10 May 2022

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 document 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 included in IUCLID 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

Manual on how to prepare registration and PPORD dossiers:
https://echa.europa.eu/documents/10162/1804633/manual_regis_and_ppord_en.pdf

ECHA contact form:
https://echa.europa.eu/contact

Webinar on revised completeness check: https://echa.europa.eu/-/revised-completeness-check-what-changes-and-how-you-can-prepare

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).

  - For petroleum substances, the information that must be provided for the manufacturing process description is explained in more detail in the Q&A 1559 on the ECHA website.

  - Text templates marked with an 'A' are available in IUCLID to facilitate the reporting of the information. These templates ('*Option2: Composition of a UVCB substance*' and '*Option 6 Composition of a petroleum UVCB substance'*) list those elements that are necessary to address when describing the manufacturing process. Select template '*Option 6 Composition of a petroleum UVCB substance'* when reporting a manufacturing process description of a petroleum UVCB substance. For all other UVCB substances select template '*Option 2: Composition of a UVCB substance'.* 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 and Q&As 1316 to 1320 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 this variability must be expressed under the 'Molecular formula' field of the reference substance. For further details please consult the Q&A 1496 and technical instructions on reporting of complex inorganic pigments available at: https://echa.europa.eu/en/support/substance-identification/sector-specific-support-for-substance-identification/complex-inorganic-pigments.

- **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 foreseen 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 must to be included in the field *Other.* For further information in support of the data waiving, use the fields *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 provide as an attachment, you must nevertheless always include a summary of the rationale of the justification in the field *Justification for data waiving*. The justification must be 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. Supporting attachments should be provided in the field *Attached justification* but these will not be considered for completeness unless their outcome has been summarised in the field *Justification for data waiving*.

- 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.

- 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 must not be submitted as data waiving, but reported as endpoint study records indicated with the appropriate *Adequacy of study*. Note that only studies/adaptations with the adequacy 'key study' or 'weight of evidence' can be used to fulfil an information requirement.

- For ongoing studies, the following scenarios exist:

  i. You have received an ECHA decision or draft decision requesting you to carry out a test for this endpoint and the request concerns the substance [and all the (nano)forms] covered by this registration.
     - You have a need to update your dossier while the test results are not yet available.

- In this case, you should 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.

ii. You have received an ECHA decision or draft decision requesting you to carry out a test for this endpoint but the request does not concern the substance covered by this registration. [Alternatively, the request concerns the substance covered by this registration, but it does not concern all the (nano)forms of the substance that are to be registered.]
   - You intend to use the information from the requested study in a read-across approach to fulfil the information requirements for the substance [and (nano)forms] registered in this dossier.
   - You have a need to update your dossier while the test results are not yet available.
   - In this case you must document your approach via a read-across testing proposal. To this end, create an endpoint study record indicated as 'experimental study planned (based on read-across)' in the field *Type of information*. Provide the endpoint-specific justification for the read-across approach in the field *Justification for type of information*. The field contains free-text templates to support the documentation of the justification. In addition, you must as a minimum indicate the *Endpoint*, *Guideline* and *Test material information* of the planned test.

iii. You have commissioned or initiated a study for which you do not have an ECHA decision or draft decision.
   - In this case, you must wait until you have the study results available and subsequently submit the information as a (robust) study summary with the appropriate *Adequacy of study.*

- Testing proposals should not be submitted as data waiving. For information on the manual verifications performed on testing proposals as part of the completeness check, please refer to chapter 3 *Testing proposals on vertebrate animals* of this document.

- Substance being previously notified under Directive 67/548/EEC (NONS): When the previous notifier becomes the lead registrant of the joint submission then the dossier must contain all the information fulfilling the requirements imposed by REACH without any possibility to make derogations due to the substance being previously notified under Directive 67/548/EEC. See Annex 4 of the manual *How to prepare registration and PPORD dossiers for further information on NONS*.

Specific advice

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

- Data waiving of pre-natal developmental toxicity studies (PNDT): please read Q&A 1437 and 1438.

- Data waiving 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 for substances used in 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

Manual on how to prepare registration and PPORD dossiers (Annex 4 on NONS)

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 approaches to fulfil the information requirements in the registration dossier.

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

- 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 or draft decision requesting you to carry out a test for an endpoint but the test results are not yet available at the time you need to update your registration dossier, please refer to section 2 *Data waiving justifications* of this document.

