

Nano and REACH Workshop

- organised by Cefic -

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RIP-oN 1

Substance ID under REACH for nanomaterials

- Scientific/technical Advice -

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“Nano and REACH” Workshop

- The provisions of REACH apply to nanomaterials;
- REACH guidance documents apply also to substances at the nano scale;
- Current guidance does not give specific advice on nanomaterials.

Ref.: Nanomaterials in REACH (CA/59/2008 rev.1)

REACH Implementation Projects on Nanomaterials (RIP-oNs)

- The objective of the projects is to provide **scientific and technical advice** on key aspects of the **implementation of REACH** with regard to **nanomaterials**.

- Three reports shall be developed:
 - **RIP-oN 1: Substance Identification (SI)**
 - **RIP-oN 2: Information Requirements**
 - **RIP-oN 3: Chemical Safety Assessment**

RIP-oN 1 on Substance Identification of Nanomaterials

The Commission Services initiated the **RIP-oN 1**

- to evaluate the applicability of the existing 'Guidance on identification and naming of substances under REACH'¹ for nanomaterials, and
- if needed, to develop specific advice on how to establish the substance identity of nanomaterials.
- A key feature of the project was that it built on **four case studies**.

1 http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

Case studies

- "bottom-up approach" generating empirical knowledge and harvesting arguments for drafting the advisory report.
- Each case study should identify the relevant characteristics that determine the identity of the specific nanomaterial by assessing the adequacy of current substance identification parameters laid down in Annex VI, item 2 of REACH.
 - Where appropriate, each case should identify additional parameters potentially relevant for the type of nanomaterial and advice on where to find or how to produce it.
 - The case studies do not present any precedent regarding duties concerning REACH.

RIP-oN 1 on Substance Identification of Nanomaterials

- Carried out by the JRC-IHCP in cooperation with an **expert group**;
- Experts were nominated by members and observers from CARACAL¹;
- Joint JRC, ECHA, DG ENV and DG ENTR **steering group**;
- Progress and (draft) results reported to **CASG Nano**², which was invited to provide written comments to various deliverables throughout the project.

1 Competent Authorities for REACH and CLP

2 Competent Authorities subgroup on Nanomaterials

Expert Group for RIP-oN 1

- **Member State Competent Authorities**
 - *direct participation*: **Austria, Germany, France, Ireland, Lithuania, Netherlands & Sweden**
 - *written consultation*: **Poland, Finland, Belgium**, add. experts FR & DE

- **Industry** - **Cefic** (European Chemical Industry Council)
 - **EPMF** (European Precious Metal Federation)
 - **FECC** (European Association of Chemical Distributors)

