Regulation and innovation dynamics for nanoresponsible development: The case of the French code de l’environnement L 523-1 to L 523-5

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Abstract. This paper examines one aspect of innovation dynamics for nanoresponsible development: the links between regulation and innovation dynamics. It focuses on the case of the French Code de l’environnement, Articles L. 523-1 to L. 523-3. Articles L. 523-1 to L. 523-3 of the French environment code provide for the obligation to declare the quantities and uses of substances at nanoscale produced, distributed or imported in France. This procedure is intended to improve knowledge of these substances and their uses as well as of their markets and volumes sold, to ensure traceability and to collect available information on their toxicological and ecotoxicological properties. The paper builds on recent work on the emergence of a regulatory framework for nanotechnologies to take stock of the current situation in France, in the EU and globally and to explore how this specific law package may influence innovation and the shaping of new markets for nanobased materials. The study shows that nano-regulation does have an impact on innovation. However, the impact is not the same with EU regulation and with French regulation, and while EU regulation seems to create a favourable context for innovation, French regulation seems to do the opposite. With this study we hope to bring new perspectives to the field of the strategic management of innovation, and also to shed some light on the roles and challenges of institutions to facilitate nanoresponsible development.

1. Introduction
The notion that innovation should go hand in hand with resource efficiency and a greener economy as part of responsible development is at the heart of much debate that can be characterized by two opposing visions: Those who contend that this approach is detrimental to competition because it is altogether more costly to aim for resource efficiency and a greener economy, and those who support the idea that the players aiming for resource efficiency and a greener economy will end up being more competitive than their contenders because their approach will have allowed them to innovate in more radical ways.

Porter’s research [1] has had a strong focus on competitiveness, and much of his work analyses the links between innovation and competitiveness. Porter and van der Linde [2] examined more specifically the connections between regulation and competitiveness, and this publication led to the
The well-known ‘Porter hypothesis’ that strict environmental regulation can help improve commercial competitiveness. Although opponents of strict environmental regulation contend that it stifles innovation because of the added costs it entails, Porter’s hypothesis suggests that it does the opposite. This happens through the ‘innovation effect process’: by triggering the introduction of cleaner technologies and environmental improvements, environmental regulation leads to more efficient production processes and in the end the cost savings achieved by better efficiency compensate the costs induced by compliance and innovation.

Environmental regulation is defined by UNEP as a system of treaties, conventions, statutes, common law, and policies that concern the protection of the natural environment as it is impacted by human activity. Some environmental laws regulate the quantity and nature of impacts of human activities while others seek to assess possible impacts before the human activities can occur. The precautionary principle underlies much of environmental regulation. It is a moral and political principle that states that if an action or policy might cause severe or irreversible harm to the public, in the absence of a scientific consensus that harm would not ensue, the burden of proof falls on those who would advocate taking the action. We consider that the French ‘Code de l’Environnement’ is part of environmental regulation. It is a package of laws that started being enacted in 2005 and that defines in seven separate books the French regulatory framework relating to the environment. Our decision to focus on its Articles L. 523-1 to L. 523-3 and on the French case to study links between regulation and innovation dynamics for nanoresponsible development comes from the fact that the scope of this mandatory nanolegislation was a first, not only in the EU, but in the entire world.

As a policy maker, the European Commission considers that innovation is at the heart of competitiveness, and that it should be supported by strong financial commitments, as well as rooted in the concept of sustainable development. Indeed, in its landmark document Europe 2020: A strategy for smart, sustainable and inclusive growth it proposed as a major target that 3% of the EU’s GDP should be invested in R&D and it put forward two mutually reinforcing priorities:

1. The development of an economy based on knowledge and innovation for smart growth.
2. The promotion of a more resource efficient, greener and more competitive economy for sustainable growth.

Why should we focus on nanotechnologies? OECD defines nanotechnology as a collective term for a set of interlinked sciences and technologies which contribute together to the understanding and control of matter and processes at very small scales (typically in the range of 1-100 nanometers, one nanometer being one billionth of a meter). Nanotechnology is therefore essentially the engineering of matter down to the level of individual atoms. For reasons that remain partially unexplained today, when particles of a given chemical substance are of nanometric size, they present properties that are not observed at a larger scale, when they are in bulk. The range of changes in the properties of elements is extremely broad and scientists are only beginning to explore a new world of possibilities where they can design new products which possess the specific characteristics they want them to have. Alongside a wide range of likely societal benefits like providing renewable energy, clean water, and improving the environment or human longevity and health, nanotechnologies are extremely interesting because they are very diffuse technologies that develop globally in diverse industrial sectors. Whether they constitute an industry per se is a subject of debate: more than being the source of entirely new sectors of business activity, they tend to diffuse in existing products and services. Indeed, nanoparticles are mostly used to enhance the qualities or specific characteristics of existing products and services. A comparison with plastic is useful: just as there is a plastic industry that produces and markets different forms of plastic, there is an industry that creates nanomaterials that are ‘raw materials’, that is the powders and substances that will be integrated in other components. But then, just as plastic is omnipresent in an extremely large number of products in various industrial sectors, nanomaterials are found in a growing number of products.

