Webinar on revised REACH annexes for nanomaterials – questions and answers

December 2019

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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 12 November 2019 on the revised annexes and how companies can prepare to meet the new requirements. The first part of the webinar explained what a nanoform is and how to build a set of similar nanoforms. It also explained how to fulfil data requirements for the characterisation of nanoforms. The second part introduced new IUCLID fields for reporting the characterisation parameters of nanoforms and gave some practical examples on how to use the different fields.

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.

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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 here. The page is updated with new links as more guidance is developed and published.

In terms of guidance and manuals, you will find:

- How to prepare registration and PPORD dossiers (*Annex 8*) [PDF] [EN]
    - 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).

2. REGISTRATION OBLIGATION

2.1. When do the nanoforms have to be registered?

By 1 January 2020, when the Commission Regulation (EU) 2018/1881 of 3 December 2018 enters into application.

2.2. I am manufacturing both bulk and nanoform of a substance. What determines the tonnage band for the hazard data?

The REACH Regulation states that the tonnage is applicable per registrant per substance, including bulk and nanoforms. It is therefore the quantity of the substance, cumulating the quantity of the bulk and nanoforms, that determines the applicable information requirements.

2.3. Is it necessary to register nanoforms produced in less than 1 tonne per year?

It depends on the total yearly tonnage of the substance that you manufacture or import. If the total amount of the substance, including all the bulk and nanoforms, is less than 1 tonne per year, you do not need to register the substance. However, if the overall volume of the substance is above 1 tonne per year, also nanoforms within that total volume need to be registered even if they represent a volume of less than 1 tonne per year.

2.4. In case an active registration in the tonnage band from 100-1000 tonnes per year also includes a nanoform which is only produced below 1 tonne per year, do I also have to consider/assess (eco-)toxicological data for this nanoform?

Yes. Information on hazard and risk from all nanoforms covered by the registration must be submitted in the dossier of the substance. The applicable information requirements (Annexes VII to X) must be determined according to the overall yearly tonnage of the substance, including bulk and nanoforms. Refer to section 2.1 of the Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification.

2.5. We joined a joint submission for 10-100 tonnes per year, but we registered our nanoform as an opt-out at Annex VII. Can you confirm that the information requirements for our nano-registration correspond to Annex VII, not Annex VIII which is the highest tonnage band for the substance in the joint submission?

The tonnage and corresponding REACH Annex is applicable per registrant per substance, including bulk and nanoforms. You are expected to cover the information requirements for the volume of the substance that you manufacture or import in your opt-out dossier.

2.6. If an EU legal entity imports a nanoform and then modifies it's surface, how should they calculate their total tonnage to identify registration requirements?

The total tonnage for nanoforms of a substance is calculated based on the overall volume of the substance as such, irrespective of surface modification.

2.7. Will the registration number remain the same if there is both a nanoform and non-nanoform reported in the dossier?

Yes, it will remain the same.

2.8. Do nanomaterial manufacturers have to register all nanomaterials or only potentially harmful materials?

They must register all substances, including bulk and nanoforms, which they manufacture or import in quantities above 1 tonne per year. This applies regardless of the hazard profile.

2.9. One of our mixtures contains 10% (w/w) of nanomaterials. We sell more than 10 tons per year of that mixture. Since the mixture contains < 50% nanos we do not have to register. Is this correct?

If you manufacture or import a nanoform in quantity above 1 tonne per year, you must register it, even if it is then mixed with other substances in a mixture. However, if you buy a nanoform in the EU, then you do not have to register it, but the manufacturer or importer in the supply chain must do so. In the latter case, you have to ensure that your use of the nanoform is covered by its registration.

2.10. Is it correct that nanomaterials only need to be registered when they are manufactured as solid forms and there is no REACH registration needed for nanoforms produced in a second step and in dispersion?

No. Nanomaterials under REACH should be registered regardless of whether they are manufactured as a solid powder or as a dispersion.

2.11. Is it possible that a polymer is a nanoform? Does it remain exempt from registration?

Yes, a polymer can also exist in nanoform.

The obligation to report nanoforms set out in Annexes VI to X only apply to substances subject to registration. Polymers are exempt from registration. However, for specific cases we recommend contacting our helpdesk for a more detailed reply.

2.12. If a nanoform is introduced during polymerisation phase, do we have to register it knowing that the nanoform is present in the final polymer without emission?

Before being introduced during the polymerisation phase, the nanoform has to be manufactured or imported. If you manufacture or import the nanoform in a quantity above 1 tonne per year, you must register it, even if it is then part of the manufacturing of a polymer. However, if you buy a nanoform in the EU, then you do not have to register it, but the manufacturer or importer in the supply chain must do so. In the latter case, you have to ensure that your use of the nanoform is covered by its registration.