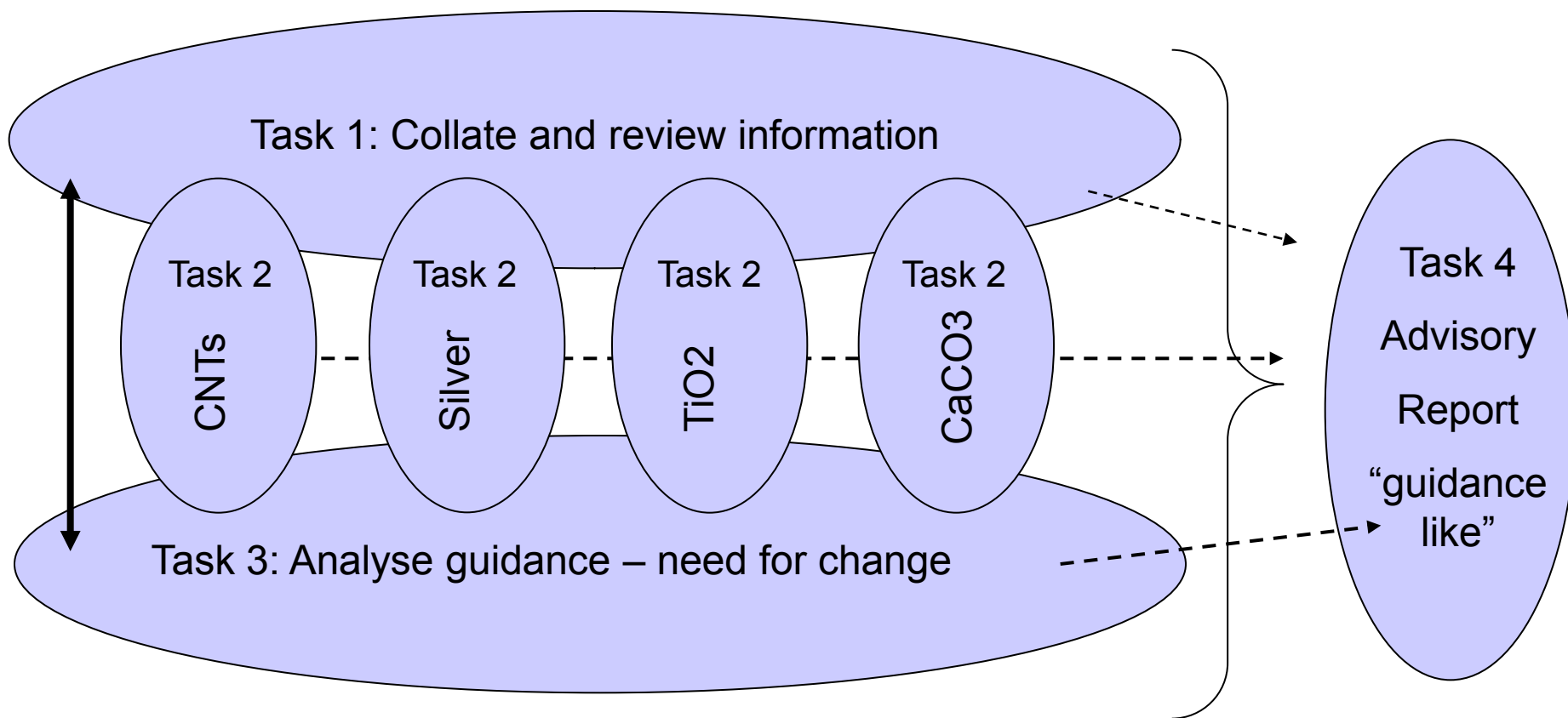
- **NGOs** - **EEB** (European Environmental Bureau)
 - **ETUC** (European Trade Union Confederation)

- **ECHA & COM** (ENV, ENTR and JRC)

Working organisation

- **Four Face to face Meetings in JRC-Ispra (Italy)**
15 October 2009, 20/21 January 2010,
22/23 March 2010 and 22/23 June 2010
- **e-mail;**
- **telephone conferences,**
- **written consultations ...**

RIP-oN 1 on Substance Identification of Nanomaterials



Case Studies: Working groups (lead in bold)

- Carbon Nanotubes:
CEFIC & ECHA, ETUC and France
- Nano-silver:
EPMF & Netherlands, EEB, Lithuania, Finland & Poland
- Nano-CaCO₃:
FECC, ETUC & Sweden
- Nano-TiO₂:
CEFIC, EEB, France, Germany, Ireland, ECHA & Austria

Advisory Report

- drafted by **JRC** based on the work carried out by the expert group;
- **Opinions diverged on several key issues** for which it was not possible to reconcile the views and arrive at consensus.
- Therefore, large parts of the report describe various options/approaches.
- Drafts of the report reviewed by the RIP-oN 1 experts;
- Draft final report reviewed by CASG Nano.



