How to bring your registration dossier in compliance with REACH – Tips and Hints Part 2

Water solubility

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Water solubility:

Water solubility (WS)

- One of the key parameters to define environmental fate properties (bioaccumulation, biodegradation). Consequently, it has a very high impact on the safety assessment of the substance

Water solubility

- REACH information requirements

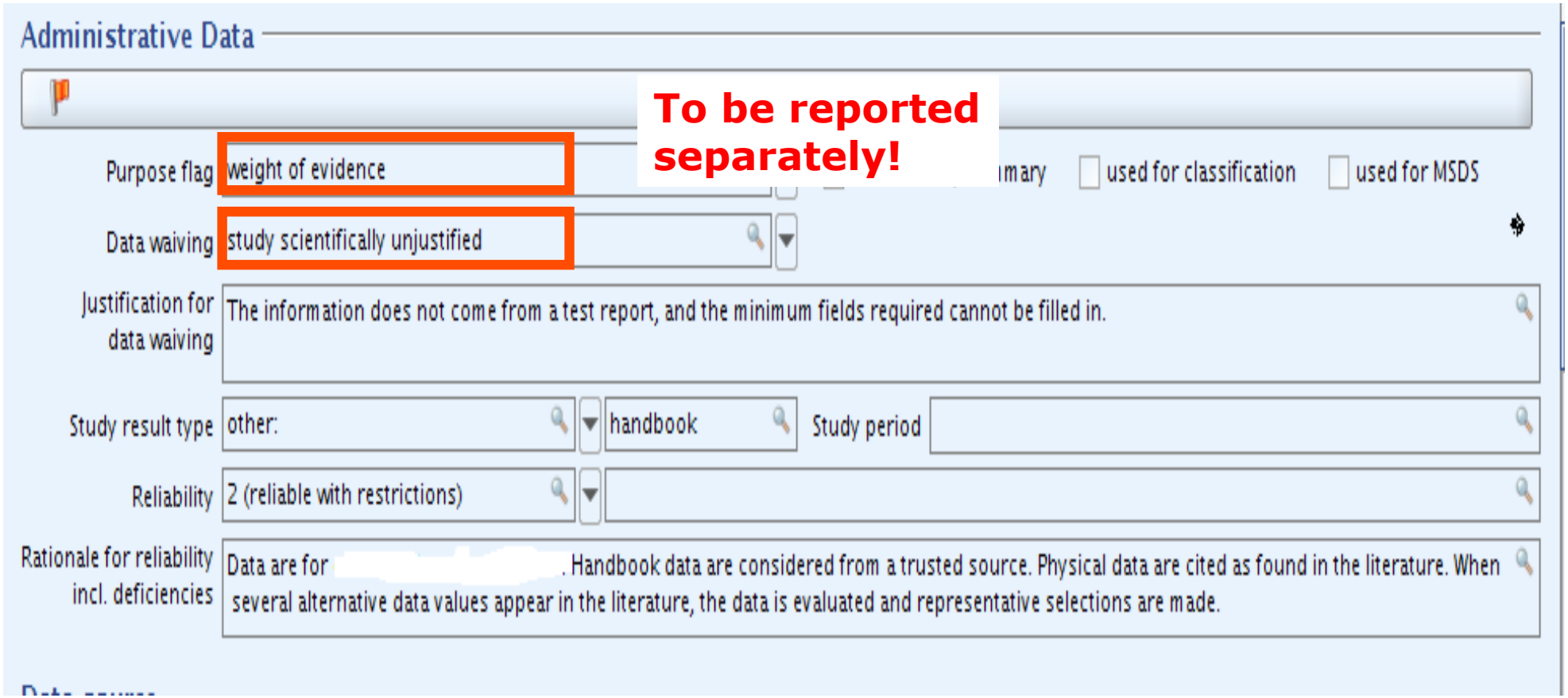
	Column 1	Column 2
Annex VII	7.7. Water solubility	The study does not need to be conducted if: **-the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours) or** **-The substance is readily oxidisable in water.** If the substance appears "insoluble" in water, a limit test up to the detection limit of the analytical method shall be performed
Annex XI	Section 2	**-Technically not possible (e.g. substance very volatile, flammable in contact with water).**

Water solubility: recommendations (1)

- Avoid conflicting information within the same endpoint study record in the IUCLID dossier
- If the intention of the registrant is to assess the different pieces of available information in reaching a conclusion concerning a property, then "weight of evidence (WoE)" has to be ticked
- If, on the other hand, the registrant considers that the study does not need to be conducted as adaptation rules (Annex VII and Annex XI) apply, then "data waiving" should be the option selected in the dossier
- If both WoE and data waiving apply, report them in separate endpoint study records (see previous presentation "Improving the compliance of registration dossiers")

Water solubility: recommendations

- **Do not select** simultaneously purpose flag (e.g. "weight of evidence") and "data waiving" (e.g. "study scientifically unjustified").

