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Nanomaterials in the European Union [the quest for a regulatory regime]

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Les llengües de treball son castellà, català, anglès i francès

Esta colección recoge una selección de investigaciones realizadas por estudiantes del Máster Universitario en Integración Europea. Previo a su publicación, los trabajos de investigación han sido tutorizados por profesores con grado doctor de diversas especialidades y han sido evaluados por un un tribunal compuesto por tres docentes distintos del tutor.

Les lenguas de trabajo son catalán, castellano, inglés y francés

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Langues de travail: catalan, castillan, anglais et français

NANOMATERIALS IN THE EUROPEAN UNION [THE QUEST FOR A REGULATORY REGIME]

Ignasi Gispert i Pi

Màster Oficial en Integració Europea,
UAB,
edició 2010-2011

Tutora: Dra. Isabel Pont i Castejón

ABSTRACT

While nanotechnologies are expected to bring substantial benefits across many sectors and contribute to competitiveness, there is a growing body of scientific data indicating that there are reasonable grounds for concern that particular nanomaterials might lead to potential risks and damaging effects on health and the environment.

My aim is to examine how the European Union is shaping a regulatory regime for nanomaterials: the regulatory option chosen, the actual legislation applicable and its effectiveness (with special focus on REACH regulatory gaps), the position taken by the different actors in this process and the expected legal developments in the short term.

Keywords:
Nanotechnology, Nanomaterials, European Union, Strategy, Regulation, REACH

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INTRODUCTION

This is the regulators' dilemma: while nanotechnologies are expected to bring substantial benefits across many sectors (chemistry, material sciences, health, transport, communication or energy) and contribute to competitiveness, innovation and job creation, there is a growing body of scientific data (inconclusive and preliminary) indicating that there are reasonable grounds for concern that particular nanomaterials might lead to potential risks and consequently damaging effects on human health and the environment. It is within this framework of scientific uncertainty, risk and precaution on one side, and innovation and competitiveness on the other, that regulatory authorities have to develop a legal framework for nanotechnologies.

My aim in this research paper in to examine how the European Union is shaping a legal framework for nanomaterials: the regulatory option chosen, the actual legislation applicable and its effectiveness, what position has taken the different actors in this process and where we stand in the quest for a regulatory regime for nanomaterials.

In Part I we present the basic framework that may allow us to enter in the complexities of nanomaterials regulation: what are nanomaterials and which are the properties that make them so different from other substances, which are the health, safety and environmental threats that may pose and which are the actual and future applications that we may expect and that have created so many expectations.

In Part II we focus on the development of the European Union policy and regulation on nanomaterials. We have structured this Part in three main Sections.

Section I present the main regulatory options open to regulators and asses in which of them can be categorized the European Union regulatory strategy from a conceptual point of view. In addition we focus on the interplay of the Precautionary Principle (as developed by the European Courts) in the shaping of the European strategy.

Section II present the European “nano-regulation” from two different angles. The first one (Section II.A) deals with the current legislation affecting nanomaterials. We will see

that the overall assessment from the Commission is that it covers "in principle" risks arising from the use of nanomaterials.

Based on this basic assessment we present in Section II.B the different Communications, Recommendations, Resolutions and proposals taken by the different actors at play, with special attention to the European Parliament Resolution that considered, on the contrary, that "current (…) rules are about as effective in addressing nanotechnology as trying to catch plankton with a cod fishing net" (Carl Schlyter -rapporteur of the European Parliament Resolution-). From a methodological point of view, we have decided to present in chronological order the different contributions to the regulatory debate, as it allows a comprehensive overlook (as all official documents are presented), it give a real sense of "regulatory process" and each contribution can be individually assessed.

In Section II.C we present the new regulatory developments that are in the pipeline, with special focus on the (second) assessment from the Commission on the regulatory aspects of nanomaterials (including those related with REACH) and the debate around the compulsory and harmonized reporting scheme for nanomaterials.

We finally close this Section (at II.D) by presenting a personal assessment of the European Union regulatory regime for nanomaterials and propose the basic pillars for the development of a consistent regulatory regime.

Part III is devoted to a case study. Our objective was to choose one of the regulations previously identified affecting nanomaterials and check whether it covers risks associated with nanomaterials. We have chosen REACH (Regulation 1907/2006) for being a comprehensive new system of (total) harmonization for the regulation of industrial chemicals throughout Europe, because its approval process may be an example if a nano specific regulation have to be designed and because "constitutes a cornerstone for addressing health, safety and environmental risks in relation with nanomaterials" (Commission staff working paper accompanying document to the Regulatory aspects of nanomaterials COM(2008)366final).

The case study identify several nanomaterials regulatory gaps within REACH,

confirming that REACH is ill-equipped for regulating the risk associated with nanomaterials.

Finally, Part IV present our main conclusions.

I would like to thank Prof. Blanca Vilà and Dr Montserrat Pi for facilitating all necessary conditions that have allowed me to conduct this research.

I would like to express my sincere gratitude to my advisor Dr Isabel Pont for her support. For many years she has been accessible and willing to help.

PARTI:INTRODUCTIONTONANOTECHNOLOGYANDNANOMATERIALS

1.-CONCEPT,HISTORY,PROPERTIESANDAPPLICATIONS

CONCEPT

Nanotechnology is an umbrella term that covers a set of technologies that enables the manipulation, study or exploitation of very small (typically less than 100 nanometres[1]) structures and systems[2], and, in doing so, contributes to novel materials, devices and products (whether at micro or macro scale) that have qualitatively different properties[3].

From this broad definition there are two elements that needs to be underlined and clarified as they are fundamental to the proper understanding of the regulatory challenges that we will be analysing, namely: "set of technologies" and "novel materials with qualitative different properties".

Nanotechnology it is not a technology on its own right, but a set of enabling technologies that will allow one or more elements of a material, product or process to

1 The word "nano" is originating from the Greek word meaning "dwarf". In science and technology a nanometre is a unit of spatial measurement that equals one billionth (10^{-9}) (= 0.000000001), thus, a nanometre (nm) is one billionth of a metre.

2 The focus on nanotechnology debate is on applications and products using "engineered" or "manufactured" nano particles (those produced intentionally for specific purposes and with defined chemical composition and size distribution). Engineered nanomaterials have to be distinguished from "natural" nano particles (those that occur in the environment -volcanic dust, lunar dust, mineral composites) and "incidental" nano particles (those that occur as the result of man made industrial processes -diesel exhaust, could combustion, welding fumes). Natural and incidental nano particles may have irregular or regular shape, while engineered nano particles most often have regular shapes, such as tubes, spheres or rings. Bell, T.E. (2006) <<Understanding Risk Assessment of Nanotechnology>>. At http:// www.nano.gov/Understanding_Risk_Assessment.pdf (Accessed December 2010).

3 The European Commission definition of nanotechnology: <<Nanotechnology refers to science and technology at the nanoscale of atoms and molecules, and to the scientific principles and new properties that can be understood and mastered when operating in this domain. Such properties can then be observed and exploited at the micro- or macro-scale, for example, for the development of materials and devices with novel functions and performance>>. <<European Commission Communication from the Commission – Towards a European strategy for nanotechnology>>. COM(2004)338 Final. At 4;
"Nanotechnology" has been defined by The International Standards Organization (ISO) Technical Committee (TC) 229 as <<the application of scientific knowledge to manipulate and control matter in the nano-scale to make use of size and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules or with bulk materials>>. Technical Committee (TC) 229 of the international Organisation for Standardisation (ISO) is the main TC responsible for standardisation work related to nanotechnologies. Within the European Standardisation Committee (CEN), Technical committee (TC) 352 deals with nanotechnologies. Many of the members of CEN/TC 352 also participate in ISO/TC 229/JWG 1 Terminology and Nomenclature. A number of nano-related definitions have already been published by ISO in Technical Specifications (TS), which can be freely consulted via the on-line ISO Concept Database (http://cdb.iso.org/); ISO TS 80004-1 Nanotechnologies – Vocabulary- Part 1: Core Terms; ISO TS 80004-2 Nanotechnologies – Terminology and definitions for nano-objects – nanoparticle, nanofibre and nanoplate; ISO TS 80004-3 Nanotechnologies – Vocabulary – Part 3: Carbon nano-objects.
See also the OECD Working Party on Nanotechnology (WPN) at http://www.oecd.org/site/0,3407,en_21571361_41212117_1_1_1_1_1,00.html. (Accessed October 2010). The WPN was stablish in 2007 with the aim to "advice upon emerging policy issues of science, technology and innovation related to the responsible development of nanotechnology".

be done differently, in this sense, nanotechnology is known as a Key Enabling Technology (KET) or General Purpose Technology (GPT)[4]. The consequence is that it is not confined to one industry or market, but offers a broad technology platform in applications to all industry sectors and scientific disciplines (it transcends the conventional boundaries between physics, chemistry, biology, mathematics, electronics, and medicine, so being inherently multidisciplinary). It is classified by the size of the material being developed and used, not by the process being used or product being produced. From a regulatory point of view, it is important to take into considerations what kind of limitations (and complexities) pose this characteristic when designing a possible overarching regulatory regime.

The second element to be clarified is that the properties of materials at the nanoscale can have some unexpected differences from their behaviour in larger bulk forms[5] that makes for new application opportunities[6]. The different behaviour is also paramount for understanding the difficulties for a regulatory design. Bulk or conventional substances has the same phsycochemical characteristics, being the difference, basically, the weight. This is the reason why "volume" is, in most regulations (for instance REACH), the basic element that is taken into consideration for thresholds setting. This logic do not work for nanosubstances, just because the phsycochemical characteristics may change, so applying current regulatory logic will inevitably lead to regulatory gaps.

It is basically due to these characteristics that, from a scientific and legal perspective, the conceptual definition of "nanotechnology" is of very limited importance since its practical use is only occasional[7], being "nanomaterial" the one with real implications.

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4 Shea, C.M., Roger G., Elmslie B. (2011) <<Nanotechnology as general-purpose technology: empirical evidence and implications>> Technology Analysis & Strategic Management. 23(2) Feb. 2011, 175 – 192. At 177.

5 For instance, in its natural bulk form, gold is inert. However, at a particle size of 2-5 nm, gold becomes highly reactive. The chemical composition of these two materials is identical: it is the different physical size of bulk materials and nanoparticles that accounts for their very different chemical properties.

6 The two reasons for this change in behaviour are: increased relative surface area (producing increased chemical reactivity) and increasing dominance of quantum effects (with effects on the material's optical, magnetic, or electrical properties). Hunt, W. H. Jr. (2004) <<Nanomaterials: Nomenclature, Novelty, and Necessity>> JOM Oct. 2004. Hypertext-Enhanced Available at http://www.tms.org/pubs/journals/JOM/0410/Hunt-0410.html (Accessed October 2010).

7 For example when evaluating whether project applications in a "nano" specific area can be regarded as nanotechnology or not, or when making estimates of the importance of the "nanotechnology" market. It is believed that the term "nanotechnology" will sooner or later cease to exist as researchers and developers study and use materials due to their functionality rather than their size. Lövestam, G. , Rauscher, H. , Roebben, G., Klüttgen, B. S., Gibson, N., Putaud , JP., Stamm, H. (2010) <<Considerations on a Definition of Nanomaterials for regulatory Purposes>>. JRC Reference Reports. June 2010. EUR 24403 EN. Available at http: //ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf. (Accessed December 2010).

At international level, the ISO Technical Committee 229 defined "nanomaterial" as <<material with any external dimension in the nanoscale or having internal structure or surface in the nanoscale>>[8].

At EU level, the efforts by the European Commission to release a legal definition of "nanomaterial" for regulatory purposes started in 2009 with the European Parliament request "for the introduction of a comprehensive science-based definition of nanomaterials"[9], that was followed in September 2010 by a draft Recommendation[10], that finally crystallised in the Recommendation of 18.10.2011 on the definition of nanomaterial[11] that "should be used as a reference for determining whether a material should be considered as a "nanomaterial" for legislative and policy purposes in the Union".

In broad terms, according with the Recommendation, "nanomaterial" is defined as a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

In addition, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

Given the complexity of the concept just outlined we remit in full to Part II Section B.8) of this research paper where the Commission Recommendation is further analysed.

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8 ISO/TS 80004-1:2010. Available at https//cdb.iso.org. (Accessed January 2011).

9 PA_T6(2009) 0328. The EP called for the introduction of a comprehensive science-based definition as part of nano-specific amendments to relevant horizontal and sectoral legislation. Also the Belgian Presidency of the Council called for the adoption of a definition. See Part II B.6) and C.2) of this research paper.

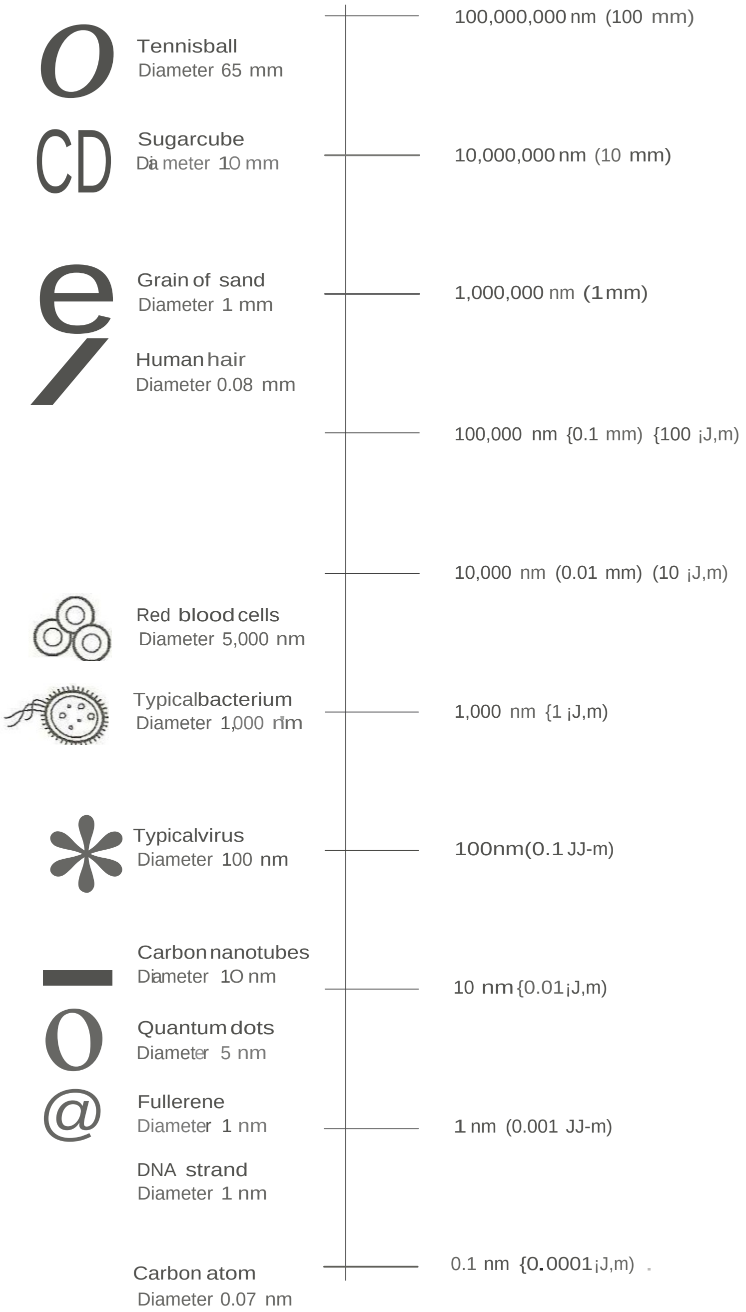
10 In September 2010 the Commission released a draft Recommendation that for the first time defined the term "nanomaterial" with the objective of becoming an "overarching, broadly applicable reference term for any Union communication or legislation addressing nanomaterials". Commission Recommendation of […] on the definition of the term "nanomaterial" C(20..) yyy final. Available at http://ec.europa.eu/environment/consultations/nanomaterials.htm (Accessed Nov. 2010).

11 Recommendation 2011/696/UE OJ L275/38 of 20.10.2011

FIGURE 2-1

Length scale showing the nanometre in context

This diagram places the nanoscale in context One nanometre (nm) is equal to one-billionth (1,000,000,000) if a metre, 1()⁹m. Most structurcs if nanomaterials which are if interest are between 1 and 100 nm in one or more dimensions. For example, carbon Buck(yballs (figure 2-111) are about lttm in diameter.



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HISTORY

From a historical perspective[12] it is generally stated that the "authoritative founding myth"[13] of (engineered) nanotechnology did not occur until 1959, when Richard Feynman, presented a talk to the American Physical Society entitled There's Plenty of Room at the Bottom[14].

The following milestone was in 1974, when Norio Taniguchi introduced the term 'nanotechnology'[15], but the real breakthrough was with the invention of the scanning tunnelling microscope (STM) in 1981[16], and subsequently, the invention of the atomic force microscope (AFM) in 1986[17].

The discovery of novel materials on the nanoscale began with the Buckminsterfullerene (also called the buckyball) in 1985[18]. In 1991, a new step was achieved with the discovery of the carbon nanotubes by Sumio Iijima. From there, and at increased pace,

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12 It has been said that the agreed conventional history of nanotechnology is used to push the importance of nanotechnology to policy makers and is invoked to direct scientists and engineers toward production, something different from the understanding of 'pure' science. Shew, A. (2008) <<Nanotech's History: An Interesting, Interdisciplinary, Ideological Split>> Bulletin of Science, Technology & Society. 28 (5): 390 – 399. Available at http://www.eric.ed.gov/ERICWebPortal/search/detailmini.jsp?_nfpb=true&_&ERICExtSearch_SearchValue_0=EJ809246&ERICExtSearch_SearchType_0=no&accno=EJ809246. (Accessed Oct. 2010); Allhoff, F. (2010) "Unit I What is Nanotechnology?"at WILEY-BLACKWELL <<What is Nanotechnology and why does it matter? From Science to Ethics>>. Pgs. 1 – 70.

13 Keiper, A. (2009) <<Happy Birthday, Nanotechnology?>>. The New Atlantis. A Journal of Technology & Society. Available at http://futurisms.thenewatlantis.com/2009/12/happy-birthday-nanotechnology.html (Accessed October 2010)

14 Feynman, R. (1959) <<There's Plenty of Room at the Bottom. An Invitation to Enter a New Field of Science>> Lecture given at the annual meeting of the American Physical Society, California Institute of Technology, December 29, 1959. http://www.zyvex.com/nanotech/feynman.html (Accessed October 2010); Toumey, C. (2009) <<Feynman and nanotechnology – anniversary reflections>>. Available at http://www.nanowerk.com/spotlight/spotid=13169.php (Accessed October 2010); Christopher Toumey (2005) <<Apostolic Succession: Does nanotechnology descends from Richard Feynman's 1959 talk?>> Engineering & Science. LXVIII (1-2): 12- Available at http://pr.caltech.edu/periodicals/EandS/articles/LXVIII1_2/Feynman.pdf (accessed October 2010); Eric Drexler <<There's Plenty of Room at the Bottom" (Richard Feynman, Pasadena, 29 December 1959>>. Available at http://metamodern.com/2009/12/29/theres-plenty-of-room-at-the-bottom%E2%80%9D-feynman-1959/ (accessed October 2010).

15 Taniguchi, defined "Nanotechnology" for the first time in 1974: <<Nano-technology' mainly consists of the processing of separation, consolidation and deformation of the materials by one atom or one molecule. Needless to say, the measurement and control techniques assure the preciseness and fineness of 1 nm play a very important role in this technology.>>.

16 Gerd Binnig and Heinrich Rohrer (IBM Zurich Laboratories). With this technology, individual atoms could be clearly identified for the first time. Despite its limitations, this breakthrough was essential for the development of nanotechnology because what had been previously concepts were now within view and testable.

17 Some of the STM limitations were eliminated through the 1986 invention of the Atomic Force Microscope. Using contact to create an image, this microscope could image non-conducting materials such as organic molecules.

18 It consists of an arrangement of 60 carbon atoms. Was created by Harry Kroto, Robert Curl and Richard Smalley. The buckyball was so named because of the resemblance to the geodesic domes from the architect Richard Buckminster.

novel nanoscale material has been reported[19].

PROPERTIES

As we have already seen, the reason for studying, manipulating and exploiting the materials at the nanoscale is that the properties of nanomaterials can have differences from their behaviour in larger bulk forms that permits new application opportunities[20].

The individual molecular and atomic dimensions and interactions determine the arrangement, stability, flexibility and function of nano structures (that permits to display such different properties). As the AFSSET[21] indicates:

<<Les propriétés des nanomatériaux varient notamment selon leur composition chimique, leur taille, leur surface spécifique, l'état de surface, ou encore la forme du nano-objet considéré. De plus, chaque nanomatériaux peut être doté d'une réactivité ou d'un comportement différent selon la formulation et la matrice du produit fini qui le contient>>.

So the complexity when dealing with nanomaterials is that the indicated different and/or unique properties are based on a number of key physicochemical characteristics [22] and on the formulation and the matrix of the finished product where it is contained.

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19 See http://www.nanowerk.com. Nanomaterial database with currently 2700 nanoparticles from 167 suppliers. (Accessed May 2011).

20 Could be different chemical, biological, electronic, magnetic, optical (photon) mechanical or structural properties depending on each substance, formulation and matrix of the finished product where it is contained. For instance, the colour of gold shows different hues of red, blue, and green at the nano-scale; zinc oxide, which is usually opaque and thus used to block ultraviolet rays, turns transparent; and aluminium, which is stable in bulk, becomes explosive. The uses of these novel particles are manifold: different shades of gold may produce new types of precious jewels; transparent versions of zinc dioxide are already being used to improve sunscreen, making it less visible yet more effective; and aluminium's explosive properties are expected to bolster rocket propulsion. Hunt, W. H. Jr. (2004).

21 Agence française de sécurité sanitaire de l'environnement et du travail-AFSSET (2010) <<Évaluation des risques liés aux nanomatériaux pour la population générale et dans l'environnement>>. Available at http://www.afsset.fr/upload/bibliotheque/460552230101468097041324565478/10_03_ED_Les_nanomateriaux_Rapport_compresse.pdf 17.03.2010. (Accessed December 2010).

22 Key physicochemical characteristics: size, aggregation and agglomeration state, chemical composition; shape; solubility; dispersibility; surface area; surface chemistry -for example hidrophobicity- and surface charge. These characteristics are the ones facilitating a proper characterisation of nanomaterials and permitting a proper comparison of toxicological test results.
ENRHES project final report states that <<(...) there is now a consensus that thorough and accurate particle characterisation is an essential part of assessing the potential toxicity of nanoparticles (...) characterisation of test materials is important to ensure that results are reproducible, and also to provide the basis for understanding the properties of nanoparticles that determine their biological effects. Some of the key parameters influencing the biological activity of nanoparticles remain unknown or to be fully understood at this point>> ENRHES (2010) <<Engineered Nanoparticles: Review of Health and Environmental Safety>>. Project webside address: http://nmi.jrc.ec.europa.eu/project/ENRHES.htm. At 315; See also Hansen, S.F., Larsen, B.H., Olsen, S.I., Baun, A. (2007) <<Characterisation framework to aid hazard identification of nanomaterials>>. Nanotoxicology.1 iFirst Article: 243-250. Available at http://www.dina.kvl.dk/~envirosymp/downloads/readingMaterials/4-Risk-Assessment-of-Nanoparticles/Optional-reading/Hazard-identification-of-nanomaterials.pdf (Accessed Nov 2010).

From a regulatory perspective, a consequence that has to be taken is that the details of individual nano particles need to be considered, rather than generalization[23].

It is the exploitation of this unique properties (by engineering a substance with nanotechnology, that basically can be linked to creating a new chemical) that grant nanotechnology the potential of catalysing technological revolution that eventually will have large impact (positive or negative) on society (from the live of individuals to industry) as we will review on following sections.

Box 1.3. Examples of nanotechnology applications

Electronics and communications

Data storage media with very high recording densities, new flat-panel plastic display technologies, new materials for semiconductors that increase processing speeds, the realisation of molecular or biomolecular electronics, spintronics and quantum computing.

Materials and construction

Use of nanoparticles and coatings for reinforced materials and machinery parts, super-hard and tough drill bits and cutting tools, "smart" magnetic fluids for vacuum seals and lubricants, scratch-proof or non-wettable surfaces, anti-bacterial construction material, self-cleaning and reactive eco-efficient windows.

Pharmaceuticals and health care

Potential applications include miniaturised diagnostics that can be implanted for the early diagnosis and monitoring of illnesses, nanoscale coatings to improve the bioactivity and biocompatibility of implants, ultra-precise nanostructured drug delivery systems, sensors for labs-on-a-chip, new materials for bone and tissue regeneration.

Machinery and tools

Nanopowders sintered into bulk materials to give special properties, extremely sensitive sensors to detect incipient failures and actuators to repair problems, chemical-mechanical polishing with nanoparticles, self-assembly of structures from molecules, bio-inspired materials and biostructures.

Energy

New types of batteries, artificial photosynthesis for clean energy, efficient low-cost photovoltaic solar cells (*e.g.* solar "paint"), safe storage of hydrogen for use as a clean fuel.

Environment and water

Enhanced membranes for water purification, nanostructured filters for removing pollutants from industrial effluents, improved remediation methods (*e.g.* photo-catalytic techniques).

Source: OECD (2005, 2009) and various others.

OECD (2010), The Impacts of Nanotechnology on Companies: Policy Insights from Case Studies, OECD At. 28

[23] Based on this different characterization of nanomaterials and from a scientific perspective, Drezec and Tour suggest the following recommendation to regulators:
a) Use toxicity standards that are understood in other fields of science, such as chemistry or drug development, avoiding generalizations;
b) Help stakeholders identify the highest quality nanotechnology studies;
c) Consider sectioning "nanotechnology" into a number of narrowly defined fields. Might include: C60 and related small fullerenes and other pseudo-zero-dimensional carbon materials; carbon nanotubs and other pseudo-one-dimension carbon materials; graphene and other two-dimensional carbon materials; gold nanoparticles; silver nanoparticles, etc.
For each field to consider features as particle size, surface coating and charges, aggregation state and typical trapped impurities, such as exogenous metals and solvents;
d) To focus on specific materials used and particular products created rather than on an underlying scientific regime or rubric. Drezec, R.A., Tour, J.M. (2010) <<Is nanotechnology too broad to practice?>> Nature Nanotechnology. 5. March 2010. At. 169.
Engineered nanomaterials can be classified into carbon-based materials (nanotubes, fullerenes), metal-based materials (metal oxides and quantum dots), dendrimers (nano-sized polymers built from branched units of unspecified chemistry) and composites (including nanoclays). See Ortiguy, C, Roberge, B., Woods, C., Soucy, B. (2010). <<Engineered Nanoparticles: Current Knowledge about Occupational Health and Safety Risks and Prevention Measures. Second Ed.>>. Studies and Research Projects. Report R-656. IRSST Institut de Recherche Robert-Sauvé en santé et sécurité du travail. Available at http://www.irsst.qc.ca (Accessed December 2011).

APPLICATIONS

Nano materials are used in a wide variety of applications in multiple sectors of the economy, including manufacturing, health, energy, textiles, aerospace, construction, mining, agriculture, information and communication technologies and even environmental remediation applications[24].

