Information on manual verification at completeness check

ECHA performs a completeness check on each incoming registration to ensure that the required information is provided as per Article 20 of the REACH Regulation. The completeness check includes manual verification by ECHA staff. The manual verification is done on certain elements of the registration dossier that cannot be checked automatically, to ascertain that all the information required by the legislation has been included.

ECHA performs a manual verification on both new registrations and updates of existing registrations. The manual verification does not assess the quality of information but ensures that the required data is provided, i.e. the dossier is complete.

The areas of the manual verification are the following:

1. Substance identification
2. Data waiving justifications
3. Testing proposals on vertebrate animals
4. Chemical safety report (CSR)
5. Justification for opting-out
6. Specific requirements for nanoforms

This document contains practical information on each of the manual verification areas and is regularly updated. It is recommended to consult this document whenever preparing a registration dossier. The advice provided in this dossier is limited to the Article 20(2) completeness check of information submitted to ECHA and it is without prejudice to the obligation to submit information that is compliant with the REACH requirements and Guidance.

Before you submit your dossier to ECHA, use the Validation assistant on your substance dataset and if it displays any failures, complete the missing information by following the advice given by the tool. If the Validation assistant does not indicate any failures, it is not an automatic confirmation that your dossier is complete, since the manual verifications done by ECHA staff are not displayed in the Validation assistant report. Therefore, consult this document for the areas indicated above to ensure that also this information is complete. Next, create your dossier and run the Validation assistant on the final dossier to ensure that no failures are reported, before submitting it to ECHA.

Further information


ECHA contact form: [https://echa.europa.eu/contact/reach](https://echa.europa.eu/contact/reach)

1. Substance identification

A clear substance identification is fundamental for registrants to be able to carry out their registration obligations. Each registrant is responsible for ensuring that they register the substance as part of the correct joint submission, and that they provide the correct substance identification information in their registration dossier. It is crucial that the substance identification information is specific to the registrant submitting the dossier. Registrants must not copy or rely on information provided by the lead registrant (such as analytical or compositional information).

- **IUPAC name of the registered substances**
  - The IUPAC name of the substance must be provided in the IUPAC name field of IUCLID section 1.1.
  - If the IUPAC nomenclature cannot be applied, a chemical name of the substance must be provided in the IUPAC name field.
  - Providing text such as “not available” instead of the IUPAC or chemical name is not considered complete.
  - For more information on how to fill in the IUPAC name field for multi-constituent substances and UVCB substances, please consult the Q&A 1197 and Q&A 1196 on the ECHA website, respectively.

- **Composition of well-defined substances**
  - When reporting the composition of well-defined substances, the “80%” and “80-10%” rules should be followed. Details of these rules are explained in chapter 4.2 of the Guidance for identification and naming of substances under REACH and CLP.
  - In principle, the composition of a mono-constituent substance should include one main constituent. The composition of a multi-constituent substance should include more than one constituent. A deviation from these principles is very exceptional and in this case you must include a scientifically fully substantiated justification in the ‘Justification for deviations’ field in IUCLID section 1.2 of each composition where the deviation takes place. Acceptable deviations are specified in the Guidance.
  - Information reported in section 1.2 must be supported by relevant analytical data in section 1.4 Analytical information.

Further advice on reporting

- As a general rule, the compositional information should be completed up to 100%.
- You must report the composition of the substance on its own. Do not report the composition of mixtures. For further information, please consult the Q&A 1200 on the ECHA website.
- The quantity of any solvent that can be removed by any means without affecting the stability or changing the composition of the substance should be removed. Only the remaining quantity of the solvent that cannot be removed contributes to the mass balance of the substance.

- Additives can be only reported if they have the stabilising function on the substance composition and this function must be specified. In principle, the stabiliser does not contribute to the naming of substances but contributes to the mass balance of a substance.

