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REGULATION AND STANDARDS

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TABLE OF CONTENTS

Executive Abstract

1 Foreword 10
1.1 Structure of the report and methodology 11

2 REGULATING NANOTECHNOLOGY 13

3 LEGISLATION/HARD REGULATION 15
3.1 European Union 15
3.2 European Countries 22
3.3 USA 26
3.4 Australia 30
3.5 Canada 31
3.6 Japan 33

4 SELF-REGULATION 34
4.1 EC Code of Conduct 34
4.2 DEFRA –VRS (UK) 35
4.3 EPA-NSMP (USA) 36
4.4 Other initiatives 37

5 STANDARDS FOR NANOTECHNOLOGIES 41
5.1 The activity of ISO TC 229 41
5.2 Other standards organisations 48
5.3 European Union efforts on standardisation 49
5.4 Organisation for Economic Co-operation and Development (OECD) 51

6 CONCLUSION 53

7 References and Literature 56
8 Annex I: Synthesis table on nanotechnology regulation 62
9 Annex II: Main standards organisations dealing with nanotechnologies 65

Executive Abstract

The umbrella terms of nanoscience and nanotechnology are still not precisely defined, however, one thing which is clear, and which all definitions share, is the ambition to understand and control the fundamental structure and behaviour of matter at the atomic and molecular level. The realm of nanotechnology is generally agreed to lie within the range of 1 and 100 nanometres. A further restriction of the definition of nanoscience and nanotechnology is that new functionalities are made available by manipulation of matter at this scale or through specificities of the nano dimensions, where the physical, chemical and biological properties of materials differ from those of the bulk matter. Nanotechnology promises advances in controlling and manipulating matter and with this promise a vision of novel ways of creating and developing a new generation of products with original features, performances and functionalities.

In the main, nanoscience and nanotechnology will form part of microsystems and macro devices or materials and thus is termed an enabler of innovations. This enabling character promises to augment innovations in a wide variety of industrial sectors, but creates difficulties in the development of regulations because it is generally part of a system of elements in a profuce. Thus nanoregulation is an entanglement of nano-specific and sector specific regulation and standards.

Over the past 10 years, anticipation has been rife around the potential benefits nanotechnolgies may bring, leading to large resources being poured into the emerging area. Equally anticipation on potential risks of nanotechnologies have become increasingly high on the agenda. With expected risks becoming ever more specific (observe the shift from broad societal changes to concerns about toxicity, privacy, transparency etc.) and the nano-enabled products on the market increasing at a rapid pace, the need to embrace the complexities of regulation nanotechnologies as they emerge has become apparent.

With little alignment in regulatory stances from the many potential stakeholders, there is a general feeling that a regulatory framework needs to be in place both to enable and constrain developments in nanotechnology to create societal beneficial technologies. This report gives a brief overview of the present situation on nanotechnology regulation. As part of the ObservatoryNANO project, it is an evolving document, taking into consideration the changes in the regulation landscape (and governance more broadly).

Currently the report identifies several factors[1], briefly indicated below, which are making the implementation of effective regulatory schemes complex:

- The wide variety of materials and applications under the umbrella term of nanotechnology
- The limited knowledge of toxicity nanomaterials on living systems and their transport in living and environmental systems The proprietary nature of

[1] These are mirrored in: Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges, US Congressional Research Service (CRS) report, (January 2008) - http://www.fas.org/sgp/crs/misc/RL34332.pdf

information on novel nanomaterials making access to relevant information a difficult issue
- The lack of harmonised standards or guidance
- The potential inadequacy of statutory authorities

Much of the concern is focused on "free" engineered nanomaterials and their effects on the environment, health and security (EHS) during their entire life cycle Combined with the ethical, legal and social aspects (ELSA) of nanotechnology R&D the question of what could be an integrated nanotechnology governance approach is rapidly becoming the most discussed topic in the nanotechnology area.

In spite of this attention, there is no specific regulation for nanotechnology-related products. In some cases, studies on nanotechnologies in specific sectors show that existing regulatory schemes should be adequate (such as the food sector[2] and for medical technologies[3]) although there is still a request for improved EHS data. In other cases there is less agreement, for example in the area of cosmetics[4]). The European Commission[5] also shows this, highlighting that, with the necessary adaptations for nanotechnologies, existing regulatory schemes can go some way in regulating the emrging field without constraining the growth too much. With this in mind, the focus is more on the improvement of instruments to ensure compliance with existing legislation.

Addressing these issues properly is essential and many countries with active nanotechnology RTD are promoting initiatives which highlight the needs for tailored standards and regulation, and the development of expertise and technical capabilities to cope with the proliferation of nanotechnologies. There have been a number of review of regulatory regimes, identifying actions and priorities, (in the main) advising the increase of funding for research aiming to better characterise nanomaterials and understand their effects on the environment, human health and security.
In Europe, within the **European Commission**, different Technical Committees and Agencies have published scientific opinions and reviews of regulation with respect to nanotechnology and a number of them have created dedicated working groups to this end. In June 2008 most of these activities have been condensed into the report "Regulatory Aspects of Nanomaterials" [6].

Though on regulatory matters, the European member states tend to follow the inputs from the EC, several countries have activities at the national level. **France, Germany, Switzerland, The Netherlands**, **UK** and a number of the **Scandinavian countries** have

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[2] EFSA (2009) Scientific Opinion of the Scientific Committee Concerning The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety. The EFSA Journal 958, 1-39

[3] Roszek B., de Jong W.H. and Geertsma R.E. (2005) Nanotechnology in medical applications: state-of-the-art in materials and devices. RIVM report 265001001/2005

[4] For an interesting assessment of strengths and weaknesses of European cosmetic regulation concerning nanotechnologies, see Bowman and van Calster (2008) Flawless or Fallible? A Review of the Applicability of the European Union's Cosmetics Directive in Relation to Nano-CosmeticsStudies in Ethics, Law, and Technology. Volume 2, Issue 3 2008 Article 6

[5] http://ec.europa.eu/nanotechnology/pdf/comm_2008_0366_en.pdf

[6] http://ec.europa.eu/nanotechnology/pdf/comm_2008_0366_en.pdf

been active in this area, with commitment at institutional level to deepen knowledge on EHS and regulatory issues.

Looking beyond Europe, the **USA, Canada and Australia** have also been active already for several years. EHS and regulatory issues are getting increasing resources within their national strategies for nanotechnology, and regulatory agencies and other interested bodies are becoming more proactive in coping with the complexity of nanoregulation. Canada and Australia in particular are countries explicitly identifying the need to adopt a precautionary approach.

At the moment, related regulatory regimes under investigation refer in to:

- chemicals and materials
- cosmetics
- foods
- occupational health and worker safety
- environmental safety,
- medical devices and pharmaceuticals.

Existing regulatory provisions regarding **chemicals and materials** have begun to include nanomaterials in their listings and the requirements to monitor/control the introduction of them into the market. Different regulatory agencies in Europe (EC/ECHA), USA (EPA), Canada (Environment Canada) and Australia (NICNAS), have already introduced into these provisions specific notification requirements to this end.

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), in particular, which regulates in Europe the production, use and commercialisation of chemicals, is at present, the most compelling legislation for nanomaterials although questions still remain in some quarters concerning its effectiveness, such as threshold levels and exemption of particular materials.. On March 2008, ECHA (European Chemicals Agency) established for this purpose the Competent Authorities Sub Group on Nanomaterials (CASG Nano).

In the US, nanomaterials fall under TSCA (*Toxic Substances Control Act)* of the EPA which is the US equivalent of REACH and regulates chemicals. However, a large separation exists between the two regulatory schemes. In Europe (REACH) it is up to the producer to demonstrate that a chemical is safe before it enters the market, whilst in the US (EPA-TSCA), it is the responsibility of the regulators to prove that a chemical is harmful before it can be restricted or removed from the market. An agreement for a common approach is fundamental to avoid barriers and mismatches.

The use of nanotechnology in **cosmetics and foods** is under strong scrutiny reflected by the recent EU parliament move for a revision of the cosmetic regulation, including a specific definition of (insoluble) manufactured nanomaterials and requirements for safety assessment procedures for all products containing these kind of nanomaterials. A similar initiative concerning food regulation is under discussion.

Regarding **occupational health and workers safety**, most efforts are devoted to evaluating and adapting the existing risk management methods, and to develop

appropriate guidance for the handling and disposal of engineered nanoparticles/nanomaterials. Reference documents have been produced by the *National Institute for Occupational Safety and Health* (NIOSH) in USA, *the German Chemical Industry Association* (VCI), the *Federal Office of Public Health* (FOPH) in Switzerland, the *Institut de recherche Robert-Sauvé en santé et en sécurité du travail* (IRSST) in Canada among others.

The lack of appropriate measurement and monitoring tools, of detailed information on hazards and exposure levels and use of nanomaterials are evident challenges to provide comprehensive indications on these matters.

With respect to **medical devices and pharmaceuticals products,** the existing provisions are generally considered adequate also for nano-related products, due to the detailed authorisation procedures required, but a case by case approach in the evaluation and authorisation procedures is envisaged to take into account their peculiar properties. One issue is the blurring of regulatory routes for adv\nced nanotechnologies, such as implantable biomaterials or nanoparticles based drug delivery systems where technologies can be defined as a device, drug and biomaterial. This can be seen outside the relams of nanotechnology, but is predicted to be particularly prevalent in this area.

Alongside the activities regarding existing "hard" regulation, other soft law approaches are being implemented or developed. Such self-regulation instruments are presently used to address the safe use of nanomaterials. In particular**: reporting schemes** (stewardship programmes) and **voluntary measures** (code of conduct, risk management systems).

Examples of the first instrument are the initiatives of USA-EPA and UK-DEFRA, or others carried out at EC level (EFSA), in Germany (UBA-VCI) and Australia (NICNAS). Most of the attention is currently focused on regulatory triggers (e.g threshold levels) and classification issues, thus on the ability to regulate and control the introduction and use of nanomaterials and nano-related products into the market. These initiatives are extremely important to build a firmer base of knowledge to support policy and regulatory decisions, and for this reason alos under consideration are *mandatory reporting schemes* (for example in Canada and France).

Codes of conduct and risk management systems are measures that can have a important role to cope with the current uncertainties about the impact of nanotechnologies during the redefinition of existing hard regulation and to raise trust on their use, through creating a culture of responsibility..

The most relevant example of code of conduct aiming to contribute to this culture of responsibility is the EC "***Code of Conduct for responsible nanoscience and nanotechnologies research" (February 2008) which*** provides principles and indications that should guide the research activity in this field. Its objectives are far reaching and among the principles that must be respected with particular relevance are (a) Sustainability, (b) Precaution and (c) Inclusiveness
The EC is actively promoting the Code and strongly recommends all Member States to adopt it.

In addition, based on the current uncertainty in the regulatory situation, some stakeholders, mainly at 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. The DuPont/Envrionmental Defence NanoRiskFramework and the CENARIOS risk management and monitoring system, are two examples of this approach.

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

Currently, it is the ISO TC229, in conjunction with IEC TC 113, that dictate the line of the activities on nanotechnology standards at the international level, but also other standard bodies have started to work on nanotechnology since 2004. Various ISO Technical Committees (TC), national standards bodies, such as BSI/NT1 in UK, SAC/TC279 in China, ANSI-NSP in USA, and Standard Developing Organisations such as ASTM and IEEE have all produced standards relevant for nanotechnology. Most of these activity are in liaison with ISO TC229 and IEC TC 113, analogously to the work of CEN, CENELEC and ETSI, that received a specific mandate on the matter from the EC.

ISO TC 229 is organised into 4 working groups that focus on issues that are crucial for the development of an effective regulation for nanotechnology-related products. In particular:

- Terminology and Nomenclature
- Measurements and Characterisation
- Health, Safety, and Environment
- Materials Specification

At present more than 30 standards documents related to the above themes are under development, but due to the lengthy process, it will be some time before the matter is thoroughly addressed. So far ISO TC 229 has produced two documents:

- ISO/TS27687 (Technical Specification): Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplates;
- ISO/TR 12885 (Technical Report): Health and safety practices in occupational settings relevant to nanotechnologies.

A contribution to the standardisation activities, will also be made by the **eight Steering Groups of OECD WPMN (Working Party on Manufactured Nanomaterials) who are** gathering reference data and information on characterisation and safety of nanomaterials.

In particular, in the OECD sponsorship programme, launched in 2007 (Steering Group 3), several countries are sharing the testing of a representative set of manufactured nanomaterials. More than 30 countries worldwide are currently participating to OECD-WPMN and most of them are also actively engaged in the sponsorship program The

Working Party agreed a priority list of 14 nanomaterials for testing [7] (based on materials which are in or close to commerce) as well as a list of 61 endpoints for which they should be tested.

In conclusion, the activity linked to nanoregulation is is increasing in intensity across the globe, nevertheless, given the gaps in the scientific knowledge and the different positions and stances of regulatory agencies around the world, it seems unlikely that new laws specific for nanotechnology will be introduced in the short term.

The demand to clarify the existing uncertainties and, at least in some cases, of specific provisions, is mounting. Recently the EU parliament has approved a resolution asking for tighter rules for the marketing of nanomaterials, invoking the principle "no data, no market".

The serious lack of data regarding risks for human health and the environment means that governments and other governing actors need to be proactive to find appropriate and proportionate actions for enabling and constraining the development of nanotechnologies. Some countries are introducing procedures for the reporting of manufactured/produced/used engineered nanomaterials on a voluntary base, and a number of authorities are considering to make these procedures mandatory.

Nanoregulation requires a dynamic approach: it must adapt to the evolution of the scientific knowledge, to the increase of applications, to the concern and attitude of current and potential stakeholders. Continuous research, cooperation and productive and constructive dialogue are key to support nanotech development and to build justified trust among stakeholders, including civil society.

The productive mixing of hard and self regulation approaches seem an appropriate option in the short-term.

Finally, except for standards, so far there is no a concerted effort aimed to elaborate common rules fro nanoregulation that could be shared at an international level. The various countries active in nanoregulation have initiatives independent from each other, although in Europe the situation is less disparate and the EC is active to foster this aim providing a glue between the activities, both within Europe and outside. The Code of Conduct if largely adopted among the Member States, could be the first step in determining a common ground for research whilst REACH provides a certain degree of coherence for product development, at least on nanomaterials. However, the development of a regulatory framework accepted at global level is necessary to have common rules for safety do as tofacilitate trade and avoid regional divide. Thus the promotion of international cooperation in nanoregulation is fundamental.

[7] Nanomaterials indicated by OECD WPMN are: *Silver nanoparticles, Iron nanoparticles, Carbon black, Titanium dioxide Aluminium oxide, Cerium oxide, Zinc oxide, Silicon dioxide, Polystyrene, Dendrimers, Nanoclays [12]*

1 Foreword

"the benefits of nanomaterials can only be realised within a clear regulatory framework that fully addresses the very nature of potential safety problems relating to nanomaterials" [8]

Nanotechnologies are cross-sectional technologies that exhibit an extremely broad range of applications, promising novel and radical innovations in different industrial sectors and spheres of human life.

These technologies are characterised by an high degree of innovation dynamics, as confirmed by the ObservatoryNano project activities and results. The today impact is generally in terms of incremental improvements of the characteristics and performances of existing products and according to some estimates the market of these products is around 50-60M$. In the medium/long term nanotechnology application promises to realise totally innovative products with unprecedented features and behaviour with market forecasts in the hundred or even thousand of billion, in a 10-15 years horizon.