From the existing databases incorporating nanomaterials can be concluded that:

a) Number of nanoproducts in the marketplace is increasing dramatically[25];

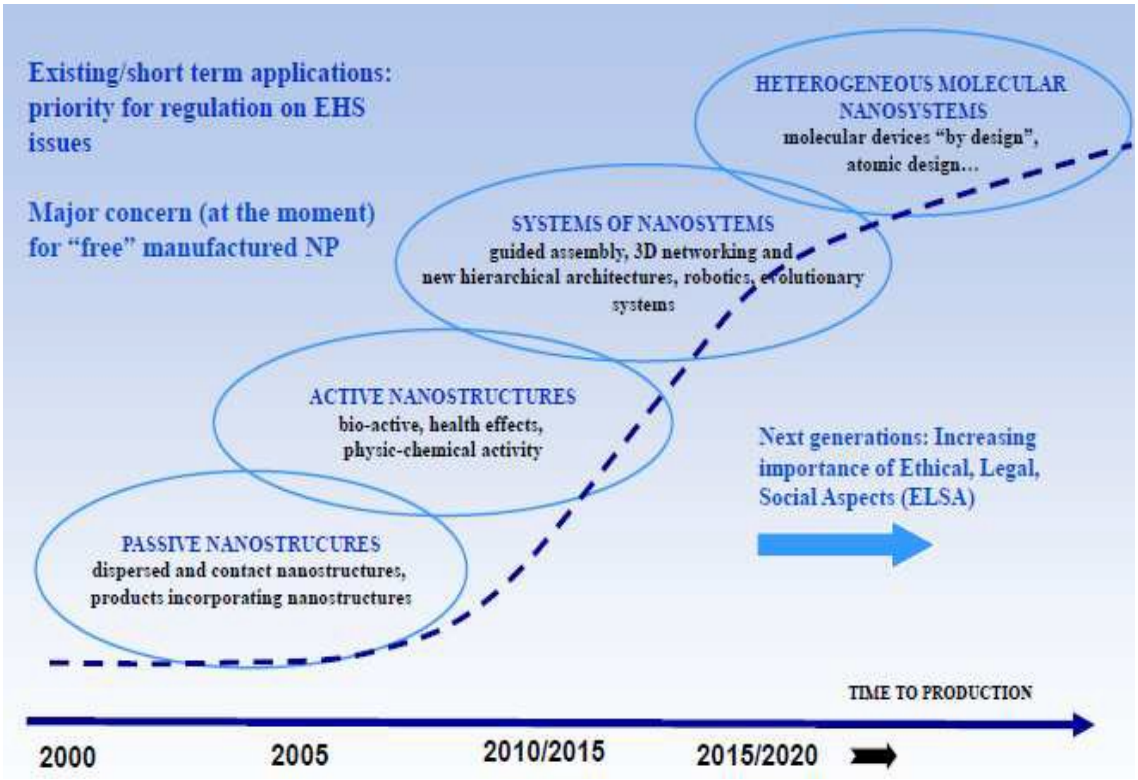
b) Nanomaterials are playing a minor role and are used to improve existing products in terms of quality or functionality (passive naostructures);

c) Consistent information can not be obtained due to lack of compulsory registration and different inventories' methodology and range of registered products[26].

[24] Engineered nanomaterials can be produced either by milling or lithographic etching of a large sample to obtain nanosized particles (an approach often called "top-down") or by assembling smaller subunits through crystal growth or chemical synthesis to grow nanomaterials of the desired size and configuration ("bottom-up"). Bell, T.E. (2006) .

[25] For instance, a three-fold increase has been identified for Europe since 2006, reaching actually 858 consumer products: Wijnhoven, S.W.P., Dekkers, S., Kooi, M. Jongeneel, W.P., de Jong. W.H. (2011) <<Nanomaterials in consumer products. Update of products on the European market in 2010>>. National Institute for Public Health and the Environment. RIVM Report 340370003/2010. Ministry of Health, Welfare and Sport.Available at http://www.nanoform.org and http://www.rivm.nl.

[26] Another databases currently available are: a) PEN The Project on Emerging Nanotechnologies. Available at http:/www.nanotechproject.org. As of March 10, 2010, the nanotechnology consumer products inventory contains 1317 products; b) ANEC – BEUC inventory of products claiming to contain nanoparticles available on the EU market. As of Oct 10, 2010, the nanotechnology consumer products inventory contains 475 products. Available at www.anec.org/attachments/ANEC-PT-2010-Nano-017.xls (Accessed May 2011) c) http://www.azonano.com/ industry oriented directory with companies, materials and applications database (Accessed May 2011); d) http://www.nanowerk.com. The purpose of the database is to give an idea of how and where in industry nanoscale materials, devices, structures and processes are being used. (Accessed May 2011).
On the other hand, the real potential of nanomaterials can also be ascertained by the analysis of the European Patent Office entries. The EPO introduced in 2009 a tagging system for all nanotechnology patent documents. The EPO created a tag (Y01N) for specifically retrieving information on nanomaterials. The EPO reported that a 15% yearly increase in nanotechnology patents -what is a higher percentage growth than general EPO applications. In 2009 the number of nanotechnology patents was of 99.992 patents. See Nanotechnology and patents. European Patent Office EPO. 2009. The EPO tagging system has now been accepted internationally under the International Patent Classification (IPC) system. The new tag as from January 2011 is B82Y. http://documents.epo.org/projects/babylon/eponet.nsf/0/623ecbb1a0fc13e1c12575ad0035efe6/$file/nanotech_brochure_en.pdf. ; http://www.epo.org/news-issues/news/2011/20110128.html



MONTOVANI, E. <<Hard e Soft Regulation per le Nanotecnologie>>. 4A Conferenza Nazionale del Programma NIC – Nanotecnologia nell'industria chimica. 2/XII/2010. AIRI/Nanotec IT, 2010.

From a regulators perspectives, and following a generally agreed nanotechnology development forecast[27], on the first and second development stages (passive and active nanostructures) regulatory focus have to be on solving the issues related with Health, Safety and Environmental issue, as by its nature (protecting human health and environment) are the most compelling ones. When entering the third and forth stage (systems of nanosystems and heterogeneous molecular nanosystems) increased focus will be on Ethical, Legal and Social aspects (ELSA) with a set of extremely compelling issues that are outside the scope of this report[28].

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27 Widmer, M., Meili, C., Mantovani, E., Porcari, A. (2009) <<Mapping study on Regulation and Governance of Nanotechnologies>>. Published under the FramingNano project as deliverable D1.1 for Work Package 1. Available at http://www.framinhnano.eu/ At. 104. (Accessed Feb. 2011)

28 Catalogue of Ethical, Legal and Societal Issues ("ELSI") surrounding nanotechnology:
a) Regulatory issues
Once EHS implications are addressed, a myriad of legal issues appears: to regulate privacy, patent law and nanotechnology, liability, criminal law, ethical issues, etc.
b) Public perception and public engagement
How the public perceives/accepts applications and risks of nanotechnology; how to engage the public in a proactive debate on risks and benefits of nanotechnology; the role of scientific and not scientific communication; how these elements can influence the governance of nanotechnology development.
c) Commercialization and governance issues
Impact of nanotechnology on economy, trade, employment at regional/national or local level; rights to access to information (also in relation with the use Intellectual Property Rights); non discrimination in the access to the

2.- HEALTH,SAFETYANDENVIRONMENTAL(HSE)ISSUES

If engineered nanomaterials have physical properties different from their bulk counterparts, might they also pose new risks to human health in their manufacture, use and disposal?

As per today, certain health and environmental hazards have been identified for a variety of manufactured nanomaterials[29], indicating potential toxic effects[30]. Similarly, the occurrence and possible adverse consequences of engineered nanoparticles in the environment has already been reported[31].

Although from a Health, Safety and Environmental (HSE) perspective it can be assessed that a growing body of scientific evidence suggests that some manufactured

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benefits of nanotechnology, including the questions of a nanotechnology divide versus the promises for a beneficial use of nanotechnology in the developing world.

d) Application specific issues (mainly in relationship with nanomedicine and security applications)

- Ethical and philosophical issues related to non therapeutic human enhancement and novel applications exploring man-machine interactions;
- Increased personal responsibility related to novel diagnostic tools providing predictive information on diseases;
- Protection of personal data, privacy, limits to personal freedom, confidentiality issues raised by novel surveillance, military and medical applications of nanotechnology;
- Use/misuse of novel applications in military, criminal or terrorist activities.

Widmer, M. et Al (2009) At 108.

29 From manufactured nanoparticles, the scientific community mainly considers that the safety concerns are related with "free", rather than fixed nanoparticles (when nanoparticles are dispersed into fluid or gaseous media they are called unbound or free nanoparticles) although there is clearly potential for the fixed nanoparticles (also) to become detached and enter natural ecosystems, especially when products containing them abrade or weather during use or when they are disposed of as waste or are recycled (when nanoparticles are dispersed into fluid or gaseous media they are called unbound or free nanoparticles). Royal Society and Royal Academy of Engineering (RS/RAE) (2004). <<Nanoscience and Nanotechnologies: Opportunities and uncertainties>>. Royal Society Policy Document 19/04. (RS/RAE).

30 Long, non-degradable nanotubes (longer than 20 micrometres) have in several experiments been found to have effects similar to hazardous asbestos, causing inflammatory reactions. Experiments also indicate that carbon nanotubes could induce a specific form of lung cancer (mesothelioma), which is also observed in relation to asbestos exposure. Sanderson, K. (2008) <<Carbon nanotubes: the new asbestos?>> ICON Backgrounder. Available at http://www.nature.com/news/2008/080520/full/news.2008.845.htm; Kulinowski, K. (2009) <<Multi-walled Carbon Nanotubes and Meshothelioma>>. ICON Backgrounder. Available at http://icon.rice.edu/resources.cfm?doc_id=12299(Accessed May 2011); Aitken, R.J., Hankin S.M., Ross, B., Tran, C.L., Stone, V., Fernandes, T.F., Donaldson, K., Duffin, R., Chaudhry, Q., Wilkins, T.A., Wilkins, S.A, Levy, L.S. Rocks, S.A, Maynard, A. (2009) <<A review of completed and near completed environment, health and safety research on nanomaterials and nanotechnology>>. Defra Project CB0409. Report TM/09/01. March 2009. EMERGNANO - SAFENANO. IOM. March 2009. (Accessed February 2011); Guix, M. (2008) <<Nanoparticles for cosmetics. How safe is safe?>> Contributions to Science. 4(2): 213 – 217. Institut d'Estudis Catalans. Available http://www.cat-science.cat. (Accessed February 2011).

31 The EMERGNANO project that identified and assessed 673 projects related with toxicology and ecotoxicology of nanomaterials concluded: <<(...) from the results presented (...), three different nanomaterials have been identified that give rise to sufficient concern. There is evidence that carbon nanotubes may have an adverse effect on human health; and that silver nanoparticles and titanium dioxide nanoparticles are detrimental to the environment. In these specific cases, further investigation as to the need to invoke the precautionary principle is required, taking into consideration all available data>>. Aitken, R.J. Et Al. At 157; Nowack, B. (2009) <<The behaviour and effects of nanoparticles in the environment>>. Environmental Pollution 157: 1063-1064.

nanomaterials <<harbour new and unusual dangers>>[32], as per today evidence of harmful impacts in "real world" has not been reported and basically the plausibility of damage has been based on the extrapolation of evidence from laboratory investigations and occupational exposure studies on dust and other substances[33].

The reasons behind the reported limited knowledge available regarding the potential health, safety and environmental impacts of nanotechnology, can be summarized as the intrinsic scientific complexity of nanosubstance characterisation (or in broader terms risk assessment shortcomings)[34] and the comparatively minor investments done in the

[32] The Scientific Committee on Emerging and Newly-Identified Health Risks -SCENIHR- (2007), <<The appropriateness of risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials>>. Adopted on 21-22 June 2007; Maynard, A.D. (2006) <<Nanotechnology: The Next Big Thing, or Much Ado about Nothing?>>. The Annals of Occupational Hygiene. 51 (1): 1 – 12.

[33] Royal Commission on Environmental Pollution (RCEP). (2008) <<Novel Materials in the Environment: The case of nanotechnology>>. Twenty-seventh Report of the RCEP presented to the UK Parliament in November 2008. Available at http://www.rcep.org.uk/reports/27-novel%20materials/27-novelmaterials.htm#supp At 2.42.

[34] Risk Assessment:
- Risk assessment can be defined as a procedure in which the risk posed by inherent hazards involved in processes or situations are estimated either quantitatively or qualitatively. EEA (1998) <<Environmental Risk Assessment: Approaches, Experiences and Information Sources>>. Environmental Issue Report no. 4. EEA.. March 1998. Available at http://www.eea.europa.eu/publications/GH-07-97-595-EN-C2. (Accessed January 2011). At Chapter 1; The European Court of Justice has defined risk assessment as a "scientific process consisting in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk" Case T-13/99 Pfizer Animal Health v Council. At 156.
- In the EU, risk assessment methodology is described in the Technical Guidance Document (TGD) on Risk Assessment. Institute for Health and Consumer Protection. European Chemicals Bureau. Joint Research Centre. European Commission. EUR20418 EN/1. 2003. The guidance given on the TGD is not legally binding. It can be used other methods or approaches if they are considered to be more appropriated, provided that they are scientifically justified. Those methods, including any assumptions, uncertainties and calculations, should be clearly described and justified. See TGD2003 At 1.3.
- The TGD characterizes risk assessment as consisting in four parts, namely hazard identification, hazard characterisation, exposure assessment, risk characterisation.
- It is generally agreed that Risk Assessment as described in the TGD cannot be directly extrapolated to nanomaterials. See European Commission's Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR (2007). At 26.
- In broader terms, risk assessment for nanomaterials precludes going further than identifying hazards -first step of risk assessment- and providing some elements of hazard characterisation (dose/response assessment). Hansen, S.F. (2009) <<Regulation and Risk Assessment of Nanomaterials – Too Little, Too Late?>> PhD Thesis, February 2009. Department of Environmental Engineering. Technical University of Denmark. Available at http: wwww.env.dtu.dk. (Accessed December 2010).
- SCENIHR has listed the shortcoming of nanomaterials risk characterisation:
1. Persistence of nanoparticles in the atmosphere, which will depend on rates of agglomeration and disagglomeration, and on degradation; 2. Relevance of routes of exposure to individual circumstances; 3. Metrics used for exposure measurements; 4. Mechanisms of translocation to different parts of the body and the possibility of degradation after nanoparticles enter the body; 5. Mechanisms of toxicity of nanoparticles; 6. Phenomenon of transfer between various environmental media.
These are not simply uncertainties in the values of some traditional parameters, but rather the uncertainties about the potentially unique or significantly modified causal mechanisms themselves. The Scientific Committee on Emerging and Newly-Identified Health Risks SCENIHR (2007) At 26.
- In order to overcome these limitations SCENIHR has proposed to assess the risk of nanomaterials on a case-by-case basis, that has been criticised as unworkable. See HANSEN, S.F. (2009). At. 71.
- Alternative decision making tools for risk assessment has been proposed, like Multi Criteria Decision Analysis (MCDA), hazard trigger algorithm or life cycle inventory analysis. See Linkov I, Satterstrom FK, Kiker G, Seager TP, Bridges T, Gardner KH, Rogers SH, Belluck DA, Meyer A (2006) <<Multicriteria decision analysis: a comprehensive decision approach for management of contaminated sediments>>. Risk Anal 26(1):61–78; Hansen, S.F. (2010) <<Multicriteria mapping of stakeholder preferences in regulating nanotechnology>> J

field of nanotechnology- related environment, health and safety (HSE) research when compared with the development of technology itself and of consumer applications[35].

Faced with scientific uncertainty, the regulator's option to postpone action until conclusive scientific knowledge is obtained do not seams reasonable, as the development of the technology could be hindered by public opinion over reaction due to lack of knowledge, fear[36], misleading information and lack of transparency[37].

From a regulatory perspective, it is commonly agreed that the legislator needs to regulate based on inconclusive and preliminary scientific evaluation indicating that there are reasonable grounds for concern that particular nanomaterial might lead to potential risks and consequently, damaging effects on the environment, or on humans, animals or plants health. It is in this context of uncertainty that the Precautionary Principle has to be invoked[38] as directly applicable, extracting from it a set of legal consequences in the regulatory field (and specifically in REACH -European Union's

2010. Available at □□□κ□□□□□ς□ς□Φ□□

s. Regulation

Nanopart Res 12:1959–1970.

35 HSE research fundings:
- The imbalance at EU level has been underlined by the Commission Communication from at <<Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. Second Implementation Report 2007-2009>>- Commission Staff Working Document. 29.10.2009. SEC(2009)1468. {COM(2009)607final} At Chapter 1; Milieu / RPA Stakeholders Conference <<Nanomaterials on the Market What Regulators Need to Know>> Brussels. 9.10.2009. At 10. Available at http://www.nanomaterialsconf.eu/further-information.html (Accessed November 2010).
It has to be underlined that the Commission has placed a considerable focus on research projects related to HSE in the FP07. For a detailed review of projects see European Commission DG Research (2008) <<Workshop on research projects on the safety of nanomaterials: reviewing the knowledge gaps>. Available at ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final_report.pdf.
- Furthermore, most research programmes are still in the very early stages and it will be a long way down the road before comprehensive information is available (lead times of "several decades" could easily be involved) to give a clear picture of what risks the different manufactured nanoparticles may pose. Royal Commission on Environmental Pollution -RCEP- (2008).

36 The nanoscale world is so small that we can't directly see or experience it, neither imagine it, so inevitably, fear is a natural human reaction in front of the unknown. Based on this added difficulty, it is interesting to note the efforts done to " visualize" this world. This objective links nanotechnology and art in a deeper way than any other of the new emerging technologies. One project worth mentioning is the "Visualization Laboratory project", who's goal is to create and study effective and innovative visualization techniques for understanding and experiencing the nanoscale. http://www.nisenet.org/viz_lab.
Fears can also came from science fiction in nanotechnology, see Milborn, C (2002) <<Nanaotechnology in the Age of Posthuman Engineering: Science Fiction as Science>> Configurations 10: 261 – 295; Lopez, J (2004) <<Bridging the Gaps: Science Fiction in Nanotechnology>> HYLE – International Journal for Philosophy of Chemistry. 10(2): 129 – 152.

37 The Commission has repeatedly stressed the need of "identify and resolve safety concerns (real or perceived) at the earliest possible stage" See Communication (2004) COM(2004) 338 final At 1.3; Communication from the Commission <<Preparing for our future Developing a common strategy for Key enabling technologies in the EU>> COM(2009) 512 final 30.09.2009. At 1.8.

38 In this sense Lin, A. C. <<Size matters: Regulating nanotechnology>>. Harvard Environmental Law Review. 31: 349 – 408. At 384.

1907/2006) that we will analyse further on[39].

As we have seen so far, the nanotechnology debate is filled with uncertainty (over terminology, methodologies, HSE risk, risk assessment, quantity and quality of products in the marketplace, on future developments of nanomaterials, etc.) and it is within this framework that regulators needs to set up a balance regulation capable of ensuring safety without hindering technological development.

On the following sections we will be analysing the EU policy on N & N and consider whether those objectives are reached, but it is important to underline once more the complexity of such a task:

<< (...) appropriate regulation of nanotechnology will be challenging. The term "nanotechnology" incorporates a broad, diverse range of materials, technologies, and products, with an even greater spectrum of potential risks and benefits. This technology slashes across the jurisdiction of many existing regulatory statutes and regulatory agencies, and does so across the globe. Nanotechnology is developing at an enormously rapid rate, perhaps surpassing the capability of any potential regulatory framework to keep pace. Finally, the risks of nanotechnology remain largely unknown, both because of the multitude of variations in the technology and because of the limited applicability of traditional toxicological approaches such as structure-activity relationship (SAR) to nanotechnology products.>>[40]

[39] Remission is made to the Precautionary Principle in Part II. Section 1.

[40] Marchand, G., Abbot, K.W., Sylvester, D.J. (2009) <<What does the History of Technology Regulation Teach Us about Nano oversight?>>. Journal of Law, Medicine & Ethics. Winter 2009. 724-731. At. 724 Available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1470446. (Accessed February 2011).

PARTII:NANOMATERIALSREGULATIONINTHEEUROPEANUNION

1.REGULATORYOPTIONSANDTHEPRECAUTIONARYPRINCIPLE

Regulatory regimes are designed (almost by definition) to handle regulatory concerns existing at the time of promulgation and, as a consequence, emerging technologies often exacerbate or create regulatory gaps[41]. In other words, regulatory systems are badly equipped to respond to new technologies. In fact, it could be seen as logical to expect that the emergence of nanotechnology creates regulatory gaps.

As the actual regulatory regime (that we will be presenting in the following Section) applicable to Nanotechnology and Nanomaterials (N&N) was not designed for nanomaterials is, (up to some point) inadequate. Following STOKES (2009)[42], there are two broad reasons for this inadequacy;

– Nanomaterials may escape regulation either because the same materials in conventional -bulk- form are themselves outside the remit of legislative control[43], or where their uses are so new that they fall outside the prescribed definition of a "regulated" substance[44].

– Provisions fails to address the fact that nanomaterials can have unique properties. The legislation is designed from the assumption that an analogy can be made between materials in their nano and bulk forms. The reported failure is caused by placing inappropriate thresholds[45] or inappropriate read-across[46].

In the following sections we will be presenting firstly, the regulatory option open to

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41 Mandel, G. N. (2009) <<Regulating Emerging Technologies>>. Law, Innovation & Technology. 1: 75 – 87. Available at http://papers.ssrn.com. Abstract 13556748. (Accessed April 2011).

42 Stokes, E. (2009) <<Regulating nanotechnologies: sizing up the options>> Legal Studies, 29 (2): 281 – 304.

43 This was the case with carbon and graphite for instance. Regulation 987/2008.

44 This is a problem not specific to nanomaterials but with the completeness of any given legislation.

45 Inappropriate thresholds: Legislation establishing thresholds can be found in a variety of sectors, from consumer products (electrical equipment, foodstuffs or cosmetics by limiting or prohibiting the content of potentially hazardous substances) to chemicals (REACH minimum threshold) or waste (setting maximum concentrations or upper limits to emissions and discharges).
The problem is that the thresholds have been established taking in consideration the bulk-scale substance only. While the safety of a substance (so risk management) is determined by production volume, nanomaterials toxicity may better be assessed taking into consideration other characteristics as size, aggregation and agglomeration state, chemical composition, shape, solubility, surface area and others. See Part I. Section 1 from this Report.

46 Inappropriate read-across: Situation in which information on bulk-scale materials is incorrectly extrapolated and applied to nanomaterials. This is caused by inappropriate data read-across (suppliers inappropriately choose not to assign a classification to nano-scale substance, or assign a classification which fails to convey their potential hazardousness or by inappropriate methodological read-across (basically related with the limitations encountered by the risk assessment of nanomaterials).

regulators and secondly the interplay of the Precautionary Principle.

It is for the regulator to decide the regulatory regime and how to modulate it but, in the European Union legal context, we understand that the interpretation given by the European Courts to the Precautionary Principle is placing specific obligations to the regulators that may guide their regulatory option (or its timely implementation).

A)REGULATORYOPTIONS

Faced with a "(nano) regulatory deficit" four broad different strategies can be identified:

(1) "Wait and see": Nanomaterials are not new materials. The existing regulatory situation is adequate. If scientific evidence indicates the need for modification, the regulatory framework will be adapted.

(2) Differentiated approach: The Differentiated approach can be defined as a regulatory process which uses existing legislative structures to the maximum together with the need of reviewing and amending (when appropriate, on a case by case basis and for specific nanomaterials and their applications) existing legislation (including the development of a specific guidance and standards to support existing regulation) and the introduction of supplementary policy. When a high potential risk is identified, the precautionary principle has to be invoked[47].

In any case, this approach have to be supplemented by:

- Support of research initiatives on HSE issues (esp. on exposure, dose-response, toxicology, and ecotoxicology);
- Promotion of risk assessment throughout the life cycle of a nanotechnology including conception, R&D, manufacturing, distribution, use, and disposal—not only at the macro, ecological level but also within the human body, as in the case of drug delivery devices;

[47] European Commission (2004) <<Nanotechnologies: A Preliminary Risk Analysis On The Basis Of A Workshop Organized In Brussels On 1–2 March 2004 By The Health And Consumer Protection Directorate General Of The European Commission, European Commission (2004) – At. 22. Available at http://europa.eu.int/comm/health/ph_risk/events_risk_en.htm (Accessed April 2011); Widmer, M., Meili, C., Mantovani, E., Porcari, A. (2010) <<The FramingNano Governance Platform: A New Integrated Approach to the Responsible Development of Nanotechnologies>>. Final Report. Available at http://www.framinhnano.eu/ (Accessed January 2011).

- Setting-up of a dialogue among all stakeholders;
- International coordination: within recognized international bodies, working group on nanotechnology have been set up to coordinate efforts among subjects involved in regulation of nanotechnology at different levels.

It could be said that the differentiated approach is, at least, a pragmatic solution[48] that can help in the recasting and adaptation of the actual regulatory framework. In addition, its implementation can be more efficient (time and resources wise), and focused to address the environmental, health and safety concerns of nanotechnology and its application.

But because the "differentiated approach" is multi-layered and flexible in design, a consistent implementation roadmap is vital. Without it, we will be faced with loose measures that could lead to greater legal uncertainty[49].

The EU regulation strategy is known as the <<safe, integrated and responsible>> strategy to nanotechnologies and is based on the so called <<incremental approach>> that (at least on its general approach) can be broadly included on the Differentiated Approach mainstream.

The Commission's <<incremental approach strategy>> can be summarized[50] as follows:

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48 This pragmatic approach implies that if in the short term the differentiated approach is followed, it does not exclude that in the longer term, a new regulatory framework could be set up, after allowing the technology to develop while regulators, industry and society continually re-evaluate regulation in light of the evolving scientific evidence and of citizen concern. In this sense, Bowman, D., Hodge, G., A., (2007) <<Nanotechnology "Down Under": Getting on Top of Regulatory Matters>>. Nanotechnology Law and Business. 4: 225-235. At 235.

49 The Royal Commission on Environmental Pollution when defining the key qualities that a governance system must comply states: <<4.11 (...) Effective and trustworthy governance arrangements must therefore have al least four key qualities. They must be informed, transparent, prospective and adaptive. To achieve these characteristics they also need to be supported by skilled regulatory bodies and decision-making processes that deliver proportionate outcomes>>. Royal Commission on Environmental Pollution (RCEP) (2008). For the basic meaning of those key qualities see Brown, S. (2009) <<The New Deficit Model>>. Nature Nanotechnology. 4: 609 – 611.

50 <<3.4.4. Regulation
Appropriate and timely regulation in the area of public health, consumer protection and the environment, is essential, also to ensure confidence from consumers, workers and investors. Maximum use should be made of existing regulation. However, the particular nature of nanotechnologies requires their re-examination and possible revision. A proactive approach should be taken. Advancing knowledge in nanosciences through R&D at both European and national level should form the basis for further action in this direction.
Aside from ensuring consistency and avoiding market distortions, harmonised regulation plays a key role in minimising risk and ensuring health and environmental protection. Existing regulation relies frequently upon parameters that may turn out to be inappropriate for certain applications of nanotechnology, e.g. loose nanoparticles. For example, thresholds are often defined in terms of production volumes or mass, below which a substance may be exempt from regulation. The relevance of such thresholds should be revisited and, when appropriate, changed.>> (COM(2004) 338 final. At 3.4.4). <<The Precautionary Principle, as used up to now, could be applied in the event that realistic and serious risks are identified>> (COM(2004) 338 final At. 3.5.1).

a) Appropriate, consistent and timely regulation;

b) Maximum use of existing regulation;

c) Proactive approach by re-examination and reviewing legislation due to the especial characteristics of nanomaterials and the updated scientific information;

d) Ensure free movement of goods by regulatory harmonization.

For being able to assess the intensity and extent of the European Union policy and regulation towards the Differentiated approach, we previously need to present the European Union policy and regulation, task that will be done in the following sections.

(3) Nano specific regulation: The existing regulatory situation is not adequate and the effort needed for adapting it could surpass the benefits. For this main reason, it may be better to set up a mandatory nano-specific regulation.

In this sense, HANSEN (2010) states:

<<at some point, regulatory agencies worldwide will have to address the question of whether it is not more effective to implement a new more authoritative and prescriptive legislative framework compared to having to implement a forever-increasing number of smaller and larger adaptations to existing legislation while simultaneously trying to overcome the limitations of chemical risk assessment.>>[51]

We consider that in the medium to long term, the recourse to a nano-specific regulation may be advisable, but as per today, it is not a solution if our objective is to tackle, as soon as possible, the regulatory deficits related with health, safety and environmental concerns caused by nanomaterials (HSE).

