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DEVELOPMENTS IN NANOTECHNOLOGIES REGULATION & STANDARDS - 2012

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The report is based on the collation and analysis of information from a set of representative documents by government departments, regulatory agencies and other authorities, industry and other stakeholders at international level, dealing with the development of regulation and standards for nanotechnologies. The majority of these documents are publicly available. Both a desk research activity and liaisons of ObservatoryNano partners were used to access information.

Priority sources of information include: OECD Working Party on Manufactured Nanomaterials; ISO TC 229, CEN TC352 (and national standards bodies); European Commission activities on nanotechnologies policy and regulation; Relevant European and international projects on these themes.
The present report focuses on the period July 2011- March 2012. Detailed information on previous periods, as well as some background information are available in the ObservatoryNano Regulation & Standards 2010 report and 2011 report.

Abstract

The present document is the last report of a series developed during the 4 years of the EU FP7 project ObservatoryNANO, to monitor the changes in the regulatory landscape (and governance more broadly) of nanotechnologies. It updates those reports and it includes a detailed description of:

- regulatory actions in the most relevant application areas of nanotechnologies;
- activities on nanoregulation in more than 20 countries worldwide;
- initiatives related to voluntary measures;
- standards and international cooperation.

This 2012 report, in addition to the highlights of the most relevant developments that have taken place in the period July 2011–March 2012 complementing the information provided in the three previous reports, includes also a commentary about the overall evolution of nanotechnologies governance during the project time.

Activities and initiatives about Environment, Health and Safety Issues (EHS) as well as Ethical, Legal and Societal Aspects (ELSA) are not taken into account in the report, except where these activities and initiatives are clearly in the context of regulation and standards, for within the project they are the subject of a dedicated effort *(see ObservatoryNano WorkPackage4 and WorkPackage5 reports for more elaborate information on EHS and ELSA [OBS3, OBS4]).*

The information gathered indicates that the European Commission is particularly active in this area and national initiatives of the Member States tend to align to its indications, but also that some European countries are pursuing their own specific initiatives.

The developments in regulation and standards during the period considered by this report can be summarised as follows:

- Publication or revision of definitions of nanomaterials for regulatory purposes (European Commission; Canada; International Cooperation on Cosmetic Regulation, ICCR);
- Publication by the French Government of the final interministerial decree regarding the annual mandatory reporting of “nanoparticulate substances” placed on the market.
- Adoption of the EU Biocidal Products Regulation (BPR) and the provision of Food Information to Consumers (labelling) by the European Parliament, including specifications for nanomaterials;
- Developments of tools and guidelines to put in force the novel Cosmetics Directive in Europe (including specifications for nanomaterials);
- Pre-market notification rules issued by some regulatory agencies for specific nanomaterials (silver nanoparticles, carbon nanotubes (CNT) and others);
- Ongoing review of the application of chemical legislation to nanomaterials (EU, USA, Canada, Australia);
- Publication/revision of tools for risk management of nanomaterials (Switzerland, Denmark, Australia, Korea) and sustainability of nano-related products (UK, USA)
- Achievements in the work on standards (ISO TC 229) and the activities of the OECD Working Party on Manufactured Nanomaterials (WPMN).

Among the main developments expected in the remainder of 2012 are the publication of:

- The revision of REACH for nanomaterials;
- The updated European Commission regulatory review on nanomaterials;
- The possible publication of the EC recommendation for Responsible Research and Innovation (as a follow up of the EC Code of Conduct for responsible nanotechnologies research).

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Introduction

The experience with previous emerging technologies has prompted a growing demand for an approach to governance where R&D and technological innovation and attention to safety and societal aspects have to be part of a unique process aiming to innovate "responsibly", for the benefit of society. Sustainable growth is a key aspect of the Europe 2020 Agenda endorsed by the European Commission [EU1] and this goal is guiding the discussion on the regulation of nanotechnology at the European level.

Despite the efforts undertaken in recent years, the process to develop, whenever needed, suitable regulatory action is complex and lengthy. The prevailing position, at the moment, is towards the use of existing provisions adapted/revised for nanotechnologies. This approach, however, is not completely satisfactory for many and the request to further improve the present situation is strong.

Considering the complex and dynamic evolution of a field such as that of nanotechnologies, other options that can complement (prepare the way for) hard regulation are being considered , including voluntary self regulation and trans-national efforts, such as the development of standards and guidance for nanotechnologies.

Hard Regulation/Enforced Self Regulation

Existing regulatory schemes are being extensively reviewed for their effectiveness to deal with nanomaterials and nano-related products. Generally speaking, with the necessary adaptations for nanotechnologies, they are considered sufficient to regulate this emerging field whilst maintaining the growth of the sector and innovation.

A range of possible improvements and adaptations have been identified, largely varying with the sector considered as well as the approach chosen by the different national/regional authorities:

- Specific guidance and standards to improve implementation and enforcement of existing regulation are being developed worldwide on a number of different sectors (occupational health and worker safety; chemicals and materials; foods; cosmetics; environmental safety and waste) and specific nanomaterials (such as CNT, nanosilver, fullerenes, TiO2). The focus is essentially on the nanomaterials listed in the OECD sponsorship programme - see annex II)

- Priority is given to: regulation of substances and chemicals, with the objective of identifying and evaluating nanomaterials from the beginning of the life cycle of a nano-related product (upstream regulation); regulation of foods and cosmetics (close contact with people).

Various positions are emerging with respect to these approaches, in particular about addressing the safety of consumer nano-related products already on the market as well as life cycle and end of life issues (environment and waste regulatory provisions).

European Union

In a non-binding resolution adopted in April 2009 [EU5], the European Parliament asked for tighter controls on nanotechnologies, in particular in the case of:

- chemicals and materials;
- cosmetics;
- foods;
- occupational health and worker safety;
- environmental safety and waste.

In response to this, the European Commission (EC) is reviewing all relevant legislation with a view to propose regulatory changes where necessary and to develop more nano-specific instruments for the implementation of regulation. This action is in parallel with the 1st revision stage of REACH, that will include an analysis of how submissions of nanomaterials in REACH have been managed so far, and options to adapt REACH to nanomaterials.

The 2nd regulatory review of REACH, which will likely represent a milestone in nanoregulation affairs worldwide, is expected to include specific information about nanomaterial types and uses on the market and relevant safety issues and views on the possible introduction of an EU nano-related product register/database. Publication of these documents is planned in mid 2012 [OECD1, EU16, EU20].

The recast in 2009 of the **Cosmetic Regulation** (EC No 1223/2009, which will come into force in 2013) already includes specific provisions for nanomaterials (definition, requirement for notification, labelling and reporting of nanomaterials) [EU7]. From the implementation plan, the European Commission has established (Jan 2012) the Cosmetics Product Notification Portal (CPNP), a central system where distributors will have to submit information on cosmetics placed on the market, including the presence of nanomaterials (direct access to the database will be limited to authorities) [EC21].

As further guidance for the implementation of the Cosmetic regulation, the European Commission gave a mandate to the Scientific Committee on Consumer Safety (SCCS) to prepare a *"Guidance on Safety Assessment of Nanomaterials in Cosmetics"*. The study will have to provide information on: safety dossiers; assessment of nanomaterials on a category-based approach, rather than on a case-by-case basis; alternative methods for the testing of nanomaterials (considering the EU ban on the testing on animals for cosmetic products after March 2013) [EC31].

A relevant activity toward harmonization in this field is being carried out by the International Cooperation on Cosmetic Regulation (ICCR), a group of cosmetic regulatory authorities from the USA, Japan, Canada and the European Commission. In July 2010 ICCR published a report *"Criteria and Methods of Detection"* of nanotechnologies in cosmetics products (including a list of definitions of nanotechnologies/nanomaterials from different authorities). In June 2011 it released a second report, on *"Currently Available Methods for Characterization of Nanomaterials"* from the ICCR Joint regulator/industry Working Group on nanomaterials [ICCR1, ICCR2].

Following the EU Parliament approval (2nd reading) on January 2012, another step was achieved on the legislative path for the revision of the **EU Biocides Regulation** about placing on the market and the use of biocidal products for non-agricultural uses. The regulation asks for labelling (material plus word "nano" in brackets) and a separate evaluation of the risks deriving from nanomaterials used in these kinds of product [EC22]. Reference is made to the EC regulatory definition of nanomaterials (see below). Examples of applications of biocidal products (that might use nanomaterials) include antifouling agents, biocides in building materials, and antimicrobial surfaces [EC23].

