



**NMP – Nanosciences, Nanotechnologies, Materials and
New Production Technologies**

Observatory**NANO** 

**DEVELOPMENTS IN NANOTECHNOLOGIES
REGULATION & STANDARDS - 2011**

N°3

Date: July 2011

**DEVELOPMENTS IN NANOTECHNOLOGIES
REGULATION AND STANDARDS– 2011**

**Published under the ObservatoryNano project as deliverable D6.2.3
for Work Package 6 (WP6).**

ObservatoryNano is a support action (SA) funded under the 7^o Framework Programme (FP7) in the area NMP - Nanosciences, Nanotechnologies, Materials and new Production Technologies.

Report prepared by:

Elvio Mantovani, Andrea Porcari, Italian Association for Industrial Research (AIRI/Nanotec IT), Italy - WorkPackage6 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

Reference this report as:

Mantovani E., Porcari A., Morrison M. D. and Geertsma R. E. Developments in Nanotechnologies Regulation and Standards 2011 - Report of the Observatory Nano. July 2011.
www.observatorynano.eu

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

Priority sources of information include: OECD Working Party on Manufactured Nanomaterials; ISO TC 229, CEN TC352 (and national standards bodies); European Commission activities on nanotechnologies policy and regulation; Relevant European and international projects on these themes.

The present report focuses on the period June 2010 - June 2011. Detailed information on previous periods, as well as some background information are available in the [ObservatoryNano Regulation & Standards 2010 report](#).

Executive summary

The present document, as part of the ObservatoryNANO project, is an evolving document, to keep pace with changes in the regulatory landscape (and governance more broadly). It follows two other reports published in the past two years, which provide in-depth information, and includes a detailed description of: regulatory actions in the most relevant application areas of nanotechnologies; activities on nanoregulation in more than 15 Countries worldwide; initiatives related to voluntary measures; standards and international cooperation.

This 2011 report, in addition to the information provided in the two previous reports, highlights the most relevant developments that have taken place in the period June 2010 – June 2011.

Activities and initiatives on Environment, Health and Safety Issues (EHS) as well as Ethical, Legal and Societal Aspects (ELSA) are not taken into account in the report, except where these activities and initiatives are clearly in the context of regulation and standards (*see ObservatoryNano WorkPackage4 and WorkPackage5 reports for more elaborate information on EHS and ELSA [OBS2, OBS3]*).

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

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

- Publication, in EU and countries outside the EU, of working/draft definitions of nanomaterials for regulatory purposes;
- Suspension of the recast of the Directive on food regulation in Europe, that included requirements for nanomaterials (reasons for suspension were not related to nanomaterial issues);
- Adjustment for nanomaterials adopted into chemical legislation in Australia;
- Ongoing review of the application of chemical legislation to nanomaterials (EU, USA, Canada);
- Discussion and development of notification rules, reporting schemes, nanomaterial registers to ensure identification of nanomaterials before they enter the market;
- Achievements in the work on standards (ISO), and the activities of the OECD – WPMN (testing of nanomaterials, database on EHS issues).

Among the main developments expected in the remainder of 2011 are the publication of the updated European Commission regulatory review and the new Action Plan 2011-2015 for Nanotechnologies of the European Commission.

This report confirms that the demand for nanoregulation remains high on the agenda, as the responsible development of nanotechnologies is considered instrumental to their success and the activity in this area is rather intense. So far regulation is still based essentially on existing provisions, albeit under revision to comply with the specificity of nanotechnologies .

Considering the existing gaps in scientific knowledge, the progress of research and the increasing number of applications, the different positions and stances of regulatory agencies around the world, the settlement of this matter cannot be expected in the short term and in any case it will remain a dynamic process. An appropriate balance between hard and soft regulation still seems the most viable option in the short-term.

Table of Contents

General outlook	5
Hard Regulation/Enforced Self regulation	7
European Union	7
European States	9
Non European Countries.....	11
Voluntary Self Regulation (soft regulation)	13
Trans-national efforts: the standards work	15
Conclusions	16
References.....	18
Annex I: List of published ISO TC 229 standards.....	20
Annex II: Snapshot table: regulatory actions vs. technology sectors	21

General outlook

The experience with previous emerging technologies has prompted a growing demand for an approach to governance where R&D and technological innovation and attention to safety and societal aspects have to be part of a unique process aiming to innovate “responsibly”, for the benefit of society. Sustainable growth is one of the pillars (Figure 1) of the Europe 2020 Agenda endorsed by the European Commission [EU1] and this goal is guiding the discussion on the regulation of nanotech at the European level.



