Introduction

Webinar: Registering nanoforms – practical advice

24 February 2020

Jenny Holmqvist, ECHA

New REACH requirements for nanoforms

- Updated information requirements for nanoforms of substances under REACH apply as of 1 January 2020.
- Companies must have a registration compliant with these requirements to manufacture or import nanoforms of substances.

What you can expect from today

- Overview of registration activity
- Practical advice for reporting nano-specific information in IUCLID
- Expectations for completeness of data
- Extensive Q&A session with experts

Agenda

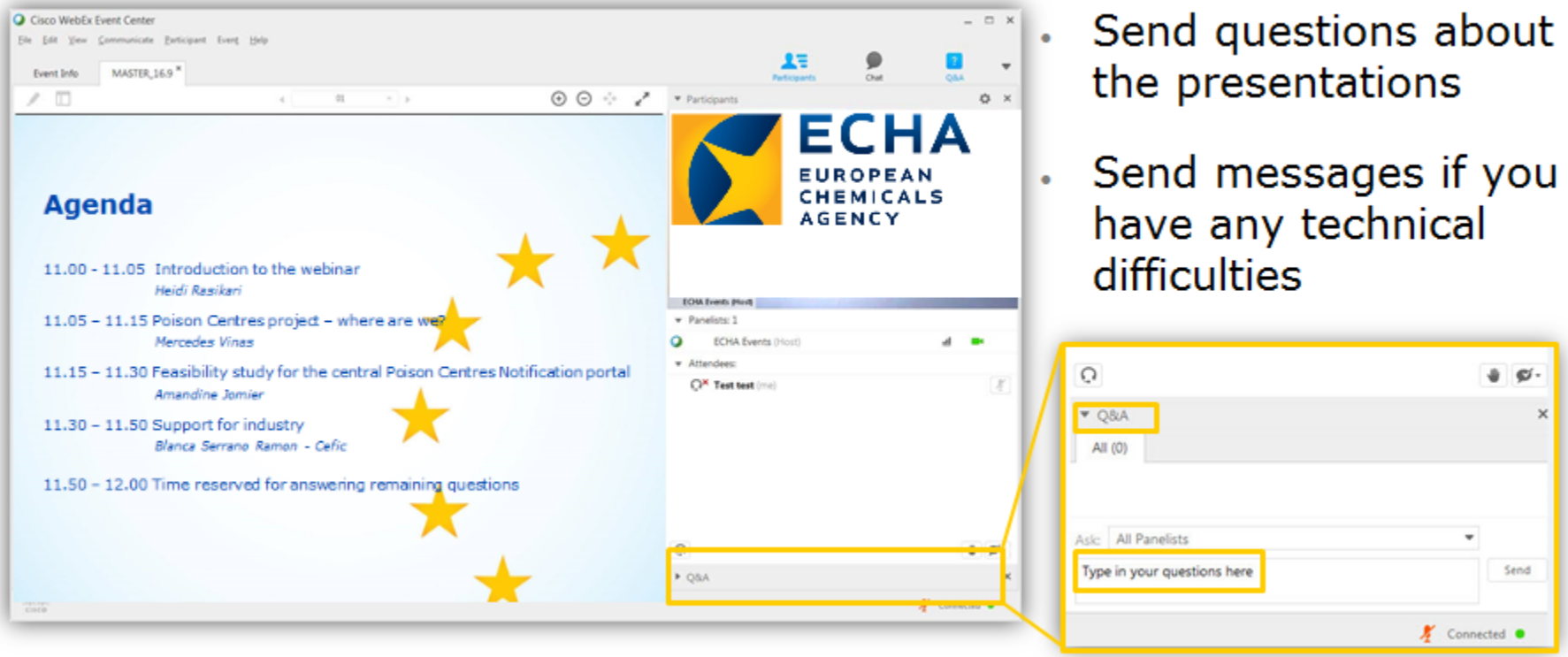
12:00 **Introduction and general observations on nanoform registrations**
Jenny Holmqvist, ECHA

12:10 **Practical advice based on received registrations**
Abdelqader Sumrein, ECHA

12:30 **Conclusions**
Jenny Holmqvist, ECHA

12:30 – 14:00 **Webinar open for questions**

Q&A panel



- Send questions about the presentations
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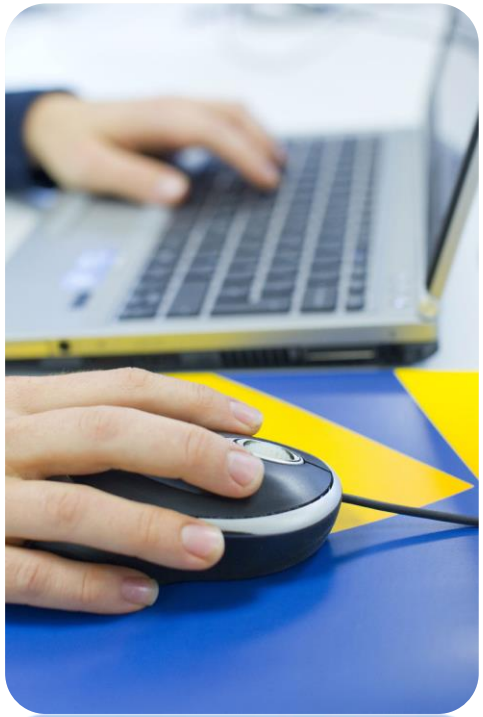
Q&A panel

- 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: echa.europa.eu/contact



Nanoform registrations

Webinar: Registering nanoforms – practical advice

24 February 2020

Jenny HOLMQVIST

New REACH requirements for nanoforms

- New REACH requirements for nanomaterials as of 1 January 2020.
- Concerns all new and existing registrations for substances with nanoforms in scope of REACH.
- Registrations for nanoforms to be submitted with IUCLID version 6.4 or above.

