ECHA
EUROPEAN CHEMICALS AGENCY

REACH 2018 webinars

Completeness check
Manual checks and common failures

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11.00 – 12.00 Helsinki time

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Manual verification as part of completeness check

Manual verification at completeness check

- As of 21 June 2016, automated completeness check was complemented with additional manual checks performed by us for certain elements of the dossier. These cannot be checked automatically
- Not displayed by the Validation assistant
- Scope of manual checks is completeness, not quality or compliance to ensure that registrants who deviate from standard requirements provide a justification that is foreseen in REACH

Current focus of manual checks

- Substance identification (IUPAC name, composition, manufacturing process description, analytical information, deviations from standard rules)
- Justification for waiving of standard information requirements
- Testing proposals on vertebrate animals (presence of considerations for adaptation possibilities)
- Justification for waiving the chemical safety report

Additional information

- Information on manual verification at completeness check
- Webinar on completeness check

Common failures and how to avoid them

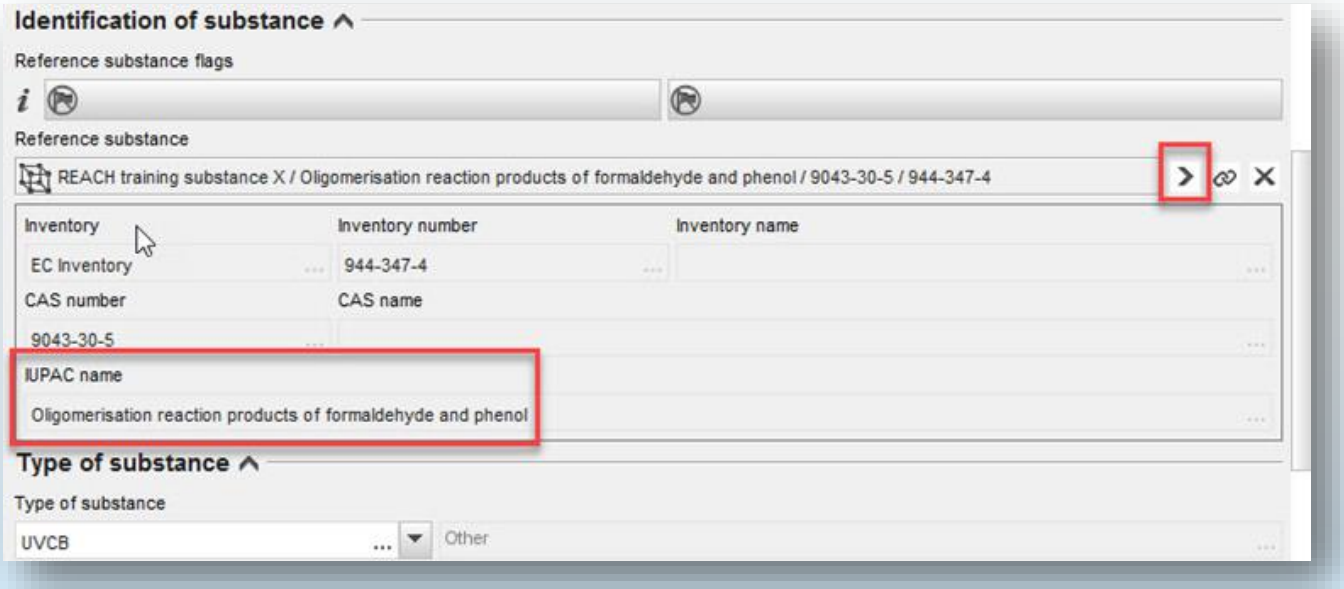
Most common failures

- Substance identification
  - IUPAC name
  - Constituents: compositions of “mono”, “multi” and UVCB substances
  - Manufacturing process description of a UVCB substance
  - Analytical information
- Justification for waiving
- Chemical safety report

Substance identification
IUPAC name of registered substance

IUPAC name always in the 'IUPAC name' field under 'Reference substance' in IUCLID section 1.1

- In case IUPAC nomenclature cannot be applied, a chemical name should be given in the IUPAC name field
- For information on how to name multi-constituent and UVCB substances, consult Q&A 1197 and Q&A 1196



Substance identification

Composition of mono- and multi-constituent substances

Mono-constituent	Multi-constituent
• **Main constituent** expected to be present in each reported composition at a **minimum of 80%**	• **Main constituents** expected to be present in each reported composition at a **maximum of 80%**
• **Impurities** expected to be present in each reported composition at a **maximum of 20%**	• **Impurities** expected to be present in each reported composition at a **maximum of 10%**

If the registered substance deviates from these rules, a scientifically substantiated justification is needed in the **'Justification for deviations'** field in IUCLID section 1.2

Substance identification
Composition of a UVCB substance

Also for a UVCB substance, constituents should be provided.

