



STANDARDIZATION

A FRAME
PROGRESS
FOR EVERYONE

EUROPEAN STANDARDIZATION IN
NANOTECHNOLOGIES AND
RELATION WITH INTERNATIONAL
WORK.

HOW STANDARDIZATION CAN
HELP INDUSTRY AND
REGULATORS IN DEVELOPING
SAFE PRODUCTS?

9 NOVEMBER 2016,
NANOSAFE 2016,
GRENOBLE, FRANCE

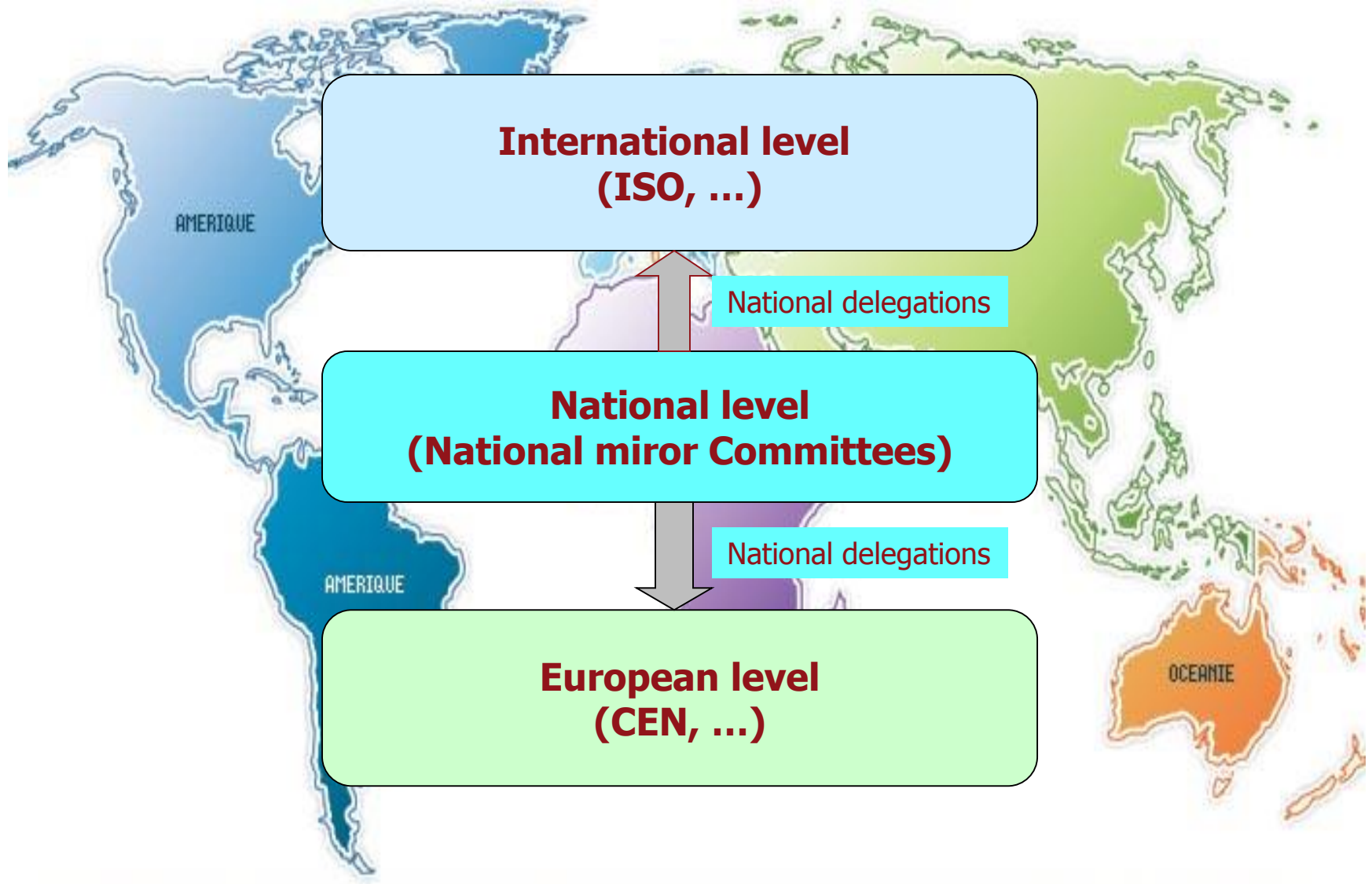
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afnor
NORMALISATION

Standardisation in France, Europe and the World

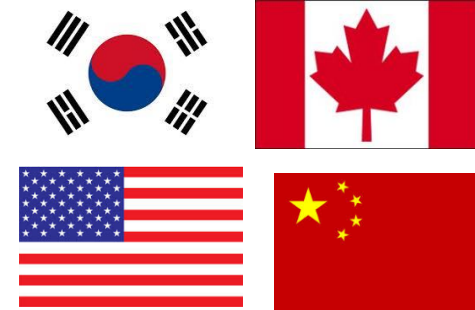


WHICH STRUCTURES ?

