

Introduction

Webinar: Getting prepared for new
REACH information requirements for
nanomaterials

12 November 2019

Jenny Holmqvist, ECHA



New REACH requirements for nanomaterials

- More clarity on what information companies must provide in their registrations
- Concerns all new and existing registrations for nanoforms
 - Assess if new requirements apply to your substances
 - Register or update your registration by 1 January 2020



Why?

- Enable companies and authorities to assess:
 - Hazardous properties of nanomaterials
 - How they are used safely
 - What risks they pose to our health and environment
 - Determine appropriate risk management measures



What changes?

- New annexes introduce clarifications and new provisions for:
 - Characterisation of nanoforms or sets of nanoforms covered by the registration (Annex VI)
 - Chemical safety assessment (Annex I)
 - Registration information requirements (Annexes III and VII-XI)
 - Downstream user obligations (Annex XII)



What you can expect from today

- What is a nanoform and how to build a set of similar nanoforms
- How you can fulfil data requirements for characterising your nanoforms
- Overview and practical examples of new IUCLID fields for reporting nanoforms

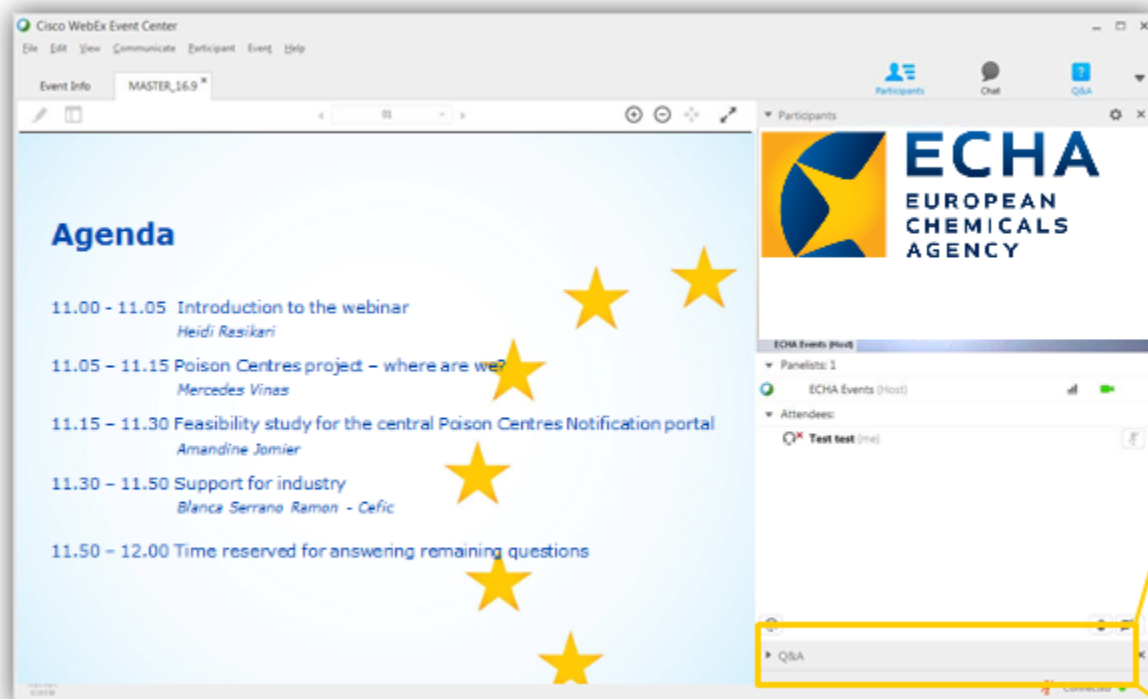




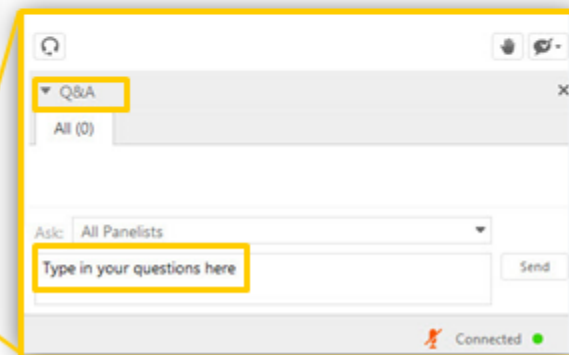
Agenda

- 11:00 **Introduction**
Jenny Holmqvist, ECHA
- 11:05 **Requirements for registration and substance identification**
Tuomas Aitasalo, ECHA
Abdelqader Sumrein, ECHA
- 11:45 **Introduction to new IT tools and formats**
Anna Daszynska, ECHA
- 11:55 **New IUCLID formats for characterisation of nanoforms**
Anna Daszynska, ECHA
- 12:10 **Reporting characterisation of nanoforms in IUCLID: illustrative examples**
Askar Nurassilov, ECHA
- 12:25 **Conclusions**
Jenny Holmqvist, ECHA
- 12:35 – 13:30 **Webinar open for questions**

Q&A panel



- Send questions about the presentations
- Send messages if you have any technical difficulties



Q&A panel

- Send questions at any time
- We can only answer questions related to the scope of the webinar
- If your question is not answered by the end of the webinar, send it via our contact form:
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Requirements for registration and substance identification

Webinar: Getting prepared for new
REACH information requirements
for nanomaterials

12 November 2019

Tuomas AITASALO
Abdelqader SUMREIN





Overview

Definitions

- Nanoform
- Set of similar nanoforms

Joint submission of data

REACH Annex VI Section 2.4.

- Particle size distribution
- Surface functionalisation or treatment
- Shape
- Crystallinity
- Specific surface area

} considered together

Definitions: Nanoform



Nanoform

- Form of a substance:
 - Particles in an unbound state or as an aggregate or as an agglomerate
 - 50% or more of the particles in the number size distribution, one or more external dimensions in the size range 1-100 nm
 - Derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm



Nanoform

- A nanoform shall be characterised in accordance with REACH Annex VI section 2.4
 - Particle size distribution and number fraction of constituent particles in the size range within 1-100 nm
 - Description of surface functionalisation or treatment
 - Shape, aspect ratio and other morphological characterisation
 - Specific surface area
- A substance may have one or more different nanoforms based on differences in characterisation parameters



Nanoform guidance

- Variation in section 2.4.2 to 2.4.5 parameters
→ a different nanoform
→ unless from a batch-to-batch variability
- Batch-to-batch variability: inherent to manufacturing process
- Process parameters can be modified only to minimise batch-to-batch variations



Definitions: Set of similar nanoforms



Set of similar nanoforms

- Group of nanoforms characterised in accordance with section 2.4, with:
 - Clearly defined boundaries in parameters in points 2.4.2 to 2.4.5
 - Justification that hazard, exposure and risk assessment can be performed jointly
 - Nanoform can only belong to one set of similar nanoforms



Set of similar nanoforms: Guidance

- Justification why hazard assessment can be performed jointly
 - Needs to be applicable for all endpoints
 - Needs to be supported by data
- Nanoforms do not need to be put in different sets due to different uses
 - All uses need to be detailed