Registration activity

- Since 1 November 2019, ECHA has started to receive dossiers for substances covering nanoforms.
- As of 1 January 2020, import or manufacture of nanoforms of a substance is not compliant with REACH without a valid registration for these nanoforms.
- The EUON estimates that ca 300 substances are manufactured/imported as nanoforms in the EEA.

EUON: European Union Observatory for Nanomaterials https://euon.echa.europa.eu/

Important to keep in mind

- To register a nanoform or set of nanoforms of a substance, you must submit a dossier in IUCLID version 6.4 or above.
- You must explicitly indicate in section 1.2 of the dossier that the legal entity composition is for a nanoform in the ’State/form’ field.
- Not valid registrations for nanoforms:
  - Dossiers with only attachments or remarks indicating manufacture/import of substances as nanoforms
  - Dossiers submitted with older IUCLID versions.

Completeness check

- If your submission fails the completeness check, you are given one attempt within a deadline of four months to submit a complete dossier.
  - If you submit a complete dossier by the deadline, it is considered that the first submission has been amended with the missing information and this first submission date is the date of registration/update.
  - If you do not submit a complete dossier by the deadline, your submission is rejected.
- Submissions to register nanoforms before 1 January 2020 are considered as registered while the completeness check is pending.

Rejection after incompleteness

- Rejection means that the new information is not added to ECHA's databases.
- For existing registrations: the registration number is not revoked, but it covers only the information that was in a dossier that **passed** the completeness check.
  - If you are updating your bulk registration to cover nanoforms, then the nanoforms are only covered once the new submission passes the completeness check.
- After rejection: amend the failures and prepare a new submission without delay to comply with REACH.

Bulk and nanoforms of the substance

- There can only be one dossier for a given substance by the same registrant.
- If you have an existing registration covering the bulk form of the substance: update your existing dossier for bulk by adding information concerning the nanoform(s) of the substance that you manufacture/import.
- This can be done either by reporting your nanoforms individually or by reporting set(s) of nanoforms covering your nanoforms.

Joint submission lead and member registrants

- REACH Article 11(1): information set out in Annex VII to X is first submitted by the lead registrant.
- Information required by Annex VI, including the characterisation of nanoforms or sets of nanoforms, is thereafter submitted separately by each registrant.
- When existing registrations are updated to cover nanoforms, this submission sequence is not enforced.

➢ Members submitting before the lead need to **ensure** that they are covered by the lead's submission.

➢ Member registrants are sent a **disclaimer** to inform them that the completeness check decision they received only covers the Annex VI information.

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Practical advice based on received registrations

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Abdelqader SUMREIN

Sets of nanoforms

Nanoforms vs. sets of nanoforms

In principle each nanoform must be reported separately, including characterisation as per Annex VI and information on nanoform properties as per Annex VII-X. However, REACH allows reporting of a set of similar nanoforms when two conditions are fulfilled:

1. The registrant reports **clearly defined** boundaries in terms of characterisation parameters of the nanoforms, which are part of the set;
2. The registrant **justifies** that the hazard, exposure and risk assessment of the nanoforms **can be performed jointly**.

Observations

- Based on the available information, the approach to register nanoforms via sets of similar nanoforms seem to have been used in *ca.* half of the dossiers.
- Characterisers for sets of nanoforms in many cases not realistic, e.g. particle size distribution given as 1-100 nm for D10, D50, and D90.
- Justifications are often not addressing the points requested in the IUCLID template, and only stating an opinion/strategy without any scientific evidence.
  - Justifications are manually verified at completeness check.

Advice for sets of nanoforms (1)

- Report **real boundaries** for characterisers;
  - describe the smallest/largest values for nanoforms included in the set.
- Ensure that you can **justify** that each nanoform of the set can rely on the same Annex VII-X information, for each endpoint.
- Support each statement by reference to relevant data which can be traced back/found in the IUCLID dossier (i.e. hazard information, literature studies)

Advice for sets of nanoforms (2)

- For a comprehensive justification you need to provide evidence that the hazard profile is unchanged for test data representing nanoforms in the set with:
  - Smallest and largest d50 value and surface area
  - Different shape(s) and crystal structure
  - Surface-treatment inducing the lowest and highest impact on hazard assessment
  - Hazardous surface-treatment agent present as such in the nanoform

Advice for sets of nanoforms (3)

- If you register your nanoforms relying on a set of similar nanoforms that has been agreed at the level of the joint submission and is covered with a joint set of Annex VII-X information:
  - Provide the **same justification** for the set as the justification provided by the other registrants relying on the same set.
- A diverging justification suggests that the set may not have been agreed on jointly and may put in doubt the use of a joint set of hazard data for the sets.

