Status Nanotechnology at OECD and ISO

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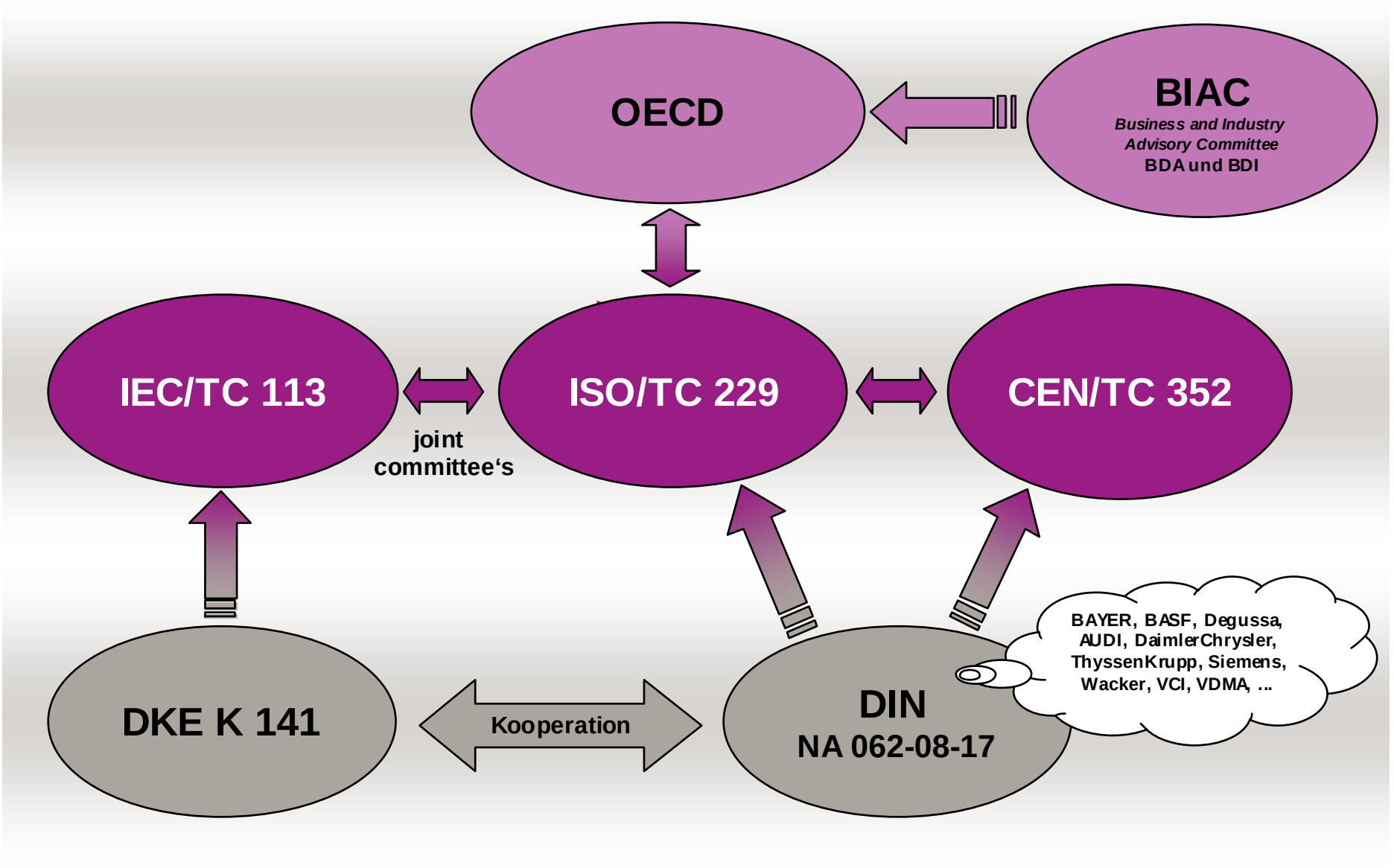
EVONIK INDUSTRIES

