

FROM RESEARCH TO INDUSTRY

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TO NAME THINGS WRONGLY IS TO ADD TO THE MISFORTUNE OF THE *NANOWORLD*



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PNS
PLATE-FORME NANO SÉCURITÉ

Nanomaterials is unfortunately an ambiguous term. Different definitions are used, mainly for regulatory purposes, in Europe and in the world.

As definitions of nanomaterials are not unanimous, for industrial producers and users, consumers and citizens, there is a lack of transparency which lead to many misunderstandings and to loss of confidence for all the stakeholders.

E.C. acknowledge the fact:

" In a multidisciplinary and cross-cutting field such as that of nanotechnology, it is desirable to harmonize the related terminology at international level."()*

"The ISO definition is developed for broad use across all possible areas, sectors, disciplines, in industry and academia alike."()*

"The EC definition, on the other hand, is developed very specifically for use in a regulatory context."()*

(*) Towards a review of the EC Recommendation for a definition of the term “nanomaterial - Part 3 Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation (2015) Edited by Hubert Rauscher and Gert Roebben - European Commission Joint Research Center

The scope *Include 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/TS 80004-1 *Nanotechnologies — Vocabulary — Part 1: Core Terms*

The Core Term definition is ...

Nanoscale

size range from approximately 1 nm to 100 nm

- 1/ 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.*
- 2/ 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.*

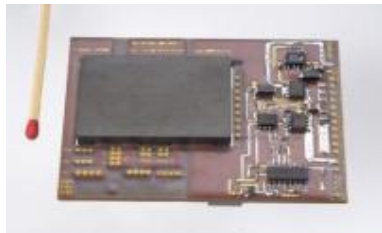
Nanomaterials and nanodevices

Nanotechnologies

Nanodevices
Nanosystems

Nanomaterials

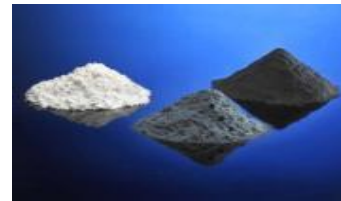
Nano electronic



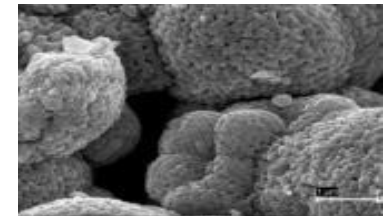
Nanorobots



Nano-objects



Nanostructured
materials



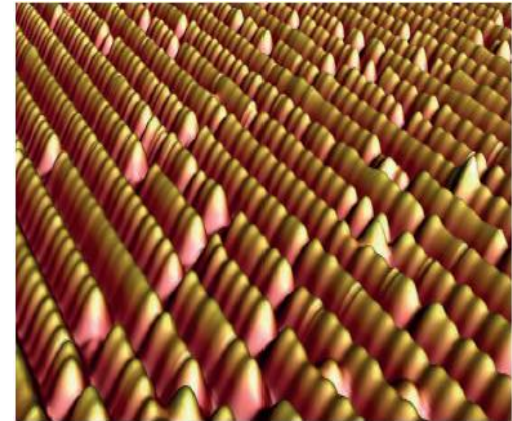
"Nano-Medecine"



What is called Nanomaterials for ISO

- **Nanomaterial**

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

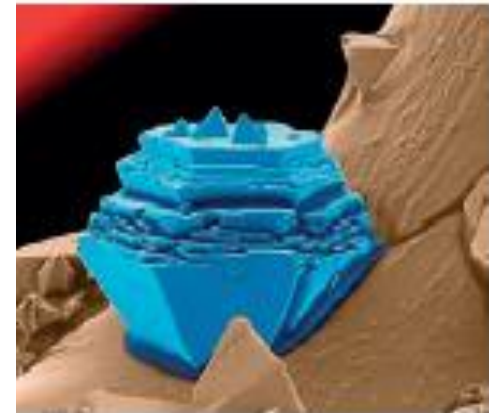


- **Nano-object**

Material with one, two or three external dimensions in the nanoscale, **Nanoparticle** has three external dimensions in the nanoscale, **NOAAs** is the acronym of nano-objects, their aggregates and agglomerates.