ISO standards:
Voluntary transposition

37 members

International
ISO/TC 229



National
e.g. :
AFNOR X457

33 members

European
CEN/TC 352



EN standards:
Compulsory
transposition

CEN/TC 352 NANOTECHNOLOGIES – 1ST ROLE: COORDINATION ACTIVITIES

- **EC recognized the need for standards in nanotechnologies and nanomaterials and asked to develop European standards in relation to Mandate M/461 which identified 4 areas for standards development:**
 - Methodologies for characterization of nanomaterial in the manufactured form and prior toxicity and eco-toxicity testing;
 - Sampling and measurement of workplace, consumer and environment exposure to nanomaterials
 - Methods to simulate exposures to nanomaterials
 - H, S & E (Health, Safety and Environment)

- **CEN/TC 352 is in charge to take the leadership for the coordination activities with other Technical Committees concerned by M/461:**
 - ➔ **Roadmap ([Nanotechnologies CEN webpages](#)):**
 - 46 Potential topics covering the four areas
 - 15 Technical Committees have been identified as potentially involved
 - 41 others Technical Committees and stakeholders possibly interested

3 TCs develop EN according to the mandate M461

**CEN/TC 137 Assessment
of workplace exposure
to chemical and
biological agents**

• **9 deliverables**

**CEN/TC 195 Air filters for
general air cleaning**

• **2 deliverables**

**CEN/TC 352
Nanotechnologies**

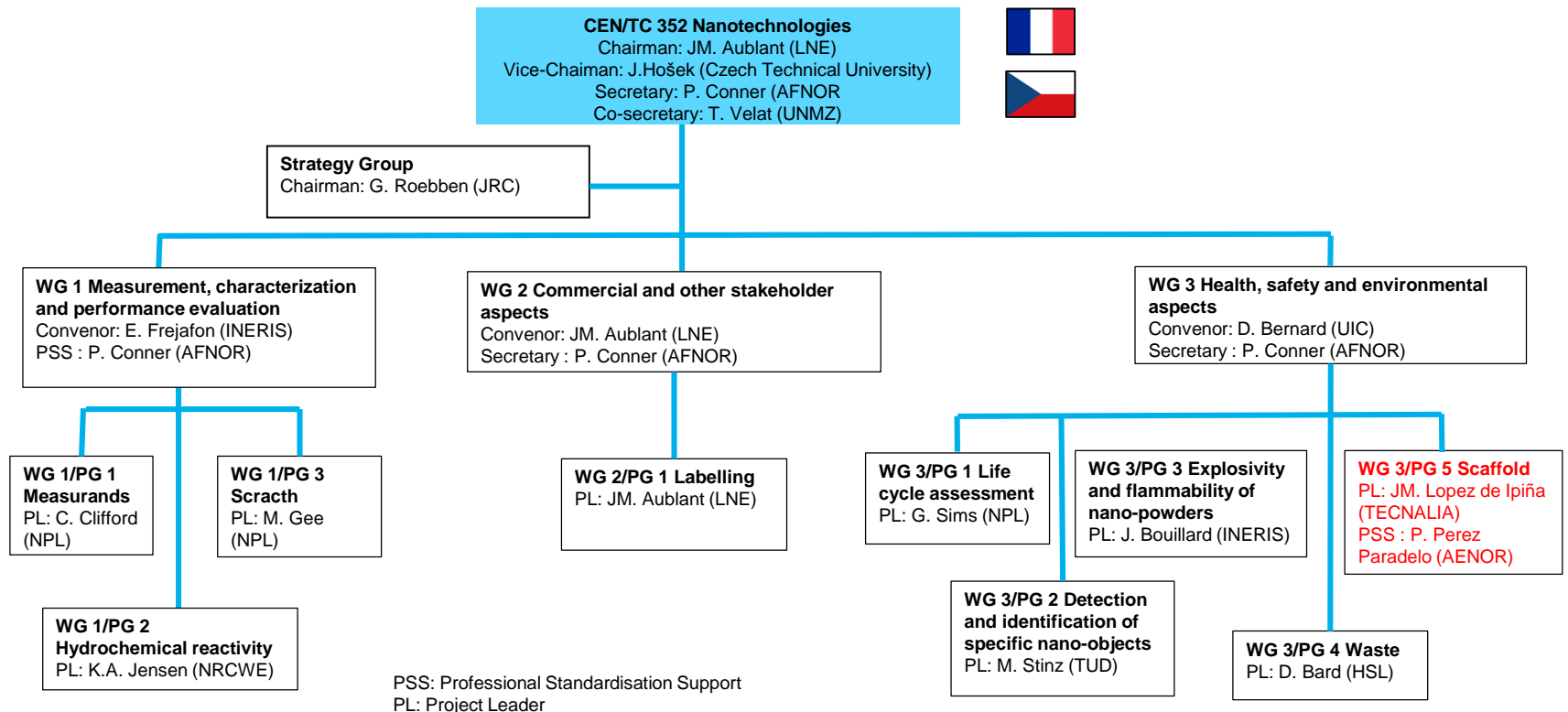
• **5 deliverables**

CEN/TC 352 NANOTECHNOLOGIES – 2ND ROLE: STANDARDIZATION ACTIVITIES

- **CEN/TC 352** : - 33 National Standardization Bodies with 13 regular countries
 - 14 standards already published + 13 draft standards
 - Establishes generic standards applicable to a wide range of industries

- **Scope** : Standardization in the field of nanotechnologies that includes either or both of the following:
 - 1) **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**;
 - 2) 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**. 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

STRUCTURE OF CEN/TC 352



CEN/TC 352/WG 1 “Measurement, characterization and performance evaluation” (France – 44 experts)

CEN/TC 352/WG 1/PG 1 “Measurands” (UK)

- [FprCEN/TS 17010 Guidance on measurands for characterizing nano-objects and materials that contain them](#) → related to M/461 + Publication Nov./Dec. 2016 ?
 - Provides guidelines for the **identification of measurands to characterize nano-objects and their agglomerates and aggregates** and to **assess specific properties relevant to the performance of materials** that contain them. It provides guidance for relevant and **reliable measurement**

