Webinar on practical advice for registering nanoforms – questions and answers

April 2020

Updated REACH Annexes for the nanoforms of substances begin to apply as of 1 January 2020. The updated Annexes introduce new concepts: nanoform and a set of similar nanoforms. The updated REACH Annex VI also defines specific characterisation parameters for the nanoforms of substances.

ECHA organised a webinar on 24 February 2020 to raise further awareness among industry on the obligation to register the nanoforms of their substances and to support those registrants in the process of preparing their submission. The webinar presentations addressed the most common shortcomings observed in the dossiers received so far.

Participants had the chance to ask questions from ECHA experts and this document compiles and groups questions and answers received during the webinar. The replies have been further elaborated and complimented with additional advice.

This document will not be updated and for the most up-to-date advice, you should always refer to our guidance or Q&As.

Table of Contents

1. SUPPORT DOCUMENTATION

1.1. Where can I find ECHA's support and guidance documents relating to nanomaterials?

You can find all our guidance, manuals and other support documentation related to nanoforms on the ECHA Nanomaterials page: https://echa.europa.eu/regulations/nanomaterials. The page is updated with new links as more guidance is developed and published.

In terms of manuals for preparing registration dossiers covering nanoforms, you can find under https://echa.europa.eu/manuals the following:

- How to prepare registration and PPORD dossiers (*Annex 8*) [PDF] [EN]
- Information on manual verification at completeness check [PDF] [EN]

The template to report practical constraints in fulfilling the information requirements for Annex VII-VIII endpoints where existing guidance and test guidelines are not applicable to nanoforms is available on the ECHA Nanomaterials page (direct link here).

The following guidance, specific to nanoforms, is available:

- Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification
- Appendix to Chapter R.6: Guidance on QSARs and Grouping of Chemicals [PDF] [EN]

In addition, the following guidance is available and will be updated where needed to better reflect amendments to the current legal text. The updating of existing guidance for human health and environmental information requirements is expected to continue during 2020.

- ECHA Guidance on Information Requirements and Chemical Safety Assessment for nanomaterials:
    - Appendix to Chapter R.7a: Endpoint specific guidance [PDF] [EN]
    - Appendix to Chapter R.7b: Endpoint specific guidance [PDF] [EN]
    - Appendix to Chapter R.7c: Endpoint specific guidance [PDF] [EN]
    - Appendix to Chapter R.8: Characterisation of dose [concentration] - response for human health [PDF] [EN]
    - Appendix to Chapter R.10: Characterisation of dose [concentration] - response for environment [PDF] [EN]
    - Appendix to Chapter R.14: Occupational exposure assessment [PDF] [EN]

To further support potential registrants in meeting the new information requirements, an updated overview of available test guidelines and other recognised methods and standards is available on the European Union Observatory for Nanomaterials (EUON).

We also encourage you to have a look at the presentation and question and answers document from the November 2019 webinar about the information requirements for nanoforms.

2. REGISTRATION OBLIGATION

2.1. Is there a difference in registration obligations depending on the purpose for bringing nanomaterials on the market, e.g. based on engineered nanomaterials; non-intentionally produced nanoparticles (NIPNPs); and process generated nanoparticles (PGNPs)? Is registration required for all of the above nanoforms?

If a form of substance fulfils the definition of nanoform as defined in the updated REACH Annex VI, the (lack of) intention to produce it does not impact the registration obligation.

2.2. How does ECHA suggest to proceed if a co-registrant claims not to produce nanoforms but does not provide any proof for this?

Each registrant is responsible for registering the nanoforms that they themselves manufacture or import. The information required by Annex VI, including the characterisation of nanoforms or sets of nanoforms, must be submitted separately by each registrant.

The information required by Annexes VII-X can be submitted jointly in the lead registrant dossier on behalf of the member registrants. Alternatively, this information can be submitted separately by each registrant via the opt-out mechanism.

Lead registrants are not responsible for the reporting by other registrants of the nanoforms they manufacture or import. If a co-registrant claims not to produce nanoforms, the other registrants of the substance should proceed with the registration of their nanoforms following the REACH requirements.

Registrants that manufacture/import nanoforms of the substance after 1 January 2020 without a registration that covers these nanoforms are in breach of the REACH regulation which may lead to enforcement measures.