- **Nanostructured material,**

Material having internal nanostructure or surface nanostructure,



- **Manufactured (Engineered) Nanomaterial**

Nanomaterial intentionnally manufactured, for commercial purpose, to **present specific properties or composition.**

Working definition

Working definition is to provide clear and unambiguous criteria to identify materials, for which special provisions might apply and to determine whether a material should be considered as a 'nanomaterial', or a NOAAs, for legislative and policy purposes, .

Special provisions (concerning for example risk assessment or ingredient labelling) are not part of the working definition, but of specific legislation in which the definition will be used.

Basic purpose is to ensure that a material, considered as a nanomaterial in one sector, will also have the same classification if used in another, in different contexts.

- **Commission Recommendation 2011/696/EU, OJ L 275, 20.10.2011**



- Second regulatory review on nanomaterials (2012):

Brussels, 3.10.2012
COM(2012) 572 final

- *"Where other definitions are used in EU legislation, provisions will be adapted in order to ensure a consistent approach, although sector specific solutions may remain necessary. The Commission will review this definition in 2014."*

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

Second Regulatory Review on Nanomaterials

(Text with EEA relevance)

- *"Proposal for a first set of detection, measurement and monitoring methods (2014)"*

European commission recommendation on the definition of nanomaterial (october 18, 2011)

"Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%.

By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials."

Commission has taken the ISO TC229, and CEN TC352 term "nanomaterial" as the basis for its definition, but limited to materials consisting of "particles" and with modifications to ensure its practical application in a regulatory context: the term «approximately», when referring to the size range, is not appropriate in a legislative context !

Technical and scientific part

- **1st JRC report: Compilation** (based on the survey done in 2013),
19 March – workshop on this report.
- **2nd JRC report: Assessment** (July 2014) (based on 1st JRC report
+ minutes from this workshop)
- **3rd JRC report: Recommendations** (~~November 2014~~) (**end of 2015 !**) (based on
2nd JRC report)
- **Public consultation**

Policy part

Commission will make decision (~~2014 (?)~~ / ~~2015~~ / 2016 ???)

Definition of the term so-called « nanomaterial » in Union should be

- **Used as a reference for determining whether a material should be considered as a 'nanomaterial' for legislative and policy purposes,**
- **Based for legislation solely on the size of the constituent particles of a material, without regard to hazard or risk,**
- **Based on available scientific knowledge,**
- **Should address "particulate nanomaterials",**
- **Be broadly applicable in Union legislation,**
- **Be in line with other approaches worldwide,**
- **Require a clear definition of the nanoscale limit, size being the only defining property.**

Nanomaterials are covered by the definition of a chemical "substance"

On 30 January 2013, the Commission has organized a workshop to present and discuss the Second Regulatory Review on Nanomaterials.

The Commission has made an impact assessment public consultation, June-September 2013, of relevant regulatory options, in particular possible amendments of REACH Annexes, to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers

()Registration, Evaluation, Authorisation and Restriction of Chemicals*

Nanomaterial definition



Why do we need only one definition
of the term “Nanomaterial” ?

Nomenclature
Terminology
Description

Detection
Identification
Characterization
Measurements
Evaluation

"To name things wrongly is to add to the misfortune of the (nano)world"
(Albert Camus).

To prevent *Babel Tower Syndrom*

European recommendation for the nanomaterials definition is limited to use, as defining properties, the external size of the material !

Without taking into account the internal size, for the nanostructured materials, and the size-dependent phenomena which enables novel properties and applications.

So the European definition for nanomaterials is limited to ultra-fine or submicronic particles having a size below 100 nm, but cannot be consider as covering the most important aspect of the “nanoworld”, the new properties and new applications.

