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Report prepared by:
Elvio Mantovani, Andrea Porcari, Italian Association for Industrial Research (AIRI/Nanotec IT), Italy - WP6 Leader

With the contribution of:
Mark Morrison, Institute of Nanotechnology (IoN), UK
Robert Geertsma, National Institute for Public Health &the Environment (RIVM), The Netherlands

Contact:
Elvio Mantovani (AIRI/Nanotec IT)
+39 068848831 | mantovani@nanotec.it
www.observatorynano.eu

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Executive Summary

The umbrella terms of nanoscience and nanotechnologiesare 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 nanotechnologies is generally agreed to lie within the range of 1 and 100 nanometres. A further restriction of the definition of nanoscience and nanotechnologies 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. Nanotechnologies 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 nanotechnologies 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. 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 nanotechnologies 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 of 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 check developments in nanotechnologies to create socially beneficial technologies.

This report gives a brief overview of the present situation on nanotechnologies regulation. As part of the ObservatoryNANO project, it is an evolving document, to keep pace with the changes in the regulation landscape (and governance more broadly).

Several factors [1], briefly indicated below, are making the implementation of effective regulatory schemes complex:

[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

- The wide variety of materials and applications under the umbrella term of nanotechnologies
- The limited knowledge on the toxic effects of nanomaterials in living systems and their transport in living and environmental systems.
- The proprietary nature of 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 nanoparticles and their effects on environment, and health and safety (EHS) during their entire life cycle. Combined with the ethical, legal and social aspects (ELSA) of nanotechnologies R&D, the question of what could be an integrated nanotechnologies governance approach is rapidly becoming one of the most discussed topic in the nanotechnologies area.

In spite of this attention, specific regulatory actions for nanotechnology-related products are still rare. In some cases, studies on nanotechnologies in specific sectors show that existing regulatory schemes should be adequate (such as for medical technologies) although there is still a request for improved EHS data. In other cases there is less agreement (for example in the area of cosmetics). The European Commission also shows this, highlighting that, with the necessary adaptations for nanotechnologies, existing regulatory schemes can go some way to regulating this emerging field without constraining 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 nanotechnologies 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 reviews of regulatory regimes, identifying actions and priorities, (in the main) advising an increase in funding for research aiming to better characterise nanomaterials and understand their EHS effects.

In the last year, results of these reviews have prompted an in depth debate within regulatory authorities and stakeholders, including civil society, that in some cases have led to the adoption of specific regulatory actions improving the applicability of existing provisions to nanomaterials and nano-related products.

In Europe, within the **European Commission**, different Technical Committees and Agencies have published scientific opinions and reviews of regulation with respect to nanotechnologies and a number of them have created dedicated working groups to this end. Most of these activities have been summarised in the report "Regulatory Aspects of Nanomaterials" published in June 2008 [2]. This concluded that the current EU legislative framework *"covers in principle the potential health, safety and environmental risks in relation to nanomaterials"*, but recognises that current regulations may need to be modified as the scientific knowledge on nanomaterials increases.

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

This position has been challenged by a non-binding resolution adopted in April 2009 by the European Parliament, following a detailed report on nanomaterials presented by the European Parliament's Environment Committee. The resolution asks for tighter controls on nanotechnologies, in particular with respect to legislation on chemicals, food, waste, air and water, workers protection.

In response, the Commission will review all relevant legislation within 2011 with a view to propose regulatory change whenever necessary and to develop nano-specific instruments for the implementation of regulation. The recent recast of the EU cosmetic regulation and the on-going discussion on the novel food regulation are also taking into consideration the position of the EU Parliament.

Though on regulatory matters, the European member states tend to follow the inputs from the EC, several countries have activities at the national level of their own. **France, Germany, Switzerland, the Netherlands**, **UK, Austria, Norway** have been the most active in this area, with commitment at institutional level to deepen knowledge on EHS and regulatory issues. Most of the other European Countries have also started activities on nanoregulation, mainly with respect to REACH and occupational and health safety aspects of nanomaterials.

Looking beyond Europe, the **USA, Canada and Australia** have also been active for several years. EHS and regulatory issues are receiving increasing resources within their national strategies for nanotechnologies, and regulatory agencies and other interested bodies are becoming more proactive in coping with the complexity of nanoregulation. Canada and Australia, in particular, explicitly identify the need to adopt a precautionary approach, and they have growing involvement from regulatory authorities in different sectors to provide guidance and adapt regulation in view of nanotechnologies.

With regards to Asia, the present document reports the situation in **China**, **Japan**, **India**, **Taiwan**. None of these countries is planning specific regulatory actions for nanotechnologies, but they are generally quite active in the field of standardization and have all established specific working groups at institutional level on nanomaterials, in particular regarding occupational and health safety aspects. Taiwan has had the NanoMark certification scheme since 2004.
Generally, Asian Countries are looking at legislation developed in Europe (and USA) as a benchmark for the development of their own. Particular attention is given to the debate on REACH and nanomaterials.

At the moment, related regulatory regimes under investigation refer 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.

Various regulatory agencies in Europe (EC/ECHA), USA (EPA), Canada (Environment Canada) and Australia (NICNAS), are considering such specific notification requirements.

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, in particular in relation to threshold levels and exemption of particular materials.

In March 2008, ECHA (European Chemicals Agency) established for this purpose the Competent Authorities Sub Group on Nanomaterials (CASG Nano). The Sub Group published two technical guidelines and has launched in 2010 three projects devoted to the application of REACH to nanomaterials (to be ended in 2012). These activities, together with the end of the first registration phase, will provide the base for further specific regulatory action for nanomaterials within REACH.

The way nanomaterials will be considered in REACH will influence also regulatory actions at national level, in particular in countries such as France, Austria and Norway that are considering to introduce notification and registration mechanisms for nanomaterials (though they would generally prefer to avoid any kind of duplication with REACH procedures).

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, there is a big difference between the two regulatory schemes. REACH requires the producer (or importer) to demonstrate that a chemical is safe before it enters the market, whilst TSCA places responsibility on the regulators to prove that a chemical is harmful before it can be restricted or removed from the market. An agreement for a common international approach is fundamental to avoid barriers and mismatches.

In effect, since mid 2009, EPA has been evaluating a series of actions to ensure an appropriate regulation of nanomaterials within TSCA, including specific notification and registration procedures for nanomaterials. Particular attention is devoted to carbon nanotubes.

The recent (April 2010) debate of the U.S. senate on the Safe Chemical Act of 2010, includes a proposal for a reform of the TSCA that would introduces relevant changes to this statute and could lead to an approach similar to the one used by REACH (burden of the proof on the producer).

In November 2009, the Council of the European Union requested the update of the European Regulation on **Cosmetic Products** to include a specific definition of (insoluble) manufactured nanomaterials and requirements for notification, labelling and reporting of all products containing these kind of nanomaterials. A similar initiative concerning **food** regulation is under discussion, in particular the labelling of foodstuffs containing nanomaterials.

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. Almost all countries surveyed have research activities and have established specific working groups at institutional level on these topics.

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 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 boundaries for advanced nanotechnologies. Both sectors are active at a European level in following the state the art, discussing the consequences of developments in nanomedicine for risk assessment and are developing guidance.

Alongside the "hard" regulation, other soft regulatory approaches are being implemented or developed, primarily addressing 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), Australia (NICNAS), Taiwan (Nanomark). 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 firm knowledge base to support policy and regulatory decisions, and for this reason also under consideration are *mandatory reporting schemes,* for example in countries such as Canada and France.

A unique source of reference on this matter is provided by a report from the OECD Working Party on Manufactured Nanomaterials (OECD WPMN, Steering Group 5), which recently was made publicly available. The document provides a detailed review and comparison of information gathering schemes and of the applicability to nanomaterials of registration and notification procedures in several different regulatory regimes.

Codes of conduct and risk management systems are measures that can have an important role to cope with 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 of particular relevance are: (a) Sustainability, (b) Precaution (c) Inclusiveness and (d) Accountability.

The EC is actively promoting the Code and strongly recommends all Member States to adopt it. A public consultation on the Code was held at the end of 2009 and the publication of the first revision of the Code is expected in mid 2010.

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 International Standards Organization (ISO) Technical Committee (TC) 229, in conjunction with the International Electrotechnical Commission (IEC) TC 113, that directs activities on nanotechnologies standards at the international level. However, other standard bodies have started to work on nanotechnologies since 2004. Various ISO Technical Committees, 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 nanotechnologies. Most of these activities are in liaison with ISO TC229 and IEC TC 113, analogous to the work of CEN, CENELEC and ETSI, which received a new mandate from the EC on the development of standards in nanotechnologies at the beginning of 2010.

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 35 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 published three 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.
- ISO/PRF TS 80004-3 (Technical Specification): Nanotechnologies -- Vocabulary -- Part 3: Carbon nano-objects

The work on standards developed quite rapidly in the last year, with different documents that reached the approval or publication stage, and some new work proposals. Most of work underway is related to terminology, nomenclature, measurement and characterization of nanomaterials.

A contribution to the standardisation activities, will also be made by the **eight Steering Groups of OECD WPMN** who are gathering reference data and information on characterisation and safety of nanomaterials, and liaise with ISO TC 229 and other relevant authorities.

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.

As an outcome of the first part of the sponsorship program (now concluded) the Working Party agreed a priority list of 14 nanomaterials for testing [3] (based on materials which are in or close to commerce) as well as a list of 61 endpoints for which they should be tested. During the implementation stage (from 2009 to 2012), the main output of the project will be to develop characterisation dossier for the substances identified.

In conclusion, the activity linked to nanoregulation 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 nanotechnologies 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. While in the period considered by the 1st year Report (2008/mid 2009) the focus was mainly on the analysis and review of existing legislation, in the last year the debate was geared around the first attempts to introduce adjustments for nanomaterials in regulatory provisions in EU and some other countries. The most relevant example of this action is the recast of the Cosmetic regulation in EU.

The adjustment/amendment to the existing legislation discussed, relates to the inclusion of a definition of nanomaterials, improved notification and registration procedures, specific guidelines for safety assessment, labelling and inventories of the use of nano-related products.

[3] 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]*

While some authorities are more oriented toward amendments of legislation, also in the form of mandatory reporting schemes, others prefer to consider the option of voluntary measures or a combination of both.

However, the number of countries (and regulatory provisions) in which authorities are planning to introduce such changes in the near future is still limited.

There is also a strong position, shared by some authorities and industries, that exiting legislation, though not specific for nano- related products, is capable of dealing with any potential risks.

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 supporting 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, another important point is highlighted by the analysis of the existing situation. Excepting international standards and the work within OECD, there is no concerted effort aimed at elaborating common rules for 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 actively fostering collaboration.

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 a necessary goal to have common to facilitate trade and avoid regional divide. Thus the promotion of international cooperation in nanoregulation is fundamental.

To cite the conclusion of the Nanotechnologies for sustainable development Conference, Brussels (12 November 2009) [4]: *"Future developments in regulation and standardisation should ensure safety and transparency and thus public trust on one hand, and give to industry sufficient certainty on the other hand, without stifling innovation*".

[4] http://ec.europa.eu/nanotechnology/pdf/swedish-presidency-event-summary_en.pdf

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" [5]

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 a high degree of innovation dynamics, as confirmed by the ObservatoryNano project activities and results. The impact today is generally in terms of incremental improvements of the characteristics and performances of existing products In the medium/long term nanotechnologies application promises to realise totally innovative products with unprecedented features and behaviour with market forecasts in the hundreds or even thousands of billions, in a 10-15 year horizon.

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

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 nanotechnologies a challenging affair.

In all countries involved with nanotechnologies. regulation, regulation is becoming more and more a pivotal issue. For some time the EC has considered the matter a priority. The question is not yet settled, but the fact that nanotechnologies are still at an early stage of their development makes it possible to tackle any issues from the beginning and develop a regulatory framework that can assure theirresponsible development.

The aim of this report is to give an overview of the existing situation, the initiatives of those in the fields of regulation and standards for nanotechnologies at national and international level, and to highlight the key issues relevant for regulating nanotechnologies.

[5] 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 nanotechnologies:
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:
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.
This section is structured on a regional/national basis.

Self-regulation:
Includes reporting schemes and voluntary codes of conduct, 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:
A review of activities developed since 2004 by international/regional/national standards organisations, and other organisations such as OECD, for the development of standards in the field of nanotechnologies.
The first part presents a detailed picture of activities by 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 nanotechnologies has been included in the annex of the report.

A detailed bibliography, structured by sections 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 levels with the development of regulation and standards for nanotechnologies. The majority of these documents are publicly available.

The search of documents followed two main phases:

First, a few acknowledged sources of information were analysed to identify the most important on-going initiatives and documents with respect to the themes considered. Apart from desk research activities, direct contacts and liaisons of ObservatoryNano partners were used, in particular regarding access to information from standards bodies

(some partners, including the authors of this report, are members of national/international standards committees). Priority sources of information included:

- OECD Working Party on Manufactured Nanomaterials
- ISO TC 229 (and other national standards bodies)
- European Commission activities on nanotechnologies policy and regulation [6]
- Relevant European and international projects on these themes [7]

In the second phase, information and documents published by government departments, regulatory agencies, other authorities, industry and other stakeholders at international level were analysed. A set of documents providing information on relevant initiatives and positions on regulation and standards in nanotechnologies has been finally selected.

This was used to update the information from the previous year's report, and most of this new data was confirmed in April-May 2010.

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

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

[7] 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 NANOTECHNOLOGIES

The number and variety of nanotechnology-related products on the market is increasing. As these products become 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 regulations for nanomaterials and nano-related products are still rare, and, consequently, these applications fall under the scope of existing regulatory schemes. However, the regulation of nanotechnologies is becoming a key issue, pressing governments, regulatory agencies, industry and other stakeholders to take a position and become proactive in defining adequate regulation and risk management structures that address the responsible development of these technologies and their applications. Environment, Health and Safety issues (EHS) and Ethical Legal Social Aspects (ELSA) are both involved.

At present the main concern about nano-related products refers to "free" engineered nanoparticles 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 [8]. Free engineered nanoparticles can be defined as manufactured materials which have all three dimensions in the nanoscale and which are not embedded in a matrix.

Diversity of materials and applications
Many bulk materials are already manufactured as nanomaterials, with others nanoforms constantly being developed. Each can have quite different behaviours and properties compared with their bulk counterparts, raising concerns about 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, although the body of knowledge is growing, a thorough understanding is still lacking about how the physical-chemical properties of nanomaterials (size, shape, composition, reactivity, surface area and/or chemistry) determine their biological effects. This situation makes it difficult to evaluate, model and predict their ecological and toxicological behaviour and consequently, to develop appropriate risk management and regulatory options.