The source of such an high expectations are the peculiar properties exhibited by the matter at the nanoscale, and the development of the ability to manipulate and control them. But these features raise also doubts on the potentially harmful effects of nanotechnologies on human health and the environment, and on the implication of their use respect societal issues.

The availability of appropriate regulatory schemes that govern the development of nanotechnologies assuring that this takes place to the benefit of the people, minimising the risks potentially associated with them, is essential for the success of these technologies.

The uncertainties related to the definition and behaviour of nanomaterials and nanotechnologies, their multi-sectoral character, the lack of appropriate standards and testing procedures, make the regulation of nanotechnology a challenging affair.

In all countries involved with nanotechnologies nanoregulation is becoming more and more a pivotal issue. Since some time the EC consider the matter a priority on its agenda. The question is not yet settled, but the fact that nanotechnology is still at an early stage of its development makes it possible to tackle the problems from the beginning and develop a regulatory framework that can assure its responsible development.

Aim of the report is to give an overview of the existing situation, the initiatives of the stakeholders in the field of regulation and standards of nanotechnology at national and international level, to highlight the key issues relevant for regulating nanotechnology.

[8] http://www.europarl.europa.eu/meetdocs/2004_2009/documents/pr/763/763225/763225en.pdf

1.1 Structure of the report and methodology

Structure:
The report has been organised in four parts:

Regulating nanotechnology:
This brief paragraph is an introduction to the gaps, challenges and needs related to the regulation of nanotechnologies and the possible actions/instruments to address them.

Legislation/hard regulation:
This part present an analysis of initiatives and positions of policy makers with respect to the development of instruments to control and regulate nanomaterials and nano-related products and to ensure the proper level of safety for human health and the environment. Initiatives of government departments, regulatory agencies and other authorities, at national and international level, have been analysed. A particular emphasis has been given to European activities.
The paragraph is structured on a regional/national basis.

Self-regulation:
This paragraph reports self-regulation and voluntary measures, such as reporting schemes and code of conducts, prompted by policy makers to support and complement existing regulation. In the last part a brief summary of voluntary measures activated mainly at industrial level, is also included.

Standards for nanotechnologies:
This part present a review of the activities developed since 2004 by international/regional/national standard organisations, and other organisations such as OECD, for the development of standards in the field of nanotechnologies.
The first part of the paragraph presents a detailed picture of activities on nanotechnologies of the International Standards Organisation (ISO), followed by initiatives from other standards organisations and a focus on European efforts on standards in this field.
A description of national standard bodies and standard developing organisations (SDOs) dealing with nanotechnology has been included in the annex of the report.

A detailed bibliography, divided basing on the paragraph subjects as described above, is included at the end of the report.

Methodology:
The report is based on the collation and analysis of information from a set of representative documents by policy makers and other stakeholders, dealing at different level with the development of regulation and standards for nanotechnologies. The great part of these documents are publicly available.

The search of documents followed two main phases:

In the first phase, few acknowledged sources of information have been carefully analysed in order to have details on the most important on going initiatives and documents with respect to the themes considered. Apart from desk research activities,

direct contacts and liaisons of partners of the ObservatoryNano project has been used to this end, in particular regarding the access to information on standard bodies activities (some partners, including the authors of this report, are members of national/international standard bodies). Priority sources of information have been:

- OECD Working Party on Manufactured Nanomaterials
- ISO TC 229 (and other national standard bodies)
- European Commission activities on nanotechnology policy and regulation [9]
- Relevant European and international projects on these themes [10]

In the second phase, the analysis has been complemented and completed by a desk research on other information and documents published by government departments, regulatory agencies, other authorities, industry and other stakeholders at international level. A set of documents giving information on relevant initiatives and positions on regulation & standards of nanotechnologies has been finally selected.

Both the websites visited and the documentation used are generally updated at March 2009.

All information have been carefully analysed and condensed in the present report.

[9] A website of the European Commission dedicated to nanotechnology policies have been activated in 2008 - http://ec.europa.eu/nanotechnology/policies_en.html

[10] In particular the EU project *FramingNano* (www.framingnano.eu), *The Innovation Society* news service on nanoregulation (http://www.innovationsgesellschaft.ch/index.php?page=56), *The International Risk Governance Council* activities (http://www.irgc.org/Nanotechnology.html), the Nanotech project of the *Woodrow Wilson Center for Scholars* in the USA (http://www.nanotechproject.org/publications/).

2 REGULATING NANOTECHNOLOGY

The number and variety of nanotechnology-related products on the market is increasing. As these products become increasingly more visible, alongside the expectations of enormous benefits, the concern about the potential risks associated with nanomaterials and the impact of this technology on civil society is coming ever more to the fore.

Specific provisions to regulate nanotechnology-related products are not yet in place, but regulation of nanotechnology, is becoming a key issue, pressing governments, regulatory agencies, industry and other stakeholders to take position and to become proactive in defining adequate regulation and risk management structures addressing effectively the responsible development of these technologies and their applications. Both Environment Health Safety issues (EHS) and Ethical Legal Social Aspects (ELSI) involved.

At present the main concern about nano-related products refers to "free" engineered nanomaterials and their effects along their entire life cycle, on human health and the environment, but several factors challenge the implementation of an effective responsible governance framework [11].

Diversity of materials and applications
Most of the existing materials or chemicals may be found in the nanoform, and novel nanomaterials are being steadily developed. With a huge number of substances having specific behaviours and properties due to their dimensions at the nanoscale, and the proliferation of applications, there are rising doubts concerning the adequacy of existing regulations.

Lack of knowledge about nanomaterials
What has emerged from the different authoritative reviews and studies [1, 2, 3, 4] is that a thorough understanding is still lacking about how the physical-chemical properties of nanomaterials (size, shape, composition, reactivity, surface area and/or chemistry) are determining their biological response. This situation makes it difficult to evaluate, model and predict their ecological and toxicological behaviour and consequently, for developing appropriate risk management and regulatory options.

Lack of standardization in nomenclature, metrics, and materials
The unique nature of nanotechnology challenges the establishment of standard procedures to describe, specify and measure nanotechnology – related materials and products. There is currently no consensus on terminology/definitions, nor on protocols for toxicity testing or for evaluating the environmental impact, nor on reference materials and standards or instruments for measurements and characterisation. Without an international agreement on the above matters the definition and implementation of appropriate legislation will not be possible.

Proprietary nature of information
An important element of the ongoing activity of nanomaterial development conducted by private entities is the economic interest that discourages data sharing. As a

[11] as reference, activities of workpackage 4 of the ObservatoryNAno explictly refer to these issues

consequence scientists often do not have access to information that is needed to detect patterns in the relationships between toxicity and the characteristics of various nanomaterials, necessary for building theoretical models for testing. As underlined by several sources [[1, 4, 5], a relevant period of time will be needed to reach a comprehensive understanding of the behaviour and a quantitative characterization of the risks posed by different nanomaterials and applications.

Risk management and regulatory systems have to deal with this type of uncertainty and governments, authorities, industry, the research community and other stakeholders are developing various kind of instruments to address nanotechnology regulation. These instruments can be synthesised in the following way:

- **Knowledge gathering:**
  A number of initiatives have been initiated aiming to increase knowledge on environmental, health and safety issues, and in particular improve methods for risk assessment and risk management of nanomaterials.

- **Self-regulation / voluntary measures**
  Based on the present status of the regulatory situation, authorities, industry and other stakeholders are developing different types of self-regulation/voluntary schemes for risk assessment to assure that a basic level trustm through best/good practice, is established among the different stakeholders.

- **"hard" Regulation**
  Regulatory bodies have started to develop expertise and technical background to cope with nanotechnology, evaluating the applicability of existing regulation or the needs of adapting them. The process could also lead, potentially, to the development of specific provisions for nanotechnology.

- **Transnational efforts**
  Initiatives aiming to define and build an international approach for the management of nanomaterial risks, and the harmonisation of standards and guidance have been initiated by standard bodies and international organisations.

These instruments are part of a more general framework, an"incremental approach", for the management of nanotechnology. A reasonable approach would follow a number of chronological stages: knowledge about the current regulatory process proceedures and where are the gaps, acquired from information gathering activities (immediate action), to multi-stakeholders norms and self regulation (short term action), followed by the establishment, if needed, of enforced self regulation (medium term) and finally by hard law legislation (long term) [6].

Many of the countries involved in nanotechnology development are taking this kind of approach, although with varying degree of support and engagement and with an emphasis on evaluating existing regulation and their applicability to nanomaterials. In the following section we describe the present situation and the activities underway at the European level and more globally, with reference in particular to voluntary measures, (hard) regulation, and standards.

3 LEGISLATION/HARD REGULATION

3.1 European Union

As mentioned in the previous section, there is no nano-specificregulations in place, but several initiatives are been promoted by the EC to augment a high level of public health, safety, environmental and consumer protection, integration of the societal dimension, development of standards and norms, definition of appropriate regulatory approaches, and international cooperation in the field of nanotechnologies.

The EC strategy for a "Safe, Integrated and Responsible" approach to nanotechnology development and regulation is clearly described in the following Commission communications "milestones" [1]:

- 2004: Towards a European strategy for nanotechnology, COM(2004) 338, 12.5.2004
- 2005: Nanotechnologies Action plan, COM(2005) 243, 7.6.2005
- 2007: Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007 (2007)
- 2008: Recommendation on a Code of Conduct, C(2008) 424, 07.02.2008
- 2008: Regulatory Aspects of Nanomaterials, COM(2008) 366, 17.6.2008
- Planned 2009 : Second Implementation Report

The most relevant documents for nano regulation are the Code of Conduct [2], described in the following paragraph, and the Regulatory Aspects of Nanomaterials [3], which summarises most of the results of the activity of various regulatory agencies, related or referring to the European Commission, that have analysed existing legislation to review and identify gaps in relation to risk assessment methodologies and regulation of nanomaterials and nano-related products. This report is currently the most relevant reference concerning the European Commission position on nanotechnology regulation.

The report examines legislation referring to the following sectors:

- Chemicals and materials,
- Health and safety of workers,
- Product requirements for health and safety of workers, consumers and protection of the environment:
    - Groups of products: plant protection products, biocides, new approach legislation, cosmetics, aerosol dispensers, medicinal products and cars;
    - Food legislation: general food law, novel food, food contact materials, food additives, food supplements, feed legislation;
- General Product Safety Directive on consumer products not covered by specific regulation,
- Environment: Directives on Integrated Pollution Prevention and Control (IPPC), major accidents (Seveso II Directive), water, waste, air quality, soil protection and environmental liability.

In view of the EC, the current EU legislative framework *"covers in principle the potential health, safety and environmental risks in relation to nanomaterials"* [3].

Nanomaterials/nanotechnologies are therefore dealt with, in the first instance, by following current regulatory schemes, reviewed for their applicability to nanomaterials. The report clearly states that with regards to nanomaterials more research is needed to improve the scientific knowledge in support of the regulatory activity. It identifies several research needs and priorities, mainly related to the improvement of risk assessment and risk management methods that have to be tackled to adapt/modify the existing regulation. The implementation of a specific regulation on nanotechnology is considered difficult due, in particular, to the complex national/supra-national regulatory scenario at European level. [4].

Very recently this position has been challenged by a report discussed (and eventually approved) within the European Parliament's Environment Committee [5]. According to this report, current EU legislation is considered inadequate to keep in check the potential health, environment and safety hazards of nanomaterials and must be reviewed within the next two years to implement specific regulation for nanomaterials. The report asks for tighter controls on nanotechnology, including the application of the 'no data, no market' principle contained in the REACH Directive.

The current EU regulations provide the most important framework for activities at national level by the EU Member States. In general, national regulatory agencies are bound to align with EU regulatory legislation, with the possibility to implement specific (more detailed or tighter) regulation at national level.

However, a number of European countries have started to collect their own information and to develop expertise to cope with nanotechnology. Opinions from specific technical committees, independent research bodies and other organisations have been commissioned by national regulatory authorities. Germany, France, UK, Switzerland, The Netherlands and some Scandinavian countries are the most active.

The following sections report some of the major regulatory frameworks and activities in relation with nanotechnologies, both at European and Member States level. A particular emphasis is given to REACH, considered at the moment as the most compelling regulation scheme to deal with nanomaterials.

3.1.1 REACH-ECHA

The legislation under which ECHA (the European Chemicals Agency) regulates the manufacture, placing on the market and use of chemical substances on their own, in preparations or in articles is covered by REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), which entered into force on 1 June 2007 (replacing several previous legislations and with an eleven year period time for manufactures to fully comply with it). This regulation complements other current product regulations (e.g cosmetics, general product safety).

REACH is based on the general principle that *"manufacturers, importers and downstream users have to ensure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment."* This means

that under REACH, the burden of proof about the safety of a substance is not on the regulator (as it was in previous EC regulations) but on manufacturers, importers and producers. This is a fundamental difference with respect to similar provisions in other Countries as, for example, the EPA-TSCA statute that regulates chemical substances in the US (see paragraph **Errore. L'origine riferimento non è stata trovata.**), where the burden of proof lies on regulators. The aim to safeguard humans and the environment is enforced by the inclusion of the Precautionary Principle, that underpins REACH provisions which is based on four main mechanisms allowing to control the risks: registration, evaluation, authorisation and restrictions.

For the EC, nanomaterials fall under the regulation of REACH. In particular [3, 6, 7, 8]:

- Nanomaterials classified as *new* are subjected, as any other new chemical, to a dedicated registration and thus to specific risk assessment procedures.
- For substance already on the market as bulk substance and produced or imported at the nanoscale (not *new*), if properties or uses of the substance in nanoform differ from those in the bulk form, specific information on properties and uses have to be updated in the registration dossier, including specific information on hazardous properties, safety assessment, risk management measures (basing on the most updated testing guidelines available). The manufacturer or producer is in charge of requesting a registration update[12].

REACH seems to provide a solid framework to regulate engineered nanomaterials, but the current lack of knowledge about their physico-chemical features and effects on human health and the environment, raise some concerns about its applicability to products using nanotechnology. Moreover, registration is volume-based, i.e. registration and risk assessment requirements dependent on the mass of the chemical manufactured, imported or produced on a year basis (1 tons/year threshold level). This limit may put some nanomaterials produced in lower volumes outside the requirements of legislation, casting doubts about its effectiveness in regulating these materials.

This concern has been raised also in recent reports from the SCHENIR EC Committee, which stressed that both threshold levels, expressed in terms of mass metric, and existing testing guidelines (included in the technical specifications for compiling the registration dossiers) could limit the validity of REACH with nanomaterials.

A specific working group within REACH, named the *Competent Authorities Sub Group on Nanomaterials* (CASG Nano), has been established in March 2008 to address these issues, with a relevant work programme for the years 2008 to 2012. Apart from fostering cooperation within the EU and at international level, aim of the WG is to deepen the understanding of REACH applicability to nanomaterials, REACH implementation issues, substance identification, registration of nanomaterials, chemicals

[12] "*When an existing chemical substance, already placed on the market as bulk substance, is introduced on the market in a nanomaterial form (nanoform), the registration dossier will have to be updated to include specific properties of the nanoform of that substance. The additional information, including different classification and labelling of the nanoform and additional risk management measures, will need to be included in the registration dossier. The risk management measures and operational conditions will have to be communicated to the supply chain"*

safety assessment and risk management, communication in supply chain and information on nanomaterials [7].
A first document reflecting the current state of the discussion on how REACH applies to nanomaterials has been published by the Sub Group in December 2008 (Nanomaterials and REACH) [13].