RIP-oN 1 Advisory Report

1. Introduction
2. Terminology and abbreviations
3. Substance Identification and Naming in REACH
4. Main Issues concerning substance identification of nanomaterials
5. Guidance on substance identification and naming of substances under REACH
6. Conclusions and recommendations

Terminology (Chapter 2 of Advisory Report)

applicable to this project only

Nanomaterial: In the absence of an agreed EU/REACH definition of "nanomaterial", the RIP-oN 1 project considered particles (such as nano-silver, nano-TiO₂ or nano-CaCO₃) and tubes (such as CNT) with at least one dimension < 100 nm as nanomaterials. However, it was outside the scope of the project to define the term "nanomaterial".

Bulk substance: Substance with particles, where all dimensions > 100 nm

REACH substance: Substance according Article 3 of the REACH Regulation; can be distinguished from other REACH substances by **identifiers**.

Form of a substance: Form of a REACH substance; can be distinguished from other forms of the same REACH substance by **characterisers**.

Terminology

Nano-form: Form of a substance with at least one dimension < 100 nm

Bulk form: Form of a REACH substance with all dimensions > 100 nm

Identification/identifier: The wording "identification/identifier" is used to distinguish a REACH substance from another REACH substance.

Characterisation/characteriser: The wording "characterisation/characterisers" is used to distinguish forms of the same REACH substance which are included within one REACH registration dossier, e.g. nano-form and bulk form.

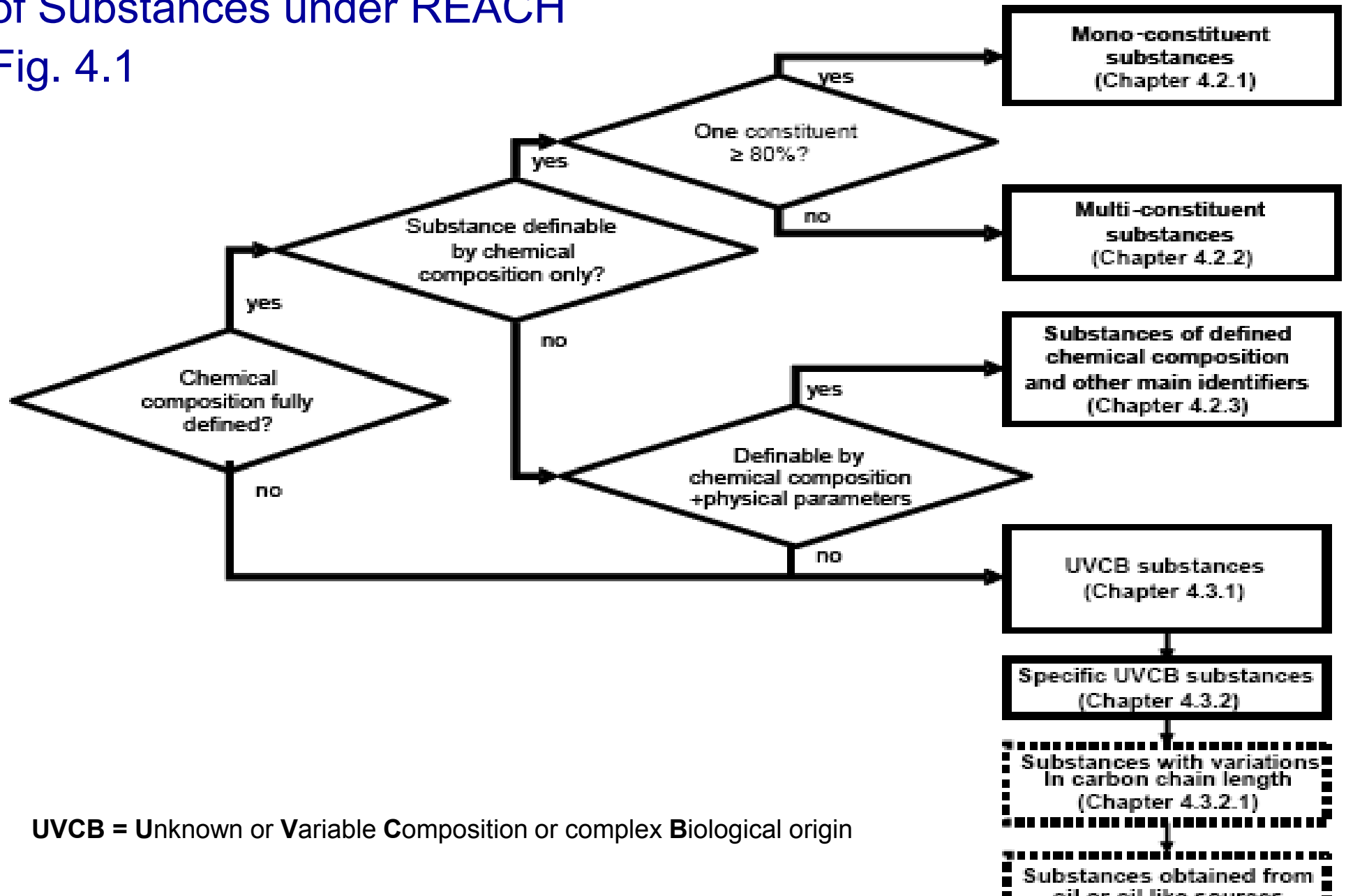
Substance Identification and naming in REACH