2.13. Does the registration obligation for nanomaterials concern the production of intermediates? We produce an active pharmaceutical ingredient which has a nanodimension, but in the last step it is granulated to the microdimension.

A nanoform is an intermediate if it is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. Transformation into another substance implies a modification of the chemical element and its compound constituting the intermediate. However, "*granulating a nanoform to the microdimension*" does not transform

the nanoform into another substance, as long as it does not imply a modification of the composition of the nanoform. Therefore, this operation would not qualify as an intermediate use.

2.14. If a material unintendedly falls into the nano-definition, but is very well soluble and thus environmental fate, ecotoxicity and toxicity (apart from specific respiration parameters) will be due to the dissolved state - do reduced requirements apply?

The obligation to register the substance and report its nanoforms applies to all nanoforms meeting the definition set out in REACH. This obligation applies irrespective of whether the manufacturer intended to manufacture a nanoform. The nanoform must be subject to all the information requirements applicable to the tonnage of the substance. However, if the nanomaterial is soluble it may not fulfil Annex III criteria and may have some reduced requirements if the tonnage is below 10 tonnes (see REACH Article 12). Depending on your situation, it may also be easier for you to justify read-across from data on the bulk form.

2.15. Does the registration of nanomaterials concern only those that are intentionally produced?

The obligation to register the substance and report its nanoforms applies to all nanoforms meeting the definition set out in REACH. This obligation applies irrespective of whether the manufacturer intended to manufacture a nanoform. Substance manufacturers are responsible for characterising their substance. If the substance contains nanoforms, then these must be reported.

2.16. When a substance is within the recently published nanomaterials list on ECHA's website, does the manufacturer need to demonstrate that the substance is not used in nanoform, and provide characterisation data?

A substance can exist as both a nanoform and a non-nanoform, or 'bulk form'. It is possible that some registrants manufacture only the bulk form of such a substance. There is no obligation for a registrant to prove in their registration dossier that they do not manufacture a substance in the nanoform. However, it is expected that each registrant carries out sufficient characterisation of their substance to know whether it exists in nanoform.

2.17. If we act as downstream users of nanomaterials, e.g. making formulations, lacquers etc., do we have to register the used nanomaterials also?

If you buy a nanoform in the EU and use it without modification, you do not have to register it. However, the manufacturer or importer in your supply chain must have registered it. As a downstream user, you must ensure that your use of the nanoform is covered by its registration or prepare a chemical safety report yourself.

2.18. If you buy a nanoform in the EU and use it without modification, you do not have to register it. However, the manufacturer or importer in your supply chain must register it. As a downstream user, you must ensure that your use of the nanoform is covered by its registration or prepare a chemical safety report yourself. When EU distributors sell a substance in the nanoform under their own trademark, can they have the registration done by their substance provider?

It depends on the location of the provider/supplier of the substance. The registration obligation applies to manufacturers and importers of substances in the EU. If the supplier of the substance is based in the EU, they must register the nanoform. If the EU distributor imports the nanoform from a supplier outside the EU, they must register.

3. DEFINITION OF A NANOFORM

3.1. What is a definition of a nanoform?

Refer to the updated REACH Annex VI text and to the Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification.

3.2. What is the impact of the revision of the European Commission's nanomaterial definition on the definition of nanoform under REACH?

The revision of the European Commission's nanomaterials definition does not impact the current definition of a nanoform used in REACH.

REACH Annex VI contains a definition for a nanoform and this definition must apply to determine the requirements applicable under REACH.

3.3. What is understood as batch-to-batch variability when a nanoform is defined?

A batch-to-batch variability results from the variation of process parameters inherent to a manufacturing process that is defined by a series of parameters (e.g. starting materials, solvents, temperature, order of manufacturing steps, etc.).

If the variation in a parameter is only due to batch-to-batch variability, then these are the same nanoform. However, if there are deliberate changes to the process parameters, then these are different nanoforms.

3.4. Can two nanoforms with very similar characterisers but from two different manufacturing processes be reported as one nanoform?

As different manufacturing processes may result in almost identical characterisers, these different nanoforms can be registered as part of a set of similar nanoforms, provided that explicit conditions are met:

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.

The justification must be supported by data.

3.5. When would a form of a substance become a new substance? E.g. based on surface modifications? What about allotropes?

A nanoform is a form of a substance. Surface modification of nanoparticles does not make it a new substance.

4. SET OF SIMILAR NANOFORMS

4.1. Is there a specific set of hazard data (tox/ecotox) requested to justify a set of nanoforms?

The set of nanoforms must be based on a justification demonstrating that a variation of the characterizers of the nanoforms in the set does not affect the hazard assessment, exposure assessment and risk assessment. The justification must apply generically to all the applicable information requirements. It must always be accompanied by the data supporting it.

