

Guidance on the Assessment of Special Preparations

ECHA guidance for downstream users

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Workshop on Special Preparations

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Downstream User (DU) Chemical Safety Report (CSR) for a Preparation

- DU can develop Exposure Scenario (ES), including Risk Management Measures (RMM) and fulfil legal obligations to prepare DU Chemical Safety Assessment (CSA) for 1 or more substance(s) for which this is required;
- The obligation of making CSR is related to single substances → CSR for preparations is voluntary;
- A DU CSR for a preparation may be more resource efficient than making several assessments for different substances separately.

DU CSR for a Preparation – In practise (1)

- Development of the ES for the preparation can be focused on the critical components in the preparation, *if it can be documented that the risks from all other substances are covered by this.*
- To identify the critical component(s) within a whole preparation, also information on substances for which no ES is received or which are not yet registered but are known to be dangerous, need to be taken into account.
- Additivity rules should be applied in the same way as is done for the classification of preparations
- Matrix effects of the preparation can be considered with regard to the mobility of the substances (in the case of alloys, e.g. casting processes)
- The final exposure scenario derived in the assessment may cover a range of substances, with different properties, in the preparation.

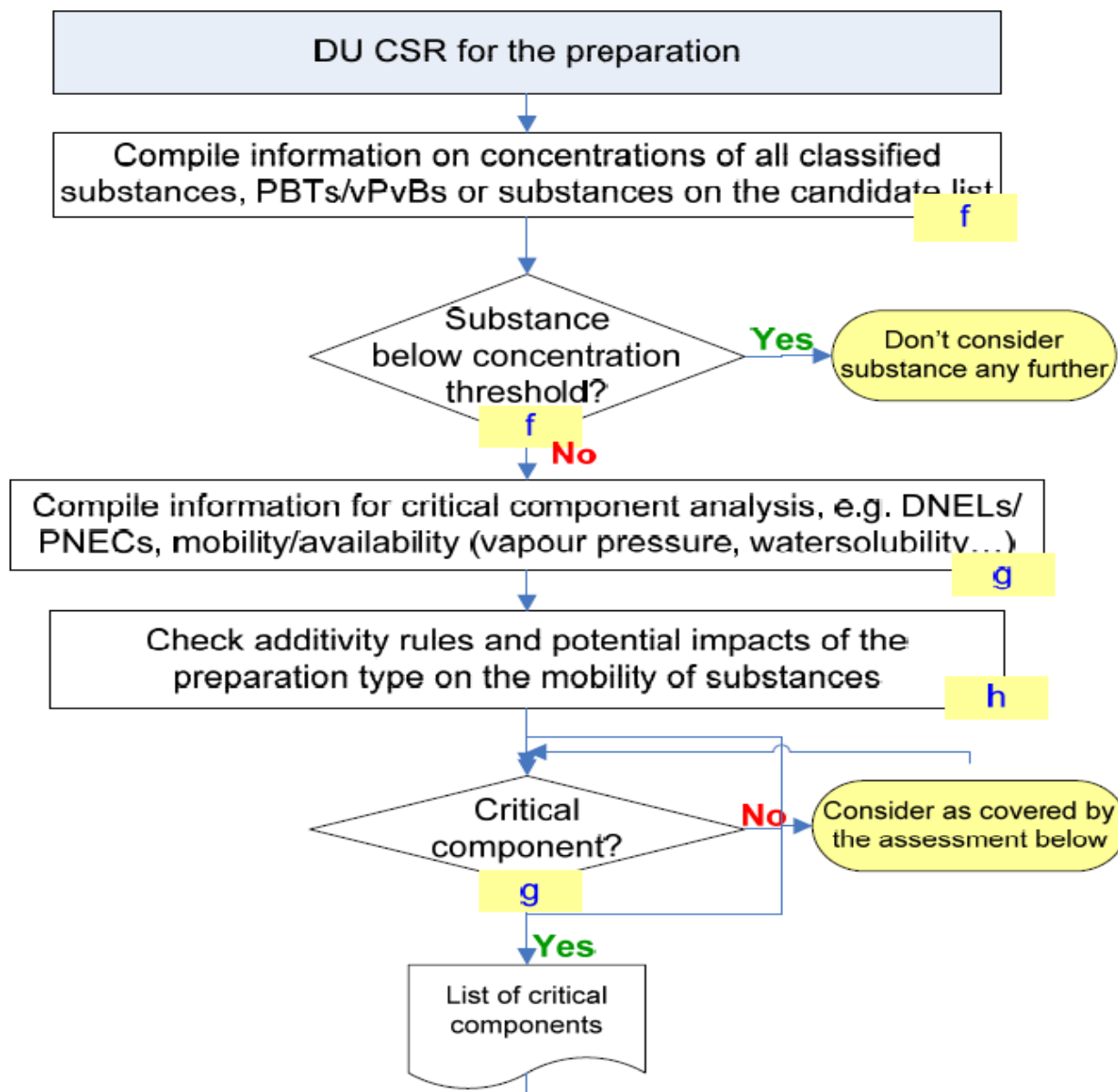
DU CSR for a Preparation – In practise (2)