This opinion is based on several factors that have to be taken into consideration, among them, the complexity of the proposed task[52], the increased regulatory agenda[53], and the

[51] HANSEN considers that the new regulatory framework should be based on fundamental principles such as protection of health and the environment, promoting green innovation, and having a high level of transparency and multi-stakeholder participation. As REACH, the burden of proof should be placed on the industry. Also propose a nanoagency. HANSEN, S.F. (2010) <<A global view of regulations affecting nanomaterials>>. WIREs Nanomedicine and Nanobiotechnology. 2: 441- 449. At 449; Also see EEB (2009) <<Small scale, big promises, divisive messages>>. Position paper on nanotechnologies and nanomaterials. February 2009. At 7.

[52] To design an overarching regulatory framework that implies multiple sectors and products its not only complex but also will be time consuming, have to involve all stakeholders, etc. In this sense, it is advisable to analyse in detail the legislative process followed with REACH (from the White Paper on European Union Chemical Policy to the actual REACH Regulation) that can be considered as a model of new regulatory governance. This is one of the reasons for choosing REACH as a Case Study in the context of the present report.

[53] Van Calster points out that in addition to HSE issues the following topics are being incorporated to the regulatory agenda:

- The requirements imposed by modern environmental and consumer protection law on the regulation of new technologies. This includes the precautionary principle (while contested, this principle at any rate applies generally in European environmental law), liability for environmental damage, etc.;
- The public participation principles of international and European environmental law, as exemplified by the Aarhus process: access to information, public participation, access to the courts;

uncertainty regarding projected applications[54].

(4) Moratorium: Until a regulatory framework is created or the existing legislation is adapted, a moratorium must be put in place on the release of nanomaterials and the use of nanotechnology applications[55]. The European Commission has explicitly rejected this approach:

<<Despite some calls for a moratorium on nanotechnology research, the Commission is convinced that this would be severely counter-productive. Apart from denying society the possible benefits, it may lead to the constitution of "technological paradises", -where research is carried out in zones without regulatory frameworks and is open to possible misuse-. Our consequent inability to follow developments and intervene under such circumstances could lead to even worse consequences>>[56].

B)THEPRECAUTIONARYPRINCIPLE

From the regulatory option reviewed, we have seen that, perhaps only for pragmatic reasons, most governments are currently relying on existing regulation to cover potential risks related to nanomaterials. Identifying the appropriate response to uncertain risks is a difficult task for policy-makers and regulators as they have to seek a compromise between conflicting interests (innovation, safety, free movement of goods, environmental protection, etc.).

Within this framework, the Precautionary Principle may guide decision-makers to balance those goals, so helping them in the shaping of a proper regulatory regime for nanomaterials.

In this section we will focus on the interpretation and scope that the European Courts have given to the Precautionary Principle and, from there, we will advance some specific legal consequences that its application may have for the EU nanomaterials

- Other requirements of international environmental governance, such as the plight of developing countries and the need to avoid what the Commission calls a "knowledge apartheid";
- The application of international trade law, in particular the law of the World Trade Organization.
Van Calster, G. (2006) <<Regulating Nanotechnology in the European Union>>. Nanotechnology Law & Business. 3: 359 – 374. At 369.

54 Projected applications with the greatest impact are far in the future (remission is made to Part I of this report), and it is unclear how to regulate technologies whose feasibility is speculative at this point.

55 For moratorium see Friends of the Earth Europe (2007) <<Nanotechnology and the current legislation – Position Paper>>.

56 European Commission (2004) Communication from the Commission: <<Towards a European Strategy for Nanotechnology>>. COM(2004) 338 final. At. 20

regime in general, and for REACH particularly.

The Precautionary Principle is not included in Article 114 of TFEU (which is the legal basis of European chemical regulation), but in the field of European environmental policy (Article 191.2 of the TFEU)

> Art 191 TFEU (ex article 174 TEC)
> 1.- (...)
> 2.- Union policy on the environment (...) shall be based on the precautionary principle and on the principle that preventive action should be taken, that environmental damage should as a priority by rectified at source and that polluter should pay>>.

The European Court of Justice has not only broadened its scope but established it as General Principles of Community Law[57].

Although the concept do not have a generally agreed definition[58] and no definition is

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57 Artegodan GmbH v. Commission (Joined Cases T-74/00, 76/00, 83/00, 84/00, 85/00, 132/00, 137/00 and 141/00) [2002] ECR II-4945.
<<183. Therefore, although the precautionary principle is mentioned in the Treaty only in connection with environmental policy, it is broader in scope. It is intended to be applied in order to ensure a high level of protection of health, consumer safety and the environment in all the Community's spheres of activity. In particular, Article 3(p) EC includes 'a contribution to the attainment of a high level of health protection' among the policies and activities of the Community. Similarly, Article 153 EC refers to a high level of consumer protection and Article 174(2) EC assigns a high level of protection to Community policy on the environment. Moreover, the requirements relating to that high level of protection of the environment and human health are expressly integrated into the definition and implementation of all Community policies and activities under Article 6 EC and Article 152(1) EC respectively.
184. It follows that the precautionary principle can be defined as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests. Since the Community institutions are responsible, in all their spheres of activity, for the protection of public health, safety and the environment, the precautionary principle can be regarded as an autonomous principle stemming from the above mentioned Treaty provisions.>>

58 The COMEST Report after reviewing precautionary principles' concept and capturing the key elements to the principle, propose a working definition that we consider that embraces the different aspects presents on the precautionary principle:
<<When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.
Morally unacceptable harm refers to harm to humans or the environment that is
- threatening to human life or health, or
- serious and effectively irreversible, or
- inequitable to present or future generations, or
- imposed without adequate consideration of the human rights of those affected.

The judgement of plausibility should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review.
Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm.
Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.>>
UNESCO (2005) <<COMEST Report. The Precautionary Principle>>. World commission on the Ethics of Scientific Knowledge and Technology. At. 14.

included on the Treaties[59], the Commission and the European Courts have given their definitions.

The European Commission issued on 2 February 2000 a Communication on the Precautionary Principle, where the principle was defined[60]:

> <<Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.>>[61]

Although the Communication has been criticized as being "so vague and imprecise that is only a good guide for arbitrariness or paralysis"[62], the basic guidelines for the application of the precautionary principle in Community law are, from the Commission point of view;

– Once the existence of a risk is known, a scientific evaluation -risk assessment- (as complete as possible) has to be obtained in order to know the objective evidence, the gaps in knowledge and the scientific uncertainties;

– Based on this evaluation, decision makers will determine whether to trigger action based on the precautionary principle balancing the potential consequences of inaction and of the uncertainties of the scientific evaluation. Transparency and societal involvement is fundamental as will assist policy makers in determining the risk management measures[63] to be taken and society's desired level of precaution and

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59 The first legislative definition of the principle can be found in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. O J L 31/1 1.2.2002, where the Precautionary Principle is defined as a <<(...) mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community>> (Recital 21).

60 Communication from the Commission on the precautionary principle. COM (2000) 1 of 2.2.2000.

61 Ibid. At. 10. The Communication has four aims: to outline the Commission's approach to using the precautionary principle, to establish Commission guidelines for applying it, to build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully, and to avoid unwarranted recourse to the precautionary principle as a disguised form of trade protectionism. The Communication also sought to provide an input to the (then) ongoing debate on the issue, both within the Community and internationally.

62 Recuerda, M. A., <<Dangerous interpretations of the Precautionary Principle and the foundational values of European Union Food Law: Risk versus Risk>>. At 29. Available at http://ssrn.com/abstract=1305545. (Accessed March 2011).

63 The application of the precautionary principle and risk management measures have to be based on a set of principles: proportionality, non-discrimination, consistency, cost-benefit analysis and examination of scientific development. Communication from the Commission on the precautionary principle. COM (2000) 1 of 2.2.2000.

protection.

In the Communication on Regulatory Aspects of Nanomaterials (COM(2008)366final) the Commission specifically stated the applicability of the Precautionary Principle to nanomaterials[64].

Obviously, the Communication could not determine the application of the precautionary principle by the European Court and, in fact, their role has greatly contributed to the development of the precautionary principle, not only on a definition but also determining when, how and by whom the principle may be relied upon in Community legal order.

The European Court of Justice developed in the BSE judgement (Case 180/96) what it had become the general definition of the Precautionary Principle within the EC[65] by holding that:

> <<99. Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.>>

The above passage lays down three basic conditions for the application of the precautionary principle in Community law: uncertainty, risk, and lack of direct causal link[66].

In the Pfizer case (T-13/99)[67], the Court defined the terms in which the principle can be

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At. 18.

64 <<Where the full extent of a risk is unknown, but concerns are so high that risk management measures are considered necessary, as is currently the case for nanomaterials, measures must be based on the precautionary principle>>.

65 Although giving shape to the precautionary principle, the BSE judgements did not refer to the principle as such. The first explicit reference in a curt ruling has been made in the Bergaderm case (Case C-353/98) at 52.

66 Christoforou, T. (2001) <<The origins, content and role of the precautionary principle in European Community Law>> At. 25. Proceedings of the Conference <<The Role of Precaution in Chemical Policy>>. Diplomatic Academy Vienna. 15 and 16 November 2001. Federal Ministry of Agriculture, Forestry, Environment and Water Management. Freytag,E., Jakl, T., Loibl, G., Wittmann, M. Ed. 2001.

67 Case T-13/99, Pfizer v. Council (2002) ECR p. II-3305, paras 143-144. Following Alemanno, we can consider the Courts statement as a procedural requirement for a valid application of the principle. This was repeated on the Case C-41/02 Commission v Netherlands para 53: <<a proper application of the precautionary principle presupposes, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research>>. Alemanno, A. (2007) <<The shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty>>. Bocconi Legal Studies Research Paper No. 1007404. Cahiers Europèens, Halley.Valori Costituzionali e nuove politiche del diritto. L. Cuocolo, L. Luparia, eds. Available at

invoked:

" […] a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified … Rather, it follows from the Community Courts' interpretation of the precautionary principle that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken".

This principle can therefore be validly applied only in situations in which;

- There is a risk, notably to human health, that have not been scientifically confirmed (has not yet been fully proved), but it is not founded in mere hypotheses.
- The precautionary principle's invocation requires a prior objective evaluation of the existing scientific relevant studies[68].

Furthermore, an attempt at defining the threshold triggering the invocation of the precautionary principle, was done in Case C-41/02 Commission v The Netherlands (para 54) by stating:

"when it proves to be impossible to determine with certainty [after having undertaken the prescribed comprehensive risk assessment] the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialize, the precautionary principle justifies the adoption of restrictive measures"

That means that under EC law precautionary action may be taken if;

a) precondition: undertaking risk assessment.

b) scientific uncertainty.

c) likelihood of real harm should the risk materialize.

Once reached this point, and faced with the scientific uncertainties surrounding nanomaterials, it is important to reproduce the statement made by the European Court of Justice in "Alpharma" where a new attempt to set up a threshold trigger for the Precautionary Principle was adopted:

> 173. Second, it is common ground between the parties that, when the precautionary principle is applied, it may prove impossible to carry out a full risk assessment, as defined at paragraph 169

http://ssrn.com/abstract=1007404.At 11. (Accessed January 2011).

[68] However, even after the Pfizer judgement, the threshold of risk which must be established by a Member State in order to validly take precautionary action would seem to remain largely undefined. Only a negative condition has been laid down in the Court's case law: it is insufficient to rely on hypothetical considerations to establish scientific uncertainty. That means that the main condition triggering the application of the principle, scientific uncertainty, can be shown only at the end of an assessment of risk Alemanno, A. (2007) At 11.

above, because of the inadequate nature of the available scientific data. A full risk assessment may require long and detailed scientific research. The case-law cited at paragraph 152 above shows that unless the precautionary principle is to be rendered nugatory, the fact that it is impossible to carry out a full scientific risk assessment does not prevent the competent public authority from taking preventive measures, at very short notice if necessary, when such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society.
174. In such a situation, the competent public authority must therefore weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Where measures for the protection of human health are concerned, the outcome of that balancing exercise will depend, account being taken of the particular circumstances of each individual case, on the level of risk which the authority deems unacceptable for society.

So it have to be concluded that if decision-makers considers that nanomaterials poses an unacceptable risk (on the bases of the limited scientific information available), they have to positively act to address it. Once reached this conclusion and before developing the consequences of it, we turn now specifically to REACH and the Precautionary Principle.

Article 1,3 REACH establishes the application of the Precautionary Principle:

> <<3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.>>

And based on this article, and following the Commission, specific provisions can be found as practical applications of the principle like safety assessment, risk management measures, and in the authorization and restriction of substances[69].

It can also be interpreted that the overarching character of the Precautionary Principle covers three principles specific from REACH: "no data-no market principle", "substitution principle" and "producer responsibility principle"[70].

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[69] - Safety assessment: If there is uncertainty over scientific evidence (e.g. conflicting data exist), the safety assessment should normally be based on the evidence that gives rise to highest concern.
- Risk management measures: While a company is awaiting further test data on a particular hazard it should make sure that the risk management measures appropriate for the potential risk are in place and describe these measures in the safety assessment; in the case of PBTs and vPvBs, industry is requested to minimise exposure at all times.
- Authorisation: Industry is required to seek authorisation for uses of substances of very high concern (SVHC, such as endocrine disruptors, PBTs, etc.), regardless of the measures taken to control the risks; in some cases, the authorisation is granted only if there are no alternatives, again regardless of the measures taken to control the risks.
- Restrictions: Member States and the Commission can suggest immediate restrictions in case there are indications of severe risks associated with the use of a given chemical. In this way the PP could be implemented in cases where it would take too long to establish the data necessary for a scientific evaluation or where data does not allow the risk to be determined with sufficient certainty.
Commission of the European Communities (2007) <<Questions and Answers on REACH>>. Available at http://ec.europe.eu/environment/chemicals/pdf/qa.pdf. (Accessed May 2011).

[70] The Producer Responsibility Principle implies a fundamental change of policy by which all major responsibilities

From the revision of the basic interpretation and triggering factors for the application of the Precautionary Principle by the Court and the consequences of its inclusion in art 1,3 of REACH, we conclude that the conditions needed for the application of the Precautionary Principle appear to be met for engineered nanoparticles and the products incorporating them: Risk of serious and irreversible damage to health and the environment deemed unacceptable to society, supported by solid and objective scientific reasons, even if uncertain.

Therefore, the European public authorities are not only allowed but compelled to take provisional measures to anticipate the potential occurrence of these risks, and that those measures must be based on general principles of risk management (and must be proportionate, non-discriminatory, consistent, based on an examination of benefits and costs of action or lack of action, and on an examination of scientific developments).

When discussing on the specific legal consequences of the above conclusion, and regarding nanomaterials, the following measures[71] can be envisaged:

- To act in order to avoid or minimize possible risks and not to be satisfied with (just) monitoring the development;
- To take into account the possible effects of nanotechnology already in the definition of EU policies[72];
- Provide funding for research on toxicology and ecotoxicology in order to allow complete scientific evaluation of the potential adverse effects, based on the available data, and carried out by independent authorities.
- Organizing the collection of information about manufactured nanoparticles and nanomaterials, their properties, their manufacturers, their uses, and the people

are placed with firms rather than on administrative bodies. Companies marketing substances falling under REACH must ensure that along the production chain dangers to health and environment will be mastered throughout all intermediate and final users of the substance or the product containing the substance.
The responsibility shift affects principally manufacturers and importers but it extends to all parts of the supply chain and to the whole life cycle of the product. Commission of the European Communities (2001) <<White Paper. Strategy for a future Chemicals Policy>>. COM (2001) 88 final. 27.2.2001. At 8).

71 When discussing the character of the measures to be taken, it is important to recall, as done by the Commission <<recourse to the precautionary principle does not necessarily mean adopting final instruments designed to produce legal effects. A wide range of activities or measures can be used, like legally binding measures, initiation of research projects or recommendations>>. Commission of the European Communities (2008) <<Regulatory Aspects of Nanomaterials>>. COM(2008)366final. 17.6.2008.

72 Haselhaus, S. (2009) <<Nanomaterials and the Precautionary Principle in the EU.>>. J Consum Policy. 33: 91 – 108. At. 96 – 97.

potentially exposed. This requirement can be met by the setting up of a compulsory inventory or reporting scheme that could be designed within REACH, but not necessarily[73].

[73] REACH could help to collect the information needed (although limited by the regulatory gaps) but changes have to be done if an inventory has to be created. The need and design of a nanomaterials inventory is discussed in the Chronology section of this report. See Desmoulin, S. (2008) <<French and European Community Law on the Nanometric forms of Chemical substances: Questions About How the Law Handles Uncertain Risks>>. Nanotechnology Law & Business. 5 (3): 341 – 352. At 348.

2.EUROPEANUNIONREGULATION:THEQUEST

In order to assess the European Union regulation strategy on Nanotechnology and Nanomaterials (N & N) we need to follow a three step process:

- We start by presenting the complex set of applicable legislation for nanomaterials in the European Union;
- Once presented, we will need to know how the European Union approaches N&N policy and regulation. For doing so, we have chosen a chronological approach that permits us, firstly, to be exhaustive on its presentation and, secondly, to present the different actors in the scene and their respective contribution to the making of the regulatory regime individually.
- Finally, we will be presenting the foreseen short term developments for nanosubstances policy and regulation that will give us clues on the future developments on nanotechnology regulation design.

With all these data in mind, we will be able to propose, in the final section, a preliminary assessment on the European Union quests for a regulatory regime.

A)APPLICABLELEGISLATIONTONANOMATERIALSINTHEEUROPEAN UNION.

GeneralFramework

There are no specific regulations for nanotechnologies or nanomaterials at EU level. Instead, the manufacture, use and disposal of nanomaterials are covered, at least in principle, by a complex set of existing regulatory regimes. This situation will probably not change (in the near future at least) as the current and expected applications of nanotechnologies are so diverse that they can fall within such a broad field of industrial and commercial sectors (and in any of their life cycle stages), that the design of an overarching specific regulation seams an extremely complex and time consuming task[74].

[74] In this sense, it is important to recall that the lack of a nano-specific legislation measures does not mean that nanotechnologies are an entirely unregulated enterprise. Their regulation falls to existing provisions designed to manage risks associated with conventional, bulk-sized materials. Van Calster, G. (2006). At 359.

A review of the applicable legislation to Nanotechnology and Nanomaterials (N & N) was presented by the Commission on its <<Communication on Regulatory aspects of nanomaterials>>, that was heavily criticized by the European Parliament afterwards.

Following the Commission Communication[75] presentation, it can be said that Nanomaterials are covered under current EU laws by;

1.- Chemicals, namely REACH, that provides an over-arching legislation applying to the manufacture, placing on the market and use of substances on their own, in preparations or in articles. REACH also complements current product regulations (e.g. Cosmetics or general product safety).

REACH does not cover explicitly nano materials. However, as REACH applies to substances on their own, in preparations or in articles, it covers areas in which nanomaterials are being used[76].

The general assessment was:[77]
<<The Commission will carefully monitor the implementation of REACH with respect to nanomaterials. Based on information regarding production and marketing, or new knowledge, for instance regarding toxicological or physical-chemical properties, current provisions, including quantitative triggers and information requirements may have to be modified.>>.

Basically it can be seen a policy of "wait and see" without rejecting the possibility of legal modifications if needed as a consequence of new scientific data, or if the regulatory gaps are considered to be too inadequate (**"based on information regarding production and marketing"**).

2.- Health and safety of workers; The general requirements in relation to occupational safety and health of workers at workplaces are presented in the EU Directive 89/391/EEC[78]. The aim of this framework directive is to ensure a high level of protection of workers at work – including those exposed to nanomaterials - through the

[75] The Communication is backed by the Commission Staff Working Document where a summary of legislation can be found and where we remit. Commission of the European Communities (2008) <<Regulatory Aspects of Nanomaterials>>. Commission Staff Working Document. Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures. SEC(2008)2036. COM(2008)366final. 17.6.2008.

[76] We remit to Part III of the present research paper.

[77] COM(2008) 366 final. At 2.1.

[78] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, Official Journal of the European Communities L, 29.06.1989, pp. 1-8. http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0391:EN:HTML

implementation of preventive measures to guard against exposure to risks, and through provision of information, consultation, balanced participation and training of workers and their representatives.

The framework Directive foresees the possibility of adopting individual directives including more specific provisions in relation to particular aspects of safety and health and workplace exposures. Relevant directives thus adopted relate to risks related to exposure to carcinogens or mutagens at work[79], risks related to chemical agents at work[80], the use of work equipment by workers at work[81], the use of personal protective equipment at the workplace[82] and safety and health protection of workers potentially at risk from explosive atmospheres[83].

3.- Product requirements (for health and safety of workers, consumers and protection of

[79] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version), Official Journal of the European Communities L 158, 30.4.2004, pp. 50-76, http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:158:0050:0076:EN:PDF

[80] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), Official Journal of the European Communities L 131, 5.5.1998, pp. 11-23. http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:131:0011:0023:EN:PDF
Because Directive 98/24/EC presents minimum requirements, the European Trade Union Confederation (ETUC) demanded nano specific measures: <<6.- Occupational health and safety issues: Workers might be exposed to dispersive nanomaterials throughout the life cycle of nanomaterials (manufacture, production, use, maintenance and disposal). In the coming years millions of employees might be impacted. The ETUC demands the development of concrete measures at the workplace in order to know who is exposed, to what extent and to what type of nanomaterials, and which prevention measures to install to avoid exposure.>>. European Trade Union Confederation -ETUC- 2010 <<2nd resolution on nanotechnologies and nanomaterials. Adopted at the Executive Committee on 1-2 December 2010>>. Available at http://www.etuc.org/. (Accessed April 2011); See also European Agency for Safety and Health at Work -EU OSHA- (2009) <<Workplace exposure to nanomaterials>> June 2009. Available at http://osha.europa.eu/en/publications/literature_reviews/workplace_exposure_to_nanoparticles. (Accessed April 2011).

[81] Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC), Official Journal of the European Communities L 393, 30.12.1989, pp. 13-17. http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0655:EN:HTML

[82] Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC), Official Journal of the European Communities L 393, 30.12.1989, pp. 18-28, accessed on 13 November 2008. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0656:EN:HTML

[83] Directive 1999/92/EC of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (15th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), Official Journal of the European Communities L 23, 28.1.2000, pp. 57- 64, accessed on 13 November 2008. http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:023:0057:0064:EN:PDF
The general assessment of the Commission was that <<The Framework Directive and the above mentioned daughter Directives present a comprehensive package of legal requirements aiming at ensuring a high level of protection of workers health and safety. The requirements, whilst they do not make explicit mention of nanomaterials and nanotechnologies, define a legislative framework that applies to most occupational risks including those arising from the presence of nanomaterials>> Commission of the European Communities (2008) <<Regulatory Aspects of Nanomaterials>>. Commission Staff Working Document. SEC(2008)2036. COM(2008)366final. 17.6.2008. At. 11

the environment):

- Groups of products: plant protection products[84], biocides[85], cosmetics, aerosol dispensers, medicinal products[86], cars, etc.;
- Food legislation: general food law, novel food[87], food contact material, food additives, food supplements, feed legislation;
- General Product Safety Directive on consumer products not covered by specific regulation[88] and Product Liability Directive (related with defective products)[89].

4.- Environment: directives on Integrated Pollution Prevention and Control (IPPC), major accidents (Seveso II Directive), water, waste (mention has to be made to electric and electronic equipment -EEE[90]), air quality, soil protection and environmental

[84] The general assessment of the Commission was that <<Directive 91/414/EEC concerning the placing of plant protection products on the market, lays down rules and procedures for approval of the active substances at EU-level. (…). Directive 91/414/EEC does cover nanomaterials adequately in its current form. However, current guidance documents (on data requirements, risk assessment and decision making) could need to be amended in order to properly address risks to nanomaterials>>. Commission of the European Communities (2008) <<Regulatory Aspects of Nanomaterials>>. Commission Staff Working Document. SEC(2008)2036. COM(2008)366final. 17.6.2008. At. 11

[85] For an overview of the pesticides and biocides Directives and their regulatory regime for nanomaterials, see Haselhaus, S. (2010) <<Risk Management of Nanomaterials: Environmental and consumer protection under existing EC legislation on Chemicals, pesticides and biocides>>. Environmental Law Review. 12: 115 – 131.

[86] From a regulator´s point of view, nanotechnology applications in the pharmaceutical and medical device sector are not only spread across a number of sectors but, increasingly, products combine multiple modes of action, thereby making strict and clear categorization difficult (between medical products, medical divides and advanced therapies medicinal products) while current regulatory pathways from those sub-sectors are clearly differentiated. Another distinct characteristic is that pharmaceutical regulation has already the highest level of safety and environmental care standards as compared with other sectors. Chowdhury, N. (2010) <<Regulation of nanomedicines in the EU: destilling lessons from the advanced therapy medicinal products approach>>. Noanomedicine. 5 (1): 135 – 142; D'Silva, J., Van Calster, G. (2009) <<Taking Temperature – A Review of European Union Regulation in Nanomedicine>>. European Journal of Health Law 16: 249 – 269.

[87] On 29.03.2011 the final conciliation meeting on the Novel Foods Directive Recast failed and the legislative process will have to start again. Opinion of the Commission pursuant to Article 294, paragraph 7, point (c) of the Treaty on the Functioning of the European Union, on the European Parliament's amendments to the Council's position regarding the proposal for a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) N° 1331/2008 and repealing Regulation (EC) N° 258/97 and Commission Regulation (EC) N° 1852/2001. COM(2010) 570 final 2008/0002 (COD). Brussels, 11.10.2010; Bergeson, L.L. (2011) <<European Parliament and EU Council Fail to Reach Agreement on Novel Foods Regulation>>. Nanotechnology Law Blog. 31.03.2011. Available at http://nanotech.lawbc.com/2011/03/ (Accessed June 2011); Nanotechnology Industries Association News -NIA- (2011) <<Clone Wars – End of the Novel Foods Regulation Recast>>. 4.4.2011. Available at http://www.nanotechnia.org. (Accessed May 2011)

[88] Directive 2001/95/EC of the European Parliament and of the Council of 3.12.2001 on general product safety. OJ L11 2002.

[89] Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products 85/374/EEC. OJ L 210, 7.8.1985, p. 29; See Ware A., Kelly, B. (2009) <<Nanotechnology and the European Product Liability Directive>> RAJPharma. April 2009 213 – 216. Available at www.rajpharma.com. (Accessed May 2011).

[90] The European Parliament (EP) approved on 24.11.2010 the recast of the "Restriction of Hazardous Substances (RoHS) Directive", which restricts the use of certain hazardous substances in electronic and electrical equipment (EEE). The final approved Directive do not include (previous EP proposed) restrictions on nanosilver and long multiwalled carbon nanotubs.
The final adopted texts includes Recital 16 where nanomaterials are cited as due for further scientific scrutiny. The results from scientific scrutiny will be discussed in the review of the Directive that will take place three years after the Directive Publication. European Parliament Procedure file available at http://www.europarl.europa.eu/oeil/file.jsp?id=5723432 (Accessed May 2011). Ref. Code COD/2008/0240; European Parliament Press release ref. 20101124IPR99509. Available at http://www.europarl.europa.eu/es/pressroom/content/20101124IPR99509/html/Parliament-votes-for-safer-

liability.

The main conclusions drawn by the Commission were[91]:

1) Current legislation covers "in principle" risks in relation to nanomaterials and risk can be dealt with under the current legislative framework;

2) Current legislation may have to be modified in the light of new information becoming available;

3) The regulatory problems have to be found on implementation and enforcement shortcomings caused by the knowledge gap: For the Administration to implement current legislation or administrative decision, and for the manufacturer or employer to comply with their obligations it is basic to rely on adequate guidance or standards (test methods and risk assessment methods).

The problem arises when the scientific basis to fully understand all properties and risks of nanomaterials is not sufficiently available (knowledge gap[92]).

Similarly, from the enforcement perspective, authorities and agencies will have to pay attention to risk in relation to nanomaterials where production and marketing are subject to pre-market control (for instance medical products).