Advice for sets of nanoforms (4)

- Incomplete justifications for sets:
  - *Explanation of why registrant decided to use the set approach instead of registering nanoforms*. ✗
  - *Characterisers are overlapping and it is not possible to register separate nanoforms*. ✗
  - *Statement that there is no difference in the ecotoxicological and toxicological profiles of the nanoforms in the set*. ✗
  - *Reference to data on nanomaterials in general, but not specific for the substance and nanoforms in question*. ✗

Compositions

Composition types

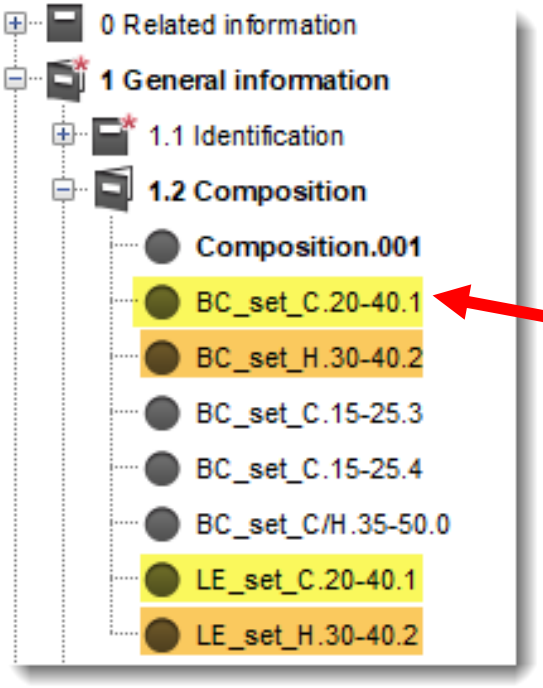
IUCLID section 1.2 compositions:

- *legal entity compositions* describe registrant's own manufactured/imported compositions and forms
- *boundary compositions* describe compositions and forms that are covered by hazard data and assessments:
  - (robust) study summaries from Annex VII-XI as reported in endpoint study records in IUCLID sections 4-7
  - classification and labelling in IUCLID section 2.1
  - PBT assessment and hazard assessment conclusions in IUCLID sections 2.3, 6 and 7 endpoint summaries

Linking of compositions

- Each nanoform or set of nanoforms must be reported separately, including Annex VI characterisation and Annex VII-X information on nanoform properties
- Critical to **link** legal entity compositions to boundary compositions in IUCLID to demonstrate coverage by data:
  - 'Related composition': electronic link from legal entity composition to boundary composition when both are present in the same dossier (JS lead; JS member opting out)
  - 'Reference to related composition(s)': textual link from legal entity composition to related boundary composition name when boundary composition is in a different dossier (JS member)

Linking of compositions



IUCLID

Report the boundary composition for (BC) and legal entity (LE) specific compositions using a consistent nomenclature in IUCLID, e.g.:

Crystal structure	Particle size (d50) / nm	Surface treatment	Set identifier
Cubic	20-40	Agent 1	C.20-40.1
Hexagonal	30-40	Agent 2	H.30-40.2
Cubic	15-25	Agent 3	C.15-25.3
Cubic	15-25	Agent 4	C.15-25.4
Mix of cubic and hexagonal	35-50	N/A	C/H.35-50.0