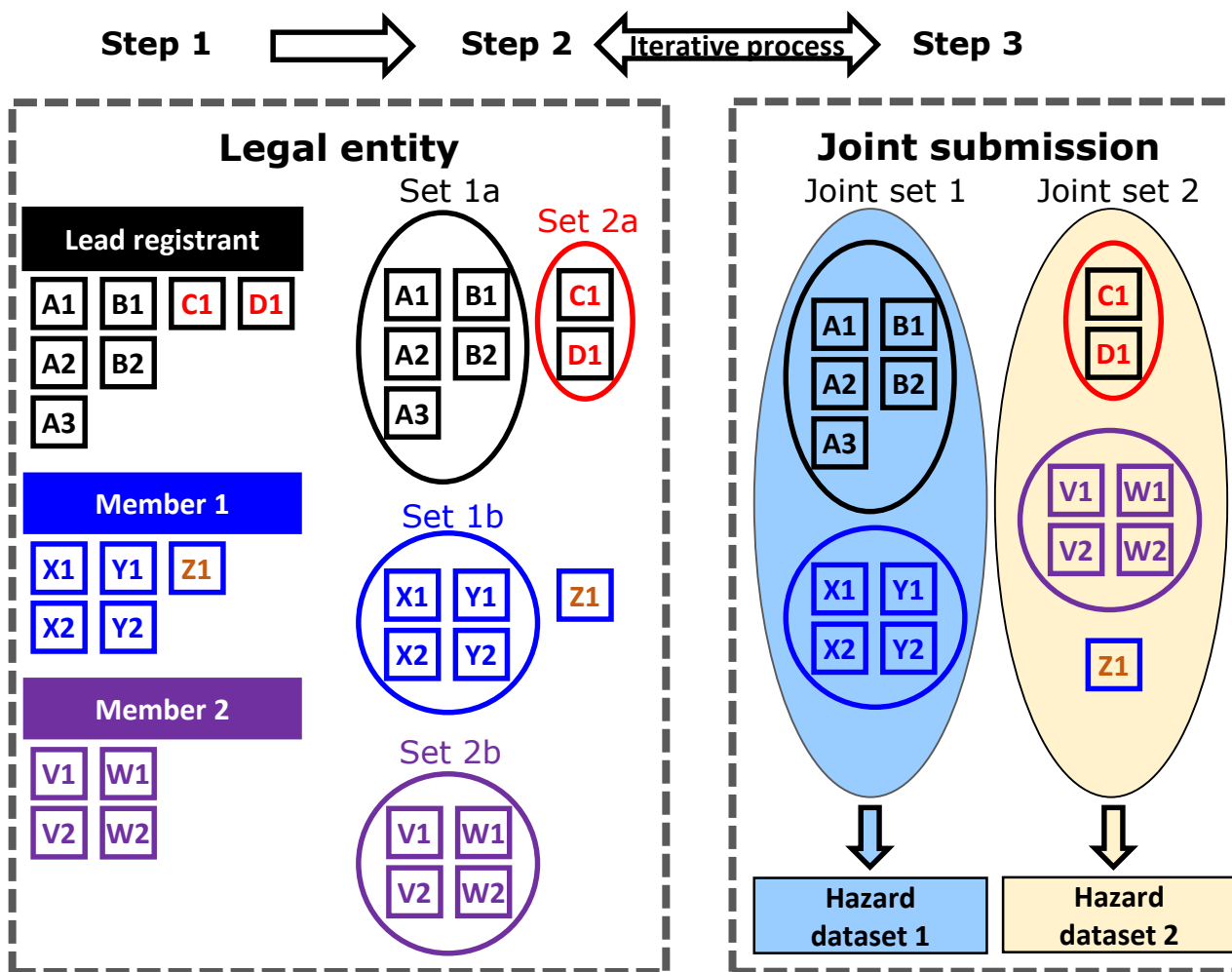


Joint submission



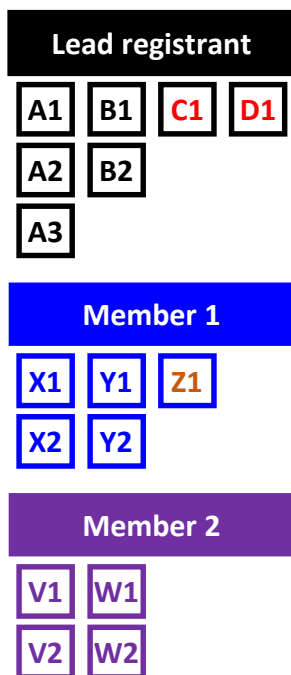


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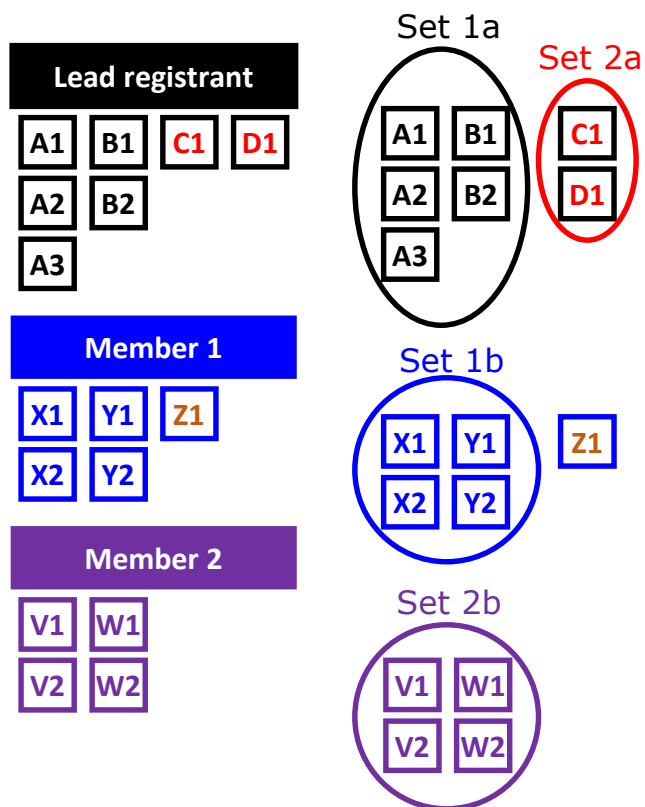


