BUSINESS PLAN
CEN/TC 352
NANOTECHNOLOGIES

EXECUTIVE SUMMARY

Since 2006 CEN/TC 352 is engaged in standardization in the field of nanotechnologies. This will include the preparation of standards for: classification, terminology and nomenclature; metrology, measurement and characterization (including procedures for calibration); health, safety and environmental issues; nanotechnology products and processes as well as commercial and stakeholder issues.

Standards in each of the above areas could be specific to a product, process or industry. CEN/TC 352 will seek to prepare standards that are as generic as possible and thereby applicable to as wide a range of industries as possible. However, given the nature of the TC's subject area, this will clearly not always be possible.

Meanwhile EC has addressed the M461 mandate to CEN, CENELEC and ETSI, in which clear co-ordination role has been required at European level. Such a role was assigned to CEN/TC 352.
Thus CEN/TC 352 will seek to be flexible enough to address specific subjects, as necessary. Where it is perceived that a standard is likely to be relatively narrow in its field of application, all necessary liaisons will be established with other relevant bodies. If another CEN-ISO/TC is better placed to develop a standard, that CEN-ISO/TC will be invited to do so. If additional expertise is needed to such CEN-ISO/TCs from CEN/TC 352, this will be provided.

CEN/TC 352 will then liaise widely at national, regional and international level. In particular, CEN/TC 352 will work closely with international committee ISO/TC 229 Nanotechnologies. For topics of mutual interest to ISO and CEN, it is recommended that the Vienna Agreement will be implemented in most cases.
CEN/TC 352 will liaise with other European and international bodies, to ensure its standards take due account of related work being undertaken elsewhere.

CEN/TC 352 will seek to make use of a research-standards interface through the appropriate mechanisms under the EU framework Programme 7 (FP 7) [EU research - Building Knowledge Europe: The EU's new Research Framework Programme 2007-2013] or Horizon 2020 (http://ec.europa.eu/programmes/horizon2020/). It is envisaged that CEN/TC 352 can play a key role in advising on the coordination and prioritization of standards-related nanotechnology R & D under FP7 or Horizon 2020, thereby enabling the translation of R & D advances into standards with regard to European innovation, technical excellence, public health and capacity for risk assessment.

CEN/TC 352 will seek to develop and maintain relevant and up to date standards.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this CEN/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

Numerous recent studies have indicated that the nanotechnology will have a major impact on virtually all technologies affecting modern life and that it will enable dramatic advances to be realized in information and communications technology, healthcare, environmental protection manufacturing, materials science, energy production and security. Industrial and consumer applications for nanotechnology are expected to increase sharply. The National Science Foundation (NSF) estimated a world market for nanotechnological products of one trillion dollars for 2015. Sustaining such growth from the current levels will call for considerable investment in the necessary technological infrastructure, and this will include the development of appropriate standards.
In the United States, this investment has been undertaken via the National Nanotechnology Initiative (see for example the NNI Strategic Plan, December 2004), and other countries have acted similarly. In 2010 the EU published its "Towards a Strategic Nanotechnologies action Pland (SNAP) 2010-2015", with a view to collect opinions on future directions for governance and all relevant policies for the intergrated, safe and responsible development and commercialisation of nanotechnologies and nanpotechnology enabled processes and products..

Conceptually, nanotechnology should be seen not as a branch of any specific technological discipline but rather as trans-disciplinary in nature, encompassing and combining relevant areas of chemical, physical, biological and information technologies. The essence of nanoscience is the ability to work at the nanometre level to generate large structures with fundamentally new molecular organisation; whilst the accompanying aim of nanotechnology is to learn to exploit novel physical, chemical and biological properties of nanostructured materials and efficiently manufacture and employ such structures.

Additionally there is an increasing recognition that nanoparticles and nanomaterials may have at large unexpected and unwanted impacts on health and the environment.

These issues will be supported and addressed by well-founded standards in the fields of:

- classification, terminology and nomenclature;
- metrology, measurement and characterization (including procedures for characterization);
- health, safety and environmental issues;
- nanotechnology products and processes.

