised by the EC) as a marker of the limited diffusion of the code. Though the sample is too small to make any extrapolation, "more than half of the respondents said they knew the CoC before the consultation. Industry contributors were more numerous to know it (66,67%) than Policy makers, CSOs and Researchers (resp. 50,00 / 50,00 and 47,37%)" and "Nearly 40% said they were applying it, Industry and Researchers being first (resp. 44,44 and 42,11 %) followed by CSOs and Policy Makers (resp. 33,33 and 16,67%)". Translating these percentages in number of firms, it simply tells that 8 firms said they were actually applying the code. This corroborates with our own investigation of the use of the EU CoC by various stakeholders. We further checked the websites of stakeholders (15 companies or public research institutes – Table 5) which have been involved one way or another with the EU CoC<sup>33</sup>. We researched for the text "EU CoC" or "nanocode". In only one case, the words are present without any ambiguity. In almost half of the cases, there is no reference at all to the EU CoC.

Table 5 – number of time the text "EU CoC" or "nanocode" is refered to in the websites of the actors who have been involved in the Nanocode project

| First page or<br>main page of the<br>website | Society and<br>communication<br>webpages | Research project<br>webpages | News section<br>webpages | Do not appear at all |
|--|--|------------------------------|--------------------------|----------------------|
| 1  | 2  | 3                            | 2                        | 8                    |

Note: the text could appear in one or more webpage category (except for the "do not appear at all category). Last access to the websites July  $23^{rd}$ , 2013

<sup>&</sup>lt;sup>32</sup> EU Commission, Analysis of the results from the public consultation on the recommendation on a code of conduct for responsible nanosciences and nanotechnologies research 1st revision, available at <u>http://ec.europa.eu/research/consultations/nano-code/results\_en.pdf</u>, last accessed, June 10th, 2013

<sup>&</sup>lt;sup>33</sup> It could be through the drafting of the code, through participation to public meetings to promote the code, through the participation to research projects (ex : nanoCode or Observatory Nano)

We more broadly investigated the use and diffusion of the EU CoC. Using the work done on nanotechnology dynamics (Delemarle et al., 2009), we selected the top 5 companies in the each European clusters identified. This gave us 37 companies from all over the globe. We visited their websites to categorize their 'nano' practices: 60% do mention such practices, but, of these, 9 out of 10 develop their own approach, and none does explicitly mentions the EU CoC (table 6).

Table 6 - use and diffusion of the EU CoC in most involved firms in nanotechnologies in Europe.

| Field of the<br>company | Number<br>of<br>compani<br>es | Number of<br>companies who<br>do not mention<br>any specific<br>guidelines linked<br>to nanotechnology | Number of<br>companies who<br>mention specific<br>guidelines<br>linked to<br>nanotechnology | Number of<br>companies<br>who refer<br>to the EU<br>CoC | Number of<br>companies<br>who develop<br>in relation to<br>nano their own<br>CoC or have a<br>written<br>position | Number of<br>companies<br>who refer to<br>industry<br>practices in<br>relation to<br>nano |
|-------------------------|-------------------------------|--|---|---|---|---|
| Chemicals               | 9                             | 5  | 4   | 0*  | 4   | 1   |
| Electronics             | 11                            | 8  | 3   | 0   | 3   | 1   |
| Energy                  | 2                             | 1  | 1   | 0   | 0   | 1   |
| Materials               | 2                             | 1  | 1   | 0   | 1   | 0   |
| Pharmacy/               | 9                             | 3  | 6   | 0   | 6   | 0   |
| biotechnology           |                               |  |   |   |   |   |
| Others                  | 4                             | 4  | 0   | 0   | 0   | 0   |
| Total                   | 37                            | 22   | 15  | 0   | 14  | 3   |

Notes : \*1 entity refers to the EU CoC in the list of references.

An interesting result lies in sectoral differences. In pharma and biotech, most companies (66%) developed a "political statement" presenting their policy towards nanotechnologies. The ratio is nearly half (45%) for the chemical and materials industries. Examples include Bayer, BASF, Evonik/Degussa or Saint-Gobain, which are key producers of nanomaterials. While those using them such as electronics or energy firms do not mention any specific practice about nanotechnology (remember that they are high knowledge producers in nanotechnology, most of the times, they only mention in passing that the products they describe were developed using nanotechnologies). In these sectors, only those developing

The last two column are not exclusive. Some companies developed their own CoC and also refer to industry practices

chips developed specific practices or refer to industrial ones (IBM, STMicroelectronics and Philips)<sup>34</sup>. This drives us to conclude that this attempt by public authorities of using soft law, through a voluntary code of conduct not articulated to any certification process, has not succeeded in its objective.