Electronic linking of compositions

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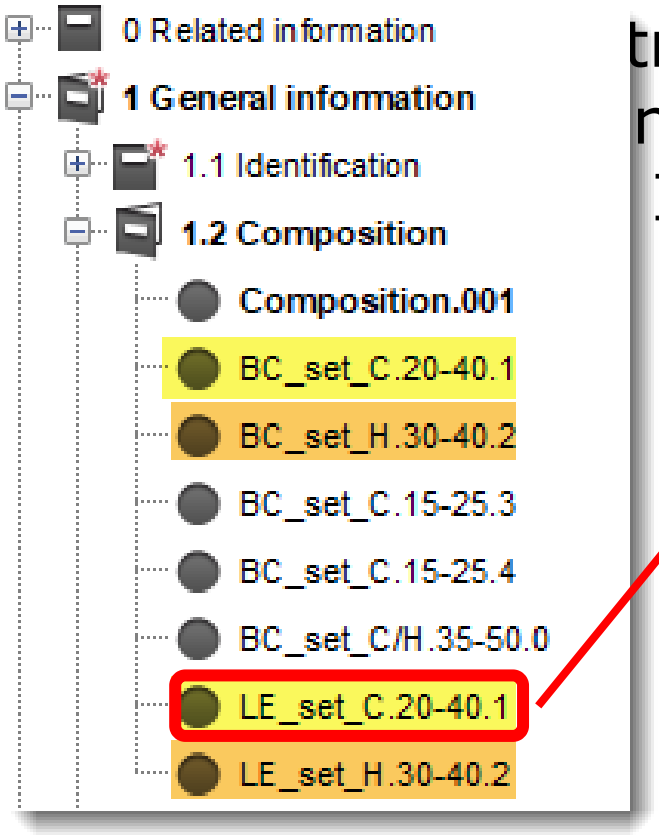
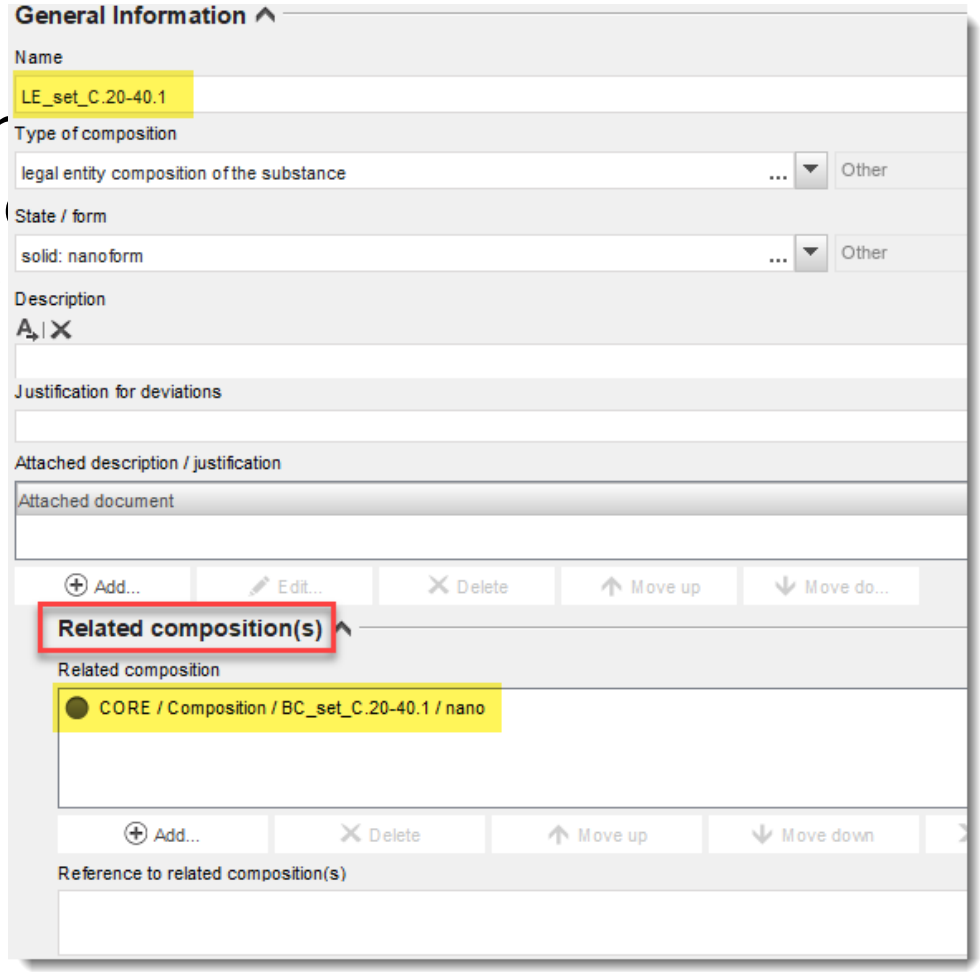
IUCLID





Annex VII – X information

Hazard data for each nanoform/set

- Each nanoform or set of nanoforms must be reported separately, including Annex VI characterisation and Annex VII-X information on nanoform properties.
- For every endpoint of each nanoform or set of nanoforms, you must submit either:
  i. studies performed on the specific nanoforms/members of the specific set
  ii. studies on other forms of the same substance accompanied by an endpoint-specific justification as to why this information is adequate for assessing the nanoform concerned (i.e. Annex XI.1.5 read-across)
  iii. Other relevant adaptations as foreseen by Annex XI of REACH or Column 2 of the relevant Annex VII-X.

Hazard data for each nanoform/set

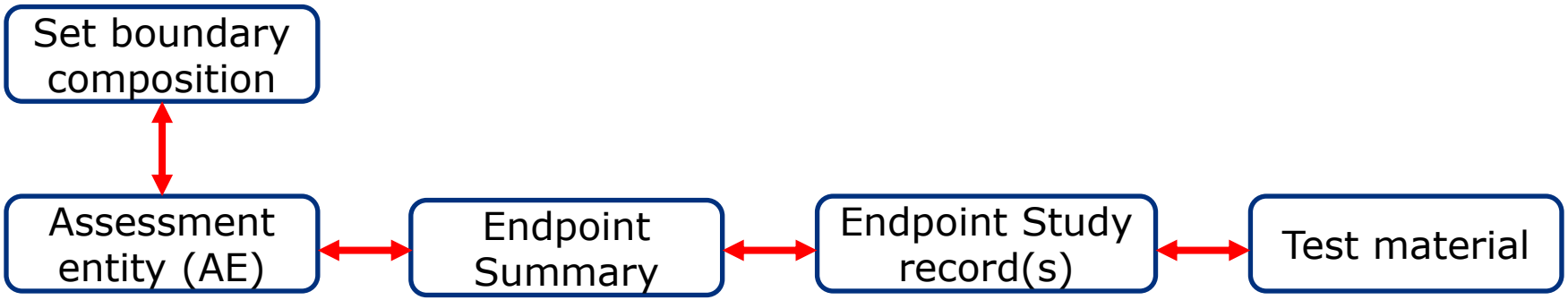
- Critical to **link** Annex VII-XI information to related nanoforms or sets of nanoforms in IUCLID to demonstrate that requirements were fulfilled:
  - Assessment entity in IUCLID section 1.10 > link section 1.2 compositions to 4-7 endpoint study records via endpoint summaries (see Annex 5 of manual *How to prepare registration and PPORD dossiers*);
  - Naming of IUCLID records e.g. by referring to nanoforms and sets of nanoforms with alphanumerical combinations.