The European Commission has addressed to CEN-CENELEC-ETSI the mandate M 461 that could be considered in some ways supporting forthcoming European Directive(s). Some aspects of the work may be associated with regulation in the future. This should be borne in mind especially in the context of the health, safety and environmental issues which may arise and which are the already the subject of numerous discussion papers in relation to nanoparticle exposure. This is equally of concern at the international level and it may be noted that similar considerations will arise in the context of ISO/TC 229 Nanotechnologies.

1.2 Quantitative Indicators of the Business Environment

In 2006 the European Commission DG Research published 'The economic development of nanotechnology – An indicator based analyis', which covered the period 2006-2015', with a view to analyse the state of art of nanotechnology by presenting available data on nanotechnology markets and market projections, on jobs, on companies and other organizations active in nanotechnologies, on public and private funding, including Venture Capital funding, on patents and scientific publications.

Most market forecasts for nanotechnology originate from the early 2000s, with a time horizon up to 2015. The National Science Foundation (NSF) of the United States has published the maybe best-known figure for the future nanotechnology market in 2001. The NSF estimated a world market for nanotechnological products of 1 trillion US Dollars for 2015. Depending on the definition of nanotechnology and its contribution to added value of the final products as well as the degree of optimism, many other forecasts vary between moderate 150 billion in 2010 (Mitsubishi Institute, 2002) and 2.6 trillion in 2014 (Lux Research, 2004). The latter, most optimistic scenario would imply that the market for nanotechnology-based products would be larger than the prospected information and communication technology market and would exceed the future biotech market by ten times.

NSF and NNCO-funded independent study identifies more than $1 trillion in global revenue from nano-enabled products in 2013.
The survey shows global funding for emerging nanotechnology has increased by 40-to-45 percent per year for the last three years. It shows that revenue from nano-enabled products grew worldwide from $339 billion in 2010 to $731 billion in 2012 and to more than $1 trillion in 2013. Revenue from the United States alone was $110 billion, $236 billion and $318 billion those same years, respectively.

As regards the R&D funding figures are taken from the EC DG Research publication 'Some figures about nanotechnology R&D in Europe and Beyond'.

The opportunities offered by nanotechnology have been clearly recognized by the world's leading economies. Public spending on nanotechnology research globally in 2004 reached slightly less than €4 billion, a rise of over 150 % on year 2001. With an additional €4 billion estimated for the private sector worldwide over the same period, the total global R & D investment in nanotechnology in 2004 may be reckoned at around €8 billion.

The launch of the National Nanotechnology Initiative in the USA in 2000 ensured the rapid growth of US federal support for nanotechnology R & D in the first five years of this decade. This is set to continue, with approximately $3.7 billion set aside for the period 2005-2008 (not including defence expenditure).

Horizon 2020 work programme for 2016-2017 published
The European Commission will invest almost €16 billion in research and innovation in the next two years under Horizon 2020.

The FP7 NMP Theme comprised 799 projects, amounting to a total cost of €4 658,44m of which the EC has contributed €3,229.37m. The FP7 NMP budget represented 6.8% of the overall FP7 budget. Under FP6, EU funding for research in NMP was €1.53b, for 444 projects.

Each project in the NMP Theme belongs to a specific part of the programme.

Nanosciences and Nanotechnologies: This area makes up about 25% of all projects funded under FP7 NMP and accounts for about 23% of EC contribution, making it the largest of NMP areas.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

As indicated above, the steep growth in applications of nanotechnology across a wide range of technological sectors will require the laying down of a considerable supporting infrastructure, which will have to include technical standards relating to the products and processes concerned.

Standards allow to open the way for innovative products and new markets CEN/TC 352 is well placed to respond to this need and to provide the impetus for development of those standards, for the benefit of both Europe and the wider world. CEN/TC 352 is expected to play a key role in advising on the coordination and prioritization of standards-related nanotechnology R & D under FP7 and followings (Horizon 2020), thereby enabling the translation of R & D advances into standards with regard to European innovation, technical excellence, public health and capacity for risk and life cycle assessments.