CEN/TC 352/WG 1/PG 2 "Hydrochemical reactivity" (Denmark)

- [prCEN/TS Determination of hydrochemical reactivity of nano-objects for toxicity studies](#)
 - Provides **specification of a test method** to determine the hydrochemical reactivity of nano-objects

CEN/TC 352/WG 1 “Measurement, characterization and performance evaluation”

CEN/TC 352/WG 1/PG 3 “Scratch” (UK)

• prCEN/TS Nano- and micro-scale scratch testing

- To specify a method for measuring the friction and wear resistance to scratching for advanced materials and coatings by means of nano- and micro- scale scratch experiments

CEN/TC 352/WG 2 “Commercial and other stakeholder aspects” (France – 61 experts)

CEN/TC 352/WG 3 “Health, safety and environmental aspects” (France - 60 experts)

CEN/TC 352/WG 3/PG 1 “Life Cycle Assessment” (UK)

⇒ [prCEN/TS Nanotechnologies – Guidelines for Life Cycle Assessment – Application of EN ISO 14044:2006 to Manufactured Nanomaterials](#)

→ related to M/461

- Provides guidelines for application of LCA of specific relevance to Manufactured Nanomaterials, including their use in other products, according to EN ISO 14044. This guidance document **does not include incidental generated nanomaterials from non-nano sources**

CEN/TC 352/WG 3/PG 2 “Detection and identification of specific nano-objects” (Germany)

⇒ [prCEN/TS Guidance on detection and identification of nano-objects in complex matrices](#) → related to M/461

- Provides guidelines for detection and identification of nano-objects in complex matrices, **like liquid environmental compartments and waste water**. This TS assumes a prior **knowledge of the nature of the nano-objects like their chemical composition**. The selected detection and identification **methods are based on combination of size classification and chemical composition analysis**. Corresponding **requirements for sampling and sample preparation** will be given. Identification can also be supported e.g. by additional morphology characterisation. The document will **provide links to measurement method standards** if available

CEN/TC 352/WG 3 “H, S & E”

CEN/TC 352/WG 3/PG 3 “Explosivity and flammability of nano-powders” (France) ■ ■

- ⇒ [prCEN/TS Guidelines for determining protocols for the explosivity and flammability of powders containing nano-objects \(for transport, handling and storage\)](#) → related to M/461
 - Provides guidelines for **determining explosivity and flammability properties of manufactured nano-objects in powder form**. The explosivity and flammability properties have to be given in the safety data sheet for a **safe storage, handling and transport of any powder**