Joint submission



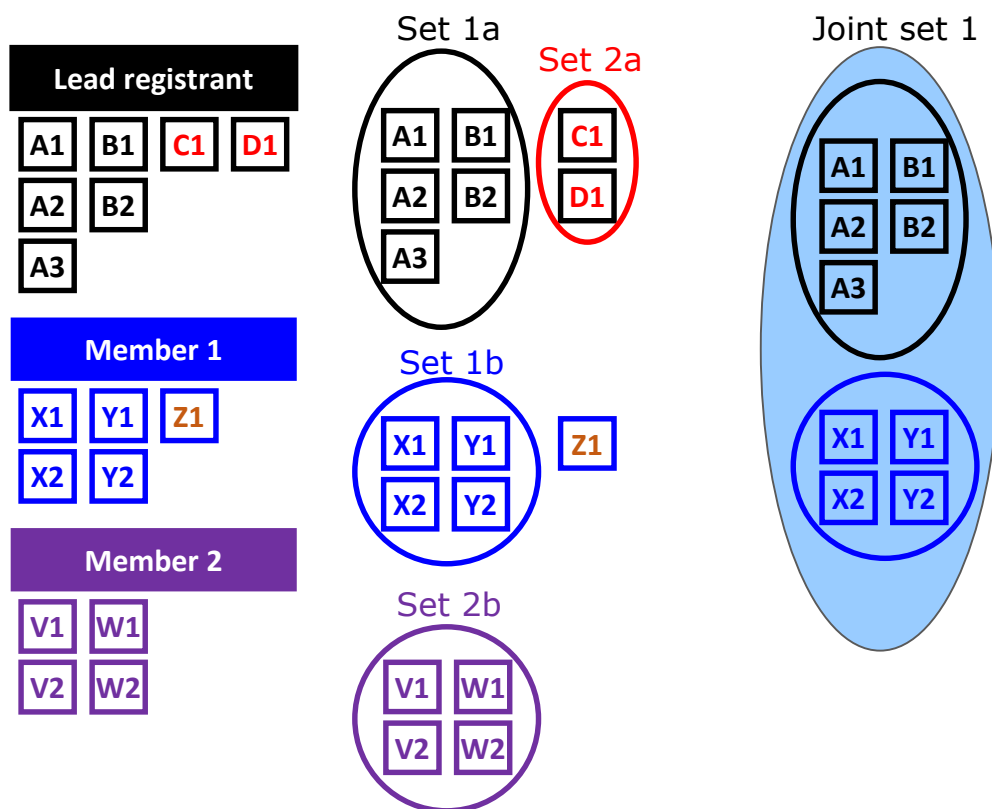


Joint submission



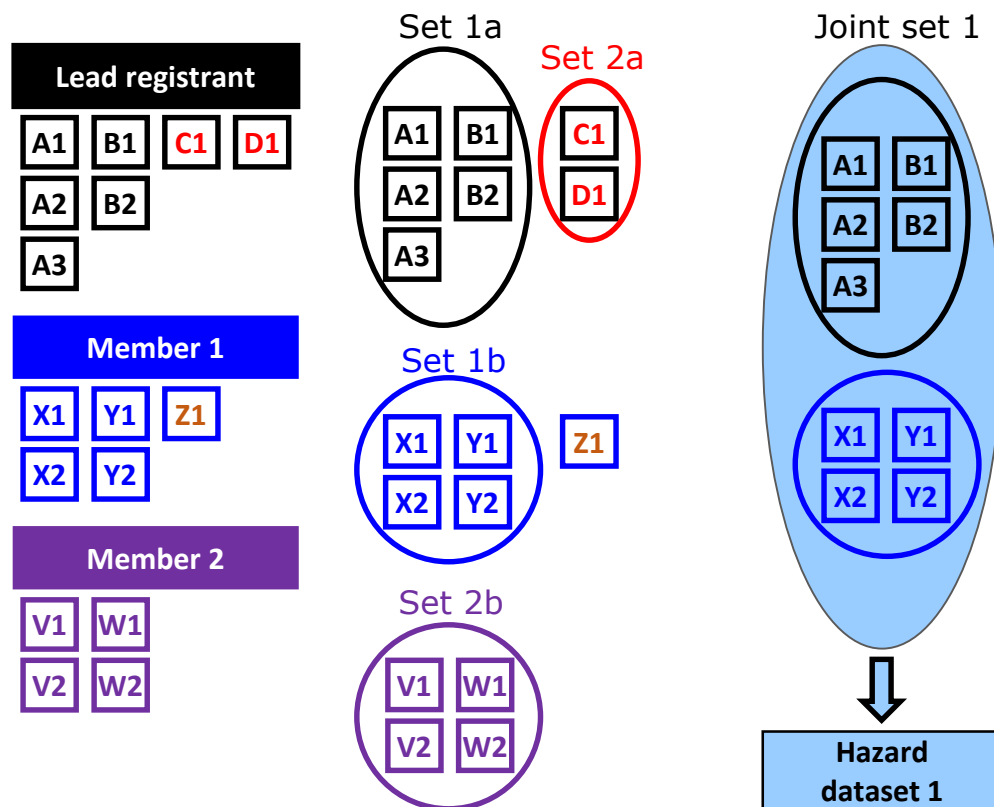


Joint submission



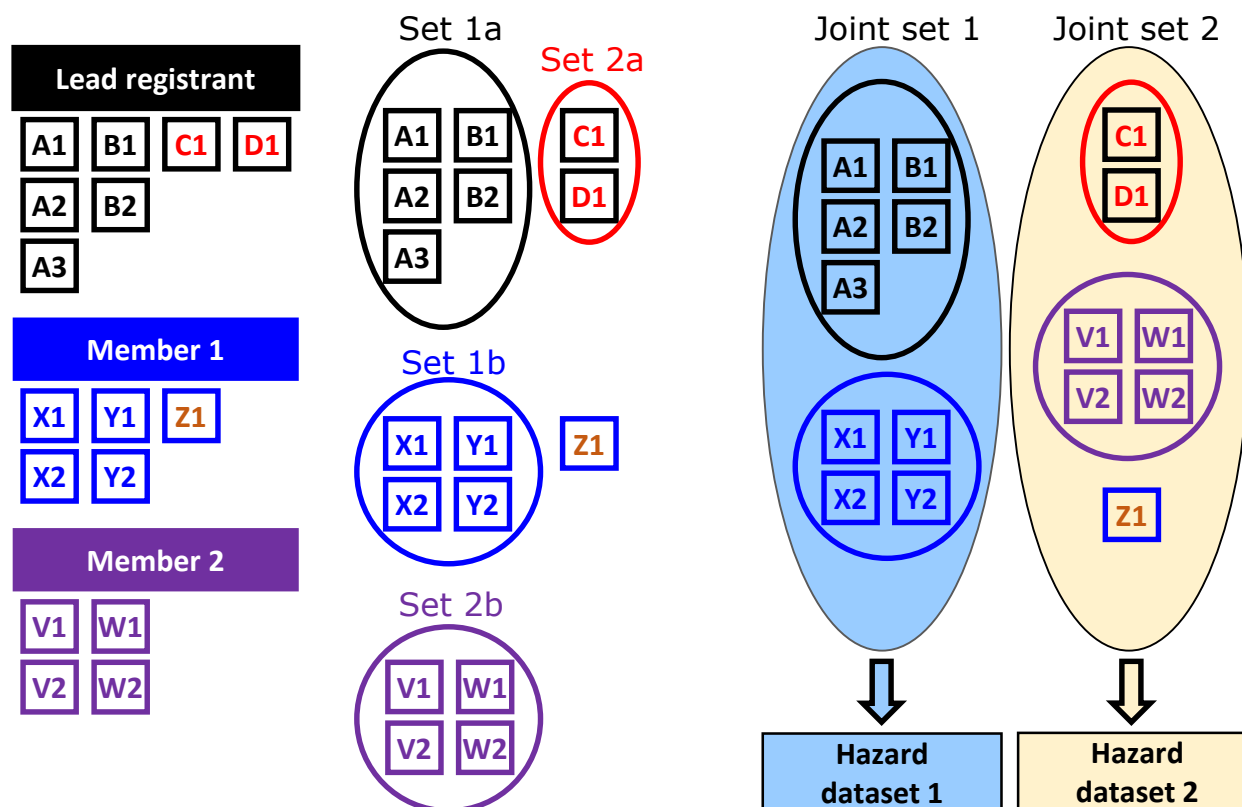


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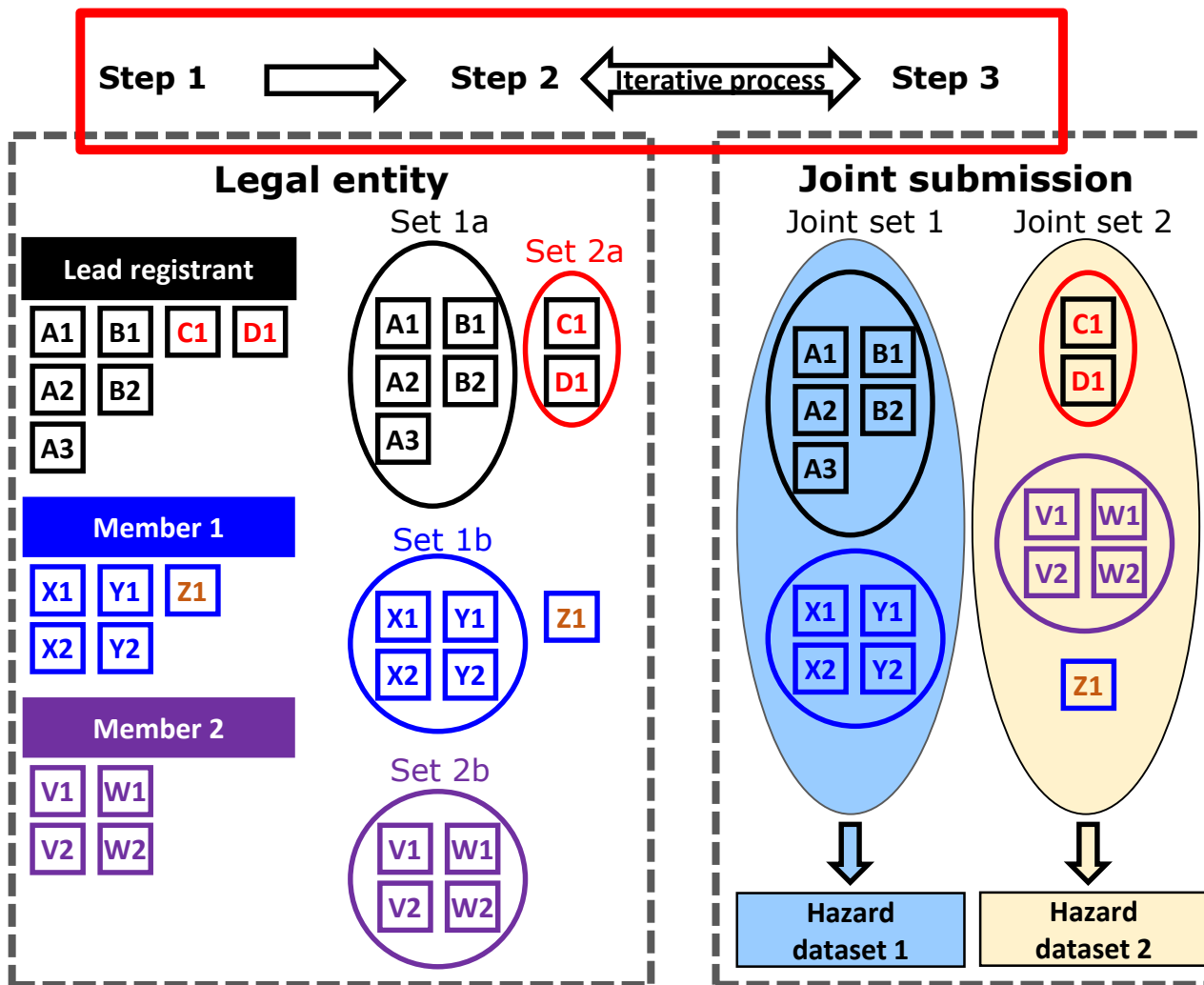


Joint submission





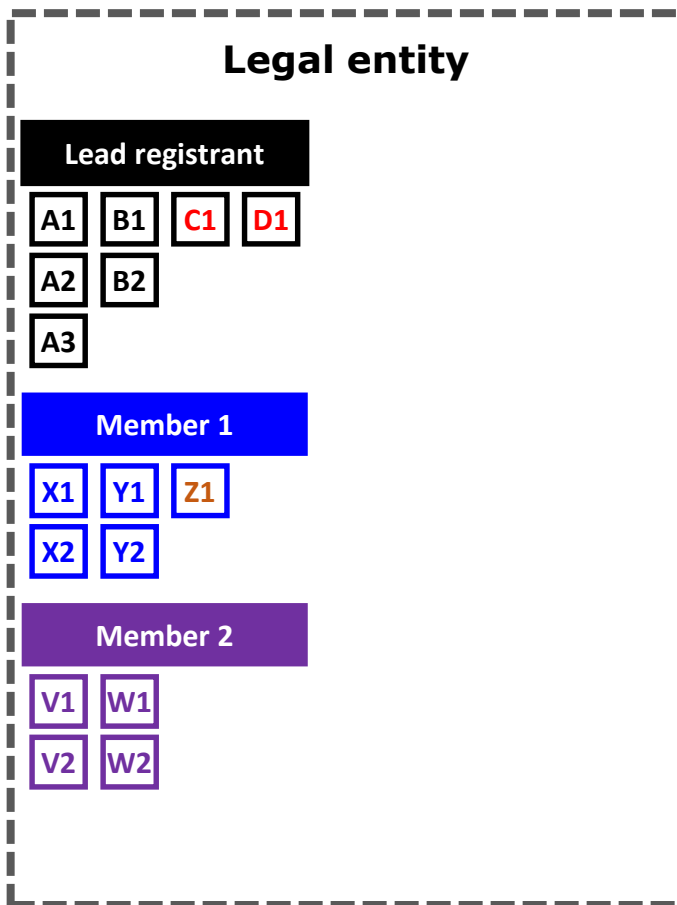
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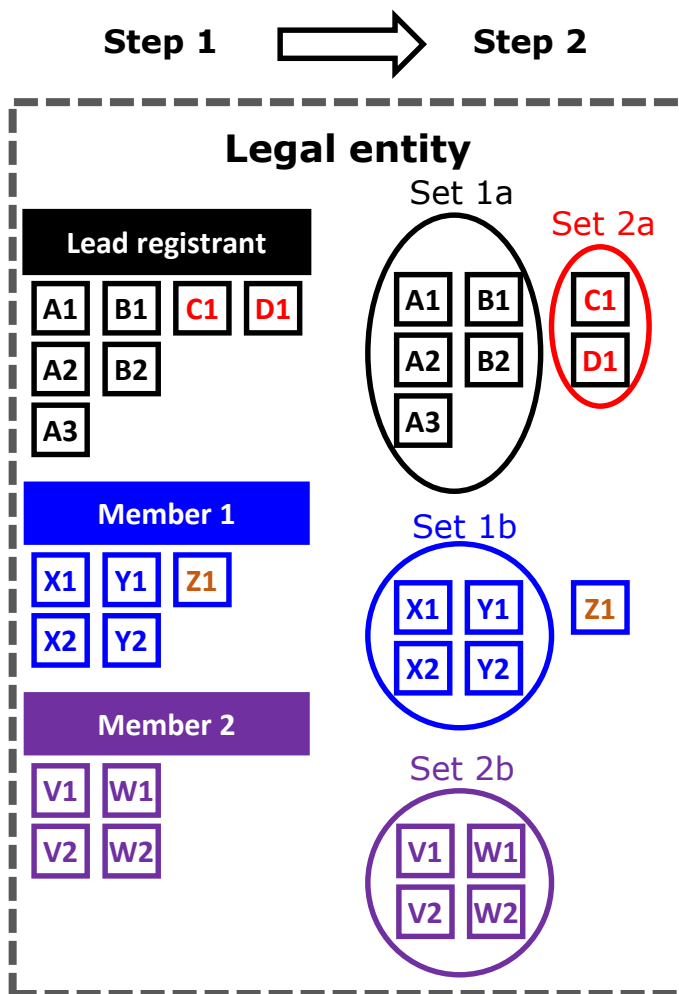
Joint submission