### 3.6. Investing in REACH (Registration, Evaluation, Authorization and Restriction of **Chemical Substances**)

It is thus interesting to investigate whether hard law has been more successful in handling the specific safety issues associated with chemical substances, a sector where Europe occupies a very unique worldwide position with the development of REACH, the central hypothesis being that issues raised by nanomaterials should drive to an evolution of the existing (but very recent) registration dossier of chemical substances in Europe.

The REACH framework is a regulatory framework enforced by the EU commission in 2007: it aims at "ensur(ing) a high level of protection of human health and the environment from the risks that can be posed by chemicals, the promotion of alternative test methods, the free circulation of substances on the internal market and enhancing competitiveness and innovation<sup>35</sup>. It is thus a mode of regulation for the chemical industry.

The principle that underlies the framework is that manufacturers and importers of chemicals are responsible for the substances they manufacture or import. They must identify and manage risks linked to them<sup>36</sup>. For each substance manufactured or imported in quantities of one ton or more per year per company, manufacturers and importers have to fill in a registration dossier, and submit it to the European Chemicals Agency (ECHA) (registration step). Selected substances of high concern may be asked to provide more information (the

 <sup>&</sup>lt;sup>34</sup> Shell also developed specific practices in the energy sector.
 <sup>35</sup> <u>http://ec.europa.eu/enterprise/sectors/chemicals/reach/index\_en.htm</u> last accessed July, 1st, 2013

<sup>&</sup>lt;sup>36</sup> http://ec.europa.eu/enterprise/sectors/chemicals/reach/how-it-works/index\_en.htm last accessed July, 1st, 2013

evaluation step) and some substances, considered of very high concern, are subject to authorisation (the authorisation step). Last the EU authorities can put "restrictions on the manufacture, use or placing on the market of substances causing an unacceptable risk to human health or the environment"<sup>37</sup>.

Concerns due to uncertainties related to nanomaterials toxicity led actors to question the relevance of REACH framework to handle nanomaterials.

While the European Commission stated in 2008 that "current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials", and "the protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation" (ibidem), several voices raised against REACH.

First, consumer associations pointed to the lack of information for the consumers as registration dossiers are not available for competitive reasons and as there is no mention of nano labelling on products (Friends of the Earth, 2013<sup>38</sup>).

Second, two technical elements of registration dossiers are emphasized as misleading for nanomaterials:

- REACH does not use the definitions set out by ISO for identifying a nano product, it uses a mass threshold to determine which particle to register. However, risk is not linked to weight but to size (particle number, surface structure and surface activity).

- REACH requires a specific process for substances of very high concern that are on a "candidate" list and that are present in concentrations above 0,1 % by weight produced in a total quantity above one ton per manufacturer and year. However, no manufactured

<sup>&</sup>lt;sup>37</sup> COM (2008) 366 final: Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory aspects of nanomaterials, 17.06.2008

<sup>&</sup>lt;sup>38</sup> Friends of the Earth, <u>http://nano.foe.org.au/node/329</u>, last accessed August, 1<sup>st</sup>, 2013

nanomaterials did fill these criteria in 2009<sup>39</sup>.

Thus work on defining specificities for nanomaterials was developed: REACH Implementation Projects on Nanomaterials (RIP-oNs)<sup>40</sup>. CEFIC members<sup>41</sup> were some of the most mobilised experts and contributors to the work providing case studies in all working groups. However, the relevance of the work is questioned by the specific definition of nanomaterials that is used by the European Commission: experts are indeed arguing that the scale effect may appear not only between 1 and 100 nm and that a product having 45% of matter at 95 nm and 55% at 105nm it is not considered as a nanomaterial (while a product having 50% of matter between 1 and 100nm is defined as a nanomaterial). Said otherwise, size cannot be a unique identifier for nanoscale effect<sup>42</sup>. In terms of identification of substances (RIP-oN1), the existing REACH registration dossier is considered relevant by industry experts. In terms of information requirements (RIP-oN2) and Exposure (RIP-oN3), a few adjustements are proposed by experts<sup>43</sup> but "for issues which are not currently technically/scientifically mature for developing detailed guidance, the need for further research and development has been indicated" (2011, xii) and experts expect results from OECD work and ISO standardisation work within TC 229 to provide answers in the future. We thus face work in progress with two main aspects: while the chemical industry has been

very reluctant to the adoption of REACH, in the case of nanomaterials, industry

 <sup>&</sup>lt;sup>39</sup> European Parliament: Report on regulatory aspects of nanomaterials (2008/2208(INI)). Committee on the Environment, Public Health and Food Safety. A6-0255/2009. Rapporteur: Carl Schlyter. 24.04.2009.
 <sup>40</sup> Work entails 3 sub work items:

RIP-oN 1 (Substance Identification)