4.2. Is dustiness to be considered when creating a set of nanoforms?

When a set is created, all the information provided according to Annex VII-XI must be considered. The submitted information must be representative for each nanoform covered within the set. This includes information according to the new nano specific endpoints like Annex VII point 7.14 bis Dustiness.

4.3. Must information on dustiness be provided for each identified nanoform or for boundary candidates of a set of similar nanoforms? Reasons for including a nanoform in a set is driven by commonality in toxicity response.

The reason to include a nanoform in a set is risk assessment driven, not only toxicity is considered. This is explicit in Annex VI of REACH.

You can provide information on dustiness for the set of nanoforms if the results are applicable to all the covered nanoforms. If results differ significantly you must split the set or assign the higher dustiness level from the forms in your set.

4.4. Is there a quantitative definition of "similar"?

ECHA Guidance on nanoforms defines that for a nanoform, the characterisation parameters can have batch-to-batch variability. If the variation goes beyond batch-to-batch variability, a different nanoform is created. In principle each nanoform must be reported separately. 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.

4.5. What is your evidence that different nanoforms or sets of nanoforms of the same substance have different hazardous properties?

They may have different properties. According to the REACH regulation, *nanoforms may have specific toxicological profiles and exposure patterns and may therefore require specific risk assessment and adequate sets of risk management measures*. The legislation therefore places the responsibility on the registrant. If a registrant concludes that he can assess several forms of the same substance together, evidence in the form of a justification must be provided.

4.6. In their individual dossier, does a registrant have to provide a justification for their individual set of similar nanoforms in addition to the sets defined at the level of the joint submission?

When the registrant relies on the jointly submitted hazard dataset, the justification must be agreed at the joint submission level and each registrant must submit the same justification.

4.7. Most products have a distribution of size/shape. Is there guidance on how boundaries of sets should be set up for this situation as there is likely to be a lot of overlap?

You can find information on this topic in section 4.1.1. of the Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification. The smallest *d10* and largest *d90* value defines the boundaries for the set. In addition, under REACH a "*nanoform can only belong to one set of similar nanoforms*".

5. PARTICLE SIZE DISTRIBUTION

5.1. What is the definition of a constituent particle and what is the difference between constituent and primary particle?

Refer to Section 2.7 in the Joint Research Centre's (JRC) report An overview of concepts and terms used in the European Commission's definition of nanomaterial.

5.2. Under "Particle size distribution and range", can I provide primary particle size as size distribution?

You must provide the number-based particle size distribution and number fraction of the constituent particles.

5.3. Why do percentile values (d10, d50 and d90) need to be reported?

They provide information on the particle size distribution and they are used to set the boundaries for a set of similar nanoforms. For more information, refer to sections 3.1.1 and 4.1.1 of the Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification.

5.4. Which method should be used for measurement of particle size distribution?

You are free to choose the measurement method if the data requirement is fulfilled. We recommend using at least one electron microscopy technique.

5.5. Is there an upper size limit for particles to be considered when the number fraction of constituent particles is determined?

No. All the measured particles must be taken into consideration when the number fraction of constituent particles is determined.

5.6. What particle size dependent threshold effects?

Particle size dependent threshold effect may be related to quantum confinement or to other properties affecting hazard, such as rigidity.

5.7. When nanoparticles are manufactured as agglomerates in micron size, do we need to characterise agglomerates and/or constituent particles?

The requirement in REACH Annex VI is to report number-based particle size distribution with indication of the number fraction of constituent particles in the size range 1-100 nm. This information is reported in sections 1.2 and 1.4 of IUCLID. Information on agglomerates can be reported in IUCLID section 4.28.1 Nanomaterial agglomeration/aggregation or 4.5 Particle size distribution (Granulometry), depending on the nature of the information. These sections are by default included in a registration dossier of an individual or lead registrant; for joint submission member registrant dossiers they can be submitted via the opt-out approach.

5.8. Are laser diffraction-based methods accepted for particle size distribution measurement?

The legal requirement under REACH Annex VI is to report number-based particle size distribution with indication of the number fraction of constituent particles in the size range 1-100 nm. If laser diffraction can provide that information, it can be used. In many cases, that may not be the case.

5.9. We have several different grades of our substance with various particle sizes. If we use a standard particle size technique such as laser diffraction, how do we conclude whether we are seeing constituent particles or agglomerates?

Measurement of particle size is a complicated subject that requires a more detailed explanation. Briefly, a technique like laser diffraction is likely to provide information on aggregate or agglomerate size, rather than constituent particle size. It is likely that one technique alone is not enough for examining all substances. You can consult the Joint Research Centre's (JRC) report: Identification of nanomaterials through measurements.