The **Novel food regulation** was expected to include similar requirements in March 2011, but after 3 years of debate it was not approved. The reasons for this decision were not related to issues on nanotechnologies or nanomaterials. The regulation, in fact, besides nano-related products, also included issues linked to cloning which raised many difficult questions, with the result that the entire regulation was deferred [EU10].

Instead, the novel **food information to consumers regulation (EU Regulation 1169/2011)** was eventually approved by the EC (July 2011) and will come into force in December 2014, combining 2 previous directives on "labelling, presentation and advertising of foodstuffs" (2000/13/EC) and "nutrition labelling for foodstuffs" (90/496/EEC). This regulation includes the requirement for labelling of ingredients in the form of nanomaterials (material plus word "nano" in brackets) [EU11].

A reference to safety issues is given by the "*Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain"* published by EFSA (European Food Safety Authority) on May 2011 [EU13].

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) regulates the use of **chemical substances** in Europe. In March 2008, the European Chemicals Agency (ECHA) established the Competent Authorities Sub Group on Nanomaterials (CASG Nano) for this purpose. The Sub Group published two technical guidelines and launched in 2010 three *"REACH Implementation projects on Nanomaterials (RIPoN)"* devoted to the analysis of information requirements, chemical safety assessment and substance identification of nanomaterials in REACH and the related CLP regulation ("Classification, Labelling and Packaging of substances and mixtures"). The reports of the first 2 projects were published in October 2011, the last is currently under review by the European Chemical Agency (ECHA) [EC 27]. Outcomes of these activities on REACH and nanomaterials will be taken into consideration in the extensive review/evaluation of REACH which is expected in 2012 [EU8, EU9, EC20]. In view of these initiatives, some Member States have also undertaken independent analysis on REACH and nanomaterials. An example is the recent study published by the Scientific Knowledge for Environmental Protection network (Aug 2011), undertaken in close collaboration with regulatory authorities in Sweden, UK, Ireland and Finland, to inform Member States about application of REACH to nanomaterials [EC28].

Regarding **occupational health and workers safety**, most efforts are devoted to evaluating and adapting the existing risk management method and to develop appropriate guidance for the handling and disposal of engineered nanoparticles/nanomaterials [OECD1, OBS1, OBS2].

The need to define and agree on specific testing procedures for nanomaterials and to have a better view of concrete exposure scenarios, remains one of the highest priorities. As with the EC mandate, an increasing commitment on the matter is expected by the European Agency for Safety and Health at Work (EU-OSHA), that published in 2009 the report *"Workplace exposure to nanoparticles"* [EC29]. The importance for Europe to investigate the matter has been confirmed by a recent (Dec 2011) EU Parliament resolution [EC30].

Another study has now been undertaken by the EC and EU-OSHA to review the existing EU Occupational Health and Safety Framework (currently covering nanomaterials, even if only by default). This will include analysis of current exposure scenarios and risk management approaches for nanomaterials as well as considerations about the setting of specific Occupation Exposure Limits (OEL) [EC31].

In the case of **medical devices and pharmaceuticals products**, the existing provisions, due to the detailed authorization procedures required in this field, are generally considered adequate for nano-related products, although a case by case approach in the evaluation and authorization procedures is envisaged to take into account the peculiar properties of nanotechnologies [OBS1, OECD1]. One issue is the blurring of regulatory boundaries for advanced nano-related technologies, such as in the case of nanomedical products combining diagnostic and therapeutic functions or products where the nature of the primary mode of action is not clear. Authorities are active in following the state of the art, discussing the consequences of developments in nanomedicine for risk assessment, and are developing guidance.

The European Medicines Agency (EMA) has established a specific expert group on nanomedicine to provide advice and review guidelines on these matters. Some medicinal products based on nanotechnologies have already been approved by EMA. Dedicated pages on the EMA website about nanomedicine and the activities of the WG have been recently created [EU14]. It is acknowledged that the development of

medicines using newer, innovative nanotechnology techniques may raise new challenges for the Agency in the future. The New and Emerging Technologies Working Group of the EC [EC34] is currently working on a 'Meddev guidance document', describing management of risks related to medical devices that make use of nanomaterials in a regulatory context. Meanwhile, the Commission is currently working on a general revision of the regulatory framework for medical devices, which is expected to have special provisions for innovative products, thus potentially including specific requirements for nanomaterials. Furthermore, they have requested a scientific opinion on health effects of nanomaterials used in medical devices from SCENIHR [EC35].

The issue of an agreed **definition of nanotechnologies and nanomaterials** has been debated for some time. Following the working definition set by the International Standards Organization in 2005, a number of other drafts have been considered by international bodies, regulatory agencies, professional organizations and others worldwide. Taking into account only recent initiatives, these include the International Cooperation on Cosmetic Regulation, ICCR (2010), Health Canada (2011), NICNAS Australia (2011), the French Government (2011). In October 2011, after one year of drafting work and public consultation, the EC published a conclusive (non draft) definition of nanomaterials for regulatory purposes, intended to provide a common reference for the different EC provisions including specifications for nanomaterials (see text box 1) [EC24]. Individual legislations may further detail the scope of the definition (that is using only size as metric) depending from the considered application.

The matter remains, nevertheless, controversial, due to scientific challenges (including choice of appropriate metrics, physical and chemical states, dimensional range, size distribution, etc), different needs related to the context considered (e.g. regulatory vs. scientific purposes; sectors of application, etc) as well as the possible technical and economical implications.

Text Box 1: "core terms" of the European Commission definition of nanomaterials [EC24]:

"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 %.

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.

Note: The definition excludes nanostructured materials having an internal or surface structure in the range between 1-100 nm (e.g. electronic components).

European States

The current EU regulations provide the most important framework for activities in this field at national level by the EU Member States. In general, national regulatory agencies must align with EU regulations, with the possibility to implement specific (more detailed or tighter) regulations at a national level.

In addition, many European Countries, in particular those that are most active in nanotechnologies, have started their own activities on regulation of nanotechnologies/nanomaterials. These are mainly in relation to occupational safety and health aspects, chemicals, and foods.

Research on EHS issues and regulatory aspects are included as a priority in all countries that have a nanotechnologies development strategy/plan. Among them, the most active are France, Germany, Switzerland, the Netherlands, and the UK.

Almost all other countries surveyed[1] have at least some initiatives on these matter and are linked to activities at EU level through participation in working groups at the institutional level (such as different Technical Committees of Member States authorities, the OECD WPMN, the EU NanoSafety Cluster of the European Commission[2]). In particular, regarding Occupational Safety and Health issues (OSH), those countries that have working groups at the institutional level, are developing guidelines and support specific research activities on the matter.

Regarding chemicals, the way nanomaterials are considered in REACH will strongly influence regulatory actions at national level. The current general attitude of Member States is to discuss REACH implementation issues for nanomaterials (in view of the planned 2012 review), instead of taking into consideration reviews to national regulation, to avoid duplication [OBS2, OECD1].

As already stated, the REACH review will provide information on nanomaterial types and uses, safety aspects as well as views regarding on an EU database/register of nanomaterials. On this latter point the EC has recently commissioned a study to investigate methodologies for the development of an inventory of consumer product containing nanomaterials (published in December 2011 by RIVM [NL4]).

On this issue **France**, following public consultation, has finally published (Feb 2012) the interministerial decree n.2012-232 (involving the Ministries of the Environment, Health and Labour, Agriculture, Defence, Justice) for a mandatory reporting scheme for the quantities and uses of nanoparticle substances or nanomaterials that are produced, distributed or imported in France. The decree, that will enter into force on January 2013, applies both to companies and public and private research laboratories producing, distributing and importing at least 100 grammes/year of substances. The scheme, that includes details on definitions, frequency of reporting and confidentially issues, is meant only as an information gathering tool, and does not foresee any restriction or limitation to the use of reported nanomaterials [FR4, FR5, FR6].

France is also publishing a series of technical guidance documents related to nanotechnologies (OSH aspects of nanomaterials in general, including a recently published *control banding* tool; carbon nanotubes; medicinal products, medical devices [FR1, FR2, FR3]).

In **Germany,** in the Nano Action Plan 2011-2015 promoted by the Federal Government, the need to develop appropriate regulation and standards for nanotechnologies is included as a priority [DE1]. One

[1] The countries surveyed at European level, selected based on their activity on nanoregulation have been: Austria, Czech Republic, Denmark, France, Italy, Ireland, Norway, Germany, UK, The Netherlands, Switzerland. Further information is available In the ObservatoryNano Regulation & Standards 2010 and 2011 reports.