RIP-oN 2 (Information Requirements): the report concludes "A comprehensive synthesis of findings, implications, issues and advice has been developed and integrated through the Task Reports and the Final Project Report. Where considered relevant, feasible and justified, specific advice for updating guidance has been provided. http://ec.europa.eu/environment/chemicals/nanotech/pdf/report\_ripon2.pdf RIP-oN 3 (Exposure & CSA)

 <sup>&</sup>lt;sup>41</sup> CEFIC is the European Chemical Industry Council. Its membership entails around 29.000 companies.
 <sup>42</sup> results of RiP-oN 1 found on <u>http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Workshops/REACH-and-Nano-Workshop/2011-06-23/Nano%20REACH%20Workshop%20-%20RIP-oN1%20industry%20perspective%20-%20Morris%20Cole.pdf last accessed July 12<sup>th</sup>, 2013
</u>

<sup>&</sup>lt;sup>43</sup> http://ec.europa.eu/environment/chemicals/nanotech/pdf/report\_ripon2.pdf

representatives have involved themselves from the start producing position papers and reference documents that are central to on-going developments. And like OECD we find an overall position that favors 'local' adaptations (for specific couples of products and use) rather than a transversal approach (e.g. a nano REACH) regulation.

### 3.7 Attempts to engage with society at large: public debates

This last section follows the participation of various actors in public debates. Processes of public engagement with nanotechnology and public debates<sup>44</sup> have been largely discussed and analyzed in research projects<sup>45</sup> (for a recent review see Srandbakken et al., 2013). Between 2004 and 2008, Scholl and Petschow (2008) reported more than 60 different deliberative processes on nanotechnologies, which vary in terms of resources and use of time, but that all have in common a bottom-up involvement of individuals in relatively complicated processes (such as juries or focus groups). The main issues in these initiatives are always: (1) the 'quality' of the information given upstream to the people attending the process and (2) the selection and the background of the persons attending the process. The common point of all initiatives is that they are organized and/or funded by the State.

The Nanoplat project identifies two generations of deliberative processes: in the first years (2004-2005), deliberative processes were organized upstream by social scientists with limited articulation with policymakers (the Demos project is an example very often referred to - for a review, see Stilgoe 2007). By difference, the second generation (2007-2009) was mostly commissioned by public authorities and more elaborated in their processes but still loosely

<sup>&</sup>lt;sup>44</sup> We do not want to enter into a discussion on the differences between public engagement, public debate and deliberative process. We use them in an interchangeable manner. See the final report of the EC funded Nanoplat research project for more details on this issue.

<sup>&</sup>lt;sup>45</sup> See the 4 EC funded projects on this specific topic:

DEEPEN: http://www.geography.dur.ac.uk/projects/deepen/Home;

FRAMINGNANO: http://www.framingnano.eu;

NANOPLAT: http://nanoplat.org;

NANOCAP: http:// www.nanocap.eu

coupled to decision-making processes. After the completion of the Nanoplat project, Randles (2010) identified the emergence of a third type, more articulated to policy-relevant issues, more focused in their coverage and developing clearer linkages between science and deliberation.

This proliferation of public consultations (whatever implementation route followed) does not mean that they have had any impact on the development and/or regulation of activities. France is a good example of this inability of public debate to generate new regulatory infrastructure. The grand opening of the Minatec technological platform in Grenoble in 2006 generated violent protests pushed by an NGO called 'Pieces et main d'oeuvre' (PMO)<sup>46</sup> which central argument lies in the type of society associated with the development of what they label 'technologies mortifères' or 'necrotechnologies' (centralized control, reduction of privacy, focus on potential military uses...). Connected with other local debates, social concerns were raised and echoed by the press about the risks surrounding nanotechnologies. It drove the Government (9 ministries jointly) to launch a national debate. The choice made by the Government was to delegate it to the "Commission nationale du débat public" (national commission for public debate), an independent body created in 2002 to insure consultation of civil society at the local level concerned by potential infrastructure projects (mainly motorways, harbors, railways and airports). This independent committee is managed by a board composed of parliamentarians, members of local authorities, magistrates, representatives from environmental NGO and from consumer associations. Between 2002 and 2007, it has organized 55 local public debates linked to the creation of new physical infrastructures such as highways, airports or roads<sup>47</sup>.