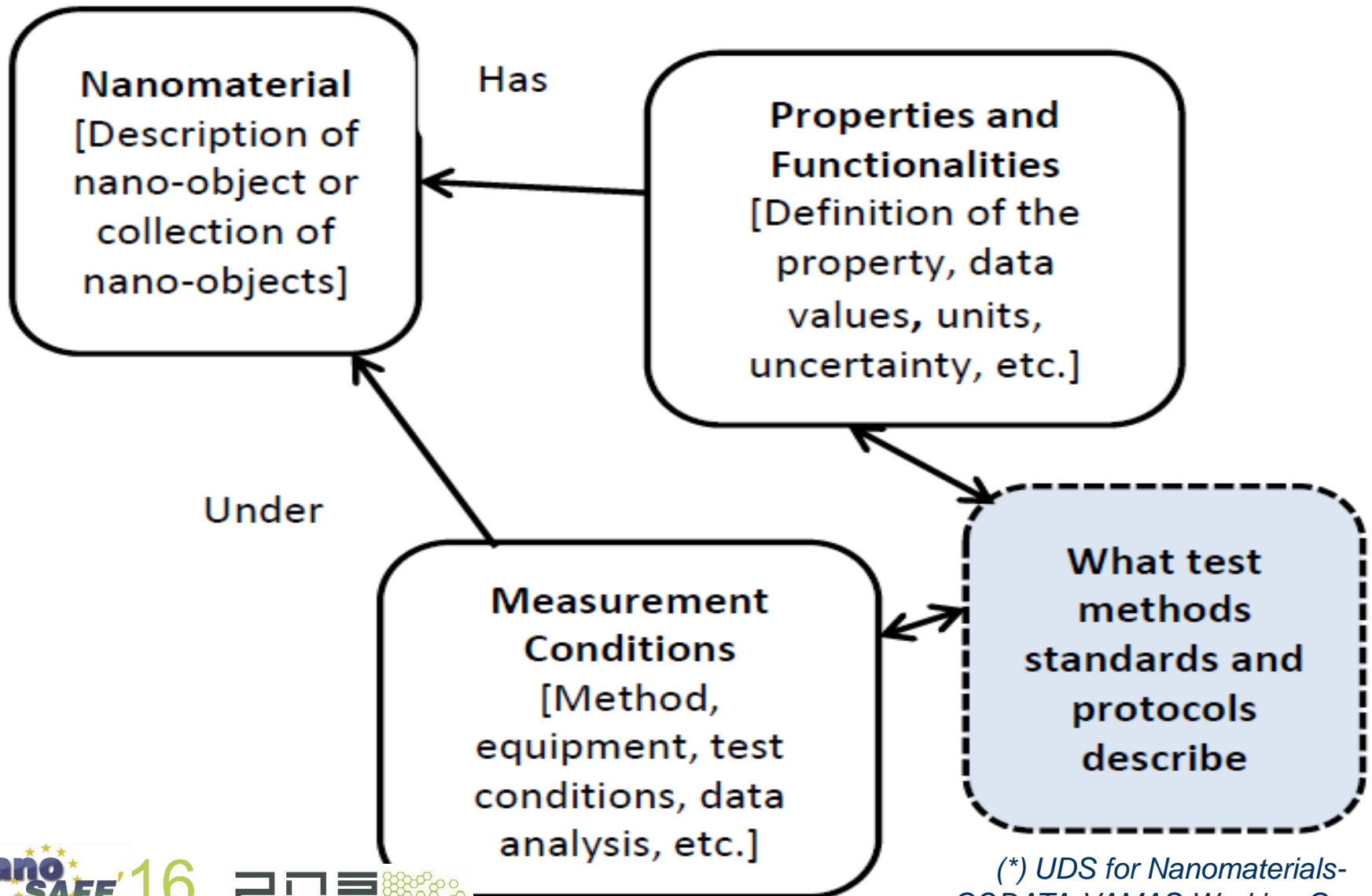
Such definition appears only to answer to the question of hazards and (inhalation) risks of ultra-fine or submicronic particles, for possible impact on health and environment, but does not cover the nanoscale advanced materials.