[2] The EU NanoSafety Cluster is an EC initiative (DG RTD NMP) to coordinate FP6 and FP7 projects addressing aspects of nanosafety including toxicology, ecotoxicology, exposure assessment, mechanisms of interaction, risk assessment and standardization. - http://www.nanosafetycluster.eu/

action has been the launch of the German NanoKommission Dialogue Initiative that involved, in the period 2006–2011, key national nanotech stakeholders to debate the opportunities and the risks of nanotechnologies. The results have been condensed into two detailed reports, providing research and policy recommendations to the Federal Government [DE3]. As a follow-up of the initiative, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) is organizing (2011-2012) Expert Dialogues focused on specific issues (risk management, sustainable and green nanotechnologies) [DE4].

The German Advisory Council on the Environment (SRU) published (Sep 2011) the report *"Precautionary Strategies for managing Nanomaterials"*, to investigate a principle enshrined both in the German and European regulatory frameworks. A series of policy recommendations has been provided, suggesting tighter control of nanomaterials in existing regulations, labelling, and further research on risks [DE5].

Several documents and guidance have been published in the past few years by German authorities and stakeholders on EHS issues and nanotechnologies[3]. In the last year, the Federal Institute for Occupational Safety and Health published a review report on OSH activities and policy issues (Dec 2011) and coordinated a study (with a number of German public and private organizations) on approaches for exposure assessment of nanoscale aerosols at the workplace (published in Aug 2011) [DE6, DE7]. DECHEMA and VCI[4] published (Oct 2011) the report *"10 Years of Research: Risk Assessment, Human and Environmental Toxicology of Nanomaterials"* summarising results of German and EU projects on safety of nanomaterials [DE8]. In the conclusion it is remarked the need to perform *"where necessary in individual cases"* a risk assessment based on internationally validated OECD methods and testing guidelines for nanomaterials (see last paragraph and annex II).

In terms of regulation, the **United Kingdom** supports EU initiatives [UK1, UK2, UK5], however it is promoting a 'case-by-case' approach to assess the risk and suitable use of individual nanomaterials in food and food contact materials. The UK Food Standards Agency monitors on a regular basis the regulatory situation of these products [UK4].

A major programme to support research on EHS issues related to nanotechnologies is the Environmental Nanosciences Intiative set up by the Natural Environment Research Council (NERC), the Department for Environment, Food and Rural Affairs (DEFRA) and the Environment Agency, running since 2006 [UK6]. Several studies on safety issues of specific nanomaterials (in particular nanosilver, carbon nanotubes, iron nanomaterials) and, among others, a bilateral call for research projects on environmental issues with the USA are ongoing [UK2, UK3, UK4, OECD1]. DEFRA also published a guide providing *"A comparative methodology for estimating the economic value of innovation in nanotechnologies" [UK7]*.

Some new standards documents are being developed by the British Standards Institution (BSI) including a guide for SMEs on nano regulation and a guide to disposal of waste containing nanomaterials [UK8]. The UK chairs the ISO TC 229 for the development of standards for nanotechnologies (see paragraph on standard work).

[3] Refer to the 2010 and 2011 ObservatoryNano Regulation& Standards report [OBS1, OBS2], for details
[4] Dechema is the German Society for Chemical Engineering and Biotechnology, VCI is the German Chemical Industry Association

The Netherlands has a clear commitment towards responsible innovation, and the principles of precaution, inclusiveness, transparency, risk/benefit balance are clearly set out in its nanotechnology development strategy. Various guidance materials are being developed on issues such as regulation, the precautionary principle, risk management, information sharing, consumer information and societal dialogue [NL1, NL2]. Research on safety issues is considered a priority, with relevant funding allocated (and required) in national nanotechnology research activities. In response to the EC recommendation on a Code of Conduct for nanotechnologies, the Netherlands has introduced a contractual obligation to comply with this Code in its national funding schemes for nanotechnology [OBS2, OECD1, EP1, NL3].

In **Denmark**, the Danish Ministry of Environment has included safety and regulation of nanomaterials amongst the priority of the Chemicals Action Plan 2010–2013. The Danish Environmental Protection Agency (DEPA), following 2 previous reports (in 2007), published (Sep 2011) the *"Survey on basic knowledge about exposure and potential environmental and health risks for selected nanomaterials"*, including evaluation of commercial use and quantity of the selected nanomaterials. Relevant data has been in particular gathered for Titanium dioxide (TiO2), Silicon dioxide (SiO2) and Nanoclays. DEPA also made available at the end of 2011 a tool to support evaluation of exposure and hazard of nanomaterials, the *"NanoRiskCat - A Conceptual Decision Support Tool for Nanomaterials"* [DK1. DK2].

In **Austria**, within the Austrian Nanotechnology Action plan, in 2011 a national EHS funding programme was launched and the Federal Ministry of Labour, Social Affairs and Consumer Protection has issued a guidance on safety issues in occupational settings for nanomaterials [AU1].

In **Ireland**, the Irish Health and Safety Authority has published an information sheet about safety at the workplace and launched in September 2011 a voluntary survey on the use of nanomaterials [IR1].

In **Italy** the Italian Workers' Compensation Authority (INAIL) coordinated a network of research organizations that led to the publication (2011) of a White Book on occupational health and safety effects of engineered nanomaterials [IT1].

As planned in the Action Plan on risk assessment and risk management of synthetic nanomaterials, **Switzerland** continues to closely monitor the regulatory situation and provide technical guidelines to support implementation of existing regulation as well as consumers' and stakeholders' awareness on safety issues. A review report on the Action Plan implementation is in preparation [CH1].

A joint effort between different authorities led to the publication of the *"Precautionary matrix"* (a multi-language web version was made available in Sep 2011), the *"Guidelines for safety data sheets"* and reports on *"Nanoparticles at workplaces"*. A working group has been established to study the disposal of waste from production, industrial processing and commercialization of nanomaterials (a draft report is already available) [CH1, CH3, CH4].

At the end of 2010, the results of an initiative promoted by the Swiss Federal Office of Public Health (FOEN) with key nanotechnology stakeholders were published (NANO Dialogue Platform, with a focus on consumers information, [CH2]). Issues related to the need for a definition of nanomaterials, labeling within foods, cosmetics, chemicals, and waste regulations were considered. As in the German case, there has been a unanimous agreement on the need for a coherent approach on regulatory matters between Swiss and EU regulations.

Non European Countries

Looking beyond Europe, the **USA, Canada** and **Australia** are the most active regarding nanotechnologies regulation.

In the **USA**, the Environmental Protection Agency (EPA) has, under the Toxic Substances Control Act (TSCA - the US regulatory provision for chemical substances), a dedicated activity on the regulation of nanomaterials.

A very basic difference with respect to the EU approach is that under TSCA the burden of proof regarding the safety of a substance is on the regulatory authority (and not on the manufacturer, as within REACH).

As in other regulations, nanomaterials are not explicitly mentioned in this statute. However, a series of actions has been put in place in the last few years to ensure notification and registration of nanomaterials. In particular *"Significant new use rules (SNUR)"*, a notification asked of companies if there is any significant new use of existing chemicals, are issued on a regular basis for specific use and type of nanomaterials (mainly carbon nanotubes, fullerenes, titanium and silica based compounds). EPA is planning to adopt such procedures for any new nanomaterials, in order to gather detailed information about the use, characteristics and safety issues, before these nanomaterials are put on the market (this would be accomplished through definition of rules under section 5 and 8 of TSCA) [US1].

EPA, under the FIFRA statute (Federal Insecticide, Fungicide and Rodenticide Act), is carefully reviewing pesticide products containing nanomaterials, in particular nanosilver, that would be used in a range of products (e.g. textile, plastic, etc.) to improve their antimicrobial properties. In an official notice published in June 2011, EPA proposed a new approach that would consider any nanomaterial as a new active ingredient for the pesticide regulation (thus differentiating them from their macro-form). Several comments have been received from stakeholders and EPA is currently reviewing them [US4, OECD1].

A task force on nanotechnologies has been active within the Food and Drug Administration (FDA) since 2007. The general approach to nanoregulation of the FDA is that existing regulation adequately covers nano forms of substances, though a careful review is generally devoted to nanotechnology products. In June 2011, the Agency issued a short draft guidance on *"Considering whether an FDA-regulated product contains nanomaterials or otherwise involves the use of nanotechnology"*, with consideration of a definition of nanotechnologies [US2].

The National Institute for Occupational Safety and Health (NIOSH) regularly updates its series of authoritative guidance on OHS issues of nanomaterials [US3].

Recently, the Office of Research and Development at EPA performed a study for integrating sustainability into the evaluation, management and development of nanoproducts and published (Sep 2011) the *"Guidance to facilitate decisions for sustainable nanotechnology"* [US7].

