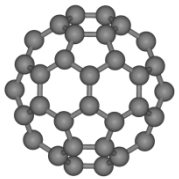
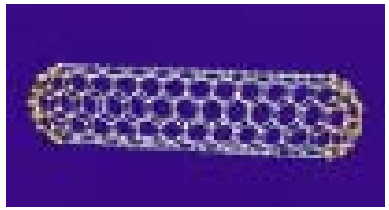
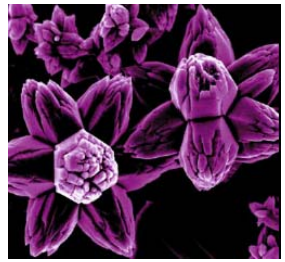






ISO TC 229 International Standards for Nanotechnology

Clive Willis

President, CWIC Inc.

Convenor JWG 1 for ISO TC 229 and IEC TC 113

Overview

Standards and standardization

- Role of standards
- Standardization organisations
- Development of formal standards

Standardization for nanotechnologies

- What needs standardizing, why and why now?
- The challenges of early standardization.
- Current status on terminology, measurement and EHS.

Standards

Standards can be of two types:

– Metrological standards *or* Written standards

Metrological or Measurement Standards:

- **Link to agreed international units**
  1. **Time**
  2. **Frequency**
  3. **Length**
  4. **Weight**
  5. **Chemical composition**
  6. **Etc.**
- **In order to:**
  1. **Ensure equivalence of entities**
  2. **Allow transactions to be meaningful**
  3. **Be a basis for applying regulations, etc.**

They are scientifically based and *ABSOLUTE*

They are *covered by international agreement*

They are not based on *CONSENSUS* but on *INTERNATIONAL COMPARISON*

Standards

Written Standards:

- **Provide agreed ways of:**
  1. **Naming, describing and specifying things,**
  2. **Measuring and testing things**
  3. **Managing things e.g. quality and environmental management**
  4. **Reporting things**
- **In order to:**
  1. **Support commercialisation, market development and established markets**
  2. **Provide a basis for procurement based on technical requirements and quality / environmental management**
  3. **Support appropriate legislation / regulation**

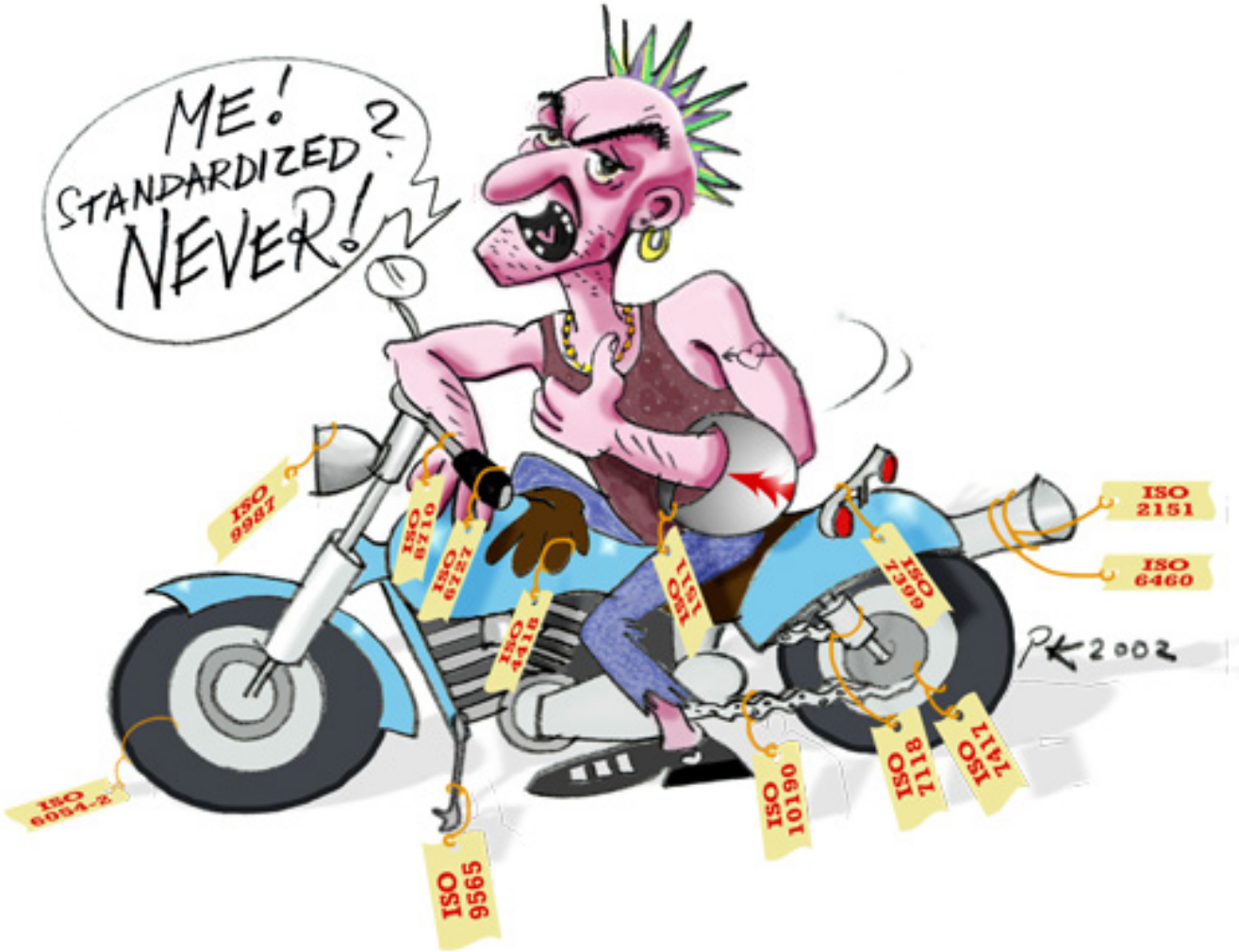
They can be *NORMATIVE*, defining what must be done

They can be *INFORMATIVE*, providing information only

They are *VOLUNTARY* unless called in a contract or regulation

They are based on *CONSENSUS* not necessarily unanimity

There are 567 ISO standards and other documents applying to road vehicles plus ISO 3779 covering the vehicle identification number (VIN)

