



Downstream Users of Chemicals Co-ordination group

***“Real life” exposure scenarios***  
***good practices and suggested improvements***  
***from the DU perspective***

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24-25 November 2011



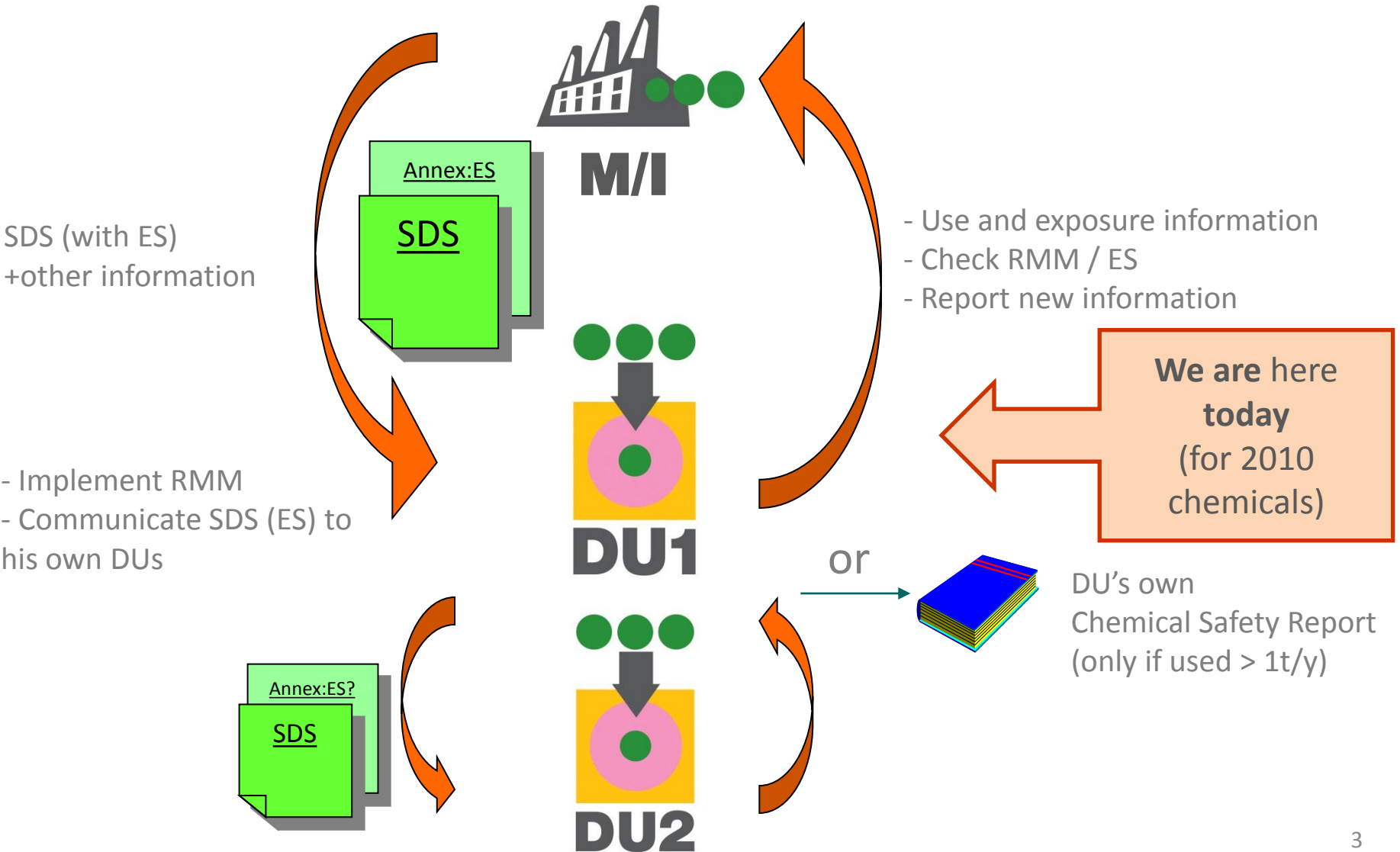
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**DUCC** = platform for associations whose member companies use chemicals to formulate mixtures as finished products for end users (consumers and professional users)