2.3. A legal entity is placing a form above 1 tpa and another form of the same substance below 1 tpa on the market. Is the second form falling under the REACH registration obligation based on the sum of the different forms placed on the market for this substance?

Yes. The REACH Regulation states that the tonnage is applicable per registrant per substance, including bulk and nanoforms. It is therefore the total quantity of the substance, including the quantities of all different forms manufactured/imported by the registrant that determines the registration obligation and applicable information requirements.

If the total volume of the substance in all its forms that the registrant manufactures/imports is above 1 tonne per year, then each nanoform of the substance needs to be registered even if they represent a volume of less than 1 tonne per year.

2.4. One of the nanoforms we manufacture/import is not covered by the joint registration for the substance which is at above 1000 tonnes per year. The volume of this nanoform is 1-10 tonnes per year. I am planning to make a full opt-out for this nanoform. Am I in this case allowed to register this nanoform within the 1-10 tonnes per year tonnage band?

You must take into account the total volume of the substance in all its forms that you manufacture/import. Then each (nano)form of the substance needs to be registered at the tonnage band corresponding to this total tonnage.

It is the total quantity of the substance, including the quantities of all different forms manufactured/imported by the registrant that determines the registration obligation and applicable information requirements.

2.5. Does the obligation to register nanoforms of the substance also apply to a substance that has already received the ELINCS number?

Yes. The status as ELINCS substance does not have impact on the registration obligations of its nanoforms.

2.6. Is the deadline of 1 January 2020 to update registrations to cover nanoforms in compliance with the new data requirements, intended to cover only nomenclature, analytical information and physico-chemical characterisation of the nanoforms?

No, the updated REACH Annexes applicable to nanoforms require also all the tonnage dependent information requirements (Annex VII-X) to be fulfilled, uses to be specified and the chemical risk assessment to carried out.

2.7. What about substances listed in the French nano inventory but not falling under the scope of REACH. Are they considered as nanoforms and have to be still registered under REACH with the required nano information?

We understand that the question may refer to the situation where the manufacturer/importer produces the substance in a total volume below 1 tonne per year. In this case, there is no obligation to register the substance under REACH. This applies to all forms of the substance; also those that are considered nanoforms under REACH. When the total volume of the substance, including all the forms of the substance, is equal to or above 1 tonne per year, the registration obligation applies and a registration dossier must be submitted to ECHA for this substance. In this case, each form of the substance that is considered a nanoform under REACH must be separately reported in the registration, irrespective of the yearly volume of the nanoform, and irrespective of whether it is listed in the French nano inventory.

Substances that have been notified under the French nano inventory as a nanomaterial may also fall under the definition of a nanoform under the REACH Regulation. However, there are some differences between the definition of a nanomaterial under the French notification scheme, and the definition of a nanoform under REACH. The tonnage thresholds are also different. The processes and obligations are also separate, and therefore a notification submitted to the French inventory does not release importers / manufacturers from the obligation to register a nanoform under REACH. A separate registration must be made under REACH, if the registration obligation applies to the substance.

If the substance does not fall under the scope of REACH due to an explicit exemption this question would require a case-specific reply based on the reason for exemption.

2.8. What can we do as downstream user of a nanomaterial if the only-representative is not planning to update the dossier to include nanomaterials?

In order to answer your question we would need more information. In general, all nanoforms falling under the scope of REACH must be registered, either by the manufacturer/importer or by an only representative appointed by a non-EU manufacturer or formulator.

2.9. Would a modernisation of the production line trigger the need to newly register the produced nanoform if its phys-chem parameters are not changed?

If the characterisation parameters of the nanoform(s)/set(s) of nanoforms reported in the existing registration dossier do not change, there is no need to update the dossier with regard to the identity of the nanoforms covered.

However, if the modernisation concerns the surface-treatment process, the description of the surface-treatment process in the registration dossier may need to be updated.

2.10. A substance is manufactured or imported in a non-nano form and marketed as such. This non-nano form could be converted into a nanoform with high energy input in the supply chain. However, this scenario never takes place during the actual use of the non-nano form. Must the substance still be registered as a nanoform or not under REACH?

All nanoforms falling under the scope of REACH must be reported to ECHA, either by the registration of the manufacturer/importer, or through a downstream user notification. This concerns nanoforms that are actually produced; nanoforms that can hypothetically be generated do not require registration.