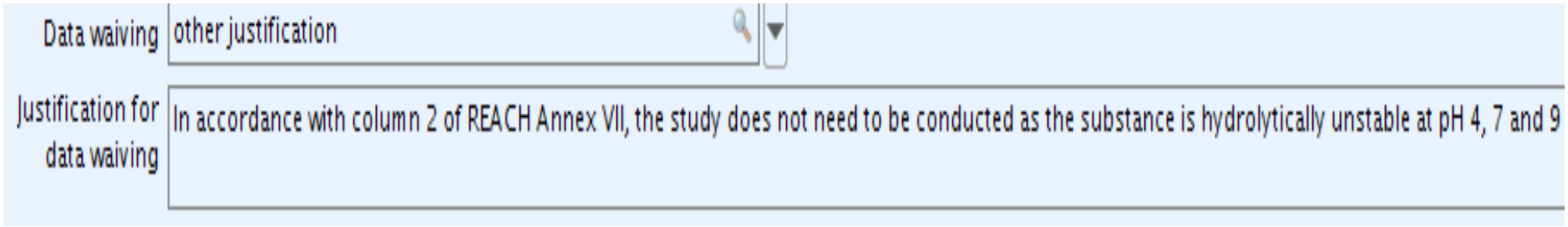


Water solubility: recommendations (2)

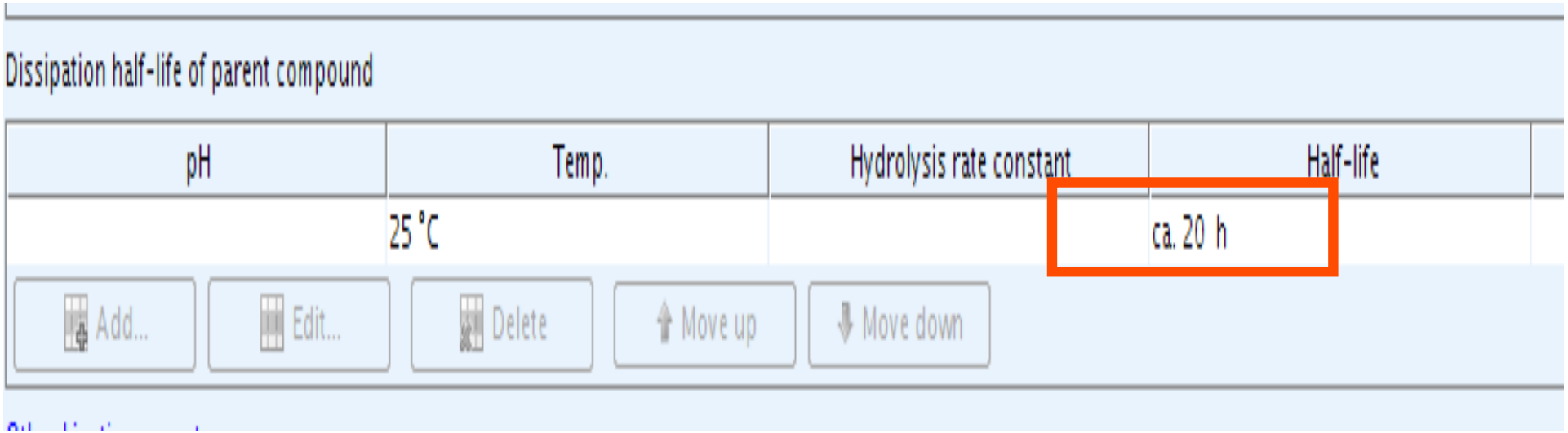
- For cases providing waiving statements based on the fact that the substance is hydrolytically unstable there should be reliable evidence of the hydrolysis of the substance as a function of the pH, if not, the waiving statement cannot be followed and the water solubility endpoint is, therefore, non compliant.

Water solubility: recommendations

- Waiving statement for water solubility

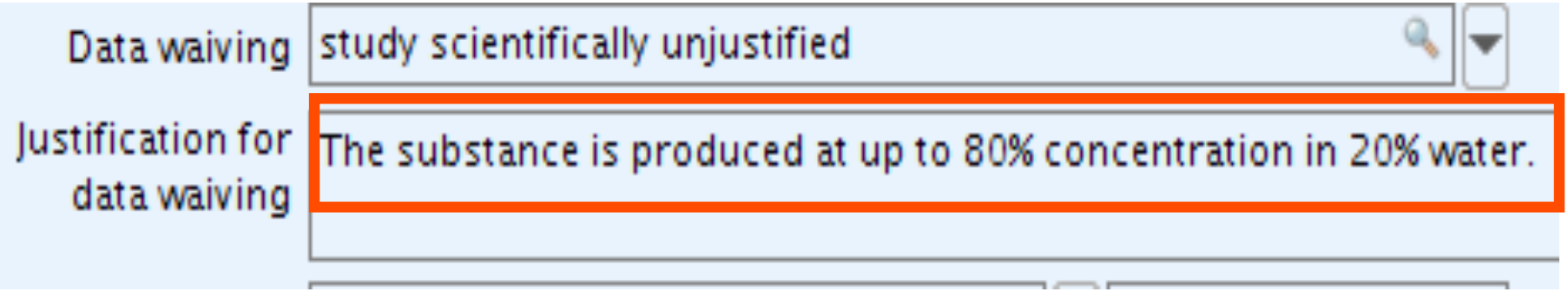


- Information on hydrolysis endpoint unacceptable as pH is not stated and half-life is not below < 12 hours