• **Manufacturing process description of UVCB substances**

  - For a UVCB substance, a description of the manufacturing process must be included in the 'Description' field of each legal entity composition in IUCLID section 1.2. Information provided elsewhere in the dossier will not be considered for completeness.

  - The manufacturing process information typically consists of the following elements: identity and ratio of starting materials; a description of the relevant manufacturing steps in the order they occur (including information on the reaction steps/mechanisms); the relevant plant operating parameters applied to control the composition (e.g. temperatures/pressures; solvents; catalysis types...); extraction/isolation steps (if applicable); clean-up/purification steps (if applicable).

  - A text template marked with an ‘A’ is available in IUCLID to facilitate the reporting of the information. This template lists those elements that are necessary to address when describing the manufacturing process description. Do not submit templates “empty”, without including the relevant details of your description: such descriptions will not be considered complete.

  - In case you have information that complements the description of the manufacturing process, for example reaction schemes and process workflows, these must be reported in an attachment in IUCLID section 1.2 in the field 'Attached description/justification'. Information attached elsewhere in the dossier will not be considered for completeness.

  - For your information, the 'Description' field of legal entity compositions is not disseminated on the ECHA website.

**Further advice on reporting**

- Please consult the [Q&A 1199](#), [Q&As 1316 to 1320](#) and [Q&A 1559](#) on the ECHA website.

• **Composition of UVCB substances**

  - The constituents for each reported composition of your UVCB substance must be provided in IUCLID section 1.2: all constituents present at ≥10% and constituents relevant for C&L and/or PBT assessment must be reported individually. Other constituents must be reported as far as possible as groups of constituents according to their chemical nature.
- In very rare cases, if you consider that it is not possible to report constituents or groups of constituents separately, you must include a scientifically fully substantiated justification in the ‘Justification for deviations’ field in IUCLID section 1.2.

- Information reported in section 1.2 must be supported by relevant analytical data in section 1.4 Analytical information.

**Further advice on reporting**

- As a general rule, the compositional information should be completed up to 100%.

- Due to the lack of differentiation between constituents and impurities, the term ‘impurity’ is not relevant for UVCB substances and therefore no impurities should be reported in IUCLID section 1.2.

- Additives can be only reported if they have the stabilising function on the substance composition and this function must be specified. In principle, the stabiliser does not contribute to the naming of substances but contributes to the mass balance of a substance.

- For inorganic substances with variability in molecular formula please consult the Q&A 1496.

- **Analytical information**

  - To fulfil the REACH requirement on the analytical data, you must provide analytical information that enables your substance to be identified, including the compositions specified in section 1.2 of the dossier.

  - Analyses carried out for both identification and quantification purposes must be provided, as identification establishes the chemical identity of the constituents, while quantification is carried out to determine the concentration of the constituents in the composition.

  - To consider your dossier complete in terms of the analytical information, the required analytical reports must be attached in IUCLID section 1.4.

  - In very rare cases, the quantification analysis may not be necessary for verifying the composition required to be reported in your dossier. If your substance belongs to these very rare cases, a justification must be provided for not submitting any quantification in the fields ‘Rationale for no results’ and ‘Justification’. The justification must be scientifically fully substantiated.

**Further information**

For further information consult the supporting documents below on how to provide information on the substance identification under REACH:

[Questions and answers – Substance Identification](#)

[Guidance for identification and naming of substances under REACH and CLP](#)
2. Data waiving justifications

Each registrant is responsible for ensuring that the registration dossier fulfils all the REACH requirements at their tonnage band. Data waiving refers to the omission of an information requirement with a justification that falls within the reasons foresee by REACH.

- For each endpoint study record marked as a Data waiving, select the appropriate rationale for waiving from the picklist, e.g. study technically not feasible when the nature of the substance does not allow it to be tested for that endpoint (Annex XI, section 2).

