



# Nanomed Round Table

risk management issues for medical devices utilising nanotechnology and considered the adequacy of the existing medical devices regulatory regime to deal with these issues. The conclusion of the working group was that, in general, the medical devices directives are adequate to deal with medical devices manufactured using nanotechnology ([http://ec.europa.eu/enterprise/medical\\_devices/net/net\\_en.htm](http://ec.europa.eu/enterprise/medical_devices/net/net_en.htm)). However, because of the specific aspects of nanotechnology and the existing knowledge gaps, recommendations have been formulated for implementation aspects of the directives. Furthermore, as we are dealing with risks that are partly new and not fully known to all stakeholders, development of regulatory guidance was recommended. Currently, the N&ET WG is writing regulatory guidance in the form of a so-called MEDDEV document.

The European Commission as well as EMEA liaise regularly with the US Food and Drug Administration (FDA). CHMP and FDA have issued several reports on nanotechnology, and are continuing to maintain regular bilateral consultations with the US agencies (primarily the FDA), and with international bodies such as the World Health Organization. The FDA is monitoring the evolution of practices in nanomedicine, but has stated that so far, they see no need for new regulatory instruments specific to the use of nanoparticles.

It is not yet clear whether the criteria in REACH<sup>1</sup> can fully capture the special properties of nanoparticles. Environmental impact of manufacturing new medical products has been addressed by several existing laws, for example Directive 2004/27/EEC on medicinal products for human use. However, it is not yet clear whether commercialisation of nanomedical products will result in special environmental challenges such as dealing with medical waste containing nanoparticles. It is thus not clear whether there are environmental issues concerning nano-medical products that are not yet addressed by Directive 2004/27/EEC, REACH and other applicable laws.

---

<sup>1</sup> REACH: On 18 December 2006 the Council of Ministers adopted Regulation (EC) No 1907/2006, a new EU regulatory framework for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). This aims to improve the protection of human health and the environment while maintaining the competitiveness and enhancing the innovative capability of the EU chemicals industry.

# Nanomed Round Table

## Annex 2 - EU Institutional Players and Nanotechnology

### The European Commission

The European Commission has the monopoly, or obligation, of preparing and proposing new legislation for the EU. In 2004 it published a report<sup>2</sup> entitled, 'Towards a European Strategy for Nanotechnology'. Following up on this, the Community strategy on health and safety at work for the period 2007–2012 includes nanotechnology as an important topic to be worked on in the context of the identification of new, emerging risks. In addition, a communication from the Commission developed an "Action Plan" to implement a safe, integrated and responsible approach for nanosciences and nanotechnologies. To ensure their safe and ethical development and use, the European Commission issued in February 2008 a Code of Conduct<sup>3</sup>. This Code is complementary to legislation and provides Member States, employers, research funders, researchers and more generally all individuals and civil society organisations involved or interested in nanosciences and nanotechnologies (N&N) research with guidelines favouring a responsible and open approach to N&N research in the Community.

#### Scientific Advisory Bodies

Three independent non-food Scientific Committees, made up of external experts, provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment:

- the Scientific Committee on Consumer Products (SCCP);
- the Scientific Committee on Health and Environmental Risks (SCHER);
- the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) and are.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

Many ongoing initiatives/activities aim at the development of safe, sustainable, and responsible research and development of this new technology. Large scale research and standardisation programmes have been started and partly finalised to establish standards, close data gaps and reduce uncertainties.

In its 2004 Communication<sup>4</sup> "Towards a European Strategy for Nanotechnology", the Commission stated that R&D and technological progress needed to be accompanied by scientific investigation and assessment of possible health or environmental risks associated with nanotechnology. The "Integrated, safe and responsible approach" has become the core of the EU policy for nanotechnology.

<sup>2</sup> Towards a European Strategy for Nanotechnology, published by the Commission, Luxembourg, 2004.

<sup>3</sup> COM(2008) 424 final of 7 2 2008.

<sup>4</sup> COM(2004) 338 final of 12 5 2004. Towards a European strategy for nanotechnology.