Lack of standardization in nomenclature, metrics, and materials
The unique nature of nanotechnologies challenges the establishment of standard procedures to describe, specify and measure nanomaterials and products. Despite increasing efforts on these matters, development of basic tools, such as common nomenclature/definitions, protocols for toxicity testing or for evaluating the environmental impact, reference materials and standards or instruments for measurements and characterisation are still at a very early stage. Without an international agreement on the above matters the definition and implementation of appropriate legislation will not be possible.

[8] as reference, activities of workpackage 4 of the ObservatoryNano explictly refer to these issues

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 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 kinds of instruments to address nanotechnologies regulation. These instruments can be synthesised in the following way:

- **Knowledge gathering** (building the evidence base and setting priorities in EHS and ELSA).

A number of initiatives have been initiated aiming to increase knowledge on EHS, and (to a lesser degree) ELSA issues. In particular to improve methods for risk assessment and risk management, differentiation and prioritisation of nanomaterials and nanotechnologies applications.

- **Self-regulation / voluntary measures** (delivering more effective practices).

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 of trust through best/good practice is established among the different stakeholders.

- **"hard" Regulation** (adapting the regulatory framework).

Regulatory bodies have started to develop expertise and technical background to cope with nanotechnologies, evaluating the applicability of existing regulation or the needs of adapting them. The process could lead to the development of specific provisions for nanotechnologies. Some legislation has already introduced specific requirements for nanomaterials and nano-related products, in the form of amendments to existing legislation and/or guidelines for the implementation of regulatory provisions.

- **Transnational efforts** (co-ordination in nanotechnologies governance).

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, international organisations and governments.

These instruments are part of a more general framework, an "incremental approach", for the management of nanotechnologies. A reasonable approach would follow a number of chronological stages: knowledge about the current regulatory process procedures and 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 legislation (long term) [6].

Many of the countries involved in nanotechnologies development are taking this kind of approach, although with varying degrees of support and engagement, and with an emphasis on evaluating existing regulations and their applicability to nanomaterials.

The increasing participation and efforts devoted to international cooperation, namely the OECD and ISO activities, provides an invaluable input to improve the knowledge base on nanomaterials, generally on EHS issues and ELSA, a precondition for any regulatory intervention in this field.

The European Union, and many European Member States, is deeply involved in these initiatives, and could be considered to be leading the development of a common and effective approach to nanotechnologies governance.

3 LEGISLATION/HARD REGULATION

3.1 European Union

Several initiatives are being 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 nanotechnologies development and regulation is clearly described in the following Commission communication "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
- 2009 : Second Implementation Report 2007-2009 (2009)
- 2010: Action Plan on Nanosciences and Nano technologies 2010-2015 (to be published)

Among the most relevant EC documents for nano regulation are the Code of Conduct [2], described in the following paragraph, and the Regulatory Aspects of Nanomaterials [3], which summarises the activities 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.

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.

The report concluded that the current EU legislative framework *"covers in principle the potential health, safety and environmental risks in relation to nanomaterials"* [3], and recognises that current regulations may need to be modified as the scientific knowledge on nanomaterials increases.

Several research needs and priorities have been identified, mainly related to the improvement of risk assessment and risk management methods, to permit existing regulations to be adapted. The implementation of a specific regulation on nanotechnologies is considered difficult due, in particular, to the complex national/supra-national regulatory scenario at European level. [4]. Nanomaterials/nanotechnologies are therefore dealt with, in the first instance, by following current regulatory schemes, reviewed for their applicability to nanomaterials.

This position has been challenged by a non-binding resolution adopted in April 2009 by the European Parliament [37], following a detailed report on nanomaterials presented by the European Parliament's Environment Committee:

According to the resolution, in the absence of any nano-specific provisions in Community law and given the lack of appropriate data and methods to assess risks related to nanomaterials, current EU legislation is considered inadequate to keep in check the potential health, environment and safety hazards of nanomaterials.

The resolution asks for tighter controls on nanotechnologies, in particular with respect to legislation on chemicals, food, waste, air and water and worker protection, including the application of the 'no data, no market' principle contained in the REACH Directive.
The document :

¨Calls on the Commission to review all relevant legislation within two years to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle, and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed;

In response, the Commission will review all relevant legislation within 2011 with a view to propose regulatory change whenever necessary and to develop nano-specific instruments for the implementation of regulation. In the foods and cosmetics sectors, provisions for nanomaterials have already been included (see below).

It is evident that safety is becoming increasingly important in nanotechnologies development. In the view of the EC safety should be an integral part of any "nanotechnology-based innovation strategy", and this should imply consideration of EHS issues from the very beginning of the R&D process[9].

Particularly important with respect to the implementation of regulation is the work of the European Commission's Independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). In 2009 SCHENIR published the Scientific Opinion "Risk Assessment of Products of Nanotechnologies" [38], which underlines the

[9] http://ec.europa.eu/nanotechnology/pdf/swedish-presidency-event-summary_en.pdf

need to perform risk assessment of nanomaterials on a case-by-case basis in the absence of a general approach.

SCENIHR has recently received a request from the EC to provide scientific input on the development of a "working definition" of nanotechnologies, that should be consistent with international standards and that could be adpated *"in individual pieces of legislation to fit the specific needs of different applications"*. The publication of a draft of the SCHENIR opinion, followed by consultation, is expected in June 2010[10].

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

Nevertheless, a number of European countries are collecting their own information and developing expertise to address nanotechnologies issues. Opinions from specific technical committees, independent research bodies and other organisations have been commissioned by national regulatory authorities.

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 manufacturers 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 withrespect to similar provisions in other countries as, for example, the EPA-TSCA statute that regulates chemical substances in the US (see paragraph 3.3.1.1), where the burden of proof lies on regulators. The aim of safeguarding humans and the environment is enforced by the inclusion of the Precautionary Principle, that underpins REACH provisions. are

[10] http://nanotechnology.ciaa.eu/docs/docs/3rd%20Nanotechnology%20Stakeholder%20meeting/Dr_Jean-Francois_Roche_-_Novel_Food.pdf

Nanomaterials come under REACH regulations, in particular [3, 6, 7, 8]:

- Nanomaterials classified as *new* materials are subjected, as any other new chemical, to a dedicated registration and thus to specific risk assessment procedures.
- For substances already on the market in bulk form and produced or imported at the nanoscale (not *new*), if properties or uses of the substance in the 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 (based on the most updated testing guidelines available). The manufacturer or producer is in charge of requesting a registration update[11].

Moreover, nanomaterials that fulfil the criteria for classification as hazardous, as stated in the "classification, labelling and packaging" regulation (CLP, regulation 1272/2008) have to be classified and labelled.

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 nanotechnologies. Moreover, registration is volume-based, i.e. registration and risk assessment requirements dependent on the mass of the chemical manufactured, imported or produced on an annual basis (1 tonne/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 (note that the limit does not apply to nanomaterials classified as hazardous based on the CLP regulation).

This concern has been raised in reports from the SCENIHR 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 for nanomaterials.

A specific working group within REACH, named the *Competent Authorities Sub Group on Nanomaterials* (CASG Nano), was 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, the aim of CASG Nano is to deepen the understanding of REACH applicability to nanomaterials, REACH implementation issues, substance identification, registration of nanomaterials, chemicals safety assessment and risk management, communication in supply chain and information on nanomaterials [7].

[11] "*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"*

Two documents reflecting the current state of the discussion on how REACH applies to nanomaterials have been published so far by CASG Nano (available on the DG Enterprise and Industry page on nanomaterials) [12] :

- Nanomaterials and REACH
- Classification, Labelling and Packaging of Nanomaterials in REACH and CLP

In order to support the work of CASG Nano, three REACH Implementation Projects on Nanomaterials (RIPoNs) were launched in January 2010 (they will be concluded before the end of 2012) with the support/coordination of the JRC Institute for Health and Consumer Protection (JRC-IHCP, Ispra, Italy):

- RIP-oN1: about Substance Identification of Nanomaterials[13]
- RIP-oN2 - REACH-NanoInfo : about REACH information requirements on intrinsic properties of nanomaterials [14]
- RIP-oN3 - REACH-NanoHazEx: about exposure assessments and hazard and risk characterisation for nanomaterials within the REACH context[15]

From the ongoing work of the EC and also activities at Member States levels (see for example the recent UK government statement on nanotechnologies - paragraph 3.2.6) it seems likely that at least the threshold levels for registration and test guidelines for nanomaterials will be reviewed.

The end of the first "pre-registration of phase-in substances" of REACH (planned in November 2010) will furnish further information and indications on the level of applicability of REACH to nanomaterials (even though this first deadline is limited to substances produced/imported in volumes greater than 1000 tonnes per year, or classified as meeting certain hazard criteria).

A recent report from the Dutch National Institute for Public Health and the Environment reviews the applicability of REACH to nanomaterials using nanosilver as a case study.[16]

3.1.2 Medicinal products (European Medicines Agency-EMA)

Medicinal products are regulated by Directive 2001/83/EC on the Community code relating to medicinal products for human use. The European Medicines Agency (EMA) is a decentralised body of the European Union, with the responsibility of the protection and promotion of public and animal health. EMA 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.

[12] http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm

[13] http://ec.europa.eu/dgs/jrc/index.cfm?id=1410&obj_id=9830&dt_code=NWS&lang=en

[14] http://www.safenano.org/REACHnanoInfo.aspx

[15] http://www.safenano.org/REACHnanoHazEx.aspx

[16] http://www.rivm.nl/bibliotheek/rapporten/601780003.html

Medicinal 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.

Nanotechnology is considered by EMA to be one of the emerging fields in science with great potential in a wide range of applications, including drug delivery, diagnostics and regenerative medicine.[17] In 2006, the agency already published a reflection paper on nanotechnology-based medicinal products for human use [9].

In order to assist applicants developing nanomedicinal products, in 2009 the EMA has established a dedicated 'nano group' within the Innovation Task Force to focus on this field. The aim of the ITF nano group is to meet with applicants, discuss informally about bottlenecks in the development of nanomedicinal products, and explore possible scientific and regulatory solutions.[18] In this way allows, in the absence of guidelines, potential developers of nanomedicine products to interact with the EMA directly at early stages of the development process.

The ITF nano group is also active in providing scientific and regulatory input on various EC initiatives and has established links with regulatory authorities in other regions.

It is recognised that new methods and models might need to be developed for nanoscale materials, but the careful benefit/risk balance that has to be proven for pharmaceuticals is considered in general appropriate to evaluate these materials. Currently, there are no specific guidance documents on nanomedicinal products. Specific guidance on quality, toxicology, clinical development and monitoring aspects may be developed in the future, once sufficient scientific experience has been gained for specifically identified sub-technologies within the field of nanomedicines.

Potential gaps could arise for novel applications of nanotechnologies, combining particular properties and functionalities, for which the applicable regulatory framework (medicines, devices, combination products, advanced therapies) can not be easily determined.[19]

Currently, the existing authorization procedures of medicinal products are considered adequate also for nanomedicine products. Some medicinal products containing nanomaterials have been already granted marketing authorisation by EMA [20].

In September 2010, EMA will hold a workshop to discuss the state-of-the-science of nanomedicines.[21] The aim of this workshop is to bring together regulatory, academic,

[17] http://www.ema.europa.eu/htms/human/mes/emergingtechnologies.htm#Nanotechnology

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

[19] http://www.rivm.nl/bibliotheek/rapporten/601785003.html

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

[21] http://www.ema.europa.eu/pdfs/conferenceflyers/nanotech_workshop/61768209en.pdf

and industry scientists to share their experiences with the development and use of nanotechnologies in Medicinal Products. By fostering the global dimension of the emerging nanomedicines, the Agency expects to further extend the dialogue opportunities on the requirements and methods considered acceptable for nanomedicines and to support the innovative development.

3.1.3 Medical devices

Medical devices are regulated via specific EC Directives, based on the New Approach on Technical Harmonisation and Standardisation: the Medical Devices Directive 93/42/EEC (MDD), the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) and the In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD).

The directives contain Essential Requirements that have to be fulfilled. The preferred way to prove compliance with these requirements would be for a manufacturer to comply with harmonized European standards and/or international standards (which may include testing), and to implement a risk management system.

A manufacturer has to affix a CE-marking on his product before he can actually bring the product to the market. Depending on the risk classification of the product, different conformity assessment procedures, which give a manufacturer the right to affix the CE-marking, can be followed.

Four classes of risks are defined, from low risk class I devices (e.g. various types of non-invasive devices) to high risk class III devices (e.g. implantable devices and long term surgically invasive devices in contact with the heart or the central nervous system). For higher risk products, a Notified Body (NB) must be consulted, who has to be convinced that the manufacturer complies with the Essential Requirements as listed in Annex 1 of each Directive. For products of the highest risk class (Class III), the NB will always review the complete design dossier and verify the acceptability of the overall residual risk of the product by assessing the scientific evidence on safety and performance/efficacy as provided by the manufacturer. For other products, the right to affix the CE-marking could also be granted based on an assessment of the manufacturer's quality management system, including an assessment, on a representative basis, of the documentation of the design of the product(s) concerned.

A report devoted to nanotechnologies and medical devices has been published in July 2007 [10] by the European Commission's Working Group on New and Emerging Technologies, as endorsed by the Medical Devices Experts Group.[22]

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 bound) and that specific regulatory requirements could be required in these cases. Moreover, the potential development of

[22] http://ec.europa.eu/enterprise/sectors/medical-devices/scientific-technical-assessment/working-group/index_en.htm

new or amended 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. Currently, the group is writing a MEDDEV guidance document for medical devices utilising nanotechnologies.

A similar position is expressed in the regulatory review published by the European Commission in June 2008, where it 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 nanotechnologies 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 between medical devices and medicinal products and very likely also classification into the different categories of medical devices.[23]

3.1.4 Foods (European Food Safety Authority-EFSA)

The European Food Safety Authority (EFSA) is 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) regulation stems from the inclusion in lists of specific authorised/non authorised substances.

Regarding nanotechnologies, the agency set up an expert working group in 2007[24], 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"*[25] to collect data on the safety of nanomaterials used in foods and feeds, in particular information related to risk assessment procedures used for nanomaterials.