- A valid and detailed justification for not fulfilling the standard information requirement must be provided in the picklist field Justification for data waiving. The picklist contains standard phrases to justify data waiving, which are endpoint-specific. It is important to keep in mind that the availability of standardised phrases does not mean that a data waiving justification in the picklist is necessarily applicable to your particular case. If a suitable standard phrase is not available, the Justification for data waiving picklist also includes the option other:. When choosing this option, ensure to clearly document the basis for the waiving in accordance with the REACH regulation in the free text field. The main argumentation for the data waiving needs to be included in one of the fields Other, Remark or Justification for type of information of the endpoint study record that is being waived. Information provided elsewhere in the dossier will not be considered for completeness.

- Columns 1 and 2 of the relevant requirement in Annexes VII to X of REACH and sections 2 and 3 of Annex XI of REACH provide the possible reasons why a study would not need to be submitted in the dossier. Only justifications falling within these reasons are considered complete.

  - If you intend to apply waiving based on section 2 of Annex XI of REACH (testing is technically not possible), the omission of testing should be thoroughly justified and the technical limitations explained. The data waiving justification needs to include the test method that has been attempted and the property of the substance that has impeded the testing. This property must be relevant for the endpoint.

  - If you intend to waive based on section 3 of Annex XI of REACH (substance-tailored exposure-driven testing), please note that the omission of testing, based on the exposure scenario(s) developed in the chemical safety report is applicable only to information requirements listed in sections 8.6 and 8.7 of Annex VIII, and in Annex IX and Annex X. Ensure to provide adequate justification and documentation for not fulfilling the standard information requirement(s) in the field Justification for data waiving. The relevant exposure scenario(s) have to be provided in the chemical safety report (CSR) attached in IUCLID section 13.1. Please follow the advice given in chapter 4 of this document for how to report exposure scenario(s).

  - If you intend to waive based on the outcome of the chemical safety assessment following provisions in column 2 of certain information requirements, ensure that a chemical safety assessment has been performed and is included in the chemical safety report (CSR) attached in IUCLID section 13.1.
If your reason for data waiving is substantiated by other documentation, for example an expert opinion that you intend to provide as an attachment, ensure to always include a summary of the rationale of the justification in line with columns 1 and 2 of the relevant endpoint in Annexes VII to X of REACH and sections 2 and 3 of Annex XI of REACH in the field Justification for data waiving. Supporting attachments should be provided in the field Attached justification.

If your reason for data waiving refers to an endpoint study record which provides relevant information that is used as a basis for the data waiving (e.g. study scientifically not necessary / other information available), use the field Cross-reference to link the data waiving endpoint study record to other records in the same IUCLID section, or to other sections that belong to the same dataset. Note that the main argument of your justification must be reported in the field Justification for data waiving of the data waiving endpoint study record even while using the field Cross-reference.

If the data waiving relies on other information (e.g. a test in another section or a classification), in addition to summarising the main argument of your justification in the data waiving endpoint, the supporting information must be included in the appropriate section of the dossier. The presence of such information is manually checked.

Ongoing studies: If you have received an ECHA decision or a draft decision requesting you to carry out a test for this endpoint but the test results are not yet available, in the field Justification for data waiving, select other: and type the following sentence in the free text field: "This information will be submitted later based on ECHA communication/decision number TPE/CCH/SEV-x-xxxxxxxxxx-xx-xx", where you replace the “x”-characters with the decision/communication number issued to you by ECHA. Note that a communication number or decision number following completeness check failure is not a valid number to justify the waiving of an information requirement.

Adaptations according to section 1 of Annex XI (use of existing data, weight of evidence, (Q)SAR, in vitro methods, grouping of substances and read-across approach) that are used to fulfil the information requirement should not be submitted as data waiving, but reported as endpoint study records indicated as ‘key study’ or as ‘weight of evidence’ in the field Adequacy of study.

Testing proposals should not be submitted as data waiving. Please follow the advice given in chapter 3 of this document for how to report a testing proposal.

Specific advice

Data waiving justification for extended one generation reproductive toxicity studies (EOGRTS): please read Q&A 1323 and 1324 on the ECHA website.

