EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods

Brussels, 2nd February 2010
M/461 EN

MANDATE ADDRESSED TO CEN, CENELEC AND ETSI FOR STANDARDIZATION ACTIVITIES REGARDING NANOTECHNOLOGIES AND NANOMATERIALS

1. SCOPE

This mandate concerns the elaboration of standardisation deliverables specified in the attached annex, relating to nanotechnologies and nanomaterials.

2. BACKGROUND

Nanotechnologies are a rapidly developing field of science, technology and innovation. As enabling technologies, their full scope of applications is potentially very wide. Major implications are expected in areas such as health care, information and communication technologies, energy production and storage, materials science/chemical engineering, manufacturing, environmental protection, consumer products, etc. The world market for nanotechnologies will increase fast and dramatically, and nanotechnologies are expected to provide a significant input to the creations of manufacturing jobs world-wide.

On the other hand, nanotechnologies and nanoparticles may expose humans and the environment to new health risks, possibly involving quite different mechanisms of interference with the physiology of human and environmental species.[1] Given the interests at stake, the European Commission has set out a European Strategy for Nanotechnologies, based on a «safe, integrated and responsible» approach.[2]

One of the building blocks of the "safe, integrated and responsible" approach is standardization. Both the Economic and Social Committee and the European Parliament have highlighted the importance to be attached to standardisation as a means to accompany the introduction on the market of nanotechnologies and nanomaterials, and a means to facilitate the implementation of regulation.

In 2007, the Commission addressed a mandate to CEN, CENELEC and ETSI, asking these bodies to elaborate a report identifying with respect to nanotechnologies and nanomaterials:

- the programme of standardisation items,
- the status of foreseen standardisation deliverables,

[1] See in particular the opinions o the Scientific Committee on Emerging and newly identified risks; http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_opinions_en.htm#nano

[2] Communications, respectively "Towards a European Strategy for Nanotechnology" and the "N&N Action Plan for Europe 2005-2009". (COM(2004) 338 final and COM(2005) 243 final)

- an assessment of the feasibility of having standardisation work carried out at the international level, and
- a draft roadmap of the progress of standardisation activities considered necessary.

Mandate 409 specifically asked the standards bodies to verify consistency and coherence of activities with activities going on in other fora, such as the OECD. This report was presented in May 2008.

3. CONTENTS OF THE REPORT

In their report, the European Standards Bodies provide a list of standardisation deliverables identified at a given moment in time and ideally to be elaborated at some point in time. The Commission takes note that given the early stage of development of nanotechnologies, the standardising documents mainly constitute Technical Specifications. The standards bodies also suggest that in view of the rapid evolution of standardization and research in nanotechnology and nanosciences, a further programming mandate be given by the EC in 5 years. Similarly, the European Standards Bodies suggest that the European Technology Platforms be requested to identify appropriate nanotechnology standardization opportunities and needs.

Finally, the European Standards Bodies suggest that a joint European Commission–European Standardization Organization (ESO) group be established to identify nanotechnology standardization opportunities and needs arising from relevant Framework Programme projects, and facilitate their development; also relevant ETPs should report to this group.

The Commission takes note that according to the report, revision of existing standards or elaboration of other standards or standardizing documents is not excluded. However, for the time being, no concrete proposals have been introduced, or at least not communicated to the European Commission.

4. DESCRIPTION OF THE MANDATE

In order to ensure consistency and efficiency of approach, the Commission, in consultation with Member States in accordance with Directive 98/34, considers that a clear division on work should be maintained between the various organisations that are involved in elaborating standardization documents, and that a clear priority should be expressed as to what is expected from the European standards bodies, closely cooperating wit their international counterparts.

As mentioned in the Commission's Communication on Regulatory Aspects of Nanomaterials, implementation of current regulation is a major challenge, mainly due to a knowledge gap and the lack of instruments that support regulation and implementation. The Communication and the accompanying Commission Staff Working Document highlight consequently the areas where further work is needed. Standardization work covered by this mandate should reflect the priorities indicated by these Commission documents.

In the current situation, work on toxicology and screening,[3] is performed mainly in the framework of the OECD. Work on risk assessment[4] for chemicals is carried out mainly by the authorities involved in the implementation of REACH, in cooperation with ECHA.