The rich array of actual, and potential, nanomaterials requires considerable detail to be differentiated from one another.

It is useful however to divide nanomaterials and the bulk materials containing them in four major types, each type of nanomaterials requires slightly different set of information to describe it completely:

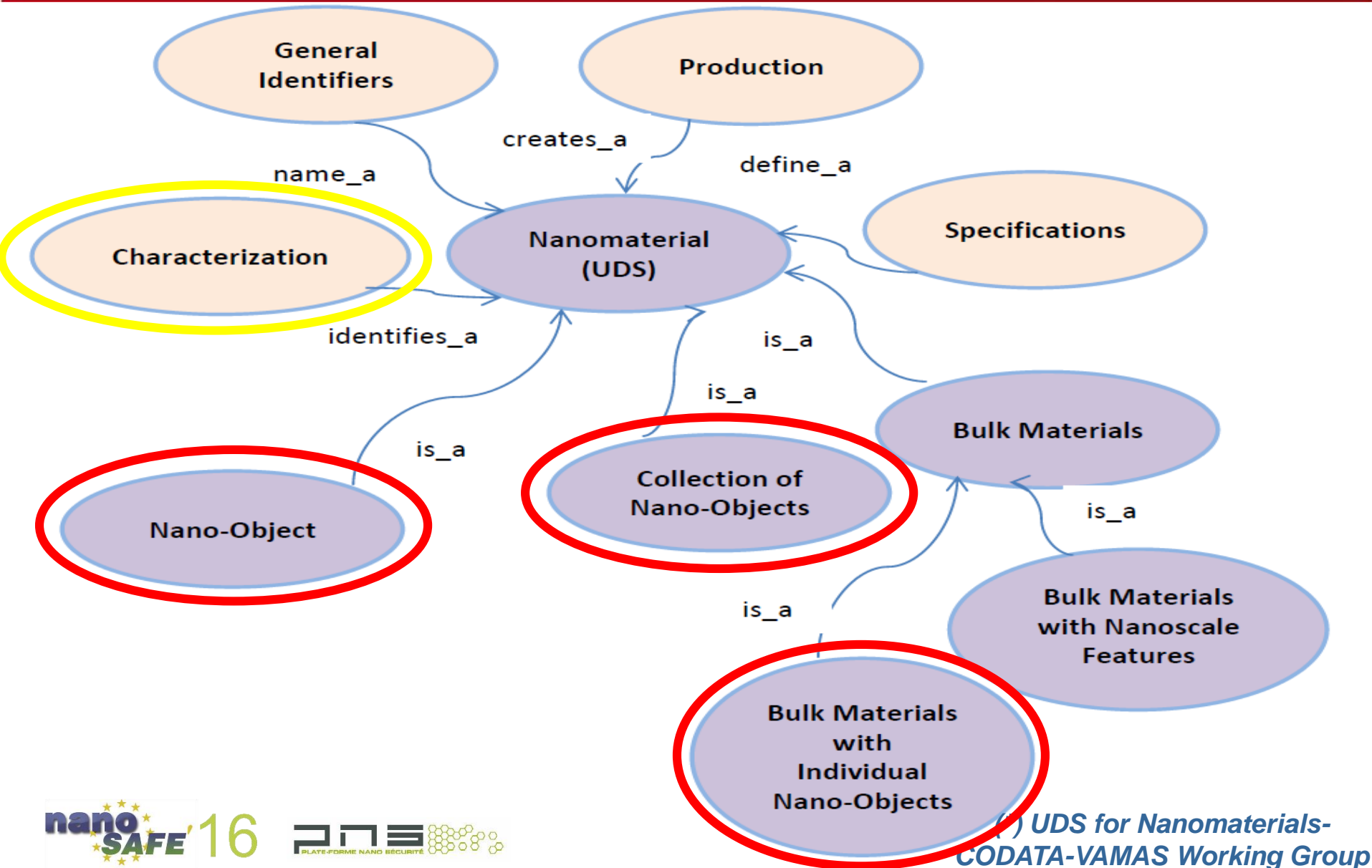
- **Individual nano-object,**
- **Collection of nano-objects:**
 - **Identical nano-objects,**
 - **Different nano-objects,**
- **Bulk material containing individually identifiable nano-objects,**
- **Bulk materials structured at the nano-scale,**