Figure 1: The three pillars of the Europe 2020 Strategy of the European Commission (elaboration by AIRI/Nanotec IT)

Much of the concern remains still focused on “free” engineered nanomaterials and their effects on the environment, health and safety (EHS) during their entire life cycle. However, the ethical, legal and societal aspects (ELSA) potentially associated with nanotechnologies are becoming ever more relevant and will increasingly influence the governance approach.

As briefly shown in Text Box 1 [OBS1, OBS3], several factors are making the implementation of effective regulatory schemes complex and cumbersome.

Text Box 1: Challenges in regulating nanotechnologies

- The wide variety of materials and applications under the umbrella term of nanotechnologies
- The limited knowledge on the toxicity 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 issues related to classification of nanomaterials (e.g. definition of nanomaterials, regulatory triggers, distinction compared to macro-substances)

Nanotechnologies-related products/activities are presently regulated essentially by using existing provisions, but given the unique features of nanotechnologies doubts exist about the effectiveness of this approach.

The use of specific **hard regulation** is advocated by some parties, but so far, the strategies from authorities worldwide have been essentially on probing the extendibility of existing regulatory schemes to nanotechnologies and/or to ensure compliance with them. In the last few years, **voluntary measures** have been endorsed by public bodies and industry to build confidence and trust, promote safety or gather data. Although voluntary measures can complement existing regulations (or prepare ground to new ones), their voluntary character often makes them poorly adopted. **Enforcing mechanisms** have been envisaged to overcome this limitation in some cases.

To support the regulatory efforts, an intense activity to increase the knowledge base and to **develop standards**, methods and protocols is also going on (formally since 2005) involving acknowledged bodies, such as ISO, CEN, OECD and, recently, WHO.

In conclusion, given its complexity, regulation of nanotechnologies and nanomaterials is a dynamic process, which evolves through the contributions of many different stakeholders. The process can be depicted as a pyramidal structure, with several levels, as shown in Figure 2. On top is the hard regulation, enforced by the regulatory authorities. Implementation can be supported by various types of soft regulation shown in the layers below.

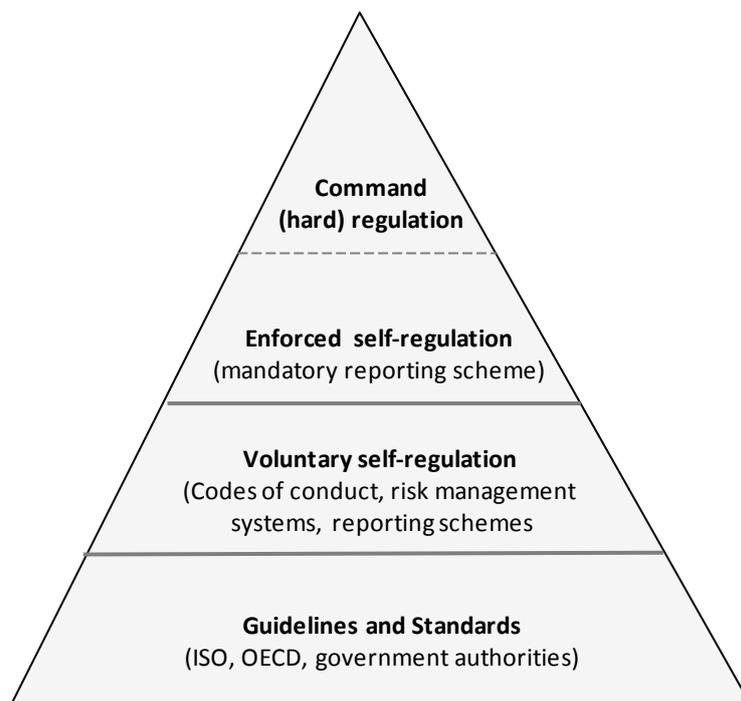


Figure 2: The regulatory pyramid (elaboration from [Ot1, Ot2])

In detail the situation is as follows:

Hard Regulation/Enforced Self Regulation

Existing regulatory schemes, with the necessary adaptations for nanotechnologies, are considered, as mentioned above, sufficient to regulate 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, but various positions are emerging with respect to this approach.

European Union

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

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

In response, the EC will review all relevant legislation by the end of 2011 with a view to propose regulatory changes where necessary and to develop more nano-specific instruments for the implementation of regulation [OECD1, EU16]. This 2nd regulatory review, that will likely represent a milestone in nanoregulation affairs worldwide, is expected to include specific information on nanomaterial types and uses and relevant safety issues.

The recast in 2009 of the **Cosmetic regulation** (which will come into force in 2013) already includes specific provisions for nanomaterials (definition, requirement for notification, labelling and reporting of nanomaterials) [EU7].