The committee was requested to organize a national debate on nanotechnologies, while it had never dealt with scientific issues before (it was not part of debates on GMO or Stem cells, the

<sup>&</sup>lt;sup>46</sup> www.pieceetmaindoeuvre.com

<sup>&</sup>lt;sup>47</sup> For an overview of its role, functioning and activities, see www.debatpublic.fr

two hottest debates on scientific issues in France in recent years). The Commission chose to organize the debates along similar lines as for infrastructures: building an information file, gathering documents produced by all types of stakeholders, and organizing public debates in different locations concerned by nanotechnologies. In this case they considered the capitals of French regions with strong university capabilities, and thus organized 17 meetings from Oct 15th 2009 to February 23rd 2010. All debates were of a similar nature: 'scientific experts' were placed on the stage facing a layman audience. Anyone could participate to the debate. Experts were not only public researchers, they also came from consumer, environmental and worker associations, and a few came from companies (both large and start-up firms). Most meetings were disturbed by activists (led by PMO, see above) that took the floor and shouted so that no discussion could take place. The last 3 meetings were even transformed in an internet-based question and answer forum, and the final synthesis meeting was turned into a restricted one between actors in favor of nanotechnologies to take lessons from the experiment. This is very visible in the unusually short report produced by CNDP (16 pages, 2010) with this open question: is fighting against nanotechnologies equal to fighting against debate (p.3)?

The public debate was thus considered a failure by many, due to the inability of participating actors to agree on what to discuss<sup>48</sup>. An example of this was the involvement of L'Oreal in the debates. L'Oréal presented their scientific results on the non-toxicity of TiO2 used in solar creams while the opponents to nanotechnology brought in the debate science fiction pictures and scenarios. Even the press, after initial coverage, stopped considering the issue: Bovet (2012) speaks of the 'silencing' of the press. Analysts like Rip or Randles underline a similar phenomenon when they consider the evolution of the presence of the theme in the websites of large firms, L'Oréal being a good example of this 'silencing'.

<sup>&</sup>lt;sup>48</sup> see for instance <u>www.nanomonde.org</u> (26/7/2011): "18 mois plus tard, le fiasco de la CNDP fait encore mal" (18 months later, the CNDP fiasco still hurts)

### Section 4. Discussion

This section discusses the immediate findings in terms of governance of nanotechnologies that can be derived from the six situations that we have presented (they are summed up in Table 7). We focus on the tentative governance work that the actors carried on. We then deepen the discussion on the findings that the notion of market infrastructure brings.

| Situation      | Level of<br>activity | Main initial objectives  | Institutional<br>localization of the<br>attempt                | Results   |
|----------------|----------------------|--|--|---|
| ISO TC229      | International        | Production of technical<br>voluntary International<br>Standard (IS)  | ISO: existing<br>organization not<br>specific to nano<br>S&T   | Production of IS beyond<br>the usual spectrum of<br>activities of TCs<br>Official mandate from<br>other important actors of<br>the field<br>Coordination activities |
| ICoN           | International        | Development of an<br>international and transparent<br>knowledge repository on<br>toxicological issues                | ICoN: new set up<br>specific to nano<br>S&T                    | Limited knowledge<br>repository. Use is<br>unknown.   |
| EU CoC         | European             | Development of a voluntary<br>European Code of Conduct<br>(focus on research good<br>practices)                      | CoC: existing set up<br>not specific to nano<br>S&T            | Developed but not used  |
| OECD WPMN      | International        | Coordination of international<br>activities on EHS issues of<br>nano<br>Production of an EHS<br>knowledge repository | OECD: existing<br>organization not<br>specific to nano<br>S&T  | Production of reports and<br>good practice<br>documentation.<br>Few nanomaterials<br>characterized.<br>No coordination activities                                   |
| Nano-REACH     | European             | Defining a European directive<br>for chemical compounds at the<br>nano-scale   | REACH: existing<br>organization not<br>specific to nano<br>S&T | Still unknown. On-going discussions   |
| Public debates | French               | Gather public opinion and<br>produce recommendation for<br>public policy action                                      | CNDP: existing<br>organization not<br>specific to nano<br>S&T  | Ruined public debate<br>Silencing of actors   |

Table 7 – Summary of the six situations

These six attempts show the importance of the efforts undertaken by the actors concerned. It is a first result per se. Indeed, most, if not all case studies of innovation in the literature simply ignore these efforts. We show here that actors recognize the importance of market shaping activities (Courtney et al., 1997), and that their investments are de facto attempts to organize the governance of markets. The nanotechnology case study sheds light on these activities. Probably the central lesson is that actors invest in trying to formalize institutional frames that help in delimiting the risks they face (as much as possible in unambiguous terms). A second lesson relates to a classical result of innovation studies - path dependency: actors first focus on activities and infrastructures which they are familiar with and for which they can mobilize existing routines (and resources) from within their own organizations.

A third result lies in the set of norms and rules highlighted by such actor investments, which tend to imply expected market infrastructures, an issue the following paragraphs reflect on.