Step 1



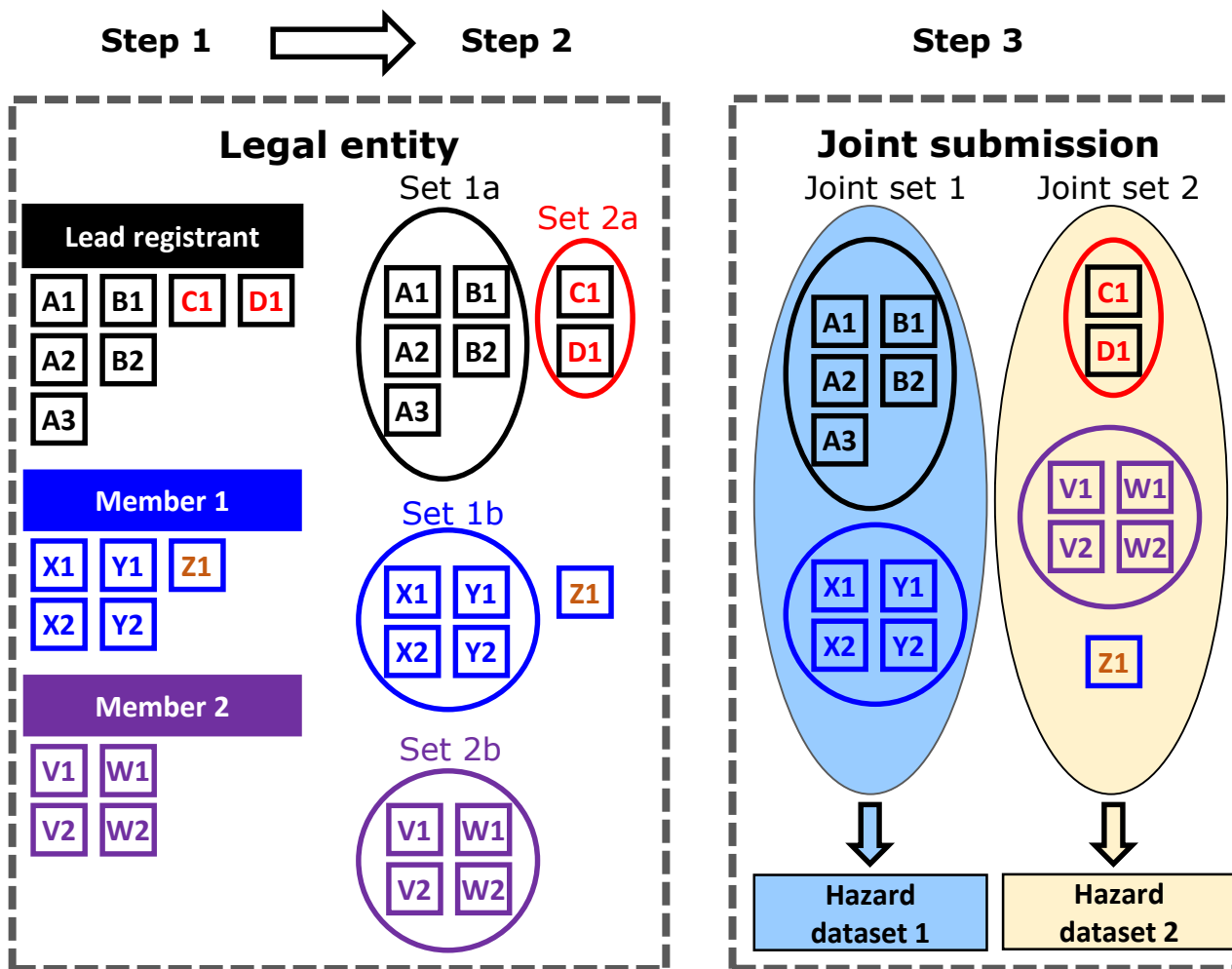


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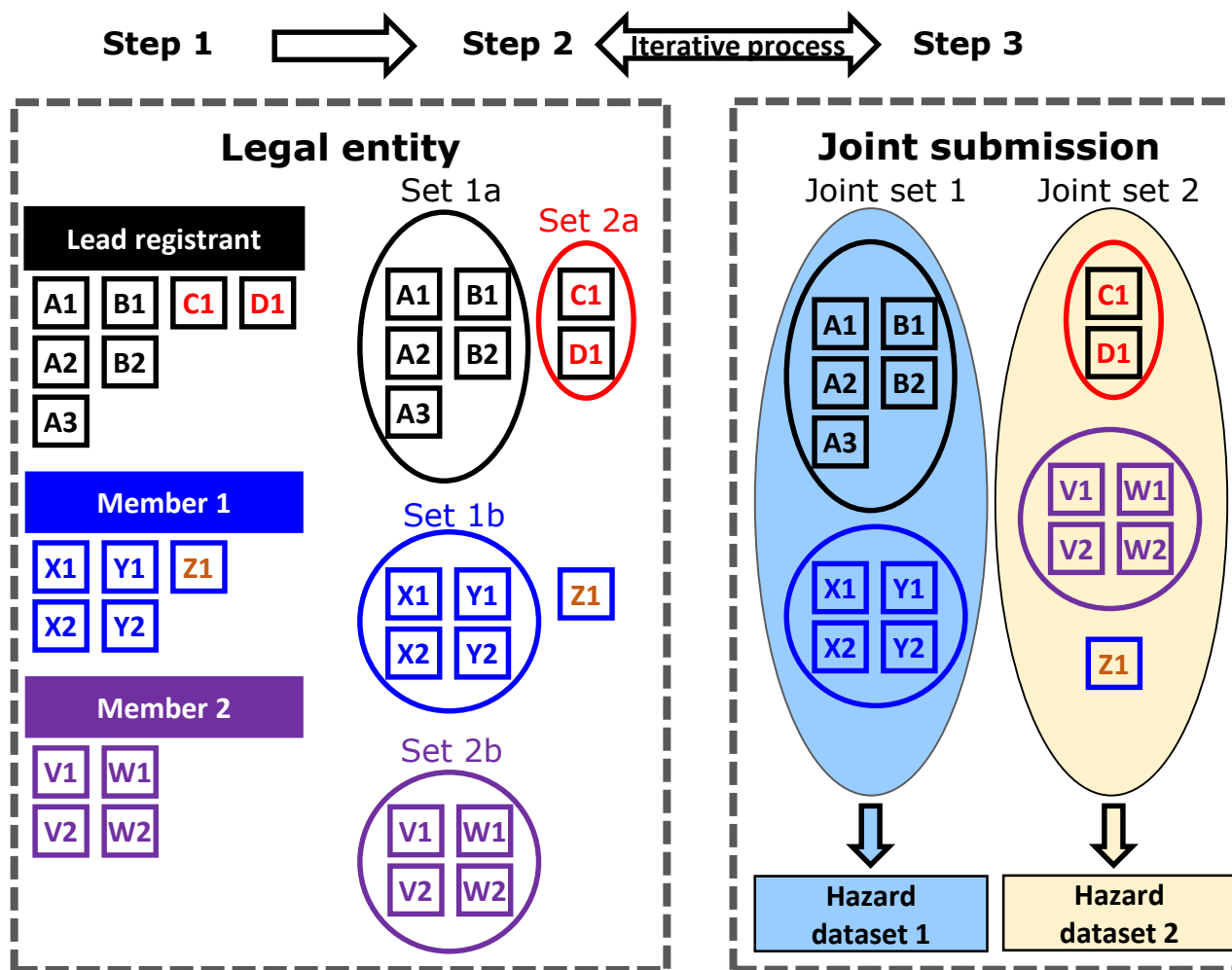


Joint submission





Joint submission



Reporting principles





Reporting principles

- Range of values reflect:
 - Batch-to-batch variability for a nanoform
 - Boundaries of the set for a set of similar nanoforms
- Analytical data needs to show:
 - Typical value of a parameter for a nanoform
 - Boundaries of a value for a set of similar nanoforms

Particle size distribution

Annex VI 2.4.2.



Particle size distribution

Reporting

- Histogram and table of values
- d_{10} , d_{50} and d_{90} values
- Number fraction of constituent particles (50-100%)
- Length of elongated particles and lateral dimensions of platelets
- Separate reporting for particles falling under different shape categories



Particle size distribution

When should nanoforms not be included in the same set?

- Threshold effects
- particle size has an impact on dissolution rate, solubility, toxicokinetic behaviour, fate, (bio)availability, (eco)toxicity



Surface functionalisation or treatment

Annex VI 2.4.3.



Surface functionalisation or treatment

Reporting

- IUPAC name and CAS or EC number of each surface treating agent
- Description of main features of the surface functionalisation/treatment process
- Molar ratio of each surface-treating agent used
- Description of functionalities introduced by treatment



Surface functionalisation or treatment

Reporting

- Information on indicative weight-by-weight contribution of surface-treating agent(s) over total weight of particle
- Indication of percentage of coverage of particles' surface if possible
- Schematics to visually describe treatment including functionalities formed on surface if applicable



Surface functionalisation or treatment

When should nanoforms not be included in the same set?