A relevant activity toward harmonisation in this field, involving the EC, is done by the working group on nanotechnologies (Nano WG) established by The International Cooperation on Cosmetic Regulation (ICCR), a group of cosmetic regulatory authorities from the USA, Japan, Canada and the European Union. In July 2010 the group published a report "*Criteria and Methods of Detection*" of nanotechnologies into cosmetics products (including a list of definitions of nanotechnologies/nanomaterials from different authorities). [ICCR1]

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

As a possible future step, in the proposal for a Food Information Regulation (adopted by the EU Council in February 2011) a reference to nanomaterial definition has also been included, as well as an indication that these will be included in the list of ingredients for food products [EU11].

A preliminary reference on safety issues is given by the (draft) "*Guidance on risk assessment of applications of nanotechnologies to food and feed*" published by EFSA (European Food Safety Authority) at the beginning of 2011. [EU13]

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulates the use of **chemical substances** in Europe. In March 2008, the European Chemicals Agency (ECHA) established the Competent Authorities Sub Group on Nanomaterials (CASG Nano) for this purpose. The Sub Group published two technical guidelines and launched three projects in 2010 devoted to the application of REACH to

nanomaterials, as well as the application of the related CLP regulation (classification, labelling and packaging of substances and mixtures). Most of the results are expected to be published during 2011¹. Outcomes of these activities on REACH and nanomaterials will be taken into consideration in the extensive review/evaluation of REACH which is expected in 2012 [EU8, EU9].

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 [OECD1, OBS1].

The need to define and agree on specific testing procedure for nanomaterials and to have a better view of concrete exposure scenarios remains amongst the highest priority. As from the EC mandate, an increasing commitment on the matter is expected by the European Agency for Safety and Health at Work (EU-OSHA). A database on information sources and case studies on nanomaterials is expected in 2011 [OECD 1, EU17].

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

The European Medicines Agency (EMA) has established a specific expert group on nanomedicine to provide advice and review guidelines on these matters [EU14]. Some medicinal products based on nanotechnologies have already been approved by EMA. For medical devices, the EC New & Emerging Technologies WG is developing a guidance document.

The EU Parliament, with reference to the EU directive on the Restriction and Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS), closely related to the more general **waste regulations**, has discussed, on November 2010, the labeling of nanomaterials as well as restrictions for nanosilver and long Multi Walled Carbon Nanotubes (MWCNT). In the end, however, the requirements related to nanomaterials were removed from the recast voted by the Parliament in February 2011 [EU12].

The issue of an agreed **definition of nanotechnologies and nanomaterials** has been debated for some time, both by regulatory and standards agencies. However, despite these efforts, a definition of nanomaterials for regulatory purposes has still to be agreed upon so that, the European Commission issued on October 2010 a draft recommendation on the definition for nanomaterials [EU6], based on a previous report published by SCENIHR [EU18] (see Text Box 2).

This definition is intended to be an overarching definition, it should provide a common starting point for developing sector-specific definitions at EU and national level in the future. Following a public consultation, a final recommendation is expected to be published by the end of 2011.

¹ The 3 projects are about: substances identification, information requirements and testing of Nanomaterials, chemical safety assessment of Nanomaterials [EU9].

**Text Box 2: Draft EC definition of nanomaterials, i.e
a material that meets at least one of the following criteria:**

- consists of particles, with one or more external dimensions in the size range 1nm -100 nm for more than 1 % of their number size distribution;
- has internal or surface structures in one or more dimensions in the size range 1nm–100nm
- has a specific surface area by volume greater than $60 \text{ m}^2/\text{cm}^3$, excluding materials consisting of particles with a size lower than 1nm.

Another relevant development in late 2010 was the proposal, by the Belgian Presidency of the EU, to establish a register to ensure the traceability of nanomaterials entering the market. This may lead in the future to a common action in this direction by (at least some) EU countries [EU16].

European States

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

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

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

Almost all other countries surveyed² have at least some initiatives on these matters, and are linked to activities at EU level through participation in working groups at the institutional level (such as different technical Committees of Member States authorities, the OECD WPMNs, the Nanosafety Hub of the European Commission). In particular, regarding Occupational Safety and Health issues (OSH), those countries that have working groups at the institutional level, are developing guidelines and support specific research activities on the matter.

Regarding chemicals, the way nanomaterials are considered in REACH will strongly influence regulatory actions at national level, in particular in countries such as France, Germany, Austria, Belgium, and Italy that are considering introducing notification and registration mechanisms for nanomaterials (though they would generally prefer to avoid any kind of duplication of REACH procedures)[OECD1, OBS1].