EUregulationsexplicitlyreferringtonanomaterials

Regardless of the assessment that the Commission and other Institutions have done on the degree of adequacy of the legal framework, the fact is that since 2008 we have seen an increasing regulatory activity related with nanomaterials. Basically, nano specific Recommendations (horizontal measures) and sectoral Regulations (within the above explained framework of non specific nano regulation). Those are:

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electronic-and-electrical-products (Accessed May 2011); Nanotechnology Industries Association News -NIA- (2010) <<European Parliament approved Agreement on EEE-Legislation>>. 24.11.2010. Available at http://www.nanotechia.org/global-news/european-parliament-approves-agreement-on-eee-legislation (Accessed April 2011) and (2011) <<RoHS Recast: Nanomaterials Escape Explicit Regulation>>. Available at http://www.nanotechia.org/global-news/rohs-recast--nanomaterials-escape-explicit-regulation 7.1.2011. (Accessed April 2011).

91 COM(2008)366 final. At 4. <<Current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation. The Commission and EU Agencies will therefore in the first place review current documents that support implementation, such as implementing legislation, standards and technical guidance with regard to their applicability and appropriateness to nanomaterials>>.

92 So the need for a rapid improvement of the knowledge basis to support the work of regulators is underlined in the Communication: Particularly in areas underpinning risk assessment and risk management, such as data on uses and exposures throughout the lifecycle of nanomaterials or products containing nanomaterials, data on toxic and eco-toxic effects (as well as test methods to generate such data) and characterisation of nanomaterials.

HORIZONTAL

Commission Recommendation of 2 February 2008 on a Code of Conduct for responsible nanosciences and nanotechnologies research C(2008) 424 (2008/345/CE) OJ L116/46 of 30.04.2008[93]

Commission Recommendation of 18 October 2011 on the definition of nanomaterials (2011/696/EU). OJ L275/38 of 20.10.2011[94]

CHEMICALS

Commission Regulation (EC) No. 987/2008 of 8 October 2008 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as regards Annexes IV and V, OJ L268/14 of 09.10.2008 by which Carbon and Graphite were removed from the exemption list from Annex IV REACH[95].

FOOD SECTOR

Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives OJ L345/16 of 31.12.2008(Art 12).

Commission Regulation (EC) No 450/2009 of 29.05.2009 on active and intelligent materials and articles intended to come into contact with food OJ L135/3 of 30.05.2009.

Commission Regulation (EU) No.10/2011 of 14.01.2011 on plastic materials and articles intended to come into contact with food. OJ L12/1 of 15.01.2011 (Arts 9, 13 and 14).

Regulation of the European Parliament and of the Council on the provisions of food information to consumers COM(2011) 475 final 2008/0028 (COD). Expected to be published in the OJ before the end of 2011.

COSMETICS

Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30.11.2009 on cosmetic products (recast). OJ L342/59 of 22.12.2009 (Arts 2 Definitions at (K), Art 2 Definitions at 3, Art 13 Notification at (F) Art 16 Nanomaterials and Art 19

93 See Part II Section B.5).

94 See Part II Section B.8).

95 Carbon and Graphite were on the Annex IV REACH list until October 2008, when they were removed from the exemption list by Regulation 987/2008. The reason for this decision is related with the reported possible health risk of carbon nanotubs.
REACH does not differentiate between nano and bulk forms inaccurately assuming that the risk of a substance is the same as whatever scale. In fact, if the nano substance would be regarded as a separate substance from the bulk, then, there will not be need for the withdrawal from the exemption. The identified gap on substances of Annex IV and V could be filled by a clear distinction between the bulk and the nano substances and this could be done by considering both as different substances (so giving a different EINECS number) or if the substance has been already recognized as phase-in substance by giving an additional code to the CAS number (Chemical Abstract Service).
It is important for Companies when setting up their R&D programmes to take into consideration a precautionary approach in their decisions. In the case of carbon nanotubs, the existence of <<concern over potential harm>> and the decision to withdraw the exception is clearly guided by precaution. In aligning the investment decision with the policy principle will make private decisions safer from possible future legal obligations derived from new scientific findings. Lee, R.G., Vaughan, S. (2010) <<REACHing Down: Nanomaterials and Chemical Safety in the European Union>>. ESRC BRASS Research Centre. Cardiff University. At 8.

Labelling)[96].

RoHS ELECTRIC AND ELECTRONIC EQUIPMENT

Directive 2011/65/EU of the European Parliament and of the Council of 08.06.2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. OJ L174/88 of 01.07.2011. (Recital 16).

Although the objectives of this research study only allow us to analyze the Recommendations , -given its horizontal character-, we could make the following general comments:

a) Deepens in the "incremental approach startegy" as it chooses to insert explicit regulation on nanomaterials in the sectoral legislation.

b) The regulation is done through Regulations and Recommendations. The Regulations -directly applicable in Member States- confirms the intention of creating a regulatory framework (fully) harmonized at EU level.

c) The use of Recommendations can be explained by the combined effect of a general trend towards better and smarter regulation (including co-regulation and self-regulation) [97], and the pressure for regulating nanotechnology. Regulatory failures (regulatory gaps) has lead regulators and industry to develop soft law mechanisms[98].

In fact, Soft Law mechanisms are considered “one of the most promising management

[96] From a regulator's point of view, cosmetics pose a special challenge as cosmetic materials are in direct contact with the body and it does already exist some evidence which points towards potential adverse effects of the use of nanoparticles and therefore the precautionary principle should be applied.
The New cosmetic legislation (Regulation (EC) No, 1223/2009) on cosmetic products entered into force on January 11, 2010 is the first European Union (EU) and include a dedicated provision expressly designed to review the safety of nanometerials. It provides a definition for the kinds of nanomaterials that are intended to be subject to the regulation, and establishes a pre-market notification or authorization and specific safety and labelling requirements applicable to cosmetic products containing nanomaterials in addition to registration (will come into force in July 2013 -art 40-). Guix, M., Carbonell, C., Comenge, J., García-Fernádez, L., Alarcón, A., Casals, E. (2008) <<Nanoparticles for cosmetics. How safe is safe?>>. Contributions to Science, 4(2): 213 217.

[97] See White Paper on European Governance. COM(2001)428; The Interinstitutional Agreement on better law-making between the European Parliament, The Council and the Commission Interinstitutional Agreement on better law-making Commission Communication on Smart Regulation COM(2010) 543 final.

[98] Following Senden, Soft Law mechanisms can be defined as <<rules of conduct that are laid down in instruments which have not been attributed legally binding force as such, but nevertheless may have certain (indirect) legal effects, and that are aimed at and may produce practical effects>>. Senden, L. <<Soft Law in European Community Law>>. Volume 1 Modern Studies in European Law. Hart Publishing. 2004. at 112.
Overall, it can be said that voluntary measures share similar principles and actions (due respect for precaution; priority on safety; raise/consider stakeholder awareness; inclusive approach) and goals (built trust and confidence in the technology; promoting health and environmental safety; gathering information). Mantovani, E., (2011) <<The role of voluntary measures in the governance of nanotechnologies: the case of the European Code of Conduct>>. AIRI/Nanotec IT. Euronanoforum 2011. Budapest. 30.05.2011.

strategies for ensuring safety and risk control in the short term"[99] and a complement (or/and a prelude) to existing mandatory regulatory approaches[100].

d) Concerns over possible health impacts from certain nanomaterials have prioritized works on food/food packaging sector and cosmetics.

e) Cosmetics Regulation includes three key features in the specific field for nanomaterials that mark a guide to follow for future legal developments in other sectors (pre-market notification or authorization, specific safety and labelling requirements and compulsory registration).

B)EUROPEANUNIONNANOMATERIALSPOLICYANDREGULATION

B.1)CommunicationontheEuropeanUnionStrategy.2004

The European Commission formally announced its intention to develop an integrated nanotechnology strategy for Europe in May 2004 in its Communication <<Towards a European Strategy for Nanotechnology>>[101].

The Strategy defined for the first time, the European policy on nanotechnology. The final goal was (by the establishment of integrated and coherent set of measures) to strike the right balance between;

a) creating a good climate and conditions for innovation and development of applications, contributing to economic growth, welfare and sustainable development and,

b) ensuring that potential risks to environment and human health, as well as public and ethical concerns, are looked into and dealt with at the earliest possible stage.

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[99] Renn, O., Roco, M <<White paper...>>. At 18.

[100] They are described as <<interim measures to fill the current risk management gap before our knowledge of the emerging technologies and the associated risk measures are developed>> Widmer, M. & Others <<The FramingNano...>>. At 81.

[101] European Commission (2004) Communication from the Commission: Towards a European Strategy for Nanotechnology>>. COM(2004)338 final. The strategy was subsequently reviewed and supported by the Competitiveness Council and the European Economic and Social Committee. Conclusions of the Competitiveness Council 24.09.2004; Opinion of the European Economic and Social Committee of 15.12.2004.

The Communication defined the EU policy as a <<safe, integrated and responsible strategy>> and established the following set of interrelated factors (for each one of them specific actions were indicated):

a) European Research Area, facilities and resources that provide essential services to the research community, attract and retain researchers in Europe;

b) Foster industrial innovation;

c) Health, Safety and Environmental (HSE) factors;

d) Ethic, Legal and Social (ELSA) aspects;

e) International cooperation

As we have seen, and from a regulatory point of view, the Communication was defined as an <<incremental approach strategy>>.

B.2)EuropeanUnionActionPlan.2005

In June 2005, and after an extensive open consultation[102], the European Commission adopted the Communication <<Nanosciences and nanotechnologies: An Action Plan for Europe 2005 – 2009>>[103].

In relation to the European strategy Paper, the Action Plan specified actions for the <<immediate implementation of a safe, integrated and responsible strategy for Nanosciences and Nanotechnologies (N&N)>> and outlines a number of specific commitments related with the actions envisaged on the 2004 Communication[104].

In addition to public health, safety, consumer protection and environmental issues, employees were added to the list of subjects to be of concern with regard to possible

[102] Nanoforum Report. December 2004. http://www.nanoforum.org . The public consultation was the largest of its kind in Europa and have to be underlined that the emphasis placed on public engagement and consultation was and has been a consistent characteristic in the development of the nanotechnology policy in the EU.

[103] Communication from the Commission to the Council, the European Parliament and the ECOSOC <<Nanosciencies and nanotechnologies: An action plan for Europe 2005 – 2009>> COM(2005)243 final

[104] The Action Plan also called on the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to provide an opinion on the ability of existing risk assessment methodologies to extend to nanotechnologies. The SCENIHR opinion, entitled <<The appropriateness of existing methodologies to asses the potential risks associated with engineered and adventitious products of nanotechnologies>> was adopted in September 2005. Following public consultation, this opinion was subsequently revised and the modified version adopted in March 2006. Adopted by the SCENIHR during the 10th plenary meeting of 10.03.2006.
The Action Plan also called upon the European Group on Ethics in Science and New Technologies to examine the ethical aspects of nanomedicine, a commitment that was fulfilled in January 2007. EGE Opinion No. 21 from 17.01.2007.

regulatory efforts, and specifically, the Commission endorser the compromise of:

<< d) Examine and, where appropriate, propose adaptations of EU regulations in relevant sectors in light of the above paying particular, but not exclusive, attention to (i) toxicity thresholds, (ii) measurement and emission thresholds, (iii) labelling requirements, (iv) risk assessment and exposure thresholds and (v) production and import thresholds, below which a substance may be exempt from regulation, are typically based upon mass quantities.>>.

On the Action Plan the Commission was taking a pro-active role on HSE related aspects: Although REACH was still under discussion, it looks like the Commission was adapting a stricter interpretation of the "no data – no market" principle from the one that was finally adopted in art. 5 of REACH. The Commission states:

<<Appropriate ex ante assessment should be carried out and risk management procedures elaborated before e.g. commencing with the mass production of engineered nanomaterials. Particular attention should be paid to products that are already or close to being on the market>>.

Above statement shows a leading policy will, underpinned by the precautionary principle that, as we will see, was lost afterwards.

B.3)EuropeanUnionActionPlan:FirstImplementationReport.2007

A first implementation report on the EU Nanosciences and Nanotechnologies Action Plan was adopted in September 2007[105].

The Commission identified public health, safety, environmental and consumer protection as the main regulatory goals and acknowledged as a crucial problem the lack of data on health and environmental risks.

Furthermore, the Commission advanced its preliminary opinion on the regulatory review and concluded that:

a) The existing legal framework was "in principle" addressing the regulatory issues related with nanomaterials[106];

b) Only in case of new scientific data or specific area regulatory needs, changes may be proposed;

[105] Communication from the Commission to the Council, the European Parliament and the ECOSOC <<Nanosciencies and nanotechnologies: An action plan for Europe 2005 – 2009. First Implementation Report 2005 - 2007>> COM(2007) 505 final.

[106] COM(2007) 505 final. At 6.1: <<6.1. Regulatory review
The Commission is finalising a review of current regulation, to establish whether new regulatory action is required to cover risks in relation to nanomaterials. Its initial finding is that current regulation addresses in principle concerns about health and environmental impacts. On the basis of scientific developments or regulatory needs in specific areas, regulatory changes may be proposed. In the course of this exercise, the EC will take account of reports on regulatory gaps produced in various Member States.>>.

c) Weakness were identified in the implementation of existing regulatory mechanisms. Updates of current texts could be envisaged (on implementing legislation, standards and technical guidance); In the framework of implementing legislation special attention should be placed to safeguard clauses or warning systems.

Once this assessment was made, two conclusions were drawn by the Commission:

1.- Up to the moment that the Commission and the Member States decide if regulatory changes and/or updates for improving implementation may be proposed, no further action has to be taken.

<<In the meantime (...) existing methods will continue to be used (...) where necessary, existing regulatory mechanisms should be used>>.

2.- The Commission knowledge that products on the marketplace containing nanomaterials can put consumers at risk.

<<Particular attention must also be given to the various mechanisms that allow authorities and agencies in charge of implementing legislation to intervene, through measures such as safeguard clauses and warning systems, in case risk are identified for products already on the market>>

B.4)CommunicationonRegulatoryAspects.2008

As announced on the Action Plan, the Commission undertook a regulatory review of the EU legislation in relevant sectors and was reflected on the <<Communication on Regulatory Aspects of Nanomaterials>>[107].

The Communication has been analysed in Part II, Section 2.A.1) where we remit in full. As stated there, the Commission presented the general framework of current legislation affecting nanomaterials and stated that it found the existing legislation in this field to be "in principle" sufficient.

From this general conclusion, basically followed a three-tiered strategy on regulatory aspects: introducing minor changes to existing regulations if considered to be necessary, building up competence for risk evaluation and assessment (considered to be the basis for a proper implementation of current legislation, and of any administrative decision

[107] Communication from the Commission to the European Parliament and the ECOSOC "Regulatory aspects of nanomaterials". C(2008)366 final. Also see the Commission Staff working document accompanying the Communication that includes a summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures;

and manufacturer's and employer's obligations) while engaging in a transparent discourse with all stakeholders, including consumers and their organizations.

B.5)EURecommendationonaCodeofConduct.2008

On February 2008 the European Commission adopted (after public consultation[108]) a Code of Conduct for responsible research in nanosciences and nanotechnologies in a Recommendation (as such, not mandatory)[109] and is one of the several initiatives which aim at regulating the field of nanomateriales on the basis of voluntary conduct[110].

The codes of conduct (in general) and the EU Code of Conduct in particular, it is not intended to supplant or delay regulation but to provide guidance on best practices during the transitional period in which the appropriate national and international regulatory frameworks are being evaluated and developed, and to complement existing regulation.

The basic objective of the Commission was that universities, research institutes and companies in the EU signed up and undertake the promotions of an integrated, safe and responsible nanosciences and nanotechnologies research in Europe and to contribute to the coordination between Member States with a view to optimize synergies among research stakeholders.

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[108] Towards a Code of Conduct for responsible nanosciences and nanotechnologies research consultation paper. Available at http://ec.europa.eu/research/consultations/pdf/nano-consultation_en.pdf

[109] Commission Recommendation of 07.02.2008 on a code of conduct for responsible nanosciences and nanotechnologies research C(2008) 424 (2008/345/CE) OJ L116/46 of 30.04.2008; Nielsen, L. (2008) <<The Code of Conduct for responsible nanosciences>>. Available at http://ec.europa.eu/research/science-society/document_library/pdf_06/nielsen-l-presentation_en.pdf. (Accessed May 2011).

[110] In addition to the EU CoC there are other codes of conduct which directly or indirectly refer to nanotechnology. They differentiate themselves through their sectoral area of application as well as their target group:
1) Responsible NanoCode (United Kingdom); 2) German NanoKommission; 3) The Swiss Retailers Association (IG DHS) Code of Conduct; 4) Other Industry codes of conduct/practices in line with the Corporate Social Responsibility (CRS): The ICCA (International Council of Chemical Associations) "Responsible Care Global Charter", the BASF "Code of Conduct on Nanotechnology", the Bayer "Code of Good Practice on the Production and on-site-use of Nanomaterials", and the DuPont "Nano Risk Framework, are telling examples of this type of initiatives.
5) Certification systems: Closely related with Codes of Conduct it's interesting to mention the Certification systems, a further voluntary measure with regard to the regulation of nanotechnology: 1.- CENARIOS (first certificable risk management and monitoring system specifically adapted to nanotechnologies); 2.- Hohenstein Quality for Nanotechnology for the textile industry; 3.- Quality Seal Nano Inside (certifies that a certain product contains nano and that the applicant obliges itself to adhere to the Responsible Nanocode); 4.- Assured Nano (accredited scheme of best practice in HSE aspects and safe handling of nanomaterials).
For further information: http://www.responsiblenanocode.org/ ; Collinson, S., Alarcon, S., Park, B., Dorey, R., Rocks, S., Friedrichs, S.,Crossley, R., Sutcliffe, H., Grayson, D., Pollard, S. (2010) <<The Responsible NanoCode>>. International Labmate. 35(6). Available at http://www.labmate-online.com/. (Accessed May 2011).
For the importance of soft law mechanisms and nanotechnology regulation see Part II, Section 2.A.2).

The Code of Conduct encompasses seven general principles (including the Precautionary Principle)[111], establishes a clear delimitation of research areas that should not be promoted[112], and underline its concern with social and ethical implications of nanotechnologies in addition to risk issues. Perhaps the most practical result so far is that the EU Commission envisions applying the Code of Conduct itself as a guideline of its research policies in the area of nanotechnology[113].

It has been said that the principles underlying the European Code of Conduct are the ones to be underpinning a good governance of nanotechnologies[114].

In recognition of the fact that the CoC has received a very low interest among stakeholders, it was launched in January 2010 a two years project (FP7) entitled <<NanoCode: a multistakeholder dialogue providing inputs to implement the European Code of Conduct for Nanosciences and Nanotechnologies Research>>, with the objective of improving and strengthening awareness of the CoC[115].

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111 Namely: Sustainability, Precaution, Inclusiveness, Excellence, Innovation and Accountability.
The Code does not contain any suggestion, guidelines, checklists, indicators or further ideas covering its operationalization or implementation. In addition, the principles are formulated in an open manner, leaving large discretion for interpretation. See note 117.
The Commission considers that in parallel with the Code of Conduct the promotion of a balanced diffusion of legal information on nanosciences and nanotechnologies is fundamental: << 4.3.2 In addition to the existence of this Code of Conduct, N&N research funding bodies should make sure that N&N researchers are aware of all relevant legislation, as well as ethical and social frameworks>>. COM(2008) 424 final.

112 <<Prohibition, restrictions or limitations
4.1.15 N&N research funding bodies should not fund research in areas which could involve the violation of fundamental rights or fundamental ethical principles, at either the research or development stages (e.g. artificial viruses with pathogenic potentials).
4.1.16 N&N research organisations should not undertake research aiming for non-therapeutic enhancement of human beings leading to addiction or solely for the illicit enhancement of the performance of the human body.
4.1.17 As long as risk assessment studies on long-term safety is not available, research involving deliberate intrusion of nano-objects into the human body, their inclusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment, should be avoided.>> COM(2008) 424 final.

113 This is not stated in the Recommendation but indicated on the Consultation Paper from the Commission when opening the Consultation process prior to the adoption of the Recommendation: <<This Code of Conduct would take the form of a European Commission Recommendation and would invite the Member States, industry, universities (...) to follow its principles. The Commission itself would follow these principles in its own action under the Community research policy>>. Commission of the European Communities consultation paper (2008) <<Towards a Code of Conduct for responsible nano sciences and nanotechnologies research>>. Available at http://ec.europa.eu/research/consultations/pdf/nano-consultation_en.pdf At 1. (Accessed May 2011).

114 Widmer, M., et Al. (2010). At 53.

115 The NanoCode consortium involves partners from eight European countries (Germany, UK, France, The Netherlands, Italy, Spain, Switzerland, the Czech Republic) and two Associated Countries (South Africa and Angentina).
On September 2010 the consortium published the <<Synthesis report on codes of conduct, voluntary measures and practices towards a responsible development of N&N>>. The report basic information is the individual country Reports covering the CoC in their own country.
For Spain, the Country Report states:
<<As resulted by the analysis made for the preparation of the Spanish Country Report, the EC CoC has not being implemented either at national or regional level.

The Code of Conduct is meant to be revised every two years[116]. Following this provision, the revision process is under way and is now waiting for the Commission final proposal.

In October 2011 the NanoCode Consortium released the final report including recommendations for the further development and implementation of the CoC and stressing the need for a fundamental revision of the current Code[117].

B.6)EuropeanParliamentResolutiononRegulatoryAspectsofNanomaterials.2009.

On the 24th April 2009 the European Parliament issued a Resolution[118] in response to

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However, some N&N centres and platforms have developed or are developing their own codes of conduct or practical guides, based on good practices in nanosafety. Most of these documents are confidential, still as drafts, or have not yet been implemented.
Interestingly, standard procedures for R&D funding of public research organisations requires that projects involving research on humans, the use of their personal data or human biological samples, experiments on animals or the use of biological agents or genetically modified organisms not only have to comply with the requirements established for each case by law, but must also be specifically authorized by the Ethics Committee of the Centre where the research is carried out. No specific aspects of N&N are taken into account, unless the research involves any of the above mentioned cases.
A considerable effort has been made in the last years in Spain to increase the level of knowledge, development and involvement in N&N, but still remains a lack of information and coordination between all interested parties working in this field>>.
<<Among the institutions developing such measures can be cited the CIBER-BBN (http://www.ciber-bbn.es) , the Nanotechnology Platform at Parc Científic Barcelona (http://www.pcb.ub.es/homepcb/live/en/p905.asp/), the Institute for Bioengineering of Catalonia (IBEC) for nanomedicine applications (http://www.ibecbarcelona.eu), the Institute of Nanoscience of Aragon (http://ina.unizar.es/index.php), the Institut Català de Nanotecnologia (http://www.icn.cat), Tecnologia Navarra de Nanoproducts S.L. (TECNAN) (http://www.tecnan-nanomat.es), Grupo Antolín (http://www.grupoantolin.com), Fundación Leia (http://www.leia.es), INASMET-Tecnalia (http://www.inasmet.es)>>.
NANOCODE Project (2010) <<Synthesis report on codes of conduct, voluntary measures and practices towards a responsible development of Nanotechnology and Nanomaterials>>. September 2010. At 40. Available at http:"www.nanocode.eu/. (Accessed Feb. 2011).

116 The need for a revision is not only stated in the Recommendation itself but also instructed by the Competitive Council of 25.09.2008 (12853/1/08 REV 1 RECH264 COMPET 311) 13672/08 <<invited>> the Commission to <<review and, as appropriate, amend its Recommendation by February 2010 and regularly thereafter, in close consultation with Member States, while taking into account the above considerations as well as the state of European competitiveness in the nanosciences and nanotechnologies and developments in this sector at European and global level, and then report back regularly to the Council and the European Parliament>>.
The revision process started with an open consultation. The final report from the consultation concludes that the basic trends are that a vast majority (about 88%) thought that the CoC needs a revision, with more than 60% suggesting adaptation or change in the principles, that one third only (32,65%) think that prohibition of research in terms of fields should be extended and slightly more than 50% wish that research be more appropriately regulated and that three quarter of the respondents think that the CoC should not be limited to research.
From the public consultation on the revision it has to be pointed out that the total amount of contributions was of 49 (against 64 from the first consultation in 2007) from research (19), industry (18), policy makers (6) and Civil Society Organisations (6).

117 In summary, the negative aspects were: lack of legitimacy, lack of practicability, stumbling blocks, lack of pressure, lack of communication and lack of commitment. Meili, C., Markus, W., Schwarzkopf, S., Montovani, E., Porcari, A. (2011) <<Master Plan: Issues and Options on the Path Forward With the EC Code of Conduct for Responsible N&N Research>> Final Version. October 2011. Available at www.nanocode.eu. (Accessed October 2011).

118 European Parliament resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials (2008/2208(INI) (2010/C 184 E/18) P6_TA(2009)0328. OJ C184E/82 of 8.7.2010

the Commission's Communication of 2008 on <<Regulatory Aspects of Nanomaterials>>.

The Resolution was jointly submitted by the five main groups in Parliament and with a virtually unanimous support[119].

The European Parliament acknowledges that the use of nanomaterials and nanotechnologies promises important advances with multiple benefits in innumerable applications and can make an important contribution to the competitiveness of the European Union's economy and to the achievement of the Lisbon strategy but, on the other hand, was very critical with the Commission handling of the nanotechnology policy and with the Communication on Regulatory Aspects in particular.

The position and opinion of the European Parliament can be summarized in a sentence quoted from CARL SCHLYTER -rapporteur of the European Parliament Resolution[120]:

<<The Commission's paper on nanotechnology considers that the current rules are adequate despite the fact that none of them are geared to the specific effects of nanotechnology. The Commission's analysis is based on a one-dimensional, legalistic overview of the current rules but those rules are about as effective in addressing nanotechnology as trying to catch plankton with a cod fishing net>>.

The key issues raised by the European Parliament were[121]

- Address explicitly nanomaterials in the scope of regulation of chemicals, food, and relevant worker protection and environmental protection;
- Review legislation and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed. In particular, to evaluate the need to review REACH, waste legislation, air and water legislation and workers protection legislation
- A comprehensive, science based definition, harmonized at the global level;

[119] 362 votes in favour, 4 votes against and 5 abstentions.
[120] On the explanatory statement from the Resolution. Available at http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=en&procnum=INI/2008/2208. (Accessed February 2011).
[121] Brekelmans, C. (2009) <<Regulatory developments>> Presentation at the Swedish Presidency Nanotechnology Event <<Nanotechnologies for Sustainable Development>>. 12.11.2009.

- An inventory of different types and uses of nanomaterials on the market;
- Better information to consumers by mandatory indicating "nano ingredients" in labelling, regardless of risk.