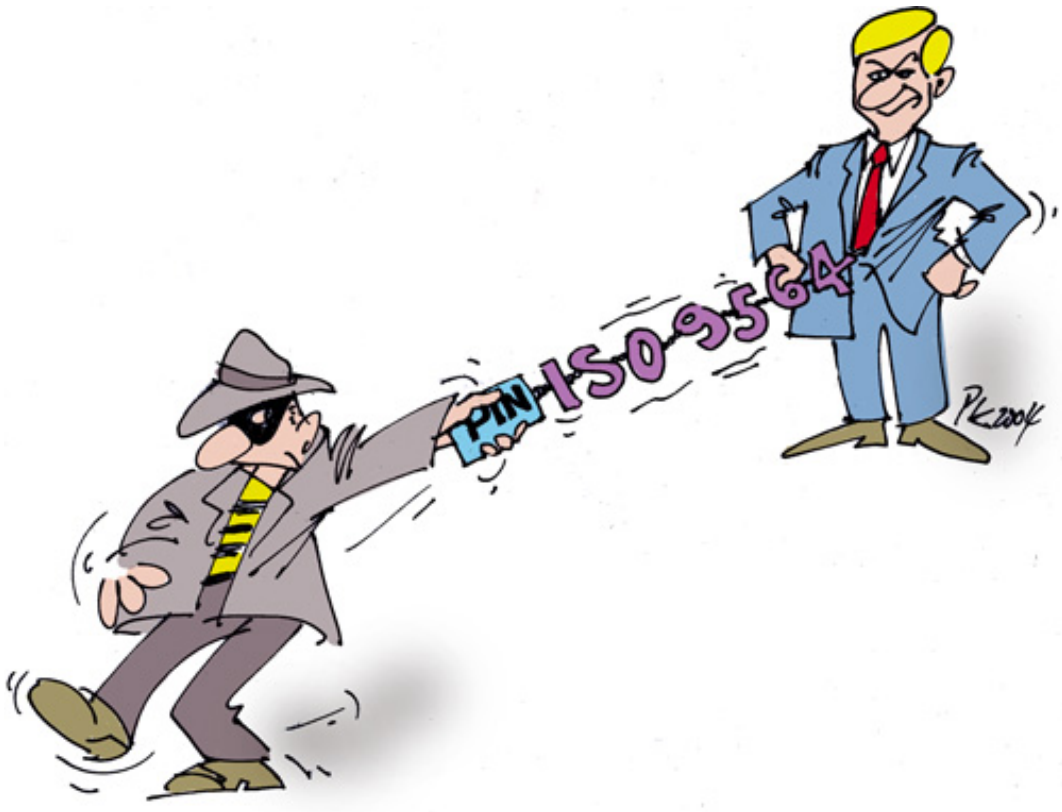


There are 193 ISO standards and other documents applying to fasteners

Even wine tasting glasses have a standard – ISO 3591, Sensory analysis – Wine tasting glass

ISO TC/145 has developed ISO 9186, Graphical symbols – Test methods for comprehensibility and for comprehension

ISO 9654-1, Banking – "Personal Identification Number management and security" provides instructions to financial institutions in the development, implementation and/or the operation of systems and procedures for the protection of PIN throughout their lifecycle.



ISO 10002:2004, Quality management -- Customer satisfaction -- Guidelines for complaints handling in organizations

ISO/TC 222 – “Personal financial planning” is developing standards in this area

Standardization

Standards can be:

- **FORMAL – developed by independent experts working under the auspices of a National, Regional or International standards body**
  - ***AFNOR, BSI, DIN, JIS, ... (NSBs)***
  - ***CEN, CENELEC, ETSI.....***
  - ***ISO, IEC & ITU***
- **INFORMAL – developed by a SDO (Standards Development Organisation)**
  - ***ASTM, IEEE, SAE, SEMI, VDI...(>600 SDOs IN US)***
- **PRIVATE – developed by a company or trade association**

FORMAL standards are:

- ***PROPOSED, DEVELOPED AND APPROVED by the members of the standards body (or an accredited organisation)***
- ***Based on CONSENSUS not necessarily unanimity.***

International Organization for Standardization (ISO)

INTERNATIONAL STANDARDS PROVIDE LEGITIMACY:

Standards are:

- ***Proposed, commented on and approved by members of the international community***
- ***Developed by experts nominated by members***
- ***Based on well established principle of CONSENSUS***
- ***VOLUNTARY***

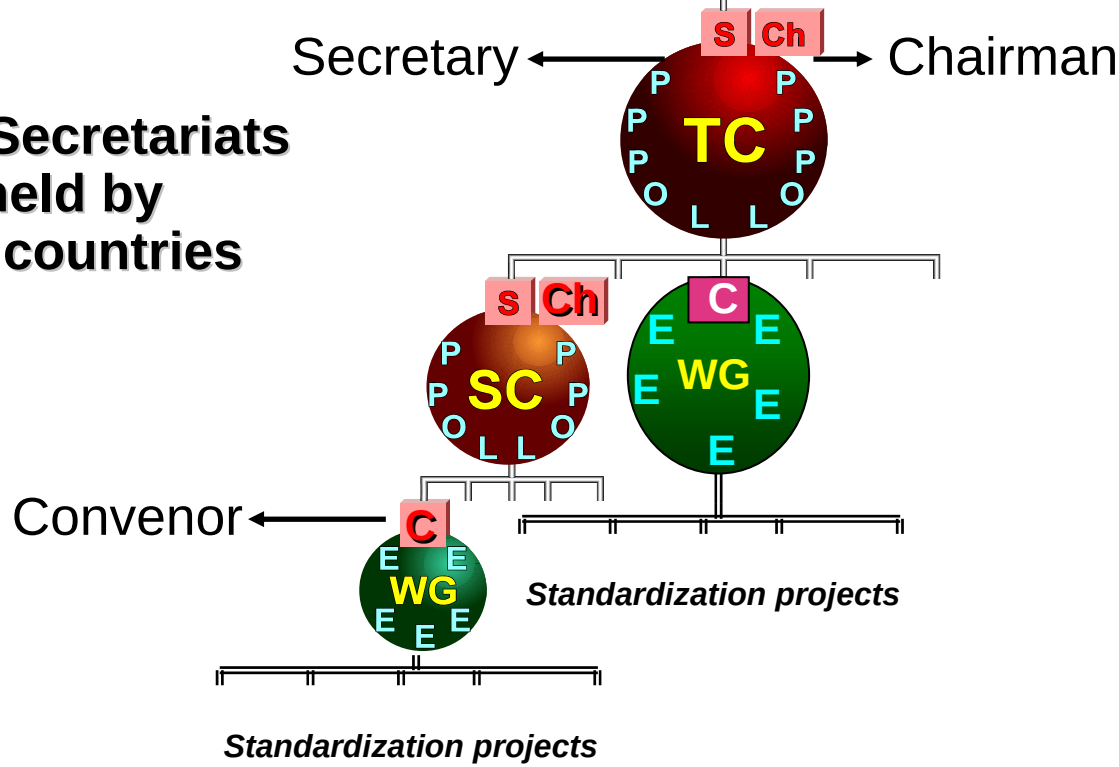
- **Standards provide critical elements of Governance through ISO 9001, 14001 (and ISO 26,000 – expected to be published in 2010).**
- **ISO structure includes committees on**
  - ***CERTIFICATION AND ASSESSMENT (CASCO),***
  - ***CONSUMER POLICY (COPOLCO),***
  - ***DEVELOPING COUNTRIES (DEVCO)***
  - ***REFERENCE MATERIALS (REMCO)***