On this issue, relevant initiatives have been lately undertaken by **France**, which is moving forward with a compulsory reporting scheme (declaration) of nanomaterials. The scheme will be devoted to specific types of nanomaterials and requires a declaration of identity, quantity and use of these substances. A public

² The countries surveyed at European level, selected based on their activity on nanoregulation have been: Austria, Czech republic, France, Italy, Norway, Germany, UK, The Netherlands, Switzerland. Further information is available In the ObservatoryNano Regulation & Standards 2010 report.

consultation on the decree issued on the matter by the Environmental Ministry ended on February 2011. A definitive version of the decree is expected soon [FR4].

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

In **Germany**, in the Nano Action Plan 2011-2015 [DE1] promoted by the Federal Government, the need to develop appropriate regulation and standards for nanotechnologies is included as a priority. In September 2010, the German NanoKommission Dialogue Initiative [DE3] (involving more than 100 key nanotech stakeholders) provided to the German Government an analysis about EU/national regulation and the concrete application of the precautionary principle, as well as considerations about a definition of nanomaterials and the creation of a nano-products register.

The report suggested a series of amendments aiming to explicitly include nanomaterials in existing regulatory provisions, though stressing the need for a coherent approach between German and EU regulation.

Several documents and guidance have been published in the last years by German authorities and stakeholders on EHS issues and nanotechnologies³, and the German Federal Institute for Occupational Safety and Health is running a second survey (the first was in 2006) on worker protection in the production/handling of nanomaterials [DE2].

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

The UK Government has confirmed its commitment toward EHS research, with new studies on safety issues of specific nanomaterials (in particular on nanosilver, carbon nanotubes, iron nanomaterials) and, among others, a bilateral call for research projects on environmental issues with the USA [UK2, UK3, UK4, OECD1]. The British Standards Institution (BSI) will publish three new standards documents on nanotech (including a guide for SMEs on nano regulation) [UK6].

The Netherlands has a clear commitment towards responsible innovation, and the principles of precaution, inclusiveness, transparency, risk/benefit balance are clearly set out in its nanotech development strategy. Various guidance materials are being developed on issues such as regulation, the precautionary principle, risk management, information sharing, consumer information (among them an inventory of consumer nano-related products in the EU) and societal dialogue [NL1, NL2]. Research on safety issues is considered a priority, with relevant funding allocated (and required) in national nanotech research activities. In response to the EC recommendation on a Code of Conduct for nanotechnologies, the Netherlands is now introducing a contractual obligation to comply with this Code in its national funding schemes for nanotech (implementation is still at an early stage) [OBS1, OECD1, EP1].

³ Refer to the 2010 ObservatoryNano Regulation& Standards report [OBS1] for details

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

A joint effort between different authorities led to the publication (beginning of 2010) of the *"Precautionary matrix"*, and more recently of the *"Guidelines for safety data sheets"* and the reports on *"Nanoparticles at workplaces"* and *"Nano waste management"* about synthetic nanomaterials. [CH1]

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

Non European Countries

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

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

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

As in other regulations, nanomaterials are not explicitly mentioned in this statute. However, a series of actions have been put in place in the last years to ensure notification and registration of nanomaterials. In particular, *"Significant new use rules (SNUR)"*, a notification asked to companies in case of any significant new use of existing chemicals, have been issued for some specific nanomaterials (mainly carbon nanotubes and fullerenes). EPA is planning to adopt such procedures on a regular basis for a number of nanomaterials, in order to gather detailed information about the use, characteristics and safety issues before the nanomaterials are put on the market [US1].

EPA, under the FIFRA statute (Federal Insecticide, Fungicide and Rodenticide Act), is carefully reviewing pesticide products containing nanosilver (as an antimicrobial). A new policy is expected shortly, that will require reporting and provision of safety information about nanoscale materials used as ingredients in pesticides.

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

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

A joint commitment between USA and EU to promote transatlantic cooperation in regulation and safety issues related to nanotechnologies has been recently established and led to the establishment of bilateral research activities on these matters as well as a series of bilateral meetings between US and EU authorities [OECD1].

In **Canada** and **Australia**, EHS and regulatory issues are receiving increasing resources within their national strategies for nanotechnologies, and the need to adopt a precautionary approach is explicitly stated. There is a growing involvement of authorities in different sectors that are working to develop regulatory, product-specific guidance documents for nanomaterials. A definition of nanomaterials is considered one of the key gaps to enable regulatory actions.

