Standardization for Nanosafety

ISO plans and Perspective

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What is standardization

- **Standardization is the process of developing and agreeing upon technical standards.**

- **Technical standards are documents that establish uniform engineering or technical specifications, criteria, methods, processes, or practices to facilitate relationship between partners:**
  - **based on *consensus* (i.e. no sustained opposition), not necessarily unanimity,**
  - **proposed, developed and approved by the members of the standards body (AFNOR, ANSI, BSI, DIN, JISC,….),**
  - **are *voluntary*, unless called in a contract or regulation.**
  - **developed by independent experts, working under the auspices of a national, regional or international standards body.**

What standards do

- **Provide governments with a technical base for health, safety and environmental legislation, and conformity assessment,**

ISO TC 229 Nanotechnologies

SCOPE:

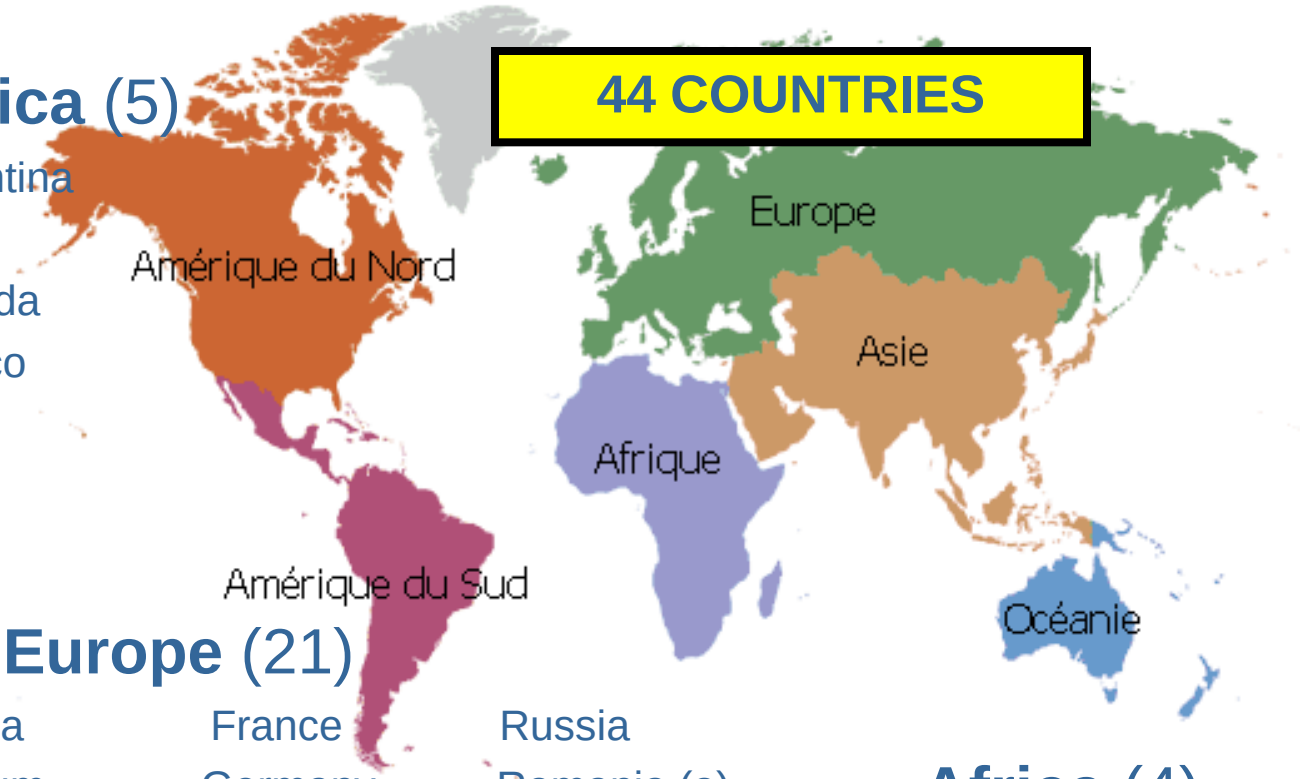
Standardization in the field of nanotechnologies that includes either or both of the following:

