

DUCC/CEFIC pilot on exposure scenario and supply chain communication Registrants testing Use Maps and formulators testing the SUMI selection method

Summary Report

Introduction

Sector Use Maps have been developed over the past years as a tool to support industry in efficiently generating and processing exposure scenarios providing realistic, concrete and understandable safe use advice. Use Maps enable downstream sectors to describe the uses and prevailing conditions of use in a way that registrants can directly feed the information into their chemical safety assessment (CSA), including the suitable phrases for communicating safe use advice down the supply chain. Downstream users in turn receive harmonised information from the various suppliers of substances in their mixtures.

In the course of 2018 and 2019 CEFIC and DUCC with a number of their member companies tested a number of Sector Use Maps and the associated Safe Use Information for Mixtures (SUMIs) with representative substances and mixture recipes. The project aimed to identify whether the structure and extent of harmonisation introduced by the sector's Use Maps and SUMIs bring the expected benefits to both registrants and formulators. Furthermore, it was tested whether the guidance available to companies allows for proper application of the tools.

The testing was performed in 2 phases: In the first phase, registrants uploaded use map information and generated for their substance exposure scenarios (ES) for communication to formulators. Based on the received exposure scenarios and their own mixture recipes, formulators selected information to be communicated with the Safety Data Sheet to end-users of the mixture (second phase).

The testing was carried out with the Chesar tool¹ and used the most up-to-date version of the ECom standard phrase catalogue². The testing was primarily focussed on exposure assessment for workers.

The present document summarises the design of the pilot project and the experience made and makes proposals for improvement and follow-up actions.

¹ ECHA's *Chemical Safety Assessment and Reporting Tool* for industry (<https://chesar.echa.europa.eu/documents/2326902/2424432/Chesar+in+a+nutshell/f9d363f7-c2a8-0260-ca21-829eeb0d3b6d>)

² Catalogue of standard phrases for expressing the titles and the content of exposure scenarios (<https://cefic.org/app/uploads/2019/11/ESCOM-STANDARD-PHRASE-CATALOGUE-AND-XML-STANDARD-EXPLANATORY-NOTE.pdf>)

A more extensive description of the learnings is available in the respective reports from the registrant (<https://cefic.org/guidance/reach-implementation/es-csr-csr-guidance/>) and formulator testing (<https://www.ducc.eu/Publications.aspx>) phases (<https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios>).

Background information on Use Maps and SUMIs

Sector Use Maps have been developed over the past years in order to better support registrants and formulators in generating and processing quality exposure scenarios. Quality means in this respect that the safe use advice in the exposure scenario is realistic, concrete, understandable, and based on the assessment methods laid down in Annex I and XII of REACH. The underlying idea of the use maps concept is that **structuring** the information on uses and conditions of use and **harmonising** it at (downstream) sector level will benefit all actors in a supply chain. Indeed, the Use Maps enable sectors to describe the uses and prevailing conditions of use in a way that registrants can directly feed into their exposure assessment, including communicating safe use advice down the supply chain. Thanks to Use Maps, downstream users received harmonised information from the various suppliers of substances in their mixtures.

In the Use Map, each use and its contributing activities is associated with defined sets of conditions of use for workers or consumers (SWED³ or SCEDs⁴) and for the environment (SPERCs⁵)⁶.

SWEDs, SCEDs and SPERCs provide the input to the registrants' assessment. Different SWEDs/SPERCs may be available in the Use Map for the same activity to reflect the different levels of exposure control that exist in the sector for that given activity.

Each SWED is linked to a corresponding SUMI pre-defined by the sector. SUMI can be attached to the SDS for mixtures by formulators supplying to end-users of mixtures. The conditions of use in a SUMI are the same as in the corresponding SWED, but the technical language plus pictograms used in the SUMI are designed to be better understood by the recipients (mixture end-users) and it facilitates the creation of Workplace Instruction Cards (WIC)/Product Information Card (PIC)/Safety Information Card⁷, where relevant.