Deutsche Beteiligung an internationaler Normung



Scope ISO TC 229 Nanotechnologies

Scope

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

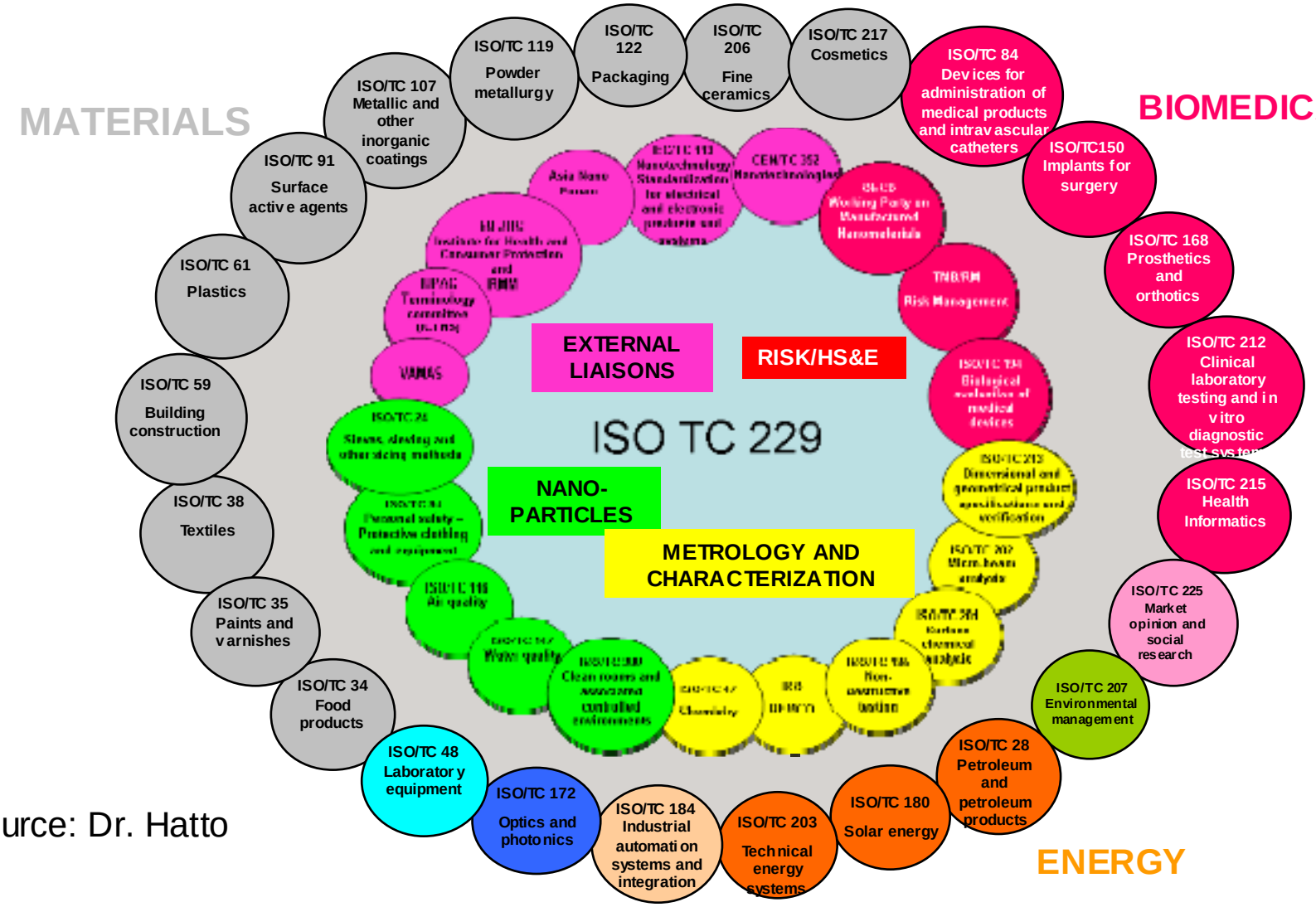
1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications.