# Nanomed Round Table

The Communication "Nanosciences and nanotechnologies: an action plan for Europe 2005 - 2009"<sup>5</sup>, specified that all applications and use of nanosciences and nanotechnologies must comply with the high level of public health, safety, consumers and workers protection, and environmental protection chosen by the Community. The Commission therefore announced a regulatory review of EU legislation in relevant sectors. The resulting communication on regulatory aspects of nanomaterials<sup>6</sup>, published in June 2008, covered nanomaterials currently in production and/or placed on the market (but did not address nanomaterials or nanoparticles that occur naturally or are unintentionally produced via combustion).

The EU executive's regulatory review of existing European legislation concluded that while the current EU legislative framework "covers in principle the potential health, safety and environmental risks in relation to nanomaterials," current laws may need to be modified as the depth of scientific knowledge on nanomaterials increases. For example, specific labelling schemes for products containing nanomaterials could be developed.

## **The European Council of Ministers**

This brings together the national ministers responsible for debating, amending and adopting legislation at European level. Although it is a single legislative body, it meets in practice as the ministers of the various departments of national governments – Agriculture, Health, Industry, Research, etc. It is also the principal point at which European Commission legislative initiatives may fail, or be substantially modified, to take account of national political constraints.

## **The European Parliament**

This is the only directly elected EU body, and its involvement in the legislative processes at European level has increased strongly over the past three decades. It can launch "Own initiative" studies and publish reports – a recent example relating to nanoscience and nanotechnology being the report<sup>7</sup> adopted in April 2009. This report is scholarly in its careful assembly of all the relevant references to existing legislation, and to study reports; but for the media of the 27 member countries of the EU and for reporting around the world, it is sensitive to the need to boil complex arguments down to simple and memorable slogans. In the Schlyter report, the phrase "no data, no market" might play this role. Such slogans may lose the detail of the research, but win publicity by short, politically effective phrases. If carried over into the text of legislation, such texts can cause major problems of implementation.

The European Commission plans to respond positively to the European Parliament's call for a number of EU policies and regulations covering health and environmental safety issues related to nanomaterials to be reviewed. It was stated at a nanoregulation conference on 9 October 2009 that the Commission would review all

---

<sup>5</sup> COM(2005) 243 final of 7 6 2005

<sup>6</sup> COM(2008) 366 final of 17 6 2008

<sup>7</sup> European Parliament, report on regulatory aspects of nanomaterials (2008/2208(INI))

# Nanomed Round Table

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. The statement represented the first response to MEPs' call for a clear regulatory and policy framework on nanomaterials.

According to sources, the Commission has adopted its response to the Parliament's request, but has not yet officially sent it. As on many other EU policy areas, there may be internal disagreement on the matter within the EU executive. While its departments for environment and health back stronger legislation and precautions on the matter, the department for enterprise and industry could do with less stringent or specific legislation.

The Parliament argued that 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, it is impossible to address their risks within the framework of current EU legislation.

It also called for amendments to the EU chemicals legislation REACH. The House wants to see registration of nanomaterials simplified, a "chemical safety report with exposure assessment for all registered nanomaterials irrespective of hazard identification" developed, and notification requirements introduced for all nanomaterials placed on the market.

# Nanomed Round Table

## Annex 3 - NGOs' Position on Nanotechnologies and Nanomedicine

NGOs exert pressure on regulatory systems. Their policy-related activities are conducted throughout the world, but especially in the national capitals of the 27 EU Member States, and in Brussels and Strasbourg; covering the whole range of political agendas; and involving institutions representing a correspondingly vast range of interests: agricultural, economic, industrial, healthcare, research, trade, etc. Risk perception varies between different sectors. In medicine, there is a long history of regulation, focusing on risk/benefit balance. In other areas, there is less history, and simplistic demands for "absolute safety".

**Patients' organisations** have developed, lobbying for more research, and for innovation to address their disease of interest: they are impatient with the long, slow processes of bureaucracy, and impatient to see promising innovations rapidly authorised for use in practice. Some of the regulatory obstacles may delay or prevent these needs from being met.

