



Feedback to Supplier about Use
(Specific Exposure Scenarios)
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Disclaimer: this presentation was not given during the workshop



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Content



- **Obligations and related communication in the supply chain**
- **Which types of feedback may be required?**
- **How can the Specific Exposure Scenario (SES) template be used for feedback upstream?**
- **When are other means more appropriate?**
- **Conclusions**

Obligations in the Supply Chain



Registration phase

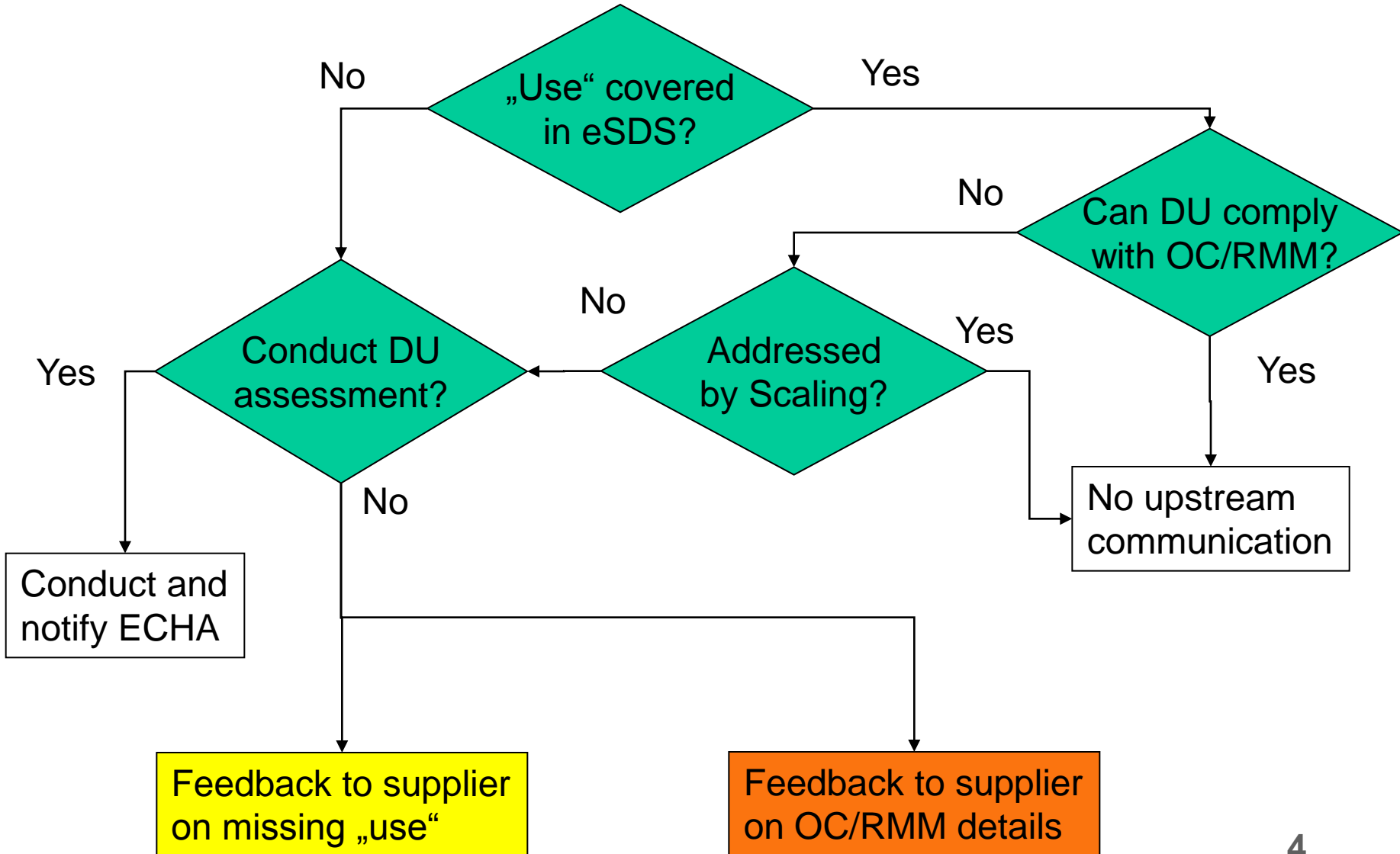
- **Manufacturers / importers (M/I)** to conduct chemical safety assessments (CSA), describe the conditions of safe use for all identified uses of the substance and document the assessment in the CSR including exposure scenarios (ES)
- **Downstream users (DU)*** have the right to make their uses known and shall provide sufficient information so that they can be covered in CSA

