

Information on manual verification at completeness check

ECHA performs a completeness check on each incoming registration to ensure that the required information is provided (Article 20 of the REACH Regulation).

As of 21 June 2016, the automated completeness check is complemented with additional manual checks of 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 will perform a manual verification on both new registrations and updates of existing dossiers.

The manual verification aims at establishing a level playing field between registrants who follow the standard information requirements set out in REACH, and those who waive or deviate from these requirements, by ensuring that the latter provide justifications foreseen by the legislation.

The manual checks are integrated in the completeness check process. Therefore, when the outcome of the manual check is that the data provided in the dossier is not considered complete, ECHA will inform the registrant and request further information within a relevant deadline according to Article 20 to give the registrant the opportunity to make the dossier complete. ECHA will not assess the quality of information at this point – this is performed during dossier evaluation – but rather ensure that the required data is provided i.e. the dossier is complete.

When preparing your dossier, keep in mind that the registration dossier should not only be prepared to pass the completeness check. It should contain all the information on the substance as specified by REACH, including a clear identification of the substance that is being registered, and should aim to demonstrate that the substance is used in a safe manner.

Please note that this document is being regularly updated with new information.

See below our general advice regarding the preparation of a complete registration dossier:

Before you submit your dossier to ECHA, use the IUCLID Validation Assistant plug-in on your substance dataset and if it displays any failures, complete the missing information by following carefully the advice reported in the plug-in. After you have corrected the failures in the dataset, as a next step, create your dossier and validate before exporting it by completing any missing information identified by the plug-in.

If the Validation Assistant does not indicate any failures, it is not an automatic confirmation of that your dossier is complete, since the technical completeness has been complemented with additional verifications done by ECHA staff that cannot be displayed by the Validation Assistant plug-in. Consequently, ensure that all the information required by the legislation is included in the dossier. Based on our experience there are certain areas of the dossiers with regular issues, therefore pay attention in particular to the four following areas:

1. Substance identification:

A clear substance identification is fundamental for registrants 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. Registrants should not rely on company-specific substance identification information, such as analytical or compositional information, provided by the lead registrant, therefore please take this into account when reporting the substance identity in your dossier.

- **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.
- 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](#). If you deviate from these rules, make sure that the justification is scientifically substantiated and included in the 'Justification for deviations' field in IUCLID section 1.2 of each composition where a deviation takes place. Acceptable deviations are specified in the Guidance.
- The composition of a mono-constituent substance should include one main constituent. The composition of multi-constituent substance should include more than one constituent. A deviation from these principles is very exceptional and 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.
- 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.

- **Manufacturing process description of UVCB substances**

- For a UVCB substance, a description of the source used and the process applied must be included in the 'Description of composition' field in IUCLID section 1.2.
- 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 free text template marked with "A" is available in IUCLID to facilitate the reporting of the information (see screenshot below). This template lists those elements that are necessary to address when describing the manufacturing process description. Please do not submit templates "empty", without including the relevant details of your description: those descriptions will not be considered complete.
- For further information, please consult the [Q&A 1199](#) 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 individual constituents present at >10%, or relevant for C&L and/or PBT assessment must be reported separately, while other constituents should be identified as far as possible, as separate constituents or as groups of generic constituents.
- 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.

- **Analytical information:**

- To fulfil the REACH requirement on the analytical data, you must provide the 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 to identify the constituents, while quantification is carried out to establish 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. (See screenshots below on the possibilities how to attach the reports).
- In very rare cases, the quantification analysis may not be necessary for verifying the composition reported in your dossier. If your substance belongs to these very rare case, 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.

IUCLID section 1.4 for reporting analytical data
Methods and results of analysis ^

Analytical determination

Purpose of analysis	Analysis type	Type of information...	Attached methods/r...	Rationale for no re...	Justification	Remarks
identification	NMR, MS, IR	methods and results	Identification_metho ds_results.docx / 0 B /			
quantification	Chromatography – HPLC	methods and results	Quantification_meth ods_results.docx /			

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Methods and results of analysis ^

Analytical determination

Purpose of analysis	Analysis type	Type of information...	Attached methods/r...	Rationale for no re...	Justification	Remarks
identification and quantification	NMR, MS, IR,	methods and results	Identification_quantifi cation.docx / 0 B / application/octet-stre			

+ Add... Edit... X Delete ↑ Move up ↓ Move down

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

[How to prepare registration and PPORD dossiers](#)

[Questions and answers – Substance Identification](#)

[Guidance for identification and naming of substances under REACH and CLP](#)

2. Data waivers:

- For each endpoint study record marked as a 'Data waiving', a valid justification for not fulfilling the standard information requirement must be provided in the field 'Justification for data waiving'.
- Sections 2 and 3 of Annex XI of REACH and Columns 1 and 2 of the relevant endpoint in Annexes VII to X provide reasons why a study would not need to be submitted in the dossier, therefore justifications not listed as one of these reasons must be fully substantiated.
- 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) and testing proposals should not be submitted as data waivers, but reported as study records.
- If your reason for data waiving is substantiated by other documentation, for example expert opinion that you intend to provide as an attachment, ensure to include the rationale of the justification to the 'Justification for data waiving' field in line with sections 2 and 3 of Annex XI of REACH and Columns 1 and 2 of the relevant endpoint in Annexes VII to X.
- Ongoing studies: if you have already received an ECHA decision requesting you to carry out a test for an endpoint but the testing has not yet been completed,

you should not report the ongoing study as a testing proposal. Instead, you must create an endpoint study record with the appropriate selection in the field 'Endpoint' and indicate the option 'other justification' in the field 'Data waiving'. Select the checkbox 'other:' in the field 'Justification for data waiving' and type the following sentence in the adjacent text field: "This information will be submitted later based on ECHA decision number TPE/CCH-D-xxxxxxxxxx-xx". Once the requested test has been performed, you need to update your dossier and replace the data waiving record with an endpoint study record documenting the study.

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

[How to prepare registration and PPORD dossiers](#)

[Endpoint specific guidance R7a, R7b and R7c](#)

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 need to provide their considerations of alternative methods in the registration dossier.
- These considerations of alternatives must be provided in the field 'Justification for type of information' for each proposed vertebrate study to pass the completeness check.
- You are strongly advised to use the text template provided in the field and marked with "A". This template lists those elements that are necessary to be addressed when documenting your considerations. Please do not submit templates "empty", without including the relevant and comprehensive details of your considerations: those considerations will not be considered complete.
- The considerations submitted 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 in the form.
- If you have already received an ECHA decision requesting you to carry out a test for an endpoint but the testing has not yet been completed, you should not report the ongoing study as a testing proposal. Instead it must be submitted as a data waiver. For further details, see the "Data waivers" 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'. However, 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.

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

[How to prepare registration and PPORD dossiers](#)

[Q&A – Information requirements, test methods and quality of data](#)

[Testing methods and alternatives](#)

4. Chemical safety reports (CSRs):

- If a CSR is not attached, 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.
- The justification should be entered in any of the fields 'Discussion' or 'Further information on the attached file' of the section 13 record.