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.

Specific tasks include developing standards for:

- terminology and nomenclature;
- metrology and instrumentation, including specifications for reference materials;
- test methodologies;
- modeling and simulation;
- science-based health, safety, and environmental practices.

Current and potential liaisons for ISO/TC 229



Source: Dr. Hatto

ISO TC 229 Nanotechnology
Organization and status

Working Groups

Working Group 1 - Terminology and nomenclature

- Hierarchy and taxonomy of definitions
- General definitions
- Definitions for nano-objects

Working Group 2 - Measurement and characterization

- Test methods around nanotubes

Working Group 3 - Health, safety and environment

- Report Safe Practices in Occupational Settings

Working Group 4 – Material Specification

- Guidance on specifying nanomaterials
- ZnO, $CaCO_3$

Project status ISO TC 229
JWG1

Project ref.	Project title	Comments
TS 27687	Nanotechnologies -- Terminology and definitions for nano-objects -- Nanoparticle, nanofibre and nanoplate	PUBLISHED on 8-2008
TR 12802	Terminology and nomenclature for nanotechnologies — Framework	WD under preparation
TS 11751	Terminology and definitions for carbon nanomaterials	WD under preparation
TS 12144	Nanotechnologies - Core Terms - Terminology and Definitions	WD under preparation
TS 12921	Nanotechnologies - Terminology and definitions for nanostructured materials	WD under preparation
TS 12808	Nanotechnologies - Terminology for the bio-nano interface	WD under preparation
TS 13013	Terminology for nanoscale measurement and instrumentation	WD under preparation
TS 12843	Terminology for medical, health and personal care applications of nanotechnologies	WD under preparation

Project status ISO TC 229
JWG2

Project ref.	Project title	Comments
TS 10797	Nanotubes -- Use of transmission electron microscopy (TEM) in w alled carbon nanotubes (SWCNTs)	WD under preparation.
TS 10798	Nanotubes -- Scanning electron microscopy (SEM) and energy dispersive X-ray analysis (EDXA) in the charaterization of single w alled carbon nanotubes (SWCNTs)	WD under preparation.
TS 10868	Nanotubes - Use of UV-Vis-NIR absorption spectroscopy in the characterization of single-w alled carbon nanotubes (SWCNTs)	WD under preparation.
TS 10867	Nanotubes -- Use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the characterization of single-w alled carbon nanotubes (SWCNTs)	WD under preparation.
TS 10929	Measurement methods for the characterization of multi-w alled carbon nanotubes (MWCNTs)	WD under preparation.
TS 11251	Nanotechnologies -- Use of evolved gas analysis-gas chromatograph mass spectrometry (EGA-GCMS) in the characterization of single-w alled carbon nanotubes (SWCNTs)	WD under preparation.
TS 11308	Nanotechnologies -- Use of thermo gravimetric analysis (TGA) in the purity evaluation of single-w alled carbon nanotubes (SWCNT)	WD under preparation
TS 10812	Nanotechnologies -- Use of Raman spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	WD under preparation.
TS 11888	Determination of mesoscopic shape factors of multiw alled carbon nanotubes (MWCNTs)	WD under preparation.
ISO 12025	General Framew ork for Determining Nanoparticle Content in Nanomaterials by Generation of Aerosols	WD under preparation.