- The constituents for each reported composition of a UVCB substance should be provided in IUCLID section 1.2. under 'Constituents':
  - All individual constituents present at >10%, or relevant for C&L and/or PBT assessment should be reported separately.
  - Other constituents should be identified as far as possible, as separate constituents or as groups of generic constituents.
  - UVCB substances not considered to contain impurities
  - In exceptional cases, if not possible to report any (groups of) constituents separately, provide a scientifically fully substantiated justification under '**Justification for deviations**'.

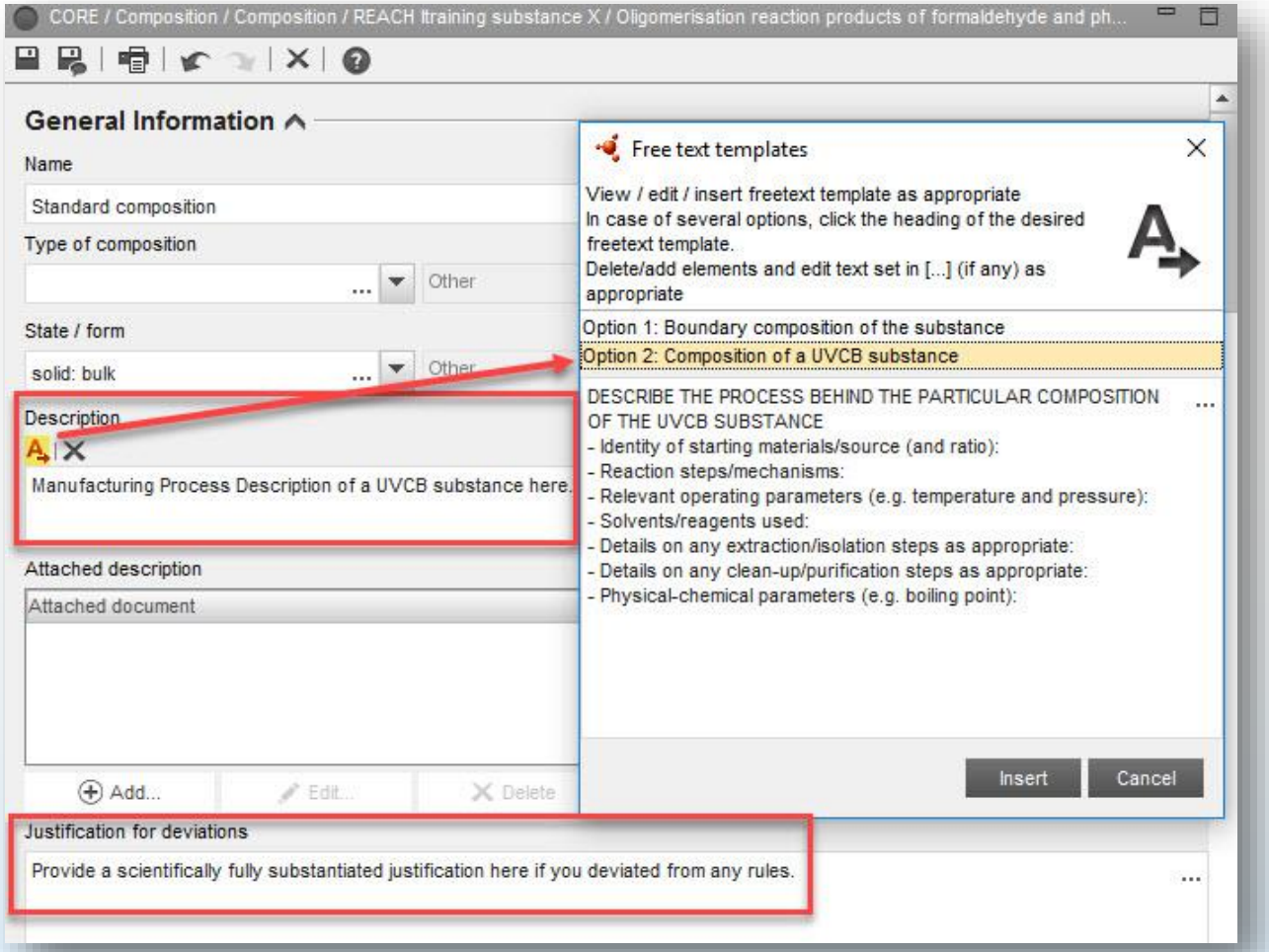
Substance identification

Manufacturing process description of a UVCB substance

- Manufacturing process description for UVCBs is always required in addition to the chemical name and chemical composition
- Should be provided in 'Description' field in IUCLID section 1.2. Template available in IUCLID (marked with "A") to help you report relevant information
  - Fill in relevant data for your substance – inserting the template alone will not be considered complete
- Refer to Q&As 1199 and 1316 to 1320

