21 November 2018

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 by ECHA staff 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, consider 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 tool on your substance dataset and if it displays any failures, complete the missing information by following carefully the advice reported in the tool. 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 tool.

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 are not displayed in the Validation assistant report. 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:

We recommend you to watch our webinar on completeness check on the ECHA website.

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 provided by the lead registrant (such as analytical or compositional information). 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 a 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' field of each legal entity composition 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. 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: 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'.

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

- For further information, 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 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.

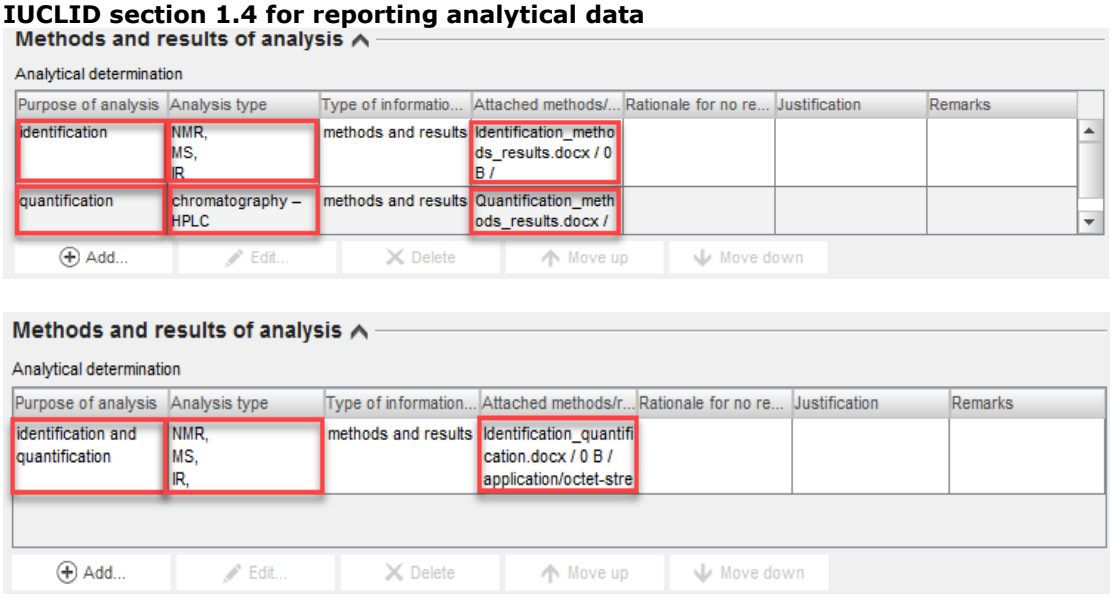
  - Analyses carried out for both identification and quantification purposes must be provided, as identification establishes the chemical identity of the constituents, while quantification is carried out to determine the concentration of the constituents in the composition.

  - To consider your dossier complete in terms of the analytical information, the required analytical reports must be attached in IUCLID section 1.4 (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 required to be 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 informatio...	Attached methods/...	Rationale for no re...	Justification	Remarks
identification	NMR, MS, IR	methods and results	Identification_methods_results.docx / 0 B /			
quantification	chromatography – HPLC	methods and results	Quantification_methods_results.docx /			

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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_quantification.docx / 0 B / application/octet-stre			

Add... Edit... Delete Move up Move down

Further information

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 the reasons why a study would not need to be submitted in the dossier. If you propose not to provide information for a certain endpoint for other reasons than those mentioned in Columns 1 and 2 of Annexes VII to X or in Annex XI, you must clearly state these reasons and provide a scientifically substantiated justification.

- 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 indicated as 'key study' or as 'weight of evidence'.

- 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 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. Supporting attachments should be provided in the field 'Attached justification'.

- Ongoing studies: If you have already received an ECHA decision or a draft decision requesting you to carry out a test for this endpoint but the information is not yet available, select 'other' from 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 communication/decision number TPE/CCH-F-xxxxxxxxxx-xx-xx", where you replace the "x"-characters with the decision/communication number issued to you by ECHA.

- If the data waiving relies on other information (e.g. a test in another section or a classification), this information must be included in the appropriate section of the dossier. The presence of such information is manually checked.

- Extended one generation reproductive toxicity studies (EOGRTS):

    - At REACH Annex IX, as indicated in Column 1 of 8.7.3, EOGRTS is a conditional requirement, which depends on the indication of adverse effects from other repeated dose toxicity studies. Therefore, if you are waiving the EOGRTS based on available repeated dose toxicity studies, you must indicate that no adverse effects or concerns have been observed in such studies and refer to these studies in the field 'Justification for data waiving'. If you are still awaiting the results of such test(s), you must follow the advice given in the Q&A 1324 on the ECHA website.

    - At REACH Annex X, EOGRTS is the standard information requirement to address reproductive toxicity. Unlike at Annex IX (Column 1, section 8.7.3), it cannot be waived based on the results from available repeated dose toxicity studies. If you are waiting for the results of another test (e.g. results from a 90-day study or from a prenatal developmental toxicity study) to decide on the study design of the EOGRTS, you should follow the advice given in Q&A 1323 on the ECHA website.

      Pre-natal developmental toxicity studies (PNDT): REACH Annex X requires registrants to provide a second pre-natal developmental toxicity study on a different species. For each of the two species, you need to provide an endpoint study record in section 7.8.2 indicated as key study, weight of evidence, data waiving, or testing proposal. If you fulfil Annex X information requirement related to PNDT studies, please read Q&A 1437 and 1438, and the newsletter on PNDT tests on the ECHA website.

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:

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: such 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 with a specific justification text. 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.

- Note that if you have received an adopted implementing decision from the European Commission regarding the amended information requirements of REACH Annexes IX and X, 8.7.3 on reproductive toxicity (IUCLID section 7.8.1), but you are updating the dossier for another reason, please proceed as follows:

    - Maintain the current testing proposal in IUCLID section 7.8.1
    - Indicate in the field 'Justification for type of information' the following sentence: "This endpoint will be updated based on the implementing

decision by the European Commission with number <provide number of adopted decision> regarding the amended information requirements of REACH Annexes IX and X, 8.7.3."

Note that you must update IUCLID section 7.8.1 by the deadline indicated in the European Commission decision according to the approach you have chosen to fulfil the amended information requirements (see instructions sent to you via REACH-IT), and remove the testing proposal submitted to address the previous information requirements.

Further information

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 CSR attached / remarks' of the section 13.1 record.

5. **Justification of opt-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 requirements' in the free text field 'Justification'.

- 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 free text field. The justification you provide must answer all the points of at least one template to be considered complete.

- The three templates are:

(a) It is disproportionately costly to submit this information jointly

(b) Submitting the information jointly will result in the disclosure of information which you consider to be commercially sensitive and is likely to cause you substantial commercial detriment

(c) You disagree with the lead registrant on the selection of the information

- You should not provide a justification as an attachment.

- The questions contained in the templates are also available at Annex VII of the Registration manual. The template questions can be copied to the 'Justification' field in section 14 'Information requirements' under 'Opt-out information for REACH requirements'.

- 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

For further information consult section 9.9.2 of the Registration manual on how to opt-out of a joint submission under REACH:

How to prepare registration and PPORD dossiers

Changes to this document

Version	Changes
4.0	November 2018 1. Information added on justification of opt-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