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, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.**

ISO TC 229 Nanotechnologies members

44 COUNTRIES



America (5)

- Argentina
- Brazil
- Canada
- Mexico
- USA

Europe (21)

- Austria
- Belgium
- Bulgaria
- Cezch republic
- Denmark
- Estonia (o)
- Finland
- France
- Germany
- Ireland
- Italy
- Netherland
- Norway
- Poland
- Russia
- Romania (o)
- Slovakia (o)
- Spain
- Sweden
- Switzerland
- United Kingdom

Africa (4)

- Egypt (o)
- Kenya
- Morocco (o)
- South Africa

Asia (14)

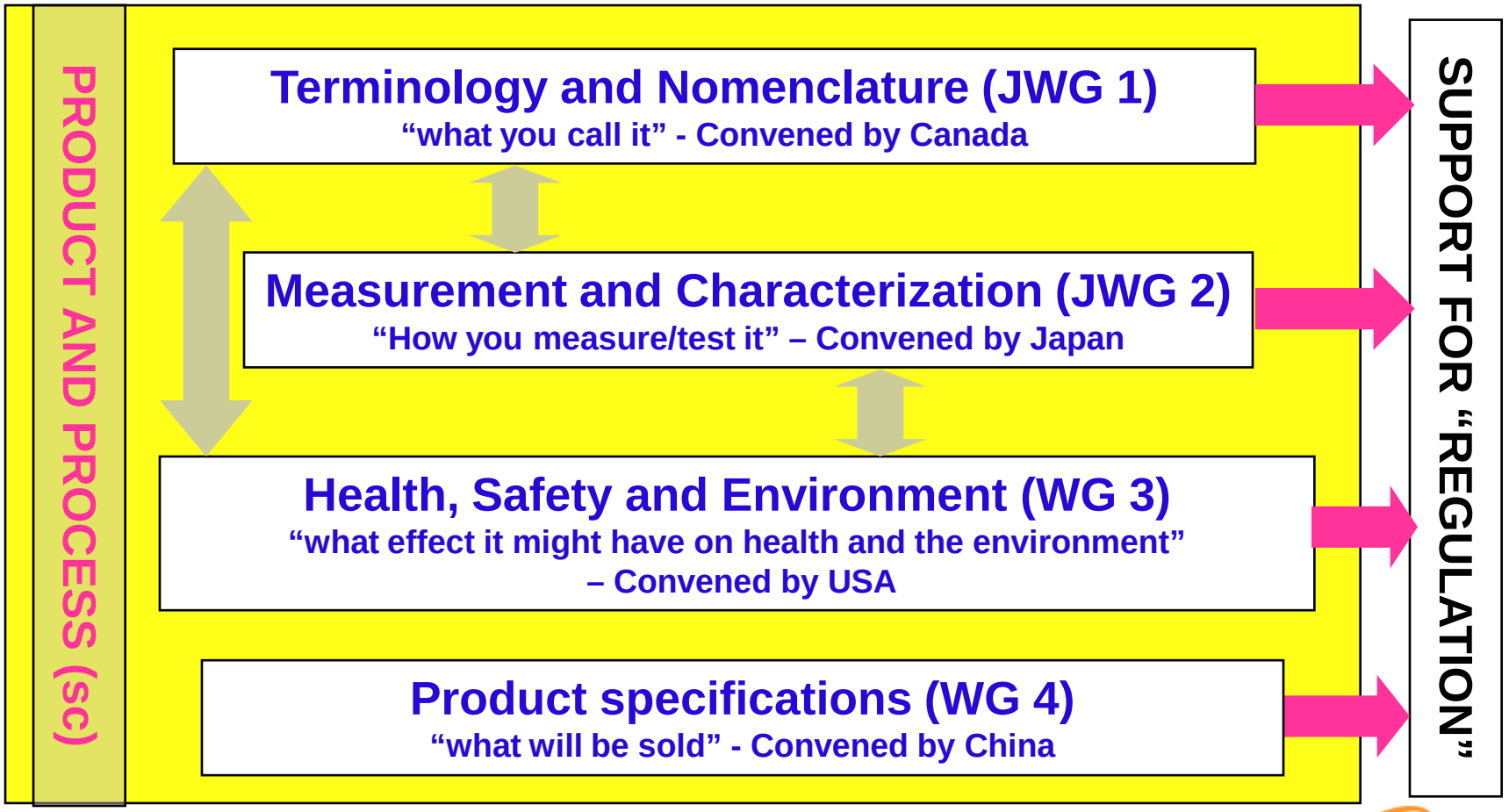
Oceania

- Australia
- China
- India
- Indonesia
- Iran
- Israel
- Japan
- Hong Kong (o)
- Kazakhastan (o)
- Korea
- Malaysia
- Singapore
- Sri Lanka (o)
- Thailand (o)

ISO TC 229 Nanotechnologies

Chairman and secretariat (UK)

4 Working group



ISO TC 229 - JWG1: *Core Terms definitions*

Nanoscale
size range from approximately 1 nm to 100 nm

Nanomaterial
material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale,

Nano-object
material with one, two or three external dimensions in the nanoscale,

Nanostructured material,
material having internal nanostructure or surface nanostructure,

Manufactured nanomaterial,
nanomaterial intentionally produced for commercial purpose to have specific properties or specific composition,

ISO TC 229 - JWG2 *Strategic Objectives*

- **To develop measurement and characterization standards for use by industry in nanotechnology-based products.**
- **To work closely with all the ISO/TC229 working groups in producing standards of common interest by developing the necessary characterization, measurement and test standards.**
- **To ensure co-ordination with relevant work in other ISO TCs, developing measurement and characterization standards, and with OECD Committees, as appropriate.**

Characterization Protocol Criteria

Must be repeatable, reproductible and accepted by w.w experts to establish a common language to prevent any

« Babel Tower syndrom »

for nanomaterials and nanotechnologies .

ISO / TC 229-WG 3

SCOPE:

The development of science-based standards in the areas of health, safety, and environmental aspects of nanotechnologies.

OBJECTIVE:

