LATEST DEVELOPMENTS/GUIDANCE ON COMMUNICATING SAFE HANDLING OF CHEMICALS UNDER REACH (Registration, Evaluation and Authorisation of Chemicals)

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- Chair of Generic Exposure Scenario Working Group, European Solvents Industry Group (ESIG)
- REACH Consultant
- Personal view
• To improve information provided in Supplier Safety Data Sheets

• For SDSs to include the required safe handling controls for the end user without the need to do their own assessment
  • In particular for SMEs with limited in-house skills

• Laudable vision, but fraught with issues known only too well by Occupational Hygienists...
Latest Developments/Guidance on safe use communication under REACH

1 Reminder on REACH requirements
2 Current situation – The Challenge?
3 What is being done about it?
4 Will it work?
5 Existing complementary approaches
6 Piloting the approaches
7 General comments
1. REACH (Registration, Evaluation and Authorisation of Chemicals)

REACH Established new Safe Use Advice requirements

- Aims to improve the protection of human health and the environment

- Registrants of classified substances to provide safe use advice for all uses via Exposure Scenarios (ES) in extended Safety Data Sheets (eSDSs)

- Downstream users (DU) to abide by specified use conditions in eSDS – add-on to Occupational H&S regulatory compliance
REACH Requirements for Registrants – for all marketed substances

- Substance Registration
  - Chemical Safety Assessment with demonstration of safe use
    - RCR <1
  - Hazard assessment (Human Health/Environment)
    - DNEL/PNEC
  - Conditions of Use (OCs)/RMMs
  - Exposure estimation
  - Use Identification through supply chain
  - Exposure assessment
  - Risk Characterisation

- Communication of safe use through the supply chain
  - Extended Safety Data Sheet
  - Chemical Safety Report
  - IUCLID Dossier
  - Exposure Scenarios
Article 37: legal obligation to follow the advice contained within the ES for their use of the substance.

Carry out a check that their use and conditions of use are covered.

1. if yes, no further action needed

2. if there isn’t an exact match, but adjustments can be applied to balance the differences and maintain an equivalent level of exposure (Scaling), no further action needed

3. if no, the following options are available:
   a. Contact the supplier to seek their use is included in the registration
   b. Implement the conditions of use from the exposure scenario
   c. Substitute for another substance meeting their conditions of use
   d. Find another supplier who covers your use
   e. Prepare a DU Chemical Safety Report
Formulators

Obliged to include in their SDS relevant exposure scenarios, and use other relevant information from the Safety Data Sheet(s) supplied to him.

This can be done by:

a. integrating the information into the main body of the SDS; or
b. appending safe use information for the mixture; or
c. attaching relevant exposure scenarios for the substances in the mixture as an annex.
2. Current Situation - The Challenge?

Formulator:
- Finding the correct Exposure Scenario (ES) in a Supplier’s SDS which may be many pages long
- Understanding the information included in the ES – can include confusing exposure assessment technical details, e.g. skin exposure area (cm$^2$)
- Not finding your use(s)/having inappropriate conditions of use information
- How to consolidate information from ES for many components into clear safe use information for the formulation?

End Users:
- Where to begin???
- What’s the added value???
3. What is being done about it?

Supply Chain Communication essential

• Exchange Network on Exposure Scenarios (ENES) est. 2011
  – Industry Sector organizations, ECHA and Member State authorities
  – Cefic (includes multitude of individual Sectors), Concawe, Eurometaux

• Related action items in the CSR/ES Roadmap
  • Improve quality of exposure information throughout supply chain
  • Support formulators in developing safe use advice for mixtures
ENES tools

Bottom up Approach - Sector driven

SUMI = Safe Use of Mixture Information
LCID = Lead Component IDentification
ECHA Use Map Elements

Overview of common uses in a Sector

Workers: Sector-specific Worker Exposure Description (SWED)

Consumers: Specific Consumer Exposure Determinant (SCED)

Environment: Specific Environmental Release Category (SPERC)

Link to ECHA Use Map Templates

Details taken directly into Substance CSA via Chesar
### Only adjustment permitted concentration

<table>
<thead>
<tr>
<th>SWED No.</th>
<th>Field name</th>
<th>Field content</th>
<th>SWED Title</th>
<th>Field code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Worker determinants of exposure

Each SWED has a corresponding SUMI – Safe Use of Mixtures Information sheet.
SUMI (Safe Use of Mixtures Information)