The NanoDefine project also has an e-tool that can help you.

5.10. If the nano-dimension is less than 1 nm (e.g. 0.8 nm), do we consider such particles as nanoparticles?

REACH does not have a definition for a nanoparticle. In the context of REACH, a form of a substance is a nanoform if 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.

5.11. Below 10 nm structure is size dependent - quantum confined chemistry. How can this be addressed?

In case the particle size distribution is such that threshold effects such as quantum confinement effects are relevant, nanoforms containing particles with sizes at ranges below the threshold should be considered as separate nanoforms or sets of nanoforms.

6. SHAPE INCLUDING ASPECT RATIO AND ASSEMBLY STRUCTURE

6.1. What is an assembly structure?

Examples of assembly structures are those found in high aspect ratio nanoparticles with hollow structures such as nanotubes, or nano-onion spherical particles with concentric multiple shell structure, as described in ISO/TS 80004-2.

Other examples include graphene-based materials that consist of multi, rather than monolayers.

6.2. Do I need to report aspect ratio for spheroidal particles?

No, aspect ratio must be reported only for elongated particles and platelets.

6.3. What is understood as rigidity of a particle?

Rigidity, in this context, is the ability of an elongated particle or platelet to retain its shape, without damage, when subject to mechanical (bending) forces.

6.4. Do I need to report the rigidity of elongated particles or platelets?

The reporting of rigidity is a recommendation. It must be reported if it is a part of the justification for the set of similar nanoforms.

6.5. How do I measure the rigidity of the particles?

There is currently no agreed measurement method for "rigidity". An indication of the rigidity of particles can be provided e.g. based on electron microscopy images (e.g. coiled/tangled vs. straight particles), based on the particle width and length, number of walls (for particles with an assembly structure), etc.

6.6. How do you recommend that companies analyse potential nanoforms which are formed in-situ in a mixture and for which the size of constituent particles is not clear?

The manufacturer must make a judgment call based on the best information they have e.g. test samples. If they consider that the component of the mixture is not a nanoform, they must be able to demonstrate it to enforcement authorities, if required. They are encouraged to keep record of the information supporting their position.

6.7. The manufacturer must make a judgment based on the best information they have, for example test samples. If they consider that the component of the mixture is not a nanoform, they must be able to demonstrate it to enforcement authorities. They are encouraged to keep record of the information supporting their position.How do I quantify the concentration of different shapes present in my nanoform? Do you mean concentration by weight or the number fraction of particles with that shape?

That should be done based on representative electron microscopy images. An indicative percentage based on your images is enough.

6.8. What is the minimum concentration of certain shape that needs to be reported?

The minimum concentration cannot be defined but in principle all different shapes that can be quantified shall be reported.

6.9. How is elongated defined?

Elongated particles are particles with two similar external dimensions and a significantly larger third dimension (aspect ratio larger than or equal to 3:1) e.g. tubes, rods, wires, etc.

6.10. It was said that for particle size, several forms can be together in a set provided there is no known threshold. However, it is also said that different external dimension in chapter "Shape" should not be in the same set. What does "external dimensions" mean?

In the context of particle size distribution, external dimensions are those detailed in the Joint Research Centre's (JRC) report: An overview of concepts and terms used in the European Commission's definition of nanomaterial .

The external dimensions of the elongated particles are width and length and those of the platelets are the thickness and the two dimensions orthogonal to the thickness.

7. SURFACE FUNCTIONALISATION / TREATMENT

7.1. How do I measure the amount of coverage of the particles' surface?

The coverage does not necessarily have to be measured but the indication of the coverage can be based on knowledge of the type of reaction/amount of starting materials used, purification

steps, etc.

7.2. Is it necessary to provide actual data for the coverage of the particles' surface or can I provide theoretical data?

Information on percentage coverage should refer to experimental data when possible. If not possible, calculated data may be used.

7.3. How is surface modification defined? Does addition of surfactants to give a stable suspension create a new nanoform? If so, does suspension in a solvent system cause a new nanoform as there will be solvent molecules associated with the surface?

Surface functionalisation or treatment can be defined as a reaction between the functional groups on the surface of a particle and a substance called surface treating agent. The surface of particles can be modified by single or multiple surface treatments and the treatment(s) can fully or partially cover the surface of the particles. Under this definition, the use of surfactants that do not involve a reaction are not surface treatment.

8. SPECIFIC SURFACE AREA (SSA)

8.1. To what extent does surface area measurement need to be reported?

You should report the specific surface area of the nanoform either by weight, volume, or both, with a description of the method. In case you report volume specific surface area, Brunauer-Emmett-Teller (BET) should be used. BET is used to get the gas adsorption isotherm for measuring (specific) surface area. You should also report the skeletal density of the particles.