Project status ISO TC 229
WG3

Project ref.	Project title	Comments
TR 12885	Safe Practices in Occupational Settings Relative to Nanotechnologies	PUBLISHED on 2008-10-01
ISO 29701	Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems	CD approved
ISO 10801	Nanotechnologies -- Generation of nanoparticles for inhalation toxicity testing	Approved DIS preparation
ISO 10808	Nanotechnologies -- Monitoring nanoparticles in inhalation exposure chambers for inhalation toxicity testing	Approved DIS preparation
TR 13014	Nanotechnologies - Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment	WD under preparation
TS 12901	Guide to safe handling and disposal of manufactured nanomaterials	WD under preparation

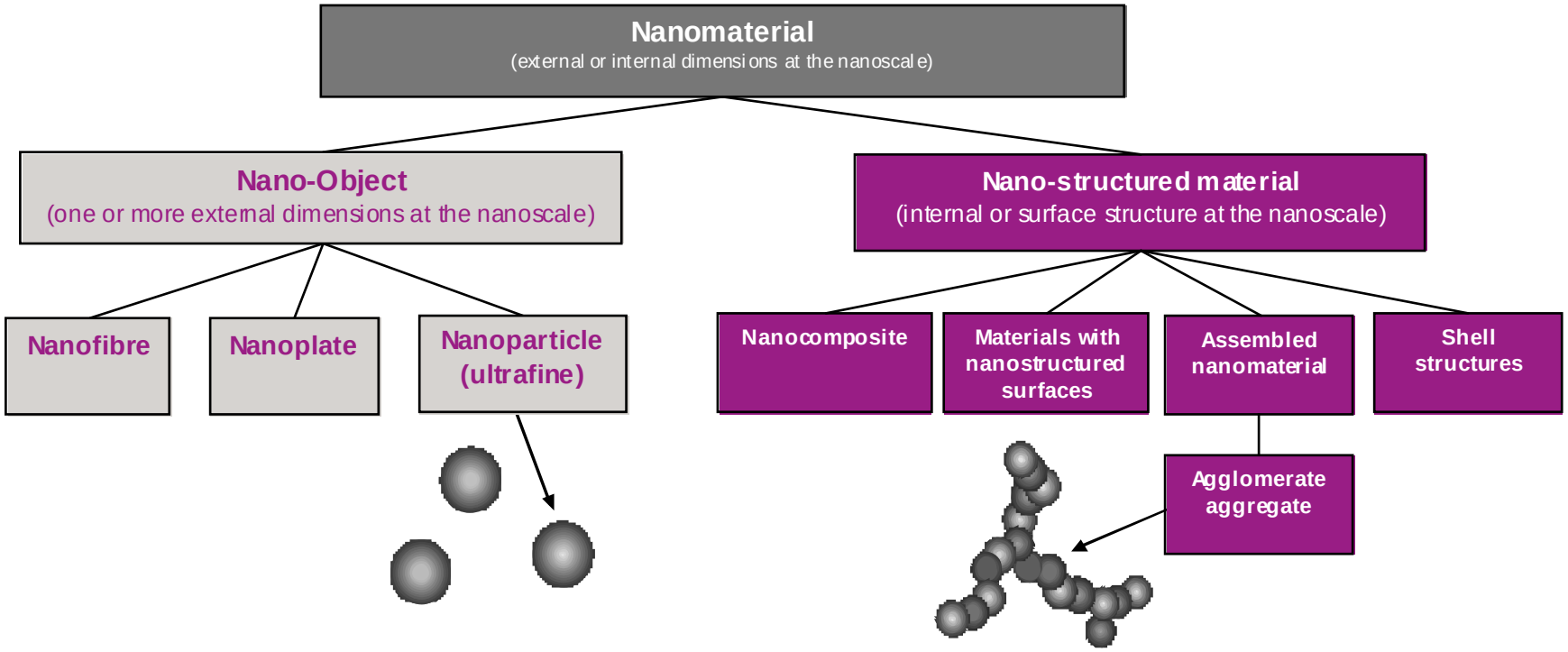
Project status ISO TC 229
WG4

Project ref.	Project title	Comments
ISO 11931	Nanotechnologies -- Nano-calcium carbonate	Approved WD under preparation. Ballot to change status to TS
ISO 11937	Nanotechnologies -- Nano-titanium dioxide	Approved WD under preparation Ballot to change status to TS
ISO TS 12805	Guidance on specifying nanomaterials	Approved WD under preparation

Wichtige Definitionen

ISO

Nanomaterialien
Definitionen und Hierarchie



ISO TS 27687
Published 8-08

ISO TS 12921
In progress

Terminology and definitions for nano-objects ISO TS 27687

2 Core Terms Related to Particles

2.1 **nanoscale**: size range from approximately 1 nm and 100 nm

2.2 **nano-object**: material with one, two, or three external dimensions at the nanoscale

3. Terms concerning particles and assemblies of particles

3.1 **particle**: minute piece of matter with defined physical boundaries.