Linking hazard data for each nanoform/set

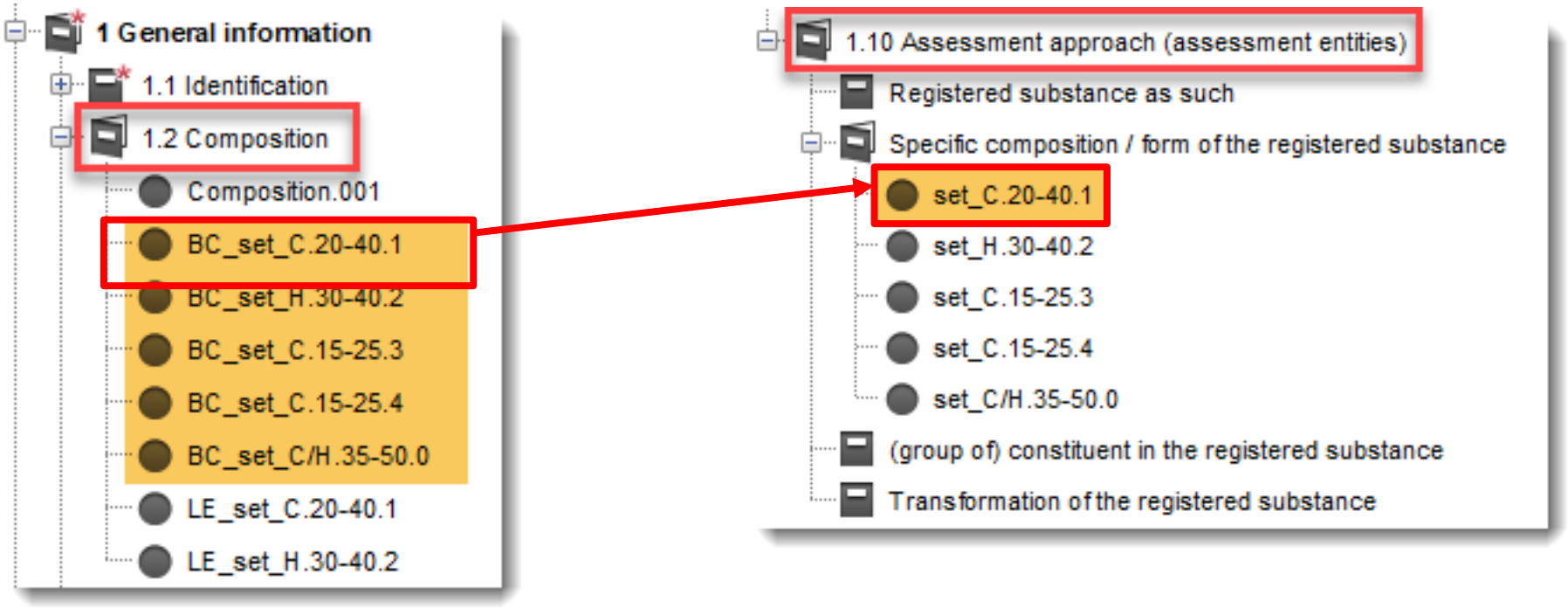
- **Lead registrants:** create an electronic link between the composition, and the data set using the assessment entity in IUCLID
- **Member dossiers**: Use a consistent naming convention to link your compositions, to those reported in the lead dossier

Linking hazard data for each nanoform/set

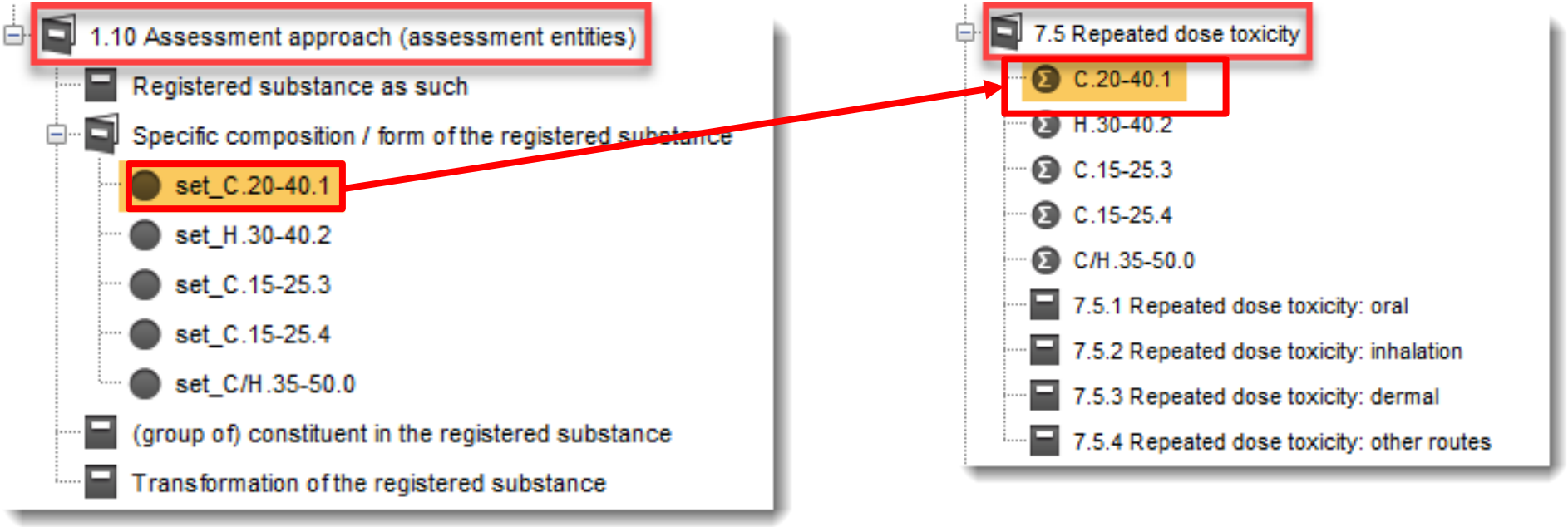
- **Lead registrants:** create an electronic link between the composition, and the data set using the assessment entity in IUCLID



