Improving safe use in the supply chain

Safer Chemicals – ECHA Conference

22 May 2019

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Head of Exposure and Supply Chain
Content

• REACH chemicals safety assessment
• Supply chain mechanisms
• Current tools and methods
• Obstacles identified
• REACH review action 3
Chemical safety assessment concept under REACH
What REACH brings

- SDS is an integral part of REACH Annex II
- Take into account the GHS rules for SDS
Chemical safety assessment needs information on substance properties and conditions of use

**Manufacturer**

Knows the properties of the substance

- Information generation
- Classification
- DNELs and PNECs

**Downstream user**

Knows how the substance is used

- Foreseen products and processes
- Concentrations and amounts
- Operational conditions
- Risk management measures
- Technical language of users

→ **Exchange of information** (via supply chain or other means)
→ Allocation of **assessment responsibility**
→ **Capacity** to carry out the assessment
REACH introduced extended SDS

Safety Data Sheet + Exposure Scenarios

**Substance-specific**
- Properties and classification
- Regulatory information (e.g. registration number)
- Overview of registered uses

**Use-specific**
- Operational conditions
- Risk management measures
- Exposure estimations (if relevant for recipient)

**REACH defines** format, content, when to provide, obligations upon receipt

**REACH defines** when to provide, obligations upon receipt

echa.europa.eu
## Extending the safety data sheet

<table>
<thead>
<tr>
<th>SDS section</th>
<th>SDS for substance</th>
<th>SDS for mixture</th>
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</thead>
<tbody>
<tr>
<td>1.2</td>
<td>Functions of the substance</td>
<td>Technical purpose of mixture</td>
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<tr>
<td>7</td>
<td>Precautions for safe handling</td>
<td>Precautions for safe handling</td>
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<tr>
<td>8.1</td>
<td>Control parameters: OELs and DNELs and PNECs</td>
<td>Control parameters: OELs and DNELs and PNECs</td>
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<tr>
<td>8.2</td>
<td>Exposure controls</td>
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<td></td>
<td>• Engineering controls</td>
<td></td>
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<td></td>
<td>• PPE</td>
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<tr>
<td></td>
<td>• Env. exposure controls</td>
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</tr>
<tr>
<td>ES Annex</td>
<td>Operational conditions and risk management <strong>per use</strong> and contributing activity</td>
<td></td>
</tr>
</tbody>
</table>

*Article 31 (7)* Include ES and other relevant information
Supply chain mechanisms
Supply chain communication

- Manufacturers
- Importers
- Formulator
- Company end-users
- Assemblers and users of articles
- Individual companies

Information on safe use of substances, mixtures and articles
Information needs

“Assessment” tasks of companies

• Safe use of chemicals at own workplaces (OSH requirements)
• Control of emission to environment
• Chemical safety of own products and services
  • Use at customers’ workplaces
    • Mixtures
    • Articles
  • Use by consumers
    • Mixtures
    • Articles
Downstream user response mechanism

Manufacturers
Importers

Formulator

User of substance as such or in mixture

Downstream user duties:
• Define expected/foreseen use of mixture
• Establish conformity with ES received or carry out own CSR
• Include received ES/SDS or own CSR information into the SDS for the mixture

ES: condition of safe use determined in CSA
Authorities get informed

Registration information

Manufacturers
Importers

Formulator

Company end-users(DU)

General public

Authorities

DU CSR notification

echa.europa.eu
Methods and Tools
ENES Tools

Manufacturers
Importers

Use maps

Chesar

Formulator

Company end users

ES template

ESCom (phrase catalogue, XML)

SUMI selection method

Leading-ESs selection (LCID)

Safe use info for mixture Template(s)
Use map elements

Workers: Sector-specific Worker Exposure Description (SWED)

Consumers: Specific Consumer Exposure Determinant (SCED)

Environment: Specific Environmental Release Category (SPERC)
### Use maps development status (1) 11/2018

<table>
<thead>
<tr>
<th>Sector association</th>
<th>Products covered</th>
<th>Use map</th>
<th>SWED</th>
<th>SPERC</th>
<th>SCED</th>
<th>Chesafile</th>
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<tbody>
<tr>
<td>AISE</td>
<td>Cleaning products</td>
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<td>PUB</td>
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<td>Cosmetics and Personal care products</td>
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<td>DEV</td>
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<tr>
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<td>DEV</td>
<td>PUB</td>
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<td>PUB</td>
<td>DEV</td>
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<td>DEV</td>
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<tr>
<td>CEPE</td>
<td>Paints and coatings products</td>
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<td>DEV</td>
<td>DEV</td>
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<td>INT</td>
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<td>Catalysts</td>
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*Starting point for workers assessment provided, for possible iteration by registrants*
# Use maps development status (2)

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<th>Use map</th>
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<td>Textile finishing supply chain</td>
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<td>Paper making supply chain</td>
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<td>Metal compounding and conversion</td>
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<td>etc............</td>
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</tbody>
</table>
ENES / ECHA achievements

- More than 50% CSRs are based on Chesar
- Significant number of industry sectors have generated or updated their sector use maps
- Tools/methods for generating, processing and communicating exposure scenario information available (ongoing “beta testing” under ENES)