- Sector-specific approach to generate and communicate information on safe use for customers
- Suited to end-use mixtures with clearly defined markets and uses
- SUMI Format: intended to communicate safe use information for mixtures to downstream end-users
- Relevant SUMIs to be ‘selected’ by formulators
- SUMIs reflect uses and Conditions of Use described in the Sector Use Map (SWED): harmonised content
**Mandatory SUMI content**

<table>
<thead>
<tr>
<th>SUMI: Safe Use of Mixtures Information for end-users</th>
<th>Sector / Company logo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**General description of process covered**

*May include use descriptor codes or reference to SWED*

<table>
<thead>
<tr>
<th>Maximum duration:</th>
<th>xx min.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other:</td>
<td>xxx</td>
</tr>
</tbody>
</table>

**Risk Management Measures**

- Required RMMs, use of pictograms
  - Reference to Section 8 of SDS for RMM specifications
  - If applicable: any environmental measures

**Disclaimer**

- Disclaimer on boundaries of SUMI use

**Optional SUMI content**

**Good practice advice**

- If relevant, applicable (sector-specific) good practice advice

**Use of pictograms**

*Available when applicable*

**Additional information on product composition**

- To include references to other relevant sections of SDS or product label

**Read in conjunction with product SDS and labels**

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*Example SUMI - CEPE*
Evolution of REACH ‘Use Maps’

- 2015 – ECHA acknowledged the need for better description of uses and conditions of use
- Intended to better address needs of (80%) formulators and end-users by
  - Reflecting typical OSH practices at a sector level
  - Delivering consistent ES across substance suppliers
  - Facilitating development of ES for mixtures
- One stop-shop ECHA’s library
  - Link to Use Map Library
4. Will it work?

• Requires all Downstream Sectors to prepare Use Maps
  • What about those Sectors without Use Maps?
  • What about those end uses without a defined Trade Assn to prepare Use Maps?

• With only concentration as the adjustable parameter –
  • For the substance: what if can’t demonstrate safe use (RCR<1)?
  • For the mixture: what if it contains 2 or more components with similar/additive health effects? Will this be taken into account by the formulator in SUMI selection?

• What about existing approaches?
5. Existing complementary approaches

2010 – 1st Registration phase – the Generic Exposure Scenarios (GES)

- Pragmatic solution endorsed via stakeholders’ communication/alignment (~ 30 titles – Industrial, Professional, Consumer)
  - Maps typical supply chain-uses and applications (standardized across sectors)
  - Incorporates low Tier (screening) exposure assessment
  - Delivers safe use advice (operational conditions and risk management measures based on typical use conditions) in ES format
- Widely relied on by registrants in developing original CSAs for High Production Volume (HPV) substances (e.g. solvents)
### GES and SWED ‘templates’ - overview

#### Table 1: Mapping Uses in the Supply Chain

<table>
<thead>
<tr>
<th>User Group</th>
<th>Contributing Scenarios</th>
<th>Typical Mapped Operating Conditions</th>
<th>Typical Mapped RM/CE</th>
<th>Process Category / TRA equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industrial</td>
<td>Bulk transfers</td>
<td>Daily: 15 min - 1 hour; ambient temp; collection of waste in container</td>
<td>Enclosed transfers, vented for points clear lines prior to decoupling</td>
<td>PROC01: Dedicated discharging to/from vessels</td>
</tr>
<tr>
<td>Industrial</td>
<td>General process exposures from enclosed processes</td>
<td>Continuous; daily; hour</td>
<td>Enclosed process, closed semi-closed sampling point</td>
<td>PROC1 and PROC2: Closed continuous process</td>
</tr>
<tr>
<td>Industrial</td>
<td>General process exposures from closed processes</td>
<td>Batch process; daily; ambient temp.</td>
<td>Closed equipment, enclosed or vented transfer points</td>
<td>PROC3 and PROC4: Closed batch process</td>
</tr>
<tr>
<td>Industrial</td>
<td>Charge from drums</td>
<td>Daily: 15 min - 1 hour; ambient temp.</td>
<td>Pumped transfer from drum to holding tanks</td>
<td>PROC02: Discharging to/from vessels</td>
</tr>
<tr>
<td>Industrial</td>
<td>Printing</td>
<td>Daily: &gt;4 hours; ambient</td>
<td>Local exhaust ventilation at roll; remove spills as they occur; PPE</td>
<td>PROC10: Roller application and brushing</td>
</tr>
<tr>
<td>Industrial</td>
<td>Roller and equipment cleaning</td>
<td>Daily: 15 min - 1 hour; ambient temp; collection of waste and wipe cloths in container; PPE</td>
<td></td>
<td>PROC12: Uses by dipping/pouring</td>
</tr>
</tbody>
</table>