Health Canada (one of the two main regulatory authorities, the other is Environment Canada) held between March and August 2010 a consultation on the *"Interim Policy Statement on Canada's Working Definition for Nanomaterial"*, and the document is now in the review phase. The main scope is to establish a working definition of nanomaterials and provide a means of gathering information on use, characteristics and safety issues of nanomaterials entering the market (among the options mentioned in 2010 by Canada has been a mandatory reporting scheme on nanomaterials). The policy statement, once finalised, will be applied under all regulation of Health Canada and Environment Canada relevant for nanomaterials (including chemicals, cosmetics, drugs, foods, pesticides, medical devices) [CA1, CA2].

In **Australia**, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), has developed a specific strategy for the regulation of nanomaterials, supported by an in depth stakeholder consultation concluded at the beginning of 2010 (*"Proposal for Regulatory Reform of Industrial Nanomaterials"*). Based on this consultation a working definition for "industrial nanomaterials", has been agreed with stakeholders and officially adopted at the end of 2010 (it may be further changed in the future, also in view of international harmonisation). A series of amendments have been introduced into the existing chemical regulation, ensuring pre-market evaluation of new nanomaterials. These requirements have been in force since January 2011, accompanied by guidance documentation, and monitoring of concrete implementation is currently ongoing [AU1,OECD1].

An intense activity on nanoregulation is ongoing also from other Australian authorities, to review existing regulation and increase the knowledge base through specific research programmes. In particular, Safe Work Australia has launched a *"Nanotechnology Work Health and Safety Program"* to develop appropriate tools and methods related to occupational and health issues. These include the *"Work health and safety assessment tool for handling engineered nanomaterials"* and a draft guidance to introduce nanomaterials into Safety Data Sheets and labeling procedures [AU2].

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

all have initiatives and research programmes at institutional level on nanomaterials, in particular regarding OSH aspects.

In **Japan** the Ministry of Economy, Trade and Industry (METI) has supported since 2008 a voluntary gathering initiative related to risk management of nanomaterials at industry level (the last periodic report was published in March 2010). Research reports on OHS issues of nanomaterials have been published (the last in December 2010) by the National Institute of Occupational Safety and Health Japan (JNIOSH).

The Republic of Korea is developing the “National Nano-safety Strategic Plan (2011-2015)” and will publish in 2011 a “*Guidance on safe management of nanotechnology based product*”. Moreover, a specific “*Risk management platform technology for nanoproducts (2009-2013)*” is in development, aiming to provide a certification system for nano-related products. Several research programmes on EHS and ELSA are in progress.

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

In **Thailand** nanosafety is among the priorities of the national policy on nanotechnologies. A first strategic plan on safety and ethical issues is expected to be proposed to the government by the National Nanotechnology Center in 2011. This will include plans for the creation of an industrial standards certification for nanotechnologies related products (called NanoQ, [TH1]).

Voluntary Self Regulation (soft regulation)

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

Some stakeholders at the industrial level have developed (or are developing) their own **risk management systems**, defining best practises and procedure for safety control and handling of nanomaterials in occupational settings, as well as certification tools that help to evaluate and monitor performance in risk management (for nanotech).

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

A relevant example of a code of conduct is the EC “**Code of Conduct for responsible nanoscience and nanotechnologies research**” (**February 2008**), which provides principles and indications to guide research activities [EU4]. Its objectives are far reaching and among the principles that must be respected are: (a) Sustainability, (b) Precaution (c) Inclusiveness and (d) Accountability. The EC is actively promoting the Code and strongly recommends all Member States to adopt it. A specific project of FP7, ending at the end of

2011 (NanoCode) has been funded to support its implementation and adoption, as well as its further revision [EP1].

These initiatives aim to complement existing regulation (or prepare the ground for new ones), helping to gather detailed information on the introduction and use of nanomaterials and nano-related products to the market (among the data generally provided/requested are their type, use, quantity and safety aspects). However, their voluntary nature has some drawbacks. When endorsed by public/government bodies, they have received a tepid response, so that some have suggested, for example in the case of reporting schemes, to make them mandatory, as it is going to happen in France and Canada. On the other hand, when promoted by private companies, these measures are treated by some stakeholders with suspicion and of little value in their opinion.

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

Besides the ongoing work for the revision of the EC Code of Conduct, the panorama of voluntary measures has not substantially changed during the period covered by this report, with respect to that of the 2010 report. The situation is summarised in Text Box 3 [OBS1, EP1, OECD1].

Text Box 3: Examples of voluntary measures related to nanotechnologies

Codes of Conduct/Practice

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

Risk Management Systems

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

Reporting/data gathering Schemes

(in brackets the regulatory authority or agency leading the initiative)

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

Trans-national efforts: the standards work

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

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

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, and are mirrored by work in European standards bodies: the European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI)⁴.

