



Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products

Downstream User Chemical Safety Assessment / Report DU CSA/CSR

Sophie Mathieu
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Introduction

DUCC Initiative

- Started in July 2011
- Examples from different sectors on going
- Compilation of inputs and sharing of examples by January 2012

Why did we do the exercise?

- Guidance on DU is limited
- No example of DU CSA/CSR available
- Annex XII is not specific
- Is it a realistic option for DUs? And When?

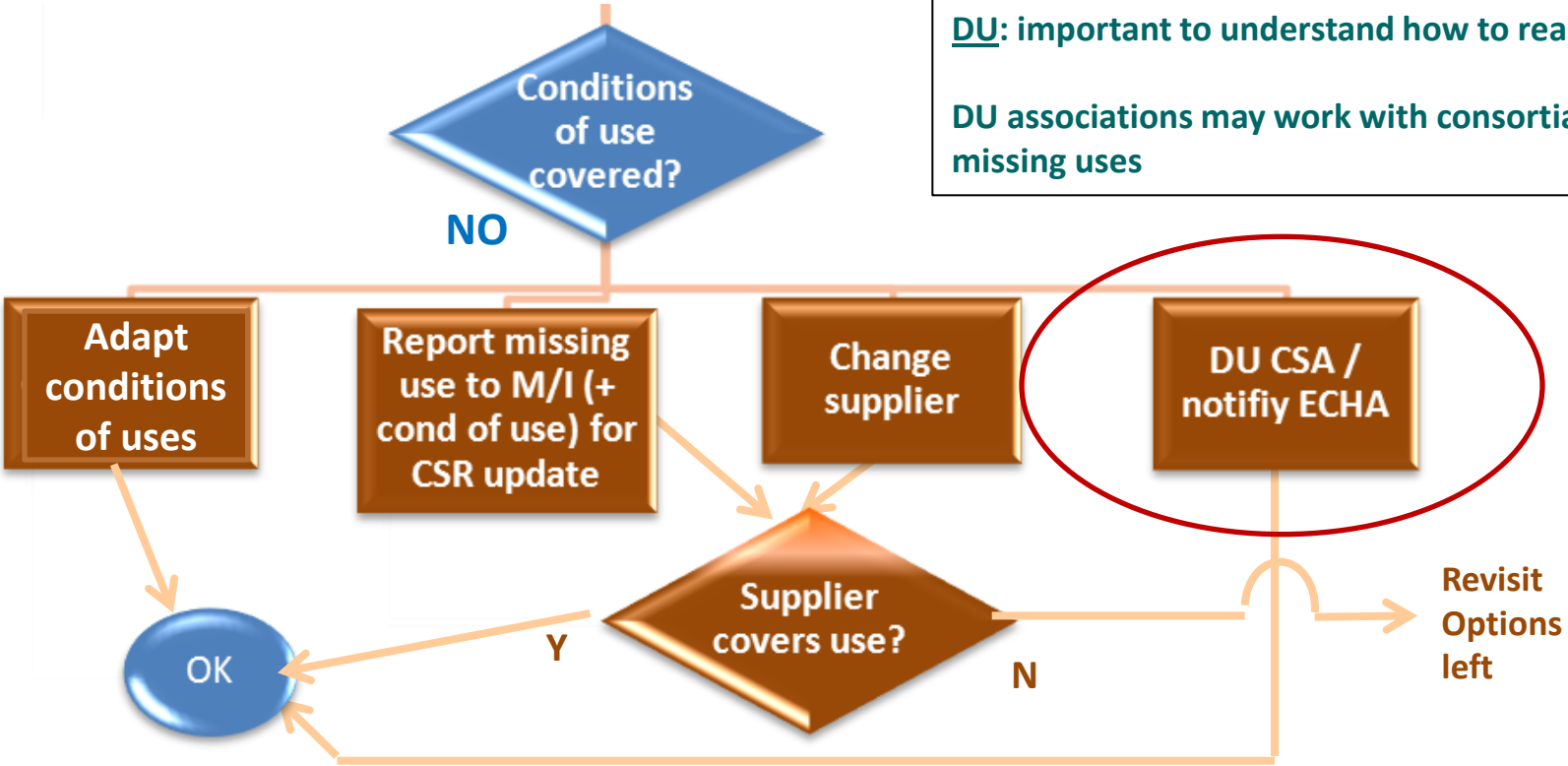
Are my uses covered? Options for DU

Caution: not all options are equivalent !

- time-wise
- feasibility

DU: important to understand how to read an ES

DU associations may work with consortia on missing uses



My use is not covered: Options for DU



Options	PROs	CONs
Adapt conditions of use (to supplier recommendations)	-If only related to PPE, may be easy to implement	- Site related measures can be very difficult to implement and very expensive
Report missing use to M/I for CSR update	-Powerful solution if good dialogue already exists (1 st level communication)	-Increase dependency on M/I -Too long if lot of levels in supply chains -Uncertainty (type of use/ insufficient info) -No standardised tool to help
Change supplier	-Quick solution (Do not apply to all cases)	-Restrict your substance sources -Uncertainty on use coverage by other supplier -Purchasing contacts may not be flexible
DU CSR	<ul style="list-style-type: none"> -Certainty on use(s) coverage -Less dependency on supplier decision -Flexibility in sourcing -Reduce SC communication -Keep use confidential 	<ul style="list-style-type: none"> -Resources and expertise needed -Data from SDS not always sufficient -Annex an ES to your SDS -Challenging timeframe (6/12 months)
Reformulation	/	<ul style="list-style-type: none"> -Uncertainty on use covered for new substance -Time and resources for re-formulation -Not sure on acceptance by customers

When is a DU CSR needed?