3.2 **agglomerate**: collection of loosely bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components

3.3 **aggregate**: particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components.

4 Terms specific to nano-objects

4.1 **nanoparticle**: particle with all three external dimensions at the nanoscale.

4.2 **nanoplate**: nano-object with one external dimension at the nanoscale and the two other external dimensions significantly larger.

4.3 **nanofibre**: nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger

4.4 **nanotube**: hollow nanofibre

4.5. **nanorod**: solid nanofibre

4.6. **nanowire**: electrically conducting or semi-conducting nanofibre

4.7 **quantum dot**: crystalline nanoparticle that exhibits size-dependent properties due to quantum confinement effects on the electronic states

Obergrenze 100 nm sinnvoll

- Alle bislang bekannten Nano-Effekte treten unterhalb von 20 nm, meist sogar erst unterhalb von 10 nm auf, wo das Oberflächen-zu-Volumenverhältnis von Materialien besonders stark ansteigt.
- Die obere Grenze von 100 nm erfasst alle bekannten Nano-Effekte.
- Die Obergrenze von 100 nm ist großzügig bemessen.
- Die von einigen geforderte Erhöhung der Obergrenze ist aus technisch-wissenschaftlicher Sicht nicht begründbar; eher wäre eine Absenkung angezeigt.

OECD-Aktivitäten

WPMN and WPN

OECD-Aktivitäten
Nanotechnologie

WPN Working Party Nanotechnology

- Untergruppe des Komittees für Wissenschafts- und Technologiepolitik (Direktorat für Wissenschaft, Technologie und Industrie)
- *gegründet März 2007*
- *Schwerpunkt Technologieförderung*

WPMN Working Party on Manufacture Nanomaterials

- Untergruppe des Chemicals Committee (Umweltdirektorat)
- *gegründet September 2006*
- *Schwerpunkt Nanosafety*

Working Party Nanotechnology

Committee for Scientific and Technology Policy

Work areas

1) **Impact and Measurement (tracing)**
2) **Science and Skills**
3) **Innovation and Commercialisation**
4) **Public Outreach and Dialogue**
5) **Policy Dialogue on the Responsible Development of Nanotechnology**

Working Party Nanotechnologie

Projekte der WPN

- **Project A: Indicators and Statistics**
  aiming at providing an overview of nanotechnology trends based on available comparable indicators and statistics, while identifying policy makers needs for further indicators.
- **Project B: Impacts on Companies and Business Environments**
  which complements the statistical work with a large set of company case studies across different application areas and countries. It analyses the impacts and business environment of nanotechnology
- **Project C: International Research Collaboration**
  designed to facilitate research collaboration in the field by mapping available research infrastructures and S&T agreements globally.
- **Project D: Outreach and Public Engagement**
  aiming at promoting the exchange of experience in outreach and public engagement through questionnaires, possible country case studies and a set of workshops.
- **Project E: Policy Dialogue**
  aiming at facilitating a policy dialogue and help develop an overall synthesis of the WPN work.
- **Project F: Nanotechnology and Water**
  which focuses on the contribution of nanotechnology to the purification of water and the barriers that will need to be addressed.

Working Party Manufactured Nanomaterials
WPMN

Objective

The objective of the Programme of Work is to promote international cooperation in human health and environmental safety related aspects of manufactured nanomaterials, in order to assist in the development of rigorous safety evaluation of nanomaterials

This committee reports to The Chemicals Committee

Working Party Manufactured Nanomaterials

ISO working definition taken as scope

Manufactured nanomaterials: Nanomaterials intentionally produced to have specific properties or specific composition.

