

ECHA Guidance for Downstream users The essentials

Chapters 7 and 8

05 March 2014

Fesil Mushtaq
Risk Management Identification
European Chemicals Agency



Chapter 7: Communication in the supply chain related to mixtures





For formulators of mixtures

- I. Legal obligations
- II. How to identify/collate/align information from suppliers regarding substances and uses
- III. How to identify safe use information to communicate
- IV. How to communicate this information

I. Legal Obligations in the Guidance

- Outline of main obligations
- Table of main Articles in Title IV of REACH with clarification **NEW**



Table of main Articles in Title IV - extract

REACH Article	Regulation	Clarification
31(1)	<p><i>The supplier of a (...) mixture shall provide the recipient of the (...) mixture with a safety data sheet compiled in accordance with Annex II:</i></p> <p><i>(a) where a (...) mixture meets the criteria for classification as dangerous in accordance with Directive 1999/45/EC;</i></p> <p>.....</p>	<p>An SDS is required if the mixture is classified as dangerous according to DPD. The requirements for the SDS are presented in Annex II of REACH. A detailed guidance is provided in the Guidance on the compilation of SDSs.</p> <p>Some of the requirements of Annex II change on 1 June 2015, to implement the transition to the CLP Regulation. The SDS for any mixtures which are on the market before 1 June 2015 (in accordance with DPD) does not have to be updated until 1 June 2017. However, if a supplied product is labelled according to CLP, the SDS must be in compliance with the later version of Annex II (June 2015).</p> <p>Note that the requirements relating to providing an SDS apply to all hazardous substances and mixtures, and not only those that are registered under REACH. Also, sub paragraphs (b) and (c) of Article 31(1) refer only to substances.</p>
31(2)	<p><i>Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment.</i></p> <p><i>If the safety data sheet is developed for a mixture and the actor in the supply chain has prepared a chemical safety assessment for that mixture, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the mixture instead of with the chemical safety assessment for each substance in the mixture</i></p>	<p>The information in the SDS must be consistent with the CSA for the substance. If a CSA is prepared for a mixture as a whole, the SDS can be based on this CSA.</p> <p>A CSA for a mixture is not defined in REACH. Annex I and Annex XII of REACH refer to CSA/CSR for single substances for registrants and downstream users respectively.</p>



II. Dealing with information received from suppliers - i

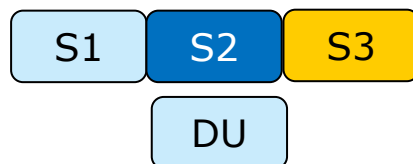
- i. Receiving information from supplier:
 - Are substances REACH-registered?
 - Are exposure scenarios expected / included?
 - Is information from all raw material SDSs included?
 - Is exposure scenario for given substance received from all suppliers? **NEW**



II. Dealing with information received from suppliers - ii

- ii. Collating information you receive:
- Align the received ES into consolidated versions if needed
 - Check classification for a given substance is the same/consistent
 - Select appropriate ES if different ES is received for the same substance from different suppliers **NEW**

Example: Selecting appropriate ES for the same substance from different suppliers



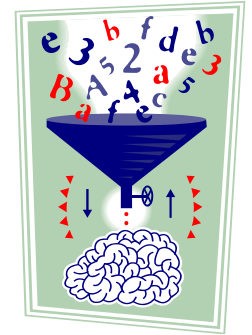
May select less stringent

If selecting exposure scenario that is not most stringent :

- verify that the substance, its properties and the use are actually the same
- confirm that the selected measures ensure safe use
- document the justification for the decision

Nevertheless, contact your suppliers and inform them of the differences with a view to aligning their exposure scenarios.

III. Identify information to communicate



- Main approaches are outlined: **NEW**
 - **Exposure Scenario approach (top down)**: Build risk management advice for the mixture from the exposure scenario information received from suppliers.
 - **Mixture Use approach (bottom up)**: Base on existing risk management advice for the mixture and check against the exposure scenario information received from suppliers.
- Core principles – Appendix 3