According to Article 37.4

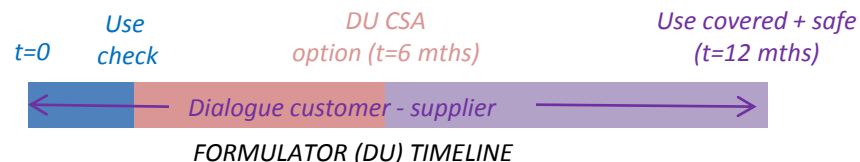
- Use outside the conditions described in an exposure scenario
- Use and exposure category outside the ones of SDS
- Use advised against
- (Use confidential – not communicated)

Except if:

- SDS is not required for substance/mixture
- CSR is not required to be completed by his supplier
- DU uses substance/mixture in total quantity < 1 tpy
- DU implements / recommends RMM communicated
- Substance present in mixture in a concentration lower than concentration limits that trigger classification
- Substance used for PPORD

Timing for DU CSR

- DU compliance deadlines on uses and ES (substance & supplier specific) start from the day you receive an extended SDS with a registration number.
- If your use is not covered and you wish to use DU CSR option you have according to Article 39:
 - 6 months to report to ECHA (online tool not available yet)
 - 12 months to carry out your own chemical safety assessment and to implement related exposure scenarios



How to perform a DU CSR?

- Accordance with annex XII
- Steps of a DU CSR:
 - Development of Exposure Scenario(s) – section 5 of annex I
 - Define OC and RMM
 - Exposure estimation
 - If necessary, refinement of hazard assessment
 - Step done by supplier, if DU considers it as appropriate no further assessment to be done
 - Otherwise, human health, physicochemical and environmental hazard assessment to be done (sections 1 to 4 of annex I)
 - Risk characterisation
 - Comparison of exposure estimation with DNEL / PNEC / physicochemical properties (section 6 of annex I)
 - Production of a CSR detailing his chemical safety assessment (section 7 – part 9 & 10 of annex I)

DU CSA – A.I.S.E. Case study

Consumer use of cleaning product

- Consumer use not covered in a surfactant ext-SDS
- Applications considered:
 - Hand dish wash product
 - Toilet block
- Today, only Human health assessment performed, stop at assessment level
- Agreement with hazard assessment of the supplier
- Consideration of a joint effort with Colipa to cover environmental part for consumer use of cleaning product and cosmetic product

Case study – Consumer use of cleaning product

– Development of exposure scenario for tier 1 tool (ECETOC TRA)

- Use descriptor
- Definition of OC (% of substance in product)
- Use of sentinel product or product subcategory in TRA as applicable
- Calculation of exposure estimate using the model

To run Tier 1 assessment tool, for consumer use of a product, limited (substance and use) information is necessary to assess human health exposure. Knowledge of exposure assessment tool is necessary. Tier 2 calculation are more complex! Unclear if all input parameters are available.

Case study – Consumer use of cleaning product

- Hazard assessment (data from SDS)*
 - Identification of data from relevant sections (8-9-10-11)
 - In case of inconsistency, verification through the ECHA dissemination website

If SDS is REACH compliant, all information would be available in the SDS to enable the DU CSA (Tier 1).

If some information are missing, how do you handle it? Based on the restricted data at your disposition can you safely derive your own DNEL, PNEC?

* In the context of this exercise it was decided to agree with the hazard data provided by the supplier

Case study – Consumer use of cleaning product

– Risk characterisation

- Comparison of exposure estimation with applicable DNEL/PNEC
 - If $RCR < 1$, stop the process
 - If $RCR > 1$, refine the exposure assessment

If $RCR < 1$, limited effort to be handled by DUs so DU CSA is a manageable exercise. Anyway even for tier 1, good knowledge of the tool is needed

If $RCR > 1$, it may become very complex and require higher level expertise (tier 2)

First learning – Findings from assessment exercise

- Not many SDS have the relevant information included in the 16 sections/ annex
- Inconsistency between main body and annexes: How to deal with that?
- Local language may be a barrier for REACH experts
- Typo mistakes and irrelevant information – Use of ECHA dissemination website
- Key information missing like no DNEL derived: How to handle it in the best way? In-house expertise needed
- What to do when needed information are missing?

Next steps – Other considerations

- When scaling stops and DU CSA starts?
- Performing a DU CSR should be feasible from information received from extended SDS / ECHA dissemination website. Is it applicable for tier 2 assessment?
- How to draft DU CSR and to communicate it via SDS was not investigated yet
- Is Chesar an option for DU CSR?
- Consideration for reporting to ECHA (article 38):
 - Substance identity?
 - 6 months notification should be kept simple : Express intent to do a DU CSR

Conclusions

- In case a use is not covered (and scaling not possible), DU CSR may be an interesting option for DU
- One of its main advantages is to become independent from individual M/I on uses coverage
- Even for a simple case, a minimum of expertise is required
- Data from SDS are not always sufficient, and thus how to handle it?
- Uncertainty on the data to be notified to ECHA via reporting tool
- Timing will be anyway a challenge (especially as the clock starts ticking as soon as SDS received) – One year is short to assess all options

Thank you for your attention

Any questions?