Data waiving justification for pre-natal developmental toxicity studies (PNDT): please read Q&A 1437 and 1438, and the newsletter on PNDT tests on the ECHA website.

Data waiving justification based on the Cosmetics Regulation: please read Q&A on cosmetics on the ECHA website.
- Clarity on interface between REACH and the Cosmetics Regulation (27/10/2014) on the ECHA website.
- **COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL** on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics (COM/2013/0135 final).

- Data waiving justification based on plant protection products: please read Questions and answers: [Q&A 0006 and Q&A 1095](#) on the ECHA website.
- **Guidance on registration**: section 2.2.4.2 'Substance for use in plant protection products'.

### Further information

For further information consult the supporting documents below on how to provide information on the information requirements in Annexes VII-XI under REACH:

**Endpoint specific guidance R7a, R7b and R7c**

**Q&As on preparing registration dossiers in IUCLID**

#### 3. Testing proposals on vertebrate animals

Since September 2015, ECHA proactively ensures that registrants have made an effort to consider the potential availability of non-animal testing methods before proposing testing on vertebrate animals ([document here](#)). For this purpose, registrants submitting new testing proposals concerning vertebrate animal tests under Annexes IX and X must provide their considerations for alternative methods in the registration dossier.

- The considerations for alternatives must be provided in the field 'Justification for type of information' for each proposed vertebrate study.

- You are advised to use the text template provided in the field and marked with an ‘A’. This template lists those elements that are necessary to be addressed when documenting your considerations. Do not submit the template “empty”, without including the relevant and comprehensive details of your considerations.

- The considerations will be published under the *Information on Chemicals* section of ECHA's website and will be linked to the Third party consultation page; therefore we advise you not to include any confidential information.

- If you have received an ECHA decision requesting you to carry out a test for an endpoint but the test results are not yet available, you should not report the ongoing study as a testing proposal. Instead it must be submitted as a data waiver with a specific justification text. For further details, see the “Data waiving justifications” section of this document.

- It is important that you indicate whether your testing proposal refers to a test on the registered substance, or on another substance than the registered substance from which you intend to read-across.

  - If the proposed test is to be conducted on a material representative of the substance you are registering in this dossier, you should indicate it as 'experimental study planned' in the field 'Type of information'.
- If you propose to test a substance other than the registered substance and read-across from the result to fulfil the information requirement for the registered substance, you should indicate the 'Type of information' as 'experimental study planned based on read-across'.

- For testing proposals on the registered substance, the full considerations for alternative methods must be provided, whereas for read-across testing proposals, the read-across hypothesis must be given.

**Further information**

For further information consult the supporting documents below on how to provide information on testing proposals under REACH:

**Q&A – Information requirements, test methods and quality of data**

**Testing methods and alternatives**

**4. Chemical safety report (CSR)**

In dossiers submitted from October 2020 onwards, ECHA will manually verify the content of the Chemical safety report (CSR) as part of the completeness check. The content of the CSR is verified against the requirements of REACH Annex I, as follows:

- The CSR must contain an exposure assessment and risk characterisation if the substance is classified as hazardous or indicated as fulfilling the PBT criteria (REACH Article 14(4)).

- Each use reported in IUCLID section 3.5 must have a corresponding exposure scenario in the CSR.

- Each contributing activity reported in IUCLID section 3.5 must have a corresponding contributing scenario in the CSR based on:
  - Environment: Environmental release type (ERC)
  - Workers: Process/activity name (PROC)
  - Consumers: Article type (AC) and/or product type (PC)

- Each contributing scenario must contain:
  - Conditions of use describing the operational conditions and the risk management measures.
  - Exposure estimates for all relevant routes / compartments.
  - Risk characterisation ratio for all individual routes of exposure / compartments.
  - Risk characterisation ratio for combined routes.
  - Environmental contributing scenarios must contain local releases for water, air and soil.