- It is important that you indicate correctly 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 the substance you are registering in this dossier, you should indicate it as 'experimental study planned' in the field *Type of information*. In the *Test material* information field the substance indicated is expected to be the registered substance.

  - 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)'. In the *Test material* information field the substance indicated is expected to be a substance other than the registered substance.

  - For registrations covering (also) nanoforms of substances, testing proposals must be specific to the particular form that is proposed to be tested, or that you propose to read-across from another (nano)form of the substance.
    - When proposing to test a particular form of the substance, this must be reported as a testing proposal of the type 'experimental study planned'. Ensure to specify in the test material information the form of the substance to be tested.
    - When proposing to read-across from study results to another form of the substance for which a testing proposal has been submitted, this must be reported as a testing proposal of the type 'experimental study planned (based on read-across)'. Ensure to specify in the test material information the form of the source substance.

  - For testing proposals of the type 'experimental study planned', the full considerations for alternative approaches to fulfil the information requirement must be provided. For read-across testing proposals, considerations for alternative methods are not needed; instead, 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)

A chemical safety report (CSR) is required in the registration of substances that are manufactured or imported in more than 10 tonnes per year. The CSR can be submitted either separately by each registrant or jointly by the lead registrant. If a CSR is required in the registration dossier, the presence of the CSR file is verified in the completeness check. If no CSR file is provided, ECHA will manually verify that a justification is provided in line with Article 14(2).

Since 1st of March 2021, the manual verification of the CSR has been extended to the content of the CSR file. The verification concentrates on the following aspects:

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

- Each use reported in IUCLID section 3.5 must have a corresponding exposure scenario in the CSR. As a general rule, there should be one exposure scenario per use.

- Each exposure scenario must contain contributing scenarios for human health (i.e. workers or consumers) and for the environment.

- The contributing scenarios per exposure scenario must cover each of the contributing activities reported for that use in IUCLID section 3.5., where:
  - a worker contributing activity is characterised by a process category (PROC)
  - a consumer contributing activity is characterised by a product category (PC) or an article category (AC).
  - an environmental contributing activity is characterised by an environmental release category (ERC).

  Again the general rule is that each contributing activity should be covered by one contributing scenario.

- Each contributing scenario in the CSR is expected to contain:
  - A description of the operational conditions and the risk management measures to be applied for controlling the risks.
  - Exposure estimates for all relevant routes of exposure for human health / environmental compartments.
  - Risk characterisation ratio for all routes of exposure / compartments.
  - Risk characterisation ratio for combined routes of exposure for humans.
  - Environmental contributing scenarios must contain local releases for water, air and soil.

- If any of the required information is missing in the CSR, a substantiated justification must be provided within the relevant exposure scenario (at the place where the information is missing) or in the relevant sub-section of chapter 9.0 of the CSR, if the justification systematically applies to many (all) exposure scenarios. The justification is manually checked by ECHA staff for its relevance.

Further advice on reporting the information

Relating the exposure scenarios in the CSR to the uses reported in the IUCLID dossier

- The exposure scenario titles in the CSR must have a clear reference to the use reported in the IUCLID dossier (i.e. name of the use = name of the exposure scenario).
- For CSRs generated by Chesar, this linking can be handled by the Chesar tool. The first two scientific FAQs published on the Chesar website explain how to ensure the synchronisation of the exposure scenarios in the CSR generated by Chesar with the use description in IUCLID.
- If the correspondence cannot be verified by the ECHA staff, the CSR will be considered incomplete.

Relating the contributing scenarios in the CSR to the contributing activities reported in the IUCLID dossier

- The contributing scenarios titles in the CSR must have a clear reference to the contributing activities reported in the IUCLID dossier (i.e. name of the contributing scenario = name of the contributing activity).
- If the correspondence cannot be verified by the ECHA staff, the CSR will be considered incomplete.

Humans exposed via environment must be assessed when general population DNELs for long-term exposure via inhalation or oral intake have been determined, and:

- 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).

Substances with several compositions and classifications

- If the registration covers multiple compositions with different classifications, the composition records must be linked with the relevant classification and use records. This is especially important for uses that do not require an assessment because a composition/form of the substance does not meet the classification criteria.

Trigger for checking the presence of exposure assessment and risk characterisation

- The manual completeness check of the CSR is triggered by the PNECs, DNELs (or other toxicological threshold) reported in the overall (eco)toxicological summaries in IUCLID. ECHA assumes that the reported PNECs or DNELs indeed indicate that (adverse) effects were observed below or at limit dose, and hence exposure assessment is required.