[23] http://www.rivm.nl/bibliotheek/rapporten/601785003.html

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

[25] http://www.efsa.europa.eu/EFSA/Call_Consultation/sc_604_call_for_data_nanomaterials.pdf

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 nanotechnologies in food and feed safety and the environment [32].

The opinion highlights that the regulatory frameworks for food and feed are appropriate but cannot 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 quandaries for the regulation of nanotechnologies in food and feed.[26]

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

Following requests by the EC, EFSA has reviewed existing data on two applications of nanomaterials in the food industry and found: insufficient data to assess the safety of silver nanoparticles in silver hydrosol; and concluded that there are no toxicological issues concerning the use of titanium nitride nanoparticles in plastic drinks bottles. In November 2009, the EC requested that EFSA produce guidance on how risks associated with engineered nanomaterials could be assessed in applications in food, feed, food supplements, and food contact materials. The first draft will be published and open to public consultation in July 2010.[27]

Several of these issues have been discussed within the EU Parliament (Committee on the Environment, Public Health and Food Safety). In a report to the European Commission (March 2009) they 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.[28]
However, considering the number of amendments proposed (1332 in total) and the imminent European Parliamentary elections; the report was re-drafted in November 2009 to include just under 800 amendments. Of those pertaining to nanomaterials only the requirement for labelling of foodstuffs was retained. These amendments were debated by the Committee in March 2010, and accepted by 52 votes in favour, 2 against and 5 abstentions. Parliament will have a first reading of the amended proposal for new regulations in food labelling in May 2010, after which the Council will adopt its position, before the proposal is again debated in the Environment Committee.[29,30] If adopted the EU Novel Foods Regulation is expected to enter fully into force in 2012.

To date, dietary supplements containing nanomaterials originating from US have been banned in two Member States (Slovenia and Finland).[31]

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

[27] http://www.efsa.europa.eu/en/sctopics/topic/nanotechnology.htm

[28] 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

[29] http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/pr/795/795512/795512en.pdf

[30] http://www.europarl.europa.eu/news/expert/infopress_page/067-70614-074-03-12-911-20100315IPR70613-15-03-2010-2010-false/default_en.htm

[31] https://webgate.ec.europa.eu/rasff-window/portal/index.cfm?event=searchResultList

Alongside EFSA a number of international fora for exploration of nanotechnologies 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, that took place in June 2009, brought together many experts to consider the status of knowledge of exposure, hazards and regulation of nanotechnologies in the agrifood sector (a detailed report of the meeting was published at the beginning of 2010 [32]) .

3.1.5 Cosmetics

The existing regulatory system for cosmetics is currently 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 has 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" [33]. 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 for 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 no validated methodology for nanomaterials.

The Opinion concludes that it is necessary to review the safety of insoluble nanomaterials presently used as UV-filters in sunscreens (up to now considered the main application of nanomaterials in cosmetics).[34]

Another important initiative was launched in 2008 by the International Cooperation on Cosmetics Regulation (ICCR), with the aim of harmonising current approaches to cosmetic regulation, in particular in the case of nanotechnologies. [35] An ICCR expert

[32] http://www.fao.org/ag/agn/agns/files/FAO_WHO_Nano_Expert_Meeting_Report_Final.pdf

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

[34] 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

[35] ICCR is an international group of cosmetic regulatory authorities from the United States (Food and

working group for nanotechnologies has been established to develop a definition and inventory of uses of nanotechnologies in cosmetics. A meeting of the group was held in July 2009, with the participation of regulatory authorities from EU, USA, Canada, Japan and representatives from the cosmetic industry. A short report "outcomes of the International Workshop on Regulatory Issues regarding the Use of Nanotechnologies in Cosmetics" has been recently published[36].

The need to improve characterization and testing methods for safety assessment has been recognised, as these are key elements in the regulation of nanomaterials, whilst the need to have a legal definition of nanomaterials caused controversy across the different legislative systems considered (EU, USA, Canada, Japan).

As a general conclusion, the workshop report states that *"existing scientific and legal paradigms seem to be sufficient to cover nanomaterials, however, challenges remain as they might need to be adapted to the specific characteristics of such materials"*

In November 2009, The Council of the European Union requested an update of the European Regulation on Cosmetic Products, after the approval of the regulation from the EU Parliament, in March 2009. The updated text (Regulation (EC) 1223/2009, [39]), will come into force in July 2013.

The updated provision includes a definition of nanomaterial: "*an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm"*. Several requirements for nanomaterials are foreseen by the new regulation, in particular:

- **Notification:** any new cosmetic products containing nanomaterials have to be notified to the EC six months prior to being placed on the market, including at least the following information (reported from the provision text):
  - *the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in paragraph 2 of the Preamble to Annexes II to VI;*
  - *the specification of the nanomaterial including size of particles, physical and chemical properties;*
  - *an estimate of the quantity intended to be placed on the market per year;*
  - *the toxicological profile of the nanomaterial;*
  - *the safety data of the nanomaterial relating to the category of cosmetic product it is being, used in such products*
  - *the reasonably foreseeable exposure conditions.*
- **Labelling:** *"All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets"*

Drug Adminstration), Japan (Ministry of Health, Labour, and Welfare) , the European Union (European Commission, DG Enterprise), and Canada (Health Canada). - http://www.fda.gov/Cosmetics/InternationalActivities/ConferencesMeetingsWorkshops/InternationalCooperationonCosmeticsRegulationsICCR/ucm182661.htm http://ihcp.jrc.ec.europa.eu/docs/workshop_outcome_july_09.pdf

[36] The workshop was organised at Joint Research Centre Institute for Health and Consumer Protection in July 2009 - http://ihcp.jrc.ec.europa.eu/docs/workshop_outcome_july_09.pdf

- **Reporting:** a catalogue of nanomaterials used in cosmetic products **(**including those used as colorants, UV-filters and preservatives) will be made publicly available and regularly updated.

This new provision is one of the first regulations explicitly referring to nanomaterials, and introduces a relevant difference between the regulatory situation (for cosmetics and nanomaterials) in the EU compared to other legislation, in particular the US.

3.1.6 Restriction of Hazardous Substances (RoHS) Directive

This Directive places restrictions on the use of certain hazardous substances in electrical and electronic equipment (particularly heavy metals and certain flame retardants). This came into force on the 1st July 2006, however in the last year there have been a number of amendments proposed by the EU Parliament Committee on the Environment, Public Health and Food Safety that particularly deal with nanomaterials:

- notification of the use of nanomaterials,
- a standard for the identification and detection of nanomaterials,
- harmonised labelling in EEE
- greater scrutiny of long multi-walled carbon nanotubes (MWCNTs) that are asbestos-like, and nano silver, with a recommendation for immediate labelling and possible ban in EEE (electrical and electronic equipment).

On June the 2nd the committee voted for a ban on nanosilver and long MWCNT, and said '*other electrical and electronic material containing nanomaterials should be labelled, and that the manufacturers should be obliged to provide safety data to the European Commission*'[37]. This will now go to a full plenary vote in the EU Parliament in July, and if passed will lead to a recast of the RoHS Directive. This also has implications for the WEEE Directive (Waste Electrical and Electronic Equipment).

3.2 European Countries

3.2.1 Austria

Activities devoted to manage the development of nanotechnologies, in terms of regulation of EHS and EHS issue and ELSA issues, are growing in Austria. This is clearly highlighted by the publication, in December 2009, of the National Austrian Action Plan [40], aiming to develop a strategic policy plan for the governance of nanotechnologies and nanomaterials in Austria.

The plan is the result of the joint work of different Austrian federal ministries and government agencies, including the Federal Ministry for "*Transport, Innovation and*

[37] Press release from the committee: http://www.europarl.europa.eu/sides/getDoc.do?type=IM-PRESS&reference=20100531IPR75278&format=XML&language=EN

Technology", "*Labour, Social Affairs and Consumer Protection"*, "*Health"*, "*Science and Research"* and of an inclusive consultation process involving different stakeholders and the public. This process was lead by the Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW).

The plan provides a careful analysis of risks and opportunities of nanotechnologies, focused in areas considered *"particularly relevant to nanotechnology in social and political terms"*: health (including employee protection), environment, business, science, research and development.

Based on this analysis, a set of more than 50 recommendations for specific actions and measures to be taken at national, European and international level was identified, with an indicative timeframe for their adoption (1 to 3 years). The implementation of such measures will be monitored starting from mid 2012.

Recommendations span over five fields, through all the areas selected (p. 14, Action Plan):

- *Verifying or guaranteeing an adequate legal framework, including support of voluntary business activities*
- *Information management, i.e., measures to inform consumers, employees, employers, and the general public, as well as inter-ministerial and inter-institutional networking*
- *Training and building the awareness in the professional world, of consumers, of the general public and in the educational system*
- *Creating a solid knowledge base for risk assessment and selective risk management*
- *Need for research*

With regards to regulation, Austria is closely following the ongoing activities at European level, and is actively participating in the REACH CASG Nano working group.
Moreover, the Action plan emphasises the need for a harmonised and coordinated approach to nanoregulation at EU level, and underlines that nanotechnologies have to be *"embedded"* in existing legal frameworks. The need for compliance with the precautionary principle ("*in all proceedings that deal specifically with nanomaterials and nanotechnologies*") as a prerequisite for the marketing of nanorelated products is also recommended.

With respect to REACH, particular emphasis is given to the need of a clear and separate classification and labelling of nanoforms of substances having altered properties compared to their macroform, providing the adequate level of description and information on risks and effects of the substance considered.

The introduction of specific information about nanomaterials in Material Safety Data Sheets is also mentioned in the document as a short term objective.

Austria is participating in the Sponsorship Programme of the OECD Working Party on Manufactured Nanomaterials.

A multi-year funding programme on nanosciences and nanotechnologies, the "Austrian Nano Initiative"[38], has been provided by several ministries since 2004, and coordinates funding and supporting measures at national and regional levels. This programme will be one of the main instruments to help the implementation of the Action Plan.

3.2.2 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 different Governmental Committees and Agencies, regarding the need for anticipatory and precautionary measures to be taken with respect to nanomaterials and their applications. Among them:

- " 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.
- "Recommendations for assessing the toxicity of medicinal products containing nanoparticles", French Agency for the Safety of Health Products (AFSSAPS), Sep 2008 [39]
- Opinion of the High Public Health Council (Haut Conseil de Santé Publique) to the French Ministry of Health: "Avis relatif à la sécurité des travailleurs lors de l'exposition aux nanotubes de carbone", January 2009 [40]
- "Évaluation des risques liés aux nanomatériaux pour la population générale et pour l'environnement", AFSSET, March 2010

In particular, the latter two documents underline the lack of knowledge on potential risks and the need to implement a precautionary framework for nanomaterials. With specific regards to carbon nanotubes (CNT) emphasis is placed on strict containment procedures during research, production and use to minimise the risk of aerosol or free particle dispersion, and (workers') exposure.

Within the broad environment "Grenelle" project launched in 2007, which will form the basis for the improvement of French environmental legislation; a critical debate took

[38] http://www.nanoinitiative.at/evo/web/nano/378_EN.555F2033347293

[39] http://www.afssaps.fr/var/afssaps_site/storage/original/application/ac7d242fbecb3c8ab0a7363fbcd9a4ec.pdf

[40] http://www.hcsp.fr/docspdf/avisrapports/hcspa20090107_ExpNanoCarbone.pdf

place regarding nanotechnology between 2008 and 2009[41]. A proposal by the Ministry for Ecology, Energy, Sustainable Development and Territorial Development explicitly referring to nanomaterials was finally adopted by the Senate in October 2009 [42] (Grenelle 2 Article 73, modification du Code de l'environnement). This legislation includes:

- requirements for declaration to authorities of the manufacturing, importing or the placing on the market of nanoparticle substances, including information about their identity, quantity and uses;
- reporting, upon request of the authority, of hazard and exposure information regarding these substances;

The French Research Ministry (Ministre de l'Enseignement Supérieur et de la Recherche) launched the Nano-INNOV plan in mid 2009, aiming to develop a strategy for the innovation in the field of nanotechnologies. The strategy will include indications and actions to :

- Improve coordination of research activities at national level
- Foster technology transfer, with a particular attention to Intellectual Property Issues
- Improve governance of nanotechnologies, promoting knowledge and dissemination of information through public debate
- Develop education and professional formation to support industrial growth on nanotechnology
- Support strengthening of nanotechnology coordination at European level

As indicated by the Grenelle 2 project and also in the objectives of the Nano-INNOV Plan, the government launched in 2009 a structured public debate about risks and opportunities of nanotechnologies[43].

3.2.3 Italy

Some activities devoted to manage the development of nanotechnologies have been started during the past years in Italy, with most of them related to research on EHS issues and, in a few cases, to ELSA. Within the National Research Programme, the main source of public funding for nanotechnology research, a certain (small) amount of the funding is devoted also to these areas.

The attention towards nanoregulation is growing, and some specific initiatives have been activated at institutional level, in particular regarding workplace safety. Italy is also closely following the activities ongoing at European level, in particular the

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

[42] http://www.assemblee-nationale.fr/13/projets/pl1965.asp

[43] http://www.debatpublic-nano.org/ - http://www.debatpublic.fr/print.html?id=99&type=debats_mo_ouverts

application of REACH to nanomaterials (Italy participates to the REACH CASG Nano through a representative of the Ministry of Health).

The agencies currently most involved in nanoregulation are:

- ISPESL (National Institute of Occupational Prevention and Safety), that established in November 2008 a Working Group dedicated to Safety of Nanomaterials at the Workplace (WG "Nanomaterials");

- INAIL (Italian Workers' Compensation Authority[44]), that established in 2008 the Working Group "Nanotechnologies";

- ISS (National Institute of Health), with specific activities on EHS issues related to nanomaterials.

In the context of the national standardization body (UNI) it has been activated a commission dedicated to Nanotechnology (Technical Commission U22-Nanotechnologies), which mirrors the activity of ISO TC229.

Italy participates in OECD WPMN with delegates from ISS and INAIL.

The INAIL WG is providing input to the Ministry of Health to evaluate the definition of a reporting scheme for nanomaterials. The preparation of information sheets for the management of risk in the production and handling of nanomaterials and of documents to support "dossiers" for nanoscale substances under REACH are among the other expected outcomes of the WG.

The ISPESL WG is preparing, with the contribution of selected experts at national level and based on stakeholders' consultation, a *"White Paper on engineered nanomaterials and occupational health effects"*. The document, that is planned to be published in mid 2010, will represent the basis for next actions in this field.