³ SWEDs: Sector-specific Workers Exposure Descriptions

⁴ SCEDs: Specific Consumer Exposure Determinants

⁵ SPERCs: Specific Environmental Release Categories

⁶ Consumer part and environment part of the approach not further explained here, as the project focussed mainly on workers conditions of use (SWEDs).

⁷ Various industry formats developed to communicate SDS information to workers end-users in an understandable way

With the SWED/SUMI approach the formulator tasks of consolidating the information from the various exposure scenarios for the ingredients of his/her mixture and of communicating the safe use advice for the mixture to the end-users is facilitated. The formulator can recognise if the sector SWED has been used as input for the assessment by registrants in the exposure scenario received⁸, and, if so, can select the appropriate, readily formatted, corresponding SUMI to be attached to the SDS for the mixture.

Depending on the composition of the mixture and the properties of the ingredient substances, different levels of exposure controls may be required for the mixture. Therefore, for one and the same type of mixtures, two or more SWED-SUMI pairs may be applicable. With the sector Use Map registrants supplying substances into the market covered by the sector can determine (and communicate) in a consistent manner the safe concentrations or amounts of their substances in the different mixture types at different levels of pre-defined exposure controls.

The SWED-SUMI approach aims to provide a common and consistent framework for the assessment and communication of safe use information within the full supply chain of a sector (registrants, formulators, end-users).

Test design and participants

For the purpose of this testing exercise, the downstream sector Use Maps from **A.I.S.E.** (International Association for Soaps, Detergents and Maintenance Products), **EFCC** (European Federation for Construction Chemicals) and **FEICA** (Association of the European Adhesive and sealant industry), as well as 2 Generic Exposure Scenario (GES) Use Map developed by the European Solvents Industry Group (**ESIG**) were tested. The test was carried out in two steps:

- First phase: 10 registrants' testers using Chesar carried out a CSA based on Use Map information for 7 test substances with a diversity of property profiles. About 20 extended SDS with about 330 exposure scenarios were generated. The exercise was organised under the lead of CEFIC and is referring to Action 2.4 of the ENES work programme⁹.
- Second phase: Downstream sector associations defined test mixtures containing the test substances from the first phase. 35 formulators' testers (from 4 sectors including **CEPE** [European Association of paints, printing inks and artist colours producers]) processed the ES received and selected the SUMIs relevant for the test mixtures. The formulators tested this step with 5 test mixtures, each containing 2 to 4 of the test substances. This exercise was carried out under the lead of DUCC and is referring to Action 4.1 of the ENES work programme.

⁸ where a SWED is used as input for the assessment, the SWED code is communicated in the ES for communication

⁹ https://echa.europa.eu/documents/10162/23915781/enes_work_programme_to_2020_en.pdf/7862a4b5-0e5b-e4ea-c47c-6caf72cee847

The testers provided feedback on their experience, and the project core team carried out more in-depth analysis on a number of identified priority issues (affecting both registrants and formulators). Learnings and actions for follow-up were discussed among testers and sector organisation at a workshop on 3 and 4 September 2019 in Brussels.

Experience

- The Use Maps and SWED/SUMI concepts have proven to work efficiently where testers followed the instructions, and where they stayed within the Use Map boundaries (i.e. input to quantitative Tier 1 assessment with TRA; not to be changed by registrant). In these conditions, the outcome among registrants is largely consistent, many formulators found it easy to navigate, ES have harmonised format and appropriate SUMIs can be selected.
- In some cases, the registrants deviated from the use map information and/or derived the assessment outcome (e.g. highest safe concentration or amount) in different ways. The resulting exposure scenarios did not support efficient SUMI selection at formulator's level anymore. Identified reasons for deviating from the Use Map input are:
 - Risk management measures added to cover qualitative hazards
 - Inputs modified as it was not possible to demonstrate safe use with TRA
 - Registrants applied different starting points for substance concentration and/or different RCR target values for demonstrating safe use.
- When formulators receive exposure scenarios derived from other sources than the downstream sector Use Map (e.g. Generic Exposure Scenarios), efficient SUMI selection is not supported anymore. The titles and content of the received exposure scenarios need to be manually compared and the conditions described in the pre-defined SUMIs are not met. A new SUMI need to be manually populated based on the SUMI template.
- There may be room to reduce the repetition of identical assessments by registrants within and across Use Maps (different uses and/or contributing activities, but same conditions of use).