The extensive and detailed European Parliament Resolution tackles all the basic regulatory problems encountered on the nanotechnology EU approach to regulation, and it is worthwhile, following SINGHOFEN[122] (2010) to present in more details the European Parliament Resolution:

1. Lack of knowledge and information

- "The current situation is characterized by a significant lack of knowledge and information, leading to disagreement starting at the level of definitions" (recital F)
- "No clear information about the actual use of nanomaterials in consumer products" (recital H)

2. Worrying mix of lack of scientific data, market reality and regulatory inaction

- "The scientific committees and Agencies of the European Union points to major deficiencies not only in key data, but even in methods of obtaining such data;" (recital K)
- "Whereas SCENIHR identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials" (recital L)
- "Nanomaterials are already on the market, particularly in sensitive applications with direct exposure of consumers" (paragraph 4)
- "Knowledge about potential health and environmental impacts of nanomaterials lags significantly behind the pace of market developments in light of the very rapid developments in the field of nanomaterials…"
- "…Thus raising fundamental questions about the ability of the current regulations to deal with emerging technologies such as nanomaterials in 'real time'" (recital N)

3. European Parliament base line: Need for clear and explicit regulatory framework

- "Is convinced that the use of nanomaterials should respond to the real needs of citizens,"
- "That their benefits should be realized in a safe and responsible manner within a clear regulatory and policy framework (legislative and other provisions)"
- "That explicitly addresses existing and expected applications of nanomaterials as well as the very nature of potential health, environmental and safety problems" (paragraph 1)

4. European Parliament position: Disagrees with the Commission approach

- "Does not agree …with the Commission's conclusions that

[122] Singhofen, A. (2010) <<Overview of European Parliament's position on how to regulate nanomaterials>>. Presentation at the Workshop <<Towards as effective governance of nanomaterials>>. Workshop of the Belgian Presidency. Bruxelles. 14 September 2010.

a) current legislation covers in principle the relevant risks relating to nanomaterials, and

b) that the protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation"

- "When due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks;" (paragraph 3)

5. European Parliament concern: "Safe, responsible and integrated approach" is jeopardized

- Considers that the concept of the "safe, responsible and integrated approach" to nanotechnologies advocated by the European Union is jeopardized

  - by the lack of information on the use and on the safety of nanomaterials that are already on the market,

  - particularly in "sensitive applications with direct exposure of consumers" (paragraph 4)

6. Review of all relevant EC legislation within 2 years

- "Calls on the Commission to review all relevant legislation within two years

  - to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle,

  - and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed" (paragraph 5)

- "The review … should implement the principle "no data, no market" for nanomaterials" (recital AA)[123]

7. Explicit provisions for nanomaterials, public inventory and labelling

- Considers it particularly important to address nanomaterials explicitly within the scope of at least legislation on chemicals (REACH, biocides), food (foodstuffs, food additives, food and feed products from genetically modified organisms), relevant legislation on worker protection, as well as legislation on air quality, water quality and waste (paragraph 9)

- Calls on the Commission to compile before June 2011 an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as recipes, and to make this inventory publicly available; furthermore calls on the Commission to report on the safety of these nanomaterials at the same time (paragraph 16)

- Reiterates its call for the provision of information to consumers on the use of nanomaterials in consumer products: all ingredients present in the form of nanomaterials in substances, mixtures or articles should be clearly indicated in the labelling of the product (paragraph 17)

There is no doubt that the European Parliament has influenced greatly on the

[123] Article 5 REACH. Basically the "no data, no market" means that chemical substances shall only be manufactured and placed on the market upon prior registration and submission of the necessary health, environmental and safety data to prove that a substance cause no harm.
The application of the "no data, no market" to nanomaterials was explicitly requested by the European Parliament (Recital AA) although watering down previous request from the European Parliament Committee on the Environment, Public Health and Food Safety (at 7) and ONG's probably because a strict implementation of the principle to nanomaterials would mean, in practice, a moratorium. See (2008/2208 (INI)) PE 418.270v 02-00. AG-0255/2009. Available at http://www.europarl.europa.eu/sides/getDoc?pubRef=-//EP//text+report+ag-2009-0255+0+DOC+XML+VO//EN; EEB (2009) At.8.

development and configuration of the N&N regulation since the Resolution was approved. The European Parliament has consistently adopted a proactive role by systematically proposing specific nano-provisions into various laws still under revision or already reviewed.

B.7)EuropeanUnionActionPlan:secondImplementationReport.2009

In autumn 2009, the Commission issued its second implementation report on the Action Plan[124]. Regarding regulation the Commission just maintained its original position of considering the current legislation as adequate "in principle", that a bigger effort had to be done in implementing actual regulations and, in addition, was open to consider whether regulatory change on specific aspects was necessary.

Also recalled that "at the request of the European Parliament, specific provisions in relation to nanomaterials have been introduced or are being considered for legislation on cosmetics, novel food and food additives" and "as planned, the Commission will present an updated regulatory review in 2011, paying particular attention to the points raised by the European Parliament".

Besides the recognition that specific provisions has been approved "at the request" of the European Parliament, the Commission itself gave the lowest possible rating ("1-relatively little progress") for its performance in launching initiatives, in promoting measures and/or issue recommendations to minimize worker, consumer and environmental exposure to nanoparticles.

B.8)Commissionrecommendationof18.10.2011onthedefinitionofnanomaterial

At EU level, the efforts by the European Commission to release a legal definition of "nanomaterial" for regulatory purposes, started in 2009 with the European Parliament request "for the introduction of a comprehensive science-based definition of

[124] COM(2009)607 final. and Commision Staff Working Document SEC(2009)1468. 29.10.2009.

nanomaterials"[125], that was followed in September 2010 by a draft Recommendation[126], and, after long discussions[127], finally crystallised in the Recommendation of 18.10.2011 on the definition of nanomaterial[128] that "should be used as a reference for determining whether a material should be considered as a "nanomaterial" for legislative and policy purposes in the Union"[129].

The Recommendation states:

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[125] PA_T6(2009) 0328. The EP called for the introduction of a comprehensive science-based definition as part of nano-specific amendments to relevant horizontal and sectoral legislation. Also the Belgian Presidency of the Council called for the adoption of a definition. See Part II B.6) and C.2) of this research paper.

[126] In September 2010 the Commission released a draft Recommendation that for the first time defined the term "nanomaterial" with the objective of becoming an "overarching, broadly applicable reference term for any Union communication or legislation addressing nanomaterials" (at 12).
Article 2 of that Recommendation stated:

1. Nanomaterial: means a material(8) that meets at least one of the following criteria:
- consists of particles, with one or more external dimensions in the size range 1 nm – 100 nm for more than 1% of their number size distribution;
- has internal or surface structures in one or more dimensions in the size range 1 nm – 100 nm;
- has a specific surface are by volume greater than 60 m^2/cm^3, excluding materials consisting of particles with a size lower than 1 nm.
2. Particle: means a minute piece of matter with defined physical boundaries (ISO 146446:2007)
(8) The term "material" is replaceable with other terms for an object used in the specific legal context.>>

Commission Recommendation of […] on the definition of the term "nanomaterial" C(20..) yyy final. Available at http://ec.europa.eu/environment/consultations/nanomaterials.htm (Accessed Nov. 2010).
The long discussions leading to the adoption of the Recommendation project of September 2010 included a public consultation and the Commission's request of reports to the JRC (Lövestam et Al. 2010) and SCENIHR (2010) <<Opinion on the Scientific Basis for the Definition of the Term "nanomaterials">> Adopted by The Scientific Committee on Emerging and Newly Identified Health Risks. Approved by written procedure on 8.12.2010 Available at http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf (Accessed January 2011).
For a detailed analysis of the Recommendation project Juet, E. (2010) <<L'émergence d'une définition juridique de référence des nanomatériaux>> Available at http://www.nanonorma.org. (Accessed November 2011). See also, Dana, D. A. (2010) <<Can the Law Track Scientific Risk and Technological Innovation?: The Problem of Regulatory Definitions and Nanotechnology>>. Northwestern Public Law Research Paper No. 10-83. Northwestern University - School of Law. Available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1710928. (Accessed January 2011).

[127] It can be said that the discussions focused on two areas: firstly, the very need to arrive at a definition and, secondly, on its content.
As for the first question, the reasons backing the adoption of a definition (following Stamm, could be synthesized in the following:
- Increasing social demand for regulating nanomaterials;
- Political requirements from the European Institutions;
- Principles of European Regulation: need to define what has to be regulated;
- Removing uncertainties for industry and regulators on how to deal with nanomaterials;
- Assuring equal treatment of nanomaterials in different types of legislation;
- Enforceability of legislation.
On the other hand, the arguments against a definition were:
- Many attributes of possible significance (size, surface area, etc);
- Large variety of nanomaterials;
- No scientific evidence for strict limits regarding physico-chemical properties;
- Experimental difficulties (lack of validated methods);
- Size distribution/mixture;
- False positive/false negative;
- Scientific basis to reconcile with policy needs regarding enforceability;
- Nanomaterials are not (intrinsically) harmful substances.
Stamm, H. (2011) <<The Needs to Define Nanomaterials for Regulatory Purposes>>. Available at http://www.fooddrinkeurope.eu/uploads/events_documents/11._Hermann_Stamm_-_Nanomaterial_Definition.pdf (Accessed November 2011).
The different positions were presented by Stamm and Maynard respectively, in two articles in Nature: Maynard,

1. Member States, the Union agencies and economic operators are invited to use the following definition of the term "nanomaterial" in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies.
2. "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.
3. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.
4. For the purposes of point (2), "particle", "agglomerate" and "aggregate" are defined as follows: (a) "Particle" means a minute piece of matter with defined physical boundaries; (b) "Agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components; (c) "Aggregate" means a particle comprising of strongly bound or fused particles.
5. Where technically feasible and requested in specific legislation, compliance with the definition in point (2) may be determined on the basis of the specific surface area by volume. A material should be considered as falling under the definition in point (2) where the specific surface area by volume of the material is greater than 60 m^2 / cm^3. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition in point (2) even if the material has a specific surface area lower than 60m^2/cm^3.
6. By December 2014, the definition set out in points (1) to (5) will be reviewed in the light of experience and of scientific and technological developments. The review should particularly focus on whether the number size distribution threshold of 50 % should be increased or decreased.
7. This Recommendation is addressed to the Member States, Union agencies and economic operators.

Synthetically, it can be said that the definition of nanomaterial is;

a) Based only on the size[130] without regard of hazard or risk:

A. (2011) <<Don't define nanomaterials>>. Nature 475, 31; Stamm, H. (2011) <<Risk factors: Nanomaterials should be defined>>. Nature 476, 399.
As for the second question, this is, the discussions surrounding with the different stakeholders positions, a general overview can be found at http://www.euractiv.com/innovation/comissions-nano-policy-lost definition-news-503665 and http://www.sciences-et-democratie.net/blog/2011/04/16/blocages-a-la-commission-europeenne-autour-de-la-definition-tant-attendue-des-nanoma.

128 Recommendation 2011/696/UE OJ L275/38 of 20.10.2011
Following Juet, we also consider that choosing a Recommendation is not a neutral election: "En premier lieu, il sera aisé pour la Commission de réformer sa définition sans passer par un processus législatif complexe. En second lieu, même si la recommandation ne lie pas, J-P. Jacqué rappelle que la CJUE a estimé "que les jurisdictions nationales devaient les utiliser comme instruments d'interprétation de mesures nationales adoptées pour leur mise en oeuvre ou lorsqu'elles viennent à l'appui d'autres mesures communautaires de caractère contraignant>>. Juet, E. (2010) <<L'émergence...>>.
Previous to this Recommendation, at EU level we could only find a definition of "nanomaterial" in the specific context of the Cosmetic Products Regulation: Regulation (EC) No 1223/2009 on cosmetic products. OJ L 342, 22.12.2009. P. 59. Article 2 provides a definition of nanomaterial <<An insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm>>.

129 Recital 4 of the Recommendation.

130 The Commission has chosen to base the definition "solely on the size of the constituent particles of a material" (Recital 4) and not on nano-specific properties because it considers that "size" is the "only universally applicable, clear and measurable criterion", for legal clarity and in order to avoid "circular reasoning" (as only would be possible to identify whether a material is a nanomaterial after the testing for those properties"). See <<Nanomaterials. Questions and Answers on the Commission Recommendation on the definition of Nanomaterial>> http://ec.europa.eu/environment/chemicals/nanotech/questions_answers.htm#2. At 7. (Accessed October 2011).
But, at the same time, the Recommendation underlines (Recital 6), that harmonised measurement methods for size (of the constituent particles) and for number size distribution (number of nanoparticles to total number of particles) has to be developed and that until harmonization is reached, "best available alternative methods should be applied", without further clarification on which alternatives have to be considered as the "best available". As stated on the Q & A document "The Commission intends to start work to provide practical guidance on measurement methods. This issue is also likely to be one of the subjects to be studied in further detail as part of the review planned for 2014" See <<Nanomaterials. Q & A>> At 9. See also at 14.
For a very critical view on the size related criteria see Jasper, N. (2010) <<Nanomaterial Safety: The Regulator's Dilemma>>. European Journal of Risk Regulation. 3/2010. 270 – 274.

<<2. “Nanomaterial” means a (…) material containing particles (…) where (…) one or more external dimensions is in the size range 1nm – 100nm>>[131].

In addition, fullerenes, graphene flakes and single wall carbon nanotubes below 1 nm have to be classified as nanomaterials:

<<3. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1nm should be considered as nanomaterials>>.

b) Particle size distribution based in the number of particles (understood as number of nanoparticles to total number of particles)[132].

Alternatively, “where technically feasible and requested in specific legislaton”, particle size distribution may be determined on the basis of the specific surface area by volume [133].

In case of discrepancy between the measurement of the specific surface area and the number size distribution, the latter will prevail and it should not be possible to use specific surface area to demonstrate that a material is not a nanomaterial.

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[131] As stated by the Commission, “There is no clear scientific justification for setting the thresholds at 1 nm and 100 nm, as specific effects may also occur at a lower and higher size range. On the other hand, there may also be no specific effects of particles within the size range of 1 to 100 nm. Nevertheless, many of the described specific properties of nanomaterials are actually within that range. Therefore, in the absence of better arguments for other thresholds, the Commission decided to follow the most commonly applied approach, i.e. a size range between 1 and 100 nm. This is also in line with the advice from SCENIHR and other scientific bodies, as well as with the size range used in the ISO term “nanomaterial” See <<Nanomaterials. Q & A>> At 8. See also Recital 8.
Several CSOs (Citizents and Social Organizations) -ANEC, BEUC and Friend of the Earth- denounce the adoption of the upper limit of 100 nm that they consider too restrictive and points out that SCENHIR´s report already indicated the existence of toxicology studies on toxicity of submicron particles over 100 nm. For a general overview on the first reactions from civil society and chemical industry see Nanowerk News <<Adoption of the new definition of nanomaterials by the European Commission: first reactions and analyses>>. Available at http://www.nanowerk.com/news/newsid=23122.php. (Accessed October 2011).
Juet E., analysing the draft Recommendation of September 2010 states that “la limite haute de 100 nm a été choisie en raison de la capacité, notamment rappelée par l'AFSSET dans son rapport de 2006 sur les nanomatériaux, des particules de dimension inférieure à 100 nm à franchir les barrières biologiques protégeant habituellement les tissus et organes” while the 1 nm limit “est justifiée par le CCR (JRC), dans son rapport de 2010, par la nécessité de distinguer les nanomatériaux des atomes et molécules qui sont les constituants des substances qui à leur tour constituent en phase condensée les (nano) matériaux. Le CCR (JRC) rappelle que l'atome le plus large, le cesium, à un diamètre de 0,6 nm et que la plupart del molécules ont une taille inférieure au nanomètre” Juet, E. (2010) <<L'émergence...>> At. 2.

[132] The Commission considered number size distribution as a more relevant metric for possible effects of nanoparticles than mass concentration, following in this point the SCHENIR argument that "a low mass concentration of nanoparticles in a product may still represent a high number of particles and a mass based distribution can be skewed by the presence of relatively few large and thus heavy particles". See <<Nanomaterials. Q & A>> At 9 and Recital 10.
The chemical industry supported using weight concentration rather than particle number distribution to determine the cut-off criteria for nanomaterials. The consequences of having been chosen the metrics for measuring number size distribution is that “there are no validated testing methodologies which enable test to be reproducible and consistent. It will result in materials which have been on the market for a long time, such as pigments, fillers and certain contruction materials, being identified as nanomaterials”. See CEFIC <<Practical nanomaterials definition needed to push forward next great innovation breakthoughs>> htpp://www.cefic.org. (Accessed November 2011); RSC <<EU proposes nanomaterial definition>> http://www.rsc.org/chemistryworld/News/2011/October/21101101.asp.

[133] Recital 13: <<Ar present it is possible to measure the specific surface area by volume for dry solid materials or powders with the nitrogen adsorption method (“BET-method). In those cases the specific surface area can be used as a proxy to identify a potential nanomaterial. New scientific knowledge may expand the possibility to use this and other methods to other types of materials in the future>>.

c) Number size distribution general threshold of 50% for the proportion of particles within a material that have to be within the 1nm - 100nm range (for a material to be considered a nanomaterial).

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

If the particle size distribution is determined by specific surface area by volume, the threshold is set at 60m²/cm³.

This has been, by far, the most surprising part of the Recommendation, as the Commission has largely raised the proportion of nano-sized materials required to qualify as nanomaterials: 50% or more of the particles in the number size distribution is 50 times higher that the September 2010 draft Recommendation proposal (1%), 333 times greater than the recommended by SCENIHR (0,15%) and even 5 times greater than the threshold proposed by the German industry[134].

The Commission justifies the 50% threshold "for practical consideration" and based "on the attempt of distinguish nanomaterials which may exhibit specific novel properties from conventional chemical substances"[135].

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[134] CIEL <<CIEL welcomes new EU definition of nanomaterials as a necessary step towards assuring safety>> http://ciel.org/CIEL/Chemicals_Program/Nano_EU_definitions_18Oct11.html. (Accessed October 2011). Possible the most critical view has been expressed by Friends of the Earth Australia: "If this definition were applied to regulation, it would mean that where 45% of particles are 95nm in size and 55% particles are 105nm in size, substances would not be regulated as nano. To put that another way, (…) even if nearly half a sample is in nano-form, it will trigger no new safety assessment or labelling. (…) In the workplace, there would be no expectation that Material Safety Data Sheets would give nano-specific information. The 'loophole' in the European Commission definition that sayd "where warranted by concerns (…) below 50% may be set" will be ineffective in practice. It puts a huge burden of proof on to the community to demonstrate not only that certain nanomaterials can cause harm but that certain nanomaterials can cause harm as specific proportion of particles in a sample." FRIENDS OF THE EARTH <<European Commission caves to industry pressure on nano definition, leave people and environment at risk>> http://nano.foe.org.au (Accessed October 2011).

[135] As nanoparticles are present in low quantities in most solid materials (for instance powders) and a lower percentage could include too broad a range of materials within the definition. See <<Nanomaterials. Q & A>> At 5 and Recital 11.
Maynard considers that "this is a laudable attempt to handle materials comprised of different sizes. But it is unclear where the scientific basis for the 50% threshold lies, how this applies to aggregates and agglomerates, and how diameter is defined (there is no absolute measure of particle diameter – it depends on how it is defined and measured)". On the contrary, some authors considers that the 50% benchmark appears not to be arbitrary. See Maynard, A. (2011) <<EC adopts cross-cutting definition of nanomaterials to be used for all regulatory purposes>> http://2020science.org/2011/10/18 (Accessed October 2011).

In addition, it is not clear who and how will be decided that the threshold might be reduced, neither is explained what "competitiveness" concerns means.

d) Inclusion:

- incidental, natural and manufactured materials[136];
- unbound particles, aggregates and agglomerates[137];
- substances and mixtures

e) Exclusions:

- materials with internal structure or surface structure in the nanoscale (such as complex nano-components nanomaterials including nano-porous and nano-composite materials that are used in some sectors)[138];
- final products[139].
- Pharmaceutical and medical devices[140].

Given the broad scope of the definition, NIA considers that "a vast number of materials will be regarded as nanomaterials, for which manufacturers until today

[136] The focus on nanotechnology debate is on applications and products using "engineered" or "manufactured" nanoparticles. Engineered nanomaterials have to be distinguished from "natural" nanoparticles (those that occur in the environment -volcanic dust, lunar dust, mineral composites) and "incidental" nanoparticles (those that occur as the result of man made industrial processes -diesel exhaust, could combustion, welding fumes). Natural and incidental nanoparticles may have irregular or regular shape, while engineered nanoparticles most often have regular shapes, such as tubes, spheres or rings. Bell, T.E. (2006).
Because the Recommendation only identifies a nanomaterial on the basis of its particle size regardless of hazard and risk and the "properties or risks posed by a nano-sized material are not determined by the intention of the manufacturer and do not differ depending on whether the nanomaterial is natural, produced incidentally, or the result of a manufacturing process with or without the explicit intention to produce a nanomaterial", the Commission concludes that it would be "therefore not logical to omit certain types of materials on the basis of their genesis". Having said that, it seams also logical that if "a specific piece of legislation only addresses manufactured materials, the same limitation would also apply to nanomaterials" (See <<Nanomaterials. Q & A>> At 6.)

[137] The reason for including agglomerated or aggregated particles is that they may exhibit the same properties as unbound particles and, additionally, there can be cases during the life-cycle of a nanomaterial where the particles are released from weakly bound agglomerates or under certain conditions even from more strongly bound aggregates. See <<Nanomaterials. Q & A>> At 10.

[138] Recital 14. The Commission did not include other types of nanostructured materials (materials with internal structure or surface structure in the nanoscale) such as nanoporous or nanocomposite. The reason being that there is not sufficient evidence to guide what materials should be included. See <<Nanomaterials. Q & A>> At 12. Maynard stresses that this king of complex nanostructured materials may present "unusual health and environmental risks -such as materials with biologically active structures that are not based on unbound nanoparticles (patterned surfaces, porous materials and nano-engineered micrometer-sized structures)"Maynard, A. (2011) <<EC adopts...>>.

[139] The Recommnedation's scope covers nanomaterials when they are substances or mixtures, but implicitly not when they are final products. This means that if a nanomaterial is used amongst other ingredients in a formulation the entire product will not become a nanomaterial. See <<Nanomaterials. Q & A>> At 13.

[140] Recital 17: <<Given the special circumstances prevailing in the pharmaceutical sector and the specalised nano-structured systems already in use, the definition in this Recommendation should not prejudice the use of the term "nano" when defining certain pharmaceutical and medical devices>>.

are not aware of, are not prepared to react and have not even started to collect information yet. (…) All companies working with material need to re-think whether and which of their materials are concerned, in order to be best prepared for sustainable exploitation of technology and guarantee access to market segments>>[141].

f) Revision of the definition by December 2014 with special focus on the number size distribution threshold and the inclusion of material with internal or surface structure in the nanoscale.

When the EP requested, back in 2009, the introduction of a comprehensive science based definition of nanomaterials in the EU, it was with the intention of setting up one of the basic pillars for a sound regulatory framework that would permit a robust assessment to be made about the safety of nanomaterials and the measures to be taken to control risk.

In fact, it could be said that the European Commission has been delaying the development of the regulatory framework until an "applicable"[142] definition for nanotechnology would be released but, once the Recommendation has been published, the first reactions points to the fact that, instead of a "sound science" based definition, we have a definition that has been considered a "trade-off between the expectations of the various stakeholders"[143], where materials with nano properties and possible toxicity, will fall outside the definition.

This implies that the regulatory focus on solving the issues related with Health, Safety and Environmental issues, as by nature (protecting human health and environment) are the most compelling ones has not been tackled. On the contrary, the Commission states

[141] NIA <<Europan Commission issues regulatory Definition of Nanomaterial>> Available at http://www.nanotechia.org/. (Accessed November 2011).

[142] Henrik Laursen, coordinator of the nano team in the Commission's environmental department, said that the Commission would not be rushed into making a decision because, once made, it would not be a working model but would immediately have a significant binding effect. http://www.euractive.com/innovation/comissions-nano-policy-lost-definition-news-503665

[143] Basically DG Enterprise defending industrial interest, and on the other DGSanco and DGEnvironment defending positions of environmental and consumer organizations. http://www.nanowerk.com/newsid=23122.php
It also have to be pointed out that, from the Commission perpective, it seemed that arriving at a definition for nanomaterials was as much about public relations as about creating good regulatory policy. It seams logical to think that working with conflicting objectives may lead to unclear results. Dexter, J (2011) <<Definitions for Nanotechnology Inform EU Citizens as mush as Regulatory Framework>> http://spectrum.ieee.org/nanoclast/semiconductors/nanotechnology/definitions-for-nanotechnology-inform-eu-citizens-as-much-as-regulatory-framework. (Accessed November 2011).

that[144]:

> The definition will primarily be used to identify materials for which special provisions (concerning for example risk assessment or ingredient labelling) might apply. Those special provisions are not part of the definition but of specific legislation in which the definition will be used.
> Nanomaterials are not intrinsically hazardous but there may be a need to take into account specific considerations in their risk assessment. Therefore one purpose of the definition is to provide clear and unambiguous criteria to identify materials for which such considerations apply. It is only the results of the risk assessment that will determine whether the nanomaterial is hazardous and whether or not further action is justified.

So, as Johnson states, "(...) they have created a class of materials that at the moment are not known to be intrinsically hazardous; but if some day they are, there is now a separate class for them. While some may see this as making some sense, the sense of it eludes me"[145].

In addition, the fact that the basis for determining whether a material or product is regulated as a nanomaterial is not based on "sound science" but a "policy decision" may have the consequences of shifting the focus from hazard and risk (evidence-based regulation) to a formal regulation of a theoretical class of materials[146].

From our point of view, some of the critics received can not be disputed, being the most worrying one that some materials at the nanoscale about which there is already concern have fallen out of the definition.

But once the Recommendation has been published in the Official Journal and knowing that a revision is going to be done by December 2014, we understand that a pragmatic position has to be taken: it is time now to properly review all sectoral legislation and

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144 See <<Nanomaterials. Q & A>> At 1.

145 Johnson, D. (2011) <<The EC Defines a Nanomaterial: Now What?>> http://spectrum.ieee.org/nanoclast/semiconductors/nanotechnology/the-ec-defines-a-nanomaterial-now-what (Accessed November 2011). Probably, a confirmation of this conclusion is that calls already has been made for starting analysis to "verify that the adopted size range captures materials about which there is already concern", so initiating (already!) the revision process scheduled for 2014. See David Azoulay (Head of CIEL's nanotechnology project) statement at http://ciel.org/CIEL/Chemicals_Program/Nano_EU_definitions_18Oct11.html.
In this same line of thinking Duprez (EEB nanotechnology policy officer) states "Definition is an important first step but does nothing to allow a robust assessment to be made about their safety, let alone take measures to control risks" http://www.eeb.org/EEB/index.cfm/news-events/news/nano-definition-too-narrow-says-eeb/

146 Maynard, a. (2011) <<Don't define nanomaterials – the evolution of an idea>> http://umrscblogs.org/2011/07/06/dont-define-nanomaterials-the-evolution-of-an-idea/. (Accessed November 2011). This is one of the main reasons way Maynard considers that "it is time to move away from dogma-driven definitions and towards science-informed guidelines that identify materials and products that raise plausible and specific concerns – irrespective of what they are called. In this way, frameworks can be developed that support resposive and adaptive regulations that are truly based on science".

identify the "special provisions" to be applied -being the fundamental ones a robust risk assessment and additional risk control measures guided by an "exposure focused" and/or "commercial relevance" approach- and in the understanding that a modulation of the overarching concept might be necessary (additional qualifiers, specific physico-chemical properties or even to include certain nanomaterials that may fall outside the general definition)[147].

C)EUROPEANUNIONFUTUREDEVELOPMENTSIN NANOMATERIALSPOLICYANDREGULATION

The short term agenda for future developments on the nanotechnology policy and regulatory is tight. In this section we will focus on the following (expected) developments:

1.- Strategic Action Plan;
2.- Revision of the general legal framework applicable to nanomaterials;
3.- REACH revision;
4.- Nanomaterials Compulsory Register.

C.1)StrategicActionPlan(SNAP)2010-2015.

The European Union Action Plan for Nanosciences and Nanotechnologies 2005-2009 came to an end in December 2009 and the European Commission was planning to develop a new action plan for the time period 2010-2015. In this context, the Commission launched a public consultation[148]. The Strategic Action Plan is scheduled

[147] Recital 16 <<The definition set out in this recommendation should not prejudge nor reflect the scope of application of any piece of Union legislation or of any provisions potentially establishing additional requirements for those materials, including those relating to risk management. It may in some cases be necessary to exclude certain materials from the scope of application of specific legislation or legislative provisions even if they fall within the definition. It may likewise be necessary to include additional materials, such as some materials with a size smaller than 1 nm or greater than 100 nm in the scope of application of specific legislation or legislative provisions suited for a nanomaterial>>.
In this sense, it will be interesting to see how the new definition will affect article 2 of Regulation (EC) No 1223/2009 on cosmetics products. The Regulation affects only manufactured nanomaterials while the Commission Recommendation applies to natural, incidental or manufactured. On the other hand, the Regulation includes nanomaterials with internal structure and nanomaterials with external dimensions in the range of 1 nm to 100 nm without any threshold. The final resolution of those discrepancies will show us how much the regulator is ready to deviate from a formal definition in order to focus in risk management.