The development of high quality health, safety and environmental standards that will improve occupational safety, consumer protection and environmental protection by promoting good practice in the production, use and disposal of nano-materials, nanotechnology products and nanotechnology-enabled systems.

ISO/TC 229-WG 3 : *Focus & Roadmap*

Nanomaterials Standard Methods for :

- Ø Assessing and Controlling Occupational Exposures,
- Ø Determining Hazard / Toxicity Potential of Nanomaterials,
- Ø Toxicological Screening,
- Ø Environmental Impact,
- Ø Ensuring Product Safety,
- Ø Risk Assessment and Risk Management,

ISO/TC 229 WG 3 Project Groups Project Status Update

ISO TS 12885 – Safe practices in occupational settings relevant to nanotechnologies,

PG 2: ISO 29701 Endotoxin test on nanomaterial samples for in vitro systems, Limulus amebocyte lysate (LAL) test, Japan

PG 3: ISO 10801 Nanotechnologies - Generation of Metal Nanoparticles with the Evaporation/Condensation Method for Inhalation Toxicity Testing, Korea

PG 4: ISO 10808 Nanotechnologies — Characterization of Nanoparticles in Inhalation Exposure Chambers for Inhalation Toxicity Testing, Korea

PG 7: ISO TR 13121 Nanomaterial Risk Evaluation, USA

Current WG 3 Project Groups

PG 5 - Guidance on physico-chemical characterization of engineered nano-objects for toxicologic assessment

Country Lead: USA, Dr. Rick Pleus

Summary:

Technical Report containing list of physico-chemical properties that should be measured prior to toxicological testing along with definitions, measurands, and methods; includes discussion of toxicological relevance of the parameter

ISO TC 229/ WG3 – PG5

Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment: Key parameters

« How you measure Nanomaterials »

- Agglomeration state / Aggregation,
- Composition, (purity / impurity, crystal structure),
- Particle size / Size distribution,
- Shape,
- Solubility / Dispersability,
- Surface area,
- Surface chemistry (including chirality, catalytic activity, surface charge),

Current WG 3 Project Groups

PG 6 - Guide to safe handling and disposal of manufactured nanomaterials

Country Lead: UK, Dr. Robert Aitken

Summary:

Technical specification to support occupational health and safety in handling and disposal based on BSI published document

Moving Forward:

Document will be "Harmonized" with Project 8 on *Control Banding* to ensure continuity of documents.