The end of the first evaluation phase of REACH (planned in 2010) will, very likely, furnish important information and indications on the level of applicability of REACH to nanomaterials.

3.1.2 Medical products (European Medicines Agency-EMEA)

The European Medicines Agency (EMEA) is a decentralised body of the European Union, with the responsibility of the protection and promotion of public and animal health. EMEA is generally in charge of authorisation procedures for medicinal products, though only authorisation at national level (or mixed national, EU authorisation procedures) is feasible in some specific cases.

Medical products are subject to specific authorisation procedures, based on established principles of risk/benefit analysis. A detailed assessment of toxicology and ecotoxicology and of methodologies used to evaluate toxicity and extensive postmarketing surveillance is foreseen by current legislation. This applies also to nanomaterials and nano-related products, even if they are not explicitly mentioned in current provisions.

Among the specific initiatives by EMEA carried out in relation with nanotechnology can be cited:

- Establishment of a specific "nanomedicine-group" within the Innovation Task Force (ITF) [14]. This allows, in the absence of guidelines, potential developers of nanomedicine products to interact with the EMEA directly at early stages of the development process
- Reflection paper on nanotechnology-based medicinal products for human use [9] by the EMEA Committee for Medicinal Products for Human Use (CMPH)

These documents, recognise that new methods and models might need to be developed for nanoscale materials, but the careful benefit/risk balance that have to be proven for pharmaceuticals is considered in general appropriate to evaluate these materials.

Potential gaps could arise for novel applications of nanotechnology, combining particular properties and functionalities, for which the applicable regulatory framework (medicines, devices, combination products, advanced therapies) can not be easily determined.

Currently, the existing authorization procedures of **medicinal products** are considered adequate also for nano-related products. Covered by other directives such as the

[13] http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf

[14] http://www.emea.europa.eu/htms/human/raguidelines/itf.htm

Medical Devices Directive (MDD), the Active Implantable Medical Devices Directive (AIMDD) and the In Vitro Diagnostic Medical Devices Directive (IVDD).

In particular, some medicinal products containing nanoparticles have been already granted marketing authorisation by EMEA [15].

3.1.3 Medical devices

Medical devices are regulated via specific EC Directives (called the New Approach on Technical Harmonisation and Standardisation). Authorisation is granted on the basis of conformity with specific EU standard (CE marking) and certification of nationally appointed bodies. Manufactures are obliged to carry out an assessment of the risks as defined in the Medical Devices directive and to adopt adequate risk management strategy, to be documented in a technical dossier.

Four classes of risks are defined depending on the type of medical device considered, from class I devices (various kind of non-invasive devices) to class III devices (as implantable devices and long term surgically invasive devices in contact with the heart or the central nervous system). Safety standards vary depending on product classification. In particular Class III devices require a careful case-by-case risk assessment and an independent verification of the risk..

A report devoted to nanotechnology and medical devices has been published by the Medical Devices Experts Group in July 2007 [10].

The report concludes that in general *"medical device legislation is suitable to deal with medical devices manufactured utilising nanotechnology"*. At the same time, the document points out that particular attention must be given to free nanoparticles (devices where nanoparticles are not encapsulated or bounded) and that specific regulatory requirements could be required in these cases. Moreover, the development of new standards and guidelines, improvements in post-marketing surveillance systems, and collection of data and information, by means of a specific information gathering initiative, are envisaged.

A similar position is expressed in the regulatory review published by the European Commission in June 2008, where is stated that the Medical Devices Directive *"allows, in principle, risks associated with nanomaterials to be covered"*, but further specific guidance or standards should be developed.

Several indications on ethical and regulatory issues related to the application of nanotechnology both to medicinal products and medical devices are also included in the report of the "European Group on Ethics in Science and New Technologies (EGE)" on the ethical aspects of nanomedicine, published in January 2007. [11]

An important issue still unresolved, identified also in other legislations (as in the case of FDA in USA), regards novel nanomedical products, combining diagnostic and therapeutics functions. These devices can challenge the current classification criteria

[15] http://www.nano-safety-for-success.eu/nano/Presentations2008/M%20Papaluca-AMAti%20Nanomedicines%20Oct%202008%20Brussels%20-MPA.pdf

between medical devices and medicinal product and very likely also classification into the different categories of medical devices.

3.1.4 Foods (European Food Safety Authority-EFSA)

The European Food Safety Authority (EFSA) in an independent source of scientific advice and communication supporting the European Commission, the European Parliament and EU Member States in taking effective and timely risk management decisions on risks associated with the food chain. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health.

A premarket authorisation procedure is foreseen for products under EFSA jurisdiction. Generally this jurisdiction includes dedicated risk assessment procedures (conducted by Member states or EFSA), while in some cases (as for food supplements and food additives) authorisation depends from the inclusion in lists of specific authorised/non authorised substances.

Regarding nanotechnology, the agency has set up in 2007 an expert working group [16], involving people from national food safety authorities. The group launched in early 2008 a *"Call for Scientific Data on Applications of Nanotechnology and Nanomaterials used in Food and Feed"*[17] to collect data on the safety of nanomaterials used in foods and feeds, in particular information related to risk assessment procedures used for nanomaterials.

Following this initiative, EFSA published first a draft and then, in February 2009, a final scientific opinion on the potential risks related to the application of nanotechnology in food and feed safety and the environment [32].

The opinion highlights that the regulatory frameworks for food and feed are appropriate but will not be able to be exercised to their full extent until methods are developed to detect and measure nanomaterials in food, feed and biological tissues, and that a better understanding of exposure and toxicity is needed. These are serious quandries for the regulation of nanotechnologies in food and feed.[18]

Regarding regulatory requirements, the opinion also recommends to include into the current definition of nanoscale materials the additional metric of specific surface area.

These matters have been discussed within the EU Parliament that in a report to the European Commission (March 2009) clearly asked for amendments in regulatory provision for foods including: introduction of a specific definition of nanomaterials, labelling, stricter requirements for risk assessment of products containing nanomaterials.[19]

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[16] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178678338323.htm

[17] http://www.efsa.europa.eu/EFSA/Call_Consultation/sc_604_call_for_data_nanomaterials.pdf - The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety[

[18] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_FAQNanotechnology.htm

[19] http://www.europarl.europa.eu/news/expert/infopress_page/067-52498-082-03-13-911-20090324IPR52497-23-03-2009-2009-false/default_en.htm - http://www.euractiv.com/en/science/meps-back-tougher-rules-nanotechnology/article-181695

Alongside EFSA a number of international fora for exploration of nanotechnology and food safety are emerging. For example the Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, taking place in early June, will bring together many experts to consider the status of knowledge of exposure, hazards and regulation of nanotechnologies in the agrifood sector.

3.1.5 Cosmetics

The existing regulation system for cosmetics is based on the Cosmetics Directive (Council Directive 76/768/EEC). The Directive places full responsibility for the product's safety on the manufacturer or importer of the cosmetic product, who have to assess the safety of the product before placing it on the market, through a documented risk assessment. No pre-market verification of the manufacturer's risk assessment by a third party is foreseen.

Control over certain ingredients and their use in cosmetics is provided in the form of a number of positive and negative lists of ingredients, through which the use of particular substances may be prohibited, restricted or expressly approved (including in particular substances used for UV-filtering).

The European Commission Scientific Committee on Consumer Products (SCCP) published on March 2008 an "Opinion on Safety of Nanomaterials in Cosmetic Products" [20]. In this study, the SCCP divides nanoparticles into two groups: 1) soluble and/or biodegradable nanoparticles; and 2) insoluble particles. The SCCP states that *"conventional risk assessment methodologies based on mass metrics may be adequate, whereas for the insoluble particles other metrics, such as the number of particles, and their surface area as well as their distribution are also required.",* identifying a clear knowledge gap on risk assessment of insoluble nanomaterials. It also underlines that regarding the ban on animal testing with respect to cosmetics, required by the Cosmetic Directive, at present there is not a validated methodology for nanomaterials.

The Opinion concludes requiring a review of the safety of the insoluble nanomaterials presently used as UV-filters in sunscreens (up to now considered the main application of nanomaterials in cosmetics).[21]

[20] http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf

[21] Details on some of the action undertaken following this opinion, including reviews on prior assessments of zinc and titanium dioxide, are available at http://ec.europa.eu/enterprise/cosmetics/html/nanotechnology_en.htm

Another important initiative has recently been launched by the International Cooperation on Cosmetics Regulation (ICCR), with the aim of harmonising current approaches to cosmetic regulation, in particular in the case of nanotechnology. [22]

After a first meeting in August 2008, an ICCR expert working group for nanotechnology has been established to develop a definition and inventory of uses of nanotechnology in cosmetics.

More recently, in March 2009, the EU parliament approved an update of EU legislation on cosmetics. The basic aim of the new regulation is to simplify the current regulatory system, transposing several amendments in one single piece of legislation, and to increase the safety of cosmetics, strengthen manufacturer responsibility and in-market control aspects [23].

The provision (that will need some years to come into full force), includes a definition of nanomaterials, identified as *"insoluble or bioresistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm"* and gives specific requirements in relation to nanomaterials, introducing *"a safety assessment procedure for all products containing nanomaterials, which could lead to a ban on a substance if there is a risk to human health. It also asks for any nanomaterials present in cosmetics to be mentioned in the list of ingredients on the packaging."* [24]

3.2 European Countries

3.2.1 France

The agencies currently collecting information on the implications of nanomaterials and nanorelated products in France are the French Agency for Environmental and Occupational Health Safety (AFSSET), with reference to the risks of workers, the French Food Safety Agency (AFSSA), monitoring food and drinking water, and the French Health Products Safety Agency (AFSSAPS), monitoring drugs, medical devices and cosmetics [12]

Recommendations have been issued by the "Comité de la Prévention et de la Précaution" (CPP) and AFSSET, regarding the need for anticipatory and precautionary measures to be taken in the workplace and to comply with the new European regulation REACH.

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[22] ICCR is an international group of cosmetic regulatory authorities from the United States (Food and Drug Adminstration), Japan (Ministry of Health, Labour, and Welfare) , the European Union (European Commission, DG Enterprise), and Canada (Health Canada). - http://www.fda.gov/oia/ICCR-2.htm, http://ec.europa.eu/enterprise/cosmetics/doc/outcome_iccr_2008.pdf

[23] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/184&format=HTML&aged=0&language=EN&guiLanguage=en

[24] http://www.europarl.europa.eu/news/expert/infopress_page/066-52333-082-03-13-911-20090323IPR52331-23-03-2009-2009-true/default_en.htm

Two reports have been published by these agencies:

- " Nanotechnologies, Nanoparticules: Quels Dangers, Quels Risques ? " - Ministère de l'Ecologie et du Développement Durable, Comité De La Prévention et de la Précaution, May 2006
- "Nanomaterials : Effects on the Environment and Human Health" - French Agency for Environmental and Occupational Health Safety (AFSSET), July 2006.

Within the broad environment project called "The Grenelle Project", launched in 2007, and that will form the basis for the improvement of France environmental legislation, a critical debate is taking place regarding nanotechnology [25]. In particular, a proposal by the Ministry for Ecology, Energy, Sustainable Development and Territorial Development, made to the National Assembly in January 2009, includes:

- requirements for declaration to authorities of the manufacturing, importing or the placing on the market of nanoparticle substances;
- reporting, upon request of the authority, of hazard and exposure information regarding these substances;
- requirements to make publicly available information related to the identity and uses of these substances.

If the proposed legislation is adopted, it will create many challenges for corporations, regulators and the French Government, as well as raise questions about the compatibility of the legislation with current EU law.

3.2.2 Germany

Responsible development of nanotechnologies is amongst the priorities of the Nano-Initiative Aktionsplan 2010 [13], launched by the Federal Government in November 2006 to provide a single strategic framework, for the development of nanotechnology at national level.

In 2006, the Federal Institute for Occupational Safety and Health and the German Chemical Industry Association (VCI), conducted a survey within the chemical industry on occupational health and safety in the handling and use of nanomaterials. This formed the nucleus of what became, in 2007, the report on the "Guidance for Handling and Use of Nanomaterials at the Workplace" [18].

Specific actions related to evaluation and improvement of knowledge about EHS issues, the development of guidance for the implementation of existing regulation and for dialogue amongst stakeholders on the risks and benefits of nanotechnology have also been explored. The government strategy has been condensed into the "Health and environmental risks of nanomaterials – Research Strategy" published in December 2007 [14].

With regards to nanoregulation, the Federal Environmental Agency (UBA) released in 2007 an expert report [15] which covered the current EU and German regulatory framework in relation to nanotechnology (with a particular emphasis on environmental

[25] http://www.safenano.org/SingleNews.aspx?NewsID=640

aspects). Gaps were identified in regulation that exist at European and national level in connection with "nanotechnologies" and possible regulatory approaches indicated.

However following this report, the German government concluded that no changes in the legal framework were necessary at that time going on to state that the available instruments at the national and European level, as well as the flexibility of these regulatory frameworks, permit appropriate responses to new scientific results or events linked to materials on the nanoscale. Eventual changes in the regulatory provisions for specific cases should be made only after common international definitions and appropriate analytical tools for risk assessment have been developed.

3.2.3 UK

The UK has been very active in recent years regarding actions and initiatives related to nanotechnology regulation. After the publication of the Royal Society/Royal Academy of Engineering report in 2004, the Government published a response to the issues raised by the document and established a Ministerial group to coordinate the national research and policy strategy on nanotechnologies, with particular emphasiss on EHS issues. Activities are detailed in the review of government's progress on nanotechnology policies and research [16] (March 2007) by the CST and the NRGC- DEFRA document "Characterising the potential risks posed by engineered nanoparticles – a Second Government Research Report" (December 2007),

Reviews of the regulatory framework in relation to the various application sectors have been commissioned or supported by UK agencies with potential regulatory responsibilities for nanomaterials. In particular, the Health and Safety Commission (HSE) (February 2006), DEFRA (March 2006), whose activity has been already described before, the Food Standards Agency (FSA) (March 2006) and the Medicines and Healthcare Products Regulatory Agency (MHRA) (September 2006) [17].

Most information in these report is summarised in a very good review published in December 2007 by Cardiff University [18] "An Overview of the Framework of Current Regulations affecting Development and Marketing of Nanomaterials", where more provisions (both national and EU) across most of application sectors of nanotechnology are carefully examined.

Similarly to the EC review, uncertainties in scientific knowledge results as the main gaps in the application of existing regulation to nanotechnology, but their conclusions are less optimistic than those of the EC review.

Following these analyses the UK government has published in February 2008 [19] a "Statement by the UK Government about Nanotechnologies". Referring to nanoregulation, the document explicitly states that *"the existing regulatory framework is broadly adequate, although there is the potential for engineered nanoscale materials to fall outside regulatory control in certain circumstances. [….]"* and *"to determine whether there is a real regulatory gap, we need a better understanding of the potential risks and thus of the adequacy of the risk assessment models that sit within the existing legislation"*.

The UK Government plans to continue to keep the regulatory situation under review, as research results and other evidence become available, and will support in particular the

development of guidance and other advice tools to respond to any potential risks posed by nanotechnologies.