8.2. What is the definition of skeletal density and BET?

Skeletal density is obtained when the volume measurement excludes measurement of void space between particles, and pore space within a particle. Skeletal density is usually measured using gas pycnometry (e.g. using ISO standard ISO 12154:2014).

BET is an abbreviation of Brunauer-Emmett-Teller (BET), which is used to get the gas adsorption isotherm for measurement of (specific) surface area.

9. REPORTING AND SUBMISSION

9.1. When does the completeness check on nanomaterial information start to apply?

The completeness check of information requirements for nanomaterials applies as of the IUCLID 6.4 release, i.e. for registration dossiers submitted from 1 November 2019 onwards.

9.2. If I already submitted my registration dossier indicating that I cover the substance in the nanoform before IUCLID 6.4, do I need to submit an update?

Yes, you will need to submit an update of your registration. Only IUCLID version 6.4 contains the formats and validation rules to ensure that you have provided the information required by the revised REACH Annexes for nanoforms, such as the characterisers specified by Annex VI and the Annex VII requirement on Dustiness.

If you rely on information provided in the joint registration to cover the information requirements applicable to your nanoform, you must justify why this information is adequate for assessing the nanoform. Otherwise, you must submit the information relevant to cover the information requirements applicable to your nanoform separately.

9.3. Where and how do I report the agglomeration of nanoparticles in IUCLID?

The requirement in REACH Annex VI is to report number-based particle size distribution with indication of the number fraction of constituent particles in the size range 1-100 nm. This information is reported in sections 1.2 and 1.4 of IUCLID.

Information on agglomerates can be reported in IUCLID section 4.28.1 Nanomaterial agglomeration/aggregation or 4.5 Particle size distribution (Granulometry), depending on the type of information.

These sections are by default included in a registration dossier of an individual or lead registrant. For joint submission member registrant dossiers, they can be submitted via the opt-out approach.

9.4. In IUCLID section 1.2: composition, I need to report different percentiles (d10, d50 and d90) for particle size distribution and range. How should this be done for a set of nanoforms? For example, do I report one mean value of D10 which includes all the nanoforms of the set, or do I have to specify these values for each nanoform of the set?

These values provide information on the particle size and distribution and they are used to define the boundaries for a set. In this case, the values must be reported as a range. The ranges should reflect the smallest and largest value of the nanoforms that are part of the set.

To support the values reported in section 1.2, you will need to provide analytical data in section 1.4 on the particle size distribution of the nanoforms included in the set with the smallest and largest d10, d50, and d90 values.

9.5. Should information on granulometry (IUCLID section 4.5) and dustiness (4.28.8) be reported by all registrants or only the lead registrant?

These tests are part of Annex VII information requirements, which are foreseen to be jointly submitted via the lead registrant dossier. If member registrants reliy on the joint information provided by the lead, they do not need to provide this information in their own dossier. However, if the member does not rely on the jointly submitted data for this endpoint, they must submit the granulometry/dustiness information in their dossier via the opt-out route. Opting out of jointly submitted information must always be accompanied by a justification that

falls under the reasons given in REACH Article 11(3) or 19(2).

9.6. Is completeness check going to focus only on the nano substance characterisation and dustiness endpoints? What about the (eco)toxicological information?

Completeness check verifies the content of the entire registration dossier. The IUCLID format was recently adapted to support the reporting of the revised Annex VI requirements for substances covering nanoforms. New completeness check rules were also put in place to verify these formats.

The remaining parts of a registration dossier for a nanoform substance, including the (eco)toxicological information, also undergoes the completeness check when submitted to us. Here, the main change in the completeness check has been its extension to verify that IUCLID section 4.28.8 – Nanomaterial dustiness is included in a dossier covering substances in the nanoform. This applies to all dossiers where Annex VII-XI information requirements are reported.

The completeness check also verifies that data waiving justifications for substances in the nanoform are in line with the amended REACH provisions.

You must also provide a complete dossier with regard to the properties of the substance. To do so, you can either rely on information provided in the joint registration to cover the information requirements applicable to your nanoform. In this case, you must also justify why this information is adequate for assessing the nanoform. Otherwise, you must submit the information relevant to cover the information requirements applicable to your nanoform separately.

9.7. What if manual completeness check fails due to an incomplete justification for the set of nanoforms?

In this case, we will inform you of the failure and set a deadline of 4 months for you to provide the missing information.

9.8. Do I need to report each nanoform separately?

In principle each nanoform has to be reported separately. 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. The justification must be supported by data.