### From national to international settings to frame governance?

The institutional frames of standardization processes are similar in most countries: they rely on delegations made up to 'experts' from industry and public research to create evidencebased compromises/consensus that build standards for products to follow<sup>49</sup>. They are periodically reviewed as the relevant technical committees are standing and can be revived as new evidence is generated. The classical standard building process is that new standards are elaborated at the national level within standardization committees operated by national standard setting agencies (AFNOR in France, BSI in UK, DIN in Germany, and ANSI in the US etc). Where standards deal with physical products, harmonization is needed to overcome what are otherwise powerful barriers against product circulation and imports: this is generally achieved within the frame of established international standard setting organizations such as ISO. ISO is the largest inter-governmental agency of this type, with a typical dual work process: on one side country delegates negotiate the standards to be harmonized (i.e., the organization's work program); on the other, established committees create groups within which countries compare their own standards and try to reach a consensus about common

<sup>&</sup>lt;sup>49</sup> such standards are the archetypes of public-private partnerships

standards. Here, the first striking point is that no country has come with its own 'ready-toadopt' standards<sup>50</sup> - most have left it to ISO to build the standards they will subsequently implement. The second unusual feature is the creation of a new technical committee (TC229) that is 'scientifically-based' - unlike the normal industry-based structures - with the purpose (at least in the first stages) of producing agreed definitions and developing approaches to insure worker and user safety. The committee has added, and this is the first time, environmental safety in its work program. Finally, while there are numerous intergovernmental organizations for standardization (for electric equipment, for forest products, etc.), we witness an aggregating role of ISO TC229 as far as 'generic' aspects are concerned (definitions and measures). Once these high-level principles are adopted, we expect to see future activity focused on specific issues and a reversal of normative work within the relevant industries and technical committees: indeed, in 2013, we start to see the development of such a movement and the emergence of new tensions about borders between committees. A last issue remains open: will we witness, when global definitions will be finalized, a reversal to traditional practices - specific product standards being made nationally and coordinated expost internationally? Or are we witnessing the birth of a new type of international governance arrangement which reflects the globalization of manufacturing industries?

# Generic or specific settings?

It is common practice that States complement norms with regulatory activities that set boundaries to what can be done and what cannot<sup>51</sup>. It is interesting to note that governments did not limit their involvement in setting market infrastructure by relying on ISO: early in the process (in 2006), a compromise emerged among a number of countries to mobilize an

<sup>&</sup>lt;sup>50</sup> With the exception of China on material specifications - but these documents were rejected and new ones were produced collectively

<sup>&</sup>lt;sup>51</sup> The asbestos case clearly highlighted what can be considered as governmental failure in this practice.

established international setting to discuss the dangers of chemical molecules. OECD was agreed upon as the place to structure knowledge around a set of defined manufactured nanomaterials. This initiative could be interpreted as a further attempt to move from the national to the global level. It thus 'transfers' another common dimension of public shaping of markets - regulatory policies - through the building of joint knowledge bases against which different counties could establish legal regulations. However, this seems to encounter difficulties: the variety of nanomaterials to address is considered too great for such a process to be effective in the long run when based upon voluntary public and private investments. And after six years of activity, OECD has mostly produced 'guidance' documents and a database about government activities on the topic. Its conclusions are that existing processes (de facto standardization) are adequate for addressing relevant issues, especially since they have enlarged to environmental issues, and better structured to address the local issues that given manufactured nanomaterials could pose.

Once could also infer that the central issue of risks associated with nanoparticles are de facto handled by a new, even if regional, regulatory framework. REACH requires a firm to build a specific safety file that the European regulating agency must approve before a product can be commercialized. REACH provides an infrastructure that is adapted to the pervasiveness of nanotechnology (focusing on chemicals rather than products). One debate is to know whether there is a need of establishing a specific regulatory framework for manufactured nanochemicals (so called nano-REACH) or whether safety issues can be handled within the existing framework, taking into account its flexibility and capacity for 'local' adaptations. The 'knowledge program' developed (with heavy involvement of chemical firms, contrary to the initial setting of REACH) arrives to similar conclusions than the OECD program: there should not be a generic regulation since most issues are raised at the application level, within given industries and for specific uses. Furthermore, the fact that REACH is only a European initiative (for instance strongly opposed by the US) does not seem to be a limitation, since the EU remains the world's largest market, so all exporters and in particular all 'global' companies must get their products registered and approved by the European agency.

Thus we face a clear trend in 'established circles' (governments and industry) towards a delegation to existing dedicated structures, and their ability to adapt to individual markets and the variety of safety issues they raise.

## Still, how to govern uncertainties? Results of a few attempts.

Still both recognize the importance of uncertainties still prevailing, thus the need for more research and for insuring adequate diffusion of state-of-the-art knowledge on toxicology effects. This may explain why some major firms have followed the initiative of a group of researchers and built an NGO - ICoN - to develop a world-level repository (in the form of a virtual journal) of the existing knowledge on the toxicology of nanoparticles. The ambition is to build a world reference that promotes transparency (to address issues highlighted by the asbestos case, an enduring reference in safety debates). Promoters argue that the pervasiveness of nanotechnology makes it necessary to build a dedicated infrastructure that will gather all the world's toxicology knowledge and make it publicly available, so as to build credibility and legitimacy. This initiative also serves a complementary purpose: to enable the segmentation of issues (what may be problematic for one application may not be for another), and thus to avoid that problems encountered in some applications (e.g. in health) hamper developments in others (e.g. in energy). However the level of use as well as the difficulty to become credible tells how difficult it is to create a new market infrastructure.