- Solvent producers do not like this approach (Critical Component Approach; CCA)
- Solvent producers developed the DPD approach (which is only based on the classification of the dangerous substances)
- We are not satisfied with that as it does not include the Matrix Effect
- Solvent producers now propose DPD+ as an alternative (which includes “availability criteria”)

DU CSR for a Preparation – In practise (3)

- The assessment of physico-chemical risks from a preparation can, and in many cases must, be based on testing of the preparation.
- The assessment of risks for human health and the environment is based on the properties of the single substances, that means the *DNELs and PNECs are used in the risk characterisation*.
- To assess exposure levels, in some cases the properties of the preparation influence the mobility of the substances, *e.g. alloys*, and this should be taken into account.

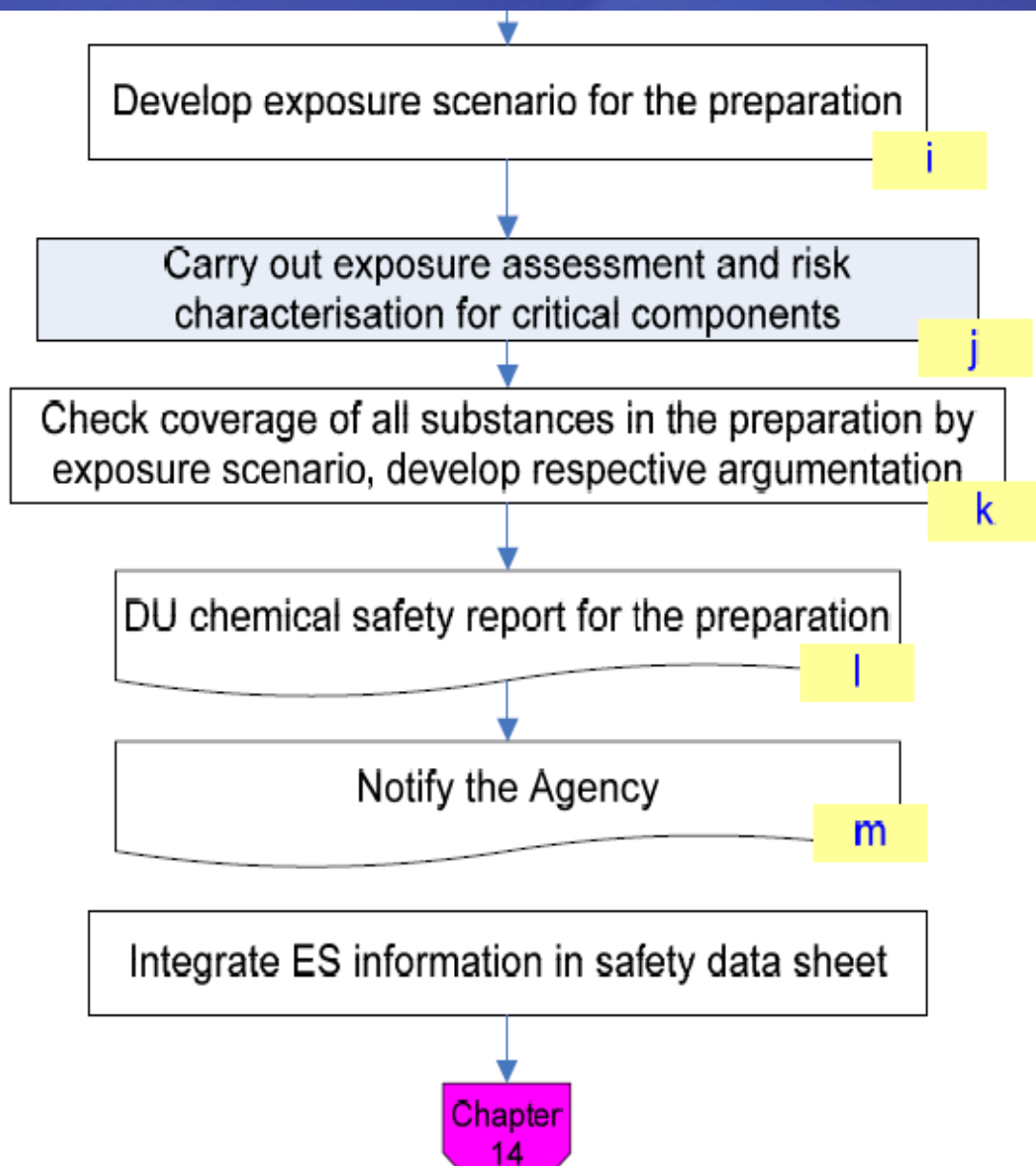
Workflow on DU CSR for preparations (1)



Abbreviations

DNEL = Derived no effect level
 DU CSR = Downstream user chemical safety report
 ES = Exposure scenario
 SDS = Safety data sheet

Workflow on DU CSR for preparations (2)



Thank you for your attention

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