



Laboratoire national de métrologie et d'essais



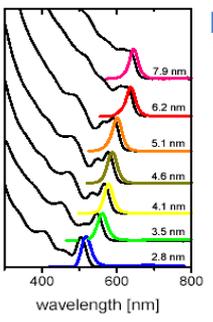
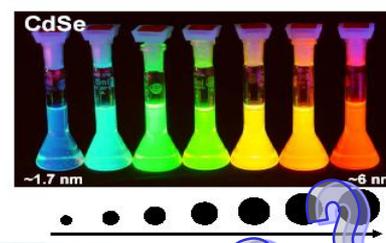
**International Workshop on Challenges to Increased Use
of Documentary Nanotechnology Standards**

European organization for standardization

CEN TC 352 Nanotechnologies

Jean-Marc Aublant

What about nanotechnologies at CEN ?



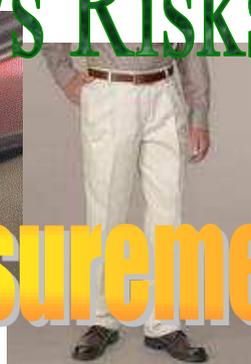
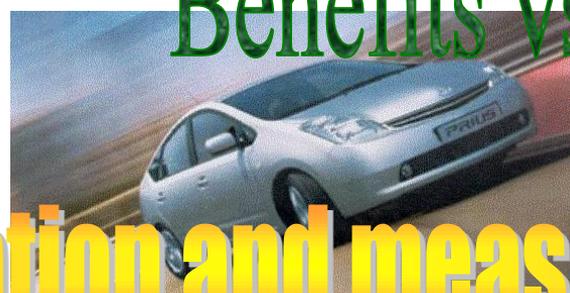
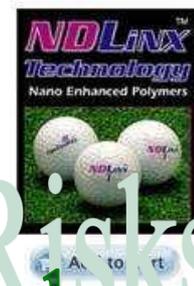
How to characterize?
How to evaluate performance?



HSE



Benefits vs Risks



Identification and measurement?

- CEN/BT/WG 166 Nanotechnologies was established in March 2004 to develop a strategy for European standardization in the area of nanotechnologies.
- In June 2005 CEN/BT/WG 166 recommends that CEN/BT establishes forthwith a new Technical Committee in the area of Nanotechnologies; Title, scope and structure were addressed.

Retrospect : CEN /TC 352 1st meeting

- The inaugural meeting of CEN/TC 352 took place on 5 April 2006 at CEN Management Centre in Bruxelles-Belgium
- The scope was amended and approved as follows:

Standardization in the field of nanotechnologies that includes either or both of the following:

- ✓ i) understanding and control of matter and processes at the nanoscale, typically, but not exclusively below 100 nanometres in one or more dimensions, where the onset of size dependent phenomena usually enables novel applications;
- ✓ ii) utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules or bulk matter, to create improved materials, devices and systems that exploit these new properties.

CEN TC 352 Title and Scope

.../...

