

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







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





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: <u>echa.europa.eu/contact</u>





Requirements for registration and substance identification

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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







































































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-byweight 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 surfacetreatment 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
- 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



Annex 2.4.4.









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)





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





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





Crystallinity

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





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





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







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

neral 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





Seneral Information		
Name nanoform A		
Type of composition legal entity composition of the substance		
State / form @~		
Please select	\sim	
gas	^	Select to activate fields
liquid		relevant to nanoforms
solid: bulk		
 solid: fibres 		
solid: nanoform	×	
solid: particulate/powder		

Not possible to submit with previous versions of IUCLID





ECHA manually checks justification during completeness check

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







'Justification for reporting set of similar nanoforms'



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



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





NEW: Fields for reporting characterisation parameters in IUCLID

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





NEW: Information published by ECHA

- Attachments, remarks and justifications in text fields are <u>not published</u>
- Other information is <u>published unless marked confidential</u> with a confidentiality flag <u>marked confidential</u> 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
Remarks None	
Related composition(s) Related composition(s) None	Parameter
	Select/Deselect all
	particle size distribution
	shape
	crystallinity
	specific surface area
	surface treatment/functionalisation
	other:



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







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







Additional support

Field specific **help text** in IUCLID: Click the question mark icon **@**~

Questions

Submit your questions to ECHA: <u>echa.europa.eu/contact</u>

More material

ECHA and IUCLID webinars



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Reporting nanoforms and sets of nanoforms: illustrative examples

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Askar Nurassilov, ECHA





Illustrative examples

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

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**











Range

%

Typical

%

Shape



Category

EUROPEAN CHEMICALS AGENCY

Form **B**

Form **B**

Sha	pe description + New	item			1		1	
ł	# Shape category	Shape	Pure shape	Typical composition		Range	Remark	s Action
	spheroidal	cubic	no	ca. 40 %		>= 30 <= 50 %	None	×
:	2 spheroidal	spherical	no	ca. 60 %		>= 50 <= 70 %	None	×
	Indicates th particles wit	e typical con th certain sha	centration of pe in the	Reflects ba nanoform	ato	ch-to-batch	n variability	in the
	nanoiorm							

Illustrative examples

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

Set of nanoforms > Particle size distribution

SET D

Form A

Particle size

Cubic

d10 20 (15-20) nm *d50* 40 (35-45) nm

d90 60 (50-70) nm

Form **B**

Particle size

Cubic Spherical *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 FORM A FORM B FORM C 1.2 Composition SET D Characterisation of nanoforms Type of Information reported set of nanoforms Justification for reporting set of similar nanoforms A Insert existing templates

SET D

SET D

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

>= 85 <= 100 %

Additional information	A Insert existing templates
PROVIDE FURTHER INFORMATION ON OTHER MORPHOLO CHARACTERISATION:	GICAL
ASSEMBLY STRUCTURE:	
Describe the type of assembly structure of the particles; e.g multi-layer platelet with indication of number of walls/shells	j. nanotube, nano-onion, s/layers.
RIGIDITY:	
Describe the rigidity of the elongated particles or platelets, i particles to retain its shape, without damage, when subject forces. Description can be based for example on electron m coiled/tangled versus straight particles), based on the parti- number of walls, etc.	i.e. ability of the to mechanical (bending) nicroscopy images (e.g. cle width and length,
Supporting analytical data can be provided in Section 1.4 of	f the IUCLID dossier.
	693/32768

Illustrative examples

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

Set of nanoforms > Crystallinity

SET D

Form	Crystal system	Typical %	Range %
Α	Hexagona] -	n/a	n/a
В	Hexagonal	40	30-50
	-Amorphous	60	50-70
	Hexagonal	30	25-40
C _	{Orthorhombic	50	45-55
	Amorphous —	20	5-25

* n/a – not applicable

SET D

Example 3

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

not applicable for the set

Illustrative examples

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

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

FORM E

Surface functionalisation / treatment
Surface treatment applied
yes

Surface treatments + New item

Surface treatment name Surface treatment name 1

FORM E

Example 4

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 Description None + New item Synonyms # Identifier Identity Remarks Action CAS information **CAS number** None CAS name None **Related substances** Identifiers of related substances + New item Group / category information None

FORM E

Surface treatment name

Treatment 1

Order	Surface treatment agent	Typical weight-by-weight	Range of weight-by-weig	Remarks	Actior
#1	None None Surface treatment agent	<= 2 % (w/w)	>= 1 <= 3	None	×
escription DESCRIBE THE PROCES TREATMENT: - Main features of the s - the type of process/re - relevant ranges of pro temperature): - any purification step: - Molar ratio of each su - Functionalities introdu Further information car	A Insert of S BEHIND THE SURFACE FUNCTIONALISATIO rface treatment/functionalisation process: action (hydrolysis, oxygen treatment, acid wash ess parameters such as reaction conditions (p face treating agent used: teed by the treatment (e.g. carboxyl, amino, hyd be provided in a document under 'Attached inf	existing templates N / hing, etc.): pH, roxyl groups) formation'. .:: 557/32768	→ Not d	lisseminat	ed

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Conclusions

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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: <u>echa.europa.eu/support/training-material/webinars</u>

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Q&A panel

- Webinar open until 13:30
 Helsinki time to answer questions
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