3 PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers by recognized European or international organizations is also possible under certain conditions.

The new twinning arrangement between AFNOR (France) and UNMZ (Czech Republic) is seen as an opportunity to encourage an active participation of members from Central and Eastern Europe.

To participate in the activities of this CEN/TC, participants are invited to contact their national standards organization.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

CEN/TC 352 will develop a set of standards addressing the following aspects of nanotechnologies:

a) Measurement, characterization and performance evaluation
b) Commercial and other stakeholder aspects
c) Health, safety and environmental issues;

NOTE. Standards, Technical Specifications and Technical Reports in each of the above areas could be specific to a product, process or industry (in that case developed by other TCs).

4.2 Identified strategies to achieve the CEN/TCs defined objectives.

CEN/TC 352 will pursue the following strategies to achieve its objectives, including those required under EC mandate M461:

(i) Production of generic standards where possible;

(ii) Use of the Vienna Agreement, when global relevance, whereby duplication of effort between CEN/TC 352 and ISO/TC 229 will be avoided;

(iii) In common with the majority of international standards work, the use of English as the working language up to the time of issue of a draft for public enquiry;

(iv) Co-ordination and liaison with appropriate other bodies, at present including:

- **CEN/TC 137** Assessment of workplace exposure to chemical and biological agents
- **CEN/TC 138** Non-destructive testing
- **CEN/TC 139** Paints and varnishes
- **CEN/TC 162** Protective clothing including hand and arm protection and lifejackets
- **CEN/TC 184** Advanced technical ceramics
- **CEN/TC 195** Air filters for general air cleaning
- **CEN/TC 230** Water analysis
- **CEN/TC 243** Cleanroom technology
- **CEN/TC 248** Textiles and textile products
- **CEN/TC 290** Dimensional and geometrical product specification and verification
- **CEN/TC 292** Characterization of waste
- **CEN/TC 386** Photocatalysis
- **CEN/TC 392** Cosmetics
- **CEN Strategic Advisory Board on Occupational Health and Safety** (CEN SAB OHS)
- **ISO/TC 24/SC 4** Particle characterization
- **ISO/TC 142** Cleaning equipment for air and other gases
- **ISO/TC 194** Biological evaluation of medical devices
- **ISO/TC 201** Surface chemical analysis
- **ISO/TC 202** Microbeam analysis
- **ISO/TC 217** Cosmetics
- **ISO/TC 229** Nanotechnologies
- **ISO/TC 256** Pigments, dyestuffs and extenders
- **IEC/TC 113** Nanotechnology standardization for electrical and electronic products and systems
- **ANEC** (European Association for the Coordination of Consumer Representation in Standardisation)
- **ECOS** (European Environmental Citizens' Organisation for Standardisation)
- **CEFIC** (European Chemical Industry Council)
- **Cerame-Unie** (European Ceramic Industry Association)
- **EC-DG Internal Market, Industry, Entrepreneurship and SMEs** (GROWTH)
- **EC-DG Environment** (ENV)
- **EC-DG Health and Food Safety** (SANTE)
- **EC-DG Joint Research Centre** (JRC)
- **EC-DG Research and Innovation** (RTD)
- **eNanoMapper** (A Database and Ontology Framework for Nanomaterials Design and Safety Assessment)
- **ETRMA** (European Tyre & Rubber Manufacturers' Association)
- **EU-VRi** (the European Virtual Institute for Integrated Risk Management)
- **IMA-Europe** (Industrial Minerals Association Europe)
- **iSTRESS Project** "Pre-standardisation of incremental FIB micro-milling for intrinsic stress evaluation at the sub-micron scale"
- **NanoDefine Project** "Development of an integrated approach based on validated and standardized methods to support the implementation of the EC recommendation for a definition of nanomaterials"
- **NANoREG Project** "a common European approach to the regulatory testing of nano-materials"
- **NanoRem Project** "Taking Nanotechnological Remediation Processes from Lab Scale to End User Applications for the Restoration of a Clean Environment"