**DUCC** focuses on DU needs, rights, duties and specificities under REACH and CLP



# DU rights and duties on safe use communication





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# Background

- Downstream Users need to be able to **understand, handle and extract information** contained in safety data sheets and exposure scenarios in order to fulfill their duties
- Main barriers today
  - Lack of practical guidance (under development)
  - Lack of standard format/phrases for ES communicated in SDS
  - Supply chain communication has been and remains chaotic
  - 12-month deadline for complying with ES is very challenging
  - Tools/methods for update of SDS of mixtures still missing
  - Language/translation issues
- The presentation focuses on **first-line formulators**



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# DUCC Workshop (27 May 2011)

- Topic: Exposure Scenarios for communication (extended SDS)
- Objective: review of current practices/first experience based on real-life exposure scenarios received by formulators
- Outcome: list of good practices / recommendations
- Notes:
  - only a fraction of extended SDS expected have been received so far (10-30%), so learning will continue
  - DUs prefer receiving well structured and clear ES even if this comes at a later stage (provided there is no new major risk identified)



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# Good practices – recommendations: locating relevant ES

- **Insert a table of content** of ES at the beginning of SDS annex
  - Simple: list of ES short titles with references, following R12 guidance advice
  - e.g. professional use of cleaning products (SU22, PC35)

Table 1. Overview of Exposure Scenarios for

ES #	Exposure Scenario
1	Manufacture of Substance and use as intermediate – Industrial
2	Distribution of Substance - Industrial
3	Formulation & (Re)packing of Substances and Mixtures – Industrial
4	Uses in Coatings – Industrial
5	Uses in Coatings – Professional
6	Uses in Coatings – Consumer
7	Uses in Cleaning Agents – Industrial
8	Uses in Cleaning Agents – Professional
9	Uses in Cleaning Agents – Consumer
10	Use in oil field drilling and production operations - Industrial
11	Lubricants – Industrial
12	Lubricants – Professional
13	Lubricants – Consumer
14	Metal working fluids/rolling oils - Industrial
15	Metal working fluids/rolling oils - Professional
16	Blowing agents - Industrial
17	Use as Binders and Release Agents – Industrial
18	Use as Binders and Release Agents – Professional
19	Use in Agrochemicals – Professional
20	Use in Agrochemicals – Consumer
21	Use as a Fuel – Industrial
22	Use as a Fuel – Professional

Example 1  
Table of content



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ES number	Manufacture	Identified uses			Resulting life cycle stage		Linked to Identified Use	Sector of Use (SU)	Product Category (PC)	Process Category (PROC)	Article Category (AC)	Environmental Release Category (ERC)
		Formulation	End use	Consumer use	Service life (for articles)	Waste stage						
1a & 1b	X							3, 8, 9	NA	1, 2, 3, 4, 8a, 8b, 15	NA	1, 4, 6a
2	X							3, 8, 9	NA	1, 2, 3, 4, 8a, 8b, 9, 15	NA	1, 2, 3, 4, 5, 6a, 7
3		X						3, 10	NA	1, 2, 3, 4, 5, 8a, 8b, 9, 14, 15	NA	2
4			X					3	NA	1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15	NA	4
5			X					22	NA	1, 2, 3, 4, 5, 8a, 8b, 10, 11, 13, 15, 19	NA	8a, 8d
6				X				21	1, 4, 8, 9, 15, 18, 23, 24, 31, 34	NA	NA	8a, 8d
7			X					3	NA	2, 3, 4, 7, 8a, 8b, 10, 13	NA	4
8			X					22	NA	2, 3, 4, 8a, 8b, 10, 11, 13	NA	8a, 8d
9				X				21	3, 4, 8, 9, 24, 35, 38	NA	NA	8a, 8d
10			X					3	NA	1, 2, 3, 4, 7, 8a, 8b	NA	4
11			X					3	NA	1, 2, 3, 4, 7, 8a, 8b, 9, 10, 13, 17, 18	NA	7, 4
12			X					22	NA	1, 2, 3, 4, 8a, 8b, 9, 10, 11, 13, 17, 18, 20	NA	8a, 8d, 9a, 9b

2 |

Example 2  
Table of content



Can we harmonise format of table of content ?