The Government also underlines that at the moment *"free manufactured nanoparticles and nanotubes, rather than fixed to or within a material NP, are the major source of concerns related to health and environmental safety"*.

Finally, the UK has been playing a leading role in international fora, such as the ISO, CEN and OECD activities on nanotechnology. The British Standard Institute has published a number of UK standards that will represent relevant inputs for the development of European and International standards.

3.2.4 The Netherlands

One of the main elements of in the Dutch *Kabinets Visie* (Cabinet's View) is the subject of managing the risks of nanotechnologies ("Cabinet's View Nanotechnologies: From small to great", 2006 [20]). In it the Dutch government highlights the desire to move towards a situation in which humans and the environment have only a negligible risk caused by nanoparticles and especially free, synthetic nanoparticles. Based on current knowledge, the government assumes that restriction of application of nanoparticles is not relevant, neither is the interference in the process of development of new nanotechnology applications. Therefore, government activities are focused on generation and sharing of knowledge and on application of existing legislation.
A well balanced precautionary approach with transparent political decision making, clear responsibilities of government, industry and civilians and the involvement of the public in the process decision making [20] is outlined in the government strategy.

The Netherlands participates within the subgroup of nanotechnology under the REACH authorities. This is a first step to include nanoparticles within the implementation of REACH. According to the Dutch Action Plan Nanotechnology, the government also considers it important, in the short term, to develop knowledge about the risks of nanoparticles. For this purpose, several pilot studies are initiated, in cooperation with other countries and a "Stakeholder group Nanotechnology Risks" with the business and social organizations [21] has been recently started.

For the longer term the government focuses on the development of standards, tools and methods for risk assessment, with the aim to generate global agreements on terminology and standardization. These aspects are handled in the OECD and by the International Organization for Standardization (ISO). The Netherlands is a member of a number of working groups working on these topics [21].

3.2.5 Switzerland

The Swiss action plan on "Risk Assessment and Risk Management for Synthetic Nanomaterials 2006–2009" was launched in spring 2006 by the Federal Office for the Environment (FOEN) and the Swiss Federal Office of Public Health (SFOPH), with a panel of experts including representatives from different other Federal Offices, and industry and academia representatives.

Following a specific study of the current state of our knowledge about the potential risks of manufactured nanoparticles [22], it was concluded that there is not yet sufficient

basic information on the scientific nature or mechanisms for a conclusive risk assessment of nanoparticles to be carried out, let alone to be regulated appropriately. In Switzerland, the basic legislative prerequisites to regulate manufactured nanoparticles are in place, but it will be necessary to adapt ordinances, norms and guidelines. For instance, instead of using threshold values for mass, new parameters such as surface area/volume will have to be considered. The Swiss regulations employ various tools such as authorisation, self-supervision, positive and negative lists, the obligation to provide information and limits for emissions.

Several concrete actions in the area of research (national research programmes), communication and risk assessment have been proposed to, and adapted by, the Federal Council in April 2008. At present, the implementation of work proposed in the action plan is underway.
Also under discussion at present is whether certain elements of REACH should be implemented into Swiss legislation. This would induce revision of the existing chemicals and environmental legislation (ChemG, USG).

In December 2008 FOEN and SFOPH published, as one of the he outcome of the Action Plan, the "precautionary matrix for synthetic nanomaterials". This "safety matrix" is a screening tool intended to support trade and industry to identify possible sources of risk in the production, use and disposal of synthetic nanomaterials. [26]

3.3 USA

The Nanotechnology Environmental and Health Implications (NEHI) Working Group (established in 2005) is in charge of coordinating the efforts related to understanding potential risks of nanotechnology of the different agencies involved in the National Nanotechnology Initiative (NNI) [27]. NEHI prepared the report "NNI-Strategy for nanotechnology related environmental, health and safety research" (February 2008) [23], underlining the commitment and increasing activities of research in this field from the NNI. The strategy identified five priority areas for EHS research, and the related coordination agencies:

- Instrumentation, metrology and analytical methods - National Institute for Standards and Technology (NIST)
- Nanomaterials and human health – National Institutes of Health (NIH)
- Nanomaterials and the environment, Environmental Protection Agency (EPA)
- Human and environmental exposure assessment – National Institute for Occupational Safety and Health (NIOSH)
- Risk management methods – Food and Drug Administration (FDA) and EPA

With reference to regulation, the FDA, EPA, the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC), NIOSH, are all actively exploring EHS implications, risks and possible needs for regulations in their fields of operation and ought to regulate also nano-related materials, products and processes.

[26] http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=en

[27] http://www.nano.gov/html/society/NEHI.html

The Federal Nanotechnology Policy Coordination Group (NPCG) addresses policy issues on nanotechnology that affect multiple federal agencies, with the aim of developing a coordinated approach to nanotechnology regulation at federal level.

Below a brief overview of the main activities on nanotechnology regulation from the above said Federal Agencies is reported, but as a general remark it can be anticipated that some of these agencies have reviewed existing environmental, health, and safety statutes for nanotechnology, have concluded that present statutes probably provide adequate authority for regulators on nanotechnology, or at least the existing scientific evidence is not sufficient to justify the development of a specific regulation [28].

Nevertheless, as in Europe, it is generally recognised that regulatory agencies should develop specific guidelines in order to facilitate the application of existing statutory requirements to nanotechnology.

3.3.1 EPA

The EPA strategy on nanomaterials is described in the EPA nanotechnology white paper [24] published in February 2007 and the Nanomaterial Research Strategy (NRS), developed by The Office of Research and Development (ORD) and issued in June 2008.[25]
The four main research themes identified in the 2008 document relevant to nanomaterials are: *identifying sources, fate, transport, and exposure; understanding human health and ecological effects to inform risk assessments and test methods; developing risk assessment approaches; preventing and mitigating risks.*

According to these documents, the statues considered most relevant evaluate and manage risks associated with nanomaterials and nanoproducts are:

- Toxic Substances Control Act (TSCA) - Chemicals,
- Federal Insecticide, Fungicide and rodenticide Act (FIFRA) - Pesticide
- Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA) – Environment
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) – Environment
- Toxics Release Inventory Program - Environment

[28] As reference, in the memorandum issued in November 2007 by NPCG, entitled "Principles for Nanotechnology Environmental, Health, and Safety Oversight" is stated:
- *"The Federal government's current understanding is that existing statutory authorities are adequate to address oversight of nanotechnology and its applications. As with an developing area, as new information becomes available the Federal government will adapt or develop additional oversight approaches, as necessary, to address the area of nanotechnology.*
[…]
- Regulation should focus where need exists and where scientific information supports action (e.g. targeted to specific groups and classes of materials instead of a "one-size fits- all" approach);
[…]
- Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information;"

So far, most of the debate has centred on the regulation of nanotechnology related to the EPA-TSCA statute, analogous to REACH in Europe, and is briefly described in the next subsection.

In 2007, EPA has also launched a Nanoscale Materials Stewardship Program (NMSP), to gather information by manufacturers on nanoproducts they are making and about any associated health or environmental risks and risk management practices (see paragraph 4.3).

3.3.1.1 EPA-TSCA

TSCA cover regulation of "chemical substances", and it define this term as *"any organic or inorganic substance of a particular molecular identity, including – (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical."*

The statute makes a clear distinction for existing substance, having the same "molecular identity" of substance included in the "TSCA Chemical Substance Inventory", and new substances (not included in the Inventory).

Nanomaterials classified as new substances are subjected, as any other new chemical, to a pre-manufacture review process (pre-manufacturing notification –PMN-), to identify and assess risks of the substance considered. Even though the definition of substances is considered by the agency broader enough to include nanomaterials, and thus to regulate nanomaterials under TSCA, one observer argued that many nanomaterials may be classified as "existing substances", having an identical chemical structure compared to the material in a macro-form.
In the view of the agency, EPA has still the authority to review and regulate them through a procedure called "significant new use rules (SNUR)", a notification asked of companies in case of any significant new use of existing chemicals. Under SNURs the EPA can require premarket notification essentially identical to those required for new chemicals.

A particular area is that of carbon nanotubes, for which EPA issued a specific Federal Register notice (October 2008), clarifying that *"CNTs are considered distinct chemical substances from graphite or other allotropes of carbon listed on the TSCA Inventory"* [26].

Since January 2005, EPA has received and reviewed more than fifty chemicals notices for nanoscale materials, some considered as new chemicals other treated through the SNURs procedure. Apart from the generation of additional EHS data, the following general principles are clearly emphasised by EPA in any case of concern[29]: *limiting the uses of the nanoscale materials; requiring the use of personal protective equipment, such as impervious gloves and NIOSH approved respirators; limiting environmental releases;*

Apart from the debate on the ability of the statute in distinguishing nanomaterials from conventional-sized materials, issues similar to other regulation have been highlighted

[29] http://www.epa.gov/oppt/nano/

regarding application of TSCA to nanomaterials, such as the presence of threshold levels based on mass/volume metrics and lack of adequate risk assessment and risk management methods for nanomaterials, that challenge the application of current statute requirements [27, 28, 29].

3.3.2 FDA

The FDA has broad regulatory authority over a range of products, such as drugs and devices for humans and animals, and biological products for humans.
The FDA established in 2006 an internal "FDA Nanotechnology Task Force", that released a report in July 2007 [30] reviewing activities and authority of the agency with respect to nano-related products, and is currently co-chairing with NIOSH the NEHI working group on new test methods/protocols to define safety of these products.

The FDA regulates products on a "product-by-product" basis, the main statutes being the Federal Food, Drug and Cosmetic Act (FFDCA) and the Public Health Service Act (PHA). The ability of FDA provisions to regulate nanomaterials varies depending of the different approval procedures foreseen for different type of products [30]. Three categories are considered:

- Products subjected to pre-market approval (pharmaceuticals, high-risk medical devices, food additives, colours, and biological products)
- Products subjected to Post Market Surveillance (as foods, cosmetics, radiation emitting electronic products, and materials such as food additives and food packaging).
- A third mixed category of products subject to premarket "acceptance".

The 2007 Task force report concluded that the FDA's authority is adequate for products subject to pre-market approval, while where manufactureres are not required to submit data prior to marketing, the ability of FDA provision may be *"less comprehensive"* (this is the case for products like cosmetics, food additives and dietary supplements, where nanotechnology is increasingly applied).

In particular, the fact that nanomaterials properties change depending on their dimensions has been underlined as one of the main challenges in regulating nanotechnology, compared to other emerging technologies. This is due to the fact that while size may affect the efficacy of nano-related products, most of the existing reporting and notification mechanisms within the FDA provisions may not require specific information on particle size.

As is the case for European legislation, the classification of medical devices having multiple properties functions (e.g. theranostic devices) is a critical issue.
Analogously to other regulatory frameworks, issues related to exposure triggers using mass/volume metrics, appropriateness of toxicological data and testing protocols have been also underlined as critical factors in regulating nanomaterials.

The agency has initiated several collaborations with public and private organisations to develop methods and data with respect to the environmental, health and safety issues of nanomaterials in response to the gaps outlined above. In particular the FDA is working

[30] http://www.fda.gov/nanotechnology/regulation.html

with the National Institutes of Health, NIST and is actively involved in the OECD nanomaterial testing programme.

3.4 Australia

Coordination of the Australian activities on nanotechnology are in charge of the Australian National Nanotechnology Strategy, that established the Health, Safety and Environment (HSE) Working Group aiming to analyse the impact of nanotechnology on national regulatory frameworks, coordinate all relevant regulatory agencies efforts (including standards Australia) and support international engagement on nanotechnology regulation. Specific funds to all relevant government agencies have been allocated to undertake activities on these topics.

Three reference documents have been published so far regarding nanoregulation:

- A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks (the Monash Report), July 2008 [33]
- The Australian Government Approach to the Responsible Management of Nanotechnology, July 2008 [34]
- The National Nanotechnology Strategy (NNS) Annual Report 2007–08, Australian Office of Nanotechnology, Jan 2009 [35]

The general conclusion of these documents is that there is no immediate need for major changes to existing regulatory frameworks, even though there are potential gaps in different regulatory areas, that should be considered in detail by regulatory agencies in order to define possible amendments.

These gaps are synthesises in six points [33, 35]:

1) *Distinction between 'New' or 'Existing' substances or Products,*
2) *Regulatory triggers based on weight or volume,*
3) *Knowledge of presence or implications of presence of nanomaterials,*
4) *Adequacy of risk assessment protocols and conventional techniques,*
5) *Research and Development exemptions,*
6) *International documents and documents sourced outside regulators (adequacy of these references).*

The government (with the NNS), has provided a feedback on all these topics and has given an explicit commitment to all relevant agencies to work on them, but it has also underlined that the activity on nanoregulation "*will be a long-term effort across multiple regulators and regulatory agencies as nanoproducts arise and as new knowledge on hazards, exposure and monitoring tools becomes available*".

A relevant activity on nanotechnology is already on-going within different national regulatory agencies.

NICNAS (National Industrial Chemical Notification and Assessment Scheme, regulatory authority responsible for industrial chemicals) has established the NICNAS

Nanotechnology Advisory Group (NAG) to define strategic approaches to address regulatory and safety impacts of industrial nanomaterials [31].
The Agency has issued in February 2006, a voluntary call to Australian industry to provide information on uses and quantities of nanomaterials imported or manufactured for industrial purposes, and use in cosmetics and personal care products. Aim of the initiative was to understand the type and volumes of nanomaterials placed in the market or close to commercialisation, in order to better assess the existing regulatory situation.
More than 20 companies answered the survey, giving information on 21 different nanomaterials, of which 17 for commercial use and the other for R&D purposes.

In 2008, the survey have been extended with a new Voluntary Call for Information (October 2008), including industrial nanomaterials at the research and development stage and requirement of information on physico-chemical and toxicity data, life cycle data, protection measures of nanomaterials. The Call closed in January 2009, results have not yet been published.

The Australian Pesticide and Veterinary Medicines Agency (APVMA) has published in December 2008 a strategy for nanotechnology, with a commitment to develop appropriate administrative process to deal with nanotechnology [32].

In 2008 the Agency also launched a "*Call for Information – Nanomaterials in Agricultural or Veterinary Chemicals, or Agricultural or Veterinary Chemical Products*", making an assessment of currently registered products using nanotechnology. The final result was that there were no products in 2008 registered using nanomaterials. The Agency is supporting further initiatives to monitor the use of nanomaterials.

Finally, the Department of Education, Employment and Workplace Relations (DEEWR) has developed a Nanotechnology OHS R&D Program, with specific actions for the identification of hazards related to nanomaterials, development of exposure measurement capability, evaluation of the effectiveness of workplace controls for preventing exposure to engineered nanoparticles [33].

3.5 Canada

The Canadian government has supported several initiatives at the research and policy level towards a safe and responsible development of nanotechnology, recognising that *"a balanced, stewardship approach is needed to permit the responsible introduction of nanotechnology to Canadian society"*[34].
Canada is currently applying to nanotechnology the existing regulatory regime, but several actions have been put in place, in particular regarding chemicals, and is not

[31] http://www.nicnas.gov.au/Current_Issues/Nanotechnology/What_Is_NICNAS_Doing.asp

[32] http://www.apvma.gov.au/nanotech/nanotech.shtml

[33] http://www.safeworkaustralia.gov.au/swa/HealthSafety/EmergingIssues/Nanotechnology/AbouttheNanotechnologyOHSProgram.htm

[34] http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/fs-fi/nt_factsheet_fichedocumentaire-eng.php

excluded that *"new approaches may be necessary in the future to keep pace with the advances in this area."*[35].