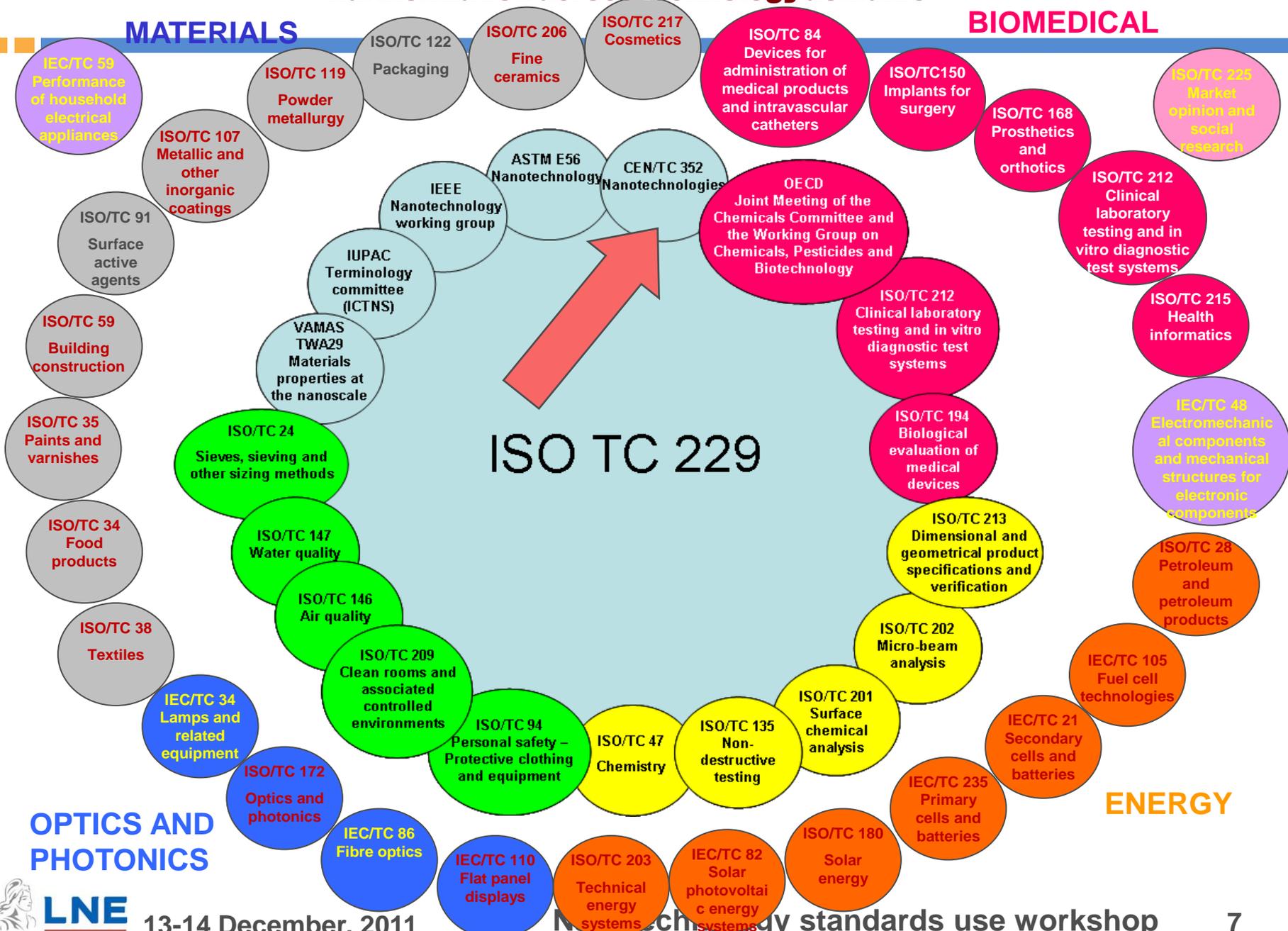
- Specific tasks include developing standards for: classification, terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; science-based health, safety and environmental practices ; and nanotechnology products and processes. Standards in each of these areas could be specific to a product, process or industry.
- Liaison will be ensured with relevant national, regional and international standardization organizations and with other relevant bodies, organizations and groupings worldwide. For topics of mutual interest to ISO (ISO/TC 229 nanotechnologies) and CEN, it is expected that work should be carried out under the Vienna Agreement with ISO lead.

Harmonization across technology domains

MATERIALS

BIOMEDICAL

ISO TC 229



- **CEN/TC 352 Nanotechnologies : Business Plan**
- CEN/TC 352 will engage 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; and nanotechnology products and processes.
- 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.

- In 2006, CEN/TC 352 established a strategy group to track the developments in TC 229. It was accepted that such a group should act in an advisory role to TC 352, rather than work independently, and that TC 352 should circulate any recommendations from the group, prior to communicating with ISO/TC 229.
- A Resolution was passed to establish the strategy group with terms of reference.

Commission mandate M409

- Commission Mandate M/409 was addressed in 2007 to CEN, CENELEC and ETSI for the elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials.
- CEN TC 352 Strategy group was entrusted with the drafting of the Report from CEN/TC 352 Nanotechnologies to EC.
- The report was issued in April 2008.

Commission mandate M409

- The European Commission, in its mandate M/409, asked CEN, CENELEC and ETSI to provide a report on a possible programme of standards to take into account the specific properties of nanotechnology and nanomaterials.

The mandate broadly calls for information to be presented on:

- ✓ - current standards relevant to nanotechnologies that may need to be revised;
- ✓ - new standards needed;
- ✓ - deliverables other than full European standards (ENs) that may be appropriate;
- ✓ - the availability of stakeholders, and requirements for their engagement in the standardization process.

Commission Mandate M461

- In February 2010, CEN received M/461 Standardization Mandate to CEN, CENLEC and ETSI for standardisation activities regarding nanotechnologies and nanomaterials.

- CEN BT decided to:
 - ✓ accept in principle M/461 ‘Standardization Mandate to CEN, CENLEC and ETSI for standardisation activities regarding nanotechnologies and nanomaterials’;
 - ✓ ask CEN/TC 352 ‘Nanotechnologies’ to take the leadership for the coordination in the execution of M/461 and to contact the relevant Technical Committees and interested stakeholders as appropriate.