- Humans exposed via environment must be assessed when:
  - The tonnage is above 1000 tpa or,
  - The tonnage is above 100 tpa and the substance is classified as STOT RE 1, carcinogen, mutagen (any category), or toxic to reproduction (categories 1A or 1B).
Specific advice

- **Joint CSR**
  - If a joint CSR if provided by the lead registrant, both the lead and the members have to indicate this in the dossier header. The joint CSR will be checked only when the lead submits a dossier.
  - Members should ensure that all their uses are covered in the joint CSR. If not, members will have to provide their own additional CSR.
  - The lead dossier must contain in section 3.5 of IUCLID all the uses that the joint CSR covers.
  - When a joint CSR exits, registrants are strongly recommended to use the field 'Related assessment' to clarify where their uses are assessed.

- **Own CSR**
  - The CSR is checked separately for each registrant when they submit a dossier.
  - If the registrant relies only on an own CSR, it must cover all uses reported in the dossier.

- **Uses that do not require assessment**
  - Art 17/18 uses do not require a chemical safety assessment.
  - When you report your uses in section 3.5 of IUCLID, indicate the type of each use in the field 'Registration/Notification status for the use'.

- **Substances with different compositions and classifications**
  - If your registration covers multiple compositions with different classifications, make sure to link the composition records with the relevant classification and use records.
  - This is especially important if you have uses that do not require an assessment because they are not classified.

- **Substances with high systemic hazard**
  - For certain high systemic hazards (e.g. Carc., Muta., Resp. sens.), often no quantitative hazard conclusions can be derived.
  - Exposure estimates are still required in the CSR, as they indicate to what extent the handling in a closed system takes place in practice.

- **No CSR attached in section 13.1**
  - If a CSR is required based on the tonnage band but no file is attached in section 13.1, a justification must be provided in line with Article 14(2) of REACH. The justification should explicitly document the conditions of Article 14(2) that the omission of the CSR is based on. A mere reference to Article 14(2) is not considered to be a complete justification.
  - For a substance which is a monomer imported in a polymer and where the monomer concentration during the polymer life cycle is sufficiently low, Article 14(2) may be used to waive the CSR requirement. In this case the justification must contain the following:
    - Identification of the applicable cut-off (threshold) for the monomer based on Art 14(2).
    - Argumentation on whether the monomer can be formed back during the life cycle of the polymer (in use or after use, e.g. during waste treatment).
    - Evidence (laboratory report, confirmation from your supplier or reference to literature) that if there is residual monomer present in the
polymer, the total concentration of the monomer is always below the applicable threshold indicated in Art 14(2).

- The justification should be entered in either of the fields 'Discussion' or 'Further information on the CSR attached / remarks' of the section 13.1 record. Any supporting documents for your justification should be attached in section 13.2 – Other assessment reports.

**Further information**

[Webinar on revised completeness check – CSR part](#)
[Webinar page including questions and answers](#)

### 5. Justification for opting-out

- If opting-out of a joint submission, either fully or partly, a justification must be provided in line with Article 11(3) or 19(2) of the REACH Regulation.

- The justification should be entered in IUCLID section 14 'Information requirements’ under ‘Opt-out information for REACH registration’ in the text field ‘Justification’.

- When preparing the opt-out dossier you should **not** use the REACH-IT online dossier feature as it is not possible to prepare a complete opt-out dossier using this route.

- There are three templates available in the free text field marked with an ‘A’. You can use the templates or enter your justification directly into the text field. The justification you provide must answer all the points of at least one template to be considered complete.

- The questions contained in the templates are also available at Annex VII of the *How to prepare registration and PPORD dossiers* manual. The template questions can be copied to the ‘Justification’ field in section 14 ‘Information requirements’ under ‘Opt-out information for REACH registration’.

- If you are opting-out of different endpoints for different reasons, you should group your IUCLID documents in separate blocks in ‘Opt-out information for REACH requirements’ under ‘Data selected for opt-out’ and then provide a justification for each block.