Extent of ISO System

~150 full-time posts

ISO CENTRAL SECRETARIAT

More than 16,500 ISO Standards



~750 Secretariats held by ~40 countries

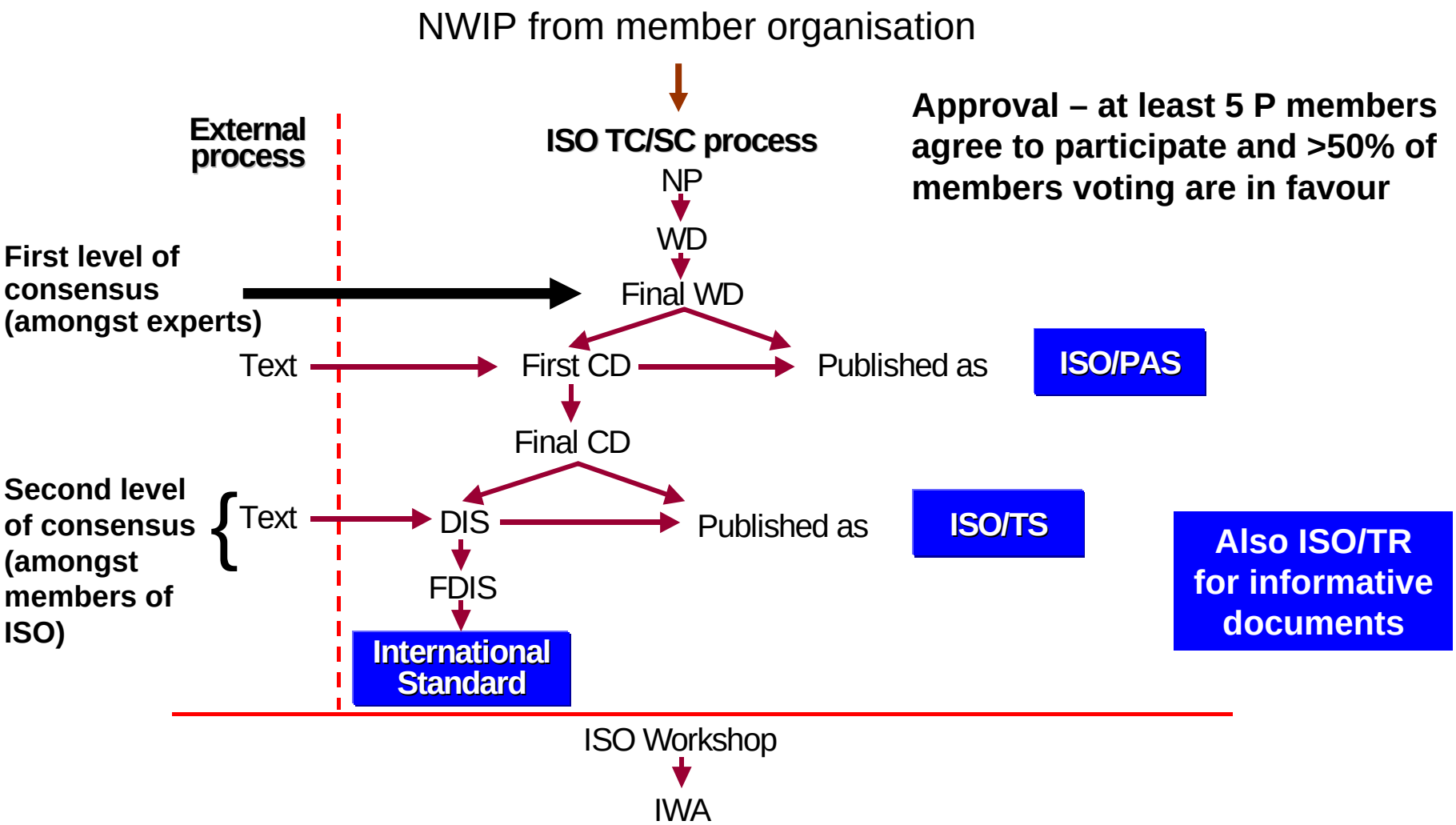
>200 TCs

>540 SCs

>2 250 WGs

~ 3,500 active projects

Development of International Standards
Process accommodates special needs



Major standardization issues for nanotechnologies

- ***Diversity of disciplines impacted by and contributing to nanotechnologies***
- ***Global impact***
- ***Rapid speed of development and apparent speed of commercialisation***
- ***Critical areas:***
  - *Coordination and harmonization across standards developers and stakeholders*
  - *Terminology*
  - *Measurement and characterization*
  - *Health, safety and environment*
  - *Material specifications*

ISO/TC 229 Nanotechnologies

- Established in June 2005
- 40 members – 32 “P” and 8 “O”
- (http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983)
- Liaisons with 16 other ISO TCs and 8 external bodies – IEC/TC 113, CEN/TCs 137 and 352, Asia Nano Forum, BIPM, EC JRC, OECD and VAMAS
- Exploring additional external liaisons for other groups (e.g. International Alliance for Nano-EHS Harmonization) and for emerging economies

IEC/TC 113
"Nanotechnology for electrical and electronic products"

- Established June 2006 with US Chair and German secretariat
- http://www.iec.ch/cgi-bin/procgi.pl/www/iecwww.p?wwwlang=e&wwwprog=dirdet.p&progdb=db1&css_color=purple&committee=TC&number=113
- 29 members - 15 "P" and 14 "O"
- Agreed to establish two Joint Working Groups with ISO TC/229:
  - JWG 1 – Terminology and nomenclature
  - JWG2 – Measurement and characterization
- Together with a third Working Group:
  - WG3 – Performance assessment

European Standardization Committee
CEN/TC 352 Nanotechnologies

- **Established November 2005 following a recommendation from CEN/BTWG 166**
- **UK chair and secretariat**
- **All 30 members of CEN are notionally members – around 12 active**
- **Works closely with ISO/TC 229 using the 'Vienna Agreement' for cooperative working.**
- **Developing a work programme to include areas of specific interest to Europe and areas that will be relevant to European legislation.**
- **Awaiting a Commission response to M409 "elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials", submitted in May 2008.**
- **Two working groups established at the last meeting:**
  - *WG 1 'Measurement, characterization and performance evaluation'*
  - *WG 2 'Commercial and other stakeholder aspects'*

What is different about the process for standards for Nanotechnology ?

- **Typically ISO works with commercially active fields where a broad knowledge base exists on products and processes.**

- **In 2004/2005 a decision evolved amongst the international community that standards must be developed for nanotechnology early, prior to the commercial development of the field and its applications.**

To avoid what was seen to have occurred with biotechnology

To take early steps towards the development of regulations

To ensure international harmonization of nanotechnology standards and regulations

Early action places a completely new set of challenges for the development of ***useful*** standards on a ***timescale*** that meets those needs

Why are early standards for nanotechnologies important ?

Standards will help to ensure that nanotechnology is developed and commercialised in an open, safe and responsible manner by supporting:

- ***safety testing, legislation and regulation***
- ***worker, public and environmental safety***
- ***commercialisation and procurement***
- ***patenting and IPR***
- ***communication about the benefits, opportunities and potential problems associated with nanotechnologies***

This will be achieved by providing agreed ways of:

- ***Naming, describing ,specifying ,measuring and testing things***
- ***Protocols for health and environmental safety testing, risk assessment and risk management***

Nanotechnology is a new field with new products, new processes and a new approach to applying science.