Should actors then apply a precautionary principle, and wait until we know more to engage further? Should there be a moratorium as there as been for the use of stem cells? Clearly the shared political answer has been negative, as is witnessed by the development in most

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countries of national nanotechnology initiatives or programs, and by the level of public funds invested? This position is shared by large firms in all sectors, as well as by venture capital and the exponential growth of start-up firms, even if most are mostly at the exploration firm or develop business models with 'R&D activities' as their main markets (Larédo et al., 2010). How, then, should R&D efforts best be organized, given the prevailing uncertainty not addressed by any of the arrangements we have examined? One option would have been to apply the rules used for viruses and drugs to all work on nanomaterials, which requires specifically equipped (so called level 3 or 4) labs. This is actually what happens in most R&D projects in life sciences or in electronics, with scientists working in "clean" rooms. But this is not the case in the fastest growing area - new materials - that now represents the majority of publications (Delemarle et al., 2009). Instead, based on initiatives by sets of economic and societal actors, some governments (in particular the UK authorities) and the European Commission have focused on establishing a voluntary code for "responsible R&D in nanotechnology". However we have seen that this attempt has only met with minimal success - very few firms have taken it up, and no quality processes have been established (e.g. through auditing, as is the case for bio, fair-trade or sustainability certification). This may be for two reasons: the first is that the initiative does not provide a safety net for companies (by clearly delimiting the risks they take) and the second is the fact that much on-going R&D takes place in public laboratories (which have limited funding and are reluctant to engage in what is not compulsory) or in start-up firms (that can easily disappear in case of any such problems). This is confirmed by the fact the only experiments we have identified have been conducted by very large chemical firms - e.g. Bayer, which has its own internal code of conduct or Arkema, which has a unique process associated with the sale of carbon nanotubes. Shall we thus witness the emergence of a de facto governance model, which (as for the pharmaceutical industry) would be associated with a clear market structuration and segmentation, organized

around world-level firms that take responsibility for the whole value chain?

A clear de facto governance model thus emerges whereby both governments and industries propose to rely on existing standardisation and regulatory mechanisms, with a shift in the capacity of initiation and in the implementation between national and international public bodies. This shift corresponds to, and amplifies, the globalization of manufacturing activities, and of firms that organize and structure 'global value chains'.

#### What role for society at large in the governance?

One would have anticipated that in a world where science is more and more discussed in society, where powerful NGO have emerged to counter balance the power of both governments and large firms (e.g. the numerous new developments around food and forestry products), nanotechnology-based developments would generate both public debates and new civil society organisations able to act upon proposed directions (as in environment). We have de facto witnessed a proliferation of public debates in multiple formats, most of them being directly initiated by public authorities. And we have shown in our analysis what has been considered as clear failures, either because, as in France, the debate could not take place, or because, results have remained stand alone with no connection what so ever with policies. It has however had an important effect with the complete "silencing" of actors that conduct R&D (whether public or private) in the public sphere (on their communication policies and their websites, and in the media), as if the issue had simply vanished (Bovet, 2012).

Furthermore, it reveals the very limited engagement of civil society organizations, especially compared with other developments in sustainable agriculture and food markets (with the emergence of powerful NGOs organized around sustainable food brand labels, the label construction and implementation with the corresponding certification and controlling bodies). Even powerful existing consumer or environmental associations, which were engaged in

shaping tentative developments (as the EC Code of Conduct) and active in early public debates, have retracted. Can we deduce from these accumulated failed attempts that we do not face, at least from the consumers/citizens' point of view, the shaping of a transversal generic market, but a succession of individual markets, with clearly defined applications which values can be discussed? This would be consistent with the other attempts we have analysed.

# Which governance for nanotechnologies? Learnings from the notion of market infrastructures

These six attempts at shaping market infrastructures encourage the idea of nanotechnology not as one new market, but as a series of markets which share common infrastructures - the potential reference infrastructure for toxicology (ICoN), the principles for standardization processes (via ISO) and for product authorization (through REACH) - and specific features substantively defined by existing sector-based structures that mobilize and tailor the generic infrastructures created to their specific problems and needs. It is also clear that attempts to create 'soft' law (e.g., via the Responsible Code of Conduct) to handle situations in which markets do not yet exist, did not work. Indeed, public authorities still face regulatory issues (about how to conduct R&D), while large firms also pushed toward a "responsible" development of R&D, fearing that smaller ones (particularly start-ups) might endanger the whole market development by 'irresponsible' practices. What we witness is a potential major inversion in normative and regulatory processes in structuring markets: the international institutions. Governments have framed for organizing compromises between their national policies may become the central mechanism of policymaking, thus matching globalised manufacturing industries. It is also interesting to note that the only specific infrastructure concerning nanotechnologies, ICoN, is about knowledge accumulation and sharing (beyond sectorial markets – providing transversal knowledge).