- If you have received an ECHA decision granting the ‘permission to refer’ to data in the context of a data sharing dispute, you must indicate the corresponding data sharing dispute number in the field ‘Justification’ as follows: “Permission to refer granted by ECHA based on data sharing dispute DSH-XX-X-XXXX-XXXX.” For any additional data submitted separately for which you have not received the ‘permission to refer’, you must provide a justification for submitting that data separately, using at least one of the templates (a, b, c) provided.

**Further information**

[Q&As on Joint submission of data by multiple registrants](#) (see section Joint submission opt-out)
6. Specific requirements for 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 or sets of nanoforms, must be submitted separately by each registrant. This information is reported in IUCLID sections 1.2 Composition and 1.4 Analytical information.

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. In either approach, the link between each nanoform or set of nanoforms and the corresponding set of Annex VII-X data must be clearly reported in the dossier.

If the joint submission relies on the approach to register nanoforms via a set of similar nanoforms, then a member registrant that relies on this set to register their nanoforms cannot opt-out of the Annex VII-X information submitted for the set. If your nanoforms are not covered, for each information requirement, by the Annex VII-X information for the set of nanoforms, then they cannot form part of this set of nanoforms. Consequently, partial opt-outs from Annex VII-X information for sets of nanoforms will not be considered complete.

Below you can find more information and practical advice on reporting in IUCLID that will help you to ensure that the required information is provided.

The Validation assistant will not detect failures related to the information described below, or elsewhere in this document. Please also note that to check the completeness of the Annex VII-X information, the Validation assistant can only detect that all information requirements have been addressed when the dossier is expected to contain one dataset of Annex VII-X data.

When the dossier includes Annex VII-X data for multiple (nano)forms or sets of nanoforms of the substance, the tool cannot detect if each Annex VII-X dataset is complete for each information requirement. It will only reliably display if all endpoint study records indicated as key study or weight of evidence have been filled in with the necessary information for completeness.

It is crucial to carefully check the information provided in a dossier covering nanoforms against the advice in this document before submitting it to ECHA.

Linking of section 1.2 information

- Nanoforms (or sets of nanoforms) that are manufactured or imported by a registrant are reported in IUCLID section 1.2 as ‘legal entity composition of the substance’.

- Nanoforms (or sets of nanoforms), for which there is a set of Annex VII-X data in the same dossier, are reported in IUCLID section 1.2 as ‘boundary composition of the substance’.

Each legal entity composition covering a nanoform (or set of nanoforms) must be explicitly linked to the boundary composition which relates to the relevant Annex VII-
Information. This is crucial, as without a link it will not be possible to establish that the information requirements for the nanoforms or sets of nanoforms reported in the legal entity composition have been fulfilled. The linking is done using the following fields in section 1.2:

- ‘Related composition’: add an electronic link from a legal entity composition to the relevant boundary composition when both are present in the same dossier (individual registration, JS lead; JS member opting out with own Annex VII-X data).

- ‘Reference to related composition(s)’: provide a textual link from legal entity composition to related boundary composition name when boundary composition is in a different dossier (JS member relying on jointly submitted Annex VII-X data).

**Linking of Annex VII-X information**

Whenever the registration dossier contains more than one nanoform, or set of nanoforms; or nanoforms and non-nanoforms of the substance, it is essential that each nanoform or set of nanoforms is linked to the related Annex VII-X information. The linking should be done as follows, for each boundary composition for a nanoform or set of nanoforms:

- Link each boundary compositions for a nanoform or set of nanoforms to an Assessment entity in IUCLID section 1.10;

- Link each Assessment entity to a specific endpoint summary, for all the Annex VII-X information requirements that apply at the tonnage of registration;

- Link each endpoint summary to the relevant endpoint study record(s) for fulfilling the information requirement. To fulfil the information requirement, at least one endpoint study record reported as a key study, weight of evidence, data waiving or testing proposal (Annex IX and X information requirements) must be linked for each information requirement.