Nanoscale: The size range **typically** between 1 nm and 100 nm.

Nanomaterial: material which is either a nano-object or is nanostructured.

Note: End products containing nanomaterials (e.g. tires, electronic equipment, coated DVDs) are not themselves nanomaterials.

Nano-object: material confined in one, two, or three dimensions at the nanoscale.

Nanostructured: having an internal or surface structure at the nanoscale.

Note 1: The WPMN considers that fullerene molecules are included within the scope of manufactured nanomaterials.

Note 2: The WPMN considers that aggregates and agglomerates are nanostructured materials along the lines of ISO.

Working Party Manufactured Nanomaterials
Teilnehmer

30 OECD Mitgliedstaaten und EU-Kommission

- Delegierte aus Ministerien und Fachbehörden, die für Chemikaliensicherheit zuständig sind.

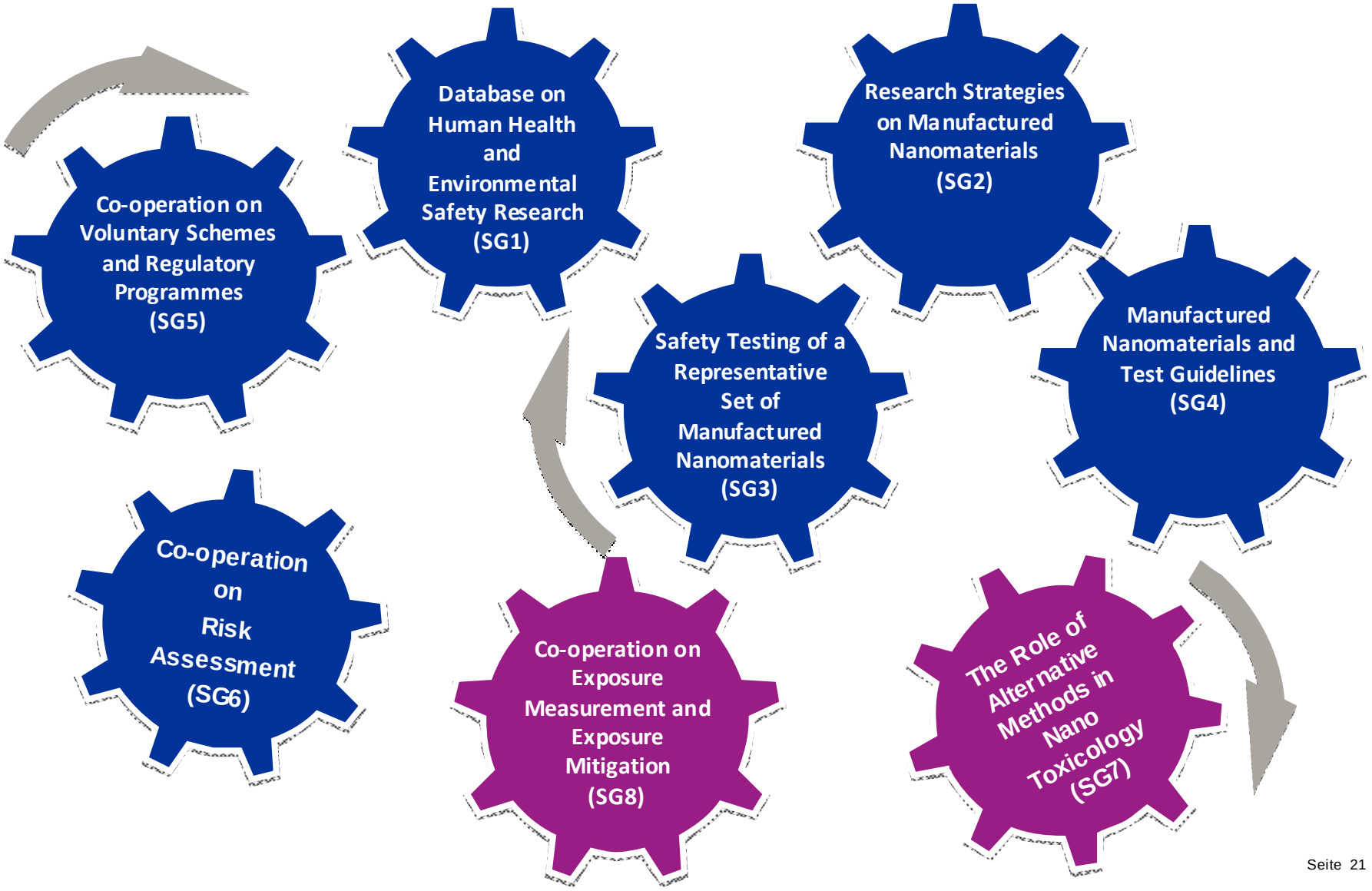
Nicht-Mitgliedstaaten (Kandidaten)