Taking the issue of the construction of market infrastructures seriously, looking at actors' investments and attempts to construct them, helps to delineate the issues new markets face, and whether or not we can speak of one market. Such an approach helps to identify actors' expectations (and probably their preferences) about market infrastructures and their constitutive elements, and demonstrates that different groups of actors (here Governments and large firms) have different preferences not so much about their objectives as about the 'market infrastructures' that might operationalize them. It also shows that - contrary to many recent thinking in social sciences - the ability of bottom-up societal developments to shape future market infrastructures has remained marginal, after early hopes (from both Governments and established NGO) of the emergence of a new technical democracy (Callon et al., 2001).

## **5-** Conclusions

The article has focused on one central limitation of the existing literature on radical innovations: the shift from exploration to exploitation (March, 1991) – to put it another way, the transition between experiments in protected spaces and wider diffusion into society (Geels, 2002; 2005). We have argued that this limitation is first and foremost linked to overstating what markets are. Building on Fligstein's notion of market infrastructure (2001), Goffman's (1975) notion of frames and Callon's notion of framing and overflowing (1999), we have shown that, to enter society at large, radical innovations require a reconsideration of the market infrastructures that frame all markets. We have qualified these as addressing a triple framing of rules (what we are allowed to do), of norms (what we ought to do) and of values (what we want to do). In most cases, these infrastructures are embedded in physical equipment (like Goffman's theatre), into formalized processes that build on specialized certification and validation by relevant bodies, and into legal obligations (with corresponding

legislation and enforcement structures). We argue that each market requires a specific set of infrastructures, even though most build on existing infrastructures. In existing markets, they are largely taken for granted, invisible - 'naturalized' to use Latour's term – and so are not part of the core innovation processes which build - cumulatively and incrementally - on existing paradigms.

This is not the case of radical innovations that require radical shifts in existing paradigms (whether in production or in use). In such situations, creating a new market involves identifying the relevant infrastructures, comparing them with existing ones and defining the order and extent of the transformations required: this is a set of activities to carry, a work by itself. To an extent, we apply lessons from innovation studies to the creation of market infrastructures that we assimilate to a full phase of the innovation process.

To turn their innovations into new products which can find effective uses in society, actors need to leave the protected spaces where they have designed and tested their new products and find ways to establish wider markets. Our assumption is that they devote specific efforts to this end, building (when they are successful) what Arie Rip calls 'de facto' governance (2009). We have demonstrated this process via a case study into the fast growing science and technology area of nanotechnology. We have looked at the efforts and the specific governance work made by actors located in the protected spaces of national nano programmes, and identified the different infrastructures they have sought to build and the market structures they have anticipated. These constitutes attempts to structure future markets, attempts to establish a governance for future markets. Our study has enabled us to identify how changes in the existing infrastructures are mobilized and the ensuing tensions over visions for practical deployment and operation. It has also shown a clear movement towards a global definition of nanotechnologies (even if levels of implementation are still national) and a very specific set up process quite distinct from the on-going 'technical democracy' debates about such

technologies (Callon et al., 2001). It has also shown that the tentative attempt by Governments to treat nanotechnology as one generic transversal market has not succeeded, and that we may be moving toward a more complex situation that involves different application markets and their specific requirements. However, and this opens opportunities for further work, the articulation between generic processes and specific substantive infrastructures remains an issue for further consideration.

We argue that our approach offers a way to study transitions in the making (and not retrospectively), and operational 'handles' to study attempts at setting up governance for emerging markets.

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# Annex 1: projects developed by ISO TC 229