Taking into consideration the patenting activity of the largest R&D industry players Delemarle et al. [3] showed that a majority of the world largest R&D actors (as accounted for by the UK DTI
scoreboard) were involved in nanotechnologies, covering all fields from electronics to food. The field of nanotechnologies therefore appears as particularly relevant to study innovation dynamics. The very differences between materials in their nano- and bulk- formats that make them of interest in new applications also suggest that these materials may interact differently with ecosystems and living cells. This raises questions linked to the management of the unknown and of potential harms to the environment or to human beings. Nanotechnologies pose new challenges to policy makers because they possess entirely new properties, and because it is therefore difficult to evaluate the way they react during their life cycle. There are two major reasons for this. Firstly, scientists are only beginning to develop nanostructures in a stable and measurable way and toxicity assessment standards and protocols are still largely non-existent. Secondly, nanoparticles are so small that it is very complex to trace them and to assess their inherent risks. One speaks here of monitors as well as of modelling capacities. Methods to analyze their impact on humans and the environment are still in the making and regulation is a key issue, mostly over the necessity – or not – to devise new laws that apply specifically to nanotechnologies [4].

2. Methods
In our paper, we seek to answer the question: ‘what are the links between French nanoregulation, EU nanoregulation and innovation dynamics’? Our methodology rests mostly on archival work, completed by some focused interviews. Archival work includes the study of a comparative database of existing regulatory frameworks, both inside and outside the EU, a synthesis of public statements, reports and public inquiries intended to measure the potential impact of regulation on innovation, as well as a study of the corporate and annual reports of CAC 40 firms. The CAC 40 (Cotation Assistée en Continu) is a benchmark French stock market index, which represents a capitalization-weighted measure of the 40 most significant values among the 100 highest market capitalizations on Euronext Paris. Euronext Paris is itself part of the Euronext Group, one of the major stock exchanges globally. Traditionally, the CAC 40 index represented the most powerful French companies and it is essentially composed of French-domiciled firms. CAC 40 firms are all operating under EU law and are illustrative of how markets could shape around the development of nanobased materials. In order to explore if and how EU regulation that bears on nanotechnologies affects innovation, we study the evolution of where CAC 40 firms locate their R&D centres globally. The link between innovation and R&D, as well as the importance of the geographical location of R&D in a globalized world has been documented in the literature [5], [6], [7]. Besides, nanotechnologies have been described as diffuse technologies that require integration to fulfil their economic promises [8] and most key industrial players carry out nano-related activities in their R&D centres [9]. Our hypothesis is that if CAC 40 firms feel that EU regulation has a negative impact on their freedom to innovate, either by restraining some fields of research, or by enforcing costly and restrictive compliance measures, they will opt to relocate R&D centres outside Europe. Taking our information from institutional and company websites, annual reports and analysts’ reports, we listed all the various locations of R&D centres, in the reference dates of 2007 and 2012. We chose year 2007 because it preceded the 2008 financial crisis and was therefore not affected by it, as shown by figure 1.
3. Nanoregulation

At the date of writing, there was no comprehensive international mandatory regulation for nanotechnologies. The United Nations Environment Program (UNEP) introduced the Strategic Approach to International Chemicals Management (SAICM) at the 2002 World Summit on sustainable development. SAICM was conceived as a global policy framework aiming to promote chemical safety around the world and its “2020 goal” was adopted as part of the Johannesburg Plan of Implementation. SAICM’s overall objective was to achieve the sound management of chemicals throughout their life cycle so that, by 2020, chemicals were produced and used in ways that minimized significant adverse impacts on human health and the environment. In the early 2010s SAICM meetings started producing non-binding resolutions on nanotechnology, but in 2014 SAICM had not produced any binding regulation.

The EU was the most advanced organization to enforce a binding law of international impact: EU Regulation 1223/2009 on cosmetic products came into force in 2013. This law – the first international law with some parts specifically designed for nanotechnologies – concerned the EU market. It included a review of the safety of nanomaterials. All cosmetic products were subject to a safety assessment and to a premarket notification and approval procedure. A new and important feature of the regulation was that in order to establish clear responsibilities, every product must be linked to a "responsible person" who was responsible for ensuring compliance with the regulation, and who must keep a product information file for a period of 10 years after the date when the last batch of the cosmetic product was placed on the market. The “responsible person” must have an address in the EU.
It could be the company that manufactured the cosmetic, or had it manufactured, or the local office or agent for a manufacturer based outside the EU. If there was no local agent for a non-EU manufacturer, then the first company importing the product into the EU was the "responsible person". The regulation also required traceability of a cosmetic product throughout the whole supply chain, as well as clear labelling including the name and address of the responsible person, and the presence of all ingredients containing nanomaterials, with their names followed by (nano).