Current WG 3 Project Groups

PG 8 - Guidelines for occupational risk management applied to engineered nanomaterials based on a control banding approach

Country Lead: France, Dr. Daniel Bloch

Summary:

Technical specification based on the system developed by a number of major pharmaceutical companies to classify compounds based on the severity of hazard, and develop the controls required to reduce exposures to acceptable levels

Current WG 3 Project Groups

PG 9 - Preparation of SDS for Nanomaterials

Country Lead: Korea, Dr. Il Je Yu

Summary:

Technical Report to provide guidance for preparation of a nanomaterial specific SDS

Current WG 3 Project Groups

PG 10 - Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method

Country Lead: Korea Dr. Nam Woong Song

Summary:

Technical specification for the identification and quantification of ligand molecules on the surface of synthetic Au NPs in aqueous solutions in order to generate reliable results in the study of the surface property-specific toxicity screening of Au NPs

Current WG 3 Project Groups

PG 11 - Compilation and description of toxicological and ecotoxicological screening methods for engineered and manufactured nanomaterials

Country Lead: USA, Dr. Laurie Locasio

Summary:.

Document will provide reader with list of toxicological and ecotoxicological screening methods for evaluating toxicity of nanomaterials.

Current WG 3 Project Groups

PG 12 - Compilation and description of sample preparation and dosing methods for engineered and manufactured nanomaterials

Country Lead: USA, Dr. Shaun Clancy

Summary:

Compilation and description of sample preparation and dosing methods for engineered and manufactured nanomaterials

Current WG 3 Project Groups

PG 13 - Determination of muramic acid as a biomarker for silver nanoparticles activity