9.9. If my company imports a powder with a specific nanoform and then modifies it with a surface treatment, can I register the two different forms by submitting a single dossier? Will I get two different registration numbers?

All the nanoforms of the same substance must be covered by one single registration. This means that you will have a single registration number for such a dossier.

9.10. Do registrants need to characterise and report each nanoform within a set of nanoforms, or is the justification for grouping sufficient?

To be able to build the set(s) of nanoforms, you may need to characterise the individual nanoforms in order to be able to allocate them in the appropriate set and provide an adequate justification.

If nanoforms are included in a set of nanoforms, you are not expected to report information on the characterisation of all the nanoforms in the set. Instead, when reporting a set of similar nanoforms, you must clearly report the boundaries of the set for each of the characterisers and provide a justification for the set per characteriser.

10. JOINT SUBMISSION

10.1. Should all nanoforms or sets of nanoforms of the same substance be part of the same joint submission?

10.2. According to REACH, the information on the properties of the same substance, including nanoforms, must be submitted first by a lead registrant acting on behalf of the other assenting registrant. However, if a registrant relies on information provided in the joint registration to cover the information requirements applicable to their nanoform, they must nevertheless justify why this information is adequate for assessing their nanoform. Alternatively, the registrant must submit the information relevant to cover the information requirements applicable to their nanoform separately.We are the lead registrant for a substance, some of which may be present in nanoform for the co-registrants. Should we do the dossier submissions individually or in the shared data part of the registration dossier?

According to REACH, information on the properties of the same substance, including nanoforms, must be submitted first by a lead registrant acting on behalf of the other assenting registrant. However, a registrant may decide to submit this information separately, if one of the conditions set out in Article 11(3) is met.

Therefore, you first need to agree with all the joint submission participants on the coverage of the joint registration dossier in relation to all the nanoforms of the substance. The decision on the coverage of the joint registration does not lie with the lead registrant only as they can act only on behalf of the assenting registrants.

If the outcome of the discussion is that the joint registration dossier will cover nanoforms, you need to set up a mechanism to share information among co-registrants on the nanoforms to be covered by the joint data. Refer to the Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification for more information.

When nanoforms or sets of nanoforms are covered by the joint registration dossier, the information outlined in REACH Article 11(1) must be submitted in the joint dossier. In this case, the dossier must also justify for each information requirement why the data submitted is adequate for assessing the hazard of each nanoform (see ECHA Guidance on Read Across for

nanoforms). More than one dataset may be required for one or more information requirements whenever there are significant differences in the properties. The joint dossier should also describe the boundaries of the nanoforms or sets of nanoforms that are covered by jointly submitted data corresponding to REACH Annexes VII-XI.

If the decision is that the joint registration dossier will not cover any or some of the nanoforms of the substance, the co-registrants of these nanoforms can submit the information via the opt-out route that is foreseen under REACH Article 11(3). In this case, the concerned registrants must submit the hazard information required for each nanoform separately.

Independently of whether the joint registration dossier covers nanoforms of the substance, each registrant is responsible for submitting in their own dossier information on the characterisation of the nanoforms or sets of nanoforms that they manufacture or import, as laid out in Annex VI of REACH.

Another general principle is that for each nanoform or set of nanoforms there must be a complete dataset of information corresponding to REACH Annexes VII-XI, as determined by the registration tonnage. Depending on the registration approach, this information is submitted either in the joint registration dossier, or separately by co-registrants, when using the opt-out mechanism. Data on the properties of the substance can also be submitted jointly by the lead registrant, while the justification for why that data is adequate for assessing the hazard of the nanoforms is submitted individually by each registrant for their respective nanoform.

10.3. We are part of an existing joint submission for a substance that has been registered in the bulk form. The lead registrant is not intending to cover nanoforms in the joint dossier, but our substance exists in the nanoform and we need to reflect this in our registration. How can we meet the requirement to register our nanoforms?

You must discuss with the joint submission participants the coverage of the joint registration dossier in relation to the nanoforms of the substance. If the decision is that the joint registration dossier will not cover your nanoform, you must submit the information via the opt-out route that is foreseen under REACH Article 11(3). In this case, you must submit separately the information on the characterisation of the nanoform in accordance with Annex VI of REACH and the hazard information required under Annexes VII to X, as applicable. You can also submit summaries of studies that are specific to your nanoform, or summaries of studies that are performed on other forms of the substance, including summaries of studies submitted jointly. In this case, you must also provide a justification for why that data is adequate for assessing the hazard of your nanoform for each information requirement (see ECHA Guidance on read across for nanoforms).

For reporting opt-out information, refer to the manual on How to prepare registration and PPORD dossiers.