Water Solubility: recommendations (3)

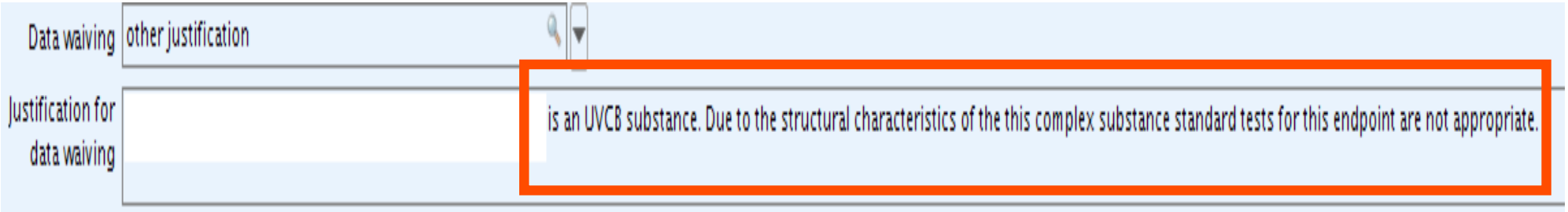
- Cases have been detected showing an insufficient justification for waiving based on factors other than hydrolysis (example 1: substance is manufactured in water, etc).



  - This waiving is unacceptable as the substance is soluble in water. It is technically possible to obtain an experimentally valid value for water solubility.

Water solubility: recommendations

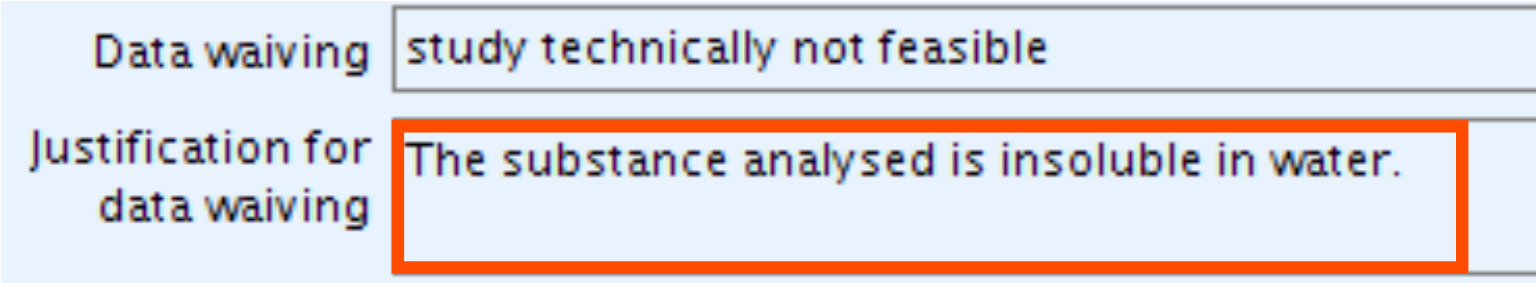
- Cases have been detected which present an insufficient justification for waiving based on factors other than hydrolysis (example 2: due to structural characteristics of UVCB substance, standard tests are not appropriate)



  - The endpoint specific guidance (see link at the end of the presentation) is very clear in this regard: "a number of standardised methods are available for the determination of single substances and complex mixtures of liquids and solids"
  - This justification is, therefore, unacceptable

Water solubility: recommendations

- Cases have been detected which present an insufficient justification for waiving based on factors other than hydrolysis (example 3: the substance analysed is insoluble in water).



- If the substance appears insoluble a limit test shall be performed; alternatively, the "insoluble nature" of the substance can be further substantiated with a documented, reliable and adequate QSAR value (see link at the end of the presentation on how to report QSARs)

Water solubility: summary

- The study needs to not be conducted only if: **the substance is hydrolytically unstable, readily oxidisable, or is technically not feasible**
- If the conditions are met for adaptation of the required information (according to the REACH Regulation annexes) the registrant shall clearly state this fact and the reasons for each adaptation. These reasons have to be scientifically substantiated
- In every other case, there has to be a valid endpoint study record for water solubility

Water solubility: guidance

- Guidance on information requirements and chemical safety assessment
- Chapter R.7a: Endpoint specific guidance
- Practical guide 2: How to report weight of evidence
- Practical guide 4: How to report data waiving
- Practical guide 5: How to report (Q)SARs

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Thank you