We understand that the term "non-nanoform" in your question refers to a form of the substance that does not meet the definition of a nanoform in REACH. Given the nature of the question, we would like to remind you of that REACH defines the nanoform as a form of a substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm.

The definition of a nanoform is based on the European Commission recommendation on the definition of a nanomaterial (http://data.europa.eu/eli/reco/2011/696/oj). The concepts and terms used in the nanomaterial definition are explained in a JRC report (https://publications.jrc.ec.europa.eu/repository/bitstream/JRC113469/kjna29647enn.pdf). It should be noted that the size distribution of the constituent particles, as defined in the JRC report, defines if a form of a substance is a nanoform. Therefore, if for a form of a substance 50 % or more of the constituent particles have one or more external dimensions is in the size range 1 nm - 100 nm, the form is a nanoform even if the breaking of the aggregates or agglomerates consisting of the constituent particles would require high energy input.

3. CHARACTERISATION OF NANOFORMS

3.1. When you report lower and upper values for e.g. surface area, do they represent range of batches, or the range of set of nanoforms? In our case we have a single nanoform (not a set)?

For a single nanoform you report a range reflecting the batch-to-batch variability. For a set of nanoforms you report a range reflecting the boundaries of the set.

3.2. If XRD didn't provide sufficient information to determine crystalline structure, which analytical assessment are we required to perform?

You are free to choose the analytical techniques as long as the data requirement is fulfilled. For questions concerning a specific nanoform, please submit the question using our contact form.

3.3. Does the particle size refer to the physical particle size or aerodynamic particle size?

For the purposes of determining whether you have a nanomaterial according to the EC definition, and for the reporting of particle size for fulfilling the information requirements of REACH Annex VI, you should report the physical size, not an aerodynamic size.

3.4. Could you clarify the definition of "granular form"?

There is no definition for the term "granular form" in the regulation. However, this can be interpreted to mean "particles". Note that all nanoforms, by definition, will have 50% of their particles by number below 100 nm, and all nanoforms will be "granular" when available in a dry powder. However, some nanoforms may be available only in suspensions, or incorporated into a matrix throughout their entire lifecycle, in which case there may be no exposure the dry powder.

3.5. How do we determine the particle size in dispersions if the particle properties are changed by e.g. drying which is necessary for measurements like electron microscopy?

Guidance on nanoforms recommends to use at least one electron microscopy technique to measure the number based particle size distribution. However, the registrant is free to choose any analytical method as long as the information requirement is fulfilled.

When choosing the most appropriate method to measure the particle size distribution, you may find useful the JRC report available at:
https://publications.jrc.ec.europa.eu/repository/bitstream/JRC118158/kjna29942enn.pdf

3.6. What is the information required on crystallinity? Is it the information that the nanoform is crystalline? An organic pigment in general has only one crystal modification. Is XRD sufficient to characterise the crystallinity?

In many cases XRD is sufficient. In any case, registrant is free to choose the analytical techniques for characterisation of the nanoform as long as the information requirements are fulfilled.

4. SET OF SIMILAR NANOFORMS

4.1. Will in the future the addition of a nanoform or a set of nanoforms in a joint registration potentially jeopardise the already registered set of similar nanoforms of a substance?

If the registration will be updated to cover additional nanoforms, the decision needs to be taken whether the nanoforms will be registered (i) on their own as separate nanoforms; (ii) as a new set of nanoforms; or (iii) by modifying the already registered set of nanoforms.

If the nanoforms are added to the registration as separate nanoforms or as a new set of nanoforms, they will not impact the already registered set of nanoforms. As for the existing set, they need to be registered by including the appropriate characterisation, set justification and Annex VII-X information in the dossier.

If the nanoforms are added to the registration in the existing set of nanoforms, you need to ensure that the nanoforms fit within the clearly defined boundaries of characterisers of the existing set. If this is not the case, you need to analyse whether the boundaries of the set can be expanded without affecting the joint hazard assessment, exposure assessment and risk assessment of all the nanoforms covered by the set. This analysis needs to be reflected in the provided justification for the set.

Finally, a nanoform can only belong to one set of similar nanoforms.