Post-registration Phase

- **Manufacturers/ importers (M/I)** to communicate the operational conditions (OC) and risk management measures (RMM) via the extended safety data sheet (eSDS) to downstream users (DU)
- **Downstream users (DU)*** have to comply with the supplier's OCs and RMMs as communicated via eSDS and to provide any information possibly calling into question the RMMs in the eSDS

* Compare REACH Art. 34 (b) and Art 37

DU Evaluation of eSDS and Options



Feedback on Missing “Use”



- **Feedback on missing “use” could refer to**
 - **Entire Exposure Scenario (ES) missing**
e.g. a specific industrial end-use
 - **Contributing Scenarios (CS) missing within ES,**
e.g. no laboratory use (PROC 15) included
- **Type of information to be communicated is in most cases equivalent to use alignment in preparation of registration (= entire sets of information)**

=> CEFIC SES template is available to communicate ES/CS information



CEFIC SES Template

- Originally in **“Top-down dialogue”** format, i.e. pairs of columns for supplier proposal and DU response
- Developed for use by the **first levels** in the supply chain
- Templates available for **different ESs** (e.g. worker/ENV, consumer/ENV) and **multiple Contributing Scenarios (CS)** can be addressed
- Use descriptors and OCs, RMM, etc. can be **entered via drop-downs** in simple technical language
- **Focus on TIER I** (ECETOC TRA) determinants for exposure assessment plus some extra determinants, e.g. dermal protection

=> The **“proposal”** or **“new use column(s)”** can be used for feedback on eSDS **or** equivalent information communicated in **structured format outside of template** (template used for reference only)

Example for Worker/ENV Template



Instructions/explanations

„Proposal“

1	Short title exposure scenario		
1.1	Internal name	Free text	
1.2	Sector(s) of Use (SU)	Listing [full description in glossary in line below] - multiple SU per ES possible. Please list as: SU 1, SU 3, ...	SU 3, SU 10
Gloss.:	SU 10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)		
1.3	Process Category(ies) (PROC)	Selection [full description in glossary in line below]	PROC 3
Gloss.:	PROC 3 Use in closed batch process (synthesis or formulation), Industrial setting;		
1.4	Product OR Article category	Select EITHER product OR article category in 1.4.1 or 1.4.2	
1.4.1	Product Category(ies). (PC)	Listing [full description in glossary in line below] - multiple PC's per ES possible. Please list as: PC 1, PC 3, ... The use of PC's in worker scenario's is optional and can often be indicated as PC not applicable	PC1, PC 3
Glossary:			
1.4.2	Article Category(ies). (AC)	Listing [full description in glossary in line below] - multiple AC per ES possible. Please list as: AC 1, AC 3, ... The use of AC's in worker scenario's is optional and can often be indicated as AC not applicable	AC 1, AC 3
Glossary:			
1.5	Environmental Release Category(ies) (ERC)	Selection [full description in glossary in line below]	ERC2
Gloss.:	ERC2 Formulation of preparations		