Substances with high systemic hazard

- If the substance meets the criteria for classification as carcinogen (cat 1), mutagen (cat 1) or respiratory sensitiser, exposure estimates are expected, regardless of whether a toxicological threshold (including DNEL/DMEL) has been reported in IUCLID. The exposure estimates are required for demonstrating the extent of exposure minimisation achieved through the use conditions described in the exposure scenarios.

Substances fulfilling the PBT/vPvB criteria

- If the substance fulfils the PBT/vPvB criteria, or is handled as if it were a PBT/vPvB, the CSR is expected to contain contributing scenarios for the environment with conditions of use (explaining how the releases are minimised) and local release rates.

Justifications for exceptions

Substances registered as intermediates under strictly controlled conditions (registered under Art 17/18)

- Uses covered under an Art 17/18 registration do not require a chemical safety assessment. If you report an Art 17/18 use in IUCLID section 3.5, you must indicate its status in the respective use record in the field 'Registration/Notification status for the use', and describe the strictly controlled conditions following the instructions of section 8.5.4.6 of the manual 'How to prepare registration and PPORD dossiers': https://echa.europa.eu/manuals.

Several contributing activities exceptionally covered by one contributing scenario

- If several contributing activities are covered by one contributing scenario in the CSR, the title of the contributing scenario must clearly refer to the use descriptors (PROC/ERC/PC/AC) that it covers.
- If an exposure estimation tool has been used, and if the contributing activity is characterised by several use descriptors, the use descriptor entered as input to the exposure tool should be clearly referred to (preferably in the exposure estimation section unless a CSA tool has been used where the information is located in another clearly identified place).

Absence of human exposure

- For workers, the exposure estimates and risk characterisation ratios cannot be waived with the justification that there is no exposure or the exposure is unlikely. A quantitative assessment is required to demonstrate the low level of exposure.
- For consumers, the same basic rule applies. However, the tools mostly applied for generating the exposure estimate (TRA and ConsExpo) indicate for some product (sub)categories that no exposure is expected on a certain route. You can waive a certain route by making clear reference to such specific exemptions in the relevant contributing scenario.

Absence of environmental release

- A relevant justification for not providing the exposure estimates and risk characterisation ratios for the environment is that there is no release of the substance to the environment. In that case, the environmental contributing scenarios should still be provided in the CSR, and they should contain the conditions of use substantiating why no release to the environment takes place. The release estimates may be set to 0.

Substance has low potential for bioaccumulation (waiving secondary poisoning)

- If a substance has a low potential for bioaccumulation (based for example on "Kow <3 and no other evidence for accumulation potential"), an assessment for secondary poisoning is not required, and 'no potential for bioaccumulation' should be selected in the corresponding summary for ecotoxicity in IUCLID section 7.

Article service life

- When a substance is expected to be present in articles, one or more service life uses are to be created in IUCLID section 3.5.6.
- Just claiming no/negligible release is not a valid argument to justify the absence of assessment in the CSR. The Q&A 1860 on the ECHA website outlines the situations and the arguments potentially justifying the absence of assessment.

Substance present in a mixture at low concentration

- If you use this argument for not carrying out the exposure assessment for a specific use, the justification must include the concentration of the substance in the product/mixture used (before possible dilution), and depending on the concentration some additional information:
    - If the concentration is below 0.1%, no further reasoning is required, unless:
        - A specific concentration limit for mixture classification is applicable for the substance (in which case such cut off should be used).
        - For substances classified for the environment as 'Acute Category 1' or 'Chronic Category 1', 0.1% is to be divided by the M-Factor to determine the substance-specific cut-off.
    - If the concentration is above 0.1%, you must provide the hazard category(ies) and class(es) of your substance and the corresponding cut-off(s) from CLP, indicating the concentration above which your substance

must be taken into account for the purposes of classification. Based on this, you can demonstrate that the concentration in the use is below the lowest cut-off relevant to your substance. For substances meeting the PBT/vPvB criteria in Annex XIII, any concentration above 0.1% would require the presence of an exposure assessment.