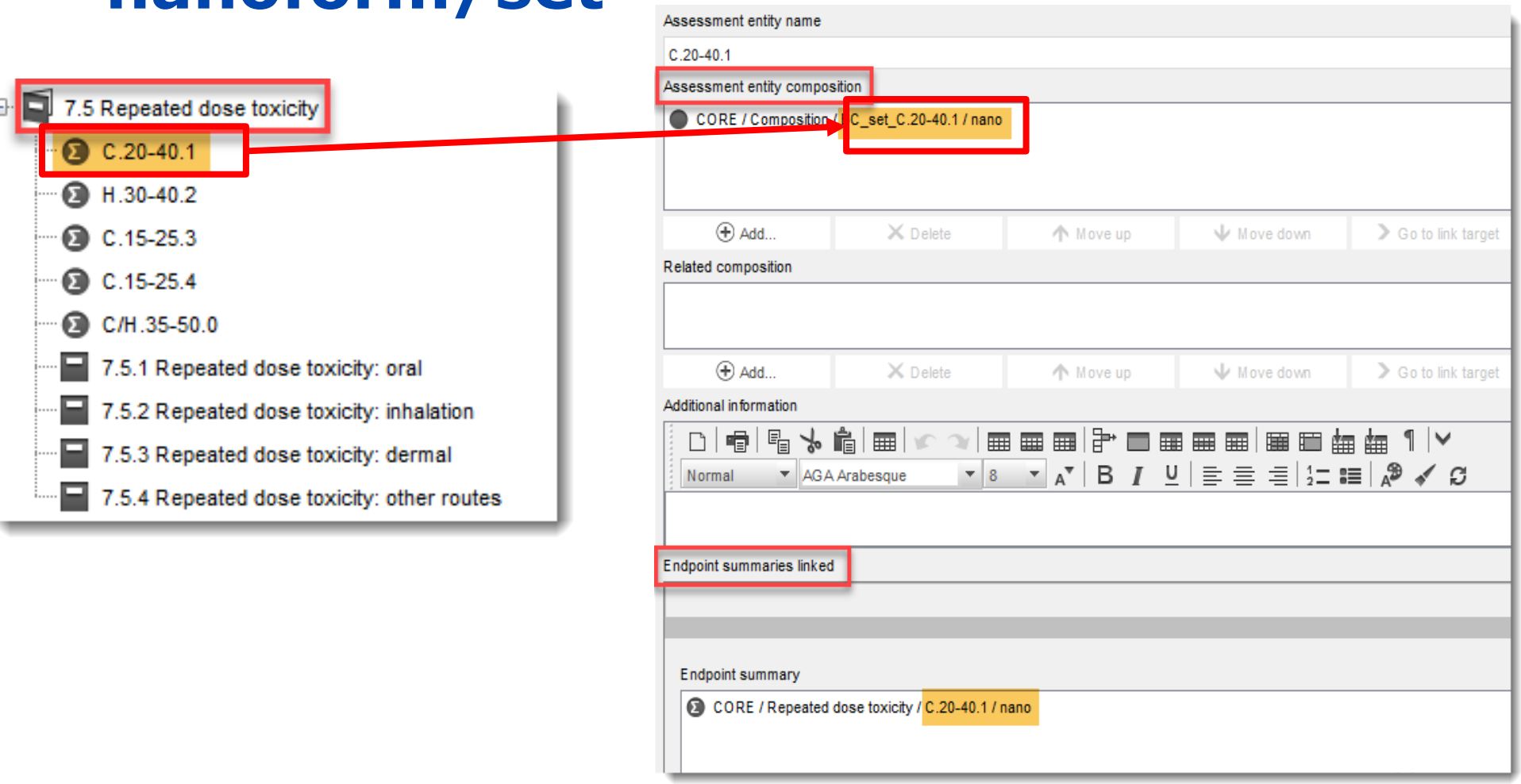
Linking hazard data for each nanoform/set