4.2. Where can I find more information on sets of similar nanoforms?

Please consult the ECHA guidance Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification:
https://echa.europa.eu/documents/10162/13655/how_to_register_nano_en.pdf

4.3. Does ECHA accept the inclusion of nanoforms within one set which contradict the limitations set out in Guidance if the registrant can justify the set formation?

The principles described in the Guidance for forming a set of nanoforms gives advice to the registrant on how build a compliant set of nanoforms. Following the principles in the Guidance reduces also the need for development of complex justification for the set.

The limitations for the formation of sets of nanoforms is based on presumptions resulting from a scientific consensus. The stronger the consensus, the stricter the limitation. For the strictest restrictions (e.g. fibres and sphere shapes must be addressed in different sets of nanoforms) the scientific consensus is such that the presumption is considered not rebuttable.

For other restrictions, deviating from the principles set in the Guidance will increase the complexity of a justification as well as the supporting evidence required, and this will increase the level of scrutiny given to the justification.

In any case, for a set of nanoforms a justification that hazard, exposure and risk assessment can be performed jointly must be always provided. It is the responsibility of a registrant to develop the justification and provide the data supporting the justification.

The completeness of the justification is checked in the technical completeness check and the

compliance in a potential compliance check.

4.4. If you have a set of nanoforms but no data, do you need to generate the data on the Annex VII-X properties for all the nanoforms in the set?

In order to create a set of nanoforms, you need to 1) clearly define the boundaries of your set of nanoforms, and 2) provide a justification to demonstrate that the hazard assessment, exposure assessment and risk assessment of the nanoforms in the set can be performed jointly for all nanoforms included in the set, without exceptions. In other words, certain data on the Annex VII-X properties of the nanoforms in the set must be submitted for you to be able to conclude that several nanoforms can be reported as a set of nanoforms.

Once a set of nanoforms has been established and scientifically justified, the complete Annex VII-X information must be provided for the set of nanoforms. It is not necessary to generate data on the Annex VII-X properties for each nanoform included in the set; indeed, as mentioned above, the justification for the set of nanoform should prove that the hazard and fate assessment of the nanoforms can be performed jointly for all nanoforms in the set. However, the data provided for each information requirement must be representative for the whole set of nanoforms.

For every information requirement as per Annex VII-X, the registrant must submit either (i) studies performed on the nanoforms concerned; or (ii) studies on other forms of the substance accompanied by endpoint-specific justifications as to why this information is adequate for assessing the nanoforms concerned; or (iii) relevant adaptations as foreseen by Annex XI of REACH or Column 2 of the relevant Annex VII-X.

As explained in chapter 6. Joint submission, the Annex VII-X information can be submitted by the lead registrant on behalf of the joint submission, or separately by co-registrants, via the opt-out mechanism.

5. REPORTING IN IUCLID

5.1. For a dossier covering one nanoform only: if information on the characterisation of the nanoform is provided in IUCLID section 1.2, is it mandatory to report this information also in section 4.28?

To register a nanoform of a substance, you must report its characterisation in sections 1.2 and 1.4 of IUCLID, as defined by REACH Annex VI. The information reported in these sections refers to the identification of the compositions/forms of the substance in scope of the registration. It is submitted separately by each registrant.

The Annex VII-X information requirements for the nanoform are then reported in sections 4-7 of IUCLID following the agreement in the joint submission. This information can be submitted jointly by the lead registrant on behalf of the joint submission; or separately by co-registrants via the opt-out mechanism.

IUCLID section 4.28 contains the templates for reporting the (robust) study summaries of physicochemical properties for nanomaterials. The only sub-section in 4.28 that corresponds to a mandatory Annex VII-X information requirement is section 4.28.8 – Nanomaterial dustiness.

It is true that certain sub-sections under IUCLID section 4.28 refer to the same characterisers

as the ones to be reported in IUCLID section 1.2. However, section 1.2 is the location where the nanoform characterisers required by Annex VI must be provided.

5.2. Can I report a set of nanoforms as two different compositional entries in IUCLID as some nanospecific parameters differ to a minor extent based on the composition (dilution)?

This question would require further information for a complete reply. Please contact ECHA via the contact form and provide more specific details about the case.

5.3. How should we report information by form in the current IUCLID system? Is only the overall quantity required and only at the level of the substance?

You only need to report the total quantity of the substance, including the quantity of the bulk and nanoforms, in section 3.2 – Estimated quantities of the IUCLID dossier.