[148] Public Consultation took the form of an online questionnaire in order to gather stakeholders opinions and ideas for the new action plan. The public consultation process ended at the 19th February 2010 and the results of this public consultation process were summarized and published: Report on the European Commission's Public Online Consultation "Towards a Strategic Nanotechnology Action Plan 2010-2015". Available at

to be presented in 2011.

The main conclusions from the public consultation process on regulatory issues were[149]:
- The major concerns regarding policy centre on the safety of nanomaterials and their regulation. Generally, more action is expected to ensure safety.
- There is overwhelming demand for an inventory of the types and uses of nanomaterials that would include safety aspects. Demand is also high for requirements to ensure that adequate information is provided on consumer products.

Specifically, the respondents were asked to express their opinions on new EU policy actions. Strong support for the following actions were reported[150]:

1.- establishment of an inventory of types and uses of nanomaterials, including safety aspects;

2.- requirement to adequate information on consumer products (e.g. Claims verification, labelling of nano-content of consumer products);

3.- development of new, specifically targeted regulation for nanotechnologies, especially related to nano-bio-cogno-applications (e.g. Human enhancement).

It seams clear that those are the basic elements on which we will see specific proposals from the Commission on the SNAP proposal and also on the "revision on the Regulatory Aspect".

C.2)RevisiononRegulatoryaspectsofnanomaterials(2011)andREACHrevision (2012)

The Commission has repeatedly taken the compromise to undergone a review of the regulatory aspect by 2011 and the first revision of REACH is scheduled for 2012[151].

http://ec.europa.eu/research/consultations/snap/report_en.pdf/. (Accessed January 2011).

149 SNAP Online Consultation Report. At 4.

150 SNAP Online Consultation Report. At 17.

151 To ensure that the provisions of the REACH Regulation are properly applied in the case of nanomaterials, the European Commission launched the REACH Implementation Projects on Nanomaterials (RIPoN) in June 2009. The projects included stakeholders from industry, environmental organizations and trade unions. The objective was to provide scientific and technical advice on three key areas: 1) substance identification (SI) RIPoN1; 2) information requirements (IR) RIPoN2; 3) chemical safety assessment (CSA) RIPoN3. These recommendations could result in amendments to the ECHA Guidance documents, but could also include proposals for amendments to the text of REACH or its Annexes.
The final reports has been released in November 2011.
It is now for ECHA to decide whether and when to recommend changes to the REACH Guidance Documents on the basis of the findings of the RIPs and for the Commission on the proposed changes to REACH.
Documents available at http://ec.europa.eu/environment/chemicals/nanotech. (Accessed October 2011).

The Commission has already advanced that the review will specifically deal with REACH regulatory gaps and basically[152];

- To set up a simplified registration for nanomaterials < 1 ton/a[153];
- Consideration of all nanomaterials as new substances;
- A chemical safety report with exposure assessment for all registered nanomaterials;
- Notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles;

The Belgian Presidency (ended in December 2010) considered that the review has to address the following regulatory issues[154]:

- Clarify the various issues to adapt REACH to the nanomaterials and to include effective modifications to REACH into its 2012 review: 1.- lower the tonnage triggers; 2.- modifications to data requirements in REACH annexes; 3.- consideration of nanomaterials as new substances; 4.- review Annex V exemptions[155]; 5.- Review Annex XIII (PBT, vPvB); 6.- include definition of nanomaterials and articles containing nanomaterials in REACH.

  Especial attention to all this regulatory gaps will be given on Part III of the present Report.
- To "urgently" approve a nanomaterial definition for regulatory

[152] Laursen, H., Puolamaa, M., (2010) <<REACH and Nanomaterials>> Belgian Presidency Workshop "Towards a regulatory framework for the paper traceability of nanomaterials".14 September 2010, Brussels. Available at http://www.health.belgium.be/eportal/Aboutus/eutrio/environment/Nanomaterials/index.htm?fodnlang=en. (Accessed February 2011).

[153] The simplified registration stated by the Commission have to be received with caution as the specific content of data requested has not been explained and there is concern that "simplified" could lead to more bureaucracy without real effectiveness. The level of data to be requested for being useful is: toxicological and ecotoxicological tests and properties, degradation and bioaccumulation. Hansen, S.F. (2010b) At 445.
It may be sensible to prioritize which data is requested and which ones could register with a "simplified registration". In this sense, an "exposure focused approach" and the "commercial relevance approach" may help to this prioritization. Widmer, M., et Al. (2010). At 62.

[154] Belgian Presidency Conclusions from the Belgian Presidency Workshop "Towards a regulatory framework for the paper traceability of nanomaterials". Brussels. 14 September 2010. Available at http://www.health.belgium.be/eportal/Aboutus/eutrio/environment/Nanomaterials/index.htm?fodnlang=en. (Accessed February 2011).

[155] Several members of the German Nanokommission, for instance, considers that a matter of principle, Annexes IV and V Exemptions from the obligation to register, should not include substances in the nanoform. Nanokommission (2010) <<Review of nanomaterials and nanoproduct regulation Working Group 3 of the Nanokommission>> 18.09.2010. Available at http://www.bmu.de/files/english/pdf/application/pdf/nano_abschlussbericht3_en_bf.pdf. (Accessed June 2011).

purposes[156];

- Better regulate labelling of products containing nanomaterials.

C.3)HarmonizedMandatoryRegister

C.3.1) Reasons for a Reporting Scheme

As we have seen in Part I of this paper, consumer products containing nanomaterials are already on the market and many more are under way at the research stage or near market access.

In order to assess the risk of nanomaterials (in toxicology and exposure) -that is a first step towards achieving regulation- it is basic to collect data on manufactured nanomaterials and their fields of application, but there is no institution within Europe which can provide information on nanomaterials used commercially or on nanomaterials being produced or used for research purposes.

A reporting scheme is aimed to gather data on nanomaterials with the objective of;

- Promote collaboration between government and industry;
- Ensure that nanomaterials and nano-related products are introduced without risk into the market;
- Provide governments with the information they require to determine whether current legislation is adequate and at informing debate on whether additional legislation is required.
- It could be understood as a practical application of the provisions of the Aarhus Convention[157].

The reporting schemes are generally related to specific provisions (for instance chemicals) and they can be voluntary[158] or enforced by legislation. On the remaining of

[156] Already approved by Recommendation of 18.10.2011. See Part II, section B.8) of this researcher paper.

[157] D'Silva, J., van Calster, G. (2010) "For Me to Know and You to Find Out? Participatory Mechanisms, The Aarhus Convention and New Technologies," Studies in Ethics, Law, and Technology: 4(2) Article 3. Available at: http://www.bepress.com/selt/vol4/iss2/art3. (Accessed February 2011).

[158] In 2006, the UK's DEFRA (British Department for Environment, Food and Rural Affairs) ran between September 2006 and September 2008 a two-year trial Voluntary Reporting Scheme (VRS).
It was aimed at collecting data concerning free engineered nanomaterials from manufacturers, commercial users, research and waste industry and focused on engineered nanoscale materials that are free at any stage of product's life-cycle.

this section we will focus on the French compulsory reporting scheme and the Belgian Presidency proposal.

C.3.2) France: compulsory reporting scheme

The French Environment Code was modified in July 2010 in order to include a new chapter "Prévention des risques pour la santé et l'environnement résultant de l'exposition aux substances à l'état nanoparticulaire" including several articles (523-1 to 523-5) establishing a mandatory[159] reporting scheme[160].

The main features of the system are;

- Addressed to manufacturers, importers and distributors placing nanomaterials and nanomaterials-containing products on the French market;
- Obligation of reporting the identity of nanomaterials, quantities on the market, uses, identity of downstream users (confidentiality clause) and available data on hazards and exposures;
- Creation of a unique database for products categories (chemicals,

Information requested include any data on: uses, benefits and exposure pathways, physico-chemical properties, toxicology, ecotoxicology and risk management practices.
The VRS was initially set up as a 2-years trial initiative and only 13 submissions were received at the end of the programme (11 from industry and 2 from academia).
The large amount of information requested, confidentiality issues and also the resources needed to participate (in particular with respect to SME's) are amongst the reasons identified by DEFRA for low participation in the VRS. At his moment the scheme is under revision but remain open to further data submission. See UK Voluntary Reporting Scheme for engineered nanoscale materials.
UK Department for Environment, Food and Rural Affairs (DEFRA). 2006. Available at http://www.defra.gov.uk/environment/quality/nanotech/policy.htm and http://www.defra.gov.uk/environment/quality/nanotech/documents/vrs-nanoscale.pdf.; <<Note of the 11th Meeting of the Nanotechnologies Staheholder Forum. DEFRA 26.09.2008. Available at http://www.defra.gov.uk/environment/quality/nanotech/documents/080926-meeting-note.pdf. Accessed January 2010.

[159] The reasons for being a mandatory scheme were: a) More information on manufactured nanomaterials on the market since their uses are already or expected widespread (better knowledge on exposure of consumers and workers and traceability to be able to take targeted measures if necessary); b) Awareness raising among stakeholders and improvement of the risk management; c) Voluntary reporting scheme already experience d in 2007 by AFSSET -Agence Française de Sécurité Sanitaire de l'Evironement et du Travail- that yield a very low response (16%).

[160] Legislative process background: In 2007 it was organized a national brainstorming in favour of a sustainable development called "Le Grenelle de l'environnement", conducted by the ministry for sustainable development and initiated by President Sarkozy.
It was a wide and open process involving all kinds of stakeholders (state and regional administration, industry, employees, NGO's, elected representative, scientific experts) and general public (consultations via internet and public meetings).
The legal framework is the Grenelle Law nr.1 (Programmation law which lays down the main objectives. Promulgation on the 3rd of August 2009. Art. 42) and Grenelle Law nr.2 (Implementation law 2010-788 which lays down the concrete measures to implement the commitment. Promulgation 12.07.2010. OJ du 13.07.2010. Art 185). Art. 185 inserts in: Code environement 523-1 to 523-5; Code santé publique 5161-1; Code rural et de la pêche maritime 253-8.

biocides, pesticides, cosmetics, food, etc.);

- Information available to the public about identity and uses of nanomaterials.

More detailed requirements will be covered by an implementing decree that has been drafted and open to public consultation[161], and is now waiting for final approval. It has been said that the French mandatory scheme is meant to be a help on the REACH implementation[162] and that is not infringing EU law[163] (opinion that is not shared by the author of this research paper).

C.4.3) Belgian Presidency proposal for a harmonized mandatory register

The Belgian Presidency of the Council of the EU (that ended in December 2010)

[161] Nanonorma Project (2011) <<Rapport et avis sur le décret relatif à la déclaration annuelle des substances à l'etat nanoparticulaire mises sur le marché tel que soumis à consultation publique le 5 jauvier 2011>> Available at http://www.nanonorma.org. (Accessed March 2011).

[162] It has been said that the mandatory reporting scheme will anticipate and be complementary to the REACH requirements because;
- knowledge of the market (quicker available and more explicit);
- knowledge covers manufacture, import and placing on the market sold below 1 tonne/year.;
- input to the REACH/nano subgroup of the competent authorities (assessment of the need to review REACH in 2012);
- awareness of industry about the need to care for its registration dossiers;
- help to prioritise registration dossiers and substances according to Title VI of REACH;
- help the authorities in charge of public health and environment to take action through REACH (SVHC, restrictions, etc...) to better manage the risk. Mir, C. (2010) <<The French initiatives regarding nanomaterials>>. Belgian Presidency Workshop "Towards a regulatory framework for the paper traceability of nanomaterials". Brussels. 14 September 2010. (Accessed February 2011). At 9. Available at http://www.health.belgium.be/eportal/Aboutus/eutrio/environment/Nanomaterials/index.htm?fodnlang=en.

[163] The compatibility of this measure with EU law is an open debate. While the Commission considers that REACH does fully harmonize the conditions related to the manufacturing, placing on the market and use of substances, either on their own, in preparations or in articles, so leaving no room for Member States to maintain or introduce national provisions (based on the provisions of Art. 128 REACH).
This interpretation is disputed by the French authorities who put forward art. 128,2 of REACH: REACH does not include substances produced below 1 tonne per year and the specific properties of nanoparticle state, except if they are considered substances of very high concern. Furthermore, the French Government considers that nanomaterials represent specific chemicals which control (objective assigned to REACH) is not ensured by the general rules (including registration) as contained in REACH. Then, setting up a national mandatory reporting mechanism to nanosubstances could be considered as an intervention in a field not harmonized by REACH. The legality of National measures should then be assessed under sections 34 and 36 TFEU.
REACH Article 128:
<<Free movement
1.Subject to paragraph 2, Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a mixture or in an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.
2.Nothing in this Regulation shall prevent Member States from maintaining or laying down national rules to protect workers, human health and the environment applying in cases where this Regulation does not harmonize the requirements on manufacture, placing on the market or use.>>
Juet E., (2010) <<Réflexions sur la légalité du mécanisme français de déclaration obligatoire au regard du droit de l'Union européenne>> September 2010. Available at http://www.nanonorma.org/ressources/articles/Reflexions%20sur%20la%20legalite%20du%20mecanisme%20francais%20de%20declaration%20obligatoire.pdf/view. (Accessed March 2011).

catalysing and consolidating several Member State regulatory projects[164], judging critically the current regulatory regime[165] and as a reply to the passive attitude from the Commission regarding the regulation of nanomaterials[166], formally proposed[167] to draw up coordinated and integrated national strategies and concrete measures in favour of risk management, information and monitoring, including the development of a harmonized compulsory databases of nanomaterials and products containing nanomaterial[168].

The Presidency Conclusions underlines the need for "taking responsibilities at the Member States level (...) during the transitory period"[169] with the objective of;

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[164] Basically were France, Italy, Belgium, Germany and The Netherlands.
For instance Italy, (in response to the EU Parliament Resolution of 24.04.2009 or Regulatory aspects of nanomaterial where the need for a notification requirement was underlined) is drafting a ministerial decree creating a national database on nanomaterials manufactured, imported and used on their own, in mixture and in articles. See Polci, M., L., <<A project of ministerial decree concerning the establishment of a National Database on Nanomaterials>> Belgian Presidency Workshop "Towards a regulatory framework for the paper traceability of nanomaterials". Brussels. 14 September 2010. Available at http://www.health.belgium.be/eportal/Aboutus/eutrio/environment/Nanomaterials/index.htm?fodnlang=en. (Accessed February 2011).
The Netherlands (that is undergoing a study on the possibilities of national measures) clearly stated the position that additional legal measures on European level are needed and that <<If the Commission is not able to come up with a definition, information requirements in REACH and to initiate legal measures on traceability on short term, the Netherlands will explore the use of art. 129>>. Reference to actual Art 169 (and former art. 153 TEC and 129A SEA) At 4. Bosman, M.T.M., <<Dutch policy on risks of nanomaterials: precaution and transparency>> Belgian Presidency Workshop "Towards a regulatory framework for the paper traceability of nanomaterials". Brussels. 14 September 2010. Available at http://www.health.belgium.be/eportal/Aboutus/eutrio/environment/Nanomaterials/index.htm?fodnlang=en. (Accessed February 2011).

[165] The critical view towards current regulatory regime was summarized by the Presidency on the following three main aspects:
a) The current legislation does not provide sufficient information to offer a response in case of an incident and to guarantee nanomaterials risk management.
b) Due to persistent doubts, it is not presently possible to guarantee sufficient protection of public health and environment.
c) There is a considerable dearth of information all along the supply chain, whereas it is essential to have this information for traceability reasons.

[166] In this sense, Mr. Maguette, minister in charge of consumer protection and environment, and speaking on behalf of the Belgian Presidency explained that although there was <<no need to be alarmed (...) it is our duty to apply due minimum of care and caution>> and that <<the current development approach for nanomaterials without prior notification of their presence or labelling of their characteristics or potential toxicity is not acceptable>>. Available at http://www.euractive.com/en/food/reach-register-ensure-traceability-nanomaterials-news-497781 Accessed Feb 2011.

[167] The Belgian Presidency formally presented the proposal at the CASG-nano meeting of 16/12/2010.

[168] Belgian Presidency Conclusions (2010) <<A regulatory framework for nanomaterials?>> Published by the Belgian Presidency of the Council of the European Union 16.09.2010. Belgian Presidency Workshop "Towards a regulatory framework for the paper traceability of nanomaterials". Brussels. 14 September 2010. Available at http://www.health.belgium.be/eportal/Aboutus/eutrio/environment/Nanomaterials/index.htm?fodnlang=en. (Accessed February 2011).

[169] It is not clearly explained what is meant for "transitory period" but it can be understood that, the time frame envisaged by the Commission (second legislative nanomaterials review by 2011 following the request of the European Parliament of 2009 and entering the regulatory changes by the 2012 REACH review) is being considered too long. SO the present strategy would be designed for setting up (basically) the Member States action plans (for those Member States that do not have them) and the compulsory databases before the Commission calendar, what represents a really tight agenda. Backing this interpretation, <<Just like the Presidency, certain stakeholders were of the opinion that the proposed time scale for making improvements to the current legislation is unacceptable. Transient measures are therefore required. (...) a certain number of

- ensuring nanomaterials traceability;
- market surveillance;
- gaining knowledge for better risk prevention;
- gaining knowledge for the improvement of the legislative framework.

It is also stressed that the data obtained have to be made accessible to stakeholders, consumers and general public, while taking into consideration industrial data protection.

The Commission would be also involved in the design process through the European Commission Joint Research Centre (JRC)[170].

stakeholders believes that a harmonised register of nanomaterials constitutes an effective and immediate response>> Belgian Presidency Conclusions (2010).

[170] The JRC will be supporting the initiative giving conceptual design and technical implementation help to provide a harmonized European approach making use of already technology and knowledge tools at the JRC as far as possible. Basically the JRC will be collaborating with the so called NanoPortal (newly planned suite of database services, containing the NAPIRAhub Database), a comprehensive IT platform dedicated to the management of information on nanomaterials, relevant for safety/risk assessment in which all data for the OECD WPMN Sponsorship Programme is collated and built on IUCLID 5 (the IT platform currently used for REACH registration purposes). Klein, Ch. <<What could a nanomaterial characterisation dataset look like>>. Belgian Presidency Workshop "Towards a regulatory framework for the paper traceability of nanomaterials". Brussels. 14 September 2010. Available at http://www.health.belgium.be/eportal/Aboutus/eutrio/environment/Nanomaterials/index.htm?fodnlang=en. (Accessed February 2011).
In February 2010, ECHA presented IUCLID 5.2 which enables the information "nanomaterial" to be included in the database. This version is used for first phase registration and CLP notification. A new nano fields has been created, allowing the entry of nanomaterials: Le Goff, F. <<IUCLID5. Project overview>>. REACH-IT/IUCLID Stakeholder Webinar. 21.06.2010.
In the process of setting up this mandatory registry it will be of great help the recent launching by the JRC (Joint Research Center) of the first European repository of nanomaterials. It contains most types of nanomaterials that are currently assumed to be used in significant volumes in consumer products. These materials will be used as a reference point by laboratories that carry out safety assessments on nanomaterials, to make sure that their results are comparable to those of other laboratories. This responds to a need expressed by experts in international standardisation organisations. Available at http://www.jrc.ec.europa.eu (Accessed May 2011).
Additionally, it has to be pointed out that the Commission was already scheduling a compulsory registry to be set up. The background from the Commission project was the proposal for an EU Reporting System for Nanomaterials as presented in Miliue/RPA Final Report (2010) <<Information from Industry and Applied Nanomaterials and their safety>>. Contract NV.D.1/SER/2008/00105r for the European Commission. May 2010.
The report advocates for a mandatory nanomaterial-specific reporting under REACH based on the following three main elements:
- designation of nanomaterials as "new" substances,
- a lower threshold for registration, and
- a deadline of 2013 for submission of registration dossiers

The study concluded 'that current reporting under REACH-CLP is unlikely to provide the complete range of information needed by regulators to assess the potential risks to public health and the environment from nanomaterials. An additional EU-level reporting system for nanomaterials on the market appears necessary.'
The report highlighted possible information gaps for nanomaterials properties under REACH, including;
- the current tonnage thresholds;
- the limitations of current guidelines for the testing of nanomaterials;
- communication issues with downstream users;
- exemptions of nanomaterials under REACH, and
- time-lags when registering lower tonnage substances

The framework of REACH should be the basis, with the European Chemicals Agency (ECHA) as the implementing agency. A two-stage approach is suggested:
1. The first stage should focus on gathering information concerning any and all nanomaterials placed on the market and their uses, i.e., a nanomaterials product register.
2.The second stage of an EU-level nanomaterials reporting scheme should focus on the gathering of the toxicological and other information needed to accurately assess the potential risks of specific nanomaterials and their uses, and to manage those risks, including specific testing of all nanomaterials intended for placement on the

The Belgian Presidency strategy was successful and on the 20th December 2010, the Council of the European Union, during its 3061st Environment Council meeting adopted a conclusion to provide a mandate to the European Commission to review the risk-assessment of nanomaterials and to develop a harmonized database for nanomaterials:

<<5. INVITES the Commission to further promote health through environment policy through the preparation as soon as possible of a second Environment and Health Action Plan (EHAP) in order to:
- (...)
- evaluate the need for the development of specific measures for nanomaterials relating to risk assessment and management, information and monitoring, including the further development of a harmonized database for nanomaterials, while considering potential impacts>>

D)ASSESSMENTONTHEEUROPEANUNION NANOMATERIALSPOLICYANDREGULATION.

The Commission, that took a leading role when issuing the European Nanotechnology Strategy has been changing toward a "wait and see" attitude[171] and, instead of proposing initiatives, has sent request for opinion to the different scientific committees or just accepted the insertion of nano specific provisions on the legislative (recast) process.

From the Commission's Strategy (Communication on the European Union Strategy. 2004) it was clear that the objective was to strike the right balance between innovation and development of applications and ensuring that health and environmental risks were looked into and dealt with at the earliest possible stage, but in practical terms, from 2004 to 2011 the Commission has released:

i. Communications (Strategy 2004; Action Plan 2005; First and Second Implementation Reports 2007 and 2009; Regulatory Aspects 2008);

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market.
It is proposed that nanomaterials be considered as "non-phase-in" (i.e., "new") substances under REACH.
The current OECD Test Guidelines and the preliminary guidance available from the OECD Working Party on Manufactured Nanomaterials (WPNM) on sample preparation and dosimetry, testing, exposure measurements and mitigation of nanomaterials should be used.

171 As graphically expressed by the ETC group, from "no data – no market" to "no data – no regulation". ETC Group (2010) <<The Big Downturn? Nanogeopolitics>>. ETC Group Communiqué # 105. December 2010. Available at http://www.etcgroup.org. At 14. (Accessed May 2011).

ii. Recommendation on a Code of Conduct (soft law). With guidelines over Nanotechnology and Nanomaterials Research in the Community.
iii. Regulation 987/2008 removing carbon and graphite from REACH Annex IV.
iv. Regulation 10/2011 on plastic materials and articles intended to come into contact with food.
v. Agreed on the content of Regulation 1333/2008 of the European Parliament and the Council on food additives following the European Parliament pressure.
vi. Agreed on the content of Regulation 1223/2009 of the European Parliament and the Council on the cosmetic product recast.
vii. Regarding supplementary policy we have to mention the 7th Framework Programme where a considerable increase of the budget is foreseen for nanotechnology but that was assessed by the European Parliament as being too low in terms of funding and too restrictive in terms of evaluation criteria for granting research projects to assess the safety of nanomaterials (European Union Communication on Regulatory Aspects at M).
viii. Organization of experts meetings and the request for expert opinions from the different aspects of nanomaterials health, environment, safety and regulation of nanomaterials.
ix. Recommendation of 18.10.2011 on the definition of nanomateriales. It is too early to assess the importance that the definition will have in the development of the regulatory framework because it will be its application in sectoral rules which will tell us if it has helped the implementation of the precautionary principle or if it will be just a formal definition that will not help to identify risk.

The global assessment points to the conclusion that the Commission has not reached its objectives in a timely manner[172] for a balanced development of nanotechnology by tackling health and environmental concerns at the earliest possible stage, because the actions taken can not be labelled as proactive (excluding the "Action Plan" and the "Strategy" at the beginning of the process, and the Code of Conduct -basically concerned with laboratory practices), and clearly departing from their own policy goals

[172] For the importance of a timely regulation see Ludlow, K., Bowman, D.M., Kirk, D.D. (2009) <<Hitting the mark or falling short with nanotechnology regulation?>>. Trends in Biotechnology. 27(11): 615 – 620.

and objectives regarding regulation[173].

In addition, it is also important to underline that the free movement of nanosubstances is being placed in jeopardize due to the Commission's inactivity, being the France compulsory registry the clearest evidence.

We consider that the same conclusion has been reached by the European Parliament (being the European Parliament Resolution on Regulatory Aspects a stunning wake-up call), by the Member States (being France the most active one), by the European Presidency and finally, by the Environmental Council.

This patchy and non proactive approach towards regulation makes that the "Incremental Approach Strategy"[174] has not been implemented, in other words, we have not seen the deployment of strategy so that a comparison with the Differentiated Approach regulatory option can not be really made.

In this final assessment we also have to underline the leading role taken by the European Parliament, based on clear policy and regulatory objectives underpinned by the Precautionary Principle. We consider that the fact that the European Parliament Resolution on Regulatory Aspects of Nanomaterials (2009) was adopted practically by unanimity, express a general consensus on regulatory matters for nanomaterials, that has to be not only taken into consideration, but adopted as a basic framework (or draft roadmap), for developing a proper and balanced regulatory regime for nanomaterials.

We also consider that some Member States have also taken a proactive role (specially France for being the first one to approve a compulsory register for nanomaterials) requesting a harmonized mandatory register as a first step for tackling HSE issues from a regulatory perspective.

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[173] It could be illustrative to state the Commission Action Plan 2005 and to compare it with the above list of practical realizations: <<Appropriate ex ante assessment should be carried out and risk management procedures elaborated before e.g. commencing with the mass production of engineered nanomaterials. Particular attention should be paid to products that are already or close to being on the market>>. COM(2005)243 final.

[174] As we have seen, the Community Strategy was based in four main elements: a) Appropriate, consistent and timely regulation; b) Maximum use of existing regulation; c) Proactive approach by re-examination and reviewing legislation due to the special characteristics of nanomaterials and the updated scientific information; d) Ensure free movement of goods by regulatory harmonization. COM(2004)338 final. At 3.4.4.

Finally, and talking about the future, it seams logical to expect (in the next two years) that we will witness major changes in the regulation of nanomaterials. Among them, and most notably, the setting up of a compulsory register and the review of the REACH Regulation, specifically addressing the nanomaterials regulatory gaps, that will be the focus of our Case Study.

PARTIII.CASESTUDY:REACHANDNANOMATERIALS

We have seen in PART II a permanent discussion between those advocating that the actual legislative framework has to be considered (in principle) to cover risks associated with nanomaterials, that changes (if needed) would follow new scientific data and that the regulatory problem was on the implementation of the different provisions, and on the other hand, those considering that the actual regulatory framework is not designed for nanomaterials (and, as a consequence, it is logic to expect regulatory gaps), that proactive and timely decisions has to be taken and that the Precautionary Principle has to underpin every legislative proposal.

The objective of PART III is to asses whether actual legislative framework does cover adequately risks associated with the use of nanomaterials, so taking position on the above mentioned discussion. As the scope and objective of our research work has not allowed us to enter on each one of the regulatory regimes presented in PART II we have opted, instead, for selecting REACH as a Case Study in order to assess whether current chemical substances Regulation adequately covers risks associated with nanomaterials.

To select REACH is based on the following basic reasons;
1) Because <<chemicals regulation, and in particular REACH, constitutes a cornerstone for addressing health, safety and environmental risks in relation with nanomaterials>> [175];
2) REACH legislative process implied extensive consultation to stakeholders and may be a model to follow if the European Union finally decides that there is a need for an overarching regulatory regime specific for nanomaterials. This is also the reason for entering a brief explanation on the making of REACH.
3) REACH can be seen as a new step on European legal integration and European legal culture.