The relationships of tests methods and protocols to the properties of Nanomaterials

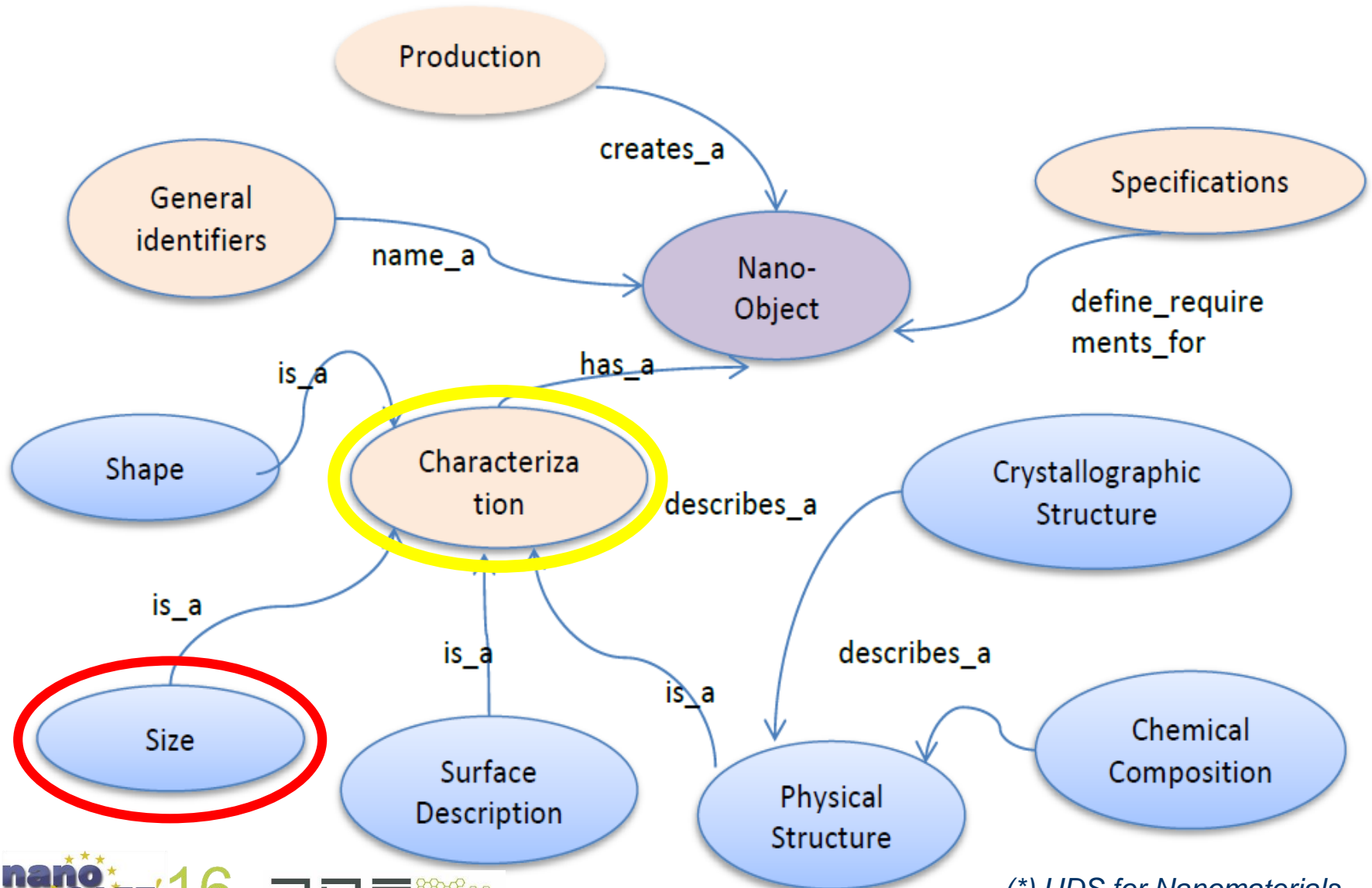


(* UDS for Nanomaterials-CODATA-VAMAS Working Group

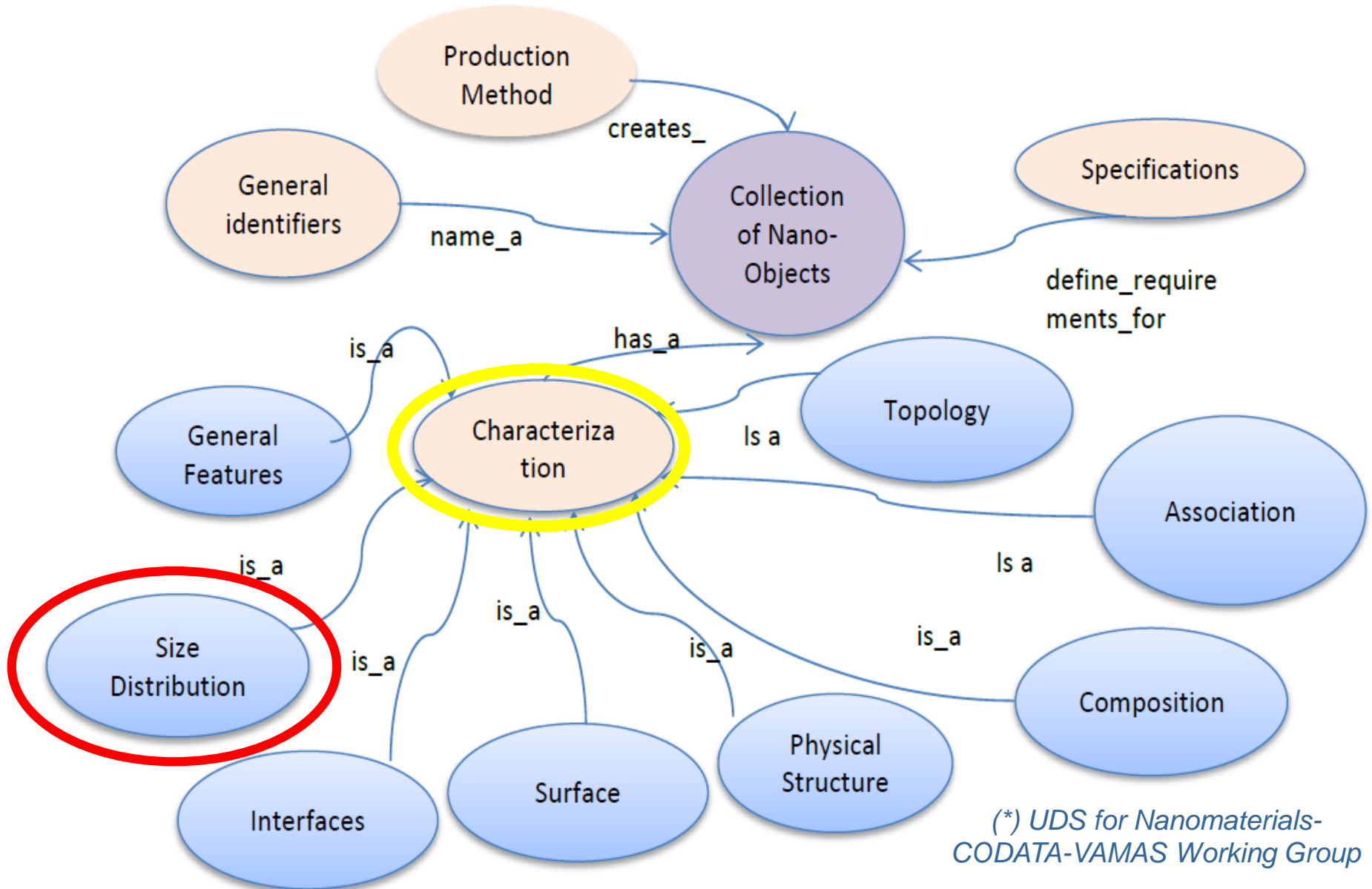
Framework for UDS for nanomaterials



Information for describing an individual nano-object



Information categories to describe a collection of nano-objects



Can definition be used without standardized protocols for characterization and measurements ?