The other law that originated in the EU was REACH, Registration, Evaluation, Authorization and Restriction of Chemical Substances - EC 1907/2006 – 2006. REACH is a comprehensive regulatory framework which was introduced by the European Commission in 2006 to replace some 40 existing legal acts and to create a single system for all chemical substances in Europe. Its main objective was to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances, and this included the plan to find substitutes for the most dangerous chemicals in use. The law entered into force on 1 June 2007. One of its characteristics was that it transferred the burden of proof for demonstrating the safe use of chemicals from EU Member States to industry.

REACH has two major components. Starting in June 2008 and before the deadline of June 2018, all firms that manufacture or import more than one ton of a chemical substance per year are required to register it in a central database, the European Chemical Agency (ECHA). Besides, all new chemical substances that were produced or imported in the EU after the cut-off date of 1981 have to undergo a strict risk assessment process. This means that all chemical substances produced before 1981 do not need to undergo the safety assessment process again, and that firms that produce or import less than one ton of a given chemical per year do not need to register these substances. The REACH provisions have been planned to be phased-in gradually over a period of 11 years because of the complexity of the process and because of the need to find replacements to some chemicals that were considered too dangerous to be retained.

REACH is a general framework and it does not apply specifically to nanosubstances. Critics of the law say that because most nano substances are so small, they are produced in quantities that are below one ton per year, which means that they go unregulated. They also criticize the fact that there are no specific provisions for them considering their novel nature. A general review of the scope of REACH including a review of the specific information requirements took place in 2012, and a new public consultation was organized in 2014 to identify and develop the most adequate means to increase transparency of nanomaterials on the market.

REACH can in fact apply to substances produced or imported in volumes below 1 ton per year if they are considered to be of very high concern. This means in effect that risks from certain nanoscale substances could be addressed through REACH if they were identified as being “substances of very high concern” as defined in Article 57, for example as being persistent, bio-accumulative and toxic (PBT) substances. Although REACH had still in 2014 no specific provision for nanotechnologies, the modification introduced in 2008 by Regulation EC 987/2008 opened the way to nano-specific regulation. Indeed, Regulation EC 987/2008 established that some chemicals which used to be exempt from regulation because they were considered well-known and safe (Regulation (EC) No 1907/2006, Article 2(7) (b)) had to be removed from the lists of exemption (annexes IV and V). This concerned, among other substances, carbon and graphite. The chemical structure of carbon and graphite was well known. Yet it was judged that there was insufficient data on their forms at the nano-scale to consider that “their use caused minimum risk because of their intrinsic properties”. So the substances registered as forms of carbon or graphite at the nano-scale on the European Inventory of Existing Commercial chemical Substances (Einecs) or on the Chemical Abstracts Service (CAS) had to be removed from the list of exemptions and be treated as new substances.

France took EU regulation one step further, and introduced the strictest law in the world concerning nanomaterials. This came as part of the Grenelle 2 law package, in the French ‘Code de l’environnement, L 523-1 to L 523-5. The full title of this specific regulation translates as Book V: prevention of pollution, risk and nuisances. Title II: chemicals, biocides and nanoparticulate
substances; Chapter III: Prevention of risks for health and the environment resulting from exposure to nanoparticulates”. As of July 2013, the law required manufacturers, importers or distributors of nanoparticulates in France to inform relevant authorities, and to provide information about the substances involved on a specific website called R-Nano (https://www.r-nano.fr/). The requested information included intended use of substance, quantities involved, identity of the professional users, and danger relative to exposure in terms of health or of environmental risks. The data provided could be made available to the public.

4. Discussion and conclusions

Our hypothesis is that if environmental regulation impacts innovation negatively by encouraging firms to locate R&D centres in countries that are not affected by this regulation, then French firms will displace their R&D centres away from France. To test this hypothesis, we surveyed where the 32 CAC 40 firms that had R&D centres had set up their research centres in 2007 and in 2012. We surveyed the 40 firms of the CAC 40 index, and excluded 8 firms for which the study was not applicable. In 2007, the 32 firms that we retained had a total of 164 R&D centres worldwide. This number rose to 229 in 2012. This increase of nearly 40% shows the importance of the perceived role of R&D centres in corporate strategy.

The introduction of the French Code de l’Environnement L 523-1 to L 523-5 was accompanied by a change in the geographical location of the R&D centres of the CAC40 firms. In 2007, 45% of the research centres were in France, but in 2012, there were only 41% of them. The drop was even larger in relative terms, considering the overall increase in the number of R&D centres (Figure 2).