The present Case Study is structured in two Sections. The first is a general introduction to REACH while the second presents a set of nanomaterials regulatory gaps.

[175] Commission of the European Communities (2008) <<Regulatory Aspects of Nanomaterials>>. Commission Staff Working Document. COM(2008)366final. 17.6.2008.

1)INTRODUCTIONTOREACH

A) THE MAKING OF REACH

At the end of 2006, the European Union (EU) adopted a comprehensive new system for the regulation of industrial chemicals throughout Europe, which is known by its acronym, REACH[176], for Registration, Evaluation, and Authorisation of Chemicals.

Chronologically, the REACH process officially started with the Commission's <<White paper strategy for a future chemical policy>>[177] that set out the core objectives and structure of the new chemical policy in the EU. On May 2003 the Commission published the Draft Regulation, presenting the regulatory details of the strategy to the public and stakeholders for comments and in October 2003 the final regulatory proposal on REACH that was finally agreed by the European Parliament on 13 December 2006 [178] and unanimously adopted by the Environmental Council on 18 December 2006, ending an extensive open debate[179] and major political, media and lobbying battle in the EU[180].

[176] Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemical Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30.12.2006.
For a consolidated version
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20090627:EN:HTML

[177] COM (2001) 88 final. On the white paper, the commission identified seven political objectives that had to be met <<in order to achieve sustainable development in the chemicals industry within the framework of the Single Market>>. Among these objectives (that at are least partly antagonistic), it can be found environmental demand such as the protection of human health and the environment, increasing transparency or promotion of non-animal testing and, on the other hand, objectives stressing the maintenance and enhancement of the competitiveness of the EU Chemicals industry, preventing fragmentation of the internal market, integration with international efforts and conformity with international obligations under the WTO (World Trade Organization).

[178] In the European Parliament (EP), the REACH second reading (codecision procedure) deal was passed by 529 votes in favour, 98 against and 24 abstentions. Infopress <<Parliament adopts REACH -new EU chemical legislation and new chemical agency>> (2006 13 December) < http://www.europarl.europa.eu/news/expert/infopress-page/064-1496-345-12.50-911-20061213IPR01493-11-122006-2006-true/default_en.htm >. This voting ended a 3 years period of formal negotiations (including a first reading opinion in the European Parliament on the 17 November 2005 (PG_TA-PROV/(2005)0434,17 November2005), A Council Common Position adopted on June 2006 (7524/8/06REV8, 27 June 2006) and the Commission Communication on REACH and forwarded to the European Parliament on 12 July 2006. SEC and Regions Committee also released their Opinion during the process.

[179] The reported open debate was canalized by two stakeholders conferences, internet consultations and working groups of experts giving opportunities for input to stakeholders in the decision making process including two stakeholders conferences, internet consultations and working groups of experts. This open governance model do not necessarily results in a better regulation and permits key stakeholders to influence decision makers in novel ways without a real enhancement of public participation. In this sense Pesendorfer, D., (2006) <<EU Environmental Policy under Pressure: Chemicals Policy Change between Antagonistic Goals?>> Environmental Politics, 15 (1): 95-114. At 111.

[180] For an in depth presentation on the REACH political process see Schöling, I. (2004) <<REACH: The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and why?>>. Brussels. Greens/European Free Alliance in the European Parliament. Available at www.mp.se. I. Schörling (member of the Green /European Free Alliance in the EP and Rapporteur for the <<White Paper – Strategy for a future Chemicals

The final text of the REACH Regulation was published in the Official Journal of the European Community on 30 December 2006. REACH entered into force on 1 June 2007[181]. The European Union also approved the CLP Regulation (for Classification, Labelling and Packaging) that complements REACH[182].

Article 114 of the TFEU (harmonization of laws – ex art. 95) is the explicit legal basis of European legislation on chemicals. This means that the fundamental objective of REACH is the establishing of the internal market by ensuring the free movement of chemical substances[183]. In addition, art. 144 paragraph 3 provides that the Commission will take as a base of its proposals a high level of protection, "taking account in particular of any new development based on scientific facts"[184].

Policy>>) states : <<The same governments that had supported REACH and requested even tighter provisions in the European Council meeting in 2001, were during 2002 and 2003 convinced to turn around and oppose the regulation. The US chemicals industry joined the battle, eagerly supported by the Bush administration. Under the vicious attacks from one of the largest industrial sectors and four of the most powerful governments in the world, the Commission backed down. The Proposal is undoubtedly a watered down version of the initial ambitions and drafts>>.

181 From its entry into force, REACH has undergone several amendments:
a) Council regulation (EC) No 1354/2007 of 15 November 2007 L304 22.11.2007;
b) Commission Regulation (EC) No 987/2008 of 8 October 2008 L268 9.10.2008;
c) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 L353 31.12.2008;
d) Commission Regulation (EC) No 134/2009 of 16 February 2009 L46 17.2.2009;
e) Commission Regulation (EC) No 552/2009 of 22 June 2009 L164 26.6.2009.
and corrections;
f) Corrigendum OJ L 136 29.5.2007 p3 (1907/06);
g) Corrigendum OJ L 141 31.5.2008 p22 (1907/06);
h) Corrigendum OJ L 036 5.2.2009 p84 (1907/06);
i) Commission Regulation (EC) No 494/2011 of 20 May 2011. L134 21.5.2011
For comments on amendments and corrections see Blainey M. (2009) <<REACH, still being developed>> JEEPL 6(1): 51-73.

182 CLP Regulation replace the current system contained in the Dangerous Preparations Directive (1999/45/EC), and aligns the European Union system of classification, labelling and packaging chemical substance and mixtures to the Globally Harmonised System (GHS). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
The CLP Regulation entered into force the 20th January 2009 and has repealed Directive 67/548/CEE on the 1st of December 2010 and will repeal Directive 1999/45 on June 2015.
The United Nations Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) provided a basis for globally uniform physical, environmental, health and safety information on hazardous chemicals through the harmonisation of the criteria for their classification and labelling. It was developed at UN level with the aim of overcoming differing labelling information requirements on physical, health and environmental hazards for the chemicals around the world. Moreover, it also aim to lower barriers to trade caused by the fact that every time a product was exported, it mostly has to be classified and labelled differently because of differing criteria.

183 This has to be taken in consideration when confronted with competing principles included in REACH

184 Following Moreno Molina, it has to be considered that this principle (as stated in article 114 TFUE) has no legally binding content beyond compelling the Commission to "take as a base a high level of protection" in its proposals. Moreno Molina, A.M., <<El régimen jurídico de los productos químicos en la Unión Europea>>. Iustel. 2010. At 67.
In the context of nanomaterials and in the light of scientific advances in the understanding of the implications for health and the environment from the use of nanomaterials, an open question is whether actual legislation is ensuring a "high" level of protection or if it should be adapted "to technical progress" (Council Resolution 15.07.1975). OJ C 168.23.07.1975). In this sense, there is no doubt that Regulation 987/2008 removing from the

The immediate consequence of REACH was the replacement of most of the complicated and confusing system of over forty different Directives and Regulations with a single (but complex) regulatory regime[185].

From a decision-making point of view, REACH has been considered "a hybrid model of governance" as it mixes direct mandate to companies (first generation regulation) with a combination of incentives directed to shape industrial behaviour (second generation regulation)[186].

From a legal perspective, FISHER (2008) highlights three different, independent but interdependent regulatory aspects of the regime: First, REACH privatizes information collection, provisions and assessment. Second, REACH represents a significant application of sustainable development and, in so doing, redefines the conditions on which the EU chemicals market operates. Third, REACH will inevitably have international jurisdictional impacts for both supranational and national legal cultures including trade law implications[187]

From the Member States perspective, the consequences of REACH will be, in the short term (especially when all the provisions will be enforced) the almost virtual

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exemption list in Annex IV Carbon and Graphite can be seen as an "adaptation" of REACH to the "technical progress". Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V.
Following this line of thinking, it seams clear that (without assessing the pace) the Commission is aware of the need to revise the regulations to better suit the special characteristics of nanomaterials in the light of new scientific advances in their characterization. As we have seen elsewhere on this report, the Commission has formally scheduled a revision on the regulatory aspects of nanomaterials by 2011 and a revision of REACH by 2012. It has to be expected that both revisions will incorporate proposals for legal modifications that will have to be based on the principle of high level of protection.

185 For a clear general view of (at that time) existing Chemical legislation see COM(2001) 88 final. 2.2.2001

186 Hey, C., Klaus J., Volkery, A. <<Better regulation by new governance hybrid? Governance models and the reform of European Chemical policy>>. FFU-report 02-2006. Environmental Policy Research Centre. Freie Universität Berlin. SSRN – id 926980.
REACH is clearly within the framework of the "new governance approach" as presented by Commission White Paper on European Governance COM (2001) 428 final 25.7.2001. The new governance approach includes elements of self regulation (non-legislative solutions - soft law) and participation of main stakeholders and general public, so strengthening the power and responsibility of Member States and private actors in policy formulation and implementation. The approached rely more on networks and voluntary action than on hierarchy, more on national responsibility than on EU harmonization, more on non governmental participation and responsibility than on state action.

187 Fisher, E., (2008) <<The "perfect storm" of REACH: charting regulatory controversy in the age of information, sustainable development, and globalization>>. Journal of Risk Research 11:541-563; Benedetto, C., (2010) <<is the European Laboratory Over-Reach-ing? the experimentation, reaction and product yielded by the European Union's Registration, Evaluation, and Authorization of Chemicals>>. 21 Villanova Environmental Law Journal 75.

disappearance of internal norms regulating the commercialization of chemicals products [188] and in the long term, and due to the European regulatory centralisation that REACH represents, a change towards a European legal culture[189].

B) REACH OVERVIEW

Possibly, the most radical change brought by REACH to the EU Chemical Law is the transfer of responsibility for carrying out the risk assessment to the producers and importers of a chemical substance, that are also requested to develop risk minimisation strategies[190], in application of the principle of producer responsibility.

Scope and exemptions:

REACH applies to substances manufactured or imported into the EU in quantities of 1 tonne or more per year. Generally, it applies to all individual chemical substances on their own, in preparations or in articles[191] (if the substance is intended to be released

[188] <<El sistema de fuentes ha sido, pues, plenamente "europeizado", con la consiguiente ablación del correspondiente espacio de conformación normativa de la realidad del que disponía los poderes públicos españoles en este sector>>. Moreno Molina A..M. (2010).At 51.
The only fields left to Member States regulation are:
1.- Penalties applicable for infringement of the provisions of the REACH Regulation (Art. 126 REACH). See Milieu Environmental Law & Policy (2009) <<Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States. Final Report>> 17.12.2009. EC DG Environment (Study contract No. 07.307/2008(520090/ETU/D1).
2.- Configuration of the internal administrative organization needed to exercise the powers and developing activities that Member States must carry out as part of the REACH implementation.

[189] Hyevaert states that the regulatory network can be affected in the long run because REACH represents an exercise in regulatory centralisation (basic functions are exercised by ECHA and the Commission), that requires a direct dialogue between EU institutions and regulatory addressees, that can change the regulatory practice and authority from the national to the European level. Hyevaert, V. <<The EU Chemical Policy: Towards Inclusive Governance?>> LSE Law, Society and Economic Working Papers 7/2008. London School of Economics and Political Science. Law Department. At 10.
In this sense, a fundamental impact and direct consequence of REACH total harmonization is that Member State courts intervention is limited to those areas where the MMSS competences has not been restricted. As Moreno Molina states, << la Administración europea (la Comisión y la Agencia) se convierte en la ejecutora-aplicadora de la ley, por lo que los tribunales "naturales" de la normativa química pasan a ser los europeos, pues ellos son los únicos que pueden controlar a las organizaciones administrativas (europeas) y " gestionan" el sistema legal. La intervención de los tribunales nacionales queda de ese modo limitada a los pocos ámbitos en los que se sigue reconociendo competencias a las administraciones internas, prencipalmente la acción de inspección, vigilancia y sanción>> Moreno Molina , A..M. (2010) At 51

[190] REACH in brief. European Commission DG Environment. October 2007. At 4. This major change is assessed by Führ as follows: <<The REACh proposal is bringing about a paradigm shift towards self-responsibility of agents and responsive regulation. The shift accepts the difficult situation of regulatory agencies in a highly complex environment with limited information about substances and their risks. REACh is highly demanding in requiring basic toxic information and explicit risk minimisation strategies along the production chain. At the moment, the regulation nonetheless falls short in changing the incentives for all relevant agents to act according to the objectives of REACh.>> Führ, M. Bizer, K. (2007) <<REACh as a paradigm shift in chemical policy – responsive regulation and behavioural models>>. Journal of Cleaner Production 15: 327-334.

[191] Substance: A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. REACH does not cover explicitly nano materials. However, as REACH applies to substances on their own, in preparations or in articles, it covers areas in which nanomaterials are being used.
Preparation: A mixture or solution composed of two or more substances.

during normal and reasonably foreseeable conditions of use from an article).

REACH does not mention explicitly nanomaterials, however, as REACH applies to substances on their own, in preparation or in articles, it covers areas in which nanomaterials are being used.

Some substances are specifically excluded[192], or have specific tailored provisions outside[193] REACH or inside[194] it.

Registration:

A major part of REACH is the requirement for manufacturers or importers of substances to register them with a central European Chemical Agency (ECHA). Registration involves a number of steps (looking for existing data, sharing data where it exists, creation of the electronic registration dossier) that finish with the sending of the registration package to ECHA[195].

The registration package is being supported by a standard set of data on that substance and the amount of data required is proportionate to the amount of substance manufactured or supplied[196]. Joint registration and data sharing are important aspects when setting up the registration package[197], and, specifically for nanomaterials, the joint

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Article: An object which during production is given a special shape, surface or design, which determines its function to a greater degree than does its chemical composition. Examples of articles are a car, a battery and a telephone.

192 Radioactive substances; Substances under customs supervision; The transport of substances; Non-isolated intermediates; Waste; Some naturally occurring low-hazard substances.

193 Human and veterinary medicines; Food and foodstuff additives; Plant protection products and biocides.

194 Isolated intermediates; Substances used for research and development.

195 Data-sharing: One of the key objectives in REACH is to obtain and share information about the properties of substances being manufactured, supplied and used in the EU. This ensures that registrations use existing data rather than commissioning new studies. REACH prohibits the duplication of animal testing. Data sharing is achieved using one of two mechanisms, SIEF or the Article 26 Inquiry. The SIEF is the data sharing forum used for phase-in substances that have been pre-registered. For non-phase-in (new) substances, the main data sharing process is the Article 26 Inquiry, This process allows prospective registrants to be put in touch with any existing registrants so that data sharing can be organised. In some cases, data can be made freely available for registration purposes.
Dossiers are created using the IUCLID software system, that helps applicants to create the file that will be sent to ECHA using their REACH-IT system. For nanomaterials ECHA has issued the guidance document <<Nanomaterials in IUCLID 5.2>>. IUCLID 5.2 Guidance and Support. June 2010 v1.0. First version.

196 Basically:
a) Common information for all registrations: Annex VI
b) Depending on the tonnage threshold:
- > 1t/yr Annex VII
- > 10 t/yr As above + Annex VIII
- > 100 t/yr As above + Proposal for Annex IX
- > 1000 t/yr As above + Proposals for Annex X

197 Joint registration and data sharing:
This is the principle that for anyone substance, a single set of information on its intrinsic properties is produced that is shared by all those companies that manufacture or supply that substance. Business specific (e.g. company name) and business sensitive (e.g. how it is used) information is submitted separately by each company. The Companies will work together to get an agreement on information sharing through a Substance Information Exchange Forum (SIEF: A Substance Information Exchange Forum (SIEF) will be formed automatically within

registration links with the concept of "sameness" between bulk substance and nanosubstance that will be reviewed in the following section.

If a particular substance needs to be registered (basically because it is produced in quantities greater than 1 Tonne/year or is a Substance of Very High Concert -SVHC- and is not exempted or excluded) but no registration is submitted, then the data will not be available and as a result, the manufacturer or supplier will no longer be able to manufacture or supply them legally, ("no data, no market" principle). In the nanotechnology debate, the application of the "no data - no market principle" has been requested by the European Parliament.

The time line for registration depends on the possibility (for the substance) to be "pre-registered" or not. If the substance can be "pre-registered" it can benefit for an extended registration period Basically, the substances that can be "pre-registered" are those considered by REACH as "phase-in substances"[198]. The registration of those substances already being manufactured or supplied (phase-in substances) is being taken place in three phases (if the substances had been pre-registered from 1st June to 1st December 2008[199]) up to 1 June 2018.

This extended registration period has important consequences for nanomaterials: Those nanomaterials that has been pre-registered -so phase-in substances- (due to be considered as the same substance than their bulk substance) will not have to be registered until 2018 (depending on the total yearly tonnage) provided that the substance is supplied at ≥ 1 tpa. For those nanomaterials, the information that will be

REACH-IT, comprising all the relevant stakeholders for each substance. You can view all the members of the SIEF through the REACH-IT system where you made your pre-registration. There is no option to opt out of a SIEF, but you can decide how active you wish to be within it. The fact of pre-registering nanosubstances based on the seamness principle/option to the bulk substance can also create problems once the SIEF is automatically assigned to the stakeholder. Scheidmann, H., Roselfeld, A., (2005) <<Forming Consortia for REACH Registration: Contractual and Competition Law Issues>>. JEEPL. 3: 173 – 183.

198 Non-phase-in substances: those not produced or marketed prior to the entry into force of REACH:
Phase-in substances: a) Substances listed on EINECS. b) Substances manufactured in the EU (including the newer member states) at least once in the 15 years before REACH became law, but were not placed on the market by the manufacturer (provided the manufacturer has documentary evidence of this). Substances that are so called 'No Longer Polymers' of Directive 67/548.
EINECS: European Inventory of Existing Commercial Chemical Substances, it is a list of all the so called "existing substances".

199 As the 1st of December 2008 deadline for general pre-registration has already passed, the only pre-registration function now available is for the so called "late pre-registration": If you manufacture or import (into the EU) a phase-in substance at one tonne or more per annum for the first time after 1 December 2008, you will be entitled to submit a pre-registration for that substance to the European Chemicals Agency (ECHA). The facility to pre-register after 1st December 2008 is sometimes referred to as "late-registration". If not pre-registered, then the applicant have to follow the registration procedure.

know up to 2018 is the limited information required on the pre-registration of a substance that is: a) Name of the chemical, including an identifying number (e.g EINECS number); b) Company's name and address and a contact name; c) An Envisaged deadline for registration and tonnage band; d) Date of first supply; e) Identifier information of any structurally similar chemical (useful evidence on hazards as part of the registration package).

Evaluation:

Dossiers submitted in support of registration will be subject to different degrees of evaluation[200].

Substances of Very High Concern:

Some substances have hazards that have serious consequences, e.g. they cause cancer (carcinogenic), or they have other harmful properties and remain in the environment for a long time (persistent) and gradually build up in animals (bioaccumulative). These are substances of very high concern[201]. One of the aims of REACH is to control the use of such substances via authorisation and encourage industry to substitute these substances for safer ones (substitution principle).

Authorisation:

In order to place on the market or use substances with properties that are deemed to be

[200] A) Compliance checking: This is a check of the quality of the information submitted by industry. It will be undertaken by the European Chemicals Agency (ECHA) in Helsinki and will be on a sample (at least 5%) of dossiers submitted at each tonnage level.
B) Dossier Evaluation: For substances registered at the highest tonnage levels (≥100 tonnes/annum) a proposal is made by the registrant detailing those animal tests they consider are required from the list of standard tests in Annexes IX and X of REACH. The ECHA will evaluate these testing proposals to prevent unnecessary animal testing.
C) Substance evaluation: This is undertaken by national Competent Authorities on substances that have been prioritised for potential regulatory action because of concerns about their hazardous properties. A key regulatory outcome of evaluation could be the imposition of restrictions on the manufacture, supply or use of a substance. Substance evaluation may also lead to a substance being added to the priority list for authorisation or a proposal to change the classification and labelling.
All dossiers will undergo an automated completeness check to ensure that all the relevant pieces of information are present. This completeness check will not assess the quality or suitability of the information.

[201] Article 57 REACH
Substances meeting these criteria may be placed on one or both of two lists that are defined in the REACH Regulation: the so called 'Candidate List' and the 'Annex XIV List'.
A potential SVHC may be prioritised by national REACH Competent Authorities, or by the European Chemicals Agency (ECHA) at the request of the European Commission (EC), and a dossier prepared for nomination of the substance for inclusion on the Candidate List. The list of proposed substances is then published on the ECHA website and interested parties are invited to submit comments within a set time frame. If no comments are received, the substance will be automatically included on the Candidate List. However, if comments are received, ECHA will refer the dossier to its Member State Committee where agreement will be sought as to whether the substance meets the Article 57 criteria. If there is failure to reach a unanimous agreement at the Member State Committee then the EC will prepare a draft proposal on the identification of the substance and a final decision subsequently taken in accordance with the comitology procedure laid out in Article 133.

of "very high concern" industry must apply for an authorisation[202].

The Authorisation procedure under REACH is relevant to nanomaterials as restriction of substances can apply regardless of quantities manufactured or placed on the market and even regardless of the fact of being registered or not.

Being this the case, it could be though that REACH could perfectly deal with nanosubstances of very high concern, but there are several elements that blur this preliminary opinion creating another regulatory gap or miss functioning that we will review on the following section.

Restrictions:
Any substance that poses a particular threat that is deemed to require Community-wide action can be restricted. Restrictions take many forms, for example, from a total ban to not being allowed to supply it to the general public. Restrictions can be applied to any substance, including those that do not require registration.

2)INVENTORYOFREACHREGULATORYGAPS RELATEDWITHNANOMATERIALS

Before entering to present the different regulatory gaps let me just summarize the outcome, because our conclusion is clear; REACH was designed with the bulk substances in mind and when faced with nanomaterials, important regulatory gaps has been found and identified.

From the analysis of the Precautionary Principle and the interpretation given by the European Court, we have reached the conclusion that the European regulator comes bounded to take those measures tending to minimize the possible risks. The existence of

[202] Substances of very high concern will be gradually included in Annex XIV of the REACH Regulation. Once included in that Annex, they cannot be placed on the market or used after a date to be set (the so-called "sunset date") unless the company is granted an Authorisation.
Decisions on authorisation are made by the European Commission, taking advice from the ECHA and Member States. Applicants will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits of their use outweigh the risks. Applicants must also analyse whether there are safer suitable alternatives or technologies. If there are then they must prepare substitution plans and if not then they should provide information on research and development activities if appropriate.

regulatory gaps generates these risks. So it can be understood that eliminating them during the REACH review (or at least to critically discuss them in the review process) can be consider as an obligation of the European legislator. By not doing so, the Commission could be in breach of Community Law. In any case, that breach can only by judged by the Court if requested to do so.

2.1) Lack of explicit mention of "nanosubstance" under REACH

There are no provisions in REACH referring specifically to nanomaterials but there is no doubt that their provisions apply to them.

As stated in art.5, REACH applies to <<substances on their own, in preparations or in articles>>, and art. 3 (1) REACH defines <<substance>> as <<a chemical element and its compounds in the natural state or obtained by any manufacturing process>>. Given this broad scope, it is accepted that REACH apply to the bulk substance as well as to the nanoform of the bulk substance[203], and the fact that REACH does not differentiate between nanoscale and bulk materials can not challenge the application of REACH to nanosubstances[204].

As stated by the Commission, as <<REACH addresses substances, on their own, in preparations or in articles>> and <<it deals with all substances, in whatever size, shape or physical state>> then <<substances at the nanoscale are therefore covered by REACH and its provisions apply. It thus follows that under REACH manufacturers, importers and downstream users have to ensure that their nanomaterials do not

[203] The Committee on Environmental Affairs of the European Parliament explicitly called for not including substances in the nanoscale in the Registration of the substance concerned on the conventional scale. The proposal was dropped in the legislative process, clearly showing that REACH covered the substances at the nanoscale but does not regard nanomaterials as a substance of their own. European Parliament <<Recommendation For Second Reading on the Council Common Position.>> A6-0352/2006. 13 OCT 2006; Proposal for Amendment No 217 to Article 56 REACH by Carl Schlyter, Caroline Lucas and Hiltrud Beyer; Commission of the European Communities (2008) <<Follow-up to the 6th Meeting of REACH Competent Authorities for the Implementation of Regulation (EC) 1907/2006 (REACH). Nanomaterials in REACH>>. 16 Dec 2008. CA/59/2008 Rev. 1 At 4-5.

[204] As Haselhaus explains, the wording of Art. 5 places the chemical element in centre field and does not differentiate between applications on the nanoscale and the bulk material. This is based in the assumption that risks arising from the behaviour of a certain chemical are attributable to a substance and not to its different physicochemical properties. Because of this assumption, the system is not able to provide fon an effective risk assessment with regard to nanomaterials. But this regulatory failure can not change the legal definition of "substance" neither the inclusion of "nanomaterials" in it (in any case, only the European Court of Justice can interpret differently the "substance" concept and consider nanomaterials to be excluded from the REACH definition of substance). Haselhaus, S. (2010) At 122.

adversely affect human health or the environment>>[205].

The importance of explicitly mentioning <<nanomaterials>> on REACH scope (or even in the <<substance>> definition), is generally accepted and although will not report legal consequences will give certainty[206].

2.2) Exemptions and exclusions

Art.2 REACH details various substances to which certain of the provisions of the Regulation do not apply. Not applicability in the form of exemptions or exclusions.

1.- Substances included in Annex V. Those which occur in nature, including minerals and ores.
The reason for excluding those substances is that the risk from base elements are well known already (art 2(7)(b) REACH). This may not be the case for the nanoforms of these substances (for instance, gold is unreactive and stable at bulk level, but highly volatile in certain of its nano forms)[207].

2.- Substances included in Annex IV. The reason for excluding those substances is that they are considered to be of minimum risk. Also in this case, what could be logical when dealing with bulk substances it is not when faced with the nanoform.

REACH does not differentiate between nano and bulk forms of substances in Annex IV and V, so inaccurately assuming that the risk of a substance is the same as whatever scale. In fact, if the "nanosubstance" would be regarded as a separate substance from the bulk, then, there will not be need for the withdrawal from the exemption as has been the case with Carbon and Graphite in the European Union[208].

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[205] Commission of the European Communities (2008) <<Follow-up ...>>. At 4-5.

[206] As Fürh states <<in order to provide those affected with a clearly perceptible indications that nanomaterials are also covered by REACH, reference to them in the definition of substance would be advisable, even if it were merely in a declaratory manner>> Führ, M., Hermann, A., Merenyi, S., Moch, K., Möller, M. (2006) <<Legal appraisal of nano technologies. Existing legal framework, the need for regulation and regulative options at a European and national level>>. Final Report . ÖKO-Institut e.V. & Sofia. FKZ 363 01 108. At 42.

[207] Lee, R.G., Vaughan, S. (2010) <<REACHing Down: Nanomaterials and Chemical Safety in the European Union>>. ESRC BRASS Research Centre. Cardiff University. At. 14.

[208] Carbon and Graphite were on the Annex IV list until October 2008, when they were removed from the exemption list by Regulation 987/2008 (Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V).
The reason for this decision is related with the reported possible health risk of carbon nanotubs (<<(3) The review

The identified gap on substances of Annex IV and V could be filled by a clear distinction between the "bulk" and the "nano" substances and this could be done by considering both as different "substances" (so giving a different EINECS number) or if the substance has been already recognized as phase-in substance by giving an additional code to the CAS number (Chemical Abstract Service)[209].

2.3) Thresholds

Art. 6 REACH states the registration obligation under REACH. Schematically, the following classification is envisaged:

i) If > 1T/year: Registration (without a Chemical Safety Assessment)

ii) If > 10T/year: Registration (with Chemical Safety Assessment through a Chemical Safety Report -CSR- Data content will depend on T/year).

iii) Without thresholds: substances of very high concern included in Annex XIV of REACH or substances of equivalent concern[210] have to be registered and the following information have to be presented:

- Chemical Safety Assessment through a Chemical Safety Report -CSR-.);
- Exposure Scenarios;
- Risk Characterisation.