- Brasilien, China, Indien, Russland, Singapur, Thailand.

Zwischenstaatliche und Nichtregierungs-Organsiationen

- Industrie (BIAC), Gewerkschaft (TUAC), Normungsorganisation (ISO), Weltgesundheitsorganisation (WHO), UNEP und Umwelt-NGOs.

Working Party Manufactured Nanomaterials
Overview strategy groups



Working Party Manufactured Nanomaterials
Tasks strategy groups 1-4

SG1 Entwicklung einer Datenbank zur Sicherheitsforschung mit Nanomaterialien (Australien)

Ziel: Schaffung einer globalen Quelle zur Sicherheitsforschung incl. laufender und geplanter Projekte. → Eingaben laufen, öffentliche Einführung 2009 geplant.

SG2 Forschungsstrategien zur Gesundheits- und Umweltsicherheit von Nanomaterialien (Deutschland)

Ziel: Informationsaustausch, um Forschungsbedarf zu identifizieren und den Wissenschaftsaustausch zwischen Forschungsgruppen zu erleichtern. → Matrix ist erstellt, Strategien zum weiteren Verfahren für “hot spots” und Lücken sollen entwickelt werden.

SG3 Prüfung einer repräsentativen Auswahl hergestellter Nanomaterialien – Arbeitsdefinition (USA und EU COM)

Ziel: Identifizierung einer repräsentativen Auswahl und deren Prüfung → Sponsorship-Programm angelaufen, Arbeitsdefinition vorhanden.

SG4 Hergestellte Nanomaterialien und Test Guidelines (USA und EU COM)

Ziel: Review bestehender Methoden und Identifizierung von methodischen Lücken → Review abgeschlossen, Guidance zur Probenvorbereitung in Arbeit.

Working Party Manufactured Nanomaterials
Tasks strategy groups 5-8

SG 5 Zusammenarbeit bei freiwilligen und regulatorischen Programmen (Kanada)

Ziel: Identifizierung verschiedener Initiativen zur Sammlung von Informationen und regulatorischer Verfahren (geplant und in Kraft) → Review zur Informationssammlung abgeschlossen zur Regulatorik laufend.

SG6 Zusammenarbeit bei der Risikobewertung (UK)

Ziel: Auswertung von Risikobewertungsansätzen und Identifizierung von Möglichkeiten zur Weiterentwicklung und Stärkung →Review läuft.

SG7 Rolle alternativer Testverfahren in der Nanotoxikologie (UK und Deutschland)

Ziel: Evaluierung und Validierung geeigneter Verfahren → Review läuft, Erprobung im Sponsorship-Programm.

SG8 Expositionsmessung und Expositionsminderung (USA)

Ziel: Entwicklung eines Leitfadens zur Expositionsermittlung und –minderung → Leitfaden für Arbeitsplatz erstellt.

SG 1: OECD Database on Safety Research

Objective

To develop a global resource, which identifies research projects that address environmental, human health and safety (EHS) issues associated with Manufactured Nanomatrials, including research projects which are planned, underway or completed.