(Chapter 3 of Advisory Report)

- 'Guidance for identification and naming of substances under REACH' (ECHA 2007).
- Generally, a substance is identified by its chemical composition, the chemical identity and the content of each constituent in the substance.
- In some cases other or additional substance identification information is required.
- The guidance does not include any specific advice for the identification and naming of nanomaterials.

Guidance Document on the Identification and Naming of Substances under REACH

Fig. 4.1



UVCB = Unknown or Variable Composition or complex Biological origin

Application of the Guidance to the case studies

- No consensus in terms of deciding whether a given example is a nanoform of a chemically identical bulk substance or a substance in its own right.

Identification approaches *discussed*

	Mono-constituent substance	Substance of defined chemical composition and other main identifiers	UVCB substances
Graphite		X	
MWCNTs		X	X
SWCNTs		X	X
Nano-silver	X	X	
Nano CaCO ₃	X	X	
Nano TiO ₂	X	X	X

Main issues concerning substance identification of nanomaterials (Chapter 4 of Advisory Report)

- **Size as identifier or characteriser**
- **Surface treatment**
- **Other potential identifiers**
- **Analytical methods to measure potential identifiers or characterisers**

Criteria discussed to decide whether an example in the case study was a nanoform of a bulk substance or a substance in its own right

	Size	Properties	Surface treatment
CNTs *		X	X
Ag	X	X	X
CaCO₃	X	X	X
TiO₂	X	X	X

* CNT case was unique in that the key issue for deciding whether it was a nanoform was based on the appropriateness of the designated bulk substance, Graphite, i.e. it was not a size issue.

'Size' as an identifier?

- As 'nano' is a size indicator, the most debated issue was whether 'size' should be an identifier.
- In some cases size does affect the properties of materials significantly.
- Consensus that information requirements, safety measures and Chemical Safety Assessments (where needed) should evaluate any changes in properties due to differences in physical forms of a substance such as size.
- No consensus in relation to whether size should somehow be reflected in the substance identity, i.e. whether 'size' should/could be an identifier.

'Size' as an identifier?

Two overall options discussed:

- Size is not an identifier, but a characteriser
- Size is an identifier, or may trigger other identifier(s)

'Size' is not an identifier, but a characteriser

- Industry experts judged that size is an important characteriser but should not be made a mandatory identifier for the purpose of substance identification for nanomaterials under REACH.
- With reference to the substance definition in REACH, it is argued that substance identity is based on chemical identity, and not on physical properties.
- Changes in physico-chemical properties may also occur in bulk substances depending on size.
- The CLP Regulation requires (Art. 9(5)) that “*the forms or physical states*” of substances are considered which might lead to different classification of the same substance depending on e.g. size if appropriate.