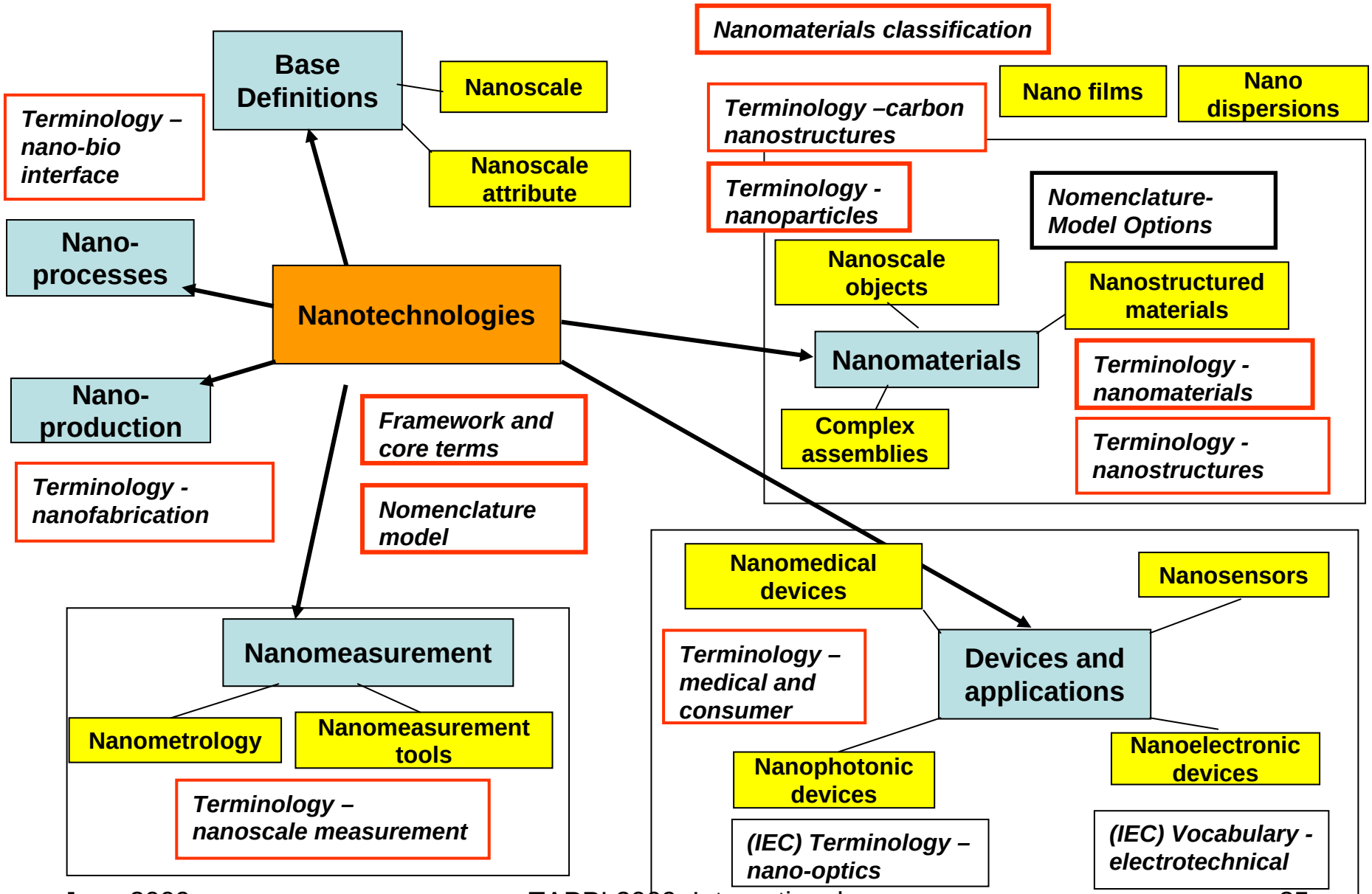
This and the diversity of the domains of applications of nanotechnology add an additional layer of major complexity to the development of early standards.

TC 229 – Horizontal activities 1

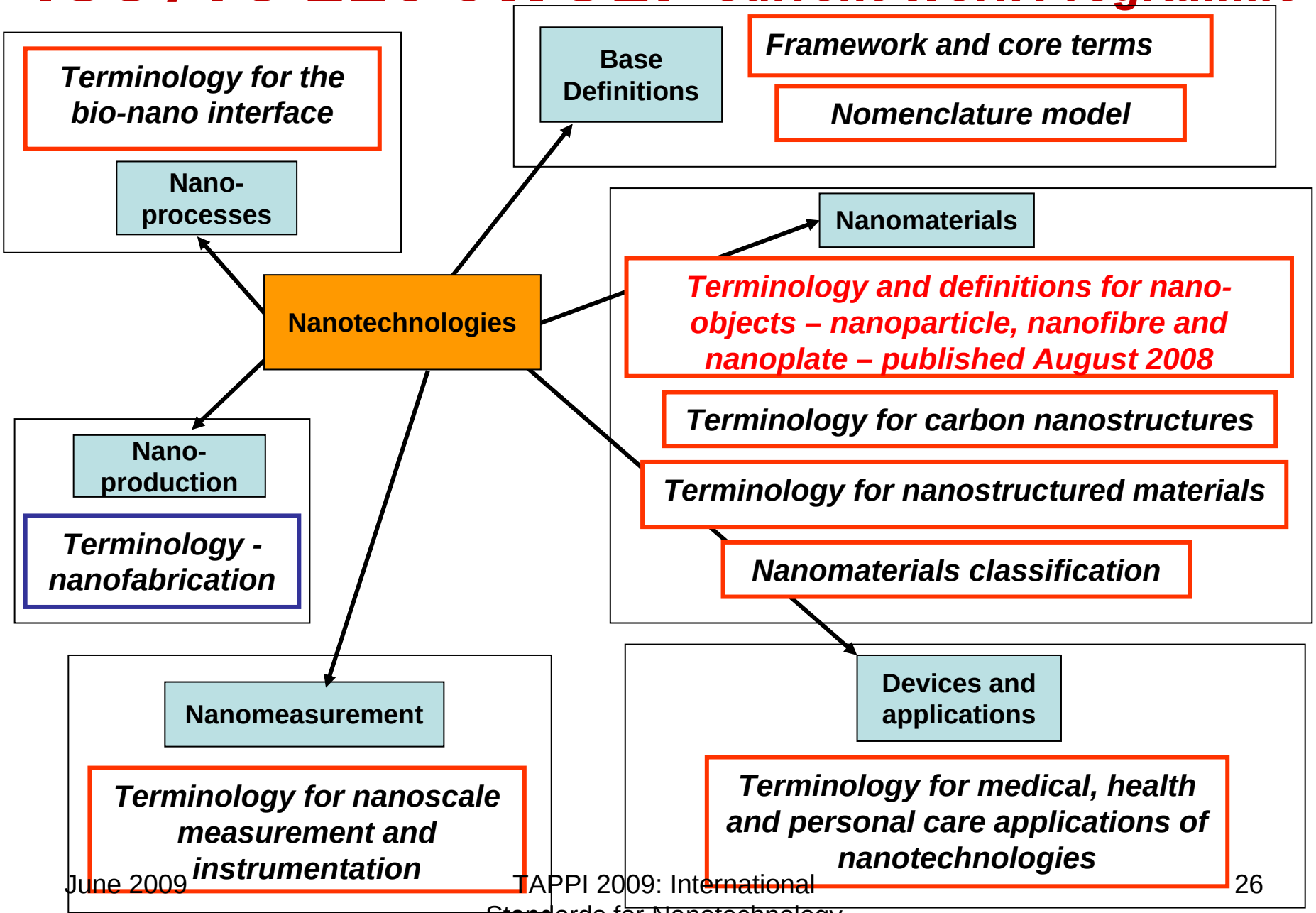
Terminology and Nomenclature (JWG 1)

"what you call it" - Convened by Canada

ISO/TC 229 JWG1: Strategic Roadmap



ISO/TC 229 JWG1: Current Work Programme



CORE DEFINITIONS

Core Term Definitions

nanoscale: **size range from approximately 1 nm to 100 nm**

- Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate.
- The lower limit in this definition (approximately 1 nm) is introduced to avoid single and small groups of atoms from being designated as nano-objects or elements of nanostructures, which might be implied by the absence of a lower limit.