See Annex 5 of the manual *How to prepare registration and PPORD dossiers* for more information on the IUCLID Assessment entity.

**Specific advice for reporting Annex VII-X information for nanoforms**

If information on one (nano)form of the substance is used to fulfil the information requirement on another nanoform, and the nanoforms are not part of the same set of nanoforms, then this must to be reported in IUCLID using a read-across approach.

- The read-across approach includes the reporting of a source record which corresponds to the experimental study on the source material, and a target record with the outcome of the read-across approach and the justification for the read-across (see chapter 9.6.3 of the manual *How to prepare registration and PPORD dossiers*).

- If the same read-across justification applies to number of target nanoforms or sets of nanoforms, then it is not necessary to replicate the target record for each of them, as long as the justification applies to and explicitly mentions all (sets of) nanoform(s) it covers. You must still report a separate endpoint summary for each nanoform or set of nanoforms for which Annex VII-X information is submitted. The common read-across target record should then be linked to the endpoint
summaries of the relevant nanoforms or sets of nanoforms.

For endpoints where there are no available data or adaptations that can address the information requirement in an adequate manner and where test guidelines and guidance for nanoforms are still under development, the following approaches can be used:

- **Annex IX and X requirements:** submit a testing proposal and indicate the guideline to be still under development. For testing proposals on vertebrate animals: in addition, see chapter 3 of this document.

- **Annex VII and VIII requirements:** you may report the practical constraints in fulfilling the information requirements in the IUCLID dossier. The approach can only be used for endpoints where it is recognised that existing test guidelines/guidance cannot be applied to nanoforms. ECHA will monitor the use of this approach and expects that the endpoints are updated in accordance with the REACH requirements once the relevant test guideline and guidance are available. To report the practical constraints to fulfil an Annex VII-VIII information requirement where test guideline development for nanoforms is ongoing:
  - Indicate the endpoint study record as a data waiving by selecting in the field ‘Data waiving’ the value ‘other justification’.
  - In the field ‘Justification for data waiving’, select only the value ‘other:’ and in the adjacent text field, type in the following statement: “This information requirement is not addressed until the finalisation of the relevant guidance and/or validated test methods for nanomaterials. Evidence that no other information exists to fulfil this requirement is provided below under ‘Attached justification’. “.
  - In the same endpoint study record, in the field ‘Attached justification’, you must attach the template available on the ECHA nanomaterials page where you have addressed all points. The justification must be specific to the endpoint where it is attached, and to the nanoforms or sets of nanoforms that it states to cover.

If you address an information requirement with data waiving (see chapter 2 of this document), and the same data waiving justification applies to number of nanoforms or sets of nanoforms, then it is not necessary to replicate the data waiving record for each of them, as long as the justification applies to and explicitly mentions all (sets of) nanoform(s) it covers. You must still report a separate endpoint summary for each nanoform or set of nanoforms for which Annex VII-X information is submitted. The common data waiving record should then be linked to the endpoint summaries of the relevant nanoforms or sets of nanoforms.

### Justification for reporting a set of similar nanoforms

- If you report a set of nanoforms, you must 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.

- A separate justification is expected for each set of nanoforms reported in the dossier.

- The justification must be entered in IUCLID section 1.2 in the field ‘Justification for
reporting set of similar nanoforms’ of each composition record that covers a set of nanoforms. The justification must demonstrate that each nanoform of the set can rely on the same Annex VII-X information, for each endpoint.

- To support the reporting of the justification, a text template is available in the field ‘Justification for reporting set of similar nanoforms’. The template can be loaded by selecting the button ‘A’. You must use this template and answer all relevant points as instructed in the template.