Commission Mandate M461

M/461 requests CEN, CENELEC and ETSI to develop the standardization deliverables avoiding any duplication of work with other organizations and listed in Annexes I and II of the mandate, and in particular:

- Annex I - Characterisation of and exposure from nanomaterials
The ESO's are invited to develop:
 - ✓ a. As interim output: a roadmap for the development of the deliverables requested as well as Technical Specifications;
 - ✓ b. **As final output: European Standards for:**
 - **i. methodologies for characterisation of nanomaterials in the manufactured form and prior toxicity and ecotoxicity testing,**
 - **ii. sampling and measurement of workplace, consumer and environmental exposure to nanomaterials,**
 - **iii. methods to simulate exposures to nanomaterials.**
- Annex II - Health, Safety, and Environment
The ESO's are requested to develop guidance documents and protocols in relation to occupational handling and exposure as identified in the response to M/409.

- 45 items are identified that are relevant to 12 different CEN, ISO or IEC technical committees. A consultation to those TCs was sent to identify interest and possible development of the work program.
- An annual appointment with EC - DG Enterprise was organized in April 2011 with the Chairman, Secretariat and CEN representative to maintain a good level of communication on M461 and the CEN TC 352 work program.

Mandate M461 Roadmap

- A roadmap outlining how the mandate is addressed was sent to EC. The tentative timetable for its execution is continuously updated.
- 5 CEN TCs, 6 ISO TCs and 1 IEC TC (including ISO TC 229 and CEN TC 352) are identified to be involved and concerned under the mandate; CEN TC 352 has taken the lead for the coordination and circulation of relevant information to CEN BT and concerned ISO and CEN TCs.

Report to CEN BT TCMG

Execution of mandate M/461 — Final roadmap and timetable

Submitted by CEN/TC 352, July 2011

Report to CEN BT TCMG



Nanotechnologies

Date: 2011-09-12

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Results on the roadmap consultation for possible New Work Item Proposals under TCs Execution of mandate M/461

FOLLOW UP

CEN/TC 352 members: For discussion at the next CEN/TC352 meeting on 14th September 2011.

According to an enquiry concerning the execution of mandate M/461 "Standardization activities regarding nanotechnologies and nanomaterials", the following relevant Technical Committees (CEN, ISO and IEC) answered regarding their intention to launch a New Work Item Proposal (see request for road map updating in document CEN/TC 352 N 153 circulated from 2011/04/22 to 2011/05/04).

COMMENTARIES/ DECISIONS

Some TCs requested an extension of this above deadline. In order to give a chance for all TCs to answer, it was decided to wait until the next CEN/TC 352 meeting.

As CEN/TC 352 "Nanotechnologies" is requested to submit a roadmap for execution of mandate M/461 to the CEN/BT/TCMG, the following draft report is submitted to the CEN/TC 352 discussion and adoption at the next CEN/TC352 meeting on 2011/09/14 prior to its circulation to CEN/BT/TCMG for final approval.

A synthesis of the answer is given in page 3 where **main information is underlined in yellow**.

SOURCE

CEN/TC352 secretariat

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http://www.afnor.org - SIRET 775 724 818 0005

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

Topic	Responsible TC	Priority	MI number (if available)	TCs answers received	MIIP
PROcedures on manufactured nanomaterials relevant to laboratory exposure	CEN/TC 107	10	10	CEN/TC 107 has a member as the TC MIIP and is also a member of the TC MIIP. The response will be sent to the TC MIIP by the end of the year.	MIIP response received

*From approval of programme and findings, where appropriate - to be agreed with relevant committee (s)

Draft report to CEN BT TCMG

Execution of mandate M/461 — Final roadmap and timetable

Submitted by CEN/TC 352, September 2011

Introduction :

Mandate M/461 identifies four areas for standards development:

- Methodologies for nanomaterial characterization in the manufactured form and before toxicity and eco-toxicity testing;
 - Sampling and measurement of workplace, consumer and environment exposure;
 - Methods to simulate exposures to nanomaterials;
 - H, S & E (health, safety and the environment)
- The first three of which are covered in Annex I and the fourth in Annex II of the mandate M/461.
- A "master list" of potential topics covering the areas identified was prepared. For each of the topics listed, the roadmap tables below identify the following:
- the standardization committee (in CEN or ISO with the most relevant scope for developing the document(s));
 - the most appropriate deliverable;
 - an approximate timetable for its delivery following completion of all necessary agreements to undertake the work.