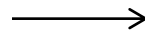
# Good practices – recommendations: use description

- **Use descriptors** are well established and broadly used
  - Sometimes inconsistently assigned or misunderstood
  - ↳ **Continue to build experience/understanding (ECHA Guidance R12)**

- Structure **ES titles around use descriptors:** will enable automation

## 1. ES 1: Consumer end-use (SU 21); washing and cleaning product

Sub-PC +  
Consexpo titles



1. Title of Exposure scenario	
PC 35: Washing and cleaning product	
Environment: Component released during end-use	ERC 8a
Consumer	
Use of laundry and dishwashing product	PC 35
Use of trigger spray cleaner products	PC 35
Use of liquid cleaning product for manual surface application	PC 35
Use of abrasive product for manual surface application	PC 35
Use of liquid cleaner for cleaning carpet	PC 35

- Use ES titles from **use mappings from sector organisations** for consistency and understanding by DU



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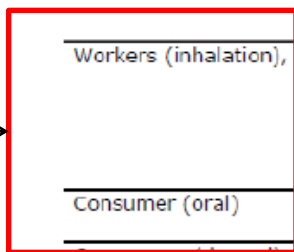
# Good practices – recommendations: ES building

- **Develop separate ES for each main user group**
  - Consumer use ES (SU21)
  - Professional use ES (SU22)
  - Industrial use ES (SU3)

3.3 Operational conditions related with substance / product	
Physical state	Liquid
Concentration of substance in mixture	Up to 12% w/w

5. Prediction of exposure resulting from the conditions described above and the substance properties	
Workers (oral)	Good workplace hygiene practice has to be followed and oral exposure is not relevant for workers.
Workers (dermal)	Dermal exposure to cleaners containing 12% w/w <input type="text"/> is possible. The use of gloves (PVC, rubber) is recommended. The use of safety glasses is required when pure cleaners are handled.
Workers (inhalation), RMMs	Calculated with ConsExpo (maximum concentration)
	Spray cleaning 0.002 mg/m <sup>3</sup> (7% w/w), acute exposure
	Cleaning by wiping, brushing 1.07 mg/m <sup>3</sup> (7% w/w), acute exposure
	Using toilet cleaner 1.16 mg/m <sup>3</sup> (12% w/w), acute exposure
	Using cleaner containing <input type="text"/> 1.07 (7% w/w), reasonable worst case long-term exposure
Consumer (oral)	Under normal use conditions oral exposure to cleaners containing the substance can be neglected.
Consumers (dermal)	Dermal exposure to cleaners containing 12% w/w <input type="text"/> is possible. The use of gloves (PVC, rubber) and safety glasses is recommended.
Consumers (inhalation)	Calculated with ConsExpo (maximum concentration)
	Spray cleaning 0.002 mg/m <sup>3</sup> (7% w/w), acute exposure
	Cleaning by wiping, brushing 1.07 mg/m <sup>3</sup> (7% w/w), acute exposure
	Using toilet cleaner 1.16 mg/m <sup>3</sup> (16% w/w), acute exposure

Worker & consumer under same scenario →



# Good practices – recommendations: ES content

- **Use standard phrases** as much as possible
  - eases translation and future automation
  - ↳ **Pursue on-going developments**
  
- Use **ECHA’s ES headings** /structure

<b>1. Title of Exposure scenario</b>
short title, activities/processes covered in the ES and corresponding use descriptors
<b>2. Conditions of use affecting exposure</b>
<b>2.1 Contributing scenario environment</b>
operational conditions and risk management measures
<b>2.2 Contributing scenario [worker or consumer]</b>
operational conditions and risk management [workers or consumer]
<b>3. Exposure estimation and reference to its source</b>
<b>Environment</b>
[worker or consumer] exposure
<b>4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b>
In particular where the DU may use scaling methods

*More details in IR/CSA guidance Part D and ECHA’s examples of ES*

# Good practices - recommendations: ES building

- Growing practice for structuring content
  - **One ES = one life-cycle stage**
  - Consistency in building/assigning **Contributing Scenarios**
    - In general, one CS = one PROC/ERC + one set of OC/RMM + corresponding RCR
    - Note: it can also be one activity, several PROCs