Working Definitions

nanotechnology: the application of scientific knowledge to control and utilize matter at the nanoscale, where size-related properties and phenomena can emerge.

nanoscience: the systematic study and understanding of matter, properties and phenomena related to the nanoscale.

Core Term Definitions: Nanomaterials

- ***nano-object:*** material with one, two or three external dimensions in the nanoscale
  - Generic term for all discrete **nanoscale objects.**
- ***nanostructured materials***
- ***nanofilms***
- ***nanocoatings***
- ***complex nanostructured assemblies***

Core Term Definitions: Nano-objects

- ***Nanoparticle:*** nano-object with all three external dimensions in the nanoscale
- ***Nanofibre:*** nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger
- ***Nanoplate:*** nano-object with one external dimension in the nanoscale and the two other external dimensions significantly larger
- ***Nanotube:*** hollow nanofibre
- ***Nanorod:*** solid nanofibre
- ***Nanowire:*** electrically conducting or semi-conducting nanofibre
- ***Quantum dot:*** crystalline nanoparticle that exhibits size-dependent properties due to quantum confinement effects on the electronic states
- ***nano-onion:*** spherical nanoparticle with concentric multiple shell structures
- ***nanocone:*** cone-shaped nano-object with two characteristic dimensions (diameters) in the nanoscale
- ***nanoribbon:*** nanofibre with one of its shorter dimensions much smaller than the other

CARBON NANO-OBJECTS

Definitions: Carbon nano-objects

- ***fullerene:*** molecule composed solely of an even number of carbon atoms, which form a closed cage-like fused-ring polycyclic system with twelve five-membered rings and the rest six-membered rings .

- ***fullerene derivative:*** compound that is formed from a **fullerene** molecule by modifying its structure and/or attaching an atom or a group of atoms

- ***endohedral fullerene:*** **fullerene derivative** with an additional atom or atoms enclosed within the **fullerene** shell

- ***metallofullerene:*** **endohedral fullerene** with a trapped metal ion or ions

- ***carbon nano-onion :*** **nano-onion** composed of carbon

Definitions: Carbon nano-objects

- ***carbon nanofibre:*** nanofibre composed of carbon
- ***graphitic nanofibre:*** nanofibre composed of **graphitic** layer structures
- ***carbon nanotube:*** nanotube composed of carbon (Usually consisting of curved graphene layers).
  - ***single-wall carbon nanotube:*** **carbon nanotube** of a single cylindrical **graphene** layer
  - ***multiwall carbon nanotube:*** ca**rbon nanotube** composed of concentrically nested multiple **graphene** sheets with interlayer distances similar to those of **graphite**
  - ***double-wall carbon nanotube:*** **carbon** nanotube composed of two concentrically nested single-wall carbon nanotubes,

Definitions: other nanoscale carbon materials

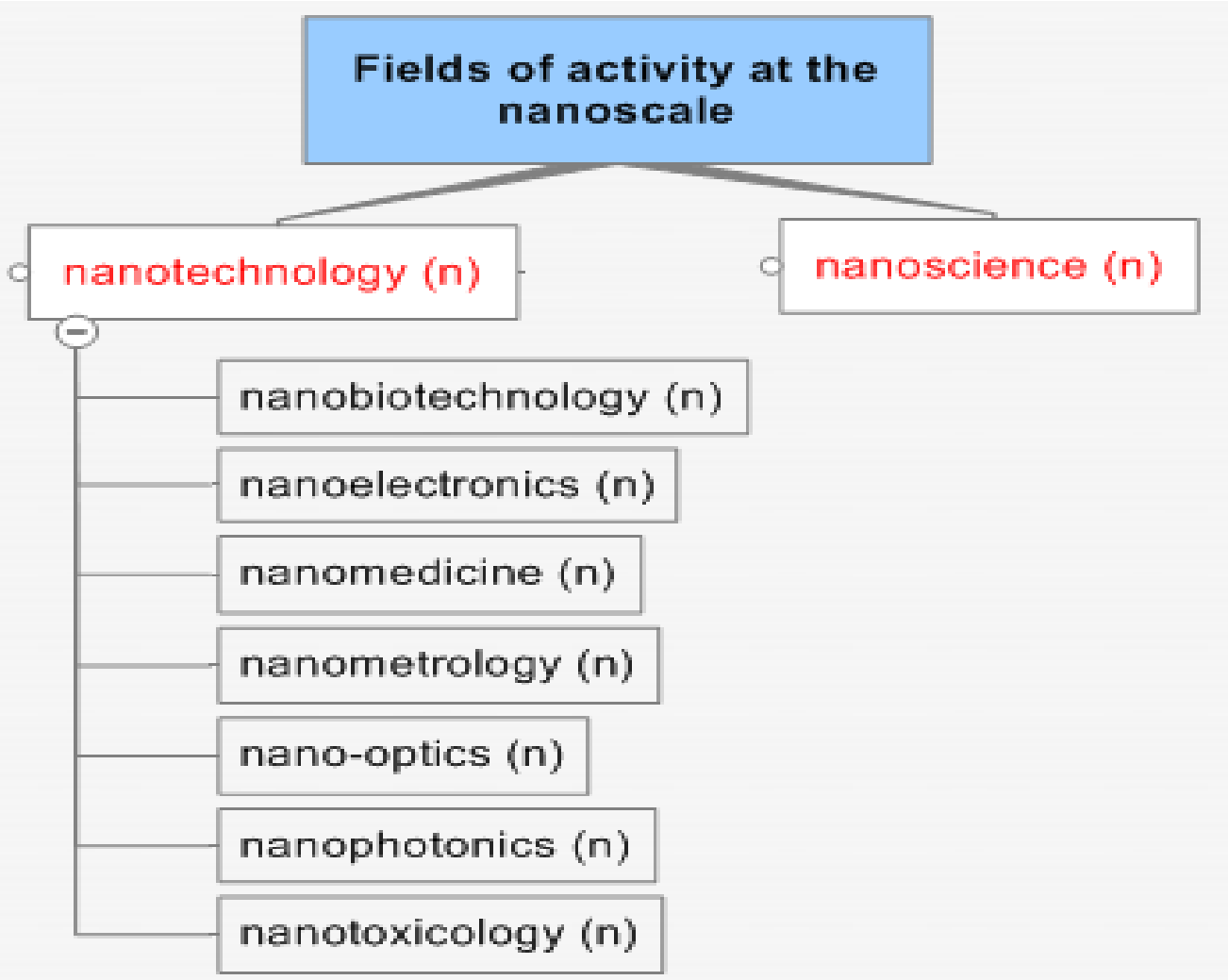
- ***diamond nanoparticles:*** related to a big group of carbon materials with very different production methods (explosive methods, chemical vapor deposition, physical vapor deposition and others), appearance, size, properties and application.