Chair: Australia

Status

- Data entry by delegations in 2008
- Public launch expected by January 2009

SG4: Manufactured Nanomaterials and Test Guidelines

Objectives

- To review existing OECD Test Guidelines for adequacy in addressing MNs
- To identify the need for development of new or revision of existing test guidelines or guidance

Co-chairs: United States and European Commission

Status

- Completed the Preliminary Review of the existing guidelines for potential applicability
- Developing guidance on sample preparation and dosimetry, and a comparison document of inhalation and instillation

SG8: Exposure Measurement and Exposure Mitigation

Objective

To develop guidance on exposure measurements and exposure mitigation, with an initial focus on occupational settings

Chair United States

Status

- Developing recommendations on measurement techniques and sampling protocols for inhalation and dermal exposures in the workplace

SG 3: Safety Testing of a Representative Set of MNs

Objective

To agree and test a representative set of manufactured nanomaterials (MNs) using appropriate test methods.

Chairs: United States and European Commission

Status

- Sponsorship Programme launched (November 2008) to test representative MNs for a base set of endpoints

OECD´s sponsorship program
Objectives

- The programme is intended to develop data that will improve the understanding of Manufactured Nanomaterials (NM), and, if possible, to understand what information may be generalized across different MNs or classes of MNs.
- The scope of Phase 1 is to provide a dataset that substantially improves understanding of “MN-intrinsic” properties of a representative MN with regard to the specific endpoints. This includes, where appropriate, the utilisation of existing relevant data.
- It was agreed that the dataset developed through this project would be of an exploratory nature. It would also be science-based, open to all stakeholders and without pre-defined consequences for any regulatory datasets

Safety of Manufactured Nanomaterials Programme www.oecd.org/env/nanosafety

Sponsorship-Programm der OECD
WPMN

Endpunkte (55)

- Daten zur Identifizierung
  - 9 Endpunkte, z. B. Name, chem. Identität, Verwendung, Coating
- Physikalisch-chemische Eigenschaften und Charakterisierung
  - 16 Endpunkte, z.B. Löslichkeit, Größe, Oberfläche, Aggregation, Agglomeration
- Umweltverhalten
  - 14 Endpunkte, z.B. biologischer Abbau, Adsorption, Akkumulation
- Ökotoxikologie
  - 5 Endpunkte, z.B. Effekte auf aquatische und terrestrische Organismen
- Humantoxikologie
  - 8 Endpunkte, z.B. Reproduktions- und Gentoxizität, Toxikokinetik
- Materialsicherheit
  - 3 Endpunkte, Entflammbarkeit, Explosivität, Inkompatiblität

Lead sponsors
Co-Sponsors and Contributors

	Lead sponsor(s)	Co-sponsor(s)	Contributor
Fullerenes(C60)	Japan, United States		Denmark, China
SWCNTs	Japan, United States		Canada, France, Germany, EC, China, BIAC
MWCNTs	Japan, United States	Korea, BIAC	Canada, France, Germany, EC, China, BIAC
Silver nanoparticles	Korea United States	Australia*, Canada, Germany, Nordic Council of Ministers	Australia, France, EC, China
Iron nanoparticles	China	BIAC	Canada, USA, Nordic Council of Ministers
Carbon black			Denmark, Germany, United States
Titanium dioxide	Germany France	Canada, Korea, Spain, United States, BIAC	Denmark China
Aluminium oxide			Germany, United States
Cerium oxide	USA, UK/BIAC(NIA)	Netherlands	Australia, Germany, EC
Zinc oxide	United Kingdom/BIAC(NIA)	Australia*, USA BIAC(CEFIC)	Australia Canada
Silicon dioxide	France EC	Korea, BIAC (CEFIC)	Denmark, France
Polystyrene			Korea
Dendrimers		Spain	United States
Nanoclays			Denmark, United States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INDUSTRIES

Take home messages

- OECD approved ISO´s suggested definition as working definition with minor changes