Substance identification

IUCLID section 1.2 fields for Manufacturing Process Description and for justifications for deviating from the mono/ multi / UVCB rules



Substance identification
Analytical information

For your dossier to be considered complete in terms of the analytical information, the required analytical reports for identification and quantification should be attached in IUCLID section 1.4.

Analytical determination

Purpose of analysis	Analysis type	Type of information...	Attached methods/r...	Rationale for no re...	Justification	Remarks
identification	NMR, MS	methods and results	identification_methods_results.docx / 17.262 KB /			
quantification	chromatography – GC	methods and results	quantification_methods_results.docx / 17.297 KB /			
identification and quantification	chromatography – HPLC	methods and results	identification_quantification_methods_results.docx / 17.372			

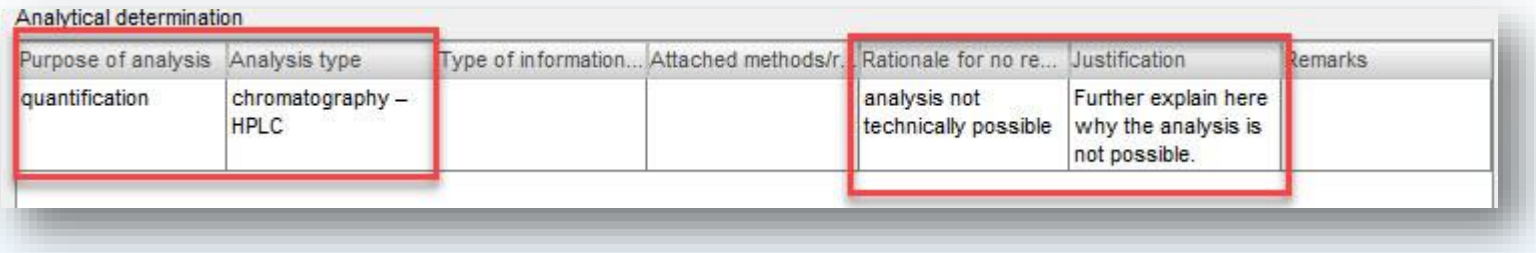
As separate reports

In the same report

Substance identification
Analytical information

In exceptional cases, when quantification is not scientifically relevant or possible, instead of an attachment, a scientifically fully substantiated justification should be given

We check the justification manually



Analytical determination

Purpose of analysis	Analysis type	Type of information...	Attached methods/r...	Rationale for no re...	Justification	Remarks
quantification	chromatography – HPLC			analysis not technically possible	Further explain here why the analysis is not possible.	

If no results for quantification, provide a **rationale** and a **justification**

Justification for data waiving

Three options available to fulfil REACH information requirements under Annex VII-VIII (IUCLID sections 4–7)

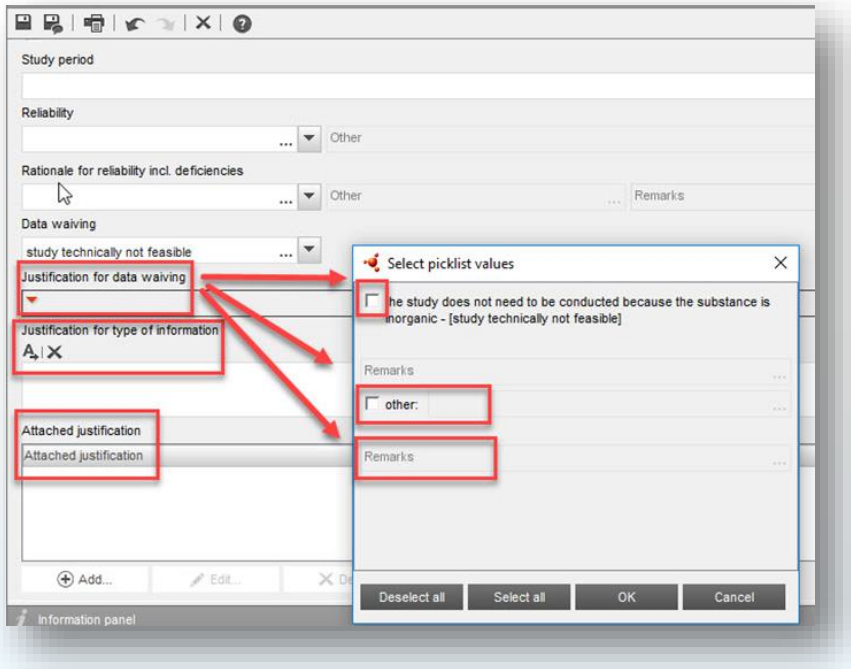
1. Provide standard required study
2. Adaptation according to section 1 of REACH Annex XI:
   - Use of existing data, weight of evidence, (Q)SAR, in vitro methods, grouping of substances and read-across