CEN/TC 352/WG 3 “H, S & E”

CEN/TC 352/WG 3/PG 4 “Waste“ (UK) 

⇒ [prCEN/TS Guidelines for the management and disposal of waste from the manufacturing and processing of manufactured nano-objects](#) → related to M/461

- Provides guidance for all waste management activities from the manufacturing and processing of manufactured nano-objects. **This guidance is of use to manufacturers and waste disposal companies.**
- This TS is **not intended** to provide guidance on the management and disposal of **nanocomposites, waste derived from consumer products** containing nano-objects or **waste containing only naturally occurring and/or incidental nano-objects**. Neither, this TS aims to give guidance on the management and disposal of **non-nanomaterials waste derived from the manufacturing and processing of manufactured nano-objects**.

CEN/TC 352/WG 3 “H, S & E”

CEN/TC 352/WG 3/PG 5 “Scaffold” (Spain)



• CEN/TR Manufactured nanomaterials (MNMs) in the construction industry. Guidelines for occupational risk management

- Provides guidelines on occupational risk management of MNMs in the construction industry. The aim is the particularization of guidelines **for implementation of OHSAS 18001 for MNMs risks on construction sector activities, including guidelines and best practices or risk management included in ISO 31000 applied to nano-risks.** The TS allows organizations of construction sector, **large and SMEs**, with an OHSAS model implemented to consider MNMs risks into their model, **and also companies with no experience in health and safety management systems**, particularly SMEs, to initiate the path to a complete OH&S management system with the implementation of MNMs Risk management as first step.

This document **can be applied in any type of organization in construction industry** regardless of type and size, in all its areas and levels. **Every subsector involved in construction cycle could apply the documents** but with different necessities, perceptions and criteria (**manufacture, building and civil construction and demolition**).

This TS is designed as a practical document with an structure that includes for every requirement a brief explanation on this requirement implementation and **specific recommendations based on the conclusions of SCAFFOLD work in product design, risk prevention, risk assessment and risk protection regarding MNMs use.**



Future work

Transposition of 2 existing ISO/TS into 2 CEN ISO/TS:

- **ISO/TS 80004-2:2015 Nanotechnologies – Vocabulary - Part 2: Nano-objects**
- **ISO/TS 80004-12 (2016?) Nanotechnologies - Vocabulary - Part 12: Quantum phenomena in nanotechnology**

4 Possible other standards

- **CEN/TS Guidance on measurement techniques relevant to different exposure routes: Ingestion**
- **CEN/TS Guidance on simulation approaches and models for the specific prediction of 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**
- **CEN/TS Guide to modelling (measurement, simulation and visualization) at the nanoscale**
- **CEN/TS or TR ? Nanocomposites - Guidance on ageing / particle release**