3.2.4 Norway

Activities and attention on nanoregulation are increasing in Norway. The strategic research programme on N&N of the Research Council of Norway (NANOMAT), supports specific research activities on EHS and ELSA, while some regulatory agencies have an increased commitment on these matters

The Climate and Pollution Agency (a Directorate under the Norwegian Ministry of the Environment, former "Norwegian Pollution Control Authority-SFT"), the Norwegian Labour Inspection Authority and the Norwegian Institute of Occupational Health, have established a working group devoted to workplace safety related to nanotechnologies.

[44] Not just a compensation authority but a global protection system for all workers http://www.inail.it/

The Climate and Pollution Agency and the Norwegian Institute for Agricultural and Environmental Research (BioForsk) have published in 2007 the report *"Environmental fate and ecotoxicity of engineered nanoparticles"*[45].

The Norwegian Board of Technology [46] published in 2008 the report *"Nanomaterials, risk and regulation"* (*"Nanomaterialer, risiko og regulering"*, executive summary available in English [47]), providing the Government with a series of recommendations on nanoregulation, including:

- Set clear commitments to what information industry must provide with respect to risk assessment of nanomaterials
- Implement mandatory registration in order to monitor the use of nanomaterials
- Extend producer responsibility through the whole life cycle of a product
- Knowledge-based management, increasing research on EHS.

The Climate and Pollution Agency is in charge of managing the Norwegian Product Register, the central register for chemical products in Norway.

Following this report, in June 2009, the agency decided to introduce into the procedure for declaration to the Product Register a specific part with information related to nanomaterials in chemical products.
This initiative will help to collect (on a voluntary basis) information on the use and marketing of nanomaterials. It is intended to supplement and integrate (not to duplicate) requirements foreseen by REACH.

3.2.5 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. Among the research activities on EHS, one of the most relevant in the

[45] http://www.klif.no/publikasjoner/2304/ta2304.pdf

[46] http://www.teknologiradet.no/FullStory.aspx?m=116

[47] http://www.teknologiradet.no/Nano_abstract_nfIkW.pdf.file

period 2006 -2009 was the project Nanocare, now concluded with the publication of a final report[48].

The government strategy has been condensed into the "Health and environmental risks of nanomaterials – Research Strategy",published in December 2007 [14].

With regard 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 aspects). Regulatory gaps were identified that exists 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 stating that the available instruments at 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.

One of the actions included in the AktionsPlan is the development of a structured dialogue on potential risks and opportunities of N&N. This dialogue was set up with the establishment of the German Federal Government's NanoKommission, led by the Federal Ministry for the Environment (BMU). The first part of the programme (2006-2008) was structured in 3 working groups devoted to discuss and develop recommendations with respect to three areas:

- Opportunities for Health and Environment
- Risks and Safety Research
- Guidelines on the Responsible Use of Nanomaterials

More than 30 dialogue meetings were held during this period. A set of recommendations and actions was provided in each of the three areas and detailed in a report published in 2009 [41] (English version, May 2009).

The last area was intended to provide indications to complement existing regulatory measures (in particular REACH and other industry-specific EU directives) that, *"while in principle applying to nanomaterials, may need to be adapted".* Five "core principles" regarding the responsible use of nanomaterials have been identified:

- *Definition and disclosure of responsibility and management (good governance)*
- *Transparency with regard to nanotechnology-relevant information, data and processes*
- *Commitment to dialogues with stakeholders*
- *Establishment of risk management structures*
- *Responsibility within the value chain*

[48] http://www.nanopartikel.info/fileadmin/user_upload/Publikationen/NanoCareFinalReport.pdf.

Quite interestingly, the dialogue was not able to reach a consensus about some relevant regulatory issues: the need for mandatory notification to authorities and/or public disclosure of information on use and safety of nanomaterials, and the possibility to ban production and marketing of nanomaterials having a potential (not ascertained) high risk.

The second part of the programme (2009-2011) will be devoted to monitor and review the implementation of these recommendations. This process could also lead to the definition of specific regulatory actions for nanotechnology.

3.2.6 UK

The UK has been very active on 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 emphasis 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 Executive (HSE) (February 2006), Defra (March 2006), whose activity has already been described, the Food Standards Agency (FSA) (March 2006) and the Medicines and Healthcare Products Regulatory Agency (MHRA) (September 2006) [17]. In 2009, HSE issued guidelines on the safe handling of carbon nanotubes[49] and Defra asked for specific guidance on nano silver from the Advisory Committee on Hazardous Substances.[50]

The UK also reflected on gaps in the regulatory framework in the 2007 report by the Centre for Business Relationships, Accountability, Sustainability and Society (BRASS) at Cardiff University [18] "An Overview of the Framework of Current Regulations affecting Development and Marketing of Nanomaterials".

Following these analyses the UK government 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".*

[49] http://www.hse.gov.uk/pubns/web38.pdf

[50] http://www.defra.gov.uk/environment/quality/chemicals/achs/documents/achs-report-nanosilver.pdf

In 2008 the UK government commissioned a consortium led by the Institute of Occupational Medicine (IOM) to report on international advances against recommendations for EHS research in the government's NRCG report. Of the 18 research objectives reviewed, and in relation to the four task areas of the NRCG, the EMERGNANO report found many gaps, and a greater number of projects focused on human health and exposure compared with environment and characterisation.[51]

The UK's strategy for nanotechnology was subsequently reviewed again in 2009-10, through three separate (but inter-linked) initiatives: TSB (Technology Strategy Board)[52], mini-IGT (Innovation Growth Team)[53] and BIS (Department of Business, Innovation and Skills- which evolved from BERR and DIUS).[54] In terms of regulation the UK supports EU initiatives, however is promoting a 'case-by-case' approach to assessing the risk and suitable use of individual nanomaterials in food and food contact materials.

At the same time the UK's House of Lords Science and Technology Select Committee consulted widely with stakeholders through a series of hearings and written submissions on the topic of nanotechnology in food. The report (published early 2010) recommended that the UK government support amendments to EU legislation to ensure that all nanomaterials used in the food industry fall within its remit.[55] It also recommended agreement on a definition of nanomaterials and their unique properties, that the FSA formally review legislation every three years to ensure it is fit for purpose, that voluntary codes of conduct be supported by government and that the FSA create a publicly accessible database listing all food and food contact materials containing nanomaterials. The UK government subsequently responded to this report identifying areas in which it was taking action and recognising others where further activity is required, for example the FSA is funding specific research into the behaviour and fate of nanoparticles in the gut while other agencies (such as the National Nanotoxicology Research Centre) are looking at risks from inhaled nanoparticles and from surgical applications.[56]

The UK government has looked at wider societal issues and in 2009 Defra funded BRASS to investigate 'the nature and application among the nanotechnologies industries of corporate social responsibility in the context of safeguarding the environment and human health'.[57] This report found that while there was variation based on company size and level of commercialisation that the majority of those interviewed '*are engaged with precautionary approaches to risk in the workplace, driven by existing regulations*'. The UK government is continuing to advance consultation and expert input to policy through the establishment of a Nanotechnologies

[51] http://randd.defra.gov.uk/Document.aspx?Document=CB0409_7911_FRP.pdf

[52] http://www.innovateuk.org/_assets/pdf/Corporate-Publications/NanoscaleTechnologiesStrategy.pdf

[53] http://www.matuk.co.uk/docs/Nano_report.pdf

[54] http://www.bis.gov.uk/assets/biscore/corporate/docs/n/10-825-nanotechnologies-strategy

[55] http://www.publications.parliament.uk/pa/ld/ldsctech.htm

[56] http://www.parliament.uk/documents/upload/GovResponseNandF.pdf

[57] 'http://www.brass.cf.ac.uk/projects/Resource_and_Technology_Management/resource-and-technology-management-for-sustainability--Nanotechnologies-and-CSR.html

Leadership Group (NLG), to replace the NRCG, which will be chaired by a Minister from BIS.

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.

3.2.7 The Netherlands

Nanotechnologies are considered a very important subject in the Netherlands. In the government paper entitled 'Kabinetsvisie nanotechnologieën - van klein naar groots' [The Dutch government's vision on nanotechnologies - from small to great] (Netherlands' government, 2006 [20]) the Dutch government sets out its vision on nanotechnologies. The view is expressed in this document that nanotechnologies could become a 'major driver' of the knowledge economy and society. At the same time it is recognised that signals are coming from the scientific community that the application of these technologies could pose certain risks to man and the environment.
The position adopted in the Netherlands is that these risks should be treated with caution, care and common sense. This is in line with the report 'Betekenis van nanotechnologie voor de gezondheid'. [Health significance of nanotechnologies] by the Health Council of the Netherlands (2006). The current substances policy and risk policy in force, as formulated in the policy document 'Nuchter omgaan met risico's' [Coping rationally with risks] (VROM, 2004), provides the framework for this. The following basic principles apply:

- transparent decision-making;
- defining responsibilities (authorities, citizens, manufacturers, scientific community);
- public consultation at an early stage in decision-making;
- balancing hazards and risks against costs and benefits to society;
- taking into account the accumulation of risks in decision-making.

In addition, the Risks of Nanotechnology Knowledge and Information Centre (KIR nano) was set up at RIVM at the request of the government.

The government paper on nanotechnology also recommended setting up an Observatory to monitor the potential risks of nanotechnology to humans and the environment.

Against this background the Risks of Nanotechnology Knowledge and Information Centre (KIR nano) was set up on 1 January 2008 at the Dutch National Institute for Public Health and the Environment (RIVM), financed by and reporting to a number of Ministries.

According to the Dutch Action Plan Nanotechnology [21], the government also considers it important to develop knowledge about the risks of nanoparticles. A national strategic research agenda was developed at the request of the government, which has recently resulted in a substantive research programme with a considerable part dedicated to risk research. Before this, several pilot studies were already initiated, some of them in cooperation with other countries. Furthermore, a "Stakeholder group Nanotechnology Risks" with the business and social organizations has been started with the aim of sharing available information.

Also ELSA is considered an important subject. To address this at a national level, a 'Commissie Maatschappelijke Dialoog' [Committee for Societal Dialogue] was installed in 2009.

The Netherlands are very active in international groups and committees. They participate in the CA subgroup of nanotechnology under the REACH authorities, OECD WPN, WPMN and a number of subgroups. They also participate in the REACH Implementation projects and in the OECD Sponsorship programme. They have active members of ISO working groups and serve on EC, EMA, EFSA, ILSI, SETAC and SCENIHR working groups.

3.2.8 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 Federal Offices, and industry and academia representatives.

Following a specific study of the current state of knowledge about the potential risks of manufactured nanoparticles [22], it was concluded that there was 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 were proposed to, and adapted by, the Federal Council in April 2008.

Different Ministries and governmental agenciesagencies are involved in the preparation of guidelines and indications concerning nanoregulation. The ones which are closest to publication and/or implementation are:

- the Precautionary Matrix [58]: a screening tool intended to support trade and industry to identify possible sources of risk in the production, use and disposal of synthetic nanomaterials, on the basis of currently available knowledge. Lead agencies are the Federal Office of Public Health (FOPH) and the Federal Office for the Environment (FOEN).
- Guidelines for safe and sustainable disposal of nano wastes. Lead agency is FOEN
- Guidelines for the provision of safety information along the value chain, in particular to include information on nanomaterials in Safety Data Sheets (MSDS). Lead agency is the Swiss State Secretariat for Economic Affairs (SECO)
- Review of the hazardous incident ordinance (HIO)- Lead agency is the Federal Office for the Environment (FOEN)

The Swiss Federal Council will make an assessment of the results of the Action Plan and of the need for legislative action with respect to manufactured nanomaterials and their application, and it is expected to report the results of this analysis to the SwissSwiss Parliament in 2011[59]. The review will also take into account regulatory developments on nanotechnologies at European level.

3.3 USA

As stated in the December 2007 NNI Strategic Plan, one of the four goals of the National Nanotechnology Initiative (NNI) is to *"support responsible development of nanotechnology that considers the technology's environmental, health, safety, and broader societal dimensions"*.

Over the last five years the level of investments on this theme within the NNI has continuously increased, with most of the resources going to EHS issues, to support work on standards developments and (to a lesser extent) ELSA. An interesting and detailed review of activities and progresses on responsible development within NNI is provided in the recent PCAST report[60].

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

[59] http://www.innovationsgesellschaft.ch/index.php?section=news&cmd=details&newsid=294 - http://www.parlament.ch/D/Suche/Seiten/geschaefte.aspx?gesch_id=20094170

[60] PCAST report, Report to the President and congress on the third assessment of the National Nanotechnology Initiative, March 12 , 2010

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 [61] (currently there are more than 30 US agencies with activities related to EHS issues).

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), and NIOSH are all actively exploring EHS implications, risks and possible needs for regulations in their fields of operation; and so would be expected to regulate nanomaterials, products and processes.

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.

There follows a brief overview of the main activities on nanotechnology regulation from these Federal Agencies, but as a general remark it can be anticipated that some of these agencies have reviewed existing environmental, health, and safety statutes for nanotechnology, and have concluded that present statutes 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 [62].

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

[62] 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;"

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 its final version in June 2009 [25].

The four main research themes identified in the 2009 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.*

The aim of NRS is to guide the research on risk assessment and risk management of nanomaterials in support to EPA regulatory provisions, through specific in-house research activities and coordination and collaboration with other relevant federal agencies. Moreover, a key action underlined in the document is the participation in the OECD Testing Programme, through co-sponsoring testing on a number of nanomaterials [63].

The document, and a recently launched dedicated website [64], have also the purpose of keeping the public informed about EPA's activities and decisions on nanomaterials.

According to these documents, the statutes considered most relevant to evaluate and manage the 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

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.

[63] EPA is contributing to the OECD sponsorship program on fullerenes, single-walled carbon nanotubes, multi-walled carbon nanotubes, silver nanoparticles and cerium oxide. Considering also the other federal agencies, US are testing also iron, carbon black, titanium dioxide, aluminum dioxide, and dedrimers.

[64] http://www.epa.gov/nanoscience/

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 defines 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 between existing substances, 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 broad 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 to the material in a macro-form [65].

In the view of EPA, it still has the authority to review and regulate nanomaterials 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.

Apart from the debate on the ability of the statute to distinguish nanomaterials from conventional-sized materials, issues similar to other regulations have been highlighted regarding application of TSCA to nanomaterials. In particularthe 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].

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 100 chemical pre-manufacturing notifications (PMN) for nanoscale materials, some considered as new chemicals, others treated through the SNUR procedure.