**Environmental NGOs** have exerted increasing influence over policy during recent decades, in particular at European level, their campaigns often motivated by the evidence of environmental damage from past economic activities. This has often led them to be suspicious of technological innovation, and to adopt fairly negative or restrictive attitudes towards new technologies. Scientific evidence might sometimes be cited, but was rarely decisive. The health sector is popular with the public (particularly the various patients' organisations), and such popularity influences the choices of campaign targets now facing the NGOs: as industry has recognised, there are both positive and negative attitudes associated with the use of nanotechnology, and with the use of the term "nano-" in labelling. Given recent history and continuing campaigns, industry is nervous of being condemned for use of technologies which NGOs may assert have been inadequately tested.

Lobbying for or against regulations (or on details of their drafting) in the European Union is complex and expensive. Recent decades have seen rapid expansion of lobbying activities in Brussels, including agricultural and industry associations, and environmental associations. When the Commission's legislative proposals are published, this initiates a cacophony of multilingual lobbying, directed in particular at members of the European Parliament; especially those members with relevant interests and responsibilities. From the Parliament, the Commission reviews the adopted amendments, and takes the amended proposal to the "Council of Ministers" – nominally a single legal entity, but in practice represented by the national ministers having responsibility for the area in question. Lobbying the ministers interacts with national activities, conducted in the various national capitals, and in the various languages of the EU Member States.

**The Nanotechnology Industries Association** is a recent and small creation, because most of the industries in which nanotechnology finds applications already

## Nanomed Round Table

have substantial representation in Brussels and elsewhere. It exists (and although based in Brussels is in principle of global scope) because industry sometimes needs a central voice to gather opinions and express them, especially on multi-sectoral policy issues. But the view of industry on regulatory matters has generally been that they can be managed under existing regulatory frameworks – be it for pharmaceuticals, food, seed or whatever – and for most or all of these sectors there is already a significant association.

**Clinicians** enjoy high public respect, but do not usually see it as their role to campaign in support of specific technological innovations. Nor do they want to be drawn into the regulatory process, unless there is a specific product or technique whose development they welcome, and would like to accelerate. But such “acceleration” is usually pursued within existing regulatory frameworks, and aims to obtain faster or more favourable decisions from the responsible minister. It is rare and recent that specific topics, such as abortion, or the use of stem cells, have brought the clinicians closer to the regulatory debate.

# Nanomed Round Table

## Annex 4 - Insurance Industry's View on Nanotechnologies and Liability Risks

The insurance industry has long experience in the management of risk. It seems at present fairly relaxed about the new situations which may be created by the advance of nanoscience and its technological applications. The industry has participated in conferences and produced reports, perhaps the best-known being that held in Zurich in July 2006 by the Centre for Global Dialogue of Swiss Re, on "The Risk Governance of Nanotechnology: Recommendations for Managing a Global Issue". The proceedings, published by the CGD<sup>8</sup>, give a balanced overview; the "Epilogue" was written by Thomas Epprecht of Swiss Re, who commented, "To avert overregulation and licensing bottlenecks, as well as unsatisfactory catch-all wording in both the legal and insurance areas, research and development should rapidly provide clarity on the risk and relevant scientific facts, in particular with regard to industrial safety". As a member of the Regulation Working Group, he contributed the following overview, extracted from a forthcoming international publication<sup>9</sup>.

"The insurance industry, as an enabler of risk taking, focuses on understanding the risks of nanotechnology in order to help its business partners to mitigate the financial consequences of possible losses. In existing casualty business, industry liability policies continue to offer implicit cover for nanotechnology, including nano-manufacturing, -tools, -products and -applications. In light of what the insurance industry has learned to date through monitoring activities, it would appear that there is at this time no urgent need to tighten underwriting. Nor, however, should one sound the 'all clear'. Nanotechnology, in its immense diversity, is developing rapidly. While current questions as to its potential risks will be answered, new ones will also emerge. From the insurer's perspective, negative effects which manifest themselves quickly do not pose a grave problem since they can be contained and stopped. Determining whether nanomaterials, and which type/s of nanomaterials in particular, hold some latent toxicity hazard is however a much more difficult task.