- In principle, each different surface-treatment result in different surface chemistry → forms with certain treating agent reported on their own
- Nanoforms containing particles without surface-treatment and with surface-treatment



Surface functionalisation or treatment

When should nanoforms not be included in the same set?

Nanoforms containing particles with different surface-treatments can be in the same set if:

1. Surface treating agents are chemically similar
2. Resulting surface chemistry is similar in terms of specific functionalities introduced and overall composition of particles' surface
3. No significant variability in percentage of coverage of particle surface
4. No difference in (eco)toxicity of used surface treating agent

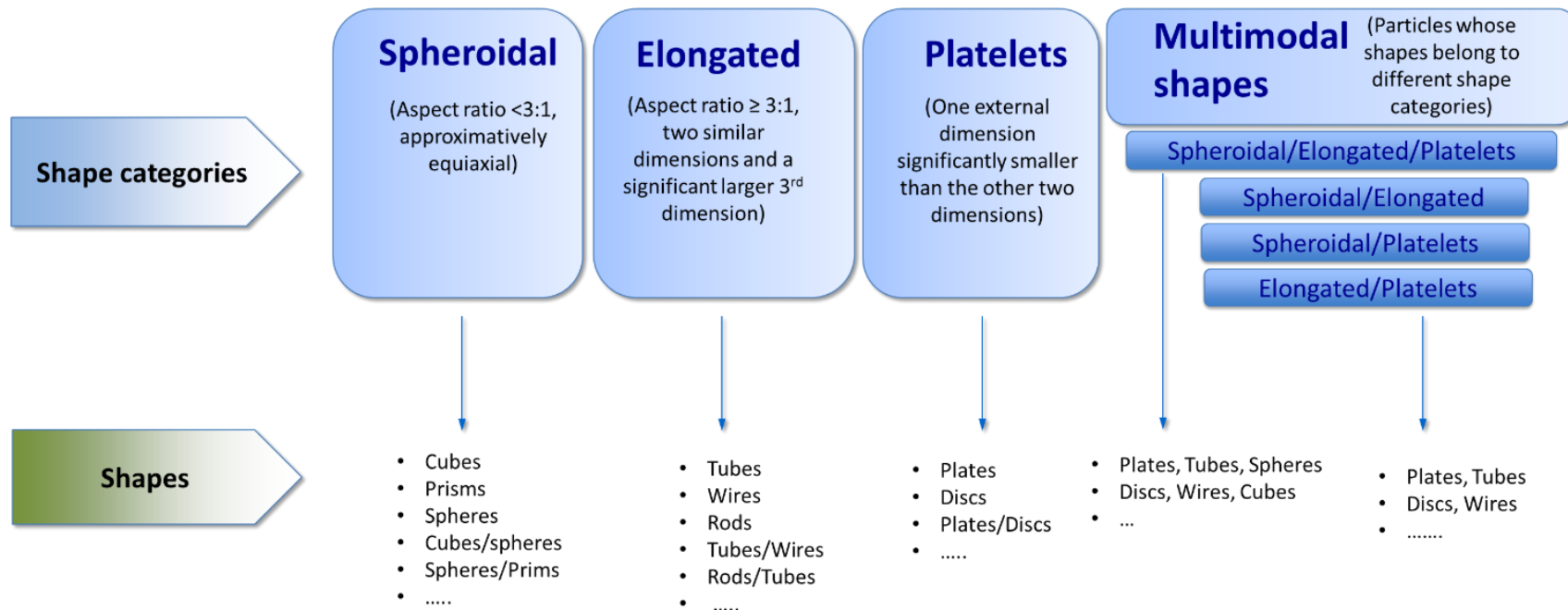


Shape including aspect ratio and information on assembly structure

Annex 2.4.4.



Shape including aspect ratio and information on assembly structure



Shape including aspect ratio and information on assembly structure

Reporting

- Shape categor(ies) and specific shape(s)
- Concentration of specific shapes, if applicable
- Number of walls or layers for assembly structure
- Elongated particles and platelets:
 - Aspect ratio
 - Rigidity (recommendation)



Shape including aspect ratio and information on assembly structure

When should nanoforms not be included in the same set?

- Shape
- External dimensions
- Aspect ratio
- Rigidity

of the nanoform particles do not enable their (eco)toxicity to be assessed jointly



Crystallinity

Annex VI 2.4.4.



Crystallinity

Reporting

- Name(s) or crystal system(s) of the structures
- Concentration of each crystal structure present, if applicable



Crystallinity

When should nanoforms not be included in the same set?

- A priori nanoforms containing particles with
 - different crystal structures
 - one specific crystal structure and mix of crystal structures
- When justified, nanoforms with different crystal structures can be in the same set



Specific surface area

Annex VI 2.4.5.



Specific surface area

Reporting

- Range of specific surface area
- Skeletal density if volume specific surface area is reported based on BET

When should nanoforms not be included in the same set?

- Specific surface area has an impact on dissolution rate, solubility, toxicokinetic behaviour, fate, (bio)availability or (eco)toxicity



Analytical methods





Analytical methods

- Analytical data needs to be obtained on the particles as manufactured
- Description of analytical methods or appropriate bibliographical references need to be provided



Analytical methods

Particle size distribution

- Recommendation to use one electron microscopy technique

Shape including aspect ratio and information on assembly structure

- Electron microscopy
- Most appropriate technique based on the material properties



Analytical methods

Crystallinity

- Electron diffraction or x-ray powder diffraction
- More than one technique may be needed for characterisation of amorphous nanoforms
- Rietveld refinement or other appropriate method for quantitative phase analysis



Analytical methods

Surface functionalisation or treatment

- Most appropriate method(s) to analyse the composition of the particles as a whole, including their surface treatment
- Recommendation to provide analytical data to identify the functionalities/treatment layer(s) formed on the particle's surface



Analytical methods

Specific surface area

- Usually gas adsorption using the Brunauer-Emmett-Teller (BET) isotherm (ISO 9277:2010)
- Skeletal density (ISO 12154:2014) needs to be measured and reported if volume specific surface area is reported based on BET

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New IT tools and formats

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Anna Daszynska, ECHA





What's new in IUCLID 6.4?

- Fields for reporting nanoforms
- Technical Completeness Check (TCC) rules
- Disseminated information on nanoforms
- Updated manuals on dossier preparation

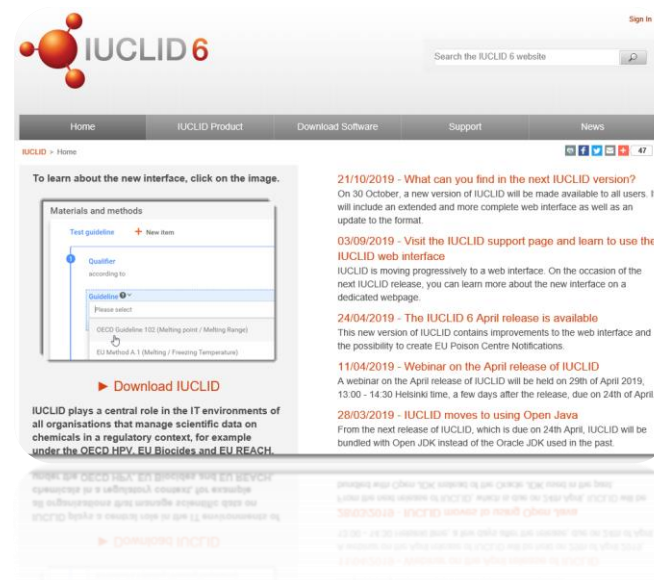
More

iuclid6.echa.europa.eu/home

IUCLID tools

Validation assistant

Dissemination preview






Section 1.2 Composition

NEW: 'State/form' mandatory for all inquiry and registration dossiers (including update dossiers)

General Information

Name
nanoform A

Type of composition
legal entity composition of the substance

State / form 

Please select

- gas
- liquid
- solid: bulk
- solid: fibres
- solid: nanoform ✓
- solid: particulate/powder

Reporting nanoforms





Section 1.2 Composition

General Information

Name
nanoform A

Type of composition
legal entity composition of the substance

State / form ?

Please select

- gas
- liquid
- solid: bulk
- solid: fibres
- solid: nanoform** ✓
- solid: particulate/powder

Select to activate fields relevant to nanoforms

Not possible to submit with previous versions of IUCLID



Section 1.2 Composition

Characterisation of nanoforms

Type of information reported ? v

Please select

single nanoform

set of nanoforms

Type of information reported
set of nanoforms

Justification for reporting set of similar nanoforms A Insert existing templates

JUSTIFICATION FOR REPORTING SET OF SIMILAR NANOFORMS
[Provide a justification under each heading: 1. Particle size, 2. Shape, 3. Crystallinity, 4. Surface functionalisation or treatment and 5. Specific surface area. Select under each heading the option applicable for your case and modify the text taking into account the listed requirements for the justification. Ensure to address all points requested for your case. Provide under each heading the sources of the scientific information on which the justification is based on and include the information as an attachment in the field Attached information or as a record in the appropriate section of the dossier.]

