

# Session 3.1 Overview of guidance for DUs with respect to Mixtures

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# Review of the Guidance for Downstream Users

Incorporates feedback from:



- Comments after presentation of guidelines at ENES3
- Partner Expert Group (May- June 2013)
- Member State Competent Authorities and Forum
- CARACAL (including observers)

**Expected Publication Date: December 2013  
(with Guidance in a Nutshell)**

## DU Guidance for formulators on mixtures



1. Legal obligations
2. How to identify/collate/align information from suppliers regarding substances and uses
3. How to identify safe use information to communicate
4. How to communicate this information

# 1. Legal Obligations in Guidance for Downstream Users

- Outline of main obligations
- Table of main articles in Title IV with clarifications **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>

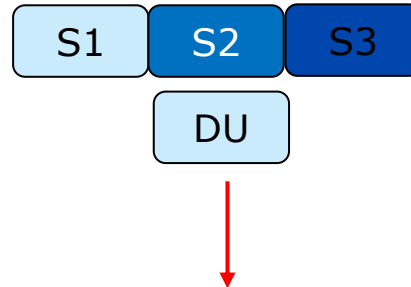
## 2a. Receive the information from suppliers

- Receiving information from the supplier of raw materials for a mixture:
  - Are substances REACH registered?
  - Are safety data sheets (SDSs) available for all raw materials?
  - Are exposure scenarios (ESs) expected / appended?
  - If exposure scenario for given substance is received, has it been received from all suppliers? **NEW**

## 2b. Collate the information from suppliers

- Collating information you receive:
  - Align the received ESs for all raw materials so that uses/conditions of use/terminology are comparable
  - If raw material is received from more than one supplier:
    - Check classification is consistent from all suppliers
    - Combine information into a consolidated ES for the substance if necessary
    - If RMMs differ significantly between suppliers, select the appropriate measures and document the decision **NEW**

## Selecting appropriate ES for the same substance from different suppliers



**May select less stringent ES**

If selecting RMMs from less stringent exposure scenario:

- 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.*



## 3. Identify information to communicate

- Main approaches are outlined: **NEW**
  - **Exposure Scenario approach:** Build risk management advice for the mixture from the exposure scenario information received (top down).
  - **Existing Controls approach:** Base on existing risk management advice for the mixture and check against the exposure scenario information received from suppliers. (bottom up).
- Detailed description of how to identify information to communicate, and how to undertake CSR for mixture was removed from original guidance

## 4. Communicate the information effectively

(i) integrate the information into the main body of the SDS  
(as SDS Guidance) **NEW**;

or

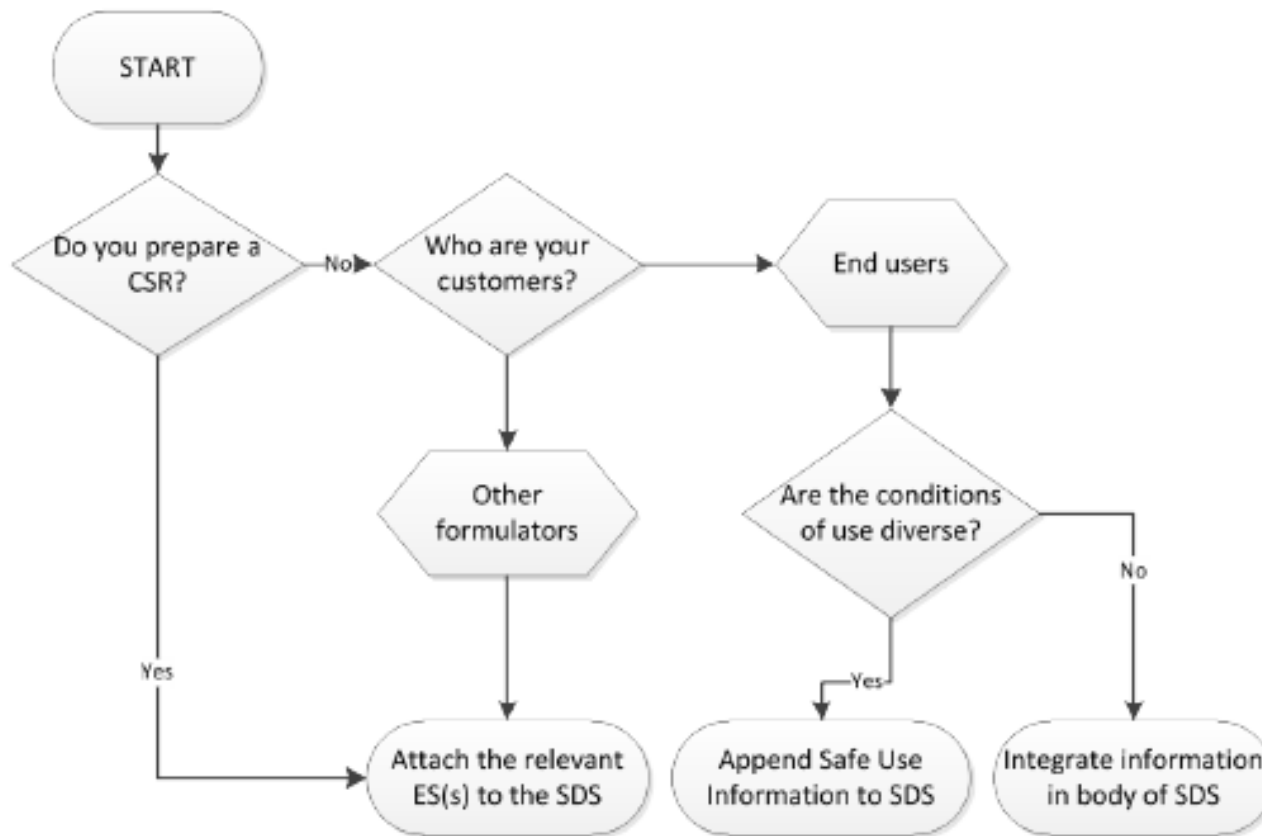
(ii) append safe use information for the mixture (previously referred to as consolidated ES for mixture) **NEW**;

or

(iii) attach relevant exposure scenarios for the substances in the mixture in an annex

The obligations of the downstream user remain the same, regardless of how the information is communicated

# Communication options illustrated



## General Guidelines for Formulators

### **For all Communication Options**

- Only include relevant identified uses
- The OCs and RMMs are appropriate and proportionate
- All relevant information received is included
- Use standardised methods and descriptors if possible
- Safety data sheets and exposure scenarios are in national language(s)
- Reviewed when new information available
- The process is documented

### **Substance ES or Safe Use Information for Mixture is annexed to SDS**

- Annex and SDS main body are consistent
- Important information is easy to retrieve and to understand
- Include relevant exposure scenarios only

### **Info from ESs is integrated in main body of SDS**

- Identify RMM information from an exposure scenario **NEW**
- See also Guidance on compilation of SDS

Thank you!

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