- The justification must be supported by scientific data on the nanoforms at the boundaries of the reported set of nanoforms. The data corresponding to the reported parameters must be summarised in the justification in connection with each characteriser and supporting studies can be provided by attaching them in the section 1.2 field ‘Attached information’ and/or by linking relevant record(s) in the dossier via the field ‘Cross-reference’. Alternatively, references to publicly available literature may be provided as long as the information refers to nanoforms that are included in the set of nanoforms, and the relevant information is summarised in the dossier.

- The justification must make explicit how the scientific data demonstrate that all the nanoforms in the set can be assessed jointly. It must refer to key outcomes of the studies used as evidence in the justification, and clearly mention the nanoforms used in these studies as well as their relevance for representing the set of nanoforms.

Further advice on justification for sets of nanoforms

- Each registrant reporting a set of nanoforms must submit in their dossier the justification for the set of nanoforms. If a set of nanoforms has been agreed at the level of the joint submission, the justification should be the same for all registrants relying on the same set, but it must be submitted by each member registrant separately to fulfil the information requirements for the Annex VI data. Providing only references to the information reported in the lead dossier would not be considered as complete.

- The reported boundaries for characterisers in section 1.2 should be derived by describing the smallest/largest values of particle size distribution and specific surface area as well as each different morphology and surface-treatment of the nanoforms included in the set.

Reporting of boundary compositions for nanoforms or sets of nanoforms

- In dossiers where Annex VII-X information is submitted for nanoforms or sets of nanoforms, boundary compositions must be reported that describe the nanoforms or sets of nanoforms that are covered by this information.

- Boundary compositions describing nanoforms or sets of nanoforms must be completed similarly to legal entity compositions for the following information:
  - Under ‘Characterisation of nanoforms’, indicate under ‘Type of information provided’ whether the boundary composition covers a single nanoform or a set of nanoforms and provide the information for all the characterisers of the boundary composition. If the boundary composition covers a single nanoform, you should report the same characterisers for the boundary composition as for the legal entity composition that it covers.
If you define the boundary composition as a set of nanoforms, you must include a justification in the field ‘Justification for reporting set of similar nanoforms’ (see previous chapter).

Further information:

- Annex 8 of the manual How to prepare registration and PPORD dossiers
- Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification
- Webinar on the revised REACH information requirements for nanoforms and related Q&A
- Webinar with practical advice for registering nanoforms
- ECHA nanomaterials page
## Changes to this document

<table>
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| **7.0** | April 2020  
1. Chemical safety report: start of the new completeness checks changed from May 2020 to October 2020  
2. Specific requirements for nanoforms: further clarification added |
| **6.0** | February 2020  
1. Chemical safety report: new advice added to explain the revised completeness check of CSRs  
2. Specific requirements for nanoforms: new advice added to explain how to provide information on nanoform substances  
3. Further editorial changes |
| **5.0** | October 2019  
1. Substance identification: further advice on reporting added  
2. Data waiving justifications: clarification on Annex XI based waiving and advice on specific endpoints and types of justifications added  
3. Justification for opting-out: information on the IUCLID versions that support opting-out added  
4. Justification for reporting a set of similar nanoforms: new area added  
5. New Q&As and links to support material added  
6. Further editorial changes |
| **4.0** | November 2018  
1. Information added on justification for opting-out |
<p>| <strong>3.0</strong> | October 2017  |</p>
<table>
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| 2.0     | February 2017 | 1. Detailed description and advice added for each areas of the manual verification, in particular for areas where recurring issues were discovered during the manual checks  
2. Q&As and supporting document links added  
3. Further editorial changes implemented |
| 1.0     | First version | 1. Substance identification: clarifications on how to report the manufacturing process description of UVCB substances  
2. Data waivers: clarifications on how to fulfil the information requirements for the extended one generation reproductive toxicity studies (EOGRTS) and the pre-natal developmental toxicity studies (PNDT)  
3. Testing proposals: advice for updating your dossier if you have received a decision from the European Commission about the amended information requirements of REACH Annexes IX and X, 8.7.3 on reproductive toxicity  
4. New Q&As and useful links added  
5. Further editorial changes implemented |