1. PARTICLE SIZE
The nanoforms in the set have the same (eco)toxicological profile because:
[provide a detailed justification addressing the impact of the particle size of the different nanoforms on each of the following]

- dissolution rate
- solubility
- toxicokinetic behaviour
- fate
- (bio)availability
- (eco)toxicity

ECHA manually checks justification during completeness check

Edit text template to **address all relevant points**



Section 1.2 Composition


'Justification for reporting set of similar nanoforms'

Attached information  New item

| # | Attached information | Action |
|---|----------------------|--------|
|---|----------------------|--------|



You can attach more information in the 'Attached information' field

Cross-reference  New item

| # | Reason / purpose | Related information | Remarks | Action |
|---|------------------|---------------------|---------|--------|
|---|------------------|---------------------|---------|--------|



Use 'Cross-reference' to link to other IUCLID sections



Section 1.2 Composition


NEW: Fields for reporting characterisation parameters in IUCLID

- Shape
- Particle size distribution and range
- Crystallinity
- Specific surface area
- Surface functionalisation/treatment



Section 1.2 Composition

NEW: Information published by ECHA

- Attachments, remarks and justifications in text fields are not published
- Other information is published unless marked confidential with a confidentiality flag  on the relevant characterisation parameter

Dissemination preview tool shows you what information is published



Section 1.4

Analytical information

NEW: Fields for reporting analytical information

Analytical determination for nanoforms + New item

| # | Parameter | Purpose ... | Analysis ... | Type of i... | Attached... | Rationale... | Justificat... | Remarks | Action |
|---|-----------|-------------|--------------|--------------|-------------|--------------|---------------|---------|--------|
| <div> <div> Remarks None </div> <div> <div>Related composition(s)</div> <div>Related composition(s)</div> <div>None</div> </div> <div> <div>Parameter</div> <div> <input type="checkbox"/> Select/Deselect all <input type="checkbox"/> particle size distribution <input type="checkbox"/> shape <input type="checkbox"/> crystallinity <input type="checkbox"/> specific surface area <input type="checkbox"/> surface treatment/functionalisation <input type="checkbox"/> other: </div> <div>None</div> </div> </div> | | | | | | | | | |



Section 1.4

Analytical information

- For each characterisation parameter reported in section 1.2: give corresponding data in section 1.4 and link the sections through 'Related composition(s)'
- If you attach an analytical report containing the analysis for more than one parameter, select the appropriate parameters and analytical methods in the applicable picklists
- If you cannot provide results for the indicated parameter, the reasoning must be clearly justified



Section 4.28.8 Nanomaterial dustiness

NEW: Endpoint section must be complete

▼ 4.28 Additional physico-chemical properties of nanomaterials 1

4.28.1 Nanomaterial agglomeration / aggregation + New ▼

4.28.2 Nanomaterial crystalline phase + New ▼

4.28.3 Nanomaterial crystallite and grain size + New ▼

4.28.4 Nanomaterial aspect ratio / shape + New ▼

4.28.5 Nanomaterial specific surface area + New ▼

4.28.6 Nanomaterial Zeta potential + New ▼

4.28.7 Nanomaterial surface chemistry + New ▼

▼ 4.28.8 Nanomaterial dustiness + New ▼ 1

Nanomaterial dustiness.001

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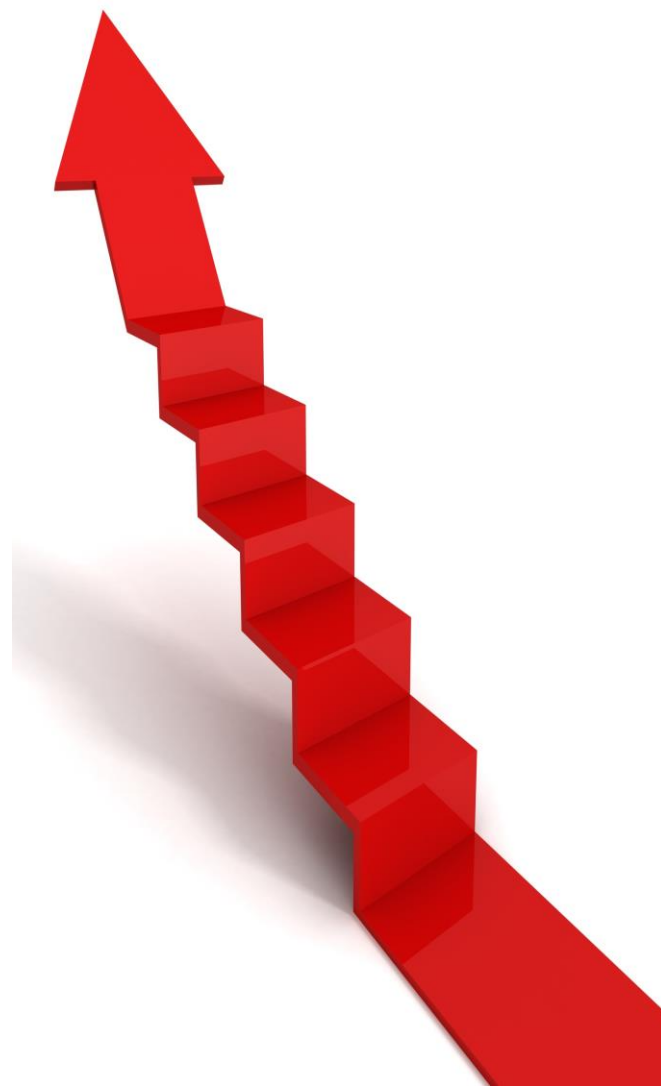


Pay attention

- Report identity and concentration of constituents, including any additives or impurities following REACH requirements
- If you report different classifications in section 2.1, make sure they are linked correctly with compositional information in section 1.2
- Report separate endpoint study records in sections 4 to 8 for each nanoform or set of nanoforms, clearly detailing the test material used in the studies

Pre-check your dossier

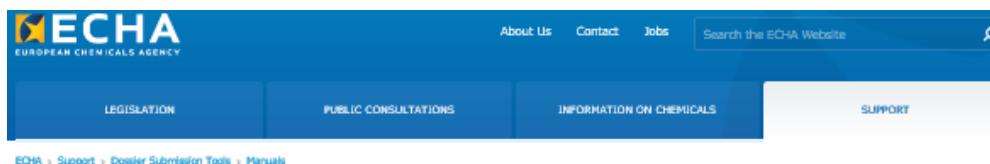
- Use **validation assistant** to minimise failures and potential rejection of your submission
- Use **dissemination preview** to simulate the information from your dossier that will be publicly available on ECHA's website





Supporting material

echa.europa.eu/manuals



ECHA > Support > Dossier Submission Tools > Manuals

Dossier Submission Tools

Manuals

REACH-IT
IUCLID

Manuals

Manuals on preparing REACH and CLP dossiers

The aim of the manuals on *How to prepare REACH and CLP dossiers* is to help companies to prepare, create and update IUCLID dossiers.

The manuals highlight the IUCLID sections that must be completed for the different dossier types, to prepare a valid and complete dossier that can be submitted to EC through REACH-IT. These manuals are also integrated in IUCLID.

Step-by-step instructions for completing the different IUCLID sections and process each submission are provided in the manuals alongside overviews of the processes and legal concepts involved.

These manuals replace the former Data Submission Manuals (DSMs).

• [Transition table between old and new manuals \(PDF\) \(EN\)](#)

How to prepare registration and PPORD dossiers

• [Download the manual \(PDF\) \(EN\)](#)

[Download the manual \(PDF\) \(EN\)](#)

Dissemination and confidentiality under the REACH Regulation

This manual helps companies who are preparing registration dossiers to understand the dissemination process, what information will be made publicly available on ECHA website, how to make a confidentiality request, how to prepare a justification and basic procedure that ECHA follows to assess such requests.

In addition, this document advises industry on how to derive a public name for a substance for which the IUCLID name is requested confidential.

• [Dissemination and confidentiality under the REACH Regulation](#)

Annex 8. Reporting information specific to nanoforms

The REACH information requirements have been revised to include specific provisions for nanoforms of substances. The amendments introduce clarifications and new provisions for the chemical safety assessment (Annex I), registration information requirements (Annexes III and VI-XI) and downstream user obligations (Annex XII) of nanoforms of substances. The amendments apply as of 1 January 2020 for all the new and existing registrations covering nanoforms.

This annex provides an overview of the different fields in IUCLID related to nanoforms and the information that is expected to be reported in a registration dossier that covers nanoforms. The main focus of the annex is on the information to be reported under Annex VI for the characterisation of nanoforms and sets of nanoforms. To this end, it provides step by step instructions and guides you through the most relevant aspects of filling in sections: 1.2 Composition, 1.4 Analytical information.

The advice for filling in IUCLID sections 4 *Physical and chemical properties*, 5 *Environmental fate and pathways*, 6 *Ecotoxicological information*, 7 *Toxicological information* and 8 *Analytical methods* applies equally for reporting studies on nanoforms of substances. Therefore, this annex only provides limited instructions for these sections.

Table 20 of this annex gives an overview of the completeness check performed on parts of the registration dossier that is specific to nanoforms.

For more information on registration obligations, including establishing the substance identity and considering joint submissions with other registrants please refer to the Appendix for nanoforms applicable to the guidance on Registration and Substance Identification available at:

<https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach>

For further support in IUCLID and to read specific help text that explains how each field should be used, click on a question mark icon ⓘ to the right of the field label.

Section 1.2 Composition

The main part of the composition record must be filled in as described in chapter 9.3.2 Section 1.2 Composition of this manual. The same concepts apply to report the identity and concentration of the constituents of the composition, including any impurities or additives.

General information

In order to fill in information concerning nanoforms you must select *solid: nanoform* in the picklist State/form. This selection activates the fields under the heading *Characterisation of nanoforms* in the same composition record where you can report the key characterisation parameters for nanoforms and sets of nanoforms. Depending on the approach chosen to fulfil the REACH information requirements, different fields may be relevant. However, the principles of reporting individual nanoforms should be applied to report the characteristics of the nanoforms that define the boundaries of the set.