     If you utilise one of the above options, provide the relevant study results marked as a key study or weight of evidence
3. Provide a data waiving in accordance with Column 2 of REACH Annexes VII-VIII, or Annex XI sections 2 and 3

Justification for data waiving

Enter justification in the field '**Justification for data waiving**'.

- **Pick-list** options in IUCLID, consider using if option(s) apply to your particular case
- If pick-list options do not apply, choose '**Other**' and provide a scientifically substantiated justification in line with appropriate REACH Annex. '**Remarks**' field for additional information
- More information can be provided in the field '**Justification for type of information**' and '**Attached justification**'



Justification for data waiving

Examples of incomplete / complete justifications for data waiving

4.5 Granulometry (REACH Annex VII, 7.14)

"According to Annex XI point 2 testing is not needed"

"According to REACH Annex VII section 7.14 column 2, the test is not needed because the substance is marketed or used in a non-solid or non-granular form"

5.4.1 Adsorption/ desorption (REACH Annex VIII, 9.3.1)

"It is technically not possible to perform the test because the substance is a UVCB"

"The test is not needed since the substance and its relevant degradation products decompose rapidly"

Justification for data waiving

Examples of incomplete / complete justifications for data waiving

6.1.7 Toxicity to micro-organisms (REACH Annex VIII, 9.1.4)

"Test not needed based on results from the test on soil microorganisms"

"There is no emission to a sewage treatment plant"

7.8.1 Toxicity to reproduction (REACH Annex VIII, 8.7.1)

"Study is on-going"

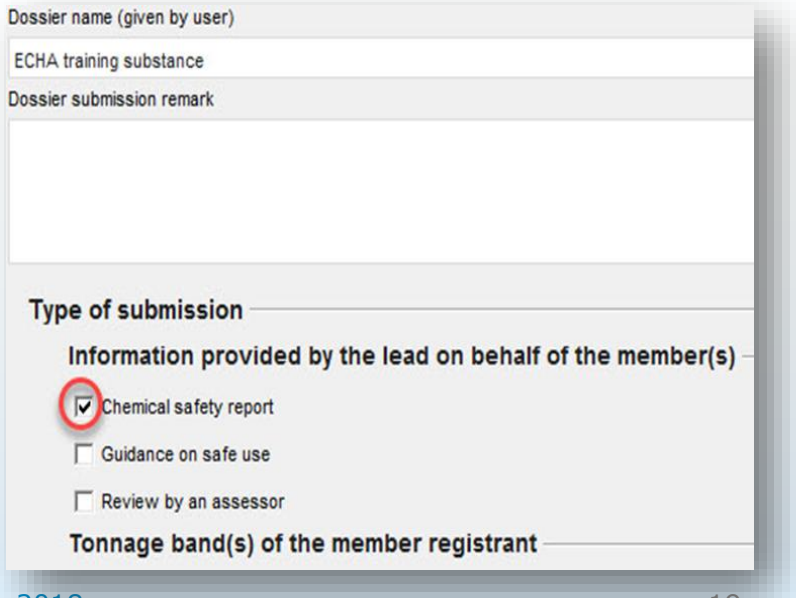
"A pre-natal developmental toxicity study (Annex IX, 8.7.2) is available"

Chemical safety report

Chemical safety report should be provided for substances manufactured or imported >10 tpa, or a justification why it is not required, should be included.

- If a chemical safety report is not attached, a justification why it is not required should be included in section 13.1 field **'Further information on the CSR attached / remarks'** or the field **'Discussion'**

- For member registrants: if the lead registrant has provided the chemical safety report on your behalf, you should indicate this in the dossier header under 'information provided by the lead registrants on behalf of the member(s)'



Take home messages

- Read the manual "How to prepare registration and PPORD dossiers"
- Insert information into correct IUCLID fields
- Use provided templates whenever possible and include relevant scientific justifications
- Justifications should be based on REACH
- More information about manual checks