Substance reacts upon use

- If you use this argument for not carrying out the exposure assessment for a specific use, the justification must include the following:
    1. Provide an explanation how the substance transforms (including the reaction mechanism and the identity of the transformation products)
    2. Quantify the remaining residual concentration of the substance in the specified use and
        - If the concentration of the substance is below 0.1%, no further reasoning is required, unless:
            - A specific concentration limit for mixture classification is applicable for the substance (in which case such cut off should be used).
            - For substances classified for the environment as 'Acute Category 1' or 'Chronic Category 1', 0.1% is to be divided by the M-Factor to determine the substance-specific cut-off.
        - If the concentration is above 0.1%, you must provide the hazard category(ies) and class(es) of your substance and the corresponding cut-off(s) from CLP, indicating the concentration above which your substance must be taken into account for the purposes of classification. Based on this, you can demonstrate that the concentration in the article material is below the lowest cut-off relevant to your substance. For substances meeting the PBT/vPvB criteria in Annex XIII, any concentration above 0.1% would require the presence of an exposure assessment.
    3. Explain the reasons why you consider that the transformation product(s) do(es) not meet the criteria for being considered hazardous.

Ongoing studies requested by ECHA decision

- If you have received an ECHA decision or draft decision requesting you to carry out a specific test which has an impact on the exposure assessment, and the information is not yet available, you may justify the absence of the exposure assessment by referring to the ECHA decision number (TPE/CCH/SEV-x-xxxxxxxxxx-xx-xx).

No CSR attached in section 13.1

- In this case the justification must refer to the specific condition of Article 14(2) that the omission of the CSR is based on, a general reference to Article 14(2) is not enough. The justification (i.e. the summary of arguments) for not providing a CSR must be entered in either of the fields *Discussion* or *Further information on the CSR attached / remarks* of the section 13.1 record. If relevant, you must clearly specify which attachments in section 13.2 are relevant for the justification.
- Any supporting documents to your justification must be attached in section 13.2 – *Other assessment reports*. Supporting attachments will not be considered for completeness unless they have been explicitly referred to, and their outcome has been summarised, in the section 13.1 fields *Discussion* or *Further information on the CSR attached / remarks*.
- In addition to the conditions mentioned in Article 14(2), it is possible to waive the CSR requirement for a substance which is a monomer imported in a polymer and

where the monomer concentration during the polymer life cycle is sufficiently low. In such case the justification must contain the following elements:

- Identification of the applicable cut-off (threshold) for the monomer based on Art 14(2). If the threshold provided is higher than 0.1%, it should be explained which classification has been used as a basis for the threshold.
- 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).
- Statement 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).
- Statement that the polymer is imported.

Further information

Webinar on the completeness check of chemical safety reports, practical advice
Practical examples of chemical safety reports
Chemical Safety Assessment and Reporting tool - CHESAR
Guidance on Information Requirements and Chemical Safety Assessment

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*.

- There are four templates (a, b, c, d) available in the *Justification* 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, in full, **all the points** of at least one template to be considered complete.

- The questions contained in the templates are also available at Annex 7 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, d) provided.

Further information

Q&As on Joint submission of data by multiple registrants (see section *E. 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 they manufacture/import, either individually or through sets of nanoforms, and to ensure that a specific dataset of Annex VII-X information 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 via the opt-out mechanism. In either approach, the link between each nanoform or set of nanoforms and the corresponding 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 registrant that relies on this set to register their nanoforms cannot opt-out of the Annex VII-X information submitted for the set by the lead registrant. In other words, if your nanoforms are not covered, for each information requirement, by the Annex VII-X information submitted by the lead registrant for the set of nanoforms, then they cannot be part of this set of nanoforms. Consequently, partial opt-outs from jointly submitted Annex VII-X information for sets of nanoforms are not accepted at completeness check.

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. 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.

In particular, it is important to 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 Validation assistant cannot detect if each Annex VII-X dataset is complete for each information requirement, or if it has been appropriately linked to the related (set of) nanoform(s). The Validation assistant will display if all endpoint study records indicated as key study or weight of evidence have been filled in with the necessary information for completeness. However, it will not detect if all the required endpoint study records have been included in the dossier, nor their linking to a specific (set of) nanoform(s). Registrants will therefore need to manually ensure that they have provided a complete and specific Annex VII-X dataset for each nanoform or set of nanoforms, when multiple (nano)forms of the substance are registered.

Linking of section 1.2 legal entity compositions to boundary compositions

- 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 Annex VII-X data submitted in the same dossier, are reported in IUCLID section 1.2 as 'boundary composition of the substance'. These compositions describe the boundaries of the characterisers of nanoforms that are covered by the Annex VII-X data.

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-X 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 a legal entity composition to the related boundary composition record name when the boundary composition is in a different dossier [JS member relying on jointly submitted Annex VII-X data].