10.4. Will there be any update regarding the data sharing regulation with respect to the complexity of nanomaterials? How to share costs of a joint submission with several nanoforms included?

Under REACH, the data sharing obligation applies to the registrant of a substance irrespective of its form, whether bulk or nanoform. The data sharing rules should therefore apply normally to all the registrants of bulk form or nanoforms of the same substance. The European Commission is the competent authority for developing and adopting REACH implementing regulations. ECHA is not aware of any discussion in the Commission on this subject.

10.5. For existing joint submissions, how can the use/ownership of specific endpoint data on nanoforms added in a dossier update, be limited to co-registrants sharing the cost of these specific data once the joint dossier is updated by the lead registrant?

When nanoforms or sets of nanoforms are covered by the joint registration dossier, the hazard information is submitted in the joint dossier by the lead registrant. More than one dataset may be required for one or more information requirements whenever there are significant differences in the properties.

The dossier must also justify for each information requirement why the data submitted is adequate for assessing the hazard of each nanoform (see ECHA Guidance on Read Across for nanoforms).

However, the lead registrant is not compelled to submit a justification to cover the nanoform of registrants that would not contribute to the cost of the data or the justification. In this case, the nanoform of the concerned registrant could not rely on that hazard data.

10.6. Alternatively, joint registrants may also agree to submit jointly by the lead registrant the hazard data, while the justification why that data is adequate for assessing the hazard of a nanoform would be submitted individually by each registrant for their respective nanoform. A commonly developed justification may be provided only to those registrants that have contributed to the cost. The nanoform of the registrant without justification could not rely on that hazard data.Information on surface treating agents and process to apply the treatment is confidential business information. Does it need to be shared with co-registrants in the joint submission?

Confidential business information does not need be shared between the co-registrants. Each legal entity needs to specify the surface treating agents they have used and to describe the process they have applied for the surface treatment.

If the justification for the sets of nanoforms is developed between the co-registrants, some information on the surface treatment must be shared to enable the reporting of clear boundaries of the set and to be able to develop the justification that apply to all surface treated nanoforms. This can be done e.g. via an independent third party (‘trustee’).

10.7. Setting up a joint submission including different sets that the lead registrant does not register would imply disclosure of company specific confidential business information to set up the boundary composition? How should this be realised?

See previous reply. You may consider using an independent third party ('trustee') to establish the necessary boundaries for the boundary compositions. We encourage you to reach out to your industry association for more information on this.

11. ANNEX VII-XI INFORMATION REQUIREMENTS

11.1. In terms of additional data requirements for nanoforms, so far I have understood that we have to address skeletal density and 'dustiness'. Are there any other additional testing requirements?

Annex VI specifies several characterisation requirements for substances covering nanoforms. These include surface functionalisation or treatment, particle size distribution, shape, aspect ratio and surface area, as well as the analytical methods corresponding to this information. Skeletal density may be needed if the surface area has been defined based on volume. The revised Annexes VII-XI contain a number of amendments and additional considerations for substances in nanoform. The main additional information requirement that concerns all registrations at Annex VII and above for substances in the nanoform is dustiness. However, registrants must ensure that the dossier also contains data on their specific nanoform for all information requirements or a read across justification if they rely on data on another form.

When hazard information is submitted jointly for a dossier covering several forms of the same substance (bulk and nanoforms), the dossier must also justify for each information requirement why the data submitted is adequate for assessing the hazard of each nanoform (see ECHA Guidance on Read Across for nanoforms).

More than one dataset may be required for one or more information requirements whenever there are significant differences in properties.

When a registrant decides to report a nanoform individually under Article 11(3), they must separately submit the hazard information required under Annexes VII to X, as applicable. In that respect they can either submit summaries of studies that are specific to their nanoform for each information requirement, or summaries of studies that are performed on other forms of the substance, including summaries of studies submitted jointly. In this case, they must also provide a justification as to why that data is adequate for assessing the hazard of their nanoform for each information requirement (see ECHA Guidance on read across for nanoforms).

11.2. Please explain the term "dustiness". Is this about particle size distribution, or something more specific?

Size distribution and dustiness are different data requirements. Dustiness may be defined as the propensity of a powder to form airborne dust. Dustiness testing is typically intended to replicate mechanisms of dust generation encountered in workplaces.

11.3. Do we need to report dustiness when the product/nanoform is manufactured as well as supplied in a water dispersion only?

According to column 2, Annex VII, 7.14.bis: The study does not need to be conducted if exposure to granular form of the substance during its life-cycle can be excluded.

11.4. Will ECHA do compliance checks on nano registrations early in 2020?

Nanoforms will be identified and prioritised for compliance check according to the same criteria as any other substance. Therefore, we will start evaluating those substances where a concern has been previously identified. In practice this means those substances in the nanoform that have been listed on the Community Rolling Action Plan (CoRAP).