In many cases, precautionary safety measures in the workplace would be appropriate even in the absence of any concrete reason to suspect a hazard. In assessing the liability exposure posed by individual risks in the 'business liability' and 'workers' compensation' lines of business, special attention should thus be given to these aspects. Other insurance lines – for example, 'product liability', 'recall', 'directors and officers liability' or 'environmental impairment liability' – may be exposed if, despite preventive measures and all claims to the contrary,

---

<sup>8</sup> "The Risk Governance of Nanotechnology: Recommendations for Managing a Global Issue", report of conference held 6-7 July 2006, in Zurich, published by Swiss Re Centre for Global Dialogue, 8803 RUESCHLIKON, Switzerland.

<sup>9</sup> Epprecht, T. K. (forthcoming 2010), 'Producing safety or managing risks? – How regulatory paradigms affect insurability', in Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard (eds), *International Handbook on Regulating Nanotechnologies*, Cheltenham: Edward Elgar.

## Nanomed Round Table

nanoparticles do not remain immobilised or 'fixed' in products. If the slightest suspicion is raised regarding any producer of, for example, cosmetics or foodstuffs, whose products contain or come into contact with nanoparticles, claims will certainly follow.

Thus, a consistent approach to assessing heterogeneous liability exposures is indispensable, in addition to company-specific assessments. However, an uncompromisingly risk-averse approach to nanotechnologies across the board would unnecessarily call into question the liability coverage provided to many industry segments. Indeed, there is at present no scientifically substantiated, immediate rationale that can call for a sweeping exclusion of nanotechnology; moreover, juridically incontestable exclusionary wording or special treatments would only be feasible and reasonable in a very limited number of cases. Exclusions<sup>10</sup> and catch-all wordings are usually inappropriate for such enormously varied, cross-sectional technologies. Thus, it would seem that the more appropriate approach would be to focus on a prudent selection of those companies which manage their risks best. In other words, when insurance is benchmarking them, those that turn out to be the 'best in class' qualify best for contractual partnership."

---

<sup>10</sup> An exclusion is always an exception. It comes as an emergency in case there are no other contractual ways to make liability exposure calculable, or if "the house is already burning". As an example, an event such as asbestos-like effects of specific nanomaterials under proven, real-life conditions could trigger targeted and limited exclusionary wording.

# Nanomed Round Table

## Annex 5 - OECD Activities and Projects Relevant to Nanotechnologies

### The role and expertise of OECD

The Organisation for Economic Cooperation and Development (OECD) has for many years provided an international forum for discussion of new technologies, coordination of research, and the publication of key reports. These have also provided valuable input to discussions of regulatory frameworks around the world.

OECD is uniquely positioned at an intergovernmental level to rapidly develop and implement harmonised, science- and rules-based tools for safety data collection, analysis and information sharing for the safety of chemicals. This is particularly important when making informed decisions about prudent measures to mitigate possible risk implications of nanotechnology.

As part of its Environment, Health and Safety programme, OECD has acquired 40 years of experience in chemical safety, establishing **120** internationally agreed guidelines for the testing of chemicals, which cover methods for determining the physical and chemical properties of a material (such as its flammability and water solubility), its effects on human health and impacts on other living organisms (such as short and long-term toxicity), as well as the fate of a chemical in the environment.

### Benefits of OECD Test Guidelines

OECD Guidelines provide sufficient details for chemicals to be tested in the same manner in laboratories around the world. In addition, they are an integral part of a system of OECD Council Decisions on the Mutual Acceptance of Data, which require OECD governments to accept test data developed for regulatory purposes in another country if these data were developed in accordance with the Test Guideline together with Principles of Good Laboratory Practice. This system increases the efficiency and effectiveness of chemical notification and registration procedures for both government and industry. It ensures high-quality test data and a common basis of information for assessing risks to human health and the environment, thereby facilitating exchange of data, government evaluations, and harmonised regulatory programmes which avoid inefficiencies caused by duplicative work and creation of non-tariff barriers to trade.