IV. Communicate the information effectively



Attach relevant
ES(s) to the SDS

NEW

Append safe use
information to SDS

Integrate
information in body
of SDS

Identify RMM info
from an ES

IV. Communicate the information effectively

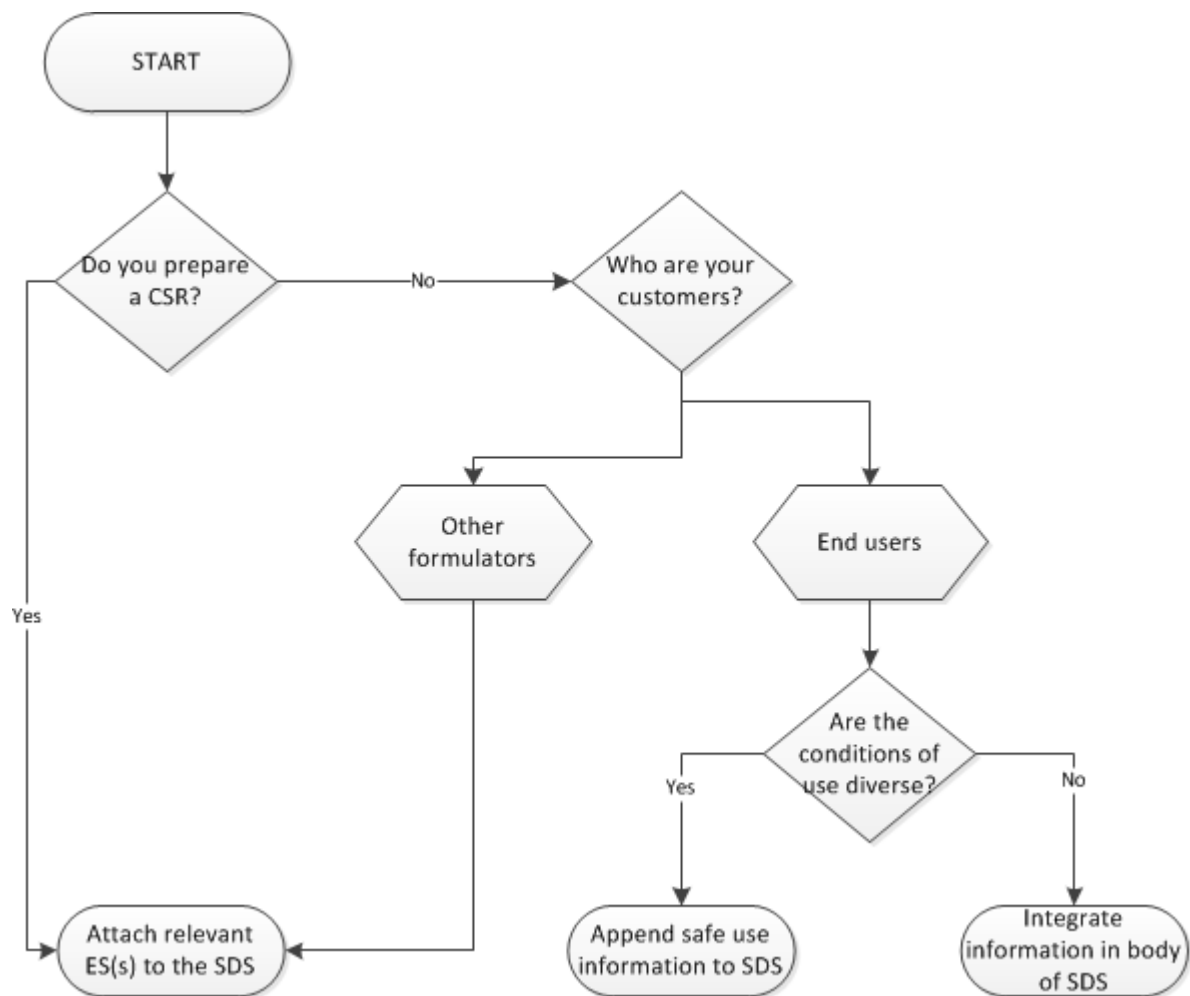
Attach relevant
ES(s) to the SDS

Append safe use
information to SDS

Integrate
information in body
of SDS

IV. Communicate the information effectively

General Guidelines
- Independent of
communication
option



Chapter 8: Requirements related to authorisation, restrictions and substances in articles



Authorisation

- REACH Process: ECHA website and Guidance
- Check Candidate List, Authorisation List
- Application for Authorisation (AfA)
 - Check Exemptions
- DU actions overview: consultations (timelines), information communication, notification to ECHA
- Seminar & workshop on Authorisation in April 2014

Restrictions

- REACH Process: ECHA website and Guidance
- Check List of Restrictions
- Check Exemptions
- DU actions overview: consultations (timelines), substance and use information communication

SECTION 15: Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use:

Other EU regulations:

Substances in articles **NEW**

- REACH Process: ECHA website and Guidance
- Check Candidate List, Registry of Intentions
- Check Exemptions
- DU actions overview: Information communication, notification to ECHA
- **Be prepared!!**

Thank you!