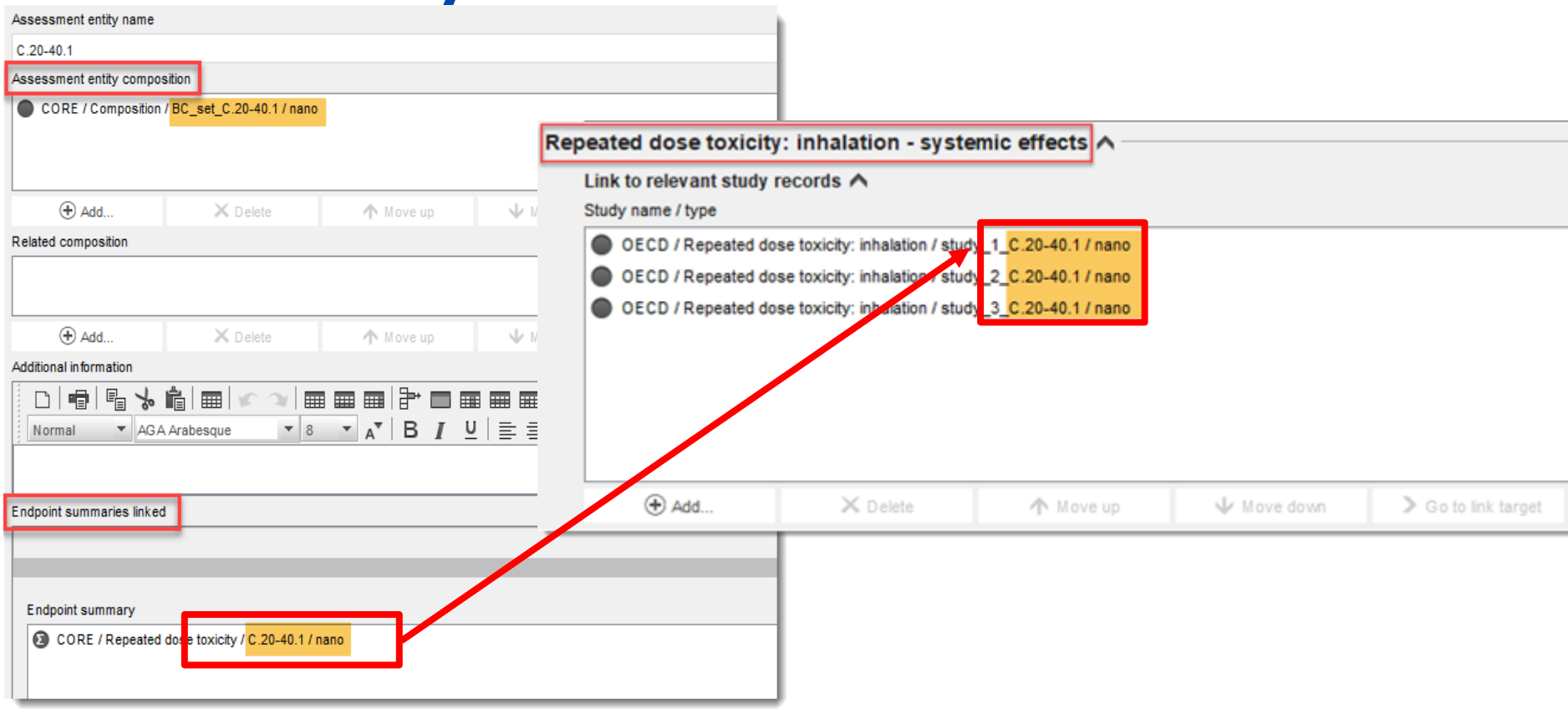
Linking hazard data for each nanoform/set



Linking hazard data for each nanoform/set

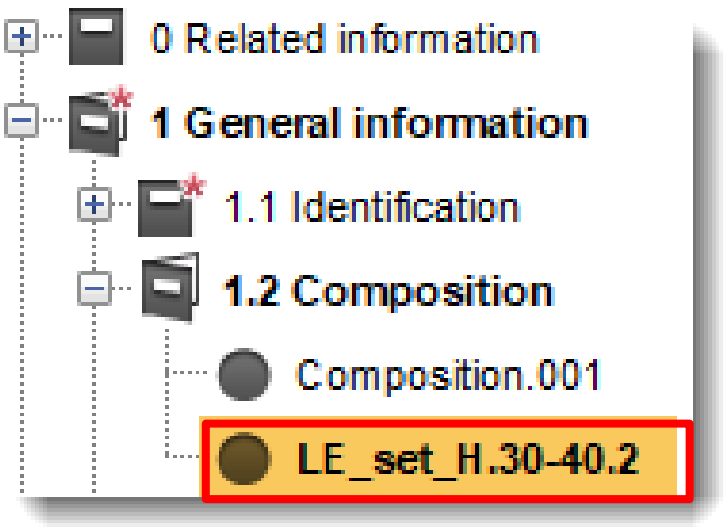


Linking hazard data for each nanoform/set



Linking member data to lead data

- **Member dossiers**: Use a consistent naming convention to link your compositions, to those reported in the lead dossier



General Information

Name

LE_set_H.30-40.2

Type of composition

legal entity composition of the substance ... Other

State / form

solid: nanoform ... Other

Description

Justification for deviations

Attached description / justification

Attached document

Add... Edit... Delete Move up Move do...

Related composition(s)

Related composition

Add... Delete Move up Move down Go t

Reference to related composition(s)

BC_set_H.30-40.2

Use of data on one form for another

Reported in IUCLID as read-across:

- Source record with original study summary + target record with outcome and read-across justification specific to endpoint and nanoform
- See also 9.6.3 – How to report read-across in IUCLID of manual *How to prepare registration and PPORD dossiers*
- Specific case where justification for read-across to multiple nanoforms is **identical** only one target record may be created if:
  - It is clearly linked to all the nanoforms or sets for which it is used.
  - The justification specifically mentions all covered nanoforms.