- ***carbon films:*** used commercially in the coatings industry to impart certain properties to materials - can be produced using a variety of different techniques such as cathodic arc, magnetron sputtering amongst others.

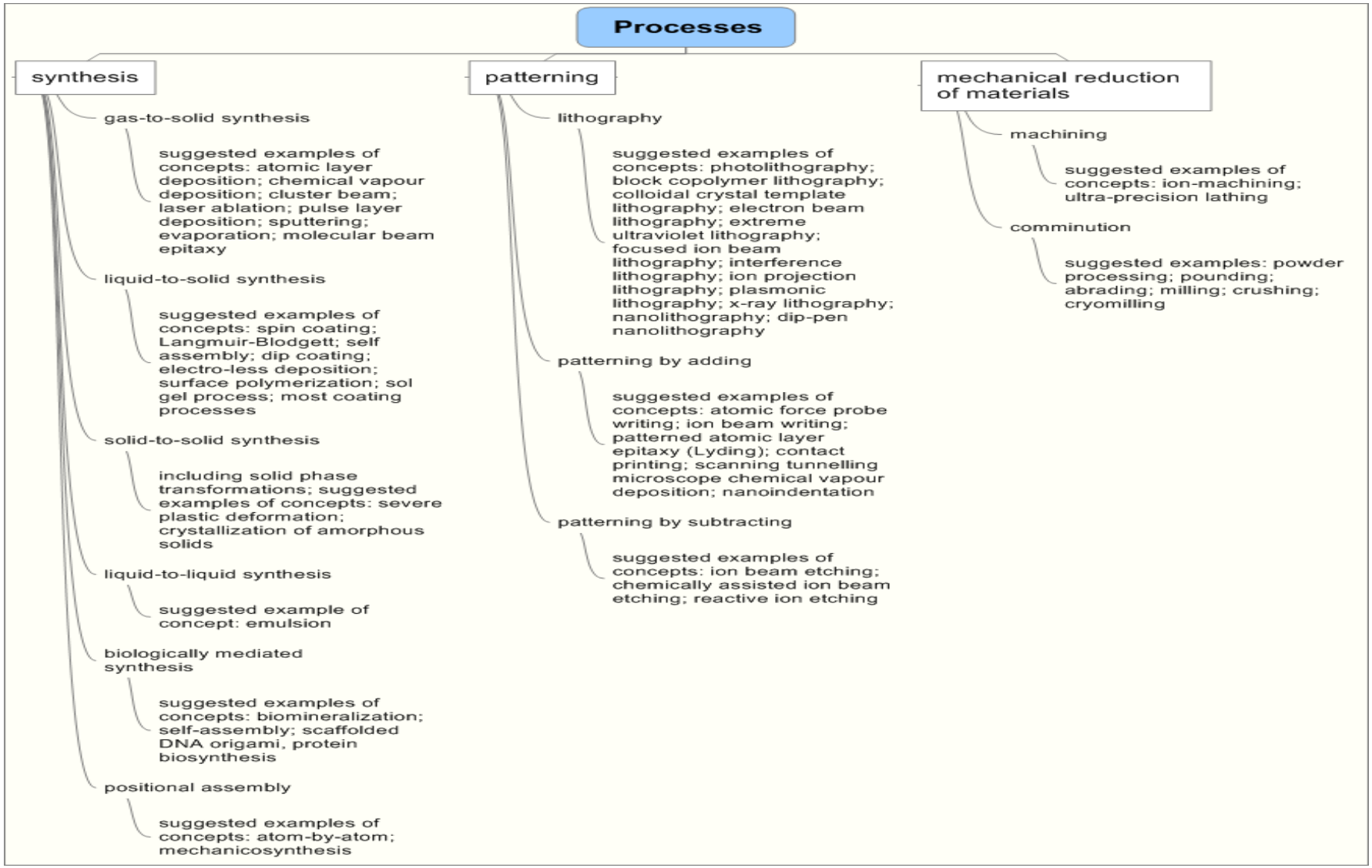
- ***carbon black:*** industrially manufactured colloidal carbon material in the form of spheres and of their aggregates with sizes below 1000 nm.

TERMINOLOGY FRAMEWORK

Terminology Framework: fields of activity



Terminology Framework: nanoprocesses



MOVING TOWARDS NOMENCLATURE

Nomenclature Models

- **ISO TC 229 is exploring potential models for Nomenclature** for nanomaterials and will collaborate with IUPAC to ensure appropriate treatment of chemical aspects

Nomenclature	General Concept	Nanoscale Concept
Structured assignment of names to living or inanimate objects to uniquely identify them	Model names are assigned to a car based on its unique design (*e.g.,* a Honda Civic®). The Civic® is further distinguished by the year it was made, fuel source, and the number of optional features (e.g. 2008 Hybrid DX, LX, and EX sub-models).	*Gold-NM; spherical, 2-12nm diameter; polystyrene functionalized Source: Environment*

Transaction requirements

- ***Unambiguous description of what product/device is in hand:***
  - Structural information
  - Functional information
  - Chemical information
- ***How the product/device was produced:***
  - Production methodology
  - Sample purification
  - Measurement methodology
- ***What regulatory regime is involved:***
  - New Chemical?

Pre-existing products/devices

- ***Nanomaterials and other nanodevices have been on the market for many years:***
  - Material specifications should be well known BUT measurement techniques may provide new insights
  - Use in new applications may produce unexpected results
  - EHS requirements may be upgraded due to nano designation

- ***What about new nomenclature approach for nanomaterials:***
  - Regulation regimes for nanotechnology are likely to be different to existing approaches for chemicals
  - Existing products/devices may be treated differently

TC 229 – Horizontal activities 2

Terminology and Nomenclature (JWG 1)