A precautionary approach is generally envisaged, as is also clearly underlined in the 2007 report commissioned by the Government to the Council of Canadian Academies, to assess the state of health and safety in nanotechnology [31].

Following consultation in a dedicated multi-stakeholder workshop, the Federal departments of Health Canada (HC) and Environment Canada (EC) have published a proposal in September 2007 for a regulatory framework for nanomaterials under the Canadian Environmental Protection Act, 1999 [36].
This document is providing the basis for regulatory actions on nanotechnology in Canada, in particular [12]:

- Canada is actively participating in the OECD and ISO initiatives on nanotechnology, and is chair of the ISO TC 229 WG1 Task Group
- Several communication and information activities toward industry and the public, with respect to regulatory responsibilities under the current legislative regime have been conducted in the last years [12, 31].
- Regarding information gathering initiatives, EC and HE will launch in Mid 2009 a mandatory survey on nanomaterials, under the *Canadian Environmental Protection Act, 1999* statute.
- Regarding regulation of chemicals and polymers, EC issued (on July 2007) an advisory note informing manufacturers and importers of nanomaterials of their regulatory responsibilities for nanomaterials under the N*ew Substances Notifications Regulations (Chemicals and Polymers),* within the Canadian Environmental Protection Act, 1999 (CEPA 1999). The note provides indications on which nanomaterials are subject to the current regulations, explicitly mentioning examples such as fullerene and titanium dioxide.[37]

Regarding occupational safety two other relevant actions have been undertaken:

- The report *"Development of a best practices guide for the safe handling of nanoparticles",* published by the Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) [32]

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[35] http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/fs-fi/nt_factsheet_fichedocumentaire-eng.php

[36] In the motivation of the proposal is stated *"Nanomaterials present challenges to the current regulatory framework under CEPA 1999 because their novel properties may give rise to new effects and behaviours which may lead to impacts on human health and the environment. The current data requirements for "traditional" chemicals and polymers may not be appropriate to permit adequate risk assessments of nanomaterials. Therefore, Environment Canada and Health Canada are proposing an approach for the development of a regulatory framework for nanomaterials under CEPA 1999. " [proposal]*

[37] as in other statutes, regulatory requirements depends from the inclusion into positive/negative list of substances. The problem regarding nanomaterials is whether they are considered similar to their macroform (thus as "existing substances" not subject to specific review) or as new substances (subject to specific risk review).
The advisory note can be found at http://www.ec.gc.ca/substances/nsb/eng/a200706_e.shtml

- In relation to the legislation on hazardous products (HPA- Hazardous Products Act, administered by HA), a working group devoted to nanotechnology has been established within the Workplace Hazardous Materials Information System (WHMIS). The WG activity aims to develop hazard criteria, guidelines and best practices and investigate needs for implementing nanomaterials information into Material Safety Data Sheets (MSDS).

Several other activities with respect to research to understand EHS and ELSI implications of nanotechnology are underway in Canada, as outlined in the documentation of the Council of Canadian Academies and OECD [31, 12].

3.6 Japan

Most of initiatives relating to environmental and human health safety activities going on in Japan are related to research on EHS issues. At the institutional level, The Ministry of Economy, Trade and Industry (METI) is conducting a 5 years project on toxicity test protocols and risk assessment methodologies for manufactured nanomaterials and the National Institute of Occupational Safety and Health Japan (JNIOSH) has started a three-year project on exposure to manufactured nanomaterials at the workplace [12].

As in all other countries, no specific regulatory measures regarding nanomaterials have been implemented in Japanese legislation. However, in the current regulatory system, the Chemical Substance Control Law obliges manufacturers to notify the government about nanomaterials if they are new chemicals subject to the law, and some notifications concerning fullerene derivatives have been submitted under the small quantities exemption of the new chemical notification. [12]

The Ministry of Economy, Trade, and Industry (METI) and the Ministry of the Environment (MOE) have both established specific working groups dedicated to nanomaterials safety.

METI has organised at the end of 2008 a preliminary survey on safety of nanomaterials in occupational settings and made an assessment of existing good practices for the handling of nanomaterials. Results of these activities have been condensed in a report (published in March 2009) pointing out potential risks in nanomaterial manufacturing and giving voluntary guidelines for the handling of nanomaterials [38].

The Ministry of Health, Labour, and Welfare (MHLW) is preparing nanotechnology guidelines related to labour and will write another set on medical practices and pharmaceuticals soon.

Japan participates in the work of OECD WPMN and ISO TC 229 (in particular is the convenor of the Working Group on Measurement and Characterization

[38] http://www.safenano.org/SingleNews.aspx?NewsID=641

4 SELF-REGULATION

Self-regulation initiatives have an important role in the short/medium term to deal with the current uncertainties and ambiguity about the regulatory situation for nanotechnologies. They can support disclosure and sharing of information, definition and dissemination of guidelines and best practices, provide common principles and values and facilitate trust among different current and potential stakeholders.
As clearly stated in the general objectives of most of these initiatives, their aim is not to replace regulation or any other legislative requirement but instead to help complement them.

Policy makers, and also other stakeholders, have developed various kind of such voluntary measures [2]:

Reporting schemes:
These instruments are used by regulatory authorities to collect information from industry actors regarding the manufacturing, production and use of nanomaterials, requiring information such as material specifications, production volumes, risk assessment and risk management data and methods, etc.
They can aide the gathering of information and increase the knowledge base on nanomaterials and enable the development of a firmer evidence base for regulatory/policy decisions. These are generally related to specific provisions (e.g. chemicals) and they can be voluntary or enforced by legislation.

Code of conducts:
Regulatory authorities and other stakeholders have proposed or implemented voluntary code of conducts, defining values, principles and practises for a safe and responsible development of nanotechnologies. Even though they generally have a non-binding character, there could be a degree of liability related to the subscription of such documents. The main purpose, however, is to provide a common reference and increase the level of trust and confidence amongst stakeholders.

Management frameworks and accreditations
These instruments are generally adopted at the industrial level, to increase the level of safety in relation with the manufacturing, production and use of nanotechnologies.
They provide guidelines and best practises in risk management and in environmental, health and safety (EHS) issues. They do not have a regulatory role, and , as in the case of accreditations, can work similarly to product quality certification systems.

The most important examples of these four measures are described in brief in the following.

4.1 EC Code of Conduct

The EC has for sometime been very active in promoting nanotechnology and has paid particular attention to assuring that the development of nanotechnology should emerge within a culture of responsibility, protecting the safety of European citizens and safeguarding the environment (see 3.1). In 2008 (7th of February), the EC recommended

the adoption of a Code of Conduct for responsible nanoscience and nanotechnologies research [1].
The code is based on a set of principles[39], comprising amongst others *precaution, inclusiveness and sustainability* and provides a series of guidelines on actions to be taken, priorities, prohibition, restrictions or limitations, to assure a safe development of nanotechnology.
The CoC covers all N&N research activities, at the European level, and is targeted to "*Member States, employers, research funders, researchers and more broadly all individuals and civil society organisations engaged, involved or interested in nanosciences and nanotechnologies (N&N) research"*.
The Code is a political signal for all member nations, which are formally asked to adopt it, and a recommendation to all other stakeholders.

Stakeholders can implement, or support the implementation, of the CoC according to their activities, role and level of responsibility. Therefore the content and degree of implementation will strongly depend on the way the general principles of the CoC will be translated into concrete measures [40].

The reaction so far has been tepid and initiatives are in the offing to promote the implementation of the Code.

4.2 DEFRA –VRS (UK)

The UK's Voluntary Reporting Scheme (VRS) for Manufactured Nanomaterials was launched in September 2006 and concluded in September 2008 [6,7,8].
The VRS was targeted at any company or organisation involved in the manufacturing, usage, the importing or management of wastes consisting of engineered nanoscale materials [41].

Information requested included any data on: uses, benefits and exposure pathways, physico-chemical properties, toxicology, ecotoxicology and risk management practices. A data reporting form has been provided.
A total of 13 submissions have been received at the end of the program, most of them from industry.

The large amount of information requested, confidentiality issues and also the resources needed to participate (in particular with respect to SMEs) are amongst the reasons identified by DEFRA for low participation to the VRS [42].

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[39] The seven CoC principles are: meaning, sustainability, precaution, inclusiveness, excellence, innovation, accountability

[40] FP7 workprogramme 2009 – Capacities – Science in Society
ftp://ftp.cordis.europa.eu/pub/fp7/docs/wp/capacities/capacities_intro_wp_200901_en.pdf

[41] "For the purposes of the Voluntary Reporting Scheme, VRS focus on engineered nanoscale materials that are free at any stage of a product's life-cycle." [6]

[42] http://www.defra.gov.uk/environment/nanotech/pdf/nrcg-meeting16-081006.pdf

The final VRS evaluation has not yet been made public, however the UK government has already expressed its commitment to continue and improve it. Also options for mandatory initiatives are under evaluation [17].

Inputs from the work of WPMN Steering Group 5 (Reporting Schemes and Regulatory Programmes) will be also used to this end (paragraph 5.4).

4.3 EPA-NSMP (USA)

The US Environmental Protection Agency (EPA) has launched on January 2008 the Nanoscale Materials Stewardship Program (NMSP) [3, 4], under the Toxic Substances Control Act (TSCA) statute devoted to chemical substances (paragraph 3.3.1.1).
The results of the first evaluation period have been condensed in a report published in January 2009, the program will end in January 2010.

The main objectives of NSMP are to gather data and information from manufactures, importers, processors and users of nanoscale materials (but also researchers are invited to participate), to promote testing of nanomaterials, to identify and encourage development and use of risk management practices in developing and commercializing nanoscale materials,.
The data collected will help to improve the knowledge base for future work and regulatory developments
The NSMP is based on the "TSCA Inventory Status of Nanoscale Substances", a supporting document giving indication of substances included in the program [4] [43].
There are two levels of participation, basic and in-depth. In the former case, the agency requires only submission of information on nanomaterials, whilst in the latter active engagement ("sponsorship") with the agency in the testing of selected nanoscale materials is foreseen.

Under the Basic program, information to be submitted includes physical and chemical properties, hazard, exposure, use and risk management practices or plans regarding the nanoscale materials considered.

As of December 2008, EPA received submissions under the basic program from 29 organisations, covering more than 123 nanoscale materials, and has involved 4 companies in the in-depth program [3].

Even though participation at the program have been far below initial expectations, the EPA considers the amount of information collected a valuable contribution to the assessment of existing regulatory procedures for nanomaterials.

Increasing both the participation and the amount of information provided by participants (in particular with respect to hazard and exposure data) are among the future needs underlined in NSMP interim report.

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[43] *"Nanoscale materials that are either new or existing chemical substances (as determined by the status of the substance on the TSCA Chemical Substances Inventory) can be included in the program. See TSCA Inventory Status of Nanoscale Substances – General Approach (2008)"* - http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf

Some relevant issues are reported, in the form of open questions, in the conclusions of the document [3]:

- *What are the characteristics of nanoscale substances that should be considered in risk assessment and risk management;*
- *Which, if any, regulatory changes may be needed to address nanoscale materials; and*
- *What further risk management practices are appropriate for nanoscale substances?*

4.4 Other initiatives

4.4.1 BASF

The participation of companies in developing scientifically well-founded databases for the evaluation of potential risks and the advancement of product related testing and assessment methods is regarded as being important for the promotion of nanotechnology-related products and several manufacturers of nanomaterials have elaborated their own codes of conduct.

A relevant example is the Code of Conduct put in place by BASF [12, 13], a voluntary commitment to guide in a responsible manner the actions of BASF's employees. The Code is based on 4 principles: protection of employees, customers and business partners; protection of the environment; participation in safety research; open communication and dialogue.

Among the commitments included in the CoC:

- identification of sources of risks related to the use of nanomaterials and definition of appropriate measures to eliminate them;
- Careful risk management of nanotechnology processes and products;
- Development of EHS database and continuous improvement of product-based testing and assessment methods;
- Openness to collaboration for the establishment of risk-appropriate, solid standards and to relevant legislation;
- Marketing of products only if safety guaranteed on the basis of all available scientific information and technology;
- transparency and engagement in dialogue initiatives, commitment to disclose of new findings to authorities and the public.

BASF keeps an up-to-date website dedicated to nanotechnology and safety aspects of nanotechnology [44].

[44] http://www.basf.com/group/corporate/en/content/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/index

4.4.2 CENARIOS

CENARIOS® [9] is the first certifiable risk management and monitoring system specifically adapted to nanotechnologies. The system has been developed by TÜV SÜD (Munich, Germany) and the Innovation Society (St Gallen, Switzerland) and is already being used in practice.

The system uses the four individually combinable modules "Risk Estimation and Risk Assessment", "Risk Monitoring", "Issues Management" and "Certification" to integrate the latest findings from science and technology as well as societal, legal and market related factors into risk management.

The system is therefore especially suitable to take control of complex technology risks under conditions of high uncertainty and highly dynamic markets.

An annual certification is foreseen to guarantee the adaptation of the latest findings in science and technology[45].

4.4.3 Du Pont Nano Risk Framework

The NANO Risk Framework [10] is a practical risk assessment guide developed by DuPont and Environmental Defense, providing a procedure to enable the development of data profiles of nanomaterials properties, inherent hazards, and exposure potential. The NANO Risk Framework puts a strong focus on toxicity and also requires the user to perform such tests; it is therefore suitable for large companies.

Sharing of information, transparency and accountability of risk management procedures are considered in the framework as key elements to build confidence among stakeholders on nanotechnology.

The procedure is based on six steps: *describe material and expected application; profile lifecycle(s); evaluate lifecycle risks; assess risk management; decide, document, and act; review and adapt.*

An updated website with all information regarding the framework and its application, including case history on specific nanomaterials, is available for reference[46].

4.4.4 German Chemical Industry Association (VCI)

In 2006 the VCI, representing over 90% of the entire German chemical industry, with the German Federal Institute for Occupational Safety and Health conducted a survey on occupational health and safety in the handling and use of nanomaterials among its members. Results of the survey have been condensed in a brief public report published in 2008 [20].

The survey focused on occupational safety, aiming to collect information on the number of companies producing, using and processing nanomaterials, the type of nanomaterials, the volumes of production, the number of workers involved, hazards and exposure data andprotection measures.

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[45] http://www.innovationsgesellschaft.ch/index.php?page=88

[46] http://www.nanoriskframework.com

Approximately 50 companies responded, but, in the view of VCI, the number of respondents was limited by the restriction criteria adopted in the questionnaire [47].
The questionnaire has been considered an important step to have a first overview of the use and production of nanomaterials in Germany, even though more information has to be collected in order to make *"a general assessment of amounts of exposure with activities involving nanomaterials"*.

Based on the results of the survey VCI published in 2007 the *"Guidance for Handling and Use of Nanomaterials at the Workplace"* [18] and in March 2008 the more general report *"Responsible Production and Use of Nanomaterials"* [19].
These documents provides detailed guidance on the handling and production of nanomaterials, including indications with respect to regulatory compliance with REACH and examples of safety data sheets for nanomaterials [48].