### The Working Party on Manufactured Nanomaterials

To proactively address potential implications of nanotechnology, OECD's Council established the Working Party on Manufactured Nanomaterials (WPMN) in 2006 as a subsidiary body of OECD's Chemicals Committee. The Working Party brings together more than 100 experts from governments and other stakeholders from:

- a) 30 OECD Member Countries and the European Commission;
- b) non-member economies such as Brazil, China, the Russian Federation, Singapore and Thailand;
- c) Inter-governmental organisations: (IOMC);

# Nanomed Round Table

- d) International Standards Organisation (ISO TC229); and
- e) Other stakeholders: business/industry; organised labour; environmental NGOs, and animal welfare organisations.

## *Major output to date:*

The Working Party is implementing its work through eight main areas:

- **Project 1: Database on Human Health and Environmental Safety Research:** Launched April 1<sup>st</sup>, 2009
- **Project 2: Research Strategy(ies) on Human Health and Environmental Safety Research:** Review of current research programmes has identified research themes which already have wide coverage globally and those less well covered
- **Project 3: Testing a Representative Set of Manufactured Nanomaterials (MN):** Sponsorship programme for the testing of 14 MNs for 53 endpoints
- **Project 4: Manufactured Nanomaterials and Test Guidelines:** Development of guidance on sample preparation and dosimetry for the testing of manufactured nanomaterials
- **Project 5: Co-operation on Voluntary Schemes and Regulatory Programmes:** Analysis of national information gathering programmes
- **Project 6: Co-operation on Risk Assessment:** Review of existing risk assessment schemes and their relevance to nanomaterials
- **Project 7: The Role of Alternative Methods in Nanotoxicology:** Reviewing alternative test methods which will avoid animal tests and which will be applicable to manufactured nanomaterials
- **Project 8: Exposure Measurement and Exposure Mitigation:** Recommendations on exposure and measurement techniques in the workplace, consumers and environment

A major focus of its work is to ensure that existing instruments (for example, the OECD Test Guidelines) can be reliably applied to nanomaterials. To this end, a vital task is to understand the types of information on 'intrinsic properties' that may be relevant to exposure and assess the effects of manufactured nanoparticles (MNs), as knowledge of intrinsic properties of MNs is essential to identify needs for risk assessment within a regulatory context. The crucial questions of this task are:

1. What information currently exists?
2. Are existing test methods (e.g. OECD test guidelines) suitable for nanomaterials? and
3. How can comparability of testing be verified?

To facilitate integration of existing information, a database was launched on 1 April 2009 covering completed, current and planned research on human health and environmental safety. OECD has initiated a review of the Test Guidelines to assess whether or not they are suitable for nanomaterials. Preliminary conclusions from the review show that most test guidelines are appropriate for nanomaterials and some may need adjustment. Recommendations of the review suggest a strong need to develop guidance on 'sample preparation and dosimetry' for use in testing (as a top priority, because nanomaterials have distinct properties that are greatly

# Nanomed Round Table

affected by the test medium in which they are used), and also the need for a comparison of Instillation vs. Inhalation studies.

The Working Party has agreed on a list of **MNs** (based on materials which are now, or soon to enter, commerce), and a list of **endpoints** for which these MNs should be tested. A 'sponsorship programme' has been developed, in which governments and other stakeholders have committed to work together to test 14 nanomaterials that are already in commerce or are expected to be in the near future. The outcome of this Sponsorship Programme will provide valuable information on the 'intrinsic properties' of nanomaterials that are unique to their nanoscale dimension.

Recognising that the workplace is the primary area of concern for exposure and adverse human health effects associated with MNs, the Working Party is in the process of prioritising and developing specific projects aimed at measuring and mitigating exposures in workplaces involving nanotechnology.

# Nanomed Round Table

## Annex 6 - The standards committees on nanotechnologies - ISO/TC 229 and CEN TC 352

The International Organisation for Standardization **Technical Committee (ISO/TC) 229 - Nanotechnologies** - was established in June 2005 with a UK secretariat and chair. The ninth meeting of the committee took place in Tel Aviv, Israel, from 18 to 22 October 2009. The committee currently has 41 members - 32 "P" and 9 "O" (see:

[http://www.iso.org/iso/standards\\_development/technical\\_committees/list\\_of\\_iso\\_technical\\_committees/iso\\_technical\\_committee.htm?commid=381983](http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983) ).