"what you call it" - Convened by Canada

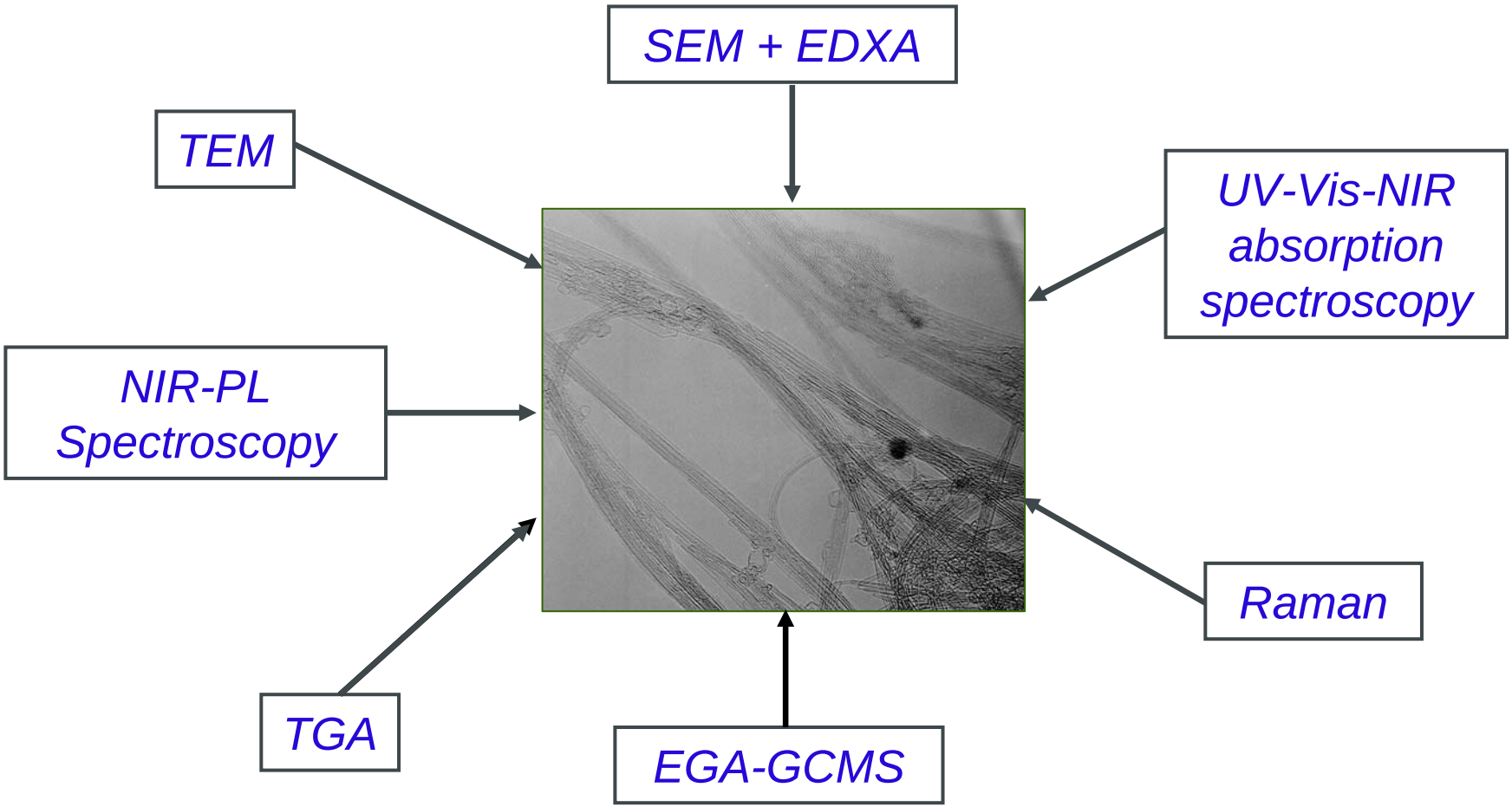
Measurement and Characterization (JWG 2)

"How you measure / test it" – Convened by Japan

Measures required to provide technical underpinning of standards

- Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nanoscale entities;
- Co-normative research to evaluate repeatability, reproducibility and intercomparability of test methods;
- Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc.
- 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;
- Development of in-situ/on-line, non-destructive techniques and contact-less measurements relevant to nanotechnologies.

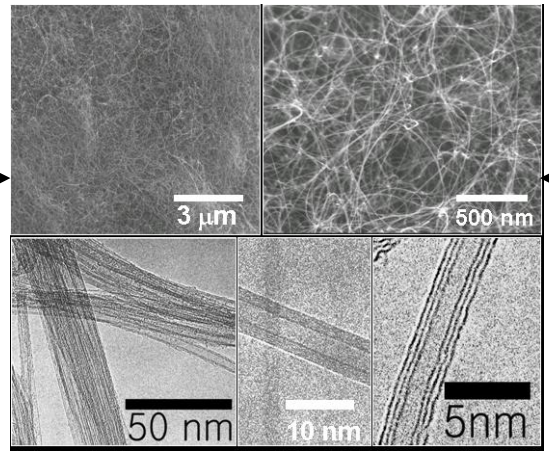
TC 229 Work programme JWG2
(SWCNT work)



JWG2 – MWCNT and other work

Electrical characterization of Carbon Nanotubes (CNTs) Using 4-Probe Measurement (TS)

Measurement Methods for the Characterization of Multi-Walled Carbon Nanotubes (TS)



Determination of meso-scopic shape factors of multiwalled carbon nanotubes (TS)

- ***ISO/IS: General Framework for Determining Nanoparticle Content in Nanomaterials by Generation of Aerosols***
- ***Joint developments with CEN (CEN lead):***
  - ***ISO/TR: Guide to nanoparticle measurement methods***
  - ***ISO/TR: Guide to methods for nano-tribology measurements***

ISO/TC 229 JWG2: Draft Roadmap

2005 2010 2015

Carbon Nano-Materials

Basic Character set
Purity Geometrical property
Morphology Dispersability Tube type

Advanced Character set
Electrical, Magnetic, Mechanical , Optical properties

Engineered nanoparticles

Basic Character set
Purity Composition, Geometrical property, Sampling method.

Advanced Character set
Elemental structure, Chemical functionality,
Electrical, Magnetic, Mechanical , Optical properties