Note that in all cases, a draft timetable of three years has been taken for document delivery following acceptance of a new work item proposal by the relevant committee. However, as the development of certain topics will be dependent on the completion of standards for other, contributory topics or of pre- or co-ognitive research (ENR/CNR), estimated timetables for some documents are considerably longer than the three year default.

In addition to the CEN and ISO TCs identified in the tables, it is recognised that other stakeholders (in particular the OECD Working Party on Manufactured Nanomaterials; might also need to be actively involved in the development of specific topics.

EXECUTION OF MANDATE M/461 - ROADMAP (Version 2011-05-16)

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

Topic	Responsible TC	Priority	MI number (if available)	TCs answers received	MIIP
EN: chemical characterisation					
• Surface analysis techniques	ISO/TC 281	13	13	ISO/TC 281 wishes the adoption of ISO/TC 281-13 to be restricted to chemical analysis with no extension to biological analysis.	To be confirmed
• Application of existing methods to nano objects	ISO/TC 281	13	13	ISO/TC 281 is interested in participating	To be confirmed
• Nanoparticle characterisation techniques	ISO/TC 281	13	13	ISO/TC 281 is interested in participating	To be confirmed
• Application of existing methods to nano objects	ISO/TC 281	13	13	ISO/TC 281 is interested in participating	To be confirmed
• Nanoparticle characterisation techniques	ISO/TC 281	13	13	ISO/TC 281 is interested in participating	To be confirmed
EN: optical characterisation - application to nano objects	CEN/TC 107	10	10	CEN/TC 107 is "conducting the required work and is interested in participating in the development of the TC MIIP. The response will be sent to the TC MIIP by the end of the year.	To be confirmed
• X-ray diffraction	CEN/TC 107	10	10	CEN/TC 107 is "conducting the required work and is interested in participating in the development of the TC MIIP. The response will be sent to the TC MIIP by the end of the year.	To be confirmed
• Electron diffraction	ISO/TC 281	13	13	ISO/TC 281 is interested in participating	To be confirmed
• EN: microscopy (shape, aspect ratio, roughness, etc.)	ISO/TC 281	13	13	ISO/TC 281 is interested in participating	To be confirmed

*From approval of programme and findings, where appropriate - to be agreed with relevant committee (s)

3. Methods to simulate exposures to nanomaterials

Topic	Responsible TC	Priority	MI number (if available)	TCs answers received	MIIP
TCs responses on laboratory approaches and methods for the specific production of:					
• Inhalation	CEN/TC 107	10	10	CEN/TC 107 is interested in participating	To be confirmed
• Ingestion and environmental	CEN/TC 107	10	10	CEN/TC 107 is interested in participating	To be confirmed
• Skin contact and environmental	CEN/TC 107	10	10	CEN/TC 107 is interested in participating	To be confirmed
• Eye contact and environmental	CEN/TC 107	10	10	CEN/TC 107 is interested in participating	To be confirmed
• Skin contact and environmental	CEN/TC 107	10	10	CEN/TC 107 is interested in participating	To be confirmed
• Eye contact and environmental	CEN/TC 107	10	10	CEN/TC 107 is interested in participating	To be confirmed

*From approval of programme and findings, where appropriate - to be agreed with relevant committee (s)



Execution of mandate M/461

List of involved Technical Committees :

- CEN/TC 137 Assessment of workplace exposure to chemical and biological agents
- CEN/TC 138 Non-destructive testing
- CEN/TC 182 Protective clothing including hand and arm protection and lifejackets
- CEN/TC 195 Air filters for general air cleaning
- CEN/TC 230 Water analysis
- CEN/TC 245 **Textiles and textile products = Not listed in the involved TCs but reference given in the replies received**
- CEN/TC 352 Nanotechnologies

- ISO/TC 24/ISO4 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 229 Nanotechnologies

IEC/TC 113 Nanotechnology standardisation for electrical and electronic products and systems

Synthesis of the replies received (TCs / WI numbers of master list):