In 2010, the Commission has drafted mandate M461 for the development of standards in the broad area of nanotechnologies and nanomaterials. In the end of 2010, CEN, CENELEC and ETSI decided to accept the mandate. For the execution of the mandate, which covers a large range of topics, it was decided to as CEN TC352 to coordinate the programme. TC352 was given the task to liaise with all relevant European and international committees and ask these committees to start work on topics in their area of interest, as identified by the mandate. Currently, this large programme is being initiated and the involved committees are at varying stages of progress [EU19].

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

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

At present more than 30 standards documents⁵ 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.

A total of 12 standards are now available (see annex), eight of them published in the last year, on fundamental issues such as terminology (core terms for naming and classification), characterisation (nanoparticles and carbon nanotubes) and health and safety practices at the workplace.

ISO has developed a working definition and published several standards regarding a vocabulary for nanotechnologies, and other definitions have been recently published by authoritative organisations worldwide⁶.

On standards and harmonisation issues related to measurement at the nanoscale (nanometrology), the European Project Co-Nanomet published in January 2011 an in-depth review and discussion paper on the

⁴ A list of activities and references in nanotechnologies of different national standard bodies is available in the ObservatoryNano Regulation & Standards 2010 report [OBS1]

⁵ A list of standards under development is available in the ISO TC 229 website [ISO1], as well as in the ObservatoryNano Regulation & Standards 2010 report [OBS1]

⁶ A list of proposed definitions from different organisations is included in ref [ICCR1], pg. 15

matter [EP3]. Current status, future needs and opportunities in different key areas⁷ for nanometrology are addressed by the document.

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

In particular, under the OECD sponsorship programme (launched in 2007), several countries are sharing the testing of a representative set of manufactured nanomaterials, to improve the understanding of the “intrinsic properties” of nanomaterials. A first draft of the guidance manual for the testing of nanomaterials was published in mid 2010 and a report devoted to critical issues in risk assessment of nanomaterials is expected in 2011. Another key programme is the database on EHS research activities and strategies, published on 2009 and updated on a regular basis. This database also provides links to other similar databases worldwide.

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

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

In particular, the Food and Agriculture Organisation of the United Nations (FAO), the United Nations Institute for Training and Research (UNITAR) and the World Health Organisation (WHO) have initiated activities on nanotechnologies, with a focus on increasing awareness of potential risks and benefits in developing countries [UNITAR1, OECD1].

WHO is developing guidelines to "*Protecting Workers from Potential Risks of Manufactured Nanomaterials*", mainly for protection of workers in low and medium-income countries [WHO1].

Conclusions

Although it must be remembered that, to date, there is no conclusive evidence that nanomaterials raise more concerns than other existing materials or products, the demand for nanoregulation remains high on the political agenda.

Some authorities and industries think that there is already enough legislation in place to deal with potential risks and that, although not specific for nanomaterials, there is a strong focus on the need for products to be safe which could make it sufficient to deal with nanorelated products. The quest to clarify the existing uncertainties, remains, however, high.

In the period considered by this report (June 2010 - June 2011) the debate around the attempts to introduce adjustment/amendment for nanomaterials in regulatory provisions in EU and some other countries has continued.

The actions discussed are strongly related to the development of a harmonised definition of nanotechnologies/nanomaterials. In the last period, there has been an intense debate on the matter, with

⁷ The areas considered by the report are: engineered nanoparticles, nanobiotechnology, thin films, critical dimensions and scanning probe techniques, modelling and simulation.

new standards released by ISO and initial draft or working definitions for regulatory purposes. The matter is, however, far from settled.

Besides the recast of the Cosmetic regulation in EU (2009), the only other adjustment for nanomaterials so far has been in the Australian regulatory statute for chemicals (in force since January 2011).

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

The evolution of nanoregulation can influence the path of the development of nanotechnology-related product and processes and the situation about the present regulation and the impact on the different technology sectors is summarised in annex II.

While some authorities are more oriented towards 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 remains still quite limited.

An important point for nanoregulation is the need of common provisions, at least in their principles and aims, among the countries, to assure a similar level of attention to EHS issues and ELSA implications and to avoid hindrances to trade. This point has strong political implications, but it must be pursued with strength. Europe, is aiming, at least amongst its Member States, towards this goal and the transatlantic initiatives that are being promoted are also trying to go beyond this issue.

Nanoregulation, as mentioned several times, requires a dynamic, transparent and inclusive 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, to evolving international relations. An appropriate balance between hard and soft regulation seems still the most efficient option in the short-term.