Example for Worker CS – PROC 3



3	Human health - Workers		
3.1	Type of use	Please select professional or industrial use or both	Industrial
3.2.1	Physical form under conditions of use	Select one of the following options:	Solid
3.3.2	Dustiness category for solid substances.	In case of a solid (powder): select one of the dustiness options.	Moderate
3.4	Max. duration of inhalatory exposure.	Explanation on exposure duration > 4 h: equals less than 8 hours 1 h - 4 h: equals less than 4 hours 15 min - 1 h: equals less than 1 hour < 15 min (short term)	> 4 hours
3.5	Outdoor or indoor operation and application of Local Exhaust Ventilation (LEV)	"outdoor" will assume 30% reduction of exposure compared to indoor without LEV, for indoor please specify whether LEV is used:	Indoor without LEV
3.6	Use of respiratory protection equipment (RPE).	Indicate type of RPE, when RPE is used on a regular basis. Please also indicate the efficiency e.g. >90% for half face mask, >95% for full face mask:	>90%
3.7	Use of dermal protective clothes and gloves.	Select Yes / No	Yes
3.8	Dilution factor of the product.	Free text. e.g. factor 2 = 50%, 4 = 25%, always based on product entering the process) [Required to determine the max. concentration of the substance in the product at process stage]	

Example for Environmental CS – ERC 2



5	Environmental exposure		
5.1	Maximum amount of product used per year. If the amount used is variable, use the higher value as the maximum tonnage to be covered.	Select tonnes of product per year	30000
5.2	Use of sewage/waste water treatment plant (STP) for selected ERC	STP may not be applicable, no STP may be used or a public (=default), onsite or a combination of both (in case of STP, please also see section 5.5.4)	Public
5.3	Max. number of emission days per year	Number of emission days per year (ERC defaults for Life Cycle Stage (LCS) and tonnage are proposed, if spERCs are used, this will be replaced by spERC default)	300
5.4.1	Industry sector for spERC	Selection of industry sector for this use to view available spERC in cell below. Industry sectors (AISE, FEICA) have developed spERC's in order to better address industry sector specific environmental release conditions. spERC's will overwrite a selected ERC in section 1.	ESVOC
5.4.2	Industry sector spERC - will overwrite ERC in risk assessment	Selection spERC's can only be selected if a suitable spERC is available	ESVOC 4

...

- * NOTE: CEFIC SES template is currently updated to
- align with ECETOC TRA v2 incl. > 170 spERCs and R.12
- reflect 4-point ES structure



Feedback on OC/RMM within CSs (1)

- **Examples for typical situations where required:**
 - Unclear RMM phrases, e.g. efficiency not specified for respiratory protection considered in TRA assessment
 - Use of LEV advised but not available at DU => subject to scaling or “minimum requirement” (Art. 37, 4 (d))?
 - Operations at elevated temperatures not covered
 - Change of physical form during process not addressed
 - ERC based assessment resulting in volume restriction or RMMs not workable for DU
 - Scaling information (ES section 4) missing or unclear
 - etc.

=> Written and/or verbal communication (phone/meeting) on OC/RMM details, as appropriate



Feedback on OC/RMM within CSs (2)

- **General Recommendations for written/verbal feedback:**
 - Avoid long free text - **stay focussed** on relevant information (use references such as ES format, SES template, CEFIC guidance documents, etc.)
 - Be **clear in locating the issue**, e.g. which product, which eSDS version, which ES, which CS, which OC/RMM
 - Follow **TIERed approach** – don't “over-communicate”
 - Clarify issues in a **dialogue** where appropriate **and document** verbal agreements in writing
 - If **higher TIER** assessments are required, try to **coordinate information collection and exchange with supplier** to make process as targeted and efficient as possible (e.g. sharing and use of references)



Conclusions

- The **SES template** can facilitate feedback on eSDSs primarily in case of **missing ESs or CSs** in a structured and targeted way for TIER I assessments
- The need for **feedback on OC/RMM details** depends on
 - how well the “alignment of uses” in the supply chain worked during the preparation for registrations
 - whether suitable phrases were selected for eSDS-ESs
 - how the scope of scaling is defined
- **Feedback to suppliers on OC/RMM details** should aim to be **structured and clear** to help clarification and to facilitate any re-assessments by the M/I
- A **better understanding of relevant use information** to be communicated in the supply chain would be helpful, particularly if iterations lead to **higher TIER assessments**
- Current experiences should help to better **align uses for 2013** registrations
- The **SES template will be further updated** to align with ECETOC TRA version 3 and CHESAR 2.0 to support 2013 registrations

Questions ?



Thank you for your attention!



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