However, you may wish to clarify how and at which quantity the different (nano)forms of the substance are used; this can be detailed under the use description section 3.5 by specifying the tonnage/use and by linking that use record to the relevant composition/form record in section 1.2.

5.4. Is there a timing defined for the next update of IUCLID which will correct some missing fields (like the cubic crystallinity shape)?

Following agreement with its various user groups, only the October IUCLID release of each year includes changes to the data format. Therefore the missing entry for 'cubic' in the 'Crystal system' dropdown list will be added in the October 2020 release of IUCLID.

Until then, please report this entry as follows: in the dropdown list 'Crystal system' select 'other:' and type "cubic" in the adjacent text field.

We are not aware of other data fields to be corrected in relation to the reporting of nanoform information. Please send us your findings via the contact form.

5.5. Our dustiness measurements are commissioned with test labs but will take weeks to be concluded. How can we report this missing information in the IUCLID without failing the completeness check?

The completeness check ensures that all the required information is reported in the dossier. Therefore, you cannot pass the completeness check by providing placeholders for missing information, even if the tests would be commissioned. If you cannot address the information requirement with available data or an adaptation (or, in the case of Annex IX-X information requirements, with a testing proposal), you will not pass the completeness check for this information requirement.

If you fail the completeness check, you will be given a standard deadline of four months to provide the missing/incomplete information. Therefore, if you fail the completeness check at first attempt and in the meantime obtain the test results, you can amend the dossier and pass the completeness check at second attempt. The submission date will correspond to the submission of your first attempt.

6. JOINT SUBMISSION

6.1. Should the lead registrant of a joint submission not update the dossier to include a boundary composition for a set of nanoforms by the time of the second completeness check deadline allocated to my company; what is the alternative option for my company to comply with the obligation to register our nanoforms?

Each registrant is responsible for registering the nanoforms that they themselves manufacture or import. Therefore, each registrant has the obligation to characterise the nanoforms (either individually or through sets of nanoforms) they manufacture/import and to ensure that a specific hazard data set is provided for each nanoform or set of nanoforms. The information required by Annex VI, including the characterisation of nanoforms, must always be submitted separately by each registrant, in section 1.2 of IUCLID.

It is up to each co-registrant to identify their own nanoform(s). It is then up to the co-registrants in the joint submission to decide whether to submit the hazard data (i.e. information requirements of Annexes VII to X) on the nanoforms of the substance jointly or separately.

By derogation to the obligation to provide hazard data on each single nanoform, co-registrants can identify sets of nanoforms with clearly defined boundaries if they can justify that the hazard, exposure and risk assessments can be performed jointly for the nanoforms included in the set. In this case, one set of hazard data can be submitted for all nanoforms within the set.

Therefore, you need to discuss and agree with the lead registrant whether your nanoforms will be covered by the hazard information jointly submitted for a set of nanoforms.

- If the set of nanoforms will cover your nanoforms, you do not have to submit the hazard data yourself. However, you must still identify and characterise your nanoforms under Annex VI and provide a justification that the hazard, exposure and risk assessments can be performed jointly for the nanoforms included in the set.

- If the set of nanoforms will not cover your nanoforms of the substance, you must ensure that a specific hazard data set is provided for these nanoforms. This hazard data may either be submitted jointly by the lead registrant, or be submitted separately by you via an opt-out, as foreseen in Article 11(3) of REACH. In this second case, you must submit all the hazard data required for your nanoforms in sections 4-7 of IUCLID.

If, in any of the situations described above, you agree with the lead registrant that the hazard information will be submitted jointly, you must link in your registration dossier your nanoforms to the corresponding hazard data submitted in the lead dossier. If you submit an update of your registration dossier to cover your nanoforms before the lead registrant has submitted the corresponding jointly submitted hazard data, ECHA will only be able to verify the completeness of the Annex VI characterisation of your nanoforms. However, ECHA cannot verify the completeness of the hazard data (Annex VII-X) if this information has not yet been jointly submitted by the lead registrant. In such a case, ECHA reserves the right to assess the completeness of your dossier in relation to the information on the properties, whenever it is submitted by the lead registrant.