Characterise the test material

- Essential for fulfilling information requirements and demonstrating that data exist on each nanoform or set of nanoforms.
- In addition to the information on the chemical composition of the test material, as a minimum, report in IUCLID for each (robust) study summary and testing proposal:
  - Test material form
  - Details on test material (use the available text template)
  - Confidential details on test material (if applicable)

Characterise the test material

- IUCLID section 4.28 contains endpoint study records to report (robust) study summaries for physicochemical properties of nanoforms.
  - Only section 4.28.8 – Nanomaterial dustiness is an information requirement and included in the completeness check
- Not to be confused with characterisers reported in IUCLID section 1.2:
  - Section 1.2 is for reporting Annex VI information requirements; refers to the registered compositions and forms of the substance; obligatory for each registrant
  - Sections 4-7 are for reporting Annex VII-XI information requirements; capture tests done on a particular test material sample
- If you have performed phys-chem studies with particular test materials that are used in Annex VII-X studies, you may report these study summaries in 4.28.X as complementary information to the test material information.

Opt-out of Annex VII-X information

- For **nanoforms**, opting out applies for one or several endpoints provided that a justification in accordance with Article 11(3) is submitted (manually checked at ECHA).
- For **sets of nanoforms**, opting out can only be applied to **all** endpoints and related assessments:
  - The exception to register nanoforms via sets of similar nanoforms relies on the principle that the hazard, exposure and risk assessment of the nanoforms can be performed jointly for all nanoforms in the set.

Test guidelines under development

Test guidelines under development

- For some REACH endpoints, test guidelines and guidance documents are being developed to suit nanomaterials.
- Test method availability and development can be followed on EUON: https://euon.echa.europa.eu/reach-test-methods-for-nanomaterials
- Before considering (vertebrate) animal testing, the use of adaptations based on column 2 of Annexes VII-X and Annex XI must always be explored first.

Reporting in IUCLID

- When an information requirement cannot be met with existing data or adaptations and test methods for nanomaterials are under development:
  - For Annex IX and X information requirements, insert a testing proposal in the corresponding IUCLID section.
  - For Annex VII and VIII information requirements, you may report **practical constraints** with the commitment to initiate testing as soon as test guidelines and guidance documents are available. ECHA will monitor the use of this approach.

Practical constraints to fulfil Annex VII/VIII information requirements

- In IUCLID, indicate the endpoint study record as a data waiving by selecting in the field 'Data waiving' the value 'other justification'.
- In the field 'Justification for data waiving', select only the value 'other:' and in the adjacent text field, type in the following statement: "This information requirement is not addressed until the finalisation of the relevant OECD Test Guideline or Guidance Document for nanomaterials. Evidence that no other information exists to fulfil this requirement is provided below under 'Attached justification'."
- In the same endpoint study record, in the field 'Attached justification', attach the template available on the https://echa.europa.eu/regulations/nanomaterials page

Support and advice

Available support

- Manual *How to prepare registration and PPORD dossiers* updated with release IUCLID 6.4 in October 2019: ***Annex 8. Reporting information specific to nanoforms*** and related document *Information on manual verification at completeness check*: https://echa.europa.eu/manuals
- Webinar on 12 November 2019; presentations and extensive Q&A available: https://echa.europa.eu/-/revised-reach-information-requirements-for-nanoforms-are-you-ready-
- Guidance documents published on 3 December 2019: Guidance for identification and naming of substances under REACH and CLP > **Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification**
- Support by ECHA experts: https://echa.europa.eu/contact

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Conclusions

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Jenny Holmqvist, ECHA

Take home messages

- Get active now to ensure that you have a valid registration to manufacture/import your nanoforms
- Use the guidance and support material available today
- 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

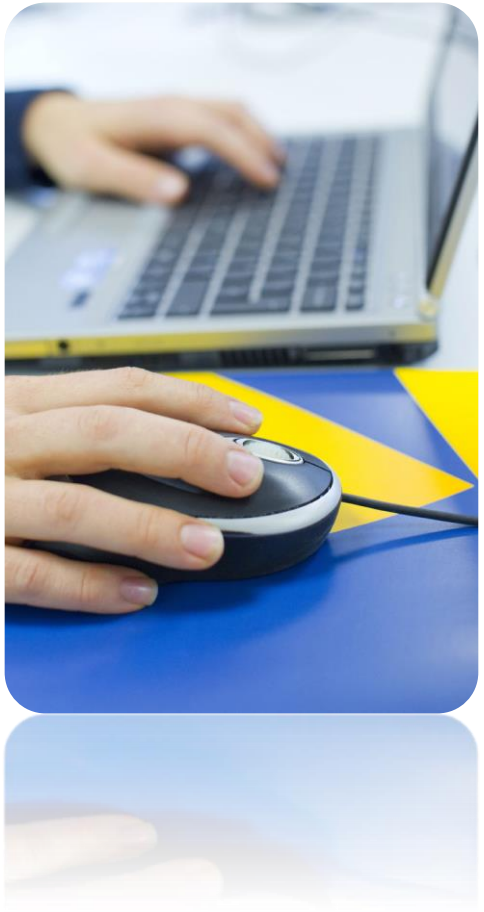
Material published

Video recording, presentations and Q&A:

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

Q&A panel

- Webinar open until **14:00 Helsinki time** to answer questions
- If your question is not answered by the end of the webinar, send it via our contact form: echa.europa.eu/contact



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