A joint commitment between the USA and EU to promote transatlantic cooperation in regulation and safety issues related to nanotechnologies led to the establishment of bilateral research activities on these matters as well as a series of meetings between US and EU authorities [US5].

The USA chairs the ISO TC 229 Working Group on Health, Safety and the Environment.

In **Canada** the strategy *"Proposed Regulatory Framework For Nanomaterials Under The Canadian Environmental Protection Act, 1999"* is set to review the application of existing regulation for nanomaterials and is managed by the two main regulatory authorities, Health Canada and Environment Canada. The strategy includes: support to national and international stakeholders; cooperation on research and standards development; information gathering initiatives; data requirements; legislative amendments for nanomaterials [CA1, CA2].

Following this plan, the two agencies jointly published in October 2011 the *"Interim Policy Statement on Canada's Working Definition for Nanomaterial",* after almost one year of public consultation and review of the document. The definition, that is expected to be updated on the basis of scientific knowledge and progress in international standards, applies to manufactured nanomaterials and makes use of size as its metric (1-100nm). It provides a general guidance that could be applied under different regulatory provisions (chemicals, foods and foods additives, drugs, medical devices, cosmetics, pesticide) in order to specify requirements for gathering information on use, characteristics and safety issues of nanomaterials entering the market [CA3].

Under the *Canadian Environmental Protection Act* (CEPA 1999), regulating chemical substances, a provision called *"Significant New Activity (SNAc)"* has been used for notification and to require submission of additional safety information about the specific use and type of nanomaterials placed on the market. Other sectors, where notification for the use of nanomaterials has been recently reviewed, include pharmaceuticals and foods. [CA1, CA2, OECD1].

Canada chairs the ISO TC 229 Working Group on terminology and nomenclature.

In **Australia,** the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), has developed a specific strategy for the regulation of nanomaterials, supported by an in depth stakeholder consultation concluded at the beginning of 2010 (*"Proposal for Regulatory Reform of Industrial Nanomaterials"*). Based on this consultation, a working definition for "industrial nanomaterials" was agreed with stakeholders and officially adopted at the end of 2010 (it may be further changed in the future, also in view of international harmonization). The definition applies to intentionally produced manufactured nanomaterials, it also includes nanostructured materials and uses size as a metric (1-100nm). It sets a threshold of 10% or more for the number of particles within a material that have to comply with the definition requirements [AU1, AU3].

As a first action of the strategy, since January 2011 Australia has implemented a guidance for *"Requirements for notification of new industrial nanomaterials"* making it compulsory for pre-market notification and submission of safety information of new "nanomaterials" (as defined above) to be placed on the market [AU3]. The document makes explicit reference to OECD WPMN test guidelines.

With respect to materials in nano forms classified as existing chemicals, the development of a mandatory reporting scheme (or product register) is one of the options currently under consideration by NICNAS [AU4].

An intense activity on nanoregulation is also ongoing from other Australian authorities to review existing provisions and increase the knowledge base through specific research programmes. In particular, Safe

Work Australia has launched a "*Nanotechnology Work Health and Safety Program"* to develop appropriate tools and methods related to occupational and health issues. These include the *"Work health and safety assessment tool for handling engineered nanomaterials"* and a draft guidance to introduce nanomaterials into Safety Data Sheets and labeling procedures [AU2].

With regards to **Asia**, the countries analysed were **China**, **Japan**, **India**, **Taiwan, South Korea** and **Thailand** [OECD1, OBS1, OBS2]. Seemingly, none of these countries is planning specific regulatory actions for nanotechnologies, but are looking at legislation developed in Europe and the USA as a benchmark for the development of their own. They pay particular attention to the debate on REACH and nanomaterials. Nevertheless, the countries mentioned above are generally quite active in the field of standardization and all have initiatives and research programmes at institutional level on nanomaterials, in particular regarding OSH aspects.

In **Japan** the Ministry of Economy, Trade and Industry (METI) has supported, since 2008, a voluntary information gathering initiative related to the safety of nanomaterials in industry (the last periodic report was published in March 2010). In December 2011, METI announced the creation of the Committee on Safety Management for Nanomaterials to increase knowledge on risk management of nanotechnologies [JP2]. Several projects are being funded on EHS issues. Particularly important is the recently launched 5 year METI programme (Sep 2011) on *"Development of Innovative methodology for Safety Assessment of Industrial Nanomaterials"* [OECD1].

Two main reports (also in English) have been published in late 2011 on risk assessment of three nanomaterials (TiO2, Fullerenes and CNT) [JP3]. Research reports on OHS issues of nanomaterials have been published also by the National Institute of Occupational Safety and Health Japan (JNIOSH) [JP4].

Japan chairs the ISO TC 229 Working Group on measurement and characterization.

The Republic of South Korea has established the interministerial *"National Nano-safety Strategic Plan (2012-2016)"*, that includes support and funding to a number of projects on safety and regulatory issues of nanotechnologies. The Ministry of Knowledge and Economy (MKE), and the affiliated Korean Agency for Technology and Standards, have prepared a *"Guidance on safe management of nanotechnology based product",* published in May 2011 as a Korean standard, and are developing a standard work on exposure monitoring and assessment of carbon nanotubes and nanosilver. The Ministry of Environment (MOE) is developing a voluntary survey on the production and use of nanomaterials to develop an inventory of nanomaterials in the market [OECD1].

In **Taiwan**, within the framework of their Strategic Plan for Responsible Nanotechnology (2009-2014), the Nanomark Certification System (coordinated by ITRI, the Industrial Technology Research Institute) has been active since 2004. This is a voluntary reporting and certification scheme that aims to increase public confidence in nanotechnology products [TW1]. In effect it is also seen as a positive step, as it is a requirement for companies to sell nanotechnology products to government departments and public authorities.

In **Thailand** nanosafety is among the priorities of the national policy on nanotechnologies. A strategic plan on safety and ethical issues was approved in 2011 that will be managed by the National Nanotechnology

Center (Nanotec). This includes the creation of an industrial standards certification for nanotechnologies related products (called NanoQ, [TH1]). An agreement between Nanotec and the United Nations Institute for Training and Research (UNITAR) was signed in September 2011 to collaborate on nanosafety issues.

Voluntary Self Regulation (soft regulation)

Risk management systems, reporting schemes and codes of conduct are measures that can have an important role to cope with current uncertainties about the impact of nanotechnologies and during the redefinition of existing hard regulation. They address key issues for the implementation of responsible practices, such as: risk evaluation, early engagement of stakeholders, sharing of information, building of trust and confidence at different levels.

Some stakeholders at the industrial level have developed (or are developing) their own **risk management systems**, defining best practises and procedure for safety control and handling of nanomaterials in occupational settings, as well as certification tools that help to evaluate and monitor performance in risk management (for nanotech). The situation in terms of new initiatives is almost unchanged compared to previous ObservatoryNANO reports. However, it should be noted that there is an increasing number of self-evaluation tools for risk management made available by authorities dealing with OSH issues. These have been mentioned above (Precautionary Matrix, Switzerland; Control banding tool, France; NanoRiskCat, Denmark; EHS assessment tool, Australia). Also interactive web fora and training tools are being regularly updated and improved, such as the US GoodNanoGuide [US6] from the International Council on Nanotechnology at the Rice University, and the Nanosmile-Safety of Nanomaterials website developed by CEA in France [FR7].

In parallel, since 2007, there have been several attempts from government agencies to develop (voluntary) **reporting/data gathering schemes** on nanomaterials, as complementary actions to regulation. As described above, these are generally under the responsibility of authorities in charge of regulating chemicals.

These initiatives aim to complement existing regulation (or prepare the ground for new ones), helping to gather detailed information on the introduction and use of nanomaterials and nano-related products to the market (among the data generally provided/requested are their type, use, quantity and safety aspects). Recently, voluntary reporting schemes have been undertaken in Ireland, South Korea and Japan [IR1, OECD1].

Another approach has been to collect information on nano-related products on the market using surveys and in depth desk research. Recent examples are the inventory of consumer products of the European Commission/RIVM [NL4] and the Denmark EPA survey [DK1]. In terms of non-governmental activities in this area, the Association of European Consumer Groups (BEUC) and the Project on Emerging Nanotechnologies in the USA have both produced inventories of consumer products on the market (Ot4, Ot5].

A key example of voluntary measure is the EC's "***Code of Conduct for responsible nanoscience and nanotechnologies research" (February 2008),*** which provides principles and indications to guide research activities [EU4]. Its objectives are far reaching and among the principles that must be respected are: (a) Sustainability, (b) Precaution (c) Inclusiveness and (d) Accountability. The EC actively promoted the Code and recommended all Member States to adopt it, but the answer was tepid. A specific project of FP7,

concluded at the end of 2011, (NanoCode) was funded to provide indications/suggestions, support its implementation and adoption, as well as its further revision [EP1].