6.2. Our dossier as a joint submission member registrant has passed the completeness check, but the dossier of the lead registrant (which is covering the Annex VII-X information of our nanoforms) is pending. Do we need to update the member dossier after the lead dossier has passed the completeness check to include a link to the boundary composition(s) in the lead dossier that are relevant to our nanoforms?

As in the reply to question 6.1, ECHA reserves the right to assess the completeness of your dossier in relation to the information on the Annex VII-X properties, whenever this information will be submitted by the lead registrant.

When the lead registrant has submitted their dossier, you must update your registration to link your nanoforms with the relevant Annex VII-X information in the lead dossier. This is done by referring to the corresponding boundary composition name(s) of the lead dossier, in the section 1.2 legal entity compositions of your own dossier by using the field 'Reference to related composition(s)'.

6.3. The lead registrant dossier only covers the Annex VII-X information requirements for the bulk form of the substance. We as a member registrant are submitting data on the nanoforms of the substance as an opt-out. We rely on several studies on the bulk form to cover the information requirements on our nanoforms. Do we need to set up a read-across approach in our dossier for the endpoints where we rely on the studies on the bulk form submitted by the lead?

Yes. Due to the differences between bulk and nanoforms you need to demonstrate for each endpoint and each nanoform why the information provided is adequate for assessing the nanoforms, i.e. that the prediction from the bulk to each nanoform is reliable and accurate, and does not underestimate the hazard.

To report the read-across in your dossier, follow the advice given in chapter 9.6.3 'How to report read-across in IUCLID' of the manual "How to prepare registration and PPORD dossiers". The direct link to the document is here:
https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf

6.4. Does a co-registrant, which only registers a single nanoform, have to include in their dossier also the boundary composition of the set of nanoforms of the lead dossier, to be able to link this composition? Or should they link their single nanoform composition with the set of nanoforms submitted by the lead registrant?

We understand that you are manufacturing/importing a single nanoform that is covered by the set of nanoforms submitted by the lead registrant with corresponding Annex VII-X data. In this case, you should not submit in your dossier the boundary composition with the set of nanoforms that is provided in the lead dossier. However, you must link in your dossier your nanoform to the relevant set of nanoforms and corresponding data submitted in the lead dossier.

To link your nanoform to the set of nanoforms of the lead dossier, you need to insert in the section 1.2 legal entity composition where you report your nanoform, in the field 'Reference to related composition(s)' the name of the lead dossier boundary composition which reports the set of nanoforms that your registration relies on.

6.5. We are a member registrant with nanoforms of a substance. We have confirmed with the lead registrant that our nanoforms are covered by the sets of nanoforms that are to be jointly submitted in the lead dossier, but they have not yet submitted the lead dossier. Should we wait for the lead registrant to first submit the dossier with the joint Annex VII-X information on nanoforms, so that we are be able to link our nanoforms to this information?

Each registrant is responsible for registering the nanoforms that they themselves manufacture or import. Therefore, each registrant has the obligation to characterise the nanoforms (either individually or through sets of nanoforms) they manufacture/import and to ensure that a specific hazard data set is provided for each nanoform or set of nanoforms.

As a registrant of nanoforms of a substance, you have the obligation to submit the information required under REACH Annex VI, including the characterisation of the nanoforms. The Annex VII-X information can either be submitted as part of the jointly submitted information in the lead registrant dossier, or in your own dossier via the opt-out mechanism.

In the case you describe, where it has been agreed that the lead registrant will submit the Annex VII-X information for your nanoforms, ECHA cannot advise you on whether you should wait with submitting your Annex VI information until the lead registrant has submitted their registration dossier or whether you should submit your own dossier before. We can only stress that, as from 1 January 2020, nanoforms of a substance can be legally manufactured and imported in the EU in cumulative quantity equal or above 1 ton per year only if they are covered by a registration.

In view of the submission of information on your nanoforms, we offer you the following considerations:

- Before you submit your member registrant dossier, you need make sure that the lead registrant has covered or will indeed cover all your nanoforms by the jointly submitted Annex VII-X information, or if not, which nanoforms are not covered.

- If the lead registrant submits this information on your behalf, you will need to link your legal entity compositions that cover nanoforms with the corresponding boundary compositions for sets of nanoforms in the lead registrant dossier. This is done by referring to the relevant boundary composition name(s) of the lead dossier, in the section 1.2 legal entity compositions of your own dossier by using the field 'Reference to related composition(s)'. If you were not able to provide this information in your first submission reporting nanoforms, you need to update your registration once the information becomes available to you, and at latest once the lead registrant has submitted their dossier.