[65] EPA recently announced that is taking into consideration a review of the procedure to decide whether a nanoscale substance is a new or existing chemical for purposes of TSCA [45].

The following general principles have been adopted with respect to substances subject to PMN[66]:

- *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;*
- *requiring tests to generate health and environmental effects data.*

A series of further actions are currently under evaluation at EPA to ensure an appropriate regulation of nanomaterials:

- **Proposal of changes to SNUR** related to specific substances already listed in TSCA Inventory, requiring manufactures to submit a Significant New Use Notice (SNUN) before manufacturing, importing or processing this substance. Information that will be required in the SNUN will include data on use, characterization, production volumes, toxicity and exposure of the specific nanomaterials considered by the SNUR.

- **Proposal of an information gathering rule for nanomaterials**, requiring manufacturers the submission to EPA of information about manufacturing and use of nanomaterials, under the section 8 (a) of TSCA [67].

- **Proposal to develop a test rule** (under section 4 of TSCA), requiring manufacturers to develop and submit data on the health and environmental effects of specific nanomaterials.

Two SNURs regarding Single Wall Carbon Nanotubes (SWCNTs) and Multiple Walls Carbon Nanotubes (MWCNTs) are currently under discussion, introducing requirements to perform specific toxicity testing and to ensure the use of protective equipment in compliance with NIOSH guidelines on these substances [68].

SNUR for nanomaterials will be issued by EPA on a case by case basis, giving specific indications depending from the substance considered (for example, different SNURs could be issued also for different types of the same nanomaterial) [69].

The recent (April 2010) debate of the U.S. senate on the Safe Chemical Act of 2010, includes a proposal for a reform of the TSCA that would introduce relevant changes to this statute and would also affect regulation of nanomaterials (even though nanomaterials were not explicitly mentioned in the debate).

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

[67] *"TSCA Section 8(a) gives EPA the broad authority to require, by rulemaking, manufacturers (includes importers) and processors of chemical substances to maintain records and/or report such data as EPA may reasonably require to carry out the TSCA mandates...."*- http://www.epa.gov/opptintr/chemtest/pubs/sect8a.html

[68] http://edocket.access.gpo.gov/2009/E9-26818.htm

[69] http://www.bdlaw.com/news-627.html#_ftn13

One of the most important points regards the proposal to shift the burden of that a chemical is safe from the regulatory authority (EPA) to industry. This would represent a significant step towards the REACH approach [70].

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 aims to determine with the aim of *"regulatory approaches that encourage the continued development of innovative, safe, and effective FDA-regulated products that use nanotechnology materials"* [71]. The structure of the Task Force includes links to different internal competence centres relevant for nanotechnologies, such as the FDA centres for *Food Safety and Applied Nutrition, Drug evaluation and research, Veterinary Medicine and Devices and Radiological Health, Toxicology,* etc.

The Task Force 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. 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 manufacturers 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).

[70] http://www.innovationsgesellschaft.ch/index.php?section=news&cmd=details&newsid=326&teaserId=11

[71] http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForce/default.htm

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 and functions (e.g. theranostic devices) is a critical issue.
Analogous to other regulatory frameworks, issues related to exposure using mass/volume metrics, appropriateness of toxicological data and testing protocols have also been 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 with the National Institutes of Health, NIST and is actively involved in the OECD nanomaterial testing programme.

The general approach to nanoregulation of FDA, that existing regulation adequately covers nano forms of substances, has been recently confirmed by the agency on different occasions. It seems also that, considering the current state of knowledge, the agencies will not adopt a definition of nanomaterials, considering it would be too restrictive to adequately regulate nanomaterials [72].

3.4 Australia

The Australian Government introduced at the end of 2009 a comprehensive national framework to guide the safe and responsible development of new technologies, called the National Enabling Technologies Strategy, including activities previously related to the Australian National Nanotechnology Strategy.

Some of the goals outlined by the strategy are particularly important with respect to nanoregulation:

- A National approach: coordinating activities at government level and supporting collaborative efforts among stakeholders on the development of nanotechnologies (including issues related to nanoregulation, EHS, ELSA).

- Balancing risk and reward: including support to regulatory agencies to continually review *"the regulatory frameworks, processes and capabilities to provide efficient, robust and adaptable regulation of nanotechnologies";*

[72] http://tacd.org/index.php?option=com_content&task=view&id=146&Itemid=1 and http://ihcp.jrc.ec.europa.eu/docs/workshop_outcome_july_09.pdf

- Developing measurement capabilities and standards in the field of nanotechnology (and other enabling technologies).

Within the National Enabling Technologies Strategy, the Health, Safety and Environment (HSE) Working Group has been set up to analyse the impact of nanotechnology (and other enabling technologies) on national regulatory frameworks, coordinate all relevant regulatory agencies efforts (including standards Australia), maintain communication with stakeholders and support international engagement on nanotechnology regulation. Specific funds to relevant government agencies have been allocated to undertake activities on these topics. Among these agencies are: National Industrial Chemical Notification and Assessment Scheme (NICNAS), Safework Australia, Food Standards Australian New Zealand (FSANZ), Therapeutic Goods Administration (TGA), Department of Environment, Water, Heritage and the Arts, Department of Innovation, Industry, Science and Research, and Department of Defense.

Three reference documents provide relevant background to the strategy with regardswith regard to 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 has been that there is no immediate need for major changes to existing regulatory frameworks, even though there are potential gaps in different regulatory areas. However, these gaps should be considered in detail by regulatory agencies in order to define possible amendments.

These gaps are synthesised assynthesised in six points [33, 35, 42]:

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) *Risk assessment processes and protocols reliant on international documents (where specifically applicable to Australian risk assessment processes).*

A relevant activity on nanotechnology is on-going within different national regulatory agencies aiming to respond to these gaps and assure an adequate regulatory framework for nanotechnologies.

NICNAS (National Industrial Chemical Notification and Assessment Scheme, the 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 [73].

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

As in other provisions, regulatory requirements under NICNAS depend on whether a chemical is considered a "new" chemical or an "existing" chemical (i.e. included in the Australian Inventory of Chemical Substances). Depending on a set of exemptions, permits and certificates for new chemicals are generally subject to pre-market assessment, while "existing chemicals" (such as some nano forms of conventional chemicals) can be introduced in the market without review or notification.

NICNAS started a consultation among stakeholders in 2009 to introduce a regulatory reform of industrial nanomaterials. The reform (detailed in the report "Proposal for Regulatory Reform of Industrial Nanomaterials Public Discussion Paper", November 2009) proposes a series of short to long term actions tackling most of the gaps underlined above:

- *Regulation of nano-forms of new chemicals*: exclusion of any exemptions for nanomaterials, assuring pre-market assessment of all nanomaterials classified as new chemicals;

- *Regulation of nano-forms of existing chemicals*: developing a reporting programme for nanomaterials *"commencing on a voluntary basis and progressing to mandatory once-off use specific reporting";*

- Developing, in the long term, an integrated approach for industrial nanomaterials within the NICNAS framework.

The proposal specifies that a mandatory reporting scheme would require relevant legislative changes and thus could only be considered as possible medium to long term options [74].

While the first consultation phase is now concluded, a "regulatory impact analysis" of the options proposed and a further consultation steps will be undertaken before implementing the reform (a decision is expected during 2010).

With regards to the reporting of nanomaterials, NICNAS has in the past few years issued two voluntary calls to Australian industry to collect information about uses and quantities of nanomaterials imported or manufactured for research or industrial purposes. The results of the last Call (2008) should be made public shortly.

Safe Work Australia has developed a Nanotechnology OHS Program [75] to ensure appropriate control and regulation of nanomaterials in occupational settings.

[74] The document "Proposal for Regulatory Reform of Industrial Nanomaterials Public Discussion Paper", November 2009, includes a model for a "mandatory notification and assessment program"

[75] http://www.safeworkaustralia.gov.au/swa/HealthSafety/EmergingIssues/Nanotechnology/NanotechnologyOHSProgram.htm

Specific actions are foreseen 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.

The Agency has recently published a literature review on *"Engineered Nanomaterials - Evidence on the Effectiveness of Workplace Controls to Prevent Exposure"* [43] and is currently working on a *"Code of Practice for Safety Data Sheets (SDS)*", including non-mandatory parameters specific for nanomaterials.

The Australian Pesticide and Veterinary Medicines Agency (APVMA) published in December 2008 a strategy for nanotechnology, with a commitment to develop appropriate administrative processes to deal with nanotechnology [76].

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 conclusion was that there were no products in 2008 registered using nanomaterials. The Agency is supporting further initiatives to monitor the use of nanomaterials.

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"*[77].

Canada is currently applying the existing regulatory regime to nanotechnology, but several actions have been put in place, in particular regarding chemicals, and the government has not excluded that *"new approaches may be necessary in the future to keep pace with the advances in this area."*[78].

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) published a proposal in September 2007 for a regulatory framework for nanomaterials under the Canadian Environmental Protection Act, 1999 [79, 80].

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

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

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

[79] 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*

This document provides 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 it is chair of the ISO TC 229 Working Group on Terminology and Nomenclature (WG1). The resolution of standard nomenclature and terminology is considered a priority action, as a basis to support the regulatory framework for nanomaterials.
- 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 regulation of chemicals and polymers, EC issued (in July 2007) an advisory note informing manufacturers and importers of nanomaterials of their regulatory responsibilities for nanomaterials under the *New 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.[81]
- EC and HE are expected to launch a mandatory survey on nanomaterials, under the *Canadian Environmental Protection Act, 1999* statute. The objective of the scheme will be to collect information from industry about: nanomaterials imported or manufactured above a threshold of 1kg, including R&D material; information on use, volume of production, type, characteristics and toxicological profiles, available best practices [45].

Regarding occupational safety some relevant actions have been undertaken:

- The report *"Best Practices Guide to Synthetic Nanoparticle Risk Management",* published by the Institut de Recherche Robert-Sauvé en Santé et en Sécurité du Travail (IRSST) [44]
- 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).

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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. " - http://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=FD117B60-1

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

[81] 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/subsnouvelles-newsubs/default.asp?lang=En&n=D179F162-1

- CSA Standards established in May 2009 a Technical Committee on Nanotechnologies - Occupational Health and Safety to follow work of ISO TC 229 and to produce a national standard on OHS of nanomaterials.

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

Very recently (March 2010) the Canadian House of Commons discussed a possible amendment to the Canadian Environmental Protection Act, that would introduce measures such as a pre-market review of all nanomaterials and nanoproducts and a public inventory of their use, and thus, in the view of the proponents, would provide a more precautionary approach to the regulation of nanomaterials.[82]

3.6 China

China has historically used legislation developed in other countries (notably US and EU) as benchmarks for the development of its own. In 2000, China established a National Steering Committee for Nanoscience and Nanotechnology (NSCNN) to coordinate national N&N research, however this excludes the regulatory agencies listed below.

Several Chinese agencies have a role in regulating nanotechnology, the most prominent of which are: Ministry of Environmental Protection (MEP), State Administration of Work Safety (SAWS), State Food and Drug Administration (SFDA), and Standardization Administration of China (SAC). All chemicals must be listed on the 'Inventory of Existing Chemical Substances Manufactured or Imported in China (IECSC)'. Manufacturers or importers of new chemicals must comply with requirements set out in 2003 regulations: 'Provision on the Environmental Administration of New Chemical Substances'. Fines and bans from manufacturing/ importing are applied to those organisations which fail to comply with the regulations. In early 2010, the legislation was further adapted to bring it in line with REACH, requiring information on risk assessment and management (for human health and the environment).[83] In the new legislation 'Measures on Environmental Management of New Chemical Substances' (or Order 7), due to come into force on 15th October 2010, chemicals will be classified into three categories: general new chemical substances, hazardous new chemical substances, and key hazardous new chemical substances. However, there is concern amongst observers that potential regulatory gaps will be difficult to manage, as enforcement is the remit of local and regional government, and not one single national agency.

[82] http://www.canadaviews.ca/2010/03/10/new-democrat-tables-nanotechnology-bill-for-the-21st-century/

[83] China updates chemical legislation (Chemistry World, 01.04.10) http://www.rsc.org/chemistryworld/News/2010/April/01041001.asp

SFDA revised its medical devices regulations in 2006 to take account of those which include nanoscale biomaterials or silver, requiring manufacturers or importers to provide more detailed pre-market approval information.

China is an active participant in international standardisation, chairing working group 4 'materials specifications' of ISO TC 229. Indeed, China has arguably been one of the pioneers of standards in nanotechnology, publishing 22 national standards since 2004 from four different agencies: SAC, AQSIQ (General Administration of Quality Supervision and Quarantine), NDRC (National Development and Reform Commission), and CATI (China Association of Textile Industry). Of these 17 are voluntary. China's nanotechnology standardization activities are overseen by the SAC National Technical Committee 279.

3.7 India

India's Department of Science and Technology (DST), part of the Ministry of Science and Technology, launched a national Nano Science and Technology Initiative (NSTI) in 2001, which evolved into the 'Nano Mission' in 2007. There are no regulations specific to nanotechnology, and while it is likely that DST will play a role in future developments, its role is not that of a regulatory agency. The other key regulatory players include: the Ministry of Environment and Forests (MoEF); the Ministry of Health and Family Welfare (MoHFW); the Ministry of Chemicals and Fertilisers; the Ministry of Consumer Affairs, Food and Public Distribution; the Ministry of Commerce and Industry (MoCI); and the Ministry of Employment and Labour (MoLE).

NIPER (the National Institute of Pharmaceutical Education and Research) has programmes developing regulatory guidelines for the approval of nanotechnology enabled pharmaceuticals. The Bureau of Indian Standards (BIS) is also planning to fund toxicology studies on various nanomaterials including titanium dioxide, zinc oxide, silver and carbon nanotubes. Other Indian institutes involved in standards and regulatory policy, that may influence the development of new regulations relating to nanotechnology include: the Central Food Technology Research Institute (CFTRI), the Central Drug Standard Control Organisation (CDSCO), the Food Safety and Standard Authority of India (FSSAI), the National Environmental Engineering Research Institute (NEERI), the National Chemical Laboratory (NCL), the National Physical laboratory (NPL), the Indian Council of Agricultural Research (ICAR), the National Environmental Protection Authority (NEPA). The issue is further complicated by the fact that some regulatory activities are the responsibility of individual states (e.g. health), while others are enforced at a national level (e.g. environment).

BIS is the Indian member to ISO TC 229, and has established a mirror group (MTD 33) to support international standardisation in nanotechnologies. However, it does not take an active role in either of the OECD working groups.