Coatings/ Nanostructured materials

Basic Character set
Geometrical property, Composition, Density

Advanced Character set
Electrical, Magnetic, Mechanical , Optical properties

Basic Metrology

Length, Depth, Force, Traceability, Definition of Measurand, Uncertainty

Interoperability

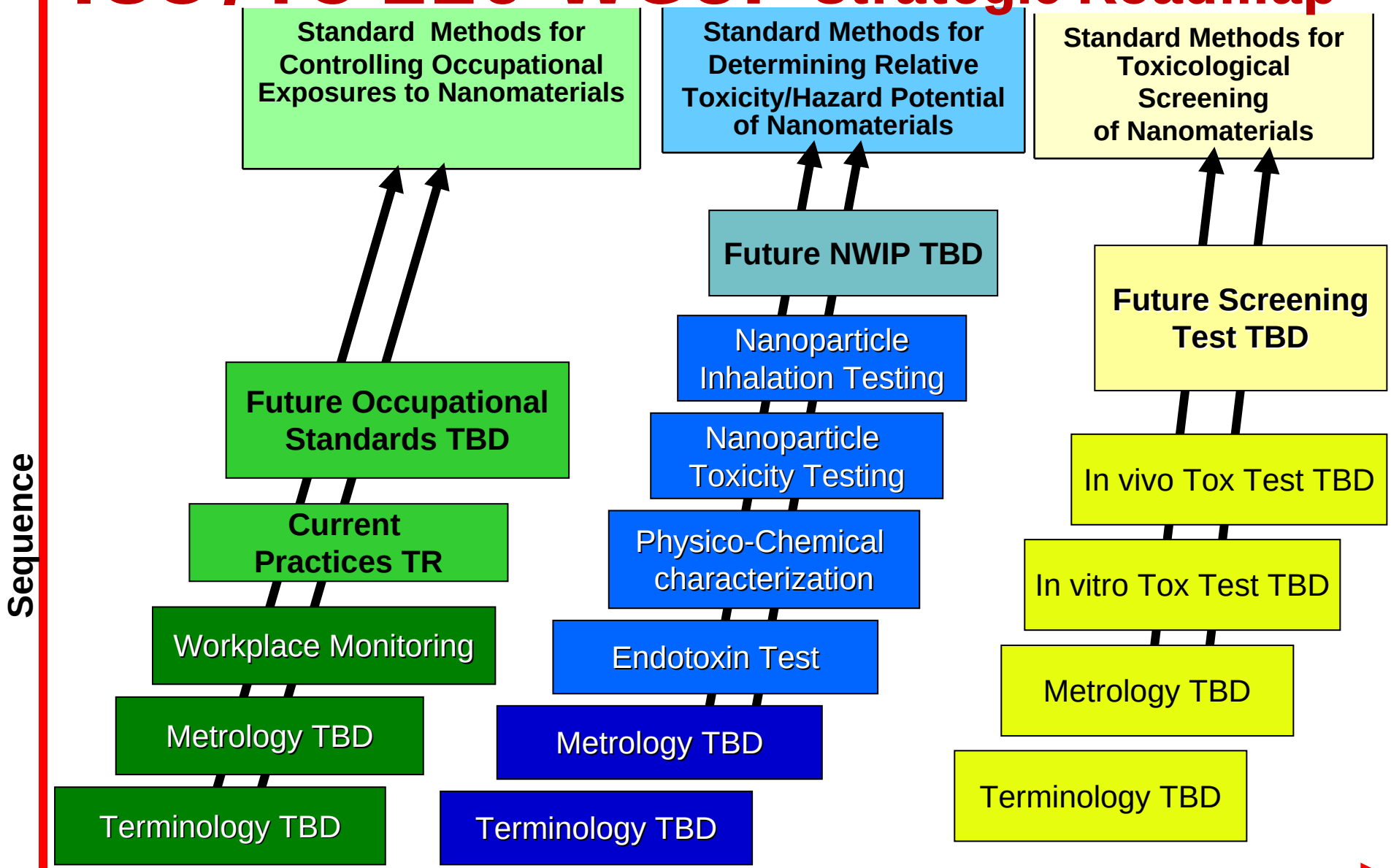
TC 229 – Horizontal activities 3

Terminology and Nomenclature (JWG 1)
"what you call it" - Convened by Canada

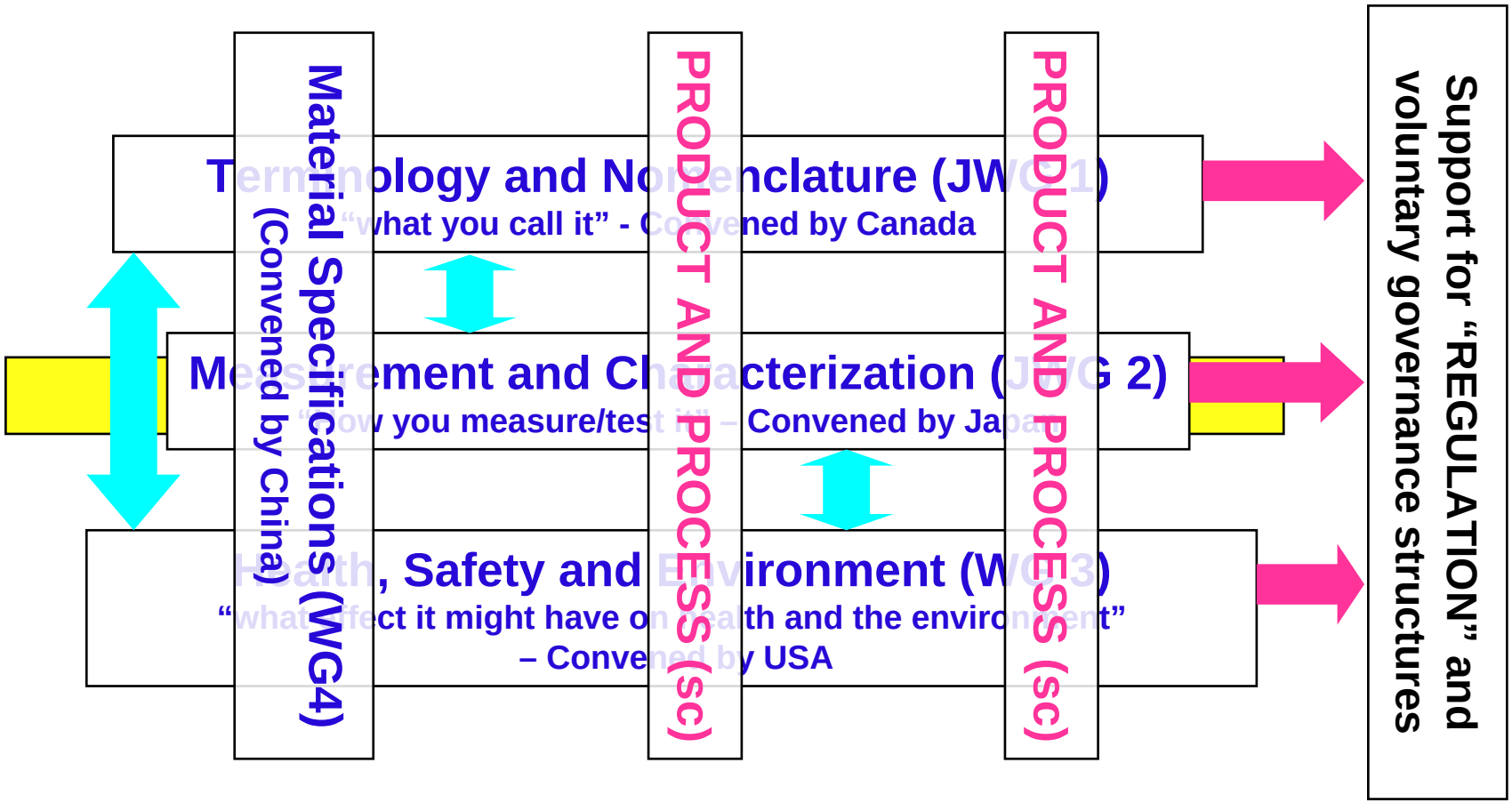
Measurement and Characterization (JWG 2)

Health, Safety and Environment (WG 3)
"effect on health and the environment" – Convened by USA

ISO/TC 229 WG3: Strategic Roadmap



TC 229 – Structure/working areas



TC 229 – Horizontal activities 4

Terminology and Nomenclature (JWG 1)
"what you call it" - Convened by Canada

Measurement and Characterization (JWG 2)
"How you measure/test it" – Convened by Japan

Health, Safety and Environment (WG 3)
"effect on health and the environment" – Convened by USA

Product Charaterization WG 4
"what it is" - Convened by China

Other TC 229 structures

- ***Chairman's Advisory Group***
- ***Task Groups on:***
  - ***Planning and Coordination;***
  - ***Business Planning;***
  - ***Material Specifications;***
  - ***Nanotechnologies and Sustainability***
- ***Nanotechnologies Liaison Coordination Group***
- ***JWG2 study groups on:***
  - ***metrology***
  - ***strategy***

Current and potential liaisons for ISO/TC 229

Acknowledgements

- ISO Central Secretariat for permission to use the cartoons at the beginning of this presentation
- Mr Pascal Krieger the artist who produced the cartoons, which are covered by ISO copyright
- Dr Peter Hatto, Chair of TC 229, for use of selected slides
- Anyone wishing to know more about ISO should visit WWW.ISO.ORG

- **Thank you!**