- If you submit an update of your registration dossier to cover your single nanoform before the lead registrant has submitted the corresponding jointly submitted hazard data, ECHA will only be able to verify the completeness of the Annex VI characterisation of your single nanoform. However, ECHA cannot verify the completeness of the hazard data (Annex VII-X) if this information has not yet been jointly submitted by the lead registrant. In such case, ECHA reserves the right to assess the completeness of your dossier in relation to the information on the properties, whenever it is submitted by the lead registrant.

6.6. The joint submission lead dossier only covers nanoforms of the substance but there are joint submission members that do not manufacture/import nanoforms of the substance. Do the member registrants have to opt-out of the Annex VII-X information for nanoforms of the substance submitted by the lead registrant and justify that this information submitted is relevant also for the non-nanoform of the substance?

Manufacturers/importers of non-nanoforms of the substance must ensure that the Annex VII-X data that they rely on is relevant for their compositions and forms of the substance. The information must be appropriate and allow that the hazard and risks are adequately assessed during manufacture and use of the substance.

If the Annex VII-X information submitted in the lead dossier is deemed appropriate to cover non-nanoforms of the substance, the lead registrant has to document this by adding a boundary composition covering the non-nanoform of the substance. If such a composition is not found in the lead dossier, then indeed registrants of the bulk form of the substance need to submit separately the Annex VII-X information via the opt-out mechanism. This information may rely on read-across to the data on the nanoforms of the substance, where applicable and justified.

6.7. Is it possible to rely on the jointly submitted information on nanoforms of the substance in the lead registrant dossier? Or it is mandatory for every registrant to submit separately the information for their nanoforms?

Each registrant has the obligation to submit separately the information required under REACH Annex VI, including the characterisation of the nanoforms (or sets of nanoforms) they manufacture/import.

Each registrant must also ensure that the information required under Annex VII-X and corresponding to the nanoforms they manufacture/import is provided. This can be submitted jointly in the lead registrant dossier on your behalf. Alternatively, the information required by Annexes VII-X can be submitted separately by a co-registrant via the opt-out mechanism.

If this information is submitted jointly by the lead registrant, you must establish that the Annex VII-X data for nanoforms, or sets of nanoforms, submitted in the lead registrant dossier are relevant for the particular nanoforms you are registering. Furthermore, you must indicate in your registration dossier the boundary compositions for nanoforms or sets of nanoforms, and corresponding Annex VII-X data in the lead dossier that your nanoforms rely on. To link your nanoforms to the corresponding information in the lead dossier, you need to insert in the section 1.2 legal entity compositions where you report your nanoforms, in the field 'Reference to related composition(s)' the name of the lead dossier boundary composition which reports the (set of) nanoforms that your registration relies on.

6.8. What is the advised strategy for a company bringing on the market a unique set of similar nanoforms and not the set covered by a joint registration?

Each registrant is responsible for registering the nanoforms that they themselves manufacture or import. Therefore, each individual registrant has the obligation to characterise the nanoforms (either individually or through sets of nanoforms) they manufacture/import and to ensure that a specific hazard data set is provided for each nanoform or set of nanoforms.

The information required by Annex VI, including the characterisation of nanoforms or sets of nanoforms, must always be submitted separately by each registrant.

The information required by Annexes VII-X can be submitted jointly in the lead registrant dossier on behalf of the member registrants. Alternatively, this information can be submitted separately by each registrant via the opt-out mechanism.

It is up to the co-registrants in the joint submission to decide what strategy they prefer; whether to submit the specific hazard data corresponding to the unique set of nanoforms in the joint registration dossier submitted by the lead, or whether the co-registrant manufacturing/importing the nanoforms in this set will submit separately all the information required.

7. TEST GUIDELINES & ANNEX VII-X INFORMATION

7.1. We understand that there are no agreed test guidelines for generating information on nanoforms for any REACH information requirement. Scientific evidence cannot be provided in the absence of agreed technical guidelines; the scientific basis would not fulfil the requirements set out in Art. 13(3). Please advise how to proceed?

We would like to remind you that there are test methods/guidelines applicable to nanoforms that are available already now. We have published a list of available methods to help registrants. If you have concern with a specific method, we are happy to discuss such case specific matter further.