Size is an identifier, or may trigger other identifier(s)

- Specific surface area and quantum confinement effects are size dependent and may not be inferable simply from the chemical composition.
- Property changes may be significant and may justify a different substance identity.
- Criteria to decide which properties are relevant or how significant any differences in properties should be have not been developed to date.
- NGO and Member State experts supported careful consideration of this approach, which may be implemented in different ways. It could either be implemented as
 - 'size in combination with significant changes in properties' *or*
 - 'size alone' as the identifier.

Surface Treatment

Nanomaterials are often **surface treated**.

- Different terms such as 'surface treatment', 'surface modification', 'coating' and 'functionalization' are often used as synonyms.
- Surface treatment is also relevant for non-nano particles, but might be of particular relevance for nanoparticles due to their higher specific surface areas.

REACH FAQ 6.3.8 (http://echa.europa.eu/reach/faq_en.asp)

Do I have to register chemically surface treated substances?

... a reaction of only a minor part (surface) of a macroscopic particle with the surface treating substance ...

... chemically surface treated substances should not be registered as such under REACH

- ECHA clarified that the FAQ 6.3.8 as written is not applicable to nanomaterials.
- However, Industry view is that this FAQ is applicable to nanomaterials.

Surface Treatment

- Discussions have generated a lot of controversy

Issues to consider:

- Nature of the bonds between the particle surface and the surface treating: "chemical" or "physical" bonding?
- Purpose of the surface treatment?
 - Only to keep the nanoparticle in suspension?
 - Intended modification of the substance and its properties?

Other potential identifiers *discussed*

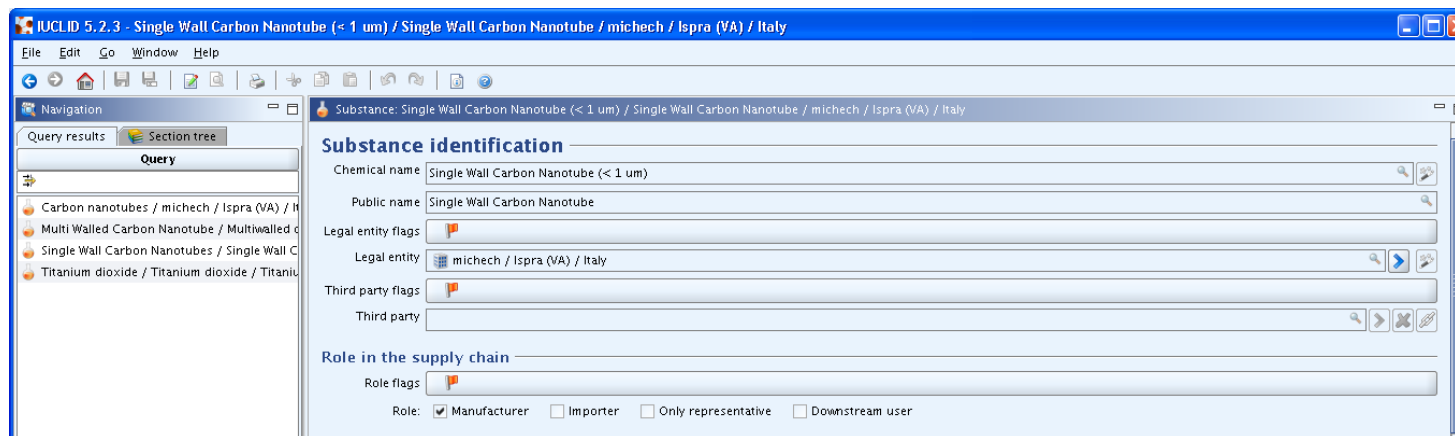
- Physico-chemical properties
 - Solubility/dispersability,
 - Photocatalytic/optical properties,
 - Surface energy / redox radical formation,
 - Density
- Geometrical parameters
 - Agglomeration/aggregation
 - **Specific Surface Area**
 - Shape, including **aspect ratio**