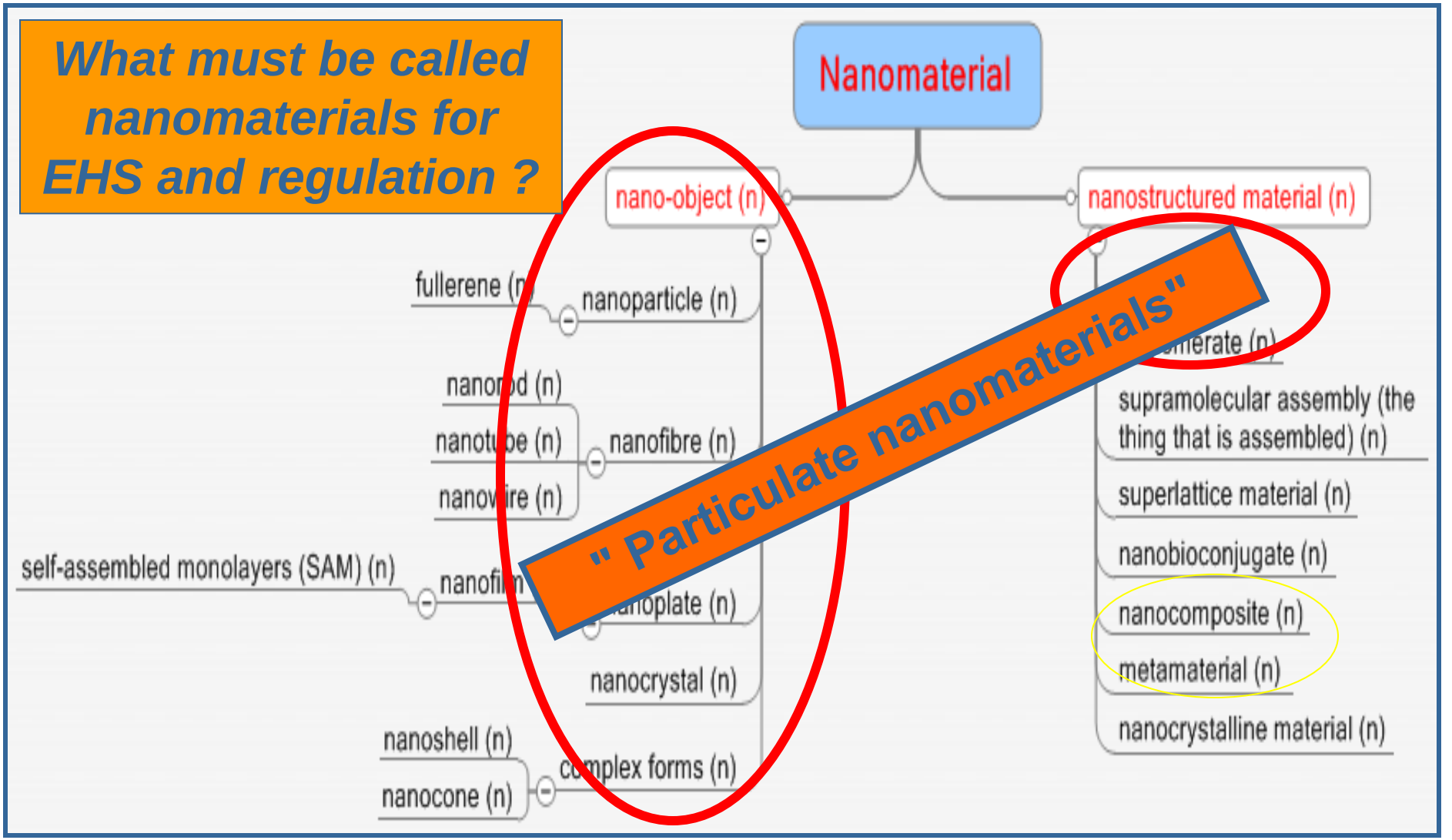
Country Lead: Iran, Dr. Alireza Ghassempour

Summary:

Document will provide method to determine activity of various types of silver nanoparticles

Nanomaterials terminology and nomenclature

What must be called nanomaterials for EHS and regulation ?



Manufactured nanomaterial: nanomaterial intentionally produced to have specific properties or composition

Conclusions

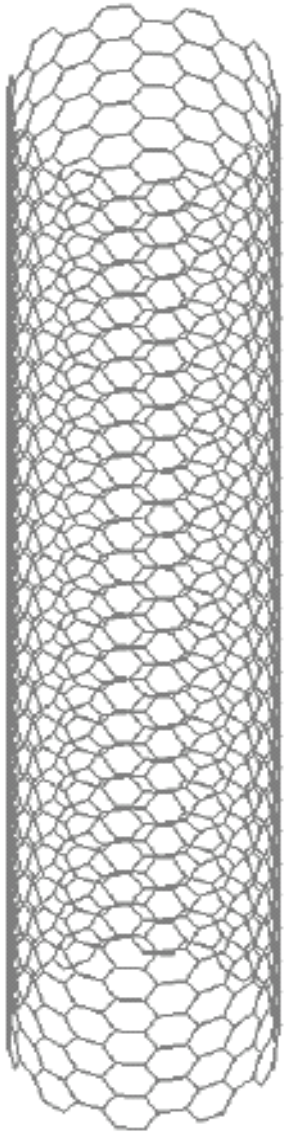
Standardization is one of the building blocks to ensure that nanomaterials are developed and commercialised in a safe, integrated and responsible manner by supporting

- Characterization and exposure assessment of nanomaterials -

- **Methodologies for nanomaterial characterization in the manufactured form and before toxicity and eco-toxicity testing,**
- **Sampling and measurement of workplace, consumer and environment exposure to nanomaterials,**
- **Methods to simulate exposures to nanomaterials,**

Ø Work on toxicology and screening is performed mainly in the framework of the OECD .

Ø Work on risk assessment for chemicals is carried out mainly by the authorities.



Thank you for your attention

Questions ?

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