11.5. Is the compliance check going to focus only on the nano substance characterisation and dustiness endpoints? What about the (eco)toxicological information?

If a compliance check is opened on a nano dossier, it can cover the entire dossier and not only characterisation and dustiness.

11.6. Should registrants wait for ECHA's feedback concerning the generation of new toxicological information or should they start with the generation of new data without delay?

To comply with REACH Annex IX and X requirements, in the absence of existing studies or adaptation possibilities under Annex XI, testing proposals for each form of the substance need to be submitted before testing can start. For information requirements outlined in REACH Annexes VII and VIII, data generation should start without delay, unless existing information or adaptation possibilities can be used.

Where nanoforms are registered as part of a set of similar nanoforms, testing should be performed/proposed on the nanoform(s) that cover the boundaries of the set.

12. CHEMICAL SAFETY ASSESSMENT AND SUPPLY CHAIN COMMUNICATION

12.1. How should the nanoforms or sets of nanoforms be addressed in the chemical safety report?

Chemical safety assessment must include all the nanoforms and sets of nanoforms covered by the registration.

12.2. What is expected to be assessed for a mixture containing nanoforms?

The nanoforms in the mixture must be assessed (if required by art.14)

12.3. What information must be forwarded in the supply chain for nanomaterials, i.e. included in the safety data sheets? In which section of the SDS should information on nanoforms be mentioned?

Same as for other substances. Note that the assessment and exposure scenarios need to cover all the nanoforms covered by the registration. The exposure scenario must reflect what nanoforms/sets are covered.

13. INQUIRY

13.1. What happens with an inquiry dossier as particulate/powder for obvious nanomaterial (e.g. carbon nano tubes) after January 2020?

We will handle it as any other inquiry dossier. You need to report the characterisation parameters for nanoform or set of similar nanoforms.

13.2. When reporting a set of nanoforms in IUCLID section 1.2, do we need to support the justification with cross-references to the relevant endpoints in sections 4 – 7?

In the inquiry step you must provide a justification, based on the text template available in the field 'Justification for reporting set of similar nanoforms' and address all relevant points. However, at this stage there is no possibility to link the provided justification with other information in the inquiry dossier as the endpoint study sections are not submitted for the purpose of inquiry.

Once you prepare your registration dossier, you are advised to use the 'Cross-reference' field and link the justification to any endpoint information that supports it. Information provided in the justification field of the registration dossier will be manually checked by us.

14. CHALLENGES

14.1. What is your advice if we are unable to meet all the information requirements related to the nanoform of the substance by the deadline of 1 January 2020?

We are aware of the challenging timeline. However, the legal deadline is to be respected. Therefore, we encourage you to register or update your existing registration dossier with all relevant and available information by January 2020. You can update your dossier at a later stage if new information becomes available to you that is relevant to the registration of your nanoform.

If you have any more specific or substance related questions, we are ready to help you via our regulatory advice service.

14.2. We have difficulties in finding suitable laboratories to support us with the analysis we need to be able to submit by 1 January 2020.

We are aware of the challenging timeline. However, the legal deadline is to be respected. Therefore, we encourage you to register or update your existing registration dossier with all relevant and available information by January 2020.

There is ECHA guidance available as well as existing test guidelines, standards and other internationally recognised methods that can be used to fulfil information requirements.

14.3. Due to the lack of guidance and OECD test guidelines, requirements to update the dossier are still not available.

The Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification has recently been published. It gives advice on how to register nanoforms, how to fulfil Annex VI information requirements regarding the characterisation of nanoforms, and how to create and justify sets of nanoforms.

For the information requirements in REACH Annexes VII-XI, we have provided an overview of available methods (test guidelines and other recognised methods/standards) to generate nano-specific data.

We are committed to keep this table updated to ensure that available knowledge relating to applicability of these methods is made available to support you when meeting your registration obligations.

If you have substance-specific questions, contact our regulatory advice service.

14.4. As the test guidelines are not ready, we cannot get quotes from test laboratories. It is therefore not possible to receive applicable data by January 2020. What should we do?

We are aware of the challenges when registrants have ordered tests in a timely manner but do not receive the results in time to complete their dossier. If this applies to your specific situation, provide substantiated evidence of the ongoing or ordered tests.

14.5. What are the consequences of not submitting a registration dossier covering nanoforms by the deadline of 1 January 2020?

Not complying with the legal deadline of January 2020 means an incompliance with the current legal requirement for nanoforms on the EU market. This may result in enforcement actions. If you have valid reasons justifying a delay, we encourage you to keep record of the evidence of your efforts in case of control by the enforcement authorities.