When registering a nanoform of the substance as a single nanoform, then each different nanoform must be reported as a separate composition record in IUCLID section

Additional support

Field specific **help text** in IUCLID:

Click the question mark icon 

Questions

Submit your questions to ECHA:

echa.europa.eu/contact

More material

[ECHA and IUCLID webinars](#)



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Reporting nanoforms and sets of nanoforms: illustrative examples

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12 November 2019

Askar Nurassilov, ECHA





Illustrative examples

| | Name | Form | Parameter to report |
|------------------|---------------|--------------------------------------|----------------------------|
| Example 1 | <i>FORM B</i> | Single nanoform | Shape |
| Example 2 | <i>SET D</i> | Set of nanoforms | Particle size distribution |
| Example 3 | <i>SET D</i> | Set of nanoforms | Crystallinity |
| Example 4 | <i>FORM E</i> | Single nanoform with treated surface | Surface treatment |

Example 1

Single nanoform > Shape



Form B

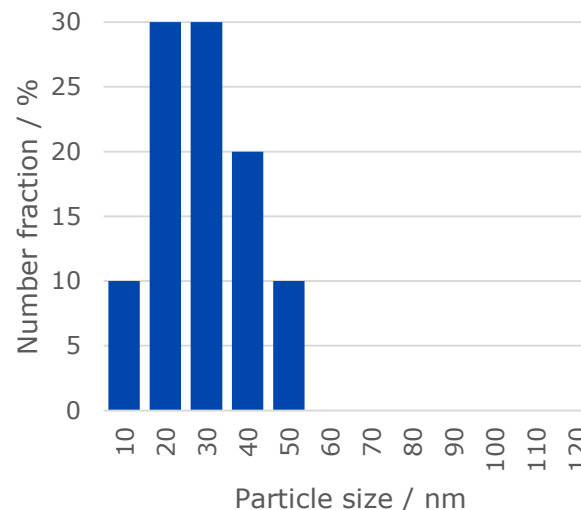
| Category | Shape | Typical % | Range % |
|------------|-----------|-----------|---------|
| Spheroidal | Cubic | 40 | 30-50 |
| Spheroidal | Spherical | 60 | 50-70 |

Particle size

d10 10 (5-15) nm

d50 25 (20-30) nm

d90 50 (40-60) nm



Form B

1.2 Composition 1

● FORM B



State / form
solid: nanoform



Characterisation of nanoforms

Type of information reported ? ▼

single nanoform × ▼

Form B

| Category | Shape | Typical % | Range % |
|------------|-----------|-----------|---------|
| Spheroidal | Cubic | 40 | 30-50 |
| Spheroidal | Spherical | 60 | 50-70 |

Shape description

+ New item

Shape category

Please select ▼

- spheroidal ✓
- elongated
- platelet

Shape

Please select ▼

- spherical
- pyramidal
- cubic ✓
- star shaped
- orthorhombic

Pure shape

Please select ▼

- yes
- no ✓

Typical composition

ca. 40 %

Range

>= 30 <= 50 %

Form B

Shape description  New item

| # | Shape category | Shape | Pure shape | Typical composition | Range | Remarks | Action |
|---|----------------|-----------|------------|---------------------|---------------|---------|--------|
| 1 | spheroidal | cubic | no | ca. 40 % | >= 30 <= 50 % | None | ✕ |
| 2 | spheroidal | spherical | no | ca. 60 % | >= 50 <= 70 % | None | ✕ |

Indicates the typical concentration of particles with certain shape in the nanoform

Reflects batch-to-batch variability in the nanoform



Illustrative examples

| | Name | Form | Parameter to report |
|------------------|---------------|--------------------------------------|----------------------------|
| Example 1 | <i>FORM B</i> | Single nanoform | Shape |
| Example 2 | <i>SET D</i> | Set of nanoforms | Particle size distribution |
| Example 3 | <i>SET D</i> | Set of nanoforms | Crystallinity |
| Example 4 | <i>FORM E</i> | Single nanoform with treated surface | Surface treatment |

Example 2

Set of nanoforms > Particle
size distribution



Example 2

SET D

Form A

Cubic

Particle size

d10 20 (15-20) nm

d50 40 (35-45) nm

d90 60 (50-70) nm

Form B

Cubic

Spherical

Particle size

d10 10 (5-15) nm

d50 25 (20-30) nm

d90 50 (40-60) nm

Form C

Cubic

Spherical

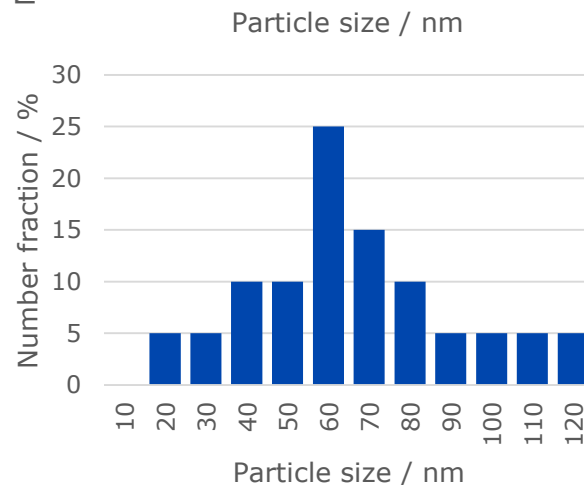
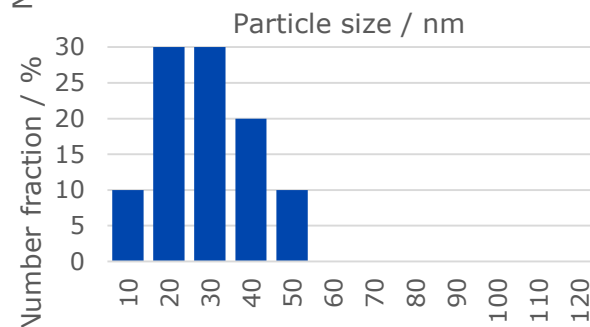
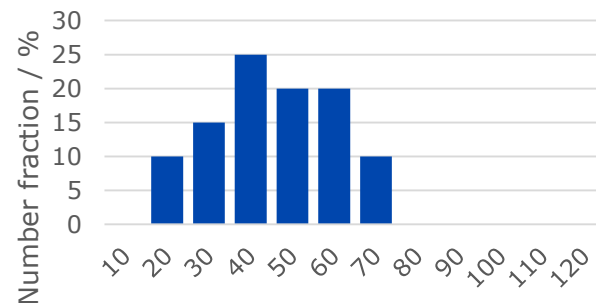
Orthorhombic

Particle size

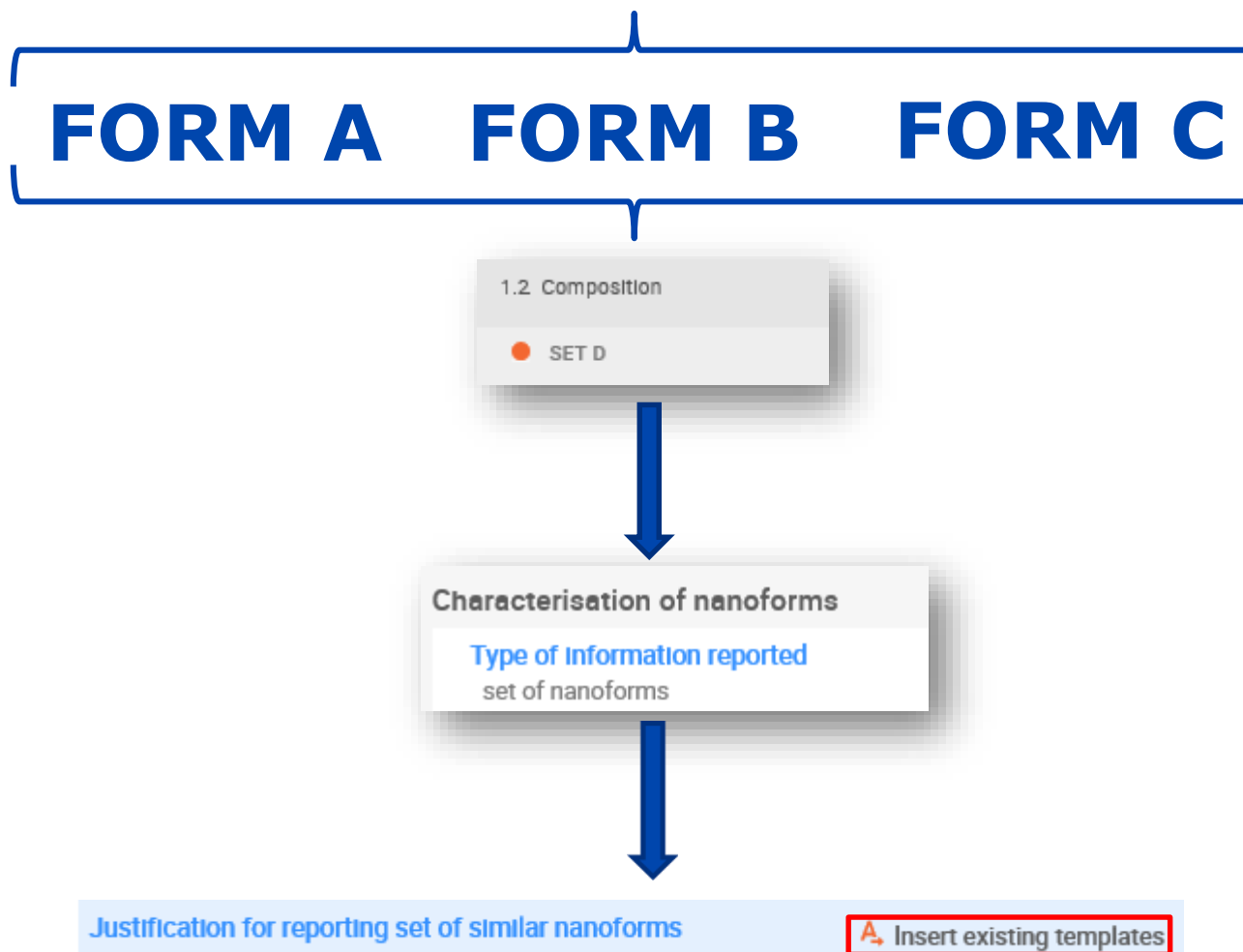
d10 30 (25-35) nm

d50 60 (50-60) nm

d90 100 (90-120) nm



SET D



SET D

Shape category

spheroidal X v

+ Add remark press Esc to close

Percentile + New item

| #. | Percentile | Typical value | Range | Remarks | Action |
|----|------------|---------------|-----------------------|---------|--------|
| 1 | D90 | None | $\geq 50 \leq 120$ nm | None | X |
| 2 | D50 | None | $\geq 20 \leq 60$ nm | None | X |
| 3 | D10 | None | $\geq 5 \leq 35$ nm | None | X |