Regulatory use of a nanomaterial definition requires consideration of how to implement it, relying on the possibility to verify through measurements whether or not a material meet with the definition,

For example, nano-objects have several external dimensions that can be interpreted as « *particle size* ». Therefore different size measurement methods may provide significantly different size values.

Guidance and standardised measurement methods, as well as knowledge about typical concentrations of nanoparticles in representative sets of materials, should be developed where feasible and reliable to facilitate the application of the definition in a specific legislative context.

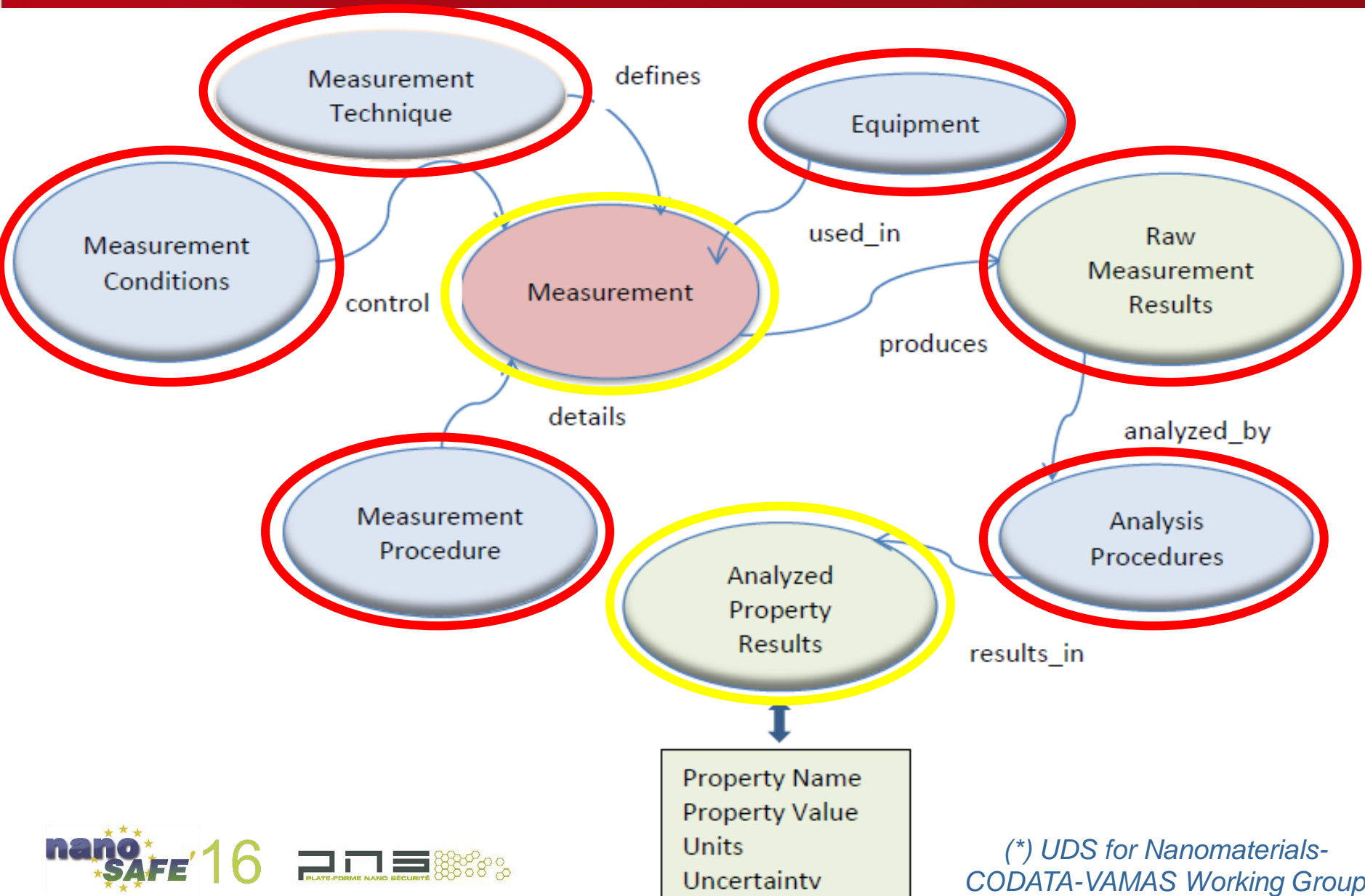
Measurement protocols must be repeatable, reproducible and validated at the international level (standards), by the scientific and technological community,