The first two documents developed by the committee were published in 2008: ISO/TS 27687 – Nanotechnologies – Terminology and definitions for nano-objects – nanoparticle, nanofibre and nanoplate; and ISO/TR 12885 – Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies.

The TC structure consists of 4 working groups (WG), the first two of which are Joint Working Groups (JWG) with IEC (International Electrotechnical Commission) TC 113 (Nanotechnology standardization for electrical and electronic products and systems): Terminology and Nomenclature (JWG1, convened by Canada); Measurement and Characterization (JWG2, convened by Japan); Health, Safety and Environmental Aspects of Nanotechnologies (WG3, convened by USA); and Material Specifications (WG4, convened by China). The work programme at 16th September 2009 contained 37 work items – listed in Annex 4.

The committee has Task Groups that are developing recommendations as to how it should address the areas of Nanotechnologies and Sustainability, and Consumer and Societal Dimensions of Nanotechnologies. Task Groups are disbanded once they have completed their work.

The TC works closely with the IEC/TC 113, chaired by the US, with Germany providing the secretariat. The two Technical Committees hold joint plenary meetings at least every two years, starting in December 2007. TC 229 also works closely with the CEN (European Committee for Standardization) TC in the area (TC 352 – Nanotechnologies, also chaired by UK), using the Vienna agreement<sup>11</sup> where

---

<sup>11</sup> The Vienna Agreement is an agreement between CEN and ISO that allows for joint working on topics of common interest. Under the terms of the agreement, such projects are developed in one or other organisation (the lead committee) with the other providing input, where appropriate, whilst agreeing not to undertake work in the area ("stand still"). The final draft is balloted through both committees in the usual way and can be adopted by one or other, both or neither committee. If confirmed by both committees the document is published as a CEN/ISO, whereas if confirmed by only one of the committees, it is published as either a CEN or ISO document, depending on which committee approves it. The process is primarily intended for the development of full CEN (EN – European Norm) and ISO (IS – International Standard) standards but can also be used, with appropriate justification, for the development of Technical Specifications.

# Nanomed Round Table

appropriate. Liaisons have been established with 25 other ISO TC's, with the OECD (Working Party on Manufactured Nanomaterials and Working Party on Nanotechnology), with the International Bureau of Weights and Measures (BIPM), with the EC Joint Research Centre (Institute for Reference Materials and Measurements (IRMM) and Institute for Health and Consumer Protection, Ispra), with the Asia Nano Forum and with VAMAS (Versailles Project on Advanced Materials and Standards).

Given the number of ISO and other committees and working parties with an interest in nanotechnologies standardisation, and in particular in the development of test methods for measurement and characterisation, the committee has established a Nanotechnology Liaison Coordination Group to ensure coordination of activities and harmonisation of deliverables amongst liaison organisations. Meetings of this group are held twice yearly, during the week long plenary meetings of ISO/TC 229.

The development of standards in ISO Technical Committees is undertaken on the basis of New Work Item Proposals (NWIP) received from, and approved, developed and adopted by members according to the procedures defined in the ISO/IEC Directives.

**CEN/TC 352** was established at the end of 2005 to develop standards of specific interest to Europe and the European single market. It has two working groups – WG1 'Measurement, characterization and performance evaluation' and WG 2 'Commercial and other stakeholder aspects'. All of its work to date has been undertaken jointly with ISO/TC 229 under the terms of the Vienna Agreement, with three items led by CEN and the others by ISO. The committee is currently awaiting a response from the European Commission to a report on "the elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials", which it prepared on behalf of the European standardization bodies (CEN, CENELEC and ETSI) and which was submitted in May 2008. The response is expected to include a programming mandate that will identify standards that are of particular interest to the Commission. CEN/TC 352 is also working closely with the NMP division of DG Research (Nanosciences, Nanotechnologies, Materials and New Production Technologies) to identify outputs of Framework projects that might be suitable for standardisation.

In view of the strict time limits on the development of projects in ISO and CEN, all of the projects identified in the Annex will either be published sometime within the next three years or be deleted from the work programmes.