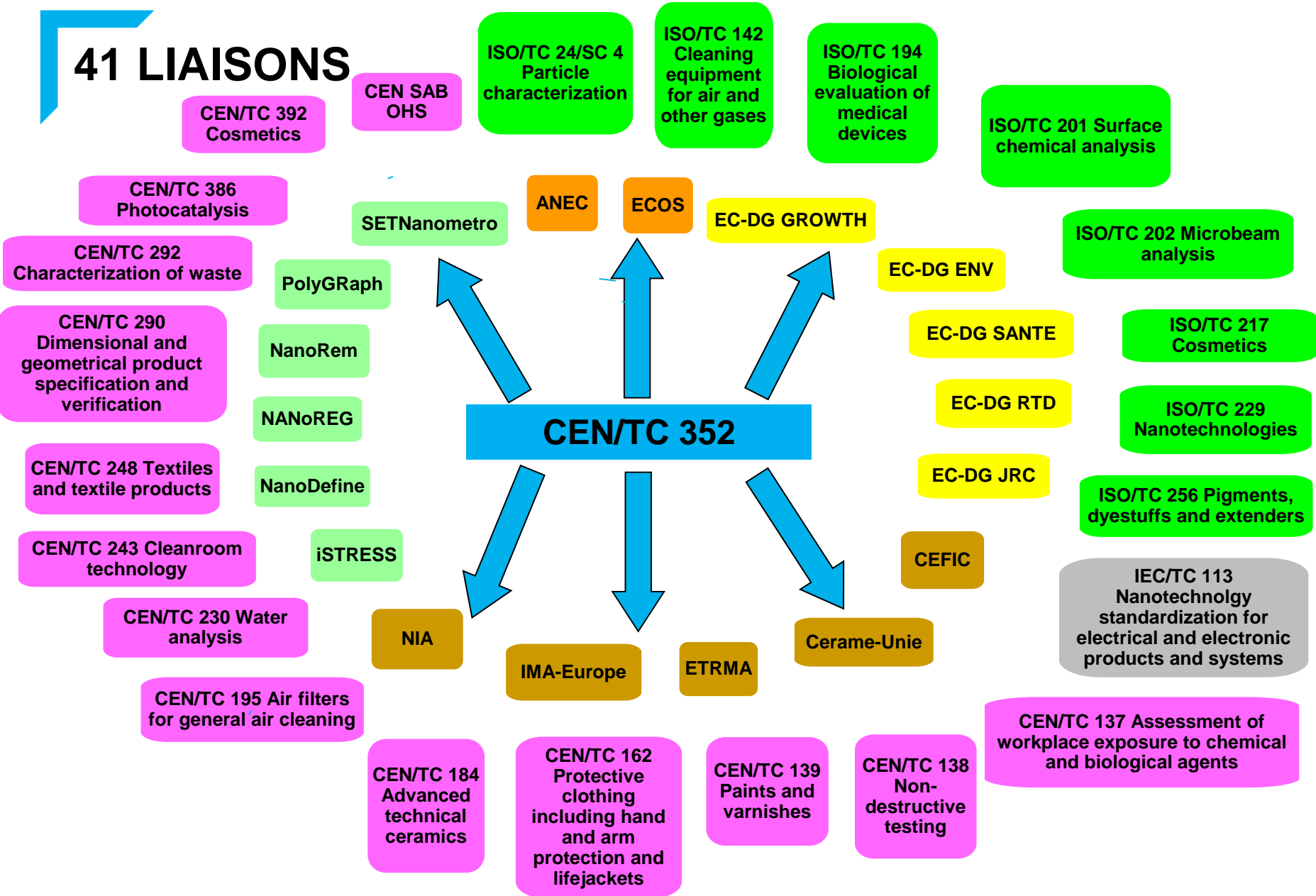
14 Standards Published

Standard	Title
EN ISO 10801:2010	Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method (ISO 10801:2010)
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EN ISO 10808:2010	Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing (ISO 10808:2010)
CEN ISO/TR 11811:2012	Guidance on methods for nano and microtribology measurements
CEN ISO/TS 13830: 2013	Guidance on voluntary labelling for consumer products containing manufactured nano-objects (ISO/TS 13830:2013)
CEN ISO/TS 27687:2009	Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate (ISO/TS 27687:2008)
EN ISO 29701:2010	Endotoxin test on nanomaterial samples for in vitro systems - Limulus amebocyte lysate (LAL) test (ISO 29701:2010)

Standards Published (end)

Standard	Title
CEN ISO/TS 12025:2015	Nanomaterials - Quantification of nano-object release from powders by generation of aerosols
CEN/TS 16937:2016	Guidance for the responsible development of nanotechnologies
CEN ISO/TS 17200:2015	Nanotechnology - Nanoparticles in powder form - Characteristics and measurements (ISO/TS 17200:2013)
CEN ISO/TS 80004-1:2014	Vocabulary – Part 1: Core terms " (ISO/TS 80004-1:2010)
CEN ISO/TS 80004-3:2014	Part 3: Carbon nano-objects (ISO/TS 80004-3:2010)
CEN ISO/TS 80004-4:2014	Part 4: Nanostructured materials (ISO/TS 80004-4:2011)
CEN ISO/TS 80004-6:2015	Part 6: Nano-object characterization
CEN ISO/TS 80004-8:2015	Part 8: Nanomanufacturing processes

41 LIAISONS



ISO/TC 229 NANOTECHNOLOGIES (LEAD BY UK)



- 37 Participating countries + 13 Observing countries

- 34 draft standards + 50 standards published

- **JWG 1 Terminology and nomenclature (Canada)**



Standards provide a common language for scientific, technical, commercial and regulatory processes

- **JWG 2 Measurement and characterization (Japan)**



Standards enable to identify nano-object in material samples

- **WG 3 Health, safety and environment (USA)**



Standards will improve occupational safety, consumer and environmental protection, promote good practice in the production, use and disposal of nano-materials and nanotechnology products

- **WG 4 Material specifications (China)**



Standards will specify the characteristics of manufactured nanoscale materials for use in specific applications

MAIN EVENT



Immediately preceding the EuroNanoForum 2017 conference, also in Malta

**Save the date:
June 20, 2017 in
Malta**

**2nd Open meeting
on
Standardisation for
Nanotechnologies
and Nanomaterials**



THANK YOU FOR YOUR ATTENTION



For participation to the work, please contact:

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