4.4.5 IG DHS

The first example of code of conduct related to nanotechnology usage in consumer products has been published in April 2008 by Switzerland's food and packaging retailers association, IG DHS [14].

The Code contains obligations for IG DHS members, regarding personal responsibility, procurement of information and information for consumers.
Organisations signing the Code have to consider product safety as a first priority, placing on the market only products being safe according to the best available knowledge. They are also responsible to provide open information to consumer about nano-related products, in particular ensuring that *"products described as employing nanotechnologies actually contain components and/or modes of action corresponding to these technologies"*.

The Code also indicates requirements for manufacturers and suppliers, both in the form of company specific requirements and product specific requirements.

Signatories are expected to require producers and suppliers to provide all the information necessary to evaluate the safety of a product. In order to commercialise their products, producers and suppliers have to give information on the benefits of the nano-related product compared to conventional products, specific properties given by the use of nanotechnology, technical data (material specification) and potential risks for human and the environment [49].

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[47] The questionnaire asked for information related to *"synthetic nanoparticles manufactured as powders which have, in at least two dimension, an extension of under 0.1micrometre, as well as their aggregates and agglomerates…"* and *"activities involving nanomaterials (production, use or processing) from 10Kg/year"* . Pag 1, reference [20].

[48] http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/Nanotechnology.html

[49] http://www.innovationsgesellschaft.ch/media/archive2/publikationen/Factsheet_CoC_engl.pdf

4.4.6 Responsible NanoCode

In the United Kingdom, the Royal Society, together with other institutions, has developed a code of conduct, the Responsible NanoCode, launched in October 2008, targeted at a variety of stakeholders, such as companies, retailers, research laboratories, universities, private or public funded bodies.

The Code [15,16] is the result of detailed preparatory work, including inputs from a wide range of stakeholders and a detailed public consultation process of the draft of the document. An accompanying document,the "Examples of Good Practice" gives suggestions on concrete measures to be taken in order to implement the principles of the Code.
It is meant as a tool to provide advice, giving indication on the strategic issues that the organisation needs to address with respect to economic and societal effects of their activities in the field of nanotechnology. Besides commercial and scientific/technical questions, ethical issues are also considered.

The Seven Principles of the Code are: *board accountability, stakeholder involvement; worker health and safety; public health, safety and environmental risks; social and ethical implications and impacts; responsible sales and marketing; engagement with suppliers*

The designing process of the Code should continue with the engagement and monitoring of organisations applying the Code ("benchmarking process") providing further inputs to improve and refine the document [50].

[50] http://www.responsiblenanocode.org/]

5 STANDARDS FOR NANOTECHNOLOGIES

Due to the innovative production processes enabled by nanotechnologies and the peculiar behaviour of the matter at the nanoscale, the system of written and physical standards established for the macroscopic and microscopic world, cannot easily be scaled down to the nanoscopic world. In particular, nanotechnology requires the development of appropriate standards documents in crucial areas, such as terminology and nomenclature, metrology, health safety and environmental aspects.

As reported in the previous sections, there is a significant effort underway to elaborate a regulatory framework to address many of the aspects related to the use of nanotechnology, but it is largely acknowledged that there is the need to improve technical guidance documents used for the application and implementation of existing regulatory frameworks. Standards play a crucial role in this process.

A structured activity on standards for nanotechnology has been started since 2004, with the first national Technical Committees (TC) devoted to nanotechnology set up in China (SAC/TC279), UK (BSI –NT/1) and U.S.A. (ANSI-NSP) and some other countries.

5.1 The activity of ISO TC 229

Given their international reach, the activity most relevant for standardisation for nanotechnology is certainly that of the International Standards Organisation (ISO), which in June 2005 has formally established the *ISO-TC229-Nanotechnology*, dedicated to norms and standards not related to the electrical/electronic field and that of the International Electrotechnical Commission (IEC), which in June 2006 has established the *IEC TC 113 - Nanotechnology for electrical and electronic products and systems*, for the development of technical standards in these specific fields.

Standardization activities from national bodies of more than 32 countries fall under the umbrella of the Nanotechnology Technical Committees of ISO and IEC, and specific TC for nanotechnology have been established in most of these countries.

As described previously, ISO TC229 and IEC TC 113 represent the main reference for standard in nanotechnologies but, as will be described in the following, there are also several other subjects involved in the development of standards relevant, or related to, nanotechnologies at the national/regional/international level. (A list of the main standards organisations dealing with nanotechnologies is reported in Appendix)

The full understanding of the behaviour of matter at the nanoscale is still in its infancy, and there are several fundamental issues that still need to be investigated, such as tools and methods for describing, measuring, and testing nanomaterials. Most of the current activities in standards are dedicated to these basic, transversal activities, and are still not product or sector specific.

This is also indicated by the scope of ISO TC 229, that is: *the standardization in the field of nanotechnologies that includes either or both of the following* [51] *:*

- *Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications,*

- *Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.*

Specific tasks include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulations; and science-based health, safety, and environmental practices.

Within ISO TC 229, the wide spectrum of issues to be faced has been organised (in collaboration with IEC) in 4 Joint Working Groups (JWG) [1]:

- **JWG 1** - **Terminology and Nomenclature**
- **JWG 2** - **Measurement and Characterization**
- **JWG 3** - **Health, Safety and Environment**
- **JWG 4** - **Material specification**

Both the development of a universally valid and internationally accepted nomenclature and the standardization of reliable, traceable measurement methods, including respective physical standards (reference materials), are the very first steps to support the development and commercialisation of nanotechnology. These activities are also key in providing inputs for the activities of the other ISO Working groups.

Considering that topics related to terminology, nomenclature, measurement and characterisation are (generally) not application specific, there has been an international agreement to join the efforts of ISO and IEC on these themes, and thus JWG 1 and JWG 2 are joint ISO/IEC working groups.

Several other liaisons have been established with ISO Technical Committees, in particular with TC dealing with different micro/nano measurements & characterisation techniques (such as ISO TC 201, ISO TC 202, ISO TC 213).

Potential risks for human health and the environment are considered within the Working Group 3. Liaisons have been initiated both with the OECD Working Party on Manufactured Nanomaterials (WPMN) and IEC TC 113. The former organisation has a very relevant activity on these topics, in particular with the launch in 2008 of *"OECD Sponsorship program for the testing of Manufactured Nanomaterials"*, an international effort for the development of appropriate methods for the testing of a relevant set of nanomaterials (see paragraph 5.4).

[51] ISO website, March 2009 - http://www.iso.org/iso/iso_technical_committee.html?commid=381983

The latter organisation, IEC TC 113, plays a minor role in this WP. Indeed, for electrotechnical products, the risk for environmental and human health is considered significantly lower than for other nano-related products, both because nanomaterials are generally embedded in a "macro" product, at least during manufacturing and use, and manufacturing is performed in controlled environments generally using known processes and techniques [2].

Within JWG3, liaisons are activated also with other TC Committee, in particular dealing with the biological and medical field (such as ISO TC 212 and ISO TC 194).

The Working Group 4 has been established at a later stage with respect to the other WGs (end of 2007). With nanomaterials already appearing on the market, the aim is to develop clear specifications of nanomaterials along the different steps of the production chain to ensure reproducible supply of nanomaterials, crucial for the industrialization of nanotechnologies. [7].

In 2006 ISO TC 229 undertook a survey to identify standardization needs and the first priorities for WG1, WG2 and WG3, on which ISO TC 229 is working, are indicated in the following table [4, 5, 6].

JWG 1 Terminology and Nomenclature Chair: Canada	JWG 2 Measurement and Characterization Chair: Japan	JWG 3 Health, Safety and Environment Chair: USA
Priorities: •*Nanotechnology* •*Nanoprocesses* •*Nanoproduction* •*Nanomeasurements* •*Nanomaterials* •*Devices and applications*	*Priorities:* • *Engineered nanoparticles* • *Coatings/nanostructured materials* • *Carbon nanomaterials* • *Basic metrology*	*Priorities:* • *Controlling occupational exposures to nanomaterials* • *Determining relative toxicity/hazard potential of nanomaterials* • *Toxicological screening of nanomaterials*

There are several kind of documents that can be published by ISO, IEC or other standard organisations, as regional standard bodies such as CEN (in this case the standard will have an European, not international, extension). Among them:

- ISO/PAS Publicly available specification
- Technical specifications (TS) - technical matter still evolving (normative document presented where the state-of-the-art is not yet stable enough for preparation of a standard)
- Technical reports (TR) - for information and transfer of information, current best practices
- International standards - international technical approval
- International Workshop Agreement (IWA) - An IWA is an ISO document produced through workshop meeting(s) and not through the technical committee process.

These documents have different levels of relevance. For example, in Europe only full standards (EN- European Standards) can be used as *"harmonized standards"* in support of regulatory provisions. But these kinds of documents should be developed only with the maturity of a technology, based on well established methods,instrumentation and consolidated experience.

Since most nanotechnology materials and products are still at an early stage of development, technical specifications (TS) and technical reports (TR) are generally expected to be the most appropriate documents at this stage [52].

Both TS and TR are valuable instruments from a regulatory point of view, because they can provide "best available options" to demonstrate compliance with regulation.

Also other non binding technical documents, such as ISO/IEC PAS (Publicly Available Specification), IWA and other types of documents from regional/national standard bodies, can provide important (and up-to-date) references to industry, policy makers and all other stakeholders. [3]

The activity of ISO is based on consensus and therefore the process for defining standards is cumbersome and time consuming, nevertheless, there is a genuine consensus among stakeholders that the work of international standard setting bodies is crucial in ensuring that the full potential of nanotechnology is realised. A recent survey conducted by the FP6 project Nanostrand has underlined that the absence of standards is considered an important barrier affecting the entering of nanotechnology-related products into the European market [3].

At present there are more than 30 standards documents under development within ISO TC229 and they are mainly focused on:

- Terminology and definition for nanomaterials and nanomanufacturing, in particular framework and core terms, carbon nanomaterials, bionano applications;
- Measurement and characterization of nanoparticles, in particular carbon nanotubes;
- Development of protocols for toxicity testing of nanomaterials;
- Safe handling and disposal of manufactured nanomaterials during manufacturing and occupational health issues;
- Specification of manufactured nanomaterials, in particular TiO2 and CaCO3.

Some of these documents are close to the final approval stage, and two have already been published. In particular [53]:

[52] At present, amendment to European Standards in relation with nanotechnologies are already considered in the medical device sector.

[53] http://www.iso.org/iso/iso_technical_committee.html?commid=381983

- **Technical Specification ISO/TS 27687**
  Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplatelets
  "ISO/TS 27687:2008 lists unambiguous terms and definitions related to particles in the field of nanotechnologies. It is intended to facilitate communications between organizations and individuals in industry and those who interact with them."

- **Technical report ISO/TR 12885**
  Health and safety practices in occupational settings relevant to nanotechnologies
  " ISO/TR 12885:2008 focuses on the occupational manufacture and use of engineered nanomaterials. It does not address health and safety issues or practices associated with nanomaterials generated by natural processes, hot processes and other standard operations which unintentionally generate nanomaterials, or potential consumer exposures or uses, though some of the information in ISO/TR 12885:2008 might be relevant to those areas. Use of the information in ISO/TR 12885:2008 could help companies, researchers, workers and other people to prevent adverse health and safety consequences during the production, handling, use and disposal of manufactured nanomaterials. This advice is broadly applicable across a range of nanomaterials and applications."

The following table shows a list of the main on-going activities at ISO TC 229. Some of them are already classified as Technical Specification (TS) or Technical Report (TR) [54].

Standard and/or project	**Stage code**
ISO/DIS 10808 Nanotechnologies -- Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing	40.20
ISO/DIS 29701 Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test	40.20
ISO/CD 10801 Nanotechnologies -- Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method	30.99
ISO/CD TS 10867 Nanotubes -- Use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	30.60
ISO/CD TS 10929 Measurement methods for the characterization of multi-walled carbon nanotubes	30.60

[54] For a detailed explanation of :

- the development stages of a standard document (international harmonized stage codes) please see: http://www.iso.org/iso/standards_development/processes_and_procedures/stages_description/stages_table.htm

- type of ISO deliverables during the approval process of a standard document (IS, TS, TR, etc) http://www.iso.org/iso/standards_development/processes_and_procedures/deliverables/deliverables_schema-2.htm

(MWCNTs)	
ISO/CD TS 11251 Nanotechnologies -- Use of evolved gas analysis-gas chromatograph mass spectrometry (EGA-GCMS) in the characterization of single-walled carbon nanotubes (SWCNTs)	30.20
ISO/CD TR 12802 Nanotechnologies - Terminology and nomenclature - Framework	30.20
ISO/WD TS 10797 Nanotubes -- Use of transmission electron microscopy (TEM) in walled carbon nanotubes (SWCNTs)	20.99
ISO/WD TS 10798 Nanotubes -- Scanning electron microscopy (SEM) and energy dispersive X-ray analysis (EDXA) in the charaterization of single walled carbon nanotubes (SWCNTs)	20.99
ISO/WD TS 10868 Nanotubes - Use of UV-Vis-NIR absorption spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	20.99
IEC/WD TS 80004-1 Nanotechnologies - Terminology and definitions -- Part 1: Carbon nano-objects	20.99
ISO/AWI TS 10812 Nanotechnologies -- Use of Raman spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	20.00
ISO/AWI TS 11308 Nanotechnologies -- Use of thermo gravimetric analysis (TGA) in the purity evaluation of single-walled carbon nanotubes (SWCNT)	20.00
ISO/AWI TR 11808 Nanotechnologies -- Guidance on nanoparticle measurement methods and their limitations	20.00
ISO/AWI TR 11811 Nanotechnologies -- Guidance on methods for nanotribology measurements	20.00
ISO/AWI TS 11888 Determination of mesoscopic shape factors of multiwalled carbon nanotubes (MWCNTs)	20.00
ISO/AWI TS 11931-1 Nanotechnologies -- Nano-calcium carbonate -- Part 1: Characteristics and measurement methods	20.00
ISO/AWI TS 11937-1 Nanotechnologies -- Nano-titanium dioxide -- Part 1: Characteristics and measurement methods	20.00
ISO/AWI 12025 Nanomaterials -- General framework for determining nanoparticle content in nanomaterials by generation of aerosols	20.00
ISO/AWI TS 12805 Nanomaterials - Guidance on specifying nanomaterials	20.00
ISO/AWI TS 12901-1 Nanotechnologies -- Guidance on safe handling and disposal of manufactured	20.00

nanomaterials	
ISO/AWI TR 13014 Nanotechnologies - Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment	20.00
ISO/AWI TR 13121 Nanotechnologies - Nanomaterial Risk Evaluation Framework	20.00
IEC/AWI TS 80004-3 Nanotechnologies -- Terminology and definitions - -- Part 3: Core terms	20.00
IEC/AWI TS 80004-4 Nanotechnologies -- Terminology and definitions -- Part 4: Nanostructured materials	20.00
IEC/AWI TS 80004-5 Nanotechnologies -- Terminology and definitions -- Part 5: Bio/Nano interface	20.00
IEC/AWI 80004-6 Nanotechnologies -- Terminology and definitions -- Part 6: Nanoscale measurement and instrumentation	20.00
IEC/AWI TS 80004-7 Nanotechnologies - Terminology and definitions -- Part 7: Medical, health and personal care applications	20.00
ISO/NP TS 11931-2 Nanotechnologies -- Nano-calcium carbonate -- Part 2: Specifications in selected application areas	10.99
ISO/NP TS 11937-2 Nanotechnologies -- Nano-titanium dioxide -- Part 2: Specifications in selected application areas	10.99
ISO/NP TS 12901-2 Guidelines for occupational risk management applied to engineered nanomaterials based on a "control banding approach"	10.99
ISO/NP TS 13126 Artificial gratings used in nanotechnology -- Description and measurement of dimensional quality parameters	10.99

5.2 Other standards organisations

Alongside the activities of ISO TC 229 and IEC TC 352, there are several other (standard) bodies currently working on standards for nanotechnology or with activities relevant for this field. Among these organisations it can be cited:

- Other ISO and IEC Technical Committees
- Regional organisations (such as CEN)
- National standard organisation
- Standard Developing Organisations (SDOs) and other private standard organizations
- International bodies (as OECD)
- Institutes doing research on metrology, industry, other stakeholders

Activities from national standard organisation fall directly under the umbrella of ISO and IEC. Other organisations are, in many cases, in liaison with international organisations, and/or developing standards for specific sectors of applications (as in the case of SDOs).