1 Exposure Scenario (2)			
Formulation and repacking			
SU 3, 10			
PC1, 3 ,4, 8, 9a, 14, 15, 21, 23, 24, 25, 26, 27, 29, 31, 32, 34, 35, 38, 39			
PROC 1, 2, 3, 4, 5, 8b, 9			
ERC 2			
Formulation/blending in batch processes, transfers and packaging will describe the group of contributing scenarios listed below:			
Scenario name	Process Category (PROC)	Type of setting	Short name
Use in closed process	PROC 1	industrial	CS 1
Used in closed, continuous process w/ occasional controlled exposure	PROC 2	industrial	CS 2
Use in closed batch process	PROC 3	industrial	CS 3
Use in batch and other process where opportunity for exposure	PROC 4	industrial	CS 4
Mixing and blending	PROC 5	industrial	CS 5
Transfer to small containers	PROC 9	industrial	CS 6
Transfer at dedicated facilities	PROC 8b	industrial	CS 7

Good practice: ES/CS split + table format

Product characteristic	
Physical state: gas/liquefied gas	
Concentration: >25% (ECETOC TRAM does not modify exposure estimates for substances in mixtures if >25%)	
Amounts used	
Not applicable	
Frequency and duration of use/exposure	
Exposure frequency: daily for all PROCs	
Scenario name	Duration of activity [hours/day]
CS 1	> 4 hours
CS 2	> 4 hours
CS 3	> 4 hours
CS 4	1-4 hours
CS 5	> 4 hours
Human factors not influenced by risk management	
None	
Other given operational conditions affecting workers exposure	
Scenario name	Use of ventilation
CS 1	Outdoors
CS 2	Indoors without LEV
CS 3	Outdoors
CS 4	Indoors without LEV
CS 5	Indoors without LEV

Good practice: one CS= one PROC = one set of OC/RMM

# Good practices - recommendations: information

- **Balance amount of information** and structure lay-out
    - Good: Exposure assessment tool + essential use parameters + RCR
    - Include RCR (or exposure values) for each PROC/PC/ERC, not just the worst case PROC/PC/ERC
- ↪ **useful for scaling / checking use is covered / margin of safety**

~~Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out in section 10.1.~~

~~These additional measures are presented in the appendix to section 10 and are coded blue. To control risks as described by RCRs presented in section 10.1a only Operational Conditions and Risk Management measures as described in section 2.2 above (coded black in the appendix to section 10) have been taken into account.~~

~~(ii) 9.1a.2 Exposure Estimation~~

~~1) 9.1a.2.1 Human Health~~

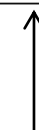
~~The endpoint for which the available data may trigger a qualitative risk characterisation includes eye irritation and is described in section 10. This qualitative CSA approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature.~~

~~Exposure Estimation for all other human health endpoint covered by DNEL or DMEL is performed in context of risk assessment and set in relation to the respective DNEL/DMEL(s) as shown in the Appendix to section 10. Resulting risk characterization ratios (RCR) are presented in section 10.1.~~

~~2) 9.1a.2.2 Environment~~

~~In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary; however a qualitative risk assessment is provided in section 10.~~

Route	Exposure concentration (EC)	DNEL	Risk characterisation ratio = EC/DNEL
dermal	2.743 mg/kg <sub>bw</sub> /day	2,158 mg/kg <sub>bw</sub> /day	0.001271
inhalation	0.266667 mg/m <sup>3</sup>	152 mg/m <sup>3</sup>	0.001754
Combined routes	2.781 mg/kg <sub>bw</sub> /day	-	0.003025



Good practice:  
Exposure +DNEL +RCR per route



Do not send copy of CSR to DUs



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## Good practices - recommendations: other

- Report **good practice advice separately** from Section 2
  - RMM/OC may go beyond CSR (not driven by REACH)
- Indicate **effectiveness of RMM**; however,
  - ‘apply appropriate measures’ is too broad
  - LEV 99% effectiveness is difficult to comply with in practice
- OC/RMM are often too **restrictive**: driven by conservatism of models? Lack of information on DU practices? Liability?
- **Provide scaling algorithms** in the ‘DU Advice’ section (Tier-1)



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## Additional considerations related to SDS

- Conflicting information from main body and annex of the SDS (uses, RMM...)
- Clarify in substance SDS **why there is no registration number + why no ES attached**
- More than ever, **quality of SDS (main body)** is essential



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# Conclusions

- ES are a novel concept for all parties: learning is on-going
- **Extended SDS: clarity is more important than size**
  - Quick localisation of relevant ES by DU
- Some good practices are emerging: capitalise of them
  - Implementing some of the above recommendations would be a nice step forward
- Flexibility vs standardisation: a Cornelian choice!
- IT support would (will) help greatly
- We are only at the beginning of a long process...



DUCE



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**Let's work together !**