![Figure 2: Evolution of the geographical location of R&D centres of the CAC 40 firms between 2007 and 2012: France vs Rest of the World. Source: authors.](image)

This change seemed to indicate a trend toward moving out of the too strict regulation. However, things are slightly different if we look at a more global perspective (Figure 3).
Indeed, the CAC firms did establish R&D centres outside France, but they did not leave massively the EU zone. On the contrary, in 2012, 59% of the R&D centres of the CAC 40 firms were located in the EU as opposed to 51% in 2007. When they offshored their R&D, CAC 40 firms clearly looked for diversification, as they spread between the Americas, Asia, and Africa.

The conclusion of this study is that nano-regulation does have an impact on innovation. However, the impact is not the same for EU regulation as for French regulation, and EU regulation seems in a way to boost innovation while French regulation stifles it. This can be explained by one major factor: the size factor. When regulation happens at different levels, from the local one to the international one, the terms “international”, “regional”, “national” and “local” usually refer to the bodies that pass the said regulations, not to the areas covered by them. For example, “Regional regulation” refers to regulation passed by a regional institution, like the EU, which includes regulatory bodies of different nations united by a specific agreement. On the whole the geographic scope of the regulation corresponds to the level at which it is passed: national regulation will apply to a specific country, and regional regulation to a region (like the EU). However, the geographic scope of some regulations goes beyond that of the body that passed them. To continue with the example of EU regulation, when a specific law targets the products or substances manufactured or imported in the EU, its scope may in effect be much larger since it may impact producers globally. Indeed, it is often too costly to run separate supply chains, and manufacturers who wish to do business with the EU have to adopt EU regulation for all their production processes. This is what is happening with cosmetics. The stricter EU nanoregulation for cosmetics is in fact affecting all cosmetics producers globally, and once producers start testing their products to comply with EU regulation, they tend to adopt the same protocols for their global production. However, with France, the situation is different: the geographic scope of the French nano decree relative to the Code de l’environnement is wider than France since it requires manufacturers, importers or distributors of nanoparticulates in France to fill the R-Nano file wherever they operate from. The problem is that while the size of the EU market is large enough to jeopardize a firm’s business if it cannot sell on this market, the size of the French market is small, and so producers of nanoparticulates will probably prefer to do without it rather than risk having their data exposed to public scrutiny, which might endanger competitive advantage based on original processes. Indeed, one of the most controversial aspects of the French decree is that the data provided by firms relative to quantities and intended use can be made available to the public.

A good illustration that EU regulation may serve as a facilitator of innovation in spite of the constraints it involves is the decision of the Organization for Economic Cooperation and Development (OECD) to terminate one of its programs, called Cooperative Chemical Assessment Program.
(CoCAP). This program has long been working to assess the hazards of chemicals across international lines. OECD has now decided that CoCAP has served its purpose and must be replaced by a different organization at the end of 2014. One of the stated reasons for the change is that the activities of the EU’s REACH program have rendered CoCAP’s current activities unnecessary. By introducing a large-scale framework adopted de facto by the European market, EU regulation sets rules that govern innovation and EU countries have a competitive advantage by being ready for the new rules. Besides, a number of countries outside of the European Union have started to implement REACH regulations or are in the process of adopting the framework (Croatia, Serbia, Switzerland, Turkey and even China are considering such a move).

This paper indicates that when the EU decides to work as a whole entity, it can act as an environmental regulator while facilitating innovation at the same time. The lesson to draw is to move as a large block and not as a small entity. The French initiative in this respect looks out of touch with reality, because the additional constraints it imposes apply to a market that is very small. French CAC 40 firms are becoming more and more global, and they have well understood this. This is why they decide to reduce their R&D activities in France and to strengthen their presence in other EU locations.

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The views expressed in this paper do not necessarily reflect the views or policy of the Labex SERENADE or of its individual members. Comments are welcome, directed to cauplat@novancia.fr

Appendix

List of Cac40 firms: (N/A: no R&D center).

Accor (N/A); Air France – KLM; Air Liquide; Alcatel-Lucent; Alstom; Arcelor Mittal; AXA (N/A); BNP Paribas (N/A); BOUYGUES; Capgemini (N/A); Carrefour (N/A); Credit Agricole (N/A); Dacia; EADS; EDF; Essilor; France Telecom; Gaz de France; Groupe Danone; L’Oreal; Lafarge; Lagardère; LVMH; Michelin; Pernod Ricard; PPR; PSA Peugeot Citroen; Renault; Saint-Gobain; Sanofi-Aventis; Schneider Electric; Societe Generale (N/A); STMicroelectronics; Suez; Total; Unibail-Rodamco (N/A); Vallourec; Veolia Environnement; VINCI; Vivendi

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