References

European Union:

- [EU1] [European Commission, Europe 2020 A strategy for smart, sustainable and inclusive growth](#)
- [EU2] [European Commission webpage on nanotechnologies policies](#)
- [EU3] [Regulatory Aspects of Nanomaterials, Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures, European Commission, \(June 2008\)](#)
- [EU4] [Commission Recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research, European Commission \(February 2008\)](#)
- [EU5] [European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials \(2008/2208\(INI\)\)](#)
- [EU6] [Draft Commission Recommendation on the definition of the term "nanomaterial"](#)
- [EU7] [Regulation of The European Parliament and of the Council on cosmetic products \(recast\) \(Nov 2009\)](#)
- [EU8] [REACH and nanomaterials, EC, DG Enterprise and Industry](#)
- [EU9] [REACH and nanomaterials, EC, DG Environment](#)
- [EU10] [EU Parliament, Press release: "Novel Foods talks collapse on Council refusal to label clone-derived products" \(March 2011\)](#)
- [EU11] [European Commission, Provision of Food Information to Consumers - Proposed Legislation](#)
- [EU12] [Recast of the EU legislation restricting the use of hazardous substances in electrical and electronic equipments](#)
- [EU13] [European Food Safety Authority – Nanotechnologies](#)
- [EU14] [European Medicines Agency – Nanotechnology experts group](#)
- [EU15] [Joint Research Centre \(JRC\) of the European Commission, Institute for Health and Consumer Protection \(IHCP\)](#)
- [EU16] [Workshop Towards a regulatory framework for nanomaterials' traceability" High level event, Brussels, 14th of September 2010.](#)
- [EU17] [European Agency for Safety and Health at Work \(EU OSHA\), Workplace Exposure to Nanoparticles \(Jun 2009\)](#)
- [EU18] [Scientific Committee on Emerging and Newly Identified Health Risks \(SCENIHR\) - Scientific Basis for the Definition of the Term "nanomaterial" \(Dec 2010\)](#)
- [EU19] [M/461 Mandate Addressed To Cen, Cenelec And Etsi For Standardization Activities Regarding Nanotechnologies And Nanomaterials \(February 2010\)](#)

France:

- [FR1] [Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail \(Anses\) – website on nanomaterials \(Evaluation biologique des dispositifs médicaux contenant des nanomatériaux, Jan 2011\)](#)
- [FR2] [French Agency for the Safety of Health Product \(Affset\)](#)
- [FR3] [Agence française de sécurité sanitaire des produits de santé \(Afssaps\)](#)
- [FR4] [French Ministry of Ecology, Sustainable Development, Transport and Housing, consultation on a Projet de décret relatif à la déclaration annuelle des substances à l'état nanoparticulaire mises sur le marché](#)

United Kingdom:

- [UK1] [UK Government's Nanotechnologies Strategy website](#)
- [UK2] [Department for Environment Food and Rural Affairs \(DEFRA\)- Nanotechnologies webpage](#)
- [UK3] [Medicines and Healthcare Products Regulatory Agency \(MHRA\) – Nanotechnologies webpage](#)
- [UK4] [Food Standard Agency: webpage on nanotechnologies](#)
- [UK5] [Nanotechnology Research Strategy Group \(NRSRG\) webpage](#)
- [UK6] [British Standards Institution \(BSI\) – Nanotechnologies webpage](#)

The Netherlands:

- [NL1] [Dutch Nano Action Plan, Dutch Ministry of Economic Affairs, The Netherlands, \(July 2008\)](#)
- [NL2] [Nanomaterials in consumer products Update of products on the European market in 2010, S.W.P. Wijnhoven et al, RIVM Report 340370003/2010](#)

Switzerland:

- [CH1] [Federal Office of Public Health: nanotechnologies webpage](#)
- [CH2] [Information for Consumers on Nanomaterials Results of the FOPH NANO-Dialogue Platform \(Dec 2010\)](#)

Germany:

- [DE1] [German Action Plan on Nanotechnologies](#)

- [DE2] [Federal Institute for Occupational Safety and Health](#)
- [DE3] [German NanoKommission](#)

USA:

- [US1] [Environmental Protection Agency - nanotechnologies webpage](#)
- [US2] [Food and Drug Administration – nanotechnologies webpage](#)
- [US3] [The National Institute for Occupational Safety and Health \(NIOSH\) – nanotechnologies webpage](#)

Canada:

- [CA1] [Health Canada website on nanotechnologies](#)
- [CA2] [Health Canada, "Interim Policy Statement on Canada's Working Definition for Nanomaterial"](#)