Source: ISO TC229, www.iso.org

| Standard and/or project  | Stage            |
|--|------------------|
| ISO/TS 10797:2012  | published        |
| Nanotechnologies Characterization of single-wall carbon nanotubes using        | published        |
| transmission electron microscopy   |                  |
| ISO/TS 10798:2011  | published        |
| Nanotechnologies Charaterization of single-wall carbon nanotubes using         | published        |
| scanning electron microscopy and energy dispersive X-ray spectrometry analysis |                  |
| ISO 10801:2010   | published        |
| Nanotechnologies Generation of metal nanoparticles for inhalation toxicity     | published        |
|  |                  |
| testing using the evaporation/condensation method ISO 10808:2010               | publiched        |
|  | published        |
| Nanotechnologies Characterization of nanoparticles in inhalation exposure      |                  |
| chambers for inhalation toxicity testing                                       | a de lie le e el |
| ISO/TS 10867:2010  | published        |
| Nanotechnologies Characterization of single-wall carbon nanotubes using near   |                  |
| infrared photoluminescence spectroscopy  | and all also and |
| ISO/TS 10868:2011  | published        |
| Nanotechnologies Characterization of single-wall carbon nanotubes using        |                  |
| ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy         |                  |
| ISO/TR 10929:2012  | published        |
| Nanotechnologies Characterization of multiwall carbon nanotube (MWCNT)         |                  |
| samples  |                  |
| ISO/TS 11251:2010  | published        |
| Nanotechnologies Characterization of volatile components in single-wall carbon |                  |
| nanotube samples using evolved gas analysis/gas chromatograph-mass             |                  |
| spectrometry   |                  |
| ISO/TS 11308:2011  | published        |
| Nanotechnologies Characterization of single-wall carbon nanotubes using        |                  |
| thermogravimetric analysis   |                  |
| ISO/TR 11360:2010  | published        |
| Nanotechnologies Methodology for the classification and categorization of      |                  |
| nanomaterials  |                  |
| ISO/TR 11811:2012  | published        |
| Nanotechnologies Guidance on methods for nano- and microtribology              |                  |
| measurements   |                  |
| ISO/TS 11888:2011  | published        |
| Nanotechnologies Characterization of multiwall carbon nanotubes                |                  |
| Mesoscopic shape factors   |                  |
| ISO/TS 11931:2012  | published        |
| Nanotechnologies Nanoscale calcium carbonate in powder form                    |                  |
| Characteristics and measurement  |                  |
| ISO/TS 11937:2012  | published        |
| Nanotechnologies Nanoscale titanium dioxide in powder form Characteristics     |                  |
| and measurement  |                  |
| ISO/DIS 12025  | on-going         |
| Nanomaterials Quantification of nano-object release from powders by generation | project          |
| of aerosols  |                  |
| ISO/TS 12025:2012  | published        |
| Nanomaterials Quantification of nano-object release from powders by generation |                  |
| of aerosols  |                  |
| ISO/TR 12802:2010  | published        |
| Nanotechnologies Model taxonomic framework for use in developing               |                  |
| vocabularies Core concepts   |                  |
|  |                  |

| ISO/TS 12805:2011<br>Nanotechnologies Materials specifications Guidance on specifying nano-<br>objects   | published   |
|--|---|
| ISO/TR 12885:2008<br>Nanotechnologies Health and safety practices in occupational settings relevant  | published   |
| to nanotechnologies<br>ISO/TS 12901-1:2012<br>Nanotechnologies Occupational risk management applied to engineered<br>nanomaterials Part 1: Principles and approaches   | published   |
| ISO/DTS 12901-2<br>Nanotechnologies - Occupational risk management applied to engineered   | on-going<br>project   |
| nanomaterials Part 2: Use of the control banding approach<br>ISO/TR 13014:2012<br>Nanotechnologies Guidance on physico-chemical characterization of engineered   | published   |
| nanoscale materials for toxicologic assessment   |   |
| ISO/TR 13014:2012/Cor 1:2012   | published   |
| ISO/TR 13121:2011<br>Nanotechnologies Nanomaterial risk evaluation   | published   |
| ISO/TS 13278:2011  | published   |
| Nanotechnologies Determination of elemental impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry   | published   |
| ISO/TR 13329:2012<br>Nanomaterials Preparation of material safety data sheet (MSDS)  | published   |
| ISO/PRF TS 13830   | on-going  |
| Guidance on the labelling of manufactured nano-objects and products containing manufactured nano-objects   | project   |
| ISO/TS 14101:2012<br>Surface characterization of gold nanoparticles for nanomaterial specific toxicity<br>screening: FT-IR method  | published   |
| ISO/DTR 14786<br>Nanotechnologies Framework for nomenclature models for nano-objects   | on-going<br>project   |
| ISO/DTS 16195  | on-going  |
| Nanotechnologies - Generic requirements for reference materials for development<br>of methods for characteristic testing, performance testing and safety testing of<br>nanoparticle and nanofibre powders  | project   |
| ISO/NP TR 16196  | on-going  |
|  | on going  |
| Nanotechnologies - Guidance on sample preparation methods and dosimetry considerations for manufactured nanomaterials  | project   |
| considerations for manufactured nanomaterials<br>ISO/NP TR 16197<br>Nanotechnologies - Guidance on toxicological screening methods for   | <b>U U</b>  |
| considerations for manufactured nanomaterials<br>ISO/NP TR 16197<br>Nanotechnologies - Guidance on toxicological screening methods for<br>manufactured nanomaterials<br>ISO/NP TS 16550<br>Nanoparticles - Determination of muramic acid as a biomarker for silver   | project<br>on-going   |
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