- **NanoValid** (Research and development of reference methods for hazard identification, LCA (Life Cycle Assessment) and risk assessment of engineered nanomaterials)
- **NIA (**Nanotechnology Industries Association)
- **POLYGRAPH Project** "Up-scaled Production of Graphene Reinforced Thermosetting Polymers for Composite, Coating and Adhesive Applications"
- **SCAFFOLD** Project "Innovative strategies, methods and tools for occupational risks management of manufactured nanomaterials (MNMs) in the construction industry"
- **SETNanoMetro Project** "Shape-engineered TiO2 nanoparticles for metrology of functional properties: setting design rules from material synthesis to nanostructured devices'"

4.3 Environmental aspects

Nanomaterials are difficult to characterize and monitor as often new testing methods are needed to assess their impacts on human health and the environment. This does not necessarily mean that new tests are needed, rather it may also require that existing tests be assessed to ensure they are relevant and effective at the nanoscale. Environmental and biological exposure pathways for many nanomaterials are still largely unknown as they have not been observed yet. Despite the fact that there is evidence concerning the effects of nanomaterials on human health, the ecotoxicity effects on the environment are still largely unknown and it is not entirely clear which properties determine and/or influence the toxicity of nanoparticles.

Taking into account that there is:

- A lack of available information about the toxicity, ecotoxicity and exposure to nano materials;
- A potential for exposure of people and the environment as more products containing nanomaterials become commercially available;
- A lack of knowledge about the risks from each particular nanomaterial and how to avoid them.

CEN/TC 352 should take into consideration:

- **Precautionary principle**
  The consolidated version of the EU Treaty mentions the precautionary principle in Article 191 devoted to the environment. The potential for nanotechnologies and nanomaterials to bring about societal benefits (including positive environmental implications) needs to be demonstrated and assessed carefully as regards detrimental and unpredictable impacts. Use of the precautionary principle is essential if responsible governance and management of these new technologies and materials is to be achieved.

- **Lifecycle approach**
  Nanomaterial lifecycle assessments – including manufacturing, transport, product use, and end-of-life management – need to be undertaken when evaluating tests related to risk assessment of these substances. Full lifecycle environmental, health, and safety impacts must be assessed prior to commercialisation.

- **Environmental and human health protection and safety**
  Preventing potential exposures to nanomaterials that have not been demonstrated safe according to approved criteria should be the ultimate aim of effective management of nanomaterials. It must concern materials included into products that are directly put on the market, and the lack of knowledge about their human health and environmental impacts.

CEN/TC 352 should develop robust and properly validated standards, while recognising the limitations of existing scientific capacity and knowledge to identify potential impacts. Some aspects should be taken into account such as:

- The development of measurement methods with devoted sampling schemes to assess the exposure, possible risks and exposure hazard of workers, consumers and the environment to nanomaterials over their entire life cycle, including in the case of accidents, a multi-disciplinary approach;

- The development of standardized laboratory procedures, biomarkers, and analytical methods for the detection of nanoparticles in biological samples should be enforced to assess risks for health and the environment. While the appropriate management measures are being developed, the necessity exists for authorities to ensure traceability of products containing nanomaterials in order to react swiftly and efficiently to limit potential impact of nanomaterials.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

Given the relatively high profile of the envisaged activity of the CEN/TC 352 for nanotechnologies, and the widely perceived need for standards to support these new technologies, the necessary resource, expertise and commitment are expected to be available in full measure.

According to BT Resolution 51 (etc.), it is anticipated that the work of CEN/TC 352 will be closely linked to that of ISO/TC 229. It is therefore expected that the pace and timing of some projects will depend upon progress in ISO/TC 229.

It is also likely that the start of one or more projects may depend upon the completion of other projects. Pre-normative and co-normative research may also be required before certain projects may commence or be completed.

It is foreseen that standards may be requested to support legislation, particularly in the areas of health, safety and the environment, and so the work programme will be influenced by what these requirements are, and when they will be needed.

It is expected that sufficient and sustainable funding from EC-DG Internal Market, Industry, Entrepreneurship and SMEs (GROWTH) under mandate M461 may facilitate and speed up the respective standardization work and requested pre-normative research when needed.

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