Linking of Annex VII-X information to a boundary composition

Whenever the registration dossier contains more than one nanoform or set of nanoforms, or both 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* of the type 'Specific composition/form of the registered substance' in IUCLID section 1.10;

- Link each Assessment entity to a specific endpoint summary, for each the Annex VII-X information requirement 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.

- Alternatively, linking of the information can be done through the clear and consistent naming of the Annex VII to X records that are relevant for a nanoform or a set of nanoforms.

- Regardless of the chosen linking method, the same linking convention must be used through the dossier i.e., it is not acceptable to use the naming convention for certain endpoints and the Assessment entity feature for other.

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 an 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/form, 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 at the present moment. 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

When nanoforms are registered via a set of similar nanoforms, a justification must be provided 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.

- The justification must be entered in IUCLID section 1.2 in the field *Justification for reporting set of similar nanoforms* or the field *Attached information* of each boundary 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.

- A specific justification is expected for each set of nanoforms reported in a boundary composition of the dossier.

- If a set of nanoforms has been agreed at the level of the joint submission, the justification must be the same for all registrants relying on the same set. It is not possible to develop registrant-specific justifications for a set covered by the joint submission. By linking/referring a legal entity composition to a boundary composition (see sub-chapters above), the legal entity composition is declared to rely on the set justification provided in the boundary composition.

- To support the reporting of the justification for a set of nanoforms, a text template is available in the IUCLID section 1.2 field *Justification for reporting set of similar nanoforms*. The template can be loaded by selecting the button 'A'. You must use this template to structure your justification and answer all relevant points as instructed in the template and as advised here below:

  i. Address separately each characteriser listed in section 2.4 of Annex VI.

  ii. Provide scientific evidence addressing the physicochemical, environmental fate, ecotoxicity and toxicity properties of nanoforms that are within the boundaries of the set of nanoforms. For each characteriser, the justification must summarise the supporting data.

  iii. Each scientific evidence summarised in the justification must refer to a (robust) study summary.
    - The (robust) study summary can be provided by attaching it in the section 1.2 field *Attached information*;
    - When the (robust) study summary is reported elsewhere in the IUCLID dossier, e.g. in IUCLID section 4-7, a reference to it can be made by linking it via the section 1.2 field *Cross-reference*;

- Alternatively, references to publicly available literature may be provided instead of a robust study summary.

In all the above cases, the findings from these studies and the characterisers of the nanoforms used in the studies must be summarised in line with the points i-iv.

iv. For each characteriser, the justification must explain how the scientific evidence demonstrates that all the nanoforms in the set can be assessed jointly. This explanation must clearly show that the nanoforms used to generate the supporting data are representative of all the nanoforms included in the boundaries of the set.

Further information:

Manual on how to prepare registration dossiers covering nanoforms

Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification

Webinar with practical advice for registering nanoforms

ECHA nanomaterials page (template to report practical constraints with fulfilling Annex VII-VIII information available in the right menu, under 'Guidance and manuals')

Q&As for nanoforms

Changes to this document

Version	Changes
11.0	May 2022 1. Broken links corrected throughout the document. 2. Substance identification: further details on reporting added for inorganic UVCB substances with variability in molecular formula. 3. Chemical safety report: Further advice added for specific situations. 4. Opt-out: Reference to REACH-IT online dossier preparation tool removed. 5. Specific requirements for nanoforms: Clarification added on linking of the Annex VII to X information with boundary compositions. 6. Further editorial changes.
10.0	February 2021 1. Chemical safety report: new advice added.
9.0	November 2020 1. Substance identification: reference added to a new IUCLID template relevant for the manufacturing process description of petroleum UVCB substances. 2. Data waiving justifications: advice added on NONS. 3. Chemical safety report: starting date of the new completeness checks removed. 4. Opt-out: number of available IUCLID templates updated. 5. Specific requirements for nanoforms: Information removed on manual checks on boundary compositions in dossiers where Annex VII-X data is submitted. The checks are done with the Validation assistant. 6. New Q&As and links to support material added. 7. Further editorial changes.
8.0	July 2020 1. Substance identification: clarification on the Q&A relevant for the manufacturing process description of petroleum UVCB substances 2. Data waiving justifications: clarification on reporting of

	ongoing studies. 3. Chemical safety report: clarification on how to report the justification when no CSR is provided. 4. Specific requirements for nanoforms: further clarifications added 5. Further editorial changes
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 clarifications 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

3.0	October 2017 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
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