However, there is a key role for standardisation as regards measurement and testing tools for the characterisation, behaviour of nanomaterials and exposure, complementing the work being carried out in the framework of the OECD and in the context of the implementation of REACH and CLP. **The Commission therefore requests CEN, CENELEC and ETSI to develop the standardisation deliverables listed in Annexes I and II to this mandate.**

In addition, in various policy documents, the Commission, the European Parliament and the European Economic and Social Committee have highlighted the need for definitions and a common terminology at the global level. The Commission therefore invites CEN and its members to actively take part in international work on definitions.

In its answer to mandate M/409, CEN suggests a wide number of other standardization deliverables. Without anticipating the position the Commission will take on these items, the Commission wishes to further explore the need to support such standardisation work in the process of an annual review, as suggested by the European Standards Bodies.

CEN will communicate to the Commission – together with the note of acceptance of this mandate - a tentative timetable with prioritisation in each of the fields specified in Annex I for the adoption of the deliverables required for the needs identified in Annexes I and II.

5. EXECUTION OF THE MANDATE

The Commission hereby asks CEN, CENELEC and ETSI to fulfil the tasks as described above, while taking into account the rationale of these standardising activities stated in the programming and in the current mandate.

Priority should be given to work carried out in conjunction with ISO. It is essential to maintain a coherent approach in relation with work in OECD. It is therefore essential that work by CEN is carried out in close collaboration with ISO and OECD.

In line with suggestions made by the European Standards Bodies, the European Commission and the European Standards Bodies will review on an annual basis progress made and newly identified needs.

CEN, CENELEC and ETSI are requested to take into account on-going pre-and co-normative research and development (including relevant work done by relevant stakeholders, industry, in national as well as international fora and the Commission's Framework Programmes for research i.e. FP6 and FP7; CIP; Life+; etc.) and co-ordinate their activities in order to avoid any duplication of work. In this respect, it is also essential that any other relevant research activities/projects from various sources (e.g. European, National and Regional and Industry (here, especially the NM project) Programmes) are taken actively and effectively into account.

[3] Points 12 – 18 CEN Report

[4] Points 20 – 25 CEN Report

Moreover, CEN, CENELEC and ETSI should also establish and/or build upon existing appropriate links for the tasks described above with relevant European Technology Platforms (ETPs), especially with the ones entitled Sustainable Chemistry (SusChem) and Industrial Safety (ETPIS – here its Nanosafety HUB), to ensure a coordinated and fast progress of their tasks.

With acceptance by CEN, CENELEC and ETSI of this mandate, the appropriate standstill period in accordance with Article 7 of the Directive 1998/34/EC will start.

6. BODIES TO BE ASSOCIATED

The execution of the mandate should be undertaken in cooperation with the widest possible range of interested groups: International standards bodies (ISO, IEC, and ITU), the Joint Research Centre of the European Commission, OECD, as well as research institutes, and the different relevant technology platforms (see section 5 of this mandate), as well as the European Agency for Safety and Health at Work.

As appropriate, CEN, CENELEC and ETSI will invite the standardisation stakeholders representing consumers' interests (ANEC), environmental protection (ECOS), workers (ETUI-REHS) and SMEs (NORMAPME) to take part in the development of the standardizing items.

Annex I
Characterisation of and exposure from nanomaterials

CEN, CENELEC and ETSI are invited to develop as final outputs, European standards for methodologies for characterisation of nanomaterials in the manufactured form and prior toxicity and eco-toxicity testing, European standards for measurement of exposures to nanomaterials and European standards for methods to simulate exposures to nanomaterials. This may include the revision of existing standards (e.g. dustiness).