Civil society in India is beginning to take an interest in the responsible development of nanotechnologies. The Energy and Resource Institute (TERI) is one such not-for-profit organization actively engaged in the public debate. It has called for amendments to

existing legislation and the formation of an expert committee to oversee the evolving regulatory process.

3.8 Japan

At the institutional level, the Ministry of Economy, Trade and Industry (METI) is conducting a 5 year project on toxicity test protocols and risk assessment methodologies for manufactured nanomaterials, coordinated by the National Institute of Advanced Industrial Science and Technology (AIST), 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].
Within the activities of the former project, AIST published in December 2009 the following documents (the English version is available on the AIST website[84]) :

- Interim reports on the risk assessment of three nanomaterials, "Titanium Dioxide (TiO_2)", "Fullerene (C_{60})" and "Carbon Nanotubes (CNTs)",
- An accompayningAccompanying brochure "The Principles and Basic Approach to Risk Assessment of Manufactured Nanomaterials (interim version)"

The reports focus on risk management measures to control and reduce exposure to nanomaterials.

As in most of the other countries, nanomaterials are regulated under the existing regulatory frameworks for conventional substances and products, and Japanese authorities do not seem to be oriented to introduce any regulatory changes for nanotechnologies, at least in the near future [85].

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 organised at the end of 2008 a preliminary survey on the 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 providing voluntary guidelines for the handling of nanomaterials [86].

[84] http://www.aist-riss.jp/main/modules/product/assessment.html

[85] Report on Current Developments/ Activities in Manufactured Nanomaterials – Tour de Table, OECD WPMN [45], http://ihcp.jrc.ec.europa.eu/docs/workshop_outcome_july_09.pdf

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

The Ministry of Health, Labour, and Welfare (MHLW) published nanotechnology guidelines related to workers and will soon issue a further set on medical practices and pharmaceuticals [45].

Japan participates in the work of OECD WPMN and ISO TC 229 (in particular it is the convener of the Working Group on Measurement and Characterization- WG2)

3.9 Taiwan

The Taiwanese government launched a dedicated National Nanotechnology Programme (NNP) in 2002, with a focus on industrial technologies and commercialisation. However, Taiwan also recognises the need to develop nanotechnologies in a responsible manner, as underlined in Phase II of the NNP, where Taiwan's Environmental Protection Administration (TEPA) recognises the need for EHS research and in Taiwan's Science and Technology Development Plan (2009-2012) where research ethics for new technologies (such as nanotechnology) are explicitly mentioned.[87,88]

All chemicals are regulated by the Council of Labour Affairs (CLA), however in 2008 updates to the existing regulations were proposed to ensure that greater information on chemical risks were required to be disclosed by manufacturers and importers. The Safety and Health Technology Centre (SAHTECH) has been tasked with drafting notification guidelines for the CLA, and takes a strong lead from the EU's REACH. TEPA also plays a role in regulating chemicals through the Toxic Chemical Substances Control Act.

Taiwan launched the first certification scheme for nanotechnology products in 2004. The Nanomark Certification System is administrated by the Industrial Technology Research Institute (ITRI) and is a voluntary scheme that aims to increase public confidence in nanotechnology products, by ensuring quality and safety. By the end of 2009 some 467 products from 24 companies were registered under the Nanomark. The scheme does not cover cosmetics or pharmaceuticals.[89]

The Taiwan Nanotechnology Industry Development Association (TANIDA), which was formed in 2004 and has 57 industrial members, contributes to the development of regulations and helped to establish the Taiwan Nanotechnology Standards Council (TNSC) in conjunction with the Bureau of Standards, Measurement and Inspection (BSMI) and ITRI. TNCS contributes to international standards, as a member of ISO TC 229.

[87] Taiwan's Strategic Plan for Responsible Nanotechnology (2009-2014) http://www.epa.gov.tw/FileLink/FileHandler.ashx?file=13491

[88] http://web1.nsc.gov.tw/public/Attachment/91214167571.PDF

[89] http://www.nanomark.com/ ; http://proj3.moeaidb.gov.tw/nanomark/Eng/

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 between 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 kinds of voluntary measures [2] as indicated below.

Reporting schemes [90]**:**
These instruments are used by regulatory authorities to collect information from industry 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 aid 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.

Codes of conduct*:*
Regulatory authorities and other stakeholders have proposed or implemented voluntary codes of conduct, defining values, principles and practices for a safe and responsible development of nanotechnologies. Although they generally have a non-binding character, there could be a degree of liability related to the subscription to 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 to the manufacturing, production and use of nanotechnologies.
They provide guidelines and best practices in risk management and in EHS issues. They do not have a regulatory role, and, as in the case of accreditation, can work similarly to product quality certification systems.

Some of the most important examples of these four measures are described briefly in brief below paragraphs.

[90] With regard to reporting schemes and more in general the issue of understanding the ability of existing legislation to identify the use of nanomaterials, an in depth review of about 24 different legislations is provided in the recently published OECD reports: "Analysis of Information Gathering Initiatives" and " Table of Comparison – Information Gathering Schemes" (see also paragraph 4.4).

4.1 EC Code of Conduct

The EC has been very active for sometime in promoting nanotechnologies and has paid particular attention to ensure that the development of nanotechnologies takes place 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 (CoC) for responsible nanoscience and nanotechnologies research [1].

The Code is based on a set of principles[91], 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 the 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 to all Member States, which have been 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 are translated into concrete measures [92].

However, the reaction so far has been tepid and initiatives are planned to promote the implementation of the Code.

In particular, the EC launched in January 2010 the two year FP7 project *"NanoCode: a multistakeholder dialogue providing inputs to implement the European Code of Conducts for Nanosciences & Nanotechnologies Research"* [93].

The objective of this project is to improve and strengthen awareness of the CoC, promote trust building among stakeholders and, as an ultimate goal, develop a framework to support the further articulation and wider application of the CoC. Nanocode involves partners from eight European Countries (Germany, UK, France, The Netherlands, Italy, Spain, Switzerland, the Czech Republic) and two Associated Countries (South Africa, Argentina)

The EC opened a public consultation on the CoC, between October 2009 and January 2010, in order to receive input from all people and organisations involved or interested

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

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

[93] http://www.nanocode.eu/

in N&N research in Europe (research, policy makers, industry, media and civil society organisations).

Following this consultation a revision of the CoC is planned for mid 2010.

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, importing or management of wastes consisting of engineered nanoscale materials [94].

Information requested included any data on: uses, benefits and exposure pathways, physico-chemical properties, toxicology, ecotoxicology and risk management practices. A data reporting form was provided, however only 13 submissions were received at the end of the programme, 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 in the VRS [95].

The final VRS evaluation has not yet been made public, however the UK government has already expressed its commitment to continue and improve it. Defra is also currently re-considering whether the VRS should include products containing nanomaterials (in addition to free nanomaterials). Options for mandatory initiatives are also under evaluation [17].

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

The Government believes that a revised version of the earlier reporting scheme will address the 'simple checklist' approach suggested by the Royal Commission, and assist greater partnership to develop our understanding of the science. This could include details of manufacturers and importers, information on quantities produced and how they are used in wider industry.

In doing this, it will also be important to keep in view the requirements of REACH, and ideally assist the nanomaterials industry in 'building a bridge' to a future REACH nanomaterials regime (which may well include a reporting requirement), rather than creating additional burdens.

The Government has not yet reached a final view on the scheme's design and work [17].

[94] "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]

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

Work is currently ongoing to define in more detail how this could effectively be introduced. However, if a revised voluntary scheme is initially offerred and industry does not respond, the Government will re-assess its consideration of a mandatory scheme. The Government will also review its existing structures and mechanisms for sharing [18] information and for stakeholder engagement, with a view to finding 'light touch' ways of encouraging researchers and companies to provide early evidence of developments without compromising their commercial advantage.

4.3 EPA-NMSP (USA)

The US Environmental Protection Agency (EPA) 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 programme ended in January 2010.

The main objectives of NMSP were to gather data and information from manufacturers, 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 programme [4] [96].
There are two levels of participation, basic and in-depth. In the former, 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 programme, 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 programme from 29 organisations, covering more than 123 nanoscale materials, and has involved 4 companies in the in-depth programme [3].

Even though participation in the programme has 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.

[96] *"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

Increasing both 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 NMSP interim report.
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. As a result, 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], which is 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 an 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 is guaranteed on the basis of all available scientific information and technology;
- transparency and engagement in dialogue initiatives, commitment to disclose new findings to authorities and the public.

BASF keeps an up-to-date website dedicated to nanotechnology and safety aspects of nanotechnology [97].

[97] http://www.basf.com/group/corporate/en/content/sustainability/dialogue/in-dialogue-with-

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 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[98].

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. tI is therefore suitable for large companies.

Sharing of information, transparency and accountability of risk management procedures are considered 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 histories of specific nanomaterials, is available for reference[99].

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 (BauA) conducted a survey on occupational health and safety in the handling and use of nanomaterials

politics/nanotechnology/index

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

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

among its members. Results of the survey were 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 and protection measures.
Approximately 50 companies responded, but, in the view of VCI, the number of respondents was limited by the restriction criteria adopted in the questionnaire [100].
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 provide 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 [101].

The German Federal Institute for Occupational Safety and Health (BauA) is currently planning to update this data with a new survey devoted to occupational safety related to nanomaterials [45].

4.4.5 IG DHS

The first example of a code of conduct related to nanotechnology usage in consumer products was 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 that are safe according to the best available knowledge. They are also responsible for providing 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".*

[100] 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].

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

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 provide 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 humans and the environment [102].

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, "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 an indication of the strategic issues that organisations need 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 design process of the Code is expected to continue through the engagement and monitoring of organisations applying the Code ("benchmarking process") providing further inputs to improve and refine the document [103].

To date the Responsible NanoCode has not been fully implemented, however one of the original partners (CPI) has developed a further scheme, AssuredNano, as a means to achieve this (see below).

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

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

4.4.7 AssuredNano

This UK-based initiative is a collaboration between the Centre for Process Innovation (CPI) and the Institute of Occupational Medicine (IOM). It offers manufacturers and suppliers of nanomaterials and devices containing nanomaterials an accredited scheme of best practice in EHS aspects and safe handling of nanomaterials. Organisations are audited annually for compliance with the scheme, which is underpinned by a regularly updated database of EHS knowledge and best practice.

The scheme provides industry with support regarding the characteristics of different nanomaterials, managing and minimising risks, and accidental exposure; and assessing the life-cycle of products containing nanomaterials.[104]

[104] http://www.assurednano.eu/index.php

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.

Nanotechnologies encompass different research fields and find their way into a large variety of sectors and markets and this challenges the definition of standards.

The development of appropriate standards is mandatory in crucial areas, such as terminology and nomenclature, metrology, environmental, health and safety (EHS) issues. With the increased number of nano-related products and applications, an increased need for product specific standards can also be expected.

As reported in the previous sections, there are significant efforts underway to elaborate a regulatory framework to address many of the aspects related to the use of nanotechnologies, 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, as well as to develop new ones. Standards play a crucial role in this process.

A structured activity on standards for nanotechnology was started in 2004, with the first national Technical Committees (TC) devoted to this field, set up in China (SAC/TC279), UK (BSI –NTI/1) and U.S.A. (ANSI-NSP).

5.1 The activity of ISO TC 229 and IEC TC 113

Given their international reach, the activities most relevant for standardisation for nanotechnologies is certainly that ofthose from the International Standards Organisation (ISO), which in June 2005 formally established the *ISO-TC 229-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 established the *IEC TC 113 - Nanotechnology for electrical and electronic products and systems*, for the development of technical standards in these specific fields.

National bodies of more than 32 countries are members of the Nanotechnology Technical Committees of ISO and IEC, and specific national committees for nanotechnology have been established in most of these countries.

As previously pointed out, ISO TC 229 and IEC TC 113 represent the main references for standards in nanotechnologies but, as will be described below, 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 Annex I)

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: *the standardization in the field of nanotechnologies that includes either or both of the following* [105] *:*

- *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 4 Working Groups (WG) [1]:

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

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.

IEC TC 113 has also established a third WG (IEC TC 113 WG 3: performance assessment) specifically devoted to the assessment of performance, reliability, and durability related to the nanotechnology-enabled aspects of components and systems in the electrical and electronic field.

Several other liaisons have been established within ISO Technical Committees. In particular those TC dealing with different micro/nano measurements and characterisation techniques (such as ISO TC 201, ISO TC 202, ISO TC 213). Relevant to this topic are also the external liaisons established with the VAMAS (Versailles Project on Advanced Materials and Standards) and with the BIPM (Bureau International des Poids et Mesures) [106].

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

[106] www.bipm.org/en/events/nanoscale

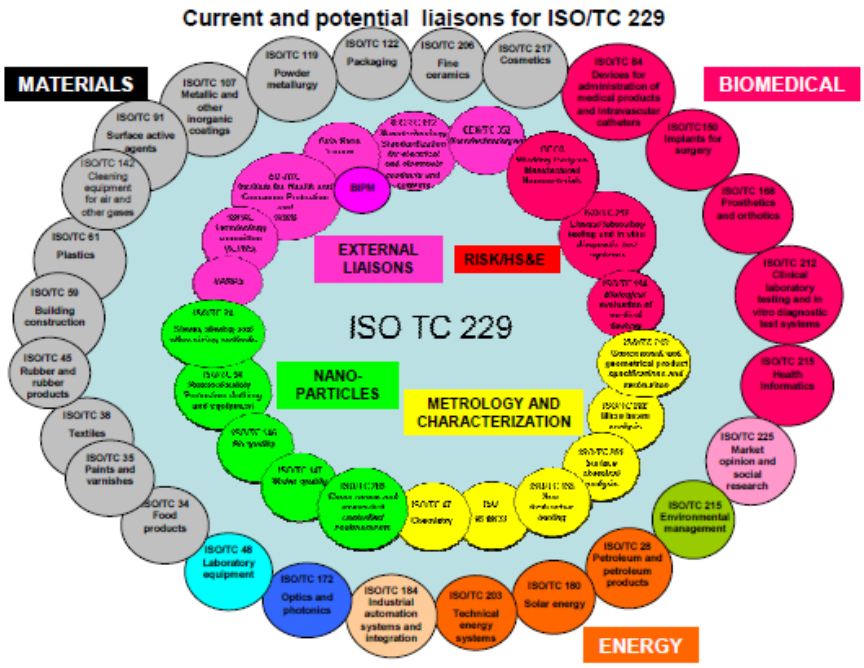

Figure 5.1 Organisations and Committees potentially involved in nanotechnology standardization / current (inner circle) and potential (outer circle) liaisons for ISO/TC 229 [107]

With respect to WG1, an external liaison is active with the Terminology Committee ICTNS of IUPAC (International Union of Pure and Applied Chemistry).