Australia:

- [AU1] [National Industrial Chemicals Notification and Assessment Scheme \(NICNAS\), nanotechnologies webpage](#)
- [AU2] [Safe Work Australia – Nanotechnologies webpage](#)

Thailand:

- [TH1] [National Nanotechnology Center](#)

Taiwan:

- [TW1] [NanoMark certification system](#)

Japan:

- [JP1] [Nanonet - Japanese Nanotech policies](#)

OECD:

- [OECD1] [Report on Current Developments/ Activities in Manufactured Nanomaterials, OECD WPMN, \(May 2011\)](#)
- [OECD2] [Nanosafety at the OECD: The First Five Years 2006 -2010](#)

IOMC/UNITAR/WHO/FAO:

- [UNITAR1] [United Nation Institute for Training and Research webpage on nanotech](#)
- [IOMC1] [Inter-Organisation Programme for the Sound Management of Chemicals \(IOMC\) webpage on nanotech](#)
- [WHO1] [WHO Guidelines on Nanomaterials and Worker's Health](#)

International Cooperation on Cosmetic Regulation (ICCR):

- [ICCR1] [Criteria and Methods of Detection of nanotechnologies into cosmetics products](#)

Standards:

- [ISO1] [Business Plan ISO/TC 229 Nanotechnologies. ISO, \(January 2011\)](#)
- [ISO2] [ISO Technical Committee TC 229: Nanotechnologies](#)
- [ISO3] [European Committee on Standardisation – Technical Committee TC 352: Nanotechnologies](#)

EU projects:

- [EP1] [Nanocode Project: Implementing the European Commission Code of Conduct for Responsible Nanotechnologies](#)
- [EP2] [EU Nanosafety Cluster webpage](#)
- [EP3] [Co-nanomet project: Coordination of nanometrology in Europe](#)
- [EP4] [Nanoimpactnet: European Network on the Health and Environmental Impact of Nanomaterials](#)
- [EP5] [Nanosafe project](#)

Other:

- [Ot1] [Nanomaterial Risk Assessment and Risk Management: Review of Regulatory Frameworks: I. Linkov et al, Real-time and Deliberative Decision Making, Dordrecht, Springer \(2008\)](#)
- [Ot2] [Risk Governance of Nanotechnology Applications in Food and Cosmetics, International Risk Governance Council, IRGC \(2008\)](#)

ObservatoryNano:

- [OBS1] [Regulation & Standards 2010 report](#)
- [OBS2] [Environment, Health and Safety Impact reports \(wp5\)](#)
- [OBS3] [Societal Issues reports \(wp5\)](#)

Annex I: List of published ISO TC 229 standards

ISO TC 229 WP1: Terminology & Nomenclature

ISO/TS 80004-1:2010

Nanotechnologies -- Vocabulary -- Part 1: Core terms

ISO/TS 27687:2008

Nanotechnologies -- Terminology and definitions for nano-objects -- Nanoparticle, nanofibre and nanoplate

ISO/TS 80004-3:2010

Nanotechnologies -- Vocabulary -- Part 3: Carbon nano-objects

ISO/TR 12802:2010

Nanotechnologies -- Model taxonomic framework for use in developing vocabularies -- Core concepts

ISO/TR 11360:2010

Nanotechnologies -- Methodology for the classification and categorization of nanomaterials

ISO TC 229 WP 2: Measurement & Characterisation; ISO TC 229 WP3: Health, Safety, and Environment

ISO 10808:2010

Nanotechnologies -- Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing

ISO/TS 10867:2010

Nanotechnologies -- Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy

ISO/TS 11251:2010

Nanotechnologies -- Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry

ISO 10801:2010

Nanotechnologies -- Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method

ISO 29701:2010

Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amoebocyte lysate (LAL) test

ISO/TR 12885:2008

Nanotechnologies -- Health and safety practices in occupational settings relevant to nanotechnologies

ISO/TR 13121:2011

Nanotechnologies -- Nanomaterial risk evaluation

(June 2011)

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

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

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

	Foods, Agriculture	Chemistry & Materials			Cosmetics		Medicinal products & medical devices	Occupational issues (OSH)	Environment	Cross sectoral (nanomaterials, nanotech in general)	
European Commission	A	A	B		A	C	A	A		A	
France			B				A	A		A	B
Germany		A						A		A	
The Netherlands		A						A		A	
Switzerland		A						A	A	A	
United Kingdom	A						A	A		A	
USA	A	A	B		A		A	A	A	A	
Canada		A	B		A		A	A		A	
Australia		A	B	C				A		A	
Japan					A		A	A		A	
Other Countries								A		A	