#### SWED Template

<table>
<thead>
<tr>
<th>Row No.</th>
<th>Field name</th>
<th>Field content</th>
<th>Information for communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>SWED title</td>
<td>Free text</td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>SWED code</td>
<td>Free text</td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Description of process activity covered*</td>
<td>Free text</td>
<td>Standard phrase</td>
</tr>
<tr>
<td>1.5</td>
<td>Relevant SUMI(s) for end-user communication</td>
<td>SUMI reference(s)</td>
<td>SUMI reference(s)</td>
</tr>
</tbody>
</table>

**1.6 Relevant contributing activity(ies)*

- **1.6a.1 Contributing activity/scenario name* | Free text | Free text/Standard phrase |
- **1.6a.2 Corresponding PROC* | Select PROC |

**2 Conditions of use for workers (input to CSA)**

- **2.1 Percentage (w/w) of substance in mixture* | Free text |
- **2.2 Duration of activity* | Enter maximum duration (units) | ESDCom phrase code(s) |
- **2.3 Place of use* | Select place of use | ESDCom phrase code(s) |
- **2.4 Physical form of the used product* | Select physical form | ESDCom phrase code(s) |
- **2.5 Operating temperature (°C)* | Enter maximum temperature | ESDCom phrase code(s) |
- **2.6 General ventilation* | Select general ventilation | ESDCom phrase code(s) |
- **2.7 Local Exhaust Ventilation (LEV)* | Select Yes/No | ESDCom phrase code(s) |
- **2.8 Use of Respiratory Protection Equipment (RPE)* | Select Yes/No | ESDCom phrase code(s) |
- **2.9 Use of gloves & other dermal protection* | Select Yes/No |
- **2.10 Use of eye protection* | Select Yes/No | ESDCom phrase code(s) |
- **2.11 Occupational Health and safety management system* | Select OHS system | ESDCom phrase code(s) |

**3 Description of other conditions of use, if relevant for specified exposure assessment tool**
6. Cefic Pilot - Use maps/SWEDs - Observations

Use maps

- Very detailed use names ➔ lengthy & repetitive use titles ➔ increased # of ESs
- Overlaps between industry sectors ➔ duplicate or contradictory ESs

GES v SWED based ES for communication... Impact for Formulators??

<table>
<thead>
<tr>
<th></th>
<th>GES</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coverage</strong></td>
<td>Wide, across-sectors</td>
<td>Increased # of ES in eSDS</td>
</tr>
<tr>
<td><strong>Inputs</strong></td>
<td>Conservative to ‘lowest common denominator’</td>
<td>Enable Tiered approach</td>
</tr>
<tr>
<td><strong>Level of detail</strong></td>
<td>Low Tier screening CSA</td>
<td>Better link with workplace RA</td>
</tr>
<tr>
<td><strong>Ease of Use</strong></td>
<td>Flexible, allow scaling on RMMs</td>
<td>One-to-one communication prone</td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td>Concise, structured eSDS</td>
<td>Higher risk of non-compliance</td>
</tr>
</tbody>
</table>
7. General comments...

• Trying to resolve supply chain block and deliver targeted safe use advice for specific chemical applications – to be applauded

• More details available on Conditions of Use – helpful for CSA iteration

• Driven by ‘requirement’ to demonstrate use alignment AND consistency with conditions of use (OCs and RMMs) in substance Exposure Scenario

• Potential conflict between incoming safe handling ‘requirement’ and outcome of existing local risk assessment – which is right?

• Is SUMI selection robust? E.g. Concentration issue

• Other mixture approaches available – to be fully developed and tested

• LCID (Lead Component Identification)/Generic SUMI (based on CSA of mixture)
General comments...

- What about general H&S guidance materials from regulators, Sectors and Suppliers?
- How does advice through the REACH process align with this?
- Running in parallel
- Not currently part of piloting activities
- There is good intention with REACH to improve safe handling of chemicals
- Much more is known about substances and their uses
- But has safe handling advice for the end user improved as a result?
- Workplace exposures typically involve a combination of chemical hazards
More work needed....
....and what about BREXIT!!

Thank you for your attention
To generate information on safe use for a mixture:

- LCID method to identify one or more lead substance(s) in the mixture
- Lead substance(s) drives the conditions for safe use
- No harmonised method yet to consolidate across exposure scenarios in case of different lead substances (for different exposure routes)
- No harmonised format (yet) for communicating the conditions for safe use for the mixture SDS
  - Format for integration into Section 8
  - Format for attachment