Analytical methods to measure potential identifiers or characterisers

- While there was no consensus about the need of additional identifiers,
- all case studies report relevant methods that could be used to measure the potential identifiers.
- Summary in Table 4 of the Advisory Report

Guidance for identification and naming of substances under REACH (Chapter 5 of Advisory Report)

- Section-by-section analysis of the Guidance (Box 2)
- **Specific advice on carbon nanotubes**
- Description of nanomaterials in IUCLID



The screenshot displays the IUCLID 5.2.3 software interface. The title bar reads "IUCLID 5.2.3 - Single Wall Carbon Nanotube (< 1 um) / Single Wall Carbon Nanotube / michech / Ispra (VA) / Italy". The main window is divided into a left navigation pane and a right main content area. The navigation pane shows a "Section tree" with a "Query" section expanded, listing various categories like "Carbon nanotubes / michech / Ispra (VA) / It", "Multi Walled Carbon Nanotube / Multiwalled c", "Single Wall Carbon Nanotubes / Single Wall C", and "Titanium dioxide / Titanium dioxide / Titaniu". The main content area is titled "Substance identification" and contains several input fields: "Chemical name" (Single Wall Carbon Nanotube (< 1 um)), "Public name" (Single Wall Carbon Nanotube), "Legal entity flags" (with a flag icon), "Legal entity" (michech / Ispra (VA) / Italy), "Third party flags" (with a flag icon), and "Third party" (with search and navigation icons). Below these is the "Role in the supply chain" section, which includes "Role flags" (with a flag icon) and a "Role:" section with checkboxes for "Manufacturer" (checked), "Importer", "Only representative", and "Downstream user".

Specific advice on carbon nanotubes

- Carbon nanotubes (CNT) can be defined as
 - any graphitic carbon material of nanometric size having a tubular shape (cylinder with a tubular cavity) or
 - a nested coaxial array of single wall nanotubes, with each nanotube being formed by a graphene sheet rolled into a cylinder of nanometre size diameter.
- CNT may vary in the number of layers, length, diameter, shape, straightness.
- Properties are dependent on the production process.
- An identification on chemical composition (carbon) solely would not allow to distinguish CNT from graphite or diamond.
- CNTs can be identified either as
 - 'well defined substance plus additional identifiers' or
 - 'UVCB substance'.

Specific advice on carbon nanotubes

consensus

- CNTs can mainly be identified by the type of tube, potentially CNT diameter and potentially CNT length.
- SWCNT, DWCNT and MWCNT are distinct types of tubes that can be manufactured and are considered to be the main identifiers.
- Length and diameter are important for the characterization of CNTs.
 - It is not yet established whether length and diameter should be considered as parameters that trigger different forms of a substance or identifiers that trigger different substances.
 - As identifiers, there is the need to develop criteria how the numerical values should be included in the name; precise values versus ranges.

Conclusions and Recommendations

(Chapter 6 of Advisory Report)

- The scope of the project was mainly to consider technical/scientific arguments.
- Opinions diverged on several key issues for which it was not possible to reconcile the views and arrive at consensus.
- The solution of the issues for which consensus could not be reached will require decisions beyond the scientific arguments.

Recommendations

- It is recommended to continue the discussion in CASG Nano and CARACAL.
- This could be done based on the different options outlined in the Advisory Report, and in particular by addressing the questions raised in the conclusions.
- It is recommended that further discussions would also consider consequences such as number of registration dossiers or the impact on the tonnage bands.
- Some of the results of the project such as the advice concerning the identification of carbon nanotubes could rather easily be integrated in the existing Guidance.

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Thank you for your attention

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