Descriptor for the size distribution of a collection of nano-objects (*)

Descriptor	Definition	Notes and example
Collection sampling type	What type of sampling was done on the collection?	Individual; Representative; Randon; Average; etc.
Sampling method	How was sampling done?	If average or representative collection,how was sample obtained,
Distribution of sizes	The amount of each size nano-object found in the collection	List of sizes or size ranges that occur in the collection and their percentage
Range of sizes	Maximum and minimum size of constituent nano-object	May be dependent on measurement method
Average size	Average size of nano-object in the collection	May be dependent on measurement method
Median size	Median size of nano-object in the collection	May be dependent on measurement method
Method of determination	Method used to determine the size distribution	Different methods lead to differennt results
Media in which determined	Media in which the size distribution measurement was made	Measurement can be very media dependent

(*) Table 10 - UDS for Nanomaterials- CODATA-VAMAS Working Group

Information categories for a measurement



The european recommandation for a definition of « *nanomaterials* » for regulatory purposes, as collections of particles containing NOAAs is targeted only on the size, and forget the novel properties and applications.

The misuse of the term « *nanomaterials* », as defined by ISO, will lead to a lack of understanding and loss of confidence for all the stakeholders in relation with all the nanomaterials, with advanced properties.

To prevent any european *Nanoexit*, a clear and indisputable naming for collections of particles containing a percentage of NOAAs is needed to prevent wrongly use of the term « *nanomaterials* ».

Wrap up (2)

To name the present so-called nanomaterials for european regulatory purpose, different proposals are possible to prevent any ambiguity:

- **1/ Keep the wording of the present definition, and use a more appropriate term to name such collections of particles and NOAAs:**
 - *Sub micronic materials, ultra fine particles or materials, nanoparticulate materials, particulate nanomaterials, nanopowders ...*

- **2/ Keep the name nanomaterials, but use a new definition fitting with the ISO definition for NOAAs and nanostructured materials:**

- **3 / Change name and definition criteria,**
 - size range: up to 1 000 nm, or 2 500nm, (inhalation risk)
 - size distribution in number, in volume, in mass, in surface;
 - NOAAs percentage (why 50% ?)
 - Other physical and/or chemical parameters; new properties (to promote advanced materials,

The discussion is open to contribute to the european debate and consultation to prevent any ambiguity.

But, we must not forget that regulatory definition will not be possible without dedicated standardized protocols for measurement and characterization of the physical and chemical properties of the materials (NanoReg 2 program, in progress), not only focus on the size.

**Thank you for
your attention !**

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