## **ISO/TC 229 Work Programme at 16<sup>th</sup> September 2009**

JWG1

- *ISO/TR: Terminology and nomenclature for nanotechnologies – Framework and core terms - **approved for publication***
- *ISO/TS: Terminology and definitions for carbon nanomaterials – **approved for publication***

# Nanomed Round Table

- *ISO/TS: Core Terms - Terminology and Definitions*
- *ISO/TS: Terminology and definitions for nanostructured materials (Joint development with CEN TC 352 – ISO led)*
- *ISO/TS: Terminology for the bio-nano interface*
- *ISO/TS: Terminology for nanoscale measurement and instrumentation*
- *ISO/TS: Terminology for medical, health and personal care applications of nanotechnologies*
- *ISO/TS: Terminology for nanofabrication/ nanomanufacturing*
- *ISO/TR: Nomenclature Models for nano-objects*

## JWG2

- *ISO/TS: The Use of Transmission Electron Microscopy (TEM) in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: The Use of Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Analysis (EDXA) in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: Technical Specification for the Use of UV-Vis-NIR absorption spectroscopy in the Characterization of Single-walled Carbon Nanotubes*
- *ISO/TS: Technical Specification for the use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the Characterization of Single-Walled Carbon Nanotubes*
- *ISO/TR: Use of Thermo Gravimetric Analysis (TGA) in the purity evaluation of Single Walled Carbon Nanotubes*
- *ISO/TR: Use of Evolved Gas Analysis-Gas Chromatograph Mass Spectrometry (EGA-GCMS) in the Characterization of Single-Walled Carbon Nanotubes*
- *ISO/TS: Use of Raman Spectroscopy in the Characterization of Single Walled Carbon Nanotubes.*
- *ISO/TS: Measurement Methods for the Characterization of Multi-Walled Carbon Nanotubes*
- *ISO/TR: Guide to nanoparticle measurement methods (Joint development with CEN TC 352 – CEN led)*
- *ISO/TR: Guide to methods for nano-tribology measurements (Joint development with CEN TC 352 – CEN led)*
- *ISO/TS: Determination of meso-scopic shape factors of multiwalled carbon nanotubes (MWCNTs)*
- *ISO/IS: General framework for determining nanoparticle content in nanomaterials by generation of aerosols*
- *ISO/TS: Electrical resistance of carbon nanotubes using 4 probe measurement*
- *ISO/TS: Artificial gratings used in nanotechnology - description and measurement of dimensional quality parameters*
- *ISO/TS: Carbon nanotubes - Determination of metal impurities in carbon nanotubes (CNTs) using inductively coupled plasma-mass spectroscopy (ICP-MS)*

## WG3

- *ISO/IS: Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amoebocyte lysate (LAL) test (Joint development with CEN TC 352 – ISO led)*

# Nanomed Round Table

- *ISO/IS: Standard for Generation of Metal Nanoparticles with the Evaporation/Condensation Method for inhalation toxicity testing (Joint development with CEN TC 352 – ISO led)*
- *ISO/IS: Standard for characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing (Joint development with CEN TC 352 – ISO led)*
- *ISO/TR: Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment (Harmonized with WPMN list – working closely to ensure that we complement each other's work and avoid duplication)*
- *ISO/TS: Guidance on safe handling and disposal of manufactured nanomaterials*
- *ISO/TR: Nanomaterial risk evaluation framework*
- *ISO/TS: Guidelines for occupational risk management of nanomaterials based on a "control banding" approach*
- *ISO/TR: Preparation of Material Safety Data Sheet (MSDS) for nanomaterials*
- *ISO/TS: Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening - FT-IR method*

## WG4

- *ISO/TS: Material specification - Nano-calcium carbonate, Part 1 – General requirements*
- *ISO/IS: Material specification - Nano-titanium dioxide, Part 1 – General requirements*
- *ISO/TS: Nanomaterial calcium carbonate (powdered form) – Part 2: Specifications for specific applications*
- *ISO/TS: Nanomaterial titanium dioxide (powdered form) – Part 2: Specifications for specific applications*
- *ISO/TS: Guidance on specifying nanomaterials.*

## Unallocated

- *ISO/TS: Guidance on labelling of manufactured nanoparticles and products containing manufactured nanoparticles (Joint development with CEN TC 352 – CEN led).*

IS = International Standard; TS = Technical Specification; TR = Technical Report.