As interim output, CEN, CENELEC and ETSI are develop a roadmap for the development of the deliverables requested and Technical Specifications (TS) for these items. Work should take into consideration to following elements:

1. Methodologies for nanomaterial characterization in the manufactured form and before toxicity and eco-toxicity testing

Emphasis must be put on the physicochemical properties relevant for hazard characterisation of nanomaterials, in particular characteristics related to: dynamics of dispersion, rate of dissolution, aggregation/agglomeration, surface area and the potential to adsorb substances onto nanomaterials' surfaces in the manufactured form and before toxicity and eco-toxicity testing. The wide range of physical and chemical properties for the characterisation of manufactured nanomaterials should be taken into consideration, in particular:

- chemical composition, crystal structure, morphology, shape, aspect ratio (length/thickness), specific surface area, particle size and size distribution,

- water solubility, octanol-water partitioning coefficient, surface chemistry, surface charge, surface topography, aggregation and agglomeration state, dispersability and stability (in the appropriate media),

This is a non-exhaustive list, and other characteristics can be included as needed.

General principles for approaching nanomaterials characterisation should be taken into consideration. Where relevant, the description of these characteristics needs to take into account known or anticipated variations over time and under varying conditions during nanomaterial life cycle.

2. Sampling and measurement of workplace, consumer and environment exposure to Nanomaterials

Particular attention must be paid to:

- General characteristics of measurement, in particular: metrics, background aspects, exposure routes, sampling aspects, measurement approaches and uncertainties including also background exposure to incidental particles such as combustion products, cooking generated aerosols, sand blasting emissions, mining emissions, metal working emissions and biomaterial degradation.

- Metrics to be used for the exposure measurements of nanomaterials (nano-objects and nanostructured materials) such as mass concentration, number concentration and

surface area concentration (the latter are likely to be more appropriate than the current mass concentration only to express the nanomaterial dose for the inflammatory or other toxic endpoints).

- Specific methods for the determination of partitioning and the fate of nanomaterial between and within different environmental compartments (e.g. air, water, soil) in the case of environmental exposure.

- Uncertainties caused by aggregation, agglomeration, dissolution and degradation as regards measurement uncertainties.

3. Methods to simulate exposures to nanomaterials

Emphasis must le laid on:

- Standardization and validation of currently available measurement methods (e.g. cascade impactors, TSI NSAM, ELPI) for monitoring of exposure to nanomaterials.

- Simulation approaches and models for the specific prediction of workplace, consumer and environmental exposure to manufactured nanoparticles taking especially into account possible but representative uses, worst case scenarios, accuracy, comparability, reproducibility, repeatability and predictability of the real situation and end-of-life issues.

- In the case of environment, environmental compartments together with their possible interactions.

European standardisation efforts should be elaborated wherever possible in cooperation with the international standards bodies. Furthermore, attention is drawn to ongoing work in the OECD especially in relation to: (a) OECD test guidelines for manufactured nanomaterials; (b) Guidance on detection and identification of nanoparticles and other nanoscale entities; (c) Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.; (d) Simulation Methods/techniques to approximate exposure; (e) Guide to performance measurement of nanoscale materials and devices; (f) Guide to modelling (measurement, simulation and visualization) at the nanoscale; (g) Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nanoscale entities; (h) Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc.; (i) Development of Reference Materials and Certified Reference Materials dedicated to existing and new techniques, particularly for challenging and checking the functioning/calibration of nanoparticle measurement and analysis equipment; (j) Development of In situ/on line non-destructive techniques and contact-less measurements relevant to nanotechnologies; (k) Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials.

Annex II

1 HS&E

2 Occupational handling and exposure

3 Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment)

4 Guidance on containment, trapping and destruction of nanoparticles and other manufactured nanoscale entities

5 Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials

6 Methodology to Determine effectiveness of Filtration Media against Nanomaterials

7 Standard Method to Assess Emissions from Handling, or Machining of Nanomaterial Containing Products

8 Protocols for determining the explosivity and flammability of nano-powders (for transport, handling and storage)

9 Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges)

10 Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.

33 Guide to the identification and definition of measurands required for characterising, evaluating functional properties and performance, etc, of materials and devices at the nanoscale

34 Product specifications for different manufactured nanomaterials

36 Guide to basic morphology and purity of manufactured nanoparticles and other nanoscale entities

37 Guides to purity evaluation of manufactured nanoparticles and other nanoscale entities

38 Guide to modelling (measurement, simulation and visualization) at the nanoscale

new *Guide to the management of waste and the disposal of nanomaterials*

Toxicology testing and screening ***Risk assessment/risk management*** ***Lisbon Agenda – General*** ***Societal agenda***	To be examined in the framework of annual review