TCs	WI numbers of master list
CEN/TC 137	13; 17; 20 but other WI: 24 but cooperation with ISO/TC 146/ISO 21WG 1 Air quality
CEN/TC 138	2 "X-ray diffraction" is outside the CEN/TC 138 scope
CEN/TC 182	Not cooperated with 25 "PPE" and propose to drop CEN/TC 182 from the roadmap
CEN/TC 195	25 but cooperation with ISO/TC 142
CEN/TC 230	6 + ISO/TC 147; 14; 16 + ISO/TC 147 Water quality + TC 190 Soil quality + CEN/TC 202 Characterization of waste; 18 + ISO/TC 147 + 190/SC 7; 20 + ISO/TC 147/SC 5; 21 + ISO/TC 147 + TC 190/SC 7; 26
CEN/TC 248	13
CEN/TC 352	13; 14; 20; 27; 28; 30; 34; 35; 36; 37
ISO/TC 24/SC4	3; 4; 5; 9; 11; 12; 15; 19; 26
ISO/TC 142	25 + CEN/TC 195
ISO/TC 194	13
ISO/TC 201	1; 8; 10

4. Health, Safety and the environment (H, S & E)

Topic	Responsible TC	Priority	MI number (if available)	TCs answers received	MIIP
TCs responses on work, handling of manufactured nanomaterials and other manufactured nanomaterials (including nanomaterials produced in the laboratory)	CEN/TC 107	10	10	CEN/TC 107 is interested in participating	To be confirmed
TCs responses on assessment, testing and detection of nanoparticles and other manufactured nanomaterials	ISO/TC 281	13	13	ISO/TC 281 is interested in participating	To be confirmed
TCs responses on detection and exposure (biomarkers) in manufactured nanomaterials	CEN/TC 107	10	10	CEN/TC 107 is interested in participating	To be confirmed

*From approval of programme and findings, where appropriate - to be agreed with relevant committee (s)



Nowadays...

- 4 ISO standards have been published as ISO EN standards
 - ✓ Endotoxin test on nanomaterial samples for in vitro systems – Limulus amoebocyte lysate (LAL) test (ISO 29701:2010)
 - ✓ Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method (ISO 10801:2010)
 - ✓ Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing (ISO 10808:2010)
 - ✓ Terminology and definitions for nanoobjects - Nanoparticle, nanofibre and nanoplate (ISO/TS 27687:2008)

- 2 draft standards under Vienna agreement are still going on
 - ✓ Guidance on methods for nanotribology measurements (ISO/DTR 11811:2010)
 - ✓ Guidance on the labelling of manufactured nano-objects and products containing manufactured nano-objects (ISO/TS 13830:2011)

- 4 new work items were endorsed in September 2011 and are about to start
 - ✓ Nano- responsible development : integration of risk and benefit assessment in the production, marketing and use of nanotechnologies, nanomaterials and/or products incorporating nanomaterials
 - ✓

But M461 is only one face of the coin

- CEN TC 352 is entitled to develop any documentary standards addressing protocols for measurement and characterization (including procedures for calibration); health, safety and environmental issues; and nanotechnology products and processes (see business plan).

Standards in each of the above areas could be specific to a product, process or industry. CEN/TC 352 is asked to prepare standards that are as generic as possible and thereby applicable to as wide a range of industries and authorities as possible.

Thus we are welcoming any initiative in that respect.... in providing either technical materials and/or relevant expertise to bring science into standards, as f.i. running open calls for proposals addressed by EC DG Research

Out of the 2012 EC open calls

Theme 4 – NMP - Nanosciences, Nanotechnologies, Materials and new Production Technologies – LARGE 2012

■ II.1.3 Ensuring the safety of Nanotechnology

- NMP.2012.1.3-1 Systematic investigations of the mechanisms and effects of engineered nanomaterial interactions with living systems and/or the environment
- NMP.2012.1.3-2 Modelling toxicity behaviour of engineered nanoparticles
- NMP.2012.1.3-3 Regulatory testing of nanomaterials

Regulatory testing of nanomaterials

■ Objectives/targets:

- Building on ongoing work
- Necessary to secure innovation on nanotechnologies
- Aiming at providing the necessary mass of data on materials and their behaviour
- Input to the OECD – WPMN
- Laboratories working in network
- Results communication compulsory
- International cooperation encouraged

■ Expected Impact:

- The project should establish seamless collaboration among authorities of the MS governments with regard to the knowledge required for appropriate risk management in this field. This collaboration should be complemented by solid mechanisms networking state and private laboratories in nanotechnology toxicity testing and exposure control.

Theme 4 – NMP - Nanosciences, Nanotechnologies, Materials and new Production Technologies – CSAs 2012

■ NMP.2012.4.0-2 Support for standardisation needs – supporting actions

- Build on the scientific and technical achievements of NMP projects, or clusters of projects
- Address the preparation of standards and metrology issues
- Deliver the elements needed to fully achieve the final standards
- Liaise in an appropriate manner with ongoing activities by National and European Standardization Organizations
- Active participation of representatives of technology providers and potential end-users
- Support to EU policies

Thank you for your kind attention...