Despite a quite limited endorsement of the Code by EU Member States (the only case has been the Netherlands), the project showed an unambiguous agreement on the Code's principles as well as a general interest in the tool from a broad range of stakeholders. However, several drawbacks were underlined, including the need to improve its format and to develop a robust implementation process. A strong commitment by all research governing bodies and the acknowledgement and sharing of principles and practices by all stakeholders are key aspects to promote its wider application. Despite its lukewarm acceptance, the tool had a role in encouraging and broadening a dialogue at European and international level on the responsible development of nanotechnologies.

Within the policy actions supporting the building of the European Research Area, and as a follow up of the EC Code of Conduct, it is likely that the European Commission will publish in late 2012 a recommendation on Responsible Research and Innovation, addressing all Key Enabling Technologies [EC26].

However, the voluntary nature of all these initiatives has some drawbacks.

When endorsed by public/government bodies, they have often received, a tepid response, such that some have suggested, for example in the case of reporting schemes, to make them mandatory, as it will happen in France. Other countries (like Canada and Australia) are considering similar actions, but in the end the general attitude is to wait for the possible review of chemical and products regulations (as is debated in the EU, USA, Canada and Australia), that could make the notification of nanomaterials to be placed on the market compulsory, therefore responding (at least partially) to the demand for having an inventory of nanomaterials and nano-related products in use.

When, on the contrary, they are endorsed by private companies, these measures, although generally viewed as a sign of responsible behaviour, by some (in particular Civil Society Organizations) are considered not very effective due to the lack of external control.

Voluntary measures, in any case, can play, as said, an important, constructive role in the present state of nanoregulation, to build a knowledge base to support policy and regulatory decisions, and on nanotechnologies oversight. Therefore they should be retained while finding ways to overcome their limitations and encourage people to use them, without changing their nature.

The panorama of voluntary measures which has not substantially changed during the period covered by this report is summarised in Text Box 2 [OBS2, EP1, OECD1].

Text Box 2: Examples of voluntary measures related to nanotechnologies [5]

Codes of Conduct/Practice

- CoC of EC for Responsible Research (EC)
- German NanoKommission "Principles" (DE)
- Responsible Nanocode (UK)
- BASF Code on nanotechnologies (DE, global)
- IG-DHS- Swiss Retailer Association Code on nanotechnologies (CH)

Risk Management Systems

- Responsible Care Global Charter (ICCA–Int. Council of Chemical Associations)
- DuPont NanoRisk Framework (USA)
- Bayer, Royal DSM, Evonik risk management systems for nanotechnologies
- Cenarios (CH)
- Stoffenmanager Nano (NL)
- AssuredNano (UK)

Reporting/Data Gathering Schemes
(in brackets the regulatory authority or agency leading the initiative)

- Europe: UK (DEFRA), Germany (BAuA), Norway (Climate and Pollution Agency), Ireland (HSA)
- Other Countries: USA (EPA, FDA), Australia (NICNAS), Japan (METI), Taiwan (Nanomark, ITRI), Thailand (NanoQ), Korea (MOE)

Trans-national efforts: the standards work

The availability of appropriate **standards** to name, describe, specify, measure and characterize nanomaterials is pivotal to implement an appropriate regulation for nanotechnologies-related products.

The **International Standards Organization** (ISO) Technical Committee (TC) 229, in conjunction with the **International Electrotechnical Commission** (IEC) TC 113 (and other national standards bodies), has been directing activities on nanotechnologies standards since 2004. European standards activities are coordinated by the **European Committee for Standardization,** Technical Committee on nanotechnologies (CEN TC352). There is a strong liaison between CEN TC352 and ISO TC229. Where possible, CEN will follow the developments at international level.

ISO TC 229 is organized into 4 working groups (WG) that focus on issues that are crucial for the development of an effective regulation for nanotechnologies-related products [ISO1]. Specifically:

- Terminology and Nomenclature (WG 1)
- Measurements and Characterization (WG 2)
- Health, Safety, and Environment (WG 3)
- Materials Specification (WG 4)

At present there are more than 40 standards documents[6] related to the above themes that have been published or are under development, but due to the lengthy process, it will be some time before the matter is thoroughly addressed.

[5] These initiatives have been described in detail in previous ObservatoryNano regulation and Standards reports (2009, 2010, 2011) – www.observatorynano.eu

A total of 22 standards are now available (see annex I), 11 of these have been published in the last year. They refer to fundamental issues such as terminology (definition and classification of nano-objects, framework and core terms, carbon nanomaterials, bio-nano and health applications); characterization (nanoparticles and carbon nanotubes); protocols for toxicity testing; health and safety practices at the workplace.

Various ISO Technical Committees, national standards bodies, such as BSI/NT1 in UK, SAC/TC279 in China, ANSI-NSP in USA, and standard developing organizations such as ASTM and IEEE have all produced standards relevant to nanotechnologies. Most of these activities are in liaison with ISO TC229 and IEC TC 113[7] and are mirrored by work in European standards bodies: the European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI)[8].

In 2010, the European Commission drafted mandate M461 for the development of standards in the broad area of nanotechnologies and nanomaterials. At the end of 2010, CEN, CENELEC and ETSI accepted this mandate. For the execution of the mandate, which covers a large range of topics, it was decided that CEN TC352 would coordinate the programme. TC352 was given the task to liaise with all relevant European and international committees and ask these committees to start work on topics in their area of interest, as identified by the mandate. Currently, this large programme is being initiated. A survey of needs and a preliminary roadmap have been drafted, and the involved committees are at varying stages of progress [EU19]. For example, in April 2012, a working group has started within ISO/TC194 to develop a technical specification for biological evaluation of medical devices utilising nanomaterials. CEN activity is structured in 3 WGs:

- Measurement, characterization and performance evaluation (CEN/TC 352/WG 1)
- Commercial and other stakeholder aspects (CEN/TC 352/WG 2)
- Health, safety and environmental aspects (CEN/TC 352/WG 3)

Some key aspects are being taken into account in CEN work, as stated in the business plan [CEN1]:

- The precautionary principle (as mentioned in the EU treaty), in particular the need for an assessment of both risk and benefits of nanomaterials;
- The need for assessments of nanomaterials safety impacts along all the lifecycle, and prior to commercialization;
- EHS protection and safety, in particular preventing potential exposure to nanomaterials that have been proven unsafe.

On standards and harmonization issues related to measurement at the nanoscale (nanometrology), the European Project Co-Nanomet published in January 2011 an in-depth review and discussion paper on the matter [EP3]. Current status, future needs and opportunities in different key areas[9] for nanometrology are addressed by the document. The project NanoImpactNet [EP4] provided a list of research protocols for hazard assessment development by different FP6 and FP7 EU projects. Other projects, which started in 2011, are expected to produce further guidance on EHS issues in the near future. These includes: Dana, SIINN, Qnano, Marina, Nanovalid and NanoTranskinetics [EP6].

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[6] A list of standards under development is available in the ISO TC 229 website [ISO1].

[7] A specific procedure called the 'Vienna Agreement' is generally used to coordinate activities between the different standard bodies.

[8] A list of activities and references in nanotechnologies of different national standard bodies is available in the ObservatoryNANO Regulation & Standards 2010 report [OBS1]

[9] The areas considered by the report are: engineered nanoparticles, nanobiotechnology, thin films, critical dimensions and scanning probe techniques, modelling and simulation.

A contribution to the standardization activities comes from the eight Steering Groups of the **OECD Working Party on Manufactured Nanomaterials** (text box 3) which is gathering reference data and information on characterization and safety of nanomaterials, and liaises with ISO TC 229 and other relevant authorities. WPMN was established in 2006 and has members from more than 30 countries worldwide [OECD2]. A list of available publications of the OECD WPMN is reported in annex II.

Text Box 3: OECD WPMN Steering Groups
SG1: Database on Human Health and Environmental Safety Research (launched in 2009).
SG2: Research Strategy(ies) on Human Health and Environmental Safety Research
SG3:Testing a Representative Set of Manufactured Nanomaterials (MN): Sponsorship programme for the testing of 14 MN
SG4:Manufactured Nanomaterials and Test Guidelines: Development of guidance on sample preparation and dosimetry for the testing of manufactured nanomaterials.
SG5: Co-operation on Voluntary Schemes and Regulatory Programmes: Analysis of national information gathering programmes and regulatory frameworks.
SG6: Co-operation on Risk Assessment: Review of existing risk assessment schemes and their relevance to nanomaterials
SG7: The Role of Alternative Methods in Nanotoxicology: Reviewing alternative test methods which will avoid animal tests and which will be applicable to manufactured nanomaterials.
SG8: Exposure Measurement and Exposure Mitigation: Development of recommendations on measurement techniques and sampling protocols for inhalation and dermal exposures in the workplace.