Potential risks for human health and the environment are considered within Working Group 3. External liaisons have been initiated with the OECD Working Party on Manufactured Nanomaterials (WPMN) and IEC TC 113. The former organisation has a 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). The end of the first phase of this programme is planned in 2010 (when the identification of a set of physico-chemical properties relevant to EHS risk assessment is planned). The results will be valuable to the support of the ongoing work on standards.

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 generally 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 [2].

[107] Picture from the presentation "Adding value to nanotechnology Framework Projects through standardization", Dr Peter Hatto, Chairman ISO TC 229, CEN TC 352 and BSI NTI/1 Nanotechnologies standardization committees, EuroNanoForum, Prague, 5th June 2009

Within WG3, liaisons are activated also with other Technical Committees, in particular dealing with the biological and medical field (such as ISO TC 212 and ISO TC 194).

Working Group 4 was established at a later stage compared with the other WGs (end of 2007). With nanotechnology – related products 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].

An initiative to investigate the role of standards with respect to ELSA implications of nanotechnologies hashas recently been started, with the establishment of two specific Task Groups within ISO TC 229:

- TG Nanotechnologies and Sustainability
- TG Societal and Consumer Dimensions of Nanotechnologies

Their objective is to provide recommendations to all four TC 229 Working Groups for a prioritized programme of standardization on these topics.

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. The result is 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*

A roadmap of activities has been defined (and is constantly updated) for each of the workpackages. A snapshot of the strategic roadmap of workpackage 1 is reported in the figure below.

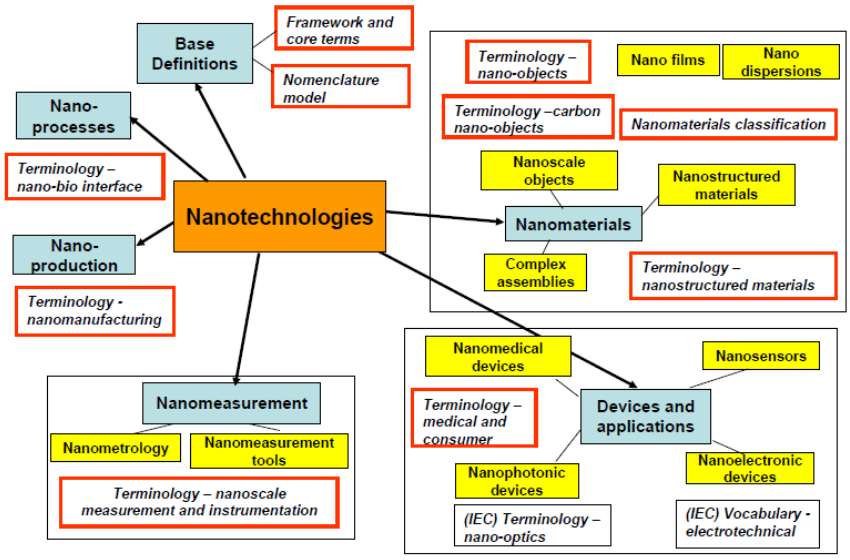

Figure 5.2 Strategic Roadmap for WG1 [108]

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

- ISO/PAS: Publicly Available Specification (defines terminologies)
- 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 ISO document produced through workshop meeting(s) and not through the technical committee process.

These documents have different levels of relevance. In Europe, a special situation exists for sectors regulated under the so-called 'New Approach'. Certain full standards (EN-European Standards) can get the qualification *"harmonized standards"*, which is acknowledged by publication of their number in the Official Journal of the European Community. Harmonised standards give the presumption of conformity with relevant, specified regulatory provisions, within the limits of the scope of the standard. 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 the most appropriate documents available[109].

[108] Picture from the presentation "Adding value to nanotechnology Framework Projects through standardization", Dr Peter Hatto, Chairman ISO TC 229, CEN TC 352 and BSI NTI/1 Nanotechnologies standardization committees, EuroNanoForum, Prague, 5th June 2009

[109] At present, amendment to European Standards in relation with nanotechnologies are already

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 agreement among stakeholders that the work of international standard setting bodies is crucial in ensuring that the full potential of nanotechnology is realised.

At present there are more than 35 standards documents under development within ISO TC 229 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 titanium dioxide and calcium carbonate.

Some of these documents are close to the final approval stage, and two have already been published[110]:

- **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."

  This Technical Specification is part of a series of documents in preparation, that will take the name "80004 - Nanotechnologies — Vocabulary…". The full list of these standards is reported below.

considered in the medical device sector.

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

- **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, ordered according to their stage of development and including a comparison with the situation in April 2009. Some of them are already classified as Technical Specification (TS) or Technical Report (TR).

Compared to April 2009, **4** standards have reached the approval/publication stage, **1** has moved from the Committee to the Enquiry stage, **8** have moved from the Preparatory to the Enquiry stage and **3** new standards documents have been proposed. Most of these documents are related to terminology, nomenclature, measurement and characterization of nanomaterials (in particular carbon nanotubes).

With regards to risk assessment and risk management, it is worth noting that a standard work about the definition of a *"Nanomaterials Risk Evaluation Framework"* is now at the Committee stage and in the last year a new document on *Material Safety Data Sheet (MSDS) for nanomaterials* has been proposed.

Standard and/or project [111]	**Stage code at April 2010**	**Stage code at April 2009**
	PUBLICATION STAGE	
ISO/PRF TS 80004-3 Nanotechnologies -- Vocabulary -- Part 3: Carbon nano-objects	60.00	20.99
	APPROVAL STAGE	
ISO/PRF TR 11811 Nanotechnologies -- Guidance on methods for nanotribology measurements	50.20	20.00
ISO/FDIS 29701 Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test	50.00	40.20

[111] 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

ISO/PRF TR 11360 Nanotechnologies -- Methodology for the classification and categorization of nanomaterials	50.00	none
	ENQUIRY STAGE	
ISO/DIS 10808 Nanotechnologies -- Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing	40.99	40.20
ISO/DIS 10801 Nanotechnologies -- Generation of metal nanoparticles by evaporation/condensation method for inhalation toxicity testing	40.99	30.99
	COMMITTEE STAGE	
ISO/DTR 12802 Nanotechnologies -- Terminology -- Initial framework model for core concepts	30.60	30.20
ISO/DTS 11888 Determination of mesoscopic shape factors of multiwalled carbon nanotubes (MWCNTs)	30.60	20.00
ISO/DTS 11308 Nanotechnologies -- Use of thermo gravimetric analysis (TGA) in the purity evaluation of single-walled carbon nanotubes (SWCNT)	30.60	20.00
ISO/DTR 10929 Measurement methods for the characterization of multi-walled carbon nanotubes (MWCNTs)	30.60	30.60
ISO/DTS 10868 Nanotubes - Use of UV-Vis-NIR absorption spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	30.60	20.99
ISO/DTS 10867 Nanotubes -- Use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	30.60	30.60
ISO/DTS 10798 Nanotubes -- Scanning electron microscopy (SEM) and energy dispersive X-ray analysis (EDXA) in the charaterization of single walled carbon nanotubes (SWCNTs)	30.60	20.99
ISO/DTS 80004-1 Nanotechnologies -- Vocabulary -- Part 1: Core terms	30.20	20.99
ISO/DTR 13121 Nanotechnologies - Nanomaterial Risk Evaluation Framework	30.20	20.00
ISO/CD 12025 Nanomaterials -- General framework for determining nanoparticle content in nanomaterials by generation of aerosols	30.20	20.00
ISO/DTS 11251 Nanotechnologies -- Use of evolved gas analysis-gas chromatograph mass spectrometry (EGA-GCMS) in the characterization of single-walled carbon nanotubes (SWCNTs)	30.20	30.20
ISO/WD TS 10797 Nanotubes -- Use of transmission electron microscopy (TEM) in walled carbon nanotubes (SWCNTs)	30.20	20.99
	PREPARATORY STAGE	
36ISO/AWI TS 80004-7 Nanotechnologies -- Vocabulary -- Part 7: Medical, health and personal care applications	20.00	20.00
35ISO/AWI 80004-6 Nanotechnologies -- Vocabulary -- Part 6: Nanoscale measurement and instrumentation	20.00	20.00

ISO/AWI TS 80004-5 Nanotechnologies -- Vocabulary -- Part 5: Bio/nano interface	20.00	20.00
ISO/AWI TS 80004-4 Nanotechnologies -- Vocabulary -- Part 4: Nanostructured materials	20.00	20.00
ISO/AWI TR 13014 Nanotechnologies - Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment	20.00	20.00
ISO/AWI TS 12901-1 Nanotechnologies -- Guidance on safe handling and disposal of manufactured nanomaterials	20.00	20.00
ISO/AWI TS 12805 Nanomaterials - Guidance on specifying nanomaterials	20.00	20.00
ISO/AWI TS 11937-1 Nanotechnologies -- Nano-titanium dioxide -- Part 1: Characteristics and measurement methods	20.00	20.00
ISO/AWI TS 11931-1 Nanotechnologies -- Nano-calcium carbonate -- Part 1: Characteristics and measurement methods	20.00	20.00
ISO/AWI TR 11808 Nanotechnologies -- Guidance on nanoparticle measurement methods and their limitations	20.00	20.00
ISO/AWI TS 10812 Nanotechnologies -- Use of Raman spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	20.00	20.00
	PROPOSAL STAGE	
ISO/NP TS 80004-8 Nanotechnologies -- Vocabulary -- Part 8: Nanomanufacturing processes	10.99	none
ISO/NP TR 13329 Nanomaterials -- Preparation of Material Safety Data Sheet (MSDS)	10.99	none
ISO/NP TS 13278 Carbon nanotubes -- Determination of metal impurities in carbon nanotubes (CNTs) using inductively coupled plasma-mass spectroscopy (ICP-MS)	10.99	none
ISO/NP TS 13126 Artificial gratings used in nanotechnology -- Description and measurement of dimensional quality parameters	10.99	10.99
ISO/NP TS 12901-2 Guidelines for occupational risk management applied to engineered nanomaterials based on a "control banding approach"	10.99	10.99
ISO/NP TS 11937-2 Nanotechnologies -- Nano-titanium dioxide -- Part 2: Specifications in selected application areas	10.99	10.99
ISO/NP TS 11931-2 Nanotechnologies -- Nano-calcium carbonate -- Part 2: Specifications in selected application areas	10.99	10.99

Acronyms: DIS - Draft International Standard; **ICS** - International classification for standards; **WD** - Working document; **CD** - Committee draft;**AWI** - Approved work item; **PRF** - Proof of a new International Standard; **FDIS** - Final draft International Standard; **NP** - New project; TS - Technical Specification; TR - Technical Report; DTR - Draft technical report; DTS - Draft technical specification

5.1.1 Notes on ISO/IEC TS 80004 standards:

Important work has been undertaken to develop the ISO/IEC TS 80004 series of Technical Specifications, dedicated to present terminology and definitions for "core terms" in the emerging vocabulary for nanotechnologies, such as (to cite a few from ISO/DTS 80004-1): "nanotechnology", "nanoscience", "nano-object" , "nanoscale", "nanomaterial", "nanostructured materials", etc.
This series will be composed of the following documents (also reported in the table above).

ISO/TS 80004 series	**Stage code**
ISO/TS 80004-1 Nanotechnologies -Vocabulary -Part 1: Core terms	30.20
ISO/TS 80004-2 Nanotechnologies -Vocabulary -Part 2: Nano-objects — Nanoparticle, nanofibre and nanoplate *	Published
ISO/TS 80004-3 Nanotechnologies -Vocabulary -Part 3: Carbon nano-objects	60.00
ISO/TS 80004-4 Nanotechnologies -Vocabulary -Part 4: Nanostructured materials	20.00
ISO/TS 80004-5 Nanotechnologies -Vocabulary -Part 5: Bio/nano interface	20.00
ISO/TS 80004-6 Nanotechnologies -Vocabulary -Part 6: Nanoscale measurement and instrumentation	20.00
ISO/TS 80004-7 Nanotechnologies -Vocabulary -Part 7: Medical, health and personal care applications	20.00
ISO/TS 80004-8 Nanotechnologies -Vocabulary -Part 8: Nanomanufacturing processes	10.99

* ISO/TS 27687:2008 *Nanotechnologies --- Terminology and definitions for nano-objects --- Nanoparticle, nanofibre and nanoplate* will be revised as Part 2 of the ISO/TS 80004 series.

5.2 Other standards organisations

Alongside the activities of ISO TC 229 and IEC TC 113, there are several other (standard) bodies currently working on standards for nanotechnology or with activities relevant for this field. Among these organisations there can be cited:

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

Activities from national standard organisations 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.

Several ISO Committees are developing standards relevant for nanotechnology, such as ISO TC 194 (biological evaluation of medical devices), and 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 –NTI/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 nanotechnology.

A list of *"existing standards and standards under development relevant to or which might have relevance for nanoscale measurement or observation"* were 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 of 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 andnanomaterials".*

CEN 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). Their aim is to develop a work programme including areas of specific interest to Europe and areas that will be relevant to European legislation. According to the CEN TC 352 website [112], the following aspects of nanotechnologies are part of the work of the TC:

- classification, terminology and nomenclature;
- metrology and instrumentation, including specifications for reference materials;
- test methodologies;
- modelling and simulation;
- science-based health, safety and environmental practices;
- nanotechnology products and processes.

CEN TC 352 is working in close collaboration with standards organisations relevant for nanotechnologies, and in particular with ISO TC 229 (through a specific agreement on technical cooperation called the "*Vienna Agreement*").

The activity of the TC has been structured through the definition of the two working groups:

- WG 1: Measurement, characterization and performance evaluation
- WG 2: Commercial and other stakeholder aspects

Various standards documents underway are the result of joint efforts between CEN and ISO (see paragraph 9 for details) [113]. Currently there are a number of work items started in CEN/TC 352 will be further developed with an ISO TC 229 lead and, vice-versa, items approved in ISO TC 229 with a CEN TC 352 leadership.