# Nanomed Round Table

## Annex 7 - The International Scene: Some Examples

### The Role of the United States of America

This report contains several references to the major US agencies involved in the regulation of nanoscience and nanotechnology: in nanomedicine, principally the Food and Drug Agency (FDA), and the Centers for Disease Control (CDC), both administered under the Department of Health and Human Services (DHHS).

Nanoscience research is conducted in many centres, public and private, including funding through grants programmes, and the activities of organisations such as the National Science Foundation, and the National Institutes of Health. Given the scale of the US national research budget, the scale of private sector investment, and its role in international trade, it is clearly a leader in reviewing and defining standards around the world, and the European Commission maintains close links with the US agencies.

The US has a strong tradition of public consultation, involving the major public research institutions, the universities, private foundations, and the private sector. Through publications, meetings, and strong professional associations, there is in effect a continuous societal learning system, feeding into the processes of drafting legislation and the political decisions on the funding of the federal agencies.

Debate on regulatory aspects of nanomedicine is conducted through many channels, over several years, the key questions focussing on whether existing regulatory instruments are sufficiently flexible to cover the latest innovations. Some public interest researchers and institutions would argue that there is a governance gap between the requirements pertaining to the nano-technologies. The novel attributes of nanotechnology demand different routes for risk-benefit assessment and risk management, and at present, nanotechnology innovation proceeds ahead of the policy and regulatory environment. It is argued that the emerging knowledge base about the hazards of nano-sized particles is inadequate to respond to these risks

However, the FDA (which regulates categories of products and not the technologies used in producing them) maintains that **existing legislation provides an adequate regulatory framework for the products so far brought to their attention**; while acknowledging that the focus on products rather than technologies tends to conflict with situations where the use of nanoscale materials changes significantly the functionality of the products. The debate continues, with a significant international dimension, facilitated by the speed and low cost of electronic communication.

### China

This report draws upon the work of regulatory authorities within the EU and around the world, and reference has been made to the key US federal agencies, with whom there is close liaison. The international character was underlined by the following

## Nanomed Round Table

contribution from Yu Jiang, from the Institute of Policy and Management (IPM), in the Chinese Academy of Sciences. It makes clear not only the strength of the Chinese effort, but also its dynamic character: the effort is being rapidly increased. Similar pictures of rapidly growing commitment of public funds could be described in many countries, in several continents.

China's current nanoscience and nanotechnology research can be traced back to the mid-1980s. In 1999, the Ministry of Science and Technology initiated a national key basic research project (973 Programme) for basic research on nanomaterials such as nanotubes. Research on nanomaterials was the primary focus of funding during this period. The government estimates that RMB 400 million (~USD 50 million) was invested in nanoscience and nanotechnology basic research before 2001.

China's National Steering Committee for Nanotechnology (CNSCN) was founded in November 2000 as the national level coordination committee for such programmes. In July 2001, the CNSCN mapped out a National Programme of Nanotechnology Development (2001-2010).

In 2001, a Nano-biological research group was established at the IHEP (Institute of High Energy Physics) of CAS. In 2006, the National Center for Nanoscience & Nanotechnology of China established the Joint Lab for Bio-Environmental effects of Nanomaterials and Nanosafety in CAS.

A national technical committee on nanotechnology standardisation was subsequently initiated in 2005 to formulate and amend basic standards on terms, methodology, and safety issues involving nanoscale measurement, processing, nanomaterials, nanodevices, and nanomedicine.

In China's newly released national guidelines on the Medium- and Long-term Programme for Science and Technology Development (2006-2020), a "Nano Research Plan" has been identified and Nano-biology and nanomedicine become the funding priorities.

Now several Chinese research groups have engaged in fields such as nano-bio effects and toxicology, nanomachines, nano/biosensors, molecular imaging, and drug delivery. In the subconference on Nano-biology and Nanomedicine at ChinaNANO 2007, 22 out of 50 oral presentations were delivered by 21 Chinese research groups.