At the beginning of 2011 the Joint Research Centre (JRC) of the EC, within the activities related to the OECD WPMN sponsorship programme, launched a nanomaterials repository providing standards samples of different type of nanomaterials and the NanoHub database on safety issues. Both initiatives are updated regularly [EU15, EU16].

OECD has engaged with other international bodies active in the field of nanomaterials safety. Several meetings and workshops on these issues have been held in the framework of **the Inter-Organization Programme for the Sound Management of Chemicals (IOMC)** [IOMC1].

In particular, the Food and Agriculture Organization of the United Nations (FAO), the United Nations Institute for Training and Research (UNITAR) and the World Health Organization (WHO) have initiated activities on nanotechnologies, with a focus on increasing awareness of potential risks and benefits in developing countries.

FAO is promoting initiatives (in particular meetings and events) on benefits and risks of the application of nanotechnologies in fields such as food, water and agriculture sectors. It published in 2010 a report on *"Application of nanotechnologies in the food and agriculture sectors: potential food safety implications"* [FAO1]

UNITAR aims to foster awareness-raising about risks, opportunities, responsible development of nanotechnologies in developing and transition countries. A series of workshops have been undertaken in the period 2009-2011 covering some world macro regions (Europe, Asia-Pacific, Africa, Latin America, Arab region). A survey to identify information on legislation and national governance, as well as experience in raising awareness has been recently concluded. UNITAR promotes also bilateral agreements with

developing countries to promote training activities on nanotechnologies. A first example is the cooperation started with Thailand on nanosafety (see first paragraph) [UNITAR 1, 2].

WHO has published a draft document proposing guidelines for *"Protecting Workers from Potential Risks of Manufactured Nanomaterials"*, mainly targeted to the protection of workers in low and medium-income countries. The document has been available for public consultation until March 2012 [WHO1].

Conclusions

Although it must be remembered that, to date, there is no conclusive evidence that nanomaterials are causing more harm than other existing materials or products, the demand for proper regulation of nanotechnology-enabled products remains high.

The prevalent position amongst authorities and industries is that existing legislation, adapted for nano-related products, is able to deal with the risks potentially associated with them.

This approach, however, is considered by many, in particular Civil Society Organizations (CSOs), as being insufficient and the quest to clarify existing uncertainties is strongly advocated.

In the period considered by this report (July 2011 – March 2012) the debate around the need to introduce further adjustments/amendments for nanomaterials in regulatory provisions in the EU and some other countries has continued.

Particularly important for regulation is the development of a harmonized definition for nanomaterials and the debate has involved ISO, the EC and other regulatory bodies. The EC published its recommendation for a regulatory definition that will be used as reference in all EC regulatory provisions related to nanotechnologies. Other regulatory authorities and organizations have implemented different draft or working definitions.

In Europe, two EU regulations already include provisions to identify and notify nanomaterials, the Cosmetics Directive (which will enter into force in 2013) and the Food Information to Consumers regulation (which will enter into force at the end of 2014), while a third one should be approved soon, the novel Biocides Regulation.

The 2nd regulatory review of nanomaterials, expected in 2012, and including provisions related to REACH, will likely introduce further requirements for nanomaterials and nano-related products.

France has just implemented a mandatory reporting scheme for nanomaterials on the market, and some similar actions are under consideration in Canada and Australia. Other authorities continue to use voluntary reporting schemes, as shown by the ongoing initiatives in Ireland, Japan, and Korea.

Among the countries most active on nanoregulation, Australia and Canada are both considering regulatory reform of nanomaterials, with Australia having already implemented specific provisions for new nanomaterials placed on the market. In the USA, the Environmental Protection Agency is carefully reviewing nanomaterials placed in the market, through standard review procedures foreseen in existing regulatory provisions for chemicals and pesticides (e.g. EPA *"Significant new use rules"*).

Improved notification and registration procedures, specific guidelines for safety assessment, labelling and inventories of the use of nano-related products are among the aspects under scrutiny for the regulation of nanomaterials and nanotechnologies.

The evolution of nanoregulation can influence the path of the development of nanotechnology-related product and processes. Indicating the technology sectors most affected by eventual changes in legislation to accommodate nanotechnologies has been a priority of the ObservatoryNANO survey since the beginning. The present situation is summarised in Annex III, but a close attention to highlight eventual unintended, unforeseen, effects of regulation on innovation from nano-enabled products and processes will always have to accompany technology planning.

Another important challenge for nanoregulation is the need for international harmonization of provisions, at least in their principles and aims, to assure a similar/common level of attention and response to EHS issues and ELSA, and to avoid different rules for commercialization and hindrances to trade. This point has strong political implications, but it must be pursued with strength.

Europe is aiming, at least amongst its Member States, towards this goal and the transatlantic initiatives that are being promoted are trying to overcome this issue.

In conclusion, nanoregulation requires a dynamic, transparent and inclusive approach: it must adapt to the evolution of scientific knowledge, to the increase in applications, to the evolving concern and attitude of current and potential stakeholders, to the changes in international relations.

In our view, an appropriate balance between hard and soft regulation continues to be the most efficient option in the short to medium-term.

COMMENTARY: 4 years of ObservatoryNano analysis

Nanotechnologies are amongst the Key Enabling Technologies (KETs) set in the Europe 2020 Agenda as drivers for development. They are already having a relevant impact on society and the economy and great expectations rest on their future development. However, in this process some key challenges can easily be identified:

- Only a few of the applications have reached a mature technology readiness level. As for other KETs, there is a consistent gap to overcome in order to translate R&D concepts and results into innovation (application and products on the market);
- Their impressive capabilities are also the source of divergence and uncertainties about the possible risks for environment, health and safety (EHS) and the ethical, legal and societal aspects (ELSA) of their use;
- Scientific knowledge and experience on EHS (and ELSA) is still limited, challenging the application of existing procedures (or the development of new ones) for the evaluation, monitoring, handling of specific nanomaterials and nanotechnologies applications;
- The proprietary nature of information on novel materials and the lack of harmonized standards or guidance (somehow typical of immature technologies).

Regulation of nanotechnologies is a cornerstone of this process. On the one hand, regulatory limitations and constraints could place (another) burden on the innovation and commercialization of nanotechnologies, but on the other hand a well-defined regulatory regime could provide common, unambiguous rules to deal with EHS, ELSA and proprietary data, thus facilitating their use. In the end promoting Responsible Research and Innovation (RRI) can become a way to gain a competitive advantage.

The past 4 years, the duration of the ObservatoryNANO project analysis, have seen the rise of a real *momentum* on the debate on nanotechnology governance.

In 2008 there were essentially two opposite positions confronting each other: the call for a moratorium on nano–related products, in consideration of the “unknowns” about their impacts, against a *business as usual* attitude confident in the robustness of existing regulatory regimes to deal also with nanotechnologies.

The publication of the European Commission regulatory review for nanomaterials (in 2008), accompanied by the general debate on the novel REACH regulation (it came into force on June 2007), that has imposed the burden of proof for safety on the manufacturer, and explicitly referring to the precautionary principle, set a milestone for this argument, providing a more balanced view:

> *The current EU legislative framework “covers in principle the potential health, safety and environmental risks in relation to nanomaterials”, but it is recognised that current regulations may need to be modified as the scientific knowledge on nanomaterials increases.*

The situation has since further evolved. Besides the improvement of implementation tools, in fact, specific requirements for nanotechnologies have been introduced in some (few) regulatory regimes, and others are planned in the near future.

Also the attitude of stakeholders has changed, generally speaking. There is an increased awareness that under the umbrella term “nanotechnologies” are a variety of different nanomaterials and nano-related products, each of them associated with completely different potential safety and societal impact and that the building of a solid scientific base is a pre-requisite to ensure effective and unambiguous regulatory actions.

Resources for increasing the scientific base of knowledge have stepped up in the last few years: almost all governmental plans for development of nanotechnologies include these aspects, generally as a priority (e.g. the recent and planned EU research framework programs on Nanotechnologies, Materials and Processes – NMP FP7 & Horizon 2020); activities on basic and applied research on EHS issues (nanotoxicology, risk assessment, etc) are growing (e.g. EU NanoSafety Cluster), professional organizations and large industry are investigating and developing risk management procedures (e.g chemical industry initiatives); NGOs and other Civil Society Organizations keep under scrutiny this process, emphasising, in particular, the lack of information on consumer products (above all foods and cosmetics, e.g. the European Environmental Bureau reports on nanotechnology).