However, quite some evidence that the communication through the supply chain is not properly working yet.
CHESAR - Introduction

• Chesar is a web application developed to support registrants in consistently:
  • carrying out chemical safety assessment
  • generating a chemical safety report (CSR) as part of their registration
  • generating exposure scenarios for communicating conditions for safe use (annex to extended safety data sheet)

• Available as desktop and server version
  • Chesar 1 was released in May 2010
  • Chesar 3.4 released in November 2018

https://chesar.echa.europa.eu
CHESAR provides opportunities for

• **Consistency**
  • Within the CSA: substance properties, uses reported in IUCLID and the chemical safety report
  • Information for the authorities (CSR) and for the supply chain (exposure scenario for communication)

• **Standardisation (efficiency gains for all actors)**
  • Systematic workflow
  • Incorporation of use maps and standard phrases (ESCom catalogue and ESComXML)
  • Standardised format for Chemical safety report, Exposure scenarios for communication
CHESAR provides opportunities for

- **Efficiency in single assessment**
  - Integrated exposure estimation tools
  - Re-use of information across substances
  - Automated generation of documents
  - Facilitated updates
Obstacles
Obstacles (1)

Limited explicit demand for safe use advice from the bottom of the supply chain

- Confusing and not sufficiently targeted information
- Unclear value of ES information for other obligations
- Lack of capacity to use/work with the information
- Lack of trust from MS OSH authorities in modelling based REACH exposure scenarios
- Recipients of mixture SDS don't recognise the "status" of exposure scenario information and associated duties
Obstacles (2)

Foreseen upstream communication mechanisms don’t deliver (→ registrants and hence authorities lack sufficiently complete overview on uses of substances)

• **Unawareness** of downstream users of their duties
• Reluctance to communicate about “innovative” uses
• **Complex** supply chains
• Communication on identified (and hence assessed) **uses** of a substance in the extended SDS does not trigger response:
  • Use description too broad, too unspecific or not understandable for downstream user
  • Downstream user does not manage to get response from suppliers
• No upstream communication system established for single company to efficiently feedback to suppliers
Obstacles (3)

- Current legal requirements on exposure scenarios difficult to enforce (→ market forces do not properly work; → insufficient driver for harmonisation)

- Inertia of existing SDS systems and their underlying IT (global players reluctant to change their running SDS system)

- Limited uptake of available solutions
  - by registrants for CSR and SDS up-date
  - by downstream sectors making use-information available to registrants in an organised way
Consequences

• ES for communication still reflecting the registrants original objective to submit a complete dossier?
  • Over-reporting and under-reporting of uses
  • Conditions of use do not necessarily reflect reality in the supply chain
  • Terminology often not understandable to recipients
  • Risk management advice not derived by OSH practitioners
• Unassessed (potentially unsafe) uses remain undiscovered
• Multi-manual transfer of information through the supply chain (errors, takes resources, frustration, slow update)
REACH review action 3
ECHA’s Strategic Objectives 2019-2023

Ensure risk management measures applied in European marketplace

Supply chain communication is an integral part of safe use

Sustainable management of chemicals through the implementation of EU legislation

Safe and sustainable use of chemicals by industry

Identification and risk management of substances of concern

Actions to invest in enabling components
REACH Review action 3
Four inter-related action areas

- **3.1 Industry**: develop harmonised formats and IT tools to
  - provide more **user-targeted** information and
  - simplify extended Safety Data Sheets
    - preparation
    - use
    - facilitate their electronic distribution

- **3.1 Industry**: use harmonised formats and IT tools

- **3.2 Commission**: consider minimum requirements for the exposure scenarios for substances and mixtures in Safety Data Sheets

- **3.2 ECHA**: develop a methodology for Safety Data Sheets for mixtures
Scoping process under action 3

Main themes

• **User targeting**: Characterise information needs (assessment tasks) of typical users of the extended safety data sheet

• **Define methodology** for extending safety data sheets for mixtures (with exposure scenarios and DNEL/PNEC information)

• Work out **potential minimum requirements** for exposure scenarios:
  - Simplification and Harmonisation (workability and efficiency)
  - Enforceability

• Collect proposals for embedding solutions in a **modernised IT concept** for the (user targeted) dissemination of information
Scoping process under action 3

Overall process

• Scoping phase (2019)
  • First Stakeholder workshop March 2019
  • Testing and exemplification of methods and tools for formulators under ENES
  • Dialogues with providers of IT solutions and services for safety data sheet authoring
  • Characterise information needs of SDS recipients (company perspective; inspectors perspective)
  • Second stakeholder workshop September 2019
  • Options for solutions to be discussed at CARACAL in November

• Development phase (2020)
• Consultation about proposed solutions (2021)
Summary

• Chemical Safety Assessment (CSA) and the resulting supply chain communication are essential to the safe use of substances
• Proper CSA relies on adequate information on hazard and use
• Tools/methods have been established to:
  1. gather and transmit the necessary information on use (ENES) and
  2. for the resulting CSA (Chesar)
    • Some gaps in both coverage (use map development) and uptake (implementation in the registration dossiers)
• Several obstacles identified in generation and transmission of safe use advice
• REACH Action 3 (and related Action 12) aims to tackle these obstacles
Thank you!
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