Several ISO Committees are developing standards relevant for nanotechnology, such as ISO TC 194 (Biological evaluation of medical devices), ISO TC 209 (clean rooms and associated controlled environments).

Among the national standard bodies that have been most active in the last years on nanotechnologies, are the BSI –NT/1 (UK), SAC/TC279 (China) and ANSI-NSP (US).

In the US, where SDOs have a more relevant role in standardisation compared to the EU, ASTM E56 (nanotechnology), ASTM E42 (Surface Analysis) and IEEE are playing an important role in nanotechnlogy.

A list of *"existing standards and standards under development relevant to or which might have relevance for nanoscale measurement or observation"* have been compiled during the international workshop on measurement and characterization for nanotechnologies, organised in February 2008 by IEC, OECD and NIST (US National Institute of Standards and Testing), and published in the final report of the event [12].

The table below is an elaboration from this list, reporting the organisations to which these standard documents refer, linking to the related sector/topic (national standard bodies not reported in the list).

Standardization body / Technical Committee	**SECTOR**
ASTM E42: Surface Analysis	Metrology&Characterization
ASTM E56: Nanotechnology	Nanotechnology - Electronic Products
IEC/TC 113: Nanotechnology standardization for electrical and electronic products and systems	Nanotechnology - Electronic Products
ISO/TC 24/SC 4: Sizing by methods other than sieving	Nanoparticles
ISO/TC 146: Air quality	Nanoparticles
ISO/TC 201: Surface chemical analysis	Metrology&Characterization
ISO/TC 209: Cleanrooms and associated controlled environments	Nanoparticles
ISO/TC 213: Dimensional and geometrical product specifications and verification	Metrology&Characterization
ISO/TC 229: Nanotechnologies	Nanotechnology
ISO REMCO: Committee for Reference Materials	Metrology&Characterization
ISO/TC 194 Biological evaluation of medical devices	Biomedical
ISO/TC 202 Micro beam analysis	Metrology&Characterization

5.3 European Union efforts on standardisation

The European Commission has underlined the importance of standards since the 2004 Action Plan [9], notwithstanding the activity of ISO, in 2007 they gave a specific mandate (M/409) to CEN, CENELEC and ETSI for the *"elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials"*.

CEN has established the working group CEN TC 352 devoted to nanotechnologies, with a scope similar to that of ISO TC 229, and CENELEC is closely following IEC TC 113 activities through the SR 113 (reporting secretariat for IEC TC 113).

CEN TC 352 is working in close collaboration with standards organisation relevant for nanotechnologies, and in particular with ISO TC 229. Various standards documents underway are the result of joint efforts between CEN and ISO (see paragraph 9 for details) [55]. Currently there is a number of work items started in CEN/TC 352 and that will be developed with an ISO TC 229 lead and, vice-versa, items approved in ISO TC 229 with a CEN TC 352 leadership.

[55] Close cooperation among standard bodies is strongly encouraged, in order to avoid duplication of work, optimise use of limited resources, establish a coherent set of standards. The "Vienna Agreement" regulates such cooperation, recognizing the primacy of international standards on regional/national ones, while taking also into account regional/national needs [CEN mandate report].

The European Commission mandate (M/409) to CEN, CENELEC and ETSI, included the request for an extensive review of existing standards to take into account the specific features of nanotechnology, based on the following tasks [11]:

- *To take stock of current standardisation relevant to nanotechnologies and nanomaterials (e.g. cosmetics, medical devices assessment, personal protective equipment, air quality, and food contact etc.) which may need a revision in the light of risks associated with nanotechnologies and nanomaterials;*
- *Identify the need for new standards;*
- *Identify the need to develop standardisation documents other than standards in relation to the above mentioned priority areas;*
- *Identify the availability of stakeholders in the EEA with a view to associate them when necessary in the standardisation process.*

In order to answer to these issues, CEN TC 352 examined the activities of CEN and CENELEC Technical Committees, European Technology Platforms and organisations and associations with a possible interest in nanotechnology, and issued to the EC a final report in May 2008.

The report gives indications on the level of interest and/or activity by these groups in current or future standardization relating to N&N; provides a set of proposed standards items, under the three general categories of *Health, worker and environmental safety*, *the Lisbon Agenda*, and *the societal agenda*; it proposes a set of recommendations for future EC policies on standards and nanotechnologies [56].
This report will be discussed within the Commission with a view to decide on possible further action [12]

The 2006 business plan of CEN TC 352 clearly identifies a key role to the TC *"in advising on the coordination and prioritization of standards-related nanotechnology R&D under FP7, thereby enabling the translation of R&D advances into standards for industry and supporting the European Commission's intentions with regard to European innovation, technical excellence, public health and capacity for risk assessment."*

[56] The report is not publicly available (March 2009), ISO/CEN members have access to a draft version from which these indications have been extracted.

5.4 Organisation for Economic Co-operation and Development (OECD)

The OECD is playing a pivotal role in the process of standardising and coordinating national activities with nanotechnologies. The activity is geared around two Working Groups:

- *Working Party on Nanotechnology*: established in March 2007 to promote international co-operation that facilitates research, development, and responsible commercialisation of nanotechnology [57]
- *Working Party on Manufactured Nanomaterials:* established in September 2006 to promote international co-operation on human health and environmental safety implications of manufactured nanomaterials, in order to assist in the development of rigorous safety evaluation of nanomaterials.

In the activities of the two WGs participates 30 OECD Member Countries, the European Commission, non-members (Brazil, China, Singapore, Thailand, Russia), ISO, WHO, UNEP and different kind of other stakeholders

The aim and objectives of OECD-WPMN are reported in "*Manufactured Nanomaterials: Work Programme 2006-2008* [58] and organised on the following Steering Groups:

- SG1: Database on Human Health and Environmental Safety Research: Database with research project - launched in March 2009 [59].
- SG2: Research Strategy(ies) on Human Health and Environmental Safety Research: Review of current research programmes has identified research themes which already have wide coverage and those less well covered
- SG3:Testing a Representative Set of Manufactured Nanomaterials (MN): Sponsorship programme for the testing of 14 MN for 61 endpoints.
- 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.

[57] http://www.oecd.org/nanosafety/

[58] http://www.olis.oecd.org/olis/2008doc.nsf/LinkTo/NT00000B76/$FILE/JT03240538.PDF

[59] http://www.oecd.org/document/26/0,3343,en_2649_37015404_42464730_1_1_1_1,00.html

A fundamental role is currently given to SG3 and SG4 activities, and in particular the NM sponsorship programme, to improve existing knowledge on manufactured nanomaterials human health and environmental safety.

With reference to regulation, SG5 activities can give an important support on the identification and comparison of existing and proposed reporting schemes, guidelines, and regulatory frameworks.
A report comparing existing information gathering initiatives is currently in preparation.

In general the OECD WPMN activities are key with respect to standards developments (in particular ISO-WG3 activities) and to provide indication for the development of appropriate guidelines for the implementation of existing regulation and/or the development of new regulatory regimes for nanotechnologies.

6 CONCLUSION

This review has seen that the regulation of nanotechnology R&D and nanotechnology-related products is high on the agenda of governments and other stakeholders.

However, this survey has observed that, in spite of this interest across the nanotechnology landscape, there is as yet no nano-specific regulation or for nano-related products. The attitude of regulatory authorities, the European Commission[60], and also of other stakeholders, is to rely on existing regulations tailored to encompass the novel properties of nanotechnologies, and in the adoption of self regulating schemes.

A key element in the patchwork of self-regulating mechanisms, at least in Europe, is the Code of Conduct for responsible nanoscience and nanotechnologies research that all Member States have been recommended to use by the European Commission.

At present, much of the concern is focused on "free" engineered nanomaterials and their effects on the environment, health and security (EHS) during their entire life cycle Combined with the ethical, legal and social aspects (ELSA) of nanotechnology R&D the question of what could be an integrated nanotechnology governance approach is rapidly becoming the most discussed topic in the nanotechnology area. In some cases, studies on nanotechnologies in specific sectors show that existing regulatory schemes should be adequate (such as the food sector[61] and for medical technologies[62]) although there is still a request for improved EHS data. In other cases there is less agreement, for example in the area of cosmetics[63]. The European Commission[64] also shows this, highlighting that, with the necessary adaptations for nanotechnologies, existing regulatory schemes can go some way in regulating the emerging field without constraining the growth too much. With this in mind, the focus is more on the improvement of instruments to ensure compliance with existing legislation.

Some of reasons for concern are stemming from the guidelines themselves that dictate the application of existing regulation, for example in the case of REACH which is presently considered, at least in Europe, the most compelling and thorough legislation for nanotechnology. Examples of these challenges, underlined by different national/international authorities are:

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[60] http://ec.europa.eu/nanotechnology/pdf/comm_2008_0366_en.pdf

[61] EFSA (2009) Scientific Opinion of the Scientific Committee Concerning The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety. The EFSA Journal 958, 1-39

[62] Roszek B., de Jong W.H. and Geertsma R.E. (2005) Nanotechnology in medical applications: state-of-the-art in materials and devices. RIVM report 265001001/2005

[63] For an interesting assessment of strengths and weaknesses of European cosmetic regulation concerning nanotechnologies, see Bowman and van Calster (2008) Flawless or Fallible? A Review of the Applicability of the European Union's Cosmetics Directive in Relation to Nano-CosmeticsStudies in Ethics, Law, and Technology. Volume 2, Issue 3 2008 Article 6

[64] http://ec.europa.eu/nanotechnology/pdf/comm_2008_0366_en.pdf

- The definition of a substance or a ingredient may not include information about its size or other physical and chemical properties that are, on the contrary, relevant to classify nanomaterials,
- Differentiating between nano and macro form of the same substance can be difficult due to current gaps in materials characterisation,
- Threshold levels based on mass or concentration, used as trigger of several legislations, are very likely not adequate for nanomaterials,
- A problem of definition or overlap between different regulatory systems may arise for peculiar applications of nanotechnology (such as in novel medical devices).

Gaps in the scientific knowledge about nanomaterials and the lack of standards and appropriate metrology are major challenges in the development of regulations for nanomaterials. Without adequate understanding of their effects on human health and the environment, and methods to monitor their presence and measure their amount, the implementation of most existing regulatory provisions can be jeopardised but also the development of specific ones can be made difficult.

The demand for stepping up the research to improve the scientific knowledge is widely shared and increasing funds are made available for this activity in Europe as well as in the other countries deeply involved with nanotechnology.

The need of appropriate standards to name, describe, specify, measure and characterise nanomaterials is also well recognised and, as shown in the report, the activity of several standards bodies and regulatory authorities is dealing with it. However, it is ISO, in conjunction with IEC, that will dictate the line.

At ISO it has been created ISO TC 229 within which 4 working groups have been created to deal with issues that are crucial for the development of an effective regulation for nanotechnology-related products. In particular:

- Terminology and Nomenclature;
- Measurements and Characterisation
- Health, Safety, and Environment;
- Materials Specification.

At present there are more than 30 standards documents related to the above themes under development but being the developments of standards a lengthy process, it will take some time before the matter is thoroughly addressed. So far ISO TC 229 has produced two documents:

- ISO/TS 27687 : Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplat; and Technical Report
- ISO/TR 12885: Health and safety practices in occupational settings relevant to nanotechnologies.

Reference data and information on characterisation and safety of nanomaterials, useful for the development of standards and regulation, are expected by the work of the *eight*

Steering Groups of OECD WPMN. In particular in the OECD sponsorship program launched in 2007 (Steering Group 3), countries are sharing the testing of a representative set of manufactured nanomaterials.

In conclusion, lacking specific guidelines and provisions, some authorities and stakeholders support the adoption of a precautionary approach with increased self-reliance of manufacturers regarding nanotechnologies. In this context, voluntary safety standards represent the first option to protect human health and the environment.

Nanoregulation requires a dynamic approach: it must adapt to the evolution of the scientific knowledge, to the increase of applications, to the concern and attitude of stakeholders. Since comprehensive data about risks to human health and the environment are still missing, regulatory activities should rely on precautionary vigilance.

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Websites of standard bodies having Technical Committees on nanotechnologies

8 Annex I: Synthesis table on nanotechnology regulation

The following table gives an overview of the main activities on nanotechnology regulation promoted in all above said countries at institutional level. These activities follow a 4 steps path:

(1) **Technical Committees/ Expert Committee opinion:** Opinions related to different aspects of EHS issues and regulation have been commissioned by government departments and regulatory agencies to both institutional Technical Committees (as in the case of SCHENIR, SCCP Committees within the European Commission) and to external organisations (as in the case of the reports commissioned by the UK government to the BRASS centre at Cardiff University and to other research centers and Universities).
In all cases these represents opinions of experts aiming to give information and advices, not formal commitments from a regulatory point of view.

(2) **Information gathering /reporting scheme**: this includes both structured information gathering initatives, such as the Voluntary Reporting Schema from DEFRA (UK), and other more generic initiatives, such as the call to "third parties" laucnhed in 2008 by EFSA to collect scientific data on applications of nanomaterials used in foods and feeds.

(3) **Regulatory review:** Policy makers, generally basing on experts opinions, published specific regulatory reviews on nanotechnology in order to give information and details to stakeholders on the procedures and position of the agency with respect to regulation of nanotechnology and/or specific applications of nanotechnology.

(4) **Specific notification/requirements for Enginerred NanoMaterials (ENM):** In some cases, basing on previous assessment of knowledge and regulation, regulatory agencies decided to introduce specific actions in the guidelines, annexes or any other accompanying document of a legislation, giving specific *indication* and/or *requirements* for nanomaterials. Examples are the removal of the exemption adopted within EU REACH legislation for carbon materials or notification mechanism for nanomaterials introduced in the chemical legislation of Canada.