The focus of nano-regulation is currently more on nanomaterials than nano-related products (horizontal issue in the value chain). Much of the concern still remains focused on "free" engineered nanomaterials (particularly insoluble and/or biopersistent nanoparticles).

Looking at the value chain of nano-related products, priority in analysing the effectiveness of the existing regulation to deal with nanomaterials is generally given to:

- "Upstream" regulation (e.g regulation of substances, chemicals), to ensure that nanomaterials are identified (and possibly evaluated) from the beginning of the life cycle of a nano-related product. This is essential to have the information needed to apply other "downstream" regulatory provisions (e.g. workplace, environment, waste regulation).
- regulation of products coming into direct contact with humans or animals (in particular medicinals products, medical devices, cosmetics, agrifoods). This is also due to different risk perception and higher attention of consumers on these types of products.

Three types of actions can be identified amongst the ones endorsed by government, regulatory bodies and other organizations worldwide regarding **hard or enforced regulation**. Examples are listed below and refer only to actions already implemented or entering into force (see specified date).

A. Provide/improve technical guidelines and procedures to support safety assessment for specific types of nanomaterials and nano-related products
(regulation on chemicals, workplace, medicinal products and medical devices, food, environment in Europe and European Member States, USA, Canada, Australia, Japan, Korea, from 2008 onward).

B. Adapt/strengthen premarket notification procedures to ensure that nanomaterials are reviewed before entering the market, including options for mandatory reporting schemes.
(mandatory scheme in France; chemical regulation in USA and Canada).

C. Introduce amendments and changes into existing legislation to ensure the inclusion of nanomaterials and nano-related products, including issues such as specific definitions, mandatory risk management procedures, labeling, restrictions, etc.
(regulation on Cosmetic, Foods and Biocidal product in the EU; chemicals in Australia; definition of nanomaterials for regulatory purposes in EC, Canada and Australia)

Amongst the various actions particularly relevant for their impact is the review of REACH for nanomaterials, the results of which are expected by mid 2012.

Despite the promising efforts undertaken in the last years, the process of understanding impacts as well as to develop, whenever needed, suitable regulatory action is, however, complex and lengthy. Even when

sufficient knowledge is available, a number of structural, economical and political factors (often competing) need to find an appropriate balance, before regulation can be defined and implemented.

In the future, with the development of scientific knowledge, evidence of potential risks might be identified for specific class of nanomaterials (such as in the case of "read across" techniques already used in REACH for other chemicals) and *ad hoc* limitation or restrictions could be introduced in existing regulatory regimes (both in upstream and downstream regulation, depending from the condition of use and related exposure).

The process of differentiating between classes of nanomaterials (in terms of characteristics, behaviour, level of risk, exposure, possible regulatory action) is still in a very preliminary phase, but increasing resources are being committed towards this end (e.g. FP7 and Horizon 2020 calls and plans on NMP from 2013 onward).

It also must be said that so far, there is no conclusive evidence that nanotechnologies and nanomaterials raise more concerns than other existing materials or products [EU25].

In a novel, complex and dynamic field such as nanotechnologies, where exhaustive evidence based management of the effects and/or consequences of innovation is often unfeasible, other options, besides hard regulation, should also be considered to address safety issues and promote trust and confidence amongst stakeholders. Both hard and soft (voluntary) regulations are necessary.

Voluntary initiatives can have, in effect, an important role to cope with current uncertainties about the impact of nanotechnologies and during the redefinition of existing regulation, complementing (or preparing ground for) hard regulation. Several of these, of various types, have been activated since the start of the ObservatoryNANO analysis (2008). In particular:

Voluntary reporting schemes to gather information on nano-related products on the market have been implemented by regulatory agencies since 2006 (e.g. UK, USA). Though the initial high expectations on these measures has been frustrated by the tepid response of industry (due to several reasons, such as confidentiality, additional administrative burden, imprecise or ambiguous requirements), they have proven useful to gather at least a minimum set of data, as well as to prompt some organizations (mainly large industry) to start specific cooperation with regulatory agencies about nanotechnologies safety.

Though mandatory reporting schemes are being implemented (e.g. France, EU discussion on a nanomaterial register), voluntary actions will continue to be used as an option for gathering information on nanomaterials and nano-related products (e.g. in 2011 Ireland, Korea and Japan).

Risk management systems to ensure safe handling and production of nanomaterials have been developed since 2006 and are increasingly used in industrial settings. These tools are generally designed for a specific scope and tailored to the need of the user(s), often self-imposed, and therefore they guarantee a high level of implementation. Different kinds of initiatives are being developed (and updated):

- general frameworks and guidelines, designed by regulatory agencies, standards bodies, professional organizations, including self-assessment tools (e.g. ISO TC 229 technical report on OSH measures, German VCI guideline, ICCA Responsible Care, Precautionary matrix, Switzerland);

- Internal procedures implemented by individual industries, ranging from complete risk management systems (e.g. NanoRisk Framework), to control banding procedures or simple precautionary measures (e.g. avoiding any process that may cause the release of free nanoparticles);
- Evaluation, accreditation and certification schemes developed by regulatory and standard bodies as well as consultancy organizations (e.g Stoffenmanager Nano in the Netherlands, Cenarios in Switzerland).

It is likely that in the future several of the initiatives on risk management of nanomaterials (at least the more general ones) will converge, or will be substituted, when more consolidated and harmonized standards and regulatory tools for nanotechnologies are available.

Codes of Conduct have been developed to share common principles and encourage dialogue amongst stakeholders. The European Commission published the EC Code of Conduct for responsible nanoscience and nanotechnologies research in 2008, and other similar Codes have been developed by individual organizations (e.g. industry, retailers) or with a broader target (e.g. German NanoKommission, ResponsibleNanoCode).

These initiatives have been often poorly implemented/adopted. Nevertheless, their actual impact to promote awareness on responsible practices in nanotechnologies and to encourage dialogue amongst stakeholders has been wider, though difficult to quantify. A recent analysis on the EC Code has shown a large interest on the Code's principles as well as on the Code itself, but it underlined also the need for some modification in its content and format and to set up a more robust implementation process (something similar to the one used for a standard would be needed).

As a follow up to the EC Code of Conduct, to accompany the building of the European Research Area, it is possible that the European Commission will publish in 2012 a recommendation for Responsible Research and Innovation (RRI), addressing enabling technologies in general, not only nanotechnologies.

If a Code of Conduct is chosen as a governance tool to promote (EU) ethical principles amongst the nanotechnologies community, a robust process to foster its full and effective implementation at European and (ideally) international level will have to be set up.

The availability of appropriate **standards** to name, describe, specify, measure and characterize nanomaterials is pivotal to implementing an appropriate regulation for nanotechnologies-related products.

The International Standards Organization (ISO), through the Technical Committee (TC) 229 has been active on nanotechnologies standards since 2004. ISO TC 229 works in conjunction with the European Committee for Standardization, Technical Committee on nanotechnologies (CEN TC352), which in 2011 received a new mandate by the European Commission for the activity in this area. Also other International, regional and national standard bodies, as well as other organizations (such as OECD), work in strong cooperation with ISO TC 229, through specific agreements and liaisons.

More than 40 standards (technical specifications and reports) are being developed by ISO TC 229, 4 coordinated by CEN, and 22 have been already published. The latter refer to terminology and nomenclature (8 standards published), measurement and characterization (9), environment, health and safety (4), material specification (1). Some of these documents focus on CNT, the others on nanomaterials and nanotechnology in general.

The discussion about a proper definition for nanomaterials (for regulatory and scientific purposes) is a core part of the debate and crucial for regulation. Besides the International Standards Organization (2005) also the European Commission (2011), Health Canada (2011), NICNAS Australia (2011), the French Government (2011), the International Cooperation on Cosmetic Regulation, ICCR (2011), have published definitions for nanomaterials, but the matter is still controversial.

The OECD Working Party on Manufactured Nanomaterials (WPMN) is also playing an essential role in promoting international cooperation for the safety of nanomaterials. About 30 reports have been published by the WPMN on different areas, such as occupational health and safety, risk assessment, characterization, regulation, voluntary measures. Since 2008 OECD WPMN has launched a sponsorship programme for the testing of a set of 14 representative nanomaterials, a huge trans-national effort to coordinate research activities on market relevant nanomaterials, amongst more than 20 countries worldwide. As ongoing result of these activities, some guidance on safety testing of nanomaterials has already been published.