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

In order to answer the Mandate, CEN TC 352 examined the activities of several organisations such as CEN and CENELEC Technical Committees, ISO TC 229 (including the ISO roadmap on standard needs), European Technology Platforms and

[112] http://www.cen.eu/CEN/sectors/sectors/nanotechnologies/Pages/default.aspx

[113] 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.

organisations and associations with a possible interest in nanotechnology, through the analysis of documents and a specific survey (undertaken in 2007 and 2008). The results were reported in May 2008 [114].

The report gives indications both on current and future standards needs and the level of activity and interest by these organisations in current or future standardization relating to N&N. The information is organised in the three general categories of:

- *health, worker and environmental safety,*
- *the Lisbon Agenda (acceleration of the transformation of research results into marketable products),*
- *the societal agenda (including benefits derived from medical applications, sustainability, security and consumer interests)*;

Part of the document is also dedicated to consideration of standards needs with respect to the application of REACH.

The report's conclusions provide a priority list of standards needs in nanotechnology and nanomaterials (including both existing and new standards work, and related to the above categories) and a series of recommendations for future EC policies on standards and nanotechnologies.

This report has been discussed within the Commission with a view to decide on possible further action [12]. At the beginning of 2010, a new EC mandate for standardization activities regarding Nanotechnologies and Nanomaterials was issued by the EC to European standards bodies. A response is now expected from CEN, CENELEC and ETSI. The need to maintain a coherent approach of work with OECD, ISO and the activity on nanomaterials related to European regulatory agencies is one of the highlights of the document.

5.3.1 European projects on standardization

Some European projects within FP6 and FP7 are explicitly devoted to standardization in nanotechnologies, among them:

- **Nanostrand (FP6) : Standardization related to Research and Development for Nanotechnologies** (finished in January 2008).

  Goal of the project was to roadmap future European standardization activities for nanotechnology which relate to pre-normative research work in order to support European organizations to play an active role in worldwide development of nanotechnology standards. Key deliverables of the project were two roadmaps on defining nanometrology research priorities and nanotechnology

[114] The report is available only to ISO/CEN members

standardization priorities. The results of the project have been integrated in the CEN report published in May 2008. [115]

- **CoNanoMet (FP7) [116] : European nanometrology strategy definition**. The project aims to develop a review of current and emerging needs for nanometrology in support of the industrial transformation of nanotechnology. A pan European co-ordinated response to the defined needs will be formed in consultation with key stakeholders. Priority areas will be agreed which reflect both European strengths and emerging legislative requirements for nanoproducts.

Several other EU project devoted to EHS issues, such as NANOSAFE, SAPHIR, NANOTOX, NANOSH, NANOIMPACTNET, have a strong relationship with the work on standards. Their activities includes the development of measurement, characterisation and testing methodology for nanomaterials and the evaluation of the appropriateness or need for adaptation of existing standards with respect to nanotechnologies. Their outcomes provide relevant information to the work of CEN TC 352.

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

The OECD plays 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 (WPN)*: established in March 2007 to promote international co-operation that facilitates research, development, and responsible commercialisation of nanotechnology [117]
- *Working Party on Manufactured Nanomaterials (WPMN):* established in September 2006 to promote international co-operationon human health and environmental safety implications of manufactured nanomaterials, in order to assist in the development of rigorous safety evaluation of nanomaterials.

30 OECD Member Countries, the European Commission, non-members (Brazil, China, Singapore, Thailand, Russia), ISO, WHO, UNEP and other relevant stakeholders participate in the activities of the two WGs.

The aim and objectives of OECD-WPMN are reported in "*Manufactured Nanomaterials: Work Programme 2006-2008* [118] and organised in the following Steering Groups:

[115] http://cordis.europa.eu/fetch?ACTION=D&SESSION=&DOC=1&TBL=EN_PROJ&RCN=80019&

[116] http://www.co-nanomet.eu

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

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

- SG1: Database on Human Health and Environmental Safety Research: Database with research project- launched in March 2009 [119].
- 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.

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 series of report comparing existing information gathering initiatives have been recently published (see table below).

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

A review of planned activities and outcomes of OECD WPMNs is detailed in the report *"Manufactured Nanomaterials: Roadmap For Activities During 2009 and 2010"*, published in September 2009. The following is a list of the most relevant (declassified) documents published or planned to be published shortly by OECD WPMN [120].

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

[120] http://www.oecd.org/department/0,3355,en_2649_37015404_1_1_1_1_1,00.html

Documents	**Steering Group**
OECD Database on Research into the Safety of Manufactured Nanomaterials	SG1
EHS research strategies on manufactured nanomaterials	SG2
- Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme - Sponsorship Programme for the Testing of Manufactured Nanomaterials: information document - Sponsorship Programme for the Testing of Manufactured Nanomaterials: interim report of Phase 1 testing	SG3
- Report: the Preliminary Review of the OECD Test Guidelines and its applicability to MN - Guidance Document on Guidance on the use of pulmonary instillation studies and consideration of value and limitations compared to inhalation studies	SG4
- Analysis of Information Gathering Initiatives - Questionnaire on Regulatory Regimes For Manufactured Nanomaterials - Table of Comparison – Information Gathering Schemes	SG5
- Report: on Risk Assessment of Manufactured Nanomaterials: critical issues - Report: supporting tools that offer the potential to strengthen and enhance risk assessment of MN - Report: gap analysis and recommendations to the WPMN to address any identified gaps	SG6
- Preliminary analysis of exposure measurement and exposure mitigation in occupational settings: Manufactured Nanomaterials - Exposure Measurement in Occupational Settings: summaries and preliminary analysis of documents relevant to exposure measurement - Exposure Mitigation in Occupational Settings: summaries and preliminary analysis of documents relevant to exposure mitigation - Analysis of guidance documents for exposure measurements and exposure mitigation in occupational settings	SG8

6 IMPACT ON TECHNOLOGY SECTORS

Regulation can affect the development of nanotechnologies and their applications, for it sets specific boundaries/requirements in relation to EHS issues and ELSA, to which nano-related processes, products and devices must comply. Both research activity and product development have to take into account the state of regulation and its evolution. The aim of this section is to point out the evolving state of nanoregulation relevant for the sectors/applications considered by the ObservatoryNano project. The data reported represent the results of a first analysis which will be updated and integrated throughout the all life of the project.

As reported in the previous sections, nanomaterials and nanorelated products are generally regulated within existing provisions, but, nevertheless, several activities are on-going to revise the effectiveness of this approach. To this end several regulatory agencies worldwide focus essentially on the following actions:

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

So far a regulation considering specifically the use of nanotechnology has been approved only for cosmetics in the EU, while in Canada and France mandatory reporting schemes have been approved by Parliament, but legislation has not yet been implemented.

The table below reports a synthesis of the initiatives undertaken with respect to the above said approaches in the countries and regulatory regimes surveyed in this report. The table has been designed to provide quick and structured references to the report contents, through short sentences underlining some of the results of the analysis performed.

The picture is not intended to be exhaustive, but it gives a rough indication of the sectors in which the evolving of regulation could have an impact. Data included are the result of a desk analysis of information from publicly available documents. Readers are strongly recommended to refer to the full report for details.

Nano - specific regulatory actions under discussion relevant for the ObservatoryNano Technology Sectors
(contents references - numbers in brackets - are detailed in the adjoined "list of references" **) .

Technology sectors	EU	USA	Canada	Australia	Taiwan	Japan	EU Member States initiatives
Agrifood	Labelling of nanomaterials (5) Safety of silver nanoparticles and EFSA guidance (5)						UK: Database on foods (2), Guidance on nanosilver (7)
Chemistry & Materials	REACH (4)	Notification for CNT (3) Registration/ reporting scheme (11)	Reporting scheme for NM (9)	Regulatory reform for NM (8)			France: Reporting scheme, guidance for CNT (17) Norway: Notification of NM (10); UK: Guidance for CNT (6) Switzerland: Guidance on MSDS Various countries: Guidance for handling of nanomaterials *
Environment							Switzerland: guidelines on waste disposal (14)
Health, Medicine & Nanobio	Cosmetics (1)					Guidance for nano-related medicinal products (12)	France: Guidance for nano-related medicinal products UK: Guidance on nanosilver (7)
ICT	Restriction for long MWCNTs and nano silver in RoHS (18)						
Cross sectoral issues	REACH (4) Review of EU legislation for NM in 2011 (19)	Notification for CNT (3) registration/ reporting scheme (11)	Reporting scheme for NM (9) Regulatory reform for N&N (9)	Regulatory reform for NM (8) Guidance on MSDS (16)	NanoMark Certification scheme for N&N (13)		Switzerland: Guidance on MSDS (15)

***** Germany, France, UK, The Netherlands, Switzerland, Australia, Canada, USA (NIOSH), Japan

*** *List of references**

Number in the table	*Synthesis of the action*	*Reference in the report text*
1	New directive on cosmetics including a definition and specific requirements for nanomaterials (notification, labelling, reporting);	Paragraph 3.1.5
2	UK Food Standards Agency (FSA) to create a publicly accessible database listing all food and food contact materials containing nanomaterials	Paragraph 3.2.6
3	EPA proposal for a significant new use rules (SNUR) for single-walled and multi-walled carbon nanotubes, asking for notification on the use of these substances	Paragraph 3.3.1
4	CASg nano working group published two guidelines on REACH and nanomaterials, Three implementation Projects on Nanomaterials launched in 2010 .	Paragraph 3.1.1
5	Proposed amendment to EU food regulation (planned in 2010) including labelling of nanomaterials; statement of the Panel on food additives and nutrient about lack of data to asses safety of silver nanoparticles in silver hydrosol. EFSA guidance on nanotechnologies in foods to be released in July 2010	Paragraph 3.1.4
6	UK - HSE issued in 2009 guidelines on the safe handling of carbon nanotubes	Paragraph 3.2.6
7	DEFRA asked for specific guidance on nano silver from the Advisory Committee on Hazardous Substances	Paragraph 3.2.6
8	Proposal from Australia – NICNAS authority for a regulatory reform of chemical regulation concerning nanomaterials	Paragraph 3.4
9	Proposal for introducing specific requirements for nanotechnologies into the Canadian Environmental Protection Act, including a mandatory reporting scheme	Paragraph 3.5
10	Norway is considering to introduce into the procedure for declaration to the Product Register a specific part with information related to nanomaterials in chemical products	Paragraph 3.2.4
11	Proposal of requirement for notification and registration of nanomaterials in the USA EPA – TSCA, including the option for a mandatory reporting scheme	Paragraph 3.3.1.1
12	The Japan Ministry of Health, Labour, and Welfare (MHLW) is publishing nanotechnology guidelines related to medical practices and pharmaceuticals	Paragraph 3.8
13	In Taiwan is active since 2004 the first (voluntary) certification scheme for nanotechnology products (Nanomark Certification System)	Paragraph 3.9
14, 15:	Guidelines for safe and sustainable disposal of nano wastes to be published by FOEN in Switzerland, Guidance about communication along the value chains (MSDS) for nanomaterialsto be published by SECO	Paragraph 3.2.8
16	Australia is going to publish guidelines for Material Safety Data Sheets (MSDS) including information on nanomaterials	Paragraph 3.4
17	In France the recently approved article 73 of the “Code de l’environnement” includes requirements for declaration to authorities of manufacturing, importing, marketing of nanoparticles substances. The High Public Council recently published	Paragraph 3.2.2

	guidelines on CNT	
18	MEPs on the Environment, Public Health and Food Safety Committee voted on June 2nd 2010 to introduce restrictions on the use of nano silver and long MWCNT in electrical and electronic equipment. This will now be put to a plenary vote in the EU Parliament in July and if passed would see a recast of the Restriction of Hazardous Substances (RoHS) Directive.	Paragraph 3.1.6
19	In response to the EU Parliament resolution on N&N of 2009, the European Commission will review all relevant legislation within 2011 with a view to propose regulatory change whenever necessary and to develop nano-specific instruments for the implementation of regulation	Paragraph 3.1

7 CONCLUSION

This review has confirmed 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, nano-specific regulation for nano-related products is still rare. The attitude of regulatory authorities, the European Commission[121], 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 nanoparticles 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 although there is still a request for improved EHS data. In other cases, there is less agreement, for example in the area of cosmetics and foods. The European Commission[122] 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. In accordance to this position, the focus is presently more on the improvement of instruments to ensure compliance with existing legislation.

However, in the last year, an in-depth debate has taken place within regulatory authorities and stakeholders, including the civil society, challenging this approach. This fact has led to the adoption or to the planning of some specific regulatory actions improving the applicability of existing provisions to nanomaterials and nano-related products, as in the case of the recent recast of EU cosmetics regulation.

Some reasons for concern stem, some times, from the guidelines themselves that dictate the application of existing regulations, which may undemine their effectiveness as in the case of REACH, presently considered, at least in Europe, the most compelling and thorough legislation for nanotechnology. Examples of these limits, underlined by different national/international authorities, are:

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

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

- The definition of a substance or an 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 the nano and macro form of the same substance can be difficult due to current gaps in material characterisation,
- Threshold levels based on mass or concentration, used as the trigger for different legislation, 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 characteristics and behaviour 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 characterize them, monitor their presence and measure their amount, the implementation of most existing regulatory provisions can be jeopardised, and the development of specific ones can be made difficult.

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

The need for appropriate standards to name, describe, specify, measure and characterise nanomaterials is also well recognised and, as shown in this report, is actively pursued by several standards bodies and regulatory authorities. However, it is ISO, in conjunction with IEC, which has the final authority.

ISO has formed TC 229 for this purpose, within which 4 working groups have been created to deal with standardisation 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 35 standards documents related to the above themes under development but as such developments are a lengthy process, it will take some time before the matter is thoroughly addressed. So far ISO TC 229 has published three standards: two technical specifications on terminology and definitions and a technical report on 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 from the work of the *eight Steering Groups of OECD WPMN*. In particular in the OECD sponsorship

programme launched in 2007 (Steering Group 3), countries are sharing the testing of a representative set of manufactured nanomaterials.

As outcome of the first part of the sponsorship programme (now concluded) the Working Party agreed a priority list of 14 nanomaterials for testing [123] (based on materials which are on or close to the market) as well as a list of 61 endpoints for which they should be tested. During the implementation stage (from 2009 to 2012), the main output of the project will be a characterisation dossiers for the substances identified.

In conclusion, lacking specific guidelines and provisions, some authorities, including the EC, and stakeholders support the adoption of a precautionary approach with increased self-reliance on 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 scientific knowledge, to the increase in 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.

[123] 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]

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Websites of standard bodies having Technical Committees on nanotechnologies

9 Annex I: 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