Main activities and players at institutional level on nanotechnology regulation

	Main Department / Agency involved	**Technical Committees/ Expert Committee opinion (1)**	**Information gathering /reporting scheme (2)**	**Regulatory Review (3)**	**Specific notification/ requirements for ENM (4)**	**Other actions (task forces, guidelines, etc.)**
European Commission	European Chemicals Agency (ECHA), REACH	X		X	X	*CASGnano* Working group
	European Food Safety Authority (EFSA)	X	X	X		
	European Medicines Agency (EMEA)	X		X		
	Medical Devices	X		X		
	Cosmetics	X		X	X (planned)	
UK	Department for Environment, Food and Rural Affairs (DEFRA) and other Dep.	X	X	X		BSI Guidance to safe handling and disposal of ENM The Royal Society Reports
France	French Agency for Environmental and Occupational Health Safety (AFSSET)	X	Under discussion			

Germany	Federal Environmental Agency (UBA) and other Dep.		X	X		VCI- BAUA Guidance on workplace safety
The Netherlands	Ministry of Economic Affairs, National Institute for Public Health & the Environment	X				Knowledge and Information point Risk of Nanotechnology (KIR nano)
Switzerland	Office for the Environment (FOEN), Swiss Federal Office of Public Health (SFOPH)	X	X	X	Under discussion	Precautionary Matrix for Synthetic Nanomaterials
Australia	Dep of Innovation, Industry, Science and Research and others	X	X	X	X	
Canada	Health Canada, Environment Canada	X	Planned	X	X	
Japan	Ministry of Economy, Trade and Industry (METI), Ministry of the Environment (MOE), Ministry of Health and Labour and Welfare (MHLW)		X (preliminary survey)			Guidances on health and environmental to be published
USA	Environmental Protection Agency (EPA)		X	X	X	NIOSH guidances on occupational safety
	Food and Drug Administration (FDA)		X	X		

9 Annex II: Main standards organisations dealing with nanotechnologies

	ISO – TC 229 Nanotechnologies
Description	ISO is the world's largest developer and publisher of International Standards. ISO is composed of the National Standards Bodies (NSBs), one per member economy. There are currently 28 Participating (P) Members and 8 Observer (O) members in ISO TC 229 on nanotechnology. ISO TC 229 strategic plan for 2005 to 2010 aim to develop robust standards and other deliverables relevant to nanotechnologies that will: • Support the sustainable and responsible development and global dissemination of these emerging technologies; • Facilitate global trade in nanotechnologies, nanotechnology products and nanotechnology enabled systems and products; • Support improvement in quality, safety, security, consumer and environmental protection, together with the rational use of natural resources in the context of nanotechnologies; • Promote good practice in the production, use and disposal of nanomaterials, nanotechnology products and nanotechnology enabled systems and products. ***Working groups:*** **- WG 1** - **Terminology and Nomenclature** Convenorship – Canada (SCC) Scope: Define and develop unambiguous and uniform terminology and nomenclature in the field of nanotechnologies to facilitate communication and to promote common understanding. **- WG 2** - **Measurement and Characterization** Convenorship – Japan (JISC) Scope: The development of standards for measurement, characterization and test methods for nanotechnologies, taking into consideration needs for metrology and reference materials. **- WG 3** - **Health, Safety and Environment** Convenorship – USA (ANSI) Scope: The development of science-based standards in the areas of health, safety, and environmental aspects of nanotechnologies. **- WG4 – Material specification** Convenorship – CHINA (SAC) Standard document under development are reported in paragraph 5.
Website	**http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983**

	IEC TC 113 - International Electrotechnical Commission (IEC) - TC113 –Nanotechnology Standardization for Electrical and Electronic Products and Systems
Description	The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes international standards for all electrical, electronic and related technologies. Aim of IEC TC 113 is preparing standards in the field of nanotechnology relevant to electricity and related technologies pertinent to IEC; ensuring co-operation and preventing duplication of work with ISO TC 229. The IEC is composed of "National Committees", one per member economy. There are currently 15 Participating (P) members and 14 Observer (O) members in IEC TC 113 on nanotechnology. The Committee secretariat is held by Germany. ***Working groups:*** **JWG 1** and **JWG2** with ISO TC 229 **WG 3: Performance assessment** **Scope:** To develop standards for the assessment of performance, reliability, and durability related to the nanotechnology-enabled aspects of components and systems in support of continuous improvement at all stages of the value adding chain) **Within IEC, ABN 20 is the Advisory Body on Nanotechnology,** coordinating nanotechnology standardization in technical committees (TC) and subcommittees (SC). Work in progress regarding WG3 (also in collaboration with DIN) is: - IEC 113/14/NP - New Work Item Proposal on Guideline for carbon nanotubes specifications for electrotechnical applications - DIN IEC 62565- Guidelines for single wall carbon nanotube specifications for electrotechnical applications (IEC 113/27/CD:2008)
Website	http://www.iec.ch/dyn/www/f?p=102:7:0::::FSP_ORG_ID:1315

	ANSI-NSP- American National Standards Institute Nanotechnology Standards Panel (NSP)
Description	ANSI is the official U.S. representative to the International Accreditation Forum (IAF), the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC). ANSI administers the U.S. Technical Advisory Group (TAG) for ISO/TC 229. A TAG formulates all U.S. positions and proposals with respect to a particular ISO committee's activities; the TAG also provides the delegates who represent the U.S. at meetings of the ISO committee and its subgroups. The NSP serves as the cross-sector coordinating body for purposes of developing standards in the area of nanotechnology including, but not limited to: • Nomenclature/terminology; • Materials properties; • Testing, measurement and characterization procedures. The panel holds secretariat of ISO TC 229 Working Group 3 on Health, Safety and Environment.
Website	http://www.ansi.org/standards_activities/standards_boards_panels/nsp/overview.aspx?

	JISC/CNSJ - Japan Industrial Standards Committee - Council on Nanotechnology Standards in Japan
Description	The **CNSJ** council mirrors the work of ISO TC 229. They are drafting an International Standardization Roadmap for Nanotechnology along with the Nanotechnology Business Creation Initiative (NBCI). NBCI is currently determining Japanese industry perspectives relating to international nanotechnology standards activities. Secretariat is held by AIST (Advanced Industrial Science and Technology). Subcommittees: • Metrology and Monitoring • Terminology and Nomenclature • Environment and Safety The Council holds secretariat of ISO TC 229 Working Group 2 on Measurement & Characterization.
Website	http://www.nbci.jp/ - http://www.jisc.go.jp/eng/pj/index.html

	SAC/TC279 - Standardization Administration of China - Committee on Nanotechnology
Description	SAC represents China to join the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and other international and regional standardization organizations. SAC/TC 279 mirrors the work of ISO/TC 229 and its activites regards: • Nomenclature • Product specifications • Test Methods There are more 15 standards relevant for nanotechnology produced by SAC since 2002. and other new nanotechnology related standards are expected ub the near future. The standards mainly regards measurement and characterization and terminology. A list of these standards are available at [12]. The Committee holds secretariat of ISO TC 229 Working Group 4 on Material specification.
Website	http://www.sac.gov.cn/

	SCC - Standards Council of Canada
Description	The Standards Council of Canada (SCC) facilitates the development and use of national and international standards and accreditation services to enhance Canada's competitiveness and social well-beingThe Standards Council of Canada (SCC) is a federal Crown corporation. It has its mandate to promote efficient and effective standardization in Canada. The organization oversees Canada's National Standards System. The council holds secretariat of ISO TC 229 Working Group 1 on Terminology and Nomenclature
Website	http://www.sac.gov.cn/

	Korean Agency for Technology and Standards (KATS) - Materials and Nanotechnology Standards Division
Description	The Korean Agency for Technology and Standards (KATS) is a government agency which has been leading national and international standards in the Republic of Korea since it was founded in 1883 as Analysis and Testing Laboratory of the Mint Office. After several changes and developments over the last several decades, KATS was reformed under Ministry of Commerce, Industry and Energy in 1999. KATS is an active member of ISO, IEC and it is also participating in PASC. Includes the following research groups: • Synthesis of standard samples; • Standardization of purity measurements; • Evaluation of mechanical and physical properties of CNTs;

	• Standardization of CNT-field emission displays (FED) performance; • Standardization of purification procedures.
Website	www.kats.go.kr

	British Standards Institution – nanotechnologies Standardization Committee
	The technical committee NTI/1. mirrors the work of ISO/TC 229 and CEN TC/352. is also the Chair and Secretariat of the ISO TC 229 **Scope**: • Formulate UK strategy for nanotech standardization through broad consultation with stakeholders, • Ensure the UK view is given due consideration within the European Union, CEN and ISO • Develop and support formal standards and other standardization documents in nanotechnologies and to promote their use; • Promote and coordinate standardization consideration by UK nanotechnology networks and organizations The TC has published 6 PAS on terminology of nanotechnology and 3 guidances . These are: Terminologies PAS 131 Terminology for medical, health and personal care applications of nanotechnologies PAS 132 Terminology for the bio-nano interface PAS 133 Terminology for nanoscale measurement and instrumentation PAS 134 Terminology for carbon nanostructures PAS 135 Terminology for nanofabrication PAS 136 Terminology for nanomaterials Guidance PAS 130 Guidance on the labelling of manufactured nanoparticles and products containing manufactured nanoparticles PD 6699-1 Nanotechnologies - Part 1. Good practice guide for specifying manufactured nanomaterials PD 6699-2 Nanotechnologies - Part 2. Guide to safe handling and disposal of manufactured nanomaterials
Website	http://www.bsigroup.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/BSI-Committee-for-Nanotechnologies/

	DIN/DKE Deutsches institut fur Normung - Steering Committee on Nanotechnology
Description	DIN is the German Institute for Standardization. DKE is the national organization responsible for the creation and maintenance of standards and safety specifications covering the areas of electrical engineering, electronics and information technology in Germany. The DKE is a joint organization of DIN and the VDE. The VDE is responsible for the daily operations of the DKE. The DIN/DKE Steering Committee on Nanotechnology mirrors the work of ISO/TC 229 IEC TC 113 and CEN TC/352. Standards under development are reported in the description of IEC TC 113.
website	http:// www.din.de

	AFNOR.X457 Association Francasie de Normalisation – X 457 Nanotechnologies
Description	AFNOR is the French member of CEN and ISO. The X457 Committee mirrors the work of ISO/TC 229 and of CEN - TC/352. Working groups: • Terminology and nomenclature; • Measurement and characterization; • Health, safety and environment.
website	http://www.afnor.fr/portail.asp

	UNI – U22 - Italian Organization for Standardization CT U22-Nanotechnologies
Description	UNI is a private association appointed by the Italian government and the European Union to develop, approve and publish technical standards in all economic sectors (industry, trade and services) except for the electric and electrotechnical ones. CT U22 Nanotechnologies is the Italian Committee for standardization in the field of micro and nanotechnologies and mirrors the work of ISO/TC 229 . Working Groups: GL1 - Terminology GL2 - Measures, instrumentation and characterization GL3 - Health, safety, environment GL4 - Nanotechnological products and processes
website	http://www.uni.com/uni/controller/en/

	CEN TC/352 European Committee for Standardization – Nanotechnologies
Description	CEN TC/352 was established in November 2005 following recommendation from CEN/BT/WG 166. CEN TC/352 develop work programmes in areas of specific interest to Europe and areas that will be relevant to European legislation. The CEN strategy includes the use of the Vienna Agreement to avoid duplication of effort between CEN/TC 352 and ISO/TC 229, as explictly mentioned in the CEN TC 352 business plan. Specific tasks include developing standards for: classification, terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; science-based health, safety, and environmental practices; and nanotechnology products and processes. Standards in each of these areas could be specific to a product, process or industry. Many of the standards under development on nanotechnology are prepared with ISO TC 229 (as CEN-ISO/TS 27687, CEN-ISO 29701, CEN- ISO 10801, CEN-ISO 10808, CEN-ISO/TR 11811).
website	http://www.cen.eu/cenorm/sectors/sectors/nanotechnologies/index.asp

	ASTM –E56 American Society for Testing Materials International Committee on Nanotechnology
Description	ASTM International is a voluntary standards development organization for technical standards for materials, products, systems, and services, E56 is the ASTM Committee dedicated to Nanotechnology. **ASTM-E56 Scope** • The development of standards and guidance for nanotechnology and nano materials; • The coordination of existing ASTM standardization related to nanotechnology needs; • The maintenance of appropriate global liaison relationships with activities related to nanotechnology; • Participation in the development of symposia, workshops and other activities to enhance the development of standards. **E56 Subcommittees** • E56.01: Terminology & Nomenclature • E56.02: Characterisation • E56.03: Environmental & Occupational Health & Safety • E56.04: International Law & Intellectual Property • E56.05: Liaison & International Co-operation • E56.06: Risk Management and Product Stewardship • E56.90: Executive • E56.91: Strategic Planning and Review

	ASTM has published the following standards (related to different E56 Committees) ASTM E2456 - 06 Standard terminology Relating to Nanotechnology ASTM E2524 - 08 Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles ASTM E2525 - 08 Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies ASTM E2526 - 08 Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells ASTM E2578 - 07 Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions ASTM E2535 - 07 Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings Several other standards documents are under development , mainly regarding the Subcommittees E56.01, E56.02, E56.03 (a complete list is available on the website)
website	http://www.astm.org/COMMIT/COMMITTEE/E56.htm

	IEEE-NTC Institute of Electrical and Electronics Engineers - Nanotechnology Council
Description	The IEEE is a developer of international standards that underpin many of today's products and services, particularly in telecommunications, information technology and power generation. The IEEE Nanotechnology Council (NTC) is an interdisciplinary group whose members are drawn from 21 IEEE Societies. Overall, the IEEE Nanotechnology Standards Initiative seeks to identify: • Nanoelectronic technologies likely to generate products and services having high commercial and/or societal value; • Areas where new standards can aid rapid commercialization, technology transfer and diffusion into the market; • People and institutions to lead and support IEEE nanotechnology standards projects. **Current IEEE nanotechnology standards projects**: • IEEE P1650™ - Test Methods for Measurement of Electrical Properties of Carbon Nanotubes • IEEE P1670™ - Chemical Vapor Deposition (CVD)Techniques for Nanotechnologies; • IEEE P1690™ - Standard Methods for the Characterization of Carbon Nanotubes Used as Additives in Bulk Materials; In April 2007 IEEE published the first version of the Nanoelectronics Standards Roadmap (NESR)
website	http://grouper.ieee.org/groups/nano/. - http://ewh.ieee.org/tc/nanotech/index.html

	SEMI - Semiconductor Equipment and Materials International
Description	SEMI is a global industry association serving companies that develop and provide manufacturing technology, materials and services to make semiconductors, flat panel displays (FPDs), micro-electromechanical systems (MEMS). The SEMI Standards Program, established in 1973, covers all aspects of semiconductor process equipment and materials, from wafer manufacturing to test, assembly and packaging, in addition to the manufacture of flat panel displays. -Currently 30 + SEMI corporate members are active in nanotechnology and SEMI is contributing to efforts in ASTM E56, ISO TC229, IEC TC113 and IEEE Standards. SEMI is in liaison with IEC TC113/WG3 and pursue collaborative efforts with other standards developing organizations, in particular ASTM and IEEE, in the field of nanotechnology.
website	http:// www.semi.org

	VAMAS Versailles Project on Advanced Materials and Standards
Description	The Versailles Project on Advanced Materials and Standards was conceived in 1982. The main objective of VAMAS is to support trade in high technology products, through international collaborative projects aimed at providing the technical basis for drafting codes of practice and specifications for advanced materials. The scope of the collaboration embraces all agreed aspects of science and technology concerned with advanced materials, including materials technology, test methods, design methods and materials databases that are required as a precursor to the drafting of standards. ISO and VAMAS have concluded a Memorandum of Understanding under which ISO may publish Technology Trends Assessments (TTAs) based on the work of VAMAS.
website	http://www.vamas.org