So, if the substance is not of special concern (iii), the general requirement for Registration laid down in Article 6(1) REACH applies from a production volume of one tonne per year and manufacturer[211].

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carried out by the Commission pursuant to Article 138(4) has revealed that three substances listed in Annex IV should be removed from that Annex, as insufficient information is known about these substances for them to be considered as causing minimum risk because of their intrinsic properties. This is the case with vitamin A, as that substance may present significant risks of reproductive toxicity. This is also the case with carbon and graphite, in particular due to the fact that the concerned EINECS and/or CAS numbers are used to identify forms of carbon or graphite at the nano-scale, which do not meet the criteria for inclusion in this Annex>>. Regulation (EC) No 987/2008.

[209] It is important for Companies when setting up their R&D programmes to take into consideration a precautionary approach in their decisions. In the case of carbon nanotubs, the existence of <<concern over potential harm>> and the decision to withdraw the exception is clearly guided by precaution. In aligning the investment decision with the policy principle will make private decisions safer from possible future legal obligations derived from new scientific findings. Lee, R.G., Vaughan, S. (2010) At 8.

[210] Substances subject to authorisation are: a) CMRs (carcinogenic, mutagenic or toxic) category 1 and 2; b) PBTs (persistent, bioaccumulating and toxic) and vPvB (very persistent and very bioaccumulating); c) substances with probable serious effects to humans or the environment which give rise to an equivalent level of concern as CMRs and PBTs/vPvBs. This is for instance the case for substances with endocrine disrupting properties. COM(2008)366final. At 7.

[211] On the framework of the discussion on the thresholds, the REACH competent Authorities Sub-Group on

The threshold gap is, as said by the Royal Commission on environmental Pollution <<the most significant potential limitation affecting the application of REACH to nanomaterials is the one tone threshold for registration. Because of the very large number of (often highly interactive) particles present even in tiny quantities of a nanomaterial (...) one tonne may be too high a threshold to capture potentially problematic effects>>[212].

There is a general concern that, as per today, an important amount of nanomaterials currently on the market will not reach this volume[213], and as a consequence, products including nanosubstances are being released in the marketplace without being registered [214].

It is commonly agreed that based on the potential health problems reported by the scientific community a reduction in the quantitative threshold for nanomaterials, at which mandatory registration applies, <<does not appears to be unreasonable>>[215], with reference to the principle of precaution (art 174 TFUE and Article 1(3) REACH) and the "no data no market" principle. Some institutions are starting to consider the need of solving the threshold issue as urgent[216].

Nanomaterials (CARACAL) stated: <<The tonnage trigger for registration apply to the total volume of a substance manufactured or imported by a registrant. Thus, for substances which exist both in a bulk form and in a nanoform, the total volume determines the need and the timing for registration and the information requirements>>.

Trying to understand the CARACAL statement, Lee & Vaughan indicates that it would seem that if a manufacturer of carbon (who produce for instance – 1000 tonnes of carbon per year) also produce an amount of carbon nanotubes (CNTs), these CNT's would be registered along with the (bulk form) carbon whatever their volume of manufacture. Although not indicated by CARACAL, this combination of volume for registration purposes should only apply where the substances, in their different forms, are considered the "same".

Commission of the European Communities (2008) <<Follow-up...>>; Lee & Vaughan (2010) At 17.

In addition, CARACAL also states that <<REACH also does not prevent companies from registering on a voluntary basis their substances if they are below the one tonne threshold>>

CARACAL is an expert group which advises the European Commission and ECHA on questions related to REACH and CLP. It is composed by representatives of Member States Competent Authorities for REACH and CLP, representatives from Competent Authorities of EEA-EFTA countries as well as a number of observers from non-EU countries, international organisations and stakeholders. For further information on CARACAL see http//:ec.europe.eu/enterprise/sectors/chemicals/reach/caracal/index_en.htm

212 Royal Commission on Environmental Pollution (RCEP) (2008) At 4.37.

213 <<The regulation of products containing nanoparticles based on tonnage, as proposed for existing chemicals under REACH, needs to be considered further because there are many more nanoparticles to the tonne than is the case for larger particles, and their behaviour in the body and in the environment may be different>>. Scientific Committee on Emerging and Newly Identified Health Risks -SCENIHR- (2006) <<The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies>>.. Modified Opinion (after public consultation). 10th plenary meeting of 10 March 2006. SCENIHR/002/05. At 3.10.9.

214 The concern arising from this regulatory gap is one of the main arguments on behalf of the adoption of a compulsory registry for nanomaterials approved by France.

215 Führ, M., et Al. (2006) At 43.

216 <<We commend the Government's commitment to address the issue of the one-tonne threshold for considering the potential toxic effects of a substance under REACH Regulation. We ask the Government to update the Committee in the progress they made towards meeting the urgent need>> in House of Lords (2009) <<Nanotechnologies and Food>>. Science and Technology Committee 1st Report of Session 2009-10. House of Lords. Vol. I Report. HL Paper 22-I. At 54.

In addition, it also would be advisable to deviate from the "weight/year" logic and to give preferences to other parameters more fitted to nanomaterials characterisation[217]

2.4) Classification difficulties

2.4.1) Nanosubstance as phase-in substance

Art. 3(20)[218] of REACH establish the basic concept that substances which have been listed on the European Inventory of Existing Commercial Chemicals Substances (EINECS) and thus were "existing" substances prior to the entry into force of REACH can be considered as phase-in substances for REACH purposes[219].

The importance of the distinction is basically the possibility (if considered phase-in substances) of opting for the deadlines established in art. 23[220] of REACH, which meant

[217] The UK Government states <<2. The Government agrees with the Royal Commission that the REACH Regulation provides the most sensible legislative framework for the regulation of nanomaterials, in tandem with more specific legislation where this exists (for example on biocidal products). Likewise, the Government recognises that functionality, rather than size, should be given particular attention>> <<5. The Government agrees that some changes may be necessary to the current framework to more effectively manage the use of nanomaterials. In particular, the Government recognises the limitations of the annual one tonne threshold for registration and that the test guidelines may need to be extended to cover risks specific to nanoparticles>>. United Kingdom Government (2009) <<Response to the Royal Commission on Environmental Pollution (RCEP) Report "Novel Materials in the Environment: The Case Of Nanotechnology>>. June 2009.
Available at http://www.official-documents.gov.uk/document/cm76/7620/7620.pdf (Accessed May 2011).

[218] <<Article 3 Definitions
20. phase-in substance: means a substance which meets at least one of the following criteria:
(a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
(b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004 or on 1 January 2007, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;
(c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004 or on 1 January 2007, by the manufacturer or importer before the entry into force of this Regulation and it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this, including proof that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive.>>

[219] CARACAL: <<A phase-in substance is defined by a substance meeting the criteria of Article 3(20) of REACH. Unless the substance is a no-longer polymer or has not been placed on the market in line with Article 3(20)(b), this means that the substance must have been listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). The intention behind this provision is to give phase-in status to substances which have been listed in EINECS in the past and which therefore were considered as existing substances before the entry into force of REACH. In interpreting whether a concrete material is covered by a particular EINECS entry, therefore historical criteria need to be applied. In other words, whenever the material was considered to be covered by a particular EINECS entry in the past, it should be considered to have phase-in status under REACH>> Commission of the European Communities (2008) <<Follow-up ...>> At 2.1. Following Lee & Vaughan (2010) the statement is not helpful as, for instance, Carbon is registered on EINECS with the number 7440-44-0, but this listing does not distinguish, for example, between carbon in a conventional form and carbon nanotubes. Lee & Vaughan (2010) At. 22

[220] For a graphic explanation of REACH registration deadlines established in art. 3. Environment Directorate

the option of getting extended registration periods[221].

Regardless of being manufactured or placed in the EU market as nano or bulk form, the only requisite for opting to a phase-in classification is the fact of being or not listed on the EINECS.

So, if a substance (in bulk) was listed on the EINECS prior to the entry into force of REACH, then the nanoform will also be phase-in substance (as nanosubstance is considered the same substance). The final consequence is that nanomaterials like CNTs (carbon nanotubs) may not be registered with safety data until 2018 (or possible not even be registered because they do not exceed the REACH registration threshold of 1 tonne or more of annual output or imports -as we have seen above-). The fundamental reason of this gap is (again) because REACH does not differentiate substance identity on the basis of physicochemical characteristics.

Faced with this problem, Fürh propose (even to) accept that nanomaterials are not considered to be a substance on their own under REACH provided that (for registration purposes) REACH assign nanomaterials a different CAS (Chemical Abstract Service) number or (like both red and white phosphorous) to be listed under EINECS number with a different index number[222].

The German NanoKommission advices that the long transitional deadlines for registration of phase-in substances (art. 23 REACH) should not apply to substances on the nanoscale because otherwise <<this would not be compatible with the precautionary principle. In order to ensure continuity of manufacturing, importation and marketing, however, a deadline should be set by which all substances in the nanoscale already on

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General European Commission (2007) <<REACH in brief>>. 2007. At. 9.

221 Substances considered "non-phase-in" (and which were manufactured or imported in quantities greater than one tonne per year) needed to be registered prior to 1 June 2008 and prior to commercialization or import could continue.

222 Führ, M., et Al. (2006) At 44; SCENIHR reach a similar conclusion: <<If the nanoparticle form of a chemical does have distinctly different properties in biological systems from other physical forms of the same chemical, it will be necessary to readily identify the nanoparticle form of each chemical for the purposes of hazard warning labels etc. One approach to ensure that the effects of the nanoparticle form of a chemical is properly assessed would be to have a unique identification for it, either assigning different CAS numbers to the nanoparticle form, or adding a code (CAS-NP50) to existing CAS numbers leaving the CAS number for identifying similar chemical compounds>>. Scientific Committee on Emerging and Newly Identified Health Risks -SCENIHR- (2006) At 3.10.9.
CAS Registry: database of organic and inorganic substances maintained by the American Chemical Society.

the market must be registered>>[223].

2.4.2) Sameness of substances

When identifying a substance, it must be clarified whether a given nanomaterial is to be regarded; a) as a substance in its own right or b) as a specific physical form of a substance.

Under REACH, the analysis of "sameness" has to be done by the Registrant[224] after undergoing a sameness analysis that should indicate whether the substance at nanoscale can be considered as a specific physical form of the bulk substance (ie both are covered by the same EINECS entry), or is a different substance than the bulk substance (ie separate EINECS entries).

When deciding this, the registrant must take into account the provisions of Art. 3 and Annex VI (2) of REACH, in conjunction with the ECHA Guidance documents.
Neither REACH, nor the ECHA Guidance documents lay down binding requirements specifically for substances in the nanoform basically due to the lack of proper scientific knowledge when deciding what information is needed for a "sameness" analysis with nano material.

In this sense, REACH does not define "sameness" and it does not foresee any formal step to confirm the establishment of sameness[225] and ECHA has not yet released guidelines on the identification of substances in the nanoscale[226] with the consequent

[223] NanoKommission (2010) <<Review....>>. At 23.

[224] <<Under REACH, this "sameness" analysis has to be done by potential registrants. Nevertheless, the outcome of this analysis is not at the discretion of potential registrants but must be in line with the substance definition, information related to molecular and structural formula, composition and other relevant provisions of REACH. Any decisions taken by SIEFs may therefore also be challenged, e.g. by ECHA during the compliance check.>> Commission of the European Communities (2008) <<Follow-up ...>>. At 2.3.

[225] <<Article 29 of the REACH Regulation provides that all Potential Registrants and Data Holders for the "same" phase-in substance shall be participants in a SIEF. However, the REACH Regulation does not define "sameness" and it does not foresee any formal step to confirm the establishment of sameness and the formation of a SIEF>>. ECHA (2007) <<Guidance on data sharing>>. September 2007. At. 34. Available at http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf. (Accessed January 2011).

[226] <<The current developments in nano-technology and insights in related hazard effects may cause the need for additional information on size of the substances in the future. The current state of development is not mature enough to include guidance on the identification of substances in the nanoform in this TGD>>. ECHA (2007b) <<Guidance for identification and naming of substances under REACH>>. June 2007. At 28. Available at http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf. (Accessed January 2011).

confusion in the registration process[227].

The issue of substance identity was being debated at EU level within RIPoN 1, but the final published report is not conclusive as the experts could not reach a consensus, therefore no recommendations will be send to ECHA[228].

2.5) Methodological gap

Under REACH the safety of a substance is determined by volume in which it is produced, failing to account for particle size and surface area as key determinants of toxicity.

For this reason, there has been no substance-specific legal duty to perform studies specially for nanomaterials[229], meaning that ecotoxicology tests performed on the nanoscale form may, from a legal point of view, need to be accepted for both macroscale and nanoscale forms by regulatory authorities.

The Commission launched the REACH Implementation Report on Nanomaterials, RIPoN2 on information requirements and RIPoN3 on Chemical safety assessment. The reports has just been published and is now for the ECHA to decide whether and when to include changes on the Technical Guidance Documents based on those recommendations[230].

2.6) Registration updates (art 22 REACH)

Article 22 REACH establish the registrants' obligation to update his registration in cases

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227 The confusion over classification of nanomaterials under REACH has led to two groups of companies using different criteria to submit data on carbon nanotube to ECHA, and are forming separate data-gathering bodies (SIEFs) to deal with carbon nanotubes. One group is setting up its own SIEF for carbon nanotubs to register them as distinct chemicals with their own safety profile while another planned to register the nanomaterials as a form of bulk graphite so that they will not require their own registration dossier. RSC – Advancing the Chemical Sciences. Available at http://www.rsc.org/chemistryworld/News/2009/June/16060901.asp

228 DG Environment & JRC <<REACH Implementation Project Substance Identification of Nanomaterials -RIPoN1- >> AA N. 070307/2009/D1534733.Advisory Report March 2011. Available at http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon1_pdf

229 Fullerenes represents an exception since they are not an EINEC substance, has received specific CAS number and (once reached the 1 Tonne/year threshold) are subject to Registration. Orthen, B. (2007) <<Nanotechnology: Health and environmental risks of nanomaterials – Research Strategy>>. BauA (German Federal Institute for Occupational Health and Safety). 2007. At 12. Available at www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/Nanotechnology.html. (Accessed February 2011).

230 Reports are available at http://ec.europa.eu/environment/chemicals/nanotech

like change in the composition, new knowledge of the risk of the substance and others.

The updating obligation is "following registration", so the duty applies only to phase-in substances (new substances) and not to non-phase-in-substances (old substances) until registration is accomplished, which will be in 2018 at the latest[231]. The gap could be closed by a wide interpretation which also comprises "pre-registration"[232].

2.7) Nanosubstances ban

The Substances of Very High Concern (SVHC) listed in Annex XIV of REACH will have to be subject to authorisation for each individual use (art. 57 REACH), if it wants to be placed on the EU market. The application for authorisation has to include a chemical safety report -CSR- and an analysis of possible alternative substances[233]

If the analysis of alternatives reveals that there is a suitable alternative, the applicant must submit a substitution plan. When the applicant can not demonstrate adequate control on risk and where no suitable alternative exists, he needs to include a socio-economic analysis in his application (SEA)[234].

The Authorisation procedure under REACH is relevant to nanomaterials as restriction of substances can apply regardless of quantities manufactured or placed on the market and even regardless of the fact of being registered or not.

Being this the case, it could be though that REACH could perfectly deal with nanosubstances of very high concern, but there are several elements that blur this preliminary opinion creating another regulatory gap or missfunctioning. Those are:

a) There must be an evidence that the substance poses unacceptable risks. As we have seen earlier, risk assessment methodology is not fully adapted to nanomaterials, so the "evidence" will not be possible to prove;
b) The procedural arrangement for the inclusion of substances in Annex XIV (Art. 58

231 Haselhaus, S. (2010) At. 123.
232 Obviously this wide interpretation if followed by the Commission or ECHA could be challenged. At the end it would be for the European Court of Justice to interpret.
233 See http://guidance.echa.europa.eu/authorisation_en.htm
234 See http://guidance.echa.europa.eu/socio_economic_en.htm

REACH) states a short list of priority substance where nanomaterials are not mention[235].

In order to properly take into consideration the special characteristics of (certain) nanomaterials it could be advisable to consider them priority substances at the same level of concern, at least, as the substances "normally" considered to be prioritized[236].

c) The analysis of alternatives could be a complex issue with nanomaterials: The bulk substance can be considered as alternative ? The applicant has to limit the possible alternatives to nanomaterials? A similar question could arise from the SEA as its purpose is to evaluate what costs and benefits an action will create for society by comparing what will happen if this action is implemented as compared to the situation where the action is not implemented.

[235] <<3. Prior to a decision to include substances in Annex XIV, the Agency shall, taking into account the opinion of the Member State Committee, recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:
(a) PBT or vPvB properties; or (b) wide dispersive use; or (c) high volumes.>>

[236] Desmoulin considers that ECHA does not seam to consider some nanoforms as substances "raising an equivalent level of concern" Desmoulin, S. (2008). At 347.

PARTIV.CONCLUSIONS

It is commonly stated that nanotechnologies will bring societal benefits, innovation and competitiveness. On the other hand, we only have a limited understanding of potential risks from nanomaterials, although a growing body of scientific data suggest that certain nanomaterials may have a negative impact on human health and the environment.

This is the base of our regulatory dilemma: if we regulate “too much”, we may hinder (nano)technology development (or force a certain number of companies to move their activities to less regulated countries or regions) but, if we do not regulate as a priority (and in a timely manner) all aspects related with Health, Safety and Environmental issues (HSE) or under-regulate nanotechnologies, we can face unexpected damaging effects and (over) reaction from public opinion that may also jeopardize nanotechnology development.

In the nanotechnology field this dilemma is further complicated by different levels of uncertainty (over terminology, methodologies, HSE risks, risk assessment, future nanomaterials developments, etc.).

Is within this complex framework (risk, benefits and uncertainties) that regulators have to decide, firstly, witch regulatory option is considered to be appropriate and, secondly, on the time line, level and intensity to be applied. Our research paper focus on analysing how the European Union has replied to above questions.

From the first Part of our research paper, we conclude that the legislator needs to regulate risks associated with nanomaterials based on inconclusive and preliminary scientific evaluation indicating that particular nanomaterials might lead to potential risks and consequently damaging effects on human health and the environment. In this context, the Precautionary Principle has to be invoked.

An added problem from nanomaterials regulation is that uncertainty is not limited to the availability of scientific conclusive data related with health, safety and environmental issues (HSE), but it also reaches issues like terminology, methodologies, risk assessment, quantity and quality of products in the marketplace and future technology

developments.

We have identified four main regulatory options, namely: “wait and see”, differentiated approach, nano-specific regulation and “moratorium”.

The two extreme options are considered inadequate for regulating nanotechnologies. To wait until scientific certainty is reached could mean to stop regulatory intervention for a long time and makes (next to) impossible to promote public involvement in the technology development or to address public concerns at the earliest possible stage.

To over-react and generalize a moratorium until the risk of nanomaterials are identified would hinder research and development and international competitiveness as it seams fairly difficult an international agreement on nanomaterials ban. Additionally, this option implies that all nanomaterials may be hazardous and provoke risk. This is not the case with nanomaterials.

The Differentiated Approach is the pragmatic option that we consider to be adequate, at least in the short term, because is based on the recognition that all regulatory systems are badly equipped to respond to new technologies, as regulatory regimes are designed for handling regulatory concerns at the time of promulgation. So we part from the assumption that is logical to expect that the emergence of nanotechnology creates or exacerbates regulatory gaps. In this sense, rejecting the actual regulatory regime just because is inadequate do nor seams reasonable.

Based on this recognition, the Differentiated Approach regulatory strategy is to use existing legislative structures to the maximum together with the need of reviewing and amending (when appropriate, on a case by case basis and for specific nanomaterials and their applications) existing regulation (including the development of a specific guidance and standards to support existing regulation) and the introduction of supplementary policy.

All this set of measures (hard law, soft law and supplementary policy) must be seen as a comprehensive regulatory regime, timely and proactive, and based on a proper assessment of the Precautionary Principle (as regard intensity/modulation).

Conceptually, we consider that the European Union regulatory strategy, the so called "Incremental Approach" strategy, is within the framework of the Differentiated Approach, although it can not be considered proactive, neither timely and only partially following the legal requirements under the Precautionary Principle.

Conscious of the different interpretations given to the Precautionary Principle (that could justify nearly any kind of regulatory intensity), we have chosen a pragmatic approach: to present the content given to the Precautionary Principle by the European Courts because represents, in legal terms, the minimum level of precaution that the European Union has to aim for in the design and implementation of regulation.

The fourth regulatory option identified is the "Nano-specific regulatory approach". We consider that in the medium to long term the recourse to this strategy can not be discarded. Depending on the technology development (among other possible factors) a specific regulation may bring a more comprehensive, authoritative and clear legislative framework. In any case, the design of a brand new overarching regulatory regime is a complex task, time consuming and requiring a well organized and thoroughly planned legislative process open to public consultation, difficult to conduct if urgent answers are expected.

The European Union Chemical Policy process, that started with the "White Paper on Chemical Policy" to the REACH approval (with an extensive public consultation) may be a model to consider for nanotechnology regulatory development.

Any regulatory option design has to incorporate the Precautionary Principle as interpreted by the European Courts. The Courts are placing to the European public authorities a mandate to take provisional measures to anticipate the occurrence of a risk (of serious and irreversible damage to health and the environment deemed unacceptable to society, supported by solid and objective scientific reasons, even if uncertain), and that those measures must be based on general principles of risk management (and must be proportionate, non-discriminatory, consistent, based on an examination of benefits and costs of action or lack of action, and on an examination of scientific developments).

From there, and trying to avoid loose interpretations over the meaning of the Courts ruling, we have listed what we consider are specific legal obligation addressed to the regulator:

- To act in order to avoid or minimize possible risks and not to be satisfied with (just) monitoring the development;
- To take into account the possible effects of nanotechnology already in the definition of EU policies;
- Provide funding for research on toxicology and ecotoxicology in order to allow complete scientific evaluation of the potential adverse effects, based on the available data, and carried out by independent authorities.
- Organizing the collection of information about manufactured nanoparticles and nanomaterials, their properties, their manufacturers, their uses, and the people potentially exposed. This requirement can be met by the setting up of a compulsory inventory or reporting scheme that could be designed within REACH, but not necessarily.

Entering to the applicable legislation to nanomaterials in the European Union we have concluded that there are no specific regulations for nanomaterials at European Union level. Instead, the manufacture, use and disposal of nanomaterials are covered, by a complex set of existing regulatory regimes: Chemicals (REACH), Health and Safety of workers, product requirements -for health and safety of workers, consumers and protection of the environment- and legislation related with general environmental protection. In addition, we have identified specific nano-regulation included in non specific regulations.

The scope and objective of our research work has not allowed us to enter on each one of those regulatory regimes and have opted, instead, for selecting REACH as a Case Study, in order to assess if it does cover adequately risks associated with the use of nanomaterials.

Although the Commission considers, basically, that the current legislation covers “in principle” risk in relation to nanomaterials, that current legislation may have to be modified in the light of new scientific data and that regulatory problems have to be

found on implementation and enforcement shortcomings, caused by the knowledge gap, we understand that current legislation framework is designed to cover risk associated with bulk forms of substances and fails to cover some of the new risks associated with nanomaterials.

The Commission that took a leading role when issuing the European nanotechnology strategy has been changing towards a "wait and see" attitude and, instead of proposing initiatives, has sent request for opinion to the different scientific committees, or just accepted the insertion of nano specific provisions on the legislative (recast) process requested by the European Parliament.

On the other hand, we have to mention the positive contributions made by the Commission's "Recommendation on a code of conduct for responsible nanosciences and nantechnologies research" [C(2008)424final] (although not very successful among stakeholders we think that it is a good example of soft law applicable to nanotechnology regulation and hope that the ongoing revision and the necessary modifications will reinforce its role) and the funding increase on the 7th Framework Programme.

In relation to the recent Recommendation of 18.10.2011 ot the definition of nanomaterial, we also consider that a pragmatic position has to be taken. Once we have a legal definition, it is time now to properly review all sectoral legislation and identify the "special provisions" to be applied -being the fundamental ones a robust risk assessment and additional risk control measures guided by an "exposure focused" and/or "commercial relevance" approach- and in the understanding that a modulation of the overarching concept might be necessary (additional qualifiers, specific physico-chemical properties or even to include certain nanomaterials that may fall outside the general definition).

The European Parliament in a Resolution (that was jointly submitted by the five main groups in Parliament and with a virtually unanimous support) was very critical with the Commission handling of the nanotechnology policy in general and with the Commission's Communication on Regulatory Aspects in particular. We consider that the European Parliament Resolution may be considered as the first intent to set up a clear (draft) roadmap for a nanotechnology regulatory regime in the European Union.

France has approved a compulsory reporting scheme in response to the passive attitude from the Commission. The compatibility of this measure with the free movement of goods within the European Union is an open debate. We consider very difficult to put forward legal arguments backing its compatibility. In any case, the French initiative has accelerated the decision making process within the European Union.

The Belgian Council Presidency, catalysing the critical opinion of several Member States regarding the Commission's regulatory framework, proposed to draw up coordinated national strategies including the development of a harmonized compulsory database of nanomaterials and products containing nanomaterials.

From our point of view, it would be advisable to create a European register, including all nanomaterials instead of sectoral databases (because the same nanomaterial may be used in different sectors). Whether the register is centralized at European level or a Member States coordinated databases, we consider that the decision must be based on efficiency, reduced costs and simplicity.

We have taken REACH as a Case Study in order to assess whether current chemical substances Regulation adequately covers risks associated with nanomaterials. Our conclusion is clear; REACH was designed with the bulk substances in mind and when faced with nanomaterials, important regulatory gaps has been found and identified.

From our point of view, the European quest for a European regulatory regime for nanomaterials could be summarized as follows:

1. Need for clear and explicit regulatory framework;
2. Current legislation does not cover the relevant risks relating to nanomaterials. The revision of all applicable legislation -that is under way- needs to identify all regulatory gaps and avoid just (another) formal review.
3. In the short term to address nanomaterials explicitly within the scope of at least legislation on Chemicals (REACH, biocides), food (food stuffs, additives, packaging) relevant legislation on worker protection, as well as legislation on air quality, water quality and waste.

4. Setting up a compulsory reporting scheme where the level of information to be requested may be guided by an "exposure focused" approach or/and the "commercial relevance" approach. Having in mind this tiered information content, a strict interpretation of the "no data – no market" principle to be implemented. All nanomaterials will have to be registered and the information requested might be modulated as previously explained.
5. In all sectoral legislation, nanomaterials have to be considered as new substances.
6. The pre-market approval mechanisms (implemented in the cosmetic and food related regulations) must be analysed in order to conclude if it can be extended to new sectors.
7. Labelling regardless of risk (as far as possible).
8. In the medium term, to initiate a debate on a specific nano regulation embracing ELSI issues above the regulatory response to HSE issues;

Finally, I would like to point to the need to carry out a debate on the role of legal science in the field of nanoscience and nanotechnology (N&N) at the UAB: While the UAB has opted to become a leading European Centre for nanotechnology sciences (being at the forefront the ICN -Catalan Institute of Nanotechnology-, the CIN2 -Research Centre on Nanoscience and Nanotechnology and the BCN-b -Barcelona Nanotechnology Cluster Bellaterra-), the role played by legal science in this challenging project is, to say the least, minor.

In this sense, I totally agree with the importance given by the European Commission to the integration of legal aspects in to scientific research, as stated on the "Recommendation on a code of conduct for responsible nanosciences and nantechnologies research" [C(2008)424final]:

> <<4.2.7. N&N research funding bodies should launch and coordinate specific research activities in order to gain a better understanding of ethical, legal and societal impacts of the new fields opened by N&N.
>
> 4.3.2. In addition to the existence of this Code of Conduct, N&N research funding bodies should make sure that N&N researchers are aware of the relevant legislation, as well as ethical and social frameworks>>.

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