Not applicable for the set


Reflects variation between nanoforms that are part of the set

SET D

Fraction of constituent particles in
the size range 1-100 nm

>= 85 <= 100 %

Additional information

 Insert existing templates

PROVIDE FURTHER INFORMATION ON OTHER MORPHOLOGICAL CHARACTERISATION:

ASSEMBLY STRUCTURE:

Describe the type of assembly structure of the particles; e.g. nanotube, nano-onion, multi-layer platelet with indication of number of walls/shells/layers.

RIGIDITY:

Describe the rigidity of the elongated particles or platelets, i.e. ability of the particles to retain its shape, without damage, when subject to mechanical (bending) forces. Description can be based for example on electron microscopy images (e.g. coiled/tangled versus straight particles), based on the particle width and length, number of walls, etc.

Supporting analytical data can be provided in Section 1.4 of the IUCLID dossier.

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Illustrative examples

| | Name | Form | Parameter to report |
|------------------|---------------|--------------------------------------|----------------------------|
| Example 1 | <i>FORM B</i> | Single nanoform | Shape |
| Example 2 | <i>SET D</i> | Set of nanoforms | Particle size distribution |
| Example 3 | <i>SET D</i> | Set of nanoforms | Crystallinity |
| Example 4 | <i>FORM E</i> | Single nanoform with treated surface | Surface treatment |

Example 3

Set of nanoforms >
Crystallinity



SET D

| Form | Crystal system | Typical % | Range % |
|----------|----------------|-----------|---------|
| A | Hexagonal | n/a | n/a |
| B | Hexagonal | 40 | 30-50 |
| | Amorphous | 60 | 50-70 |
| C | Hexagonal | 30 | 25-40 |
| | Orthorhombic | 50 | 45-55 |
| | Amorphous | 20 | 5-25 |

* n/a – not applicable

SET D

The smallest and largest concentration of particles with certain structure in the nanoforms that are part of the set

Crystallinity ☐ None ☐ None

Structures New item

| # | Structure | Name | Pure structure | Typical composition | Range | Crystal system | Bravais lattice | Action |
|---|-----------------------|------------------|----------------|---------------------|---------------|----------------|-----------------|--------|
| 1 | crystalline | Structure name 1 | yes | None | None | ✓ hexagonal | None | ✕ |
| 2 | partially-crystalline | Structure name 1 | no | None | >= 25 <= 50 % | ✓ hexagonal | None | ✕ |
| 3 | partially-crystalline | Amorphous | no | None | >= 5 <= 70 % | None | None | ✕ |
| 4 | partially-crystalline | Structure name 2 | no | None | >= 45 <= 55 % | ✓ orthorhombic | None | ✕ |

not applicable for the set



Illustrative examples

| | Name | Form | Parameter to report |
|------------------|---------------|--------------------------------------|----------------------------|
| Example 1 | <i>FORM B</i> | Single nanoform | Shape |
| Example 2 | <i>SET D</i> | Set of nanoforms | Particle size distribution |
| Example 3 | <i>SET D</i> | Set of nanoforms | Crystallinity |
| Example 4 | <i>FORM E</i> | Single nanoform with treated surface | Surface treatment |

Example 4

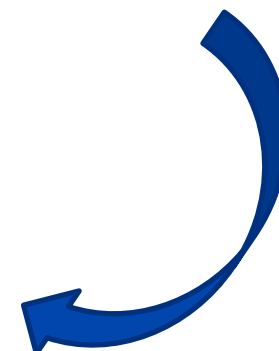
Single nanoform > Surface
functionalisation/treatment



FORM E

| Shape | Category | Typical % | Range % | Crystal system | Typical % | Range % | Surface treatment |
|-------|------------|-----------|---------|----------------|-----------|---------|-------------------|
| Cubic | Spheroidal | n/a | | Hexagonal | n/a | | Yes |

| Name | Agent | w/w % | | External layer |
|---------------------|---------------------------|---------|-------|----------------|
| | | Typical | Range | |
| Surface treatment 1 | Surface treatment agent 1 | 2 | 1-3 | hydrophobic |



FORM E

Surface functionalisation / treatment

Surface treatment applied

yes

Surface treatments + New item

Surface treatment name

Surface treatment name 1



Surface treatment agent

+ Select



Create Reference substance

General information

Reference substance name* ? v

Surface treatment agent 1

FORM E

Create Reference substance

General information

Reference substance name*

Surface treatment agent

Inventory

Inventory number

None

No inventory information available

Justification

None

Reference substance information

None None

IUPAC name

0/2000

press Esc to close

Description

None

Synonyms

+ New item

| # | Identifier | Identity | Remarks | Action |
|--|------------|----------|---------|--------|
| <div>CAS information</div> <div>CAS number</div> <div>None</div> <div>CAS name</div> <div>None</div> | | | | |

Related substances

Identifiers of related substances + New item

Group / category information

None

Save

FORM E

Surface treatment name

Treatment 1

Surface treatment + New item

| # | Order | Surface treatment agent | Typical weight-by-weight... | Range of weight-by-weig... | Remarks | Action |
|---|-------|---|-----------------------------|----------------------------|---------|--------|
| 1 | #1 | <div> <div>None</div> <div>None</div> <div>Surface treatment agent</div> </div> | <= 2 % (w/w) | >= 1 <= 3 | None | ✕ |

Description

A. Insert existing templates

DESCRIBE THE PROCESS BEHIND THE SURFACE FUNCTIONALISATION / TREATMENT:

- Main features of the surface treatment/functionalisation process:
- the type of process/reaction (hydrolysis, oxygen treatment, acid washing, etc.):
- relevant ranges of process parameters such as reaction conditions (pH, temperature):
- any purification step:
- Molar ratio of each surface treating agent used:
- Functionalities introduced by the treatment (e.g. carboxyl, amino, hydroxyl groups)

Further information can be provided in a document under 'Attached information'.

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Not disseminated

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Conclusions

Webinar: Getting prepared for new
REACH information requirements for
nanomaterials

12 November 2019

Jenny Holmqvist, ECHA



Take home messages

- Get familiar with the new requirements now – don't wait until the last moment
- Do the best you can with the guidance and support material available by 1 January – do your best to justify what you can't fulfil
- ECHA and Member States are here to support you



Take home messages (2)

- Guidance activities ongoing to provide information on the best advice to fulfil information requirements
- Further development of test guidelines ongoing – key priority for application of regulation
- Search for nanomaterials on the EU market and overview of REACH information requirements and available methods


euon.echa.europa.eu/search-for-nanomaterials



Material published

Video recording, presentations and Q&A:

echa.europa.eu/support/training-material/webinars



The screenshot shows the ECHA website interface. At the top, there is a header with the ECHA logo, the text "An agency of the European Union", and navigation links for "News and Events", "Press", "Contact", and a language selector set to "English (en)". Below the header is a search bar with the placeholder text "Search the ECHA Website". A main navigation menu includes links for "About Us", "Regulations", "Addressing Chemicals of Concern", "Information on Chemicals", "Chemicals in our Life", and "Support". The "Support" link is highlighted. Below the navigation menu, the breadcrumb trail reads "ECHA > Support > Webinars". On the left side, there is a sidebar with a list of links: "About Us", "Regulations", "Addressing Chemicals of Concern", "Information on Chemicals", "Chemicals in our Life", "Support", and "Guidance". The "Support" link is expanded, showing the "Webinars" page. The main content area is titled "Webinars" and contains the following text: "Webinars are information sessions hosted online, and consisting of presentations, video and other interactive features such as questions and answers, desktop sharing and audio conferencing. Up to one thousand participants can remotely join a webinar at once." "A registration link will be available for each individual webinar closer to the event date and all webinars, including a webinar programme and registration link will be announced in ECHA's weekly e-News." "The webinar programme is subject to change. Exact dates will be confirmed as they become available." "Each webinar will be recorded and later published on the ECHA website." Below the text is a table with the following columns: "REACH 2018", "Upcoming", "2017", "2016", "2015", "2014", "2013", "2012", "2011", and "All Webinars". The "Upcoming" column is highlighted in orange.

| REACH 2018 | Upcoming | 2017 | 2016 | 2015 | 2014 | 2013 | 2012 | 2011 | All Webinars |
|------------|----------|------|------|------|------|------|------|------|--------------|
| | | | | | | | | | |

Q&A panel

- Webinar open until **13:30 Helsinki time** to answer questions
- If your question is not answered by the end of the webinar, send it via our contact form:
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