Other international organizations, such as SAICM, WHO, UNITAR and FAO have recently started to promote cooperation and information exchange activities on the safety of nanomaterials. Their role on the international scene is likely to increase in the near future.

International cooperation is playing a key role in setting benchmarks of the implication on EHS and ELSA deriving from nanotechnologies and it should also incorporate regulation. This process could likely be further enhanced, in particular facilitating and further increasing participation of Member States (and other international countries) with limited activities on nanotechnologies. This would help to spread responsible practices also to newcomers and/or low performers in the nanotechnology landscape (that might have limited resources to invest in EHS and ELSA).

With an increasing number of individuals being potentially exposed to certain classes of nanomaterials, in the first place workers and consumers, the demand for addressing uncertainties related to nanotechnologies and providing proper regulation remains high.

As shown in the ObservatoryNANO reports, several instruments have been put in place to this end, with hard regulation being the pinnacle of a series of knowledge building, information gathering and dialogue processes that all together can be exemplified in a regulatory pyramid (figure 1).

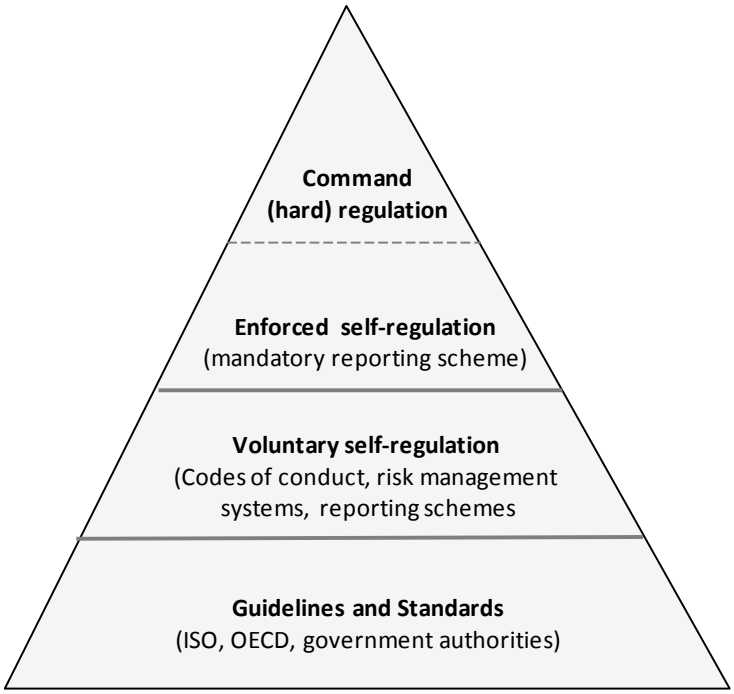

Figure 1: The regulatory pyramid (ObservatoryNano elaboration from [Ot1, Ot2])

Responsible growth is paramount and regulation of nanotechnologies must reflect this need. Its evolution can have unintended/unforeseen impacts that must be constantly taken into account for it can profoundly influence the path of the development of nanotechnology-related products and processes.

Some recommendations and highlights properly addressing this matter that can be drawn from the analysis undertaken by the ObservatoryNANO are outlined in the box below.

- **Multistakeholder approaches** addressing EHS and ELSA issues can foster trust building and confidence amongst stakeholders and help with the management of the most controversial issues. Concrete follow up of results must be ensured.

- A **responsive and adaptive regulatory framework**, following the dynamics of nanotechnologies developments, is needed to ensure timely transfer of scientific knowledge, key developments in EHS and ELSA.

- **Voluntary tools, such as codes of conduct and risk management systems**, are a viable option for sharing of common principles and practices for responsible Research and Innovation (R&I). They can be effective to anticipate and complement hard regulation, but need strong commitment and coordination between stakeholders (both top-down and bottom-up).

- **International coordination and harmonization**, both on research and policy issues, should be further promoted. This is essential to avoid regulatory divergence, which could cause unequal safety conditions (for workers, consumers, products), hinder technological cooperation, and hamper commercialization.

- **Responsible Research and Innovation (RRI)**, if appropriately addressed, can become a driver for promoting competition and growth.

- **Setting a framework for observing and interconnecting** the multi-disciplinary and multi-faceted aspects of nanotechnologies (technology, R&I, regulation, EHS, ELSA) could support and facilitate strategic research and policy decisions in this field. The ObservatoryNANO project provided such an example.

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Annex I: List of published ISO TC 229 standards , technical specifications and technical reports

ISO TC 229 WG1:
Terminology & Nomenclature

ISO/TS 80004-1:2010
Nanotechnologies -Vocabulary -Part 1: Core terms
ISO/TS 27687:2008
Nanotechnologies -Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate
ISO/TS 80004-3:2010
Nanotechnologies -Vocabulary -Part 3: Carbon nano-objects
ISO/TR 12802:2010
Nanotechnologies -Model taxonomic framework for use in developing vocabularies -Core concepts
ISO/TR 11360:2010
Nanotechnologies -- Methodology for the classification and categorization of nanomaterials
ISO/TS 80004-4:2011
Nanotechnologies - Vocabulary --Part 4: Nanostructured materials
ISO/TS 80004-5:2011
Nanotechnologies -Vocabulary -Part 5: Nano/bio interface
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ISO TC 229 WG2:
Measurement & Characterization

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ISO/TS 11308:2011
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ISO/TS 11888:2011
Nanotechnologies -- Characterization of multiwall carbon nanotubes -- Mesoscopic shape factors
ISO/TS 13278:2011
Nanotechnologies -- Determination of elemental impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry

ISO TC 229 WG3: Health, Safety, and Environment
ISO 10801:2010
Nanotechnologies -- Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method
ISO 29701:2010
Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test
ISO/TR 12885:2008
Nanotechnologies -- Health and safety practices in occupational settings relevant to nanotechnologies
ISO/TR 13121:2011
Nanotechnologies -- Nanomaterial risk evaluation

ISO TC 229 WG4: Materials Specification

ISO/TS 12805:2011
Nanotechnologies -- Materials specifications -- Guidance on specifying nano-objects

(March 2011)

Annex II: List of some the most relevant (public) OECD WPMN documents

OECD WPMN Documents (available on the OECD WPMN website)	**Steering Group**
• OECD Database on Research into the Safety of Manufactured Nanomaterials	SG1
• *EHS Research Strategies on Manufactured Nanomaterials: Compilation of Outputs (No. 9, 2009)*	SG2
• *Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision (No. 25, 2010)* • *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing Manufactured Nanomaterials: Revised (No. 27, 2010)*	SG3
• *Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials (No. 15, 2009)* • *Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials (No. 24, 2010)*	SG4
• *Analysis of Information Gathering Initiative on Manufactured Nanomaterials (No. 19, 2009)* • *Regulated Nanomaterials: 2006-2009 (No. 30, 2011)* • *Information Gathering Schemes On Nanomaterials: Lessons Learned And Reported Information (No. 31, 2011)*	SG5
• *Report of the Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Context (No. 21, 2010)*	SG6
• *Identification, Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials (No. 10, 2009)* • *Emission Assessment for the Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance (No. 11, 2009)* • *Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials (No. 12, 2009)* • *Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials (No. 13, 2009)* • *Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories (No. 28, 2010)*	SG8

Annex III: Snapshot table: regulatory actions vs. technology sectors

The table below reports a snapshot of the initiatives undertaken in the countries and regulatory regimes included in the paragraph related to hard/enforced regulation. These initiatives have been classified with respect to the country/region, sector, and type of action. Three general types of action have been considered:

A. Provide/improve technical guidelines and procedures to support safety assessment for specific types of nanomaterials/nano-related products.
B. Adapt/strengthen premarket notification procedures to ensure nanomaterials are reviewed before entering the market, including options for mandatory reporting schemes.
C. Introduce amendments and changes into existing legislation to ensure inclusion of nanomaterials and nano-related products (including issues such as specific definitions for nanotechnologies/nanomaterials, mandatory risk management procedures, labelling, restrictions, etc).

	Foods, Agri-culture	Chemistry & Materials			Cos-metics		Medicinal products & medical devices		Occup-ational issues (OSH)	Environ-ment	Cross sectoral (nanomaterials, nanotech in general)	
European Commission	C	A	B		A	C	A		A		A	C
France			B				A		A		A	B
Germany		A							A		A	
The Netherlands		A							A		A	
Switzerland		A							A	A	A	
United Kingdom	A						A		A		A	
USA	A	A	B		A		A		A	A	A	B
Canada		A	B		A		A		A		A	C
Australia		A	B	C					A		A	C
Japan					A		A		A		A	
Other Countries									A		A	