The list can be found here: https://euon.echa.europa.eu/reach-test-methods-for-nanomaterials

Note that the assessment of the acceptability and thereby also the relevance of a certain method for a specific nanoform, is in the hands of the registrants. Also, note that the list is indicative, not an exclusive registry and we aim at keeping it updated.

7.2. You mention that the assessment of the acceptability and relevance of a certain method for a specific nanoform is in the hands of the registrants. How does this reflect the conditions set out in Art. 13(3)?

If data already has been generated using existing methods, this data should be used and its relevance should be assessed and documented in the registration dossier. In cases when new data has to be generated and there are uncertainties regarding the applicability of currently existing methods and guidance, you should follow the advice given in the webinar presentation (see also question 7.3).

7.3. What should be reported in IUCLID for an information requirement that lacks specific guidance and/or test methods for nanoforms?

As in the reply to the previous question 7.2, if data already exists for this information requirement, these data should be used as far as possible to fulfil the information requirement and their relevance should be assessed and documented in the registration dossier. In cases when new data have to be generated and there are acknowledged uncertainties regarding the guidance and test methods for nanoforms for that specific endpoint, you should report it as

follows:

- For Annex IX and X information requirements, you should submit a testing proposal and indicate that the test guideline/guidance is still under development.

- For Annex VII-VIII information requirements, you may report practical constraints in fulfilling the information requirements in the absence of test guidelines/guidance appropriate for nanoforms. To do this, you need to download the template available on the ECHA nanomaterials page (https://echa.europa.eu/regulations/nanomaterials > Guidance and manuals > ECHA), address all points and attach it to the relevant endpoint study record. For more detailed instructions on how to fill in the endpoint study record to report practical constraints, please consult the document Information on manual verification at completeness check (chapter 6. Specific requirements for nanoforms).

7.4. Published information on the hazards of nanomaterials almost exclusively lack sufficient information to assign the test item to a particular set of nanoforms. Would it be appropriate to discuss this in a weight of evidence approach relevant for the nanoforms of the substance in general?

We understand that the question refers to the use of a weight of evidence adaptation for the fulfilment of the Annex VII-X information requirements.

The REACH regulation stipulates that for each set of nanoforms, specific Annex VII-X information must be submitted. Whenever information generated on a test material/form that does not belong to the set of nanoforms is used to fulfil the information requirement for the set, a read-across approach must be used, including the justification of why the data is applicable to assess this property for the set of nanoforms.

We understand from the question that you have study information on nanomaterials that cannot directly be identified to belong to any particular set of nanoforms. If you are not able to thoroughly identify and characterise the test material/form of a study, it cannot be used as a source study in a read-across approach.

7.5. Do you have any recommendation on the method to measure dustiness?

The CEN standard EN 17199-1:2019 "Workplace exposure - Measurement of dustiness of bulk materials that contain or release respirable NOAA and other respirable particles - Part 1: Requirements and choice of test methods" gives advice on the methodology and provides guidance to choose the most adequate test method. It is recommended to choose the methods more relevant to simulate the operations/tasks expected to be performed.

7.6. How to deal with data which have been generated using guidelines not revisited by either JRC or the Malta project?

Similar to bulk substances, ECHA will assess on a case by case basis the information provided in the endpoint study record (e.g. material and methods, characterisation of test material, raw results, conclusion) to establish the relevance and reliability of the provided information.

7.7. Is it foreseen that the PEG efforts for the finalisation of the human health and environmental Guidance documents for nanoforms are re-initiated soon?

We are planning to initiate the revision of the remaining two guidance packages this year.

8. GENERAL

8.1. The capacities of contract laboratories are fully booked for a long time. How shall a (SME) company provide the required long-term studies in this short transition period, if no measurement time is available?

If the requirements that you refer to belong to REACH Annex IX or X (you refer to long-term studies), you should submit a testing proposal before initiating the testing.

8.2. You mentioned about half of the dossiers for nanoforms of substances use the approach of sets of nanoforms and that many failed the manual check of the justification for the set formation. How many dossiers for nanoforms passed the completeness check?

We recently published a news release with more information on received submissions - https://echa.europa.eu/-/companies-need-to-provide-more-data-on-nanoforms.