Proposals for improvement

Based on the experience from testing and the subsequent analysis, improvements are proposed. Note: Smaller corrections or amendments in single Use Maps are not included.

- The test demonstrated that further harmonisation and improvement of the **ES** for communication in terms of **data structure** and **layout** is desirable, to support more efficient processing of the information by formulators. In particular:
 - The Chesar format for the ES communication works well and should be used as a reference towards harmonisation, also by other tools owners¹⁰.
 - The Table of Contents (ToC) of the ES Annex could be improved so that formulators can more easily find the exposure scenarios relevant for their mixture types.

¹⁰ Note: As an outcome of the current REACH review action 3, and based on the experience of tool testing under ENES, slight adaptation of the Chesar format can be expected.

- The title section of the ES could include for each listed contributing activity the SWED code and the highest safe concentration of the substance under the defined SWED conditions, so that formulators can more quickly check compliance for their mixture.
- In general, develop and implement a system for **more intelligent transfer of data** contained in an extended SDS:
 - Harmonised, interactive PDFs as a first step
 - to data objects (e.g. xml) in the longer term.
- Include parameters for **higher tier** assessment into sector Use Maps (if relevant for the sector), to achieve consistency across registrants also for substances where a Tier 1 assessment with TRA cannot demonstrate control of risk. The outcome of ENES action 3.2 “Harmonization of workers CoU” may serve as a basis for this¹¹.
- Develop common rules on how **qualitative hazards** (i.e. classified hazards with no DNEL available, for example irritation/corrosion) should be considered in Use Maps, registrants’ exposure scenarios and SUMIs. Such common rules will help to prevent variations of exposure scenarios across registrants. They will also support formulators when processing the information and selecting the appropriate SUMIs (as it will be more transparent how the registrants have addressed the qualitative hazards).
- Develop common principles for **normalizing Tier 1 assessments** under REACH. The key principles proposed are the following:
 - Input for the assessment: The assessor takes the fixed packages of conditions of use from sectors Use Map. Downstream sectors ensure that i) the Use Map is in compliance with the “hierarchy of controls” logic and ii) that the set duration of activities takes into account aggregated exposure of worker due to different activities during the shift.
 - Output of the assessment: Highest safe concentration (for workers) and amount (for environment) of the substance in mixture under Use Map conditions.
 - RCR = 1 serves as a regular benchmark for demonstrating safe use in the assessment.
- Map the existing **Generic Exposure Scenarios (GES)** with **downstream sector Use Maps** for overlapping uses.
- Work out further **Guidance** for registrants and formulators to address common issues identified during the testing e.g.
 - What to do at registrant level
 - for selecting the relevant uses and contributing activities (for the substance to be assessed) from a Use Map?

¹¹ Under this project, a set of harmonised core conditions of use has been developed, serving the assessment with various workers exposure estimation tools, and to be implemented in the SWED template and Chesar (as built-in conditions of uses). Once available in the SWED template and Chesar (planned for spring 2020), the phrasing of the safe use advice will become more independent from the exposure estimation tool used.

- if safe use cannot be demonstrated based under Use Map conditions (not with the TRA or not in higher Tier assessment)?
 - to take into account i) aerosol formation and ii) qualitative hazards when processing the information uploaded with the Use Map?
 - to set the RCR in line with the sector Use Map approach?
 - What to do at formulator level when receiving exposure scenarios
 - without SWED reference?
 - in which different SWED codes are indicated for the same activity with the mixture and selection of the appropriate RMM level is required?
 - where the technically required concentration of one or more ingredients is not covered?
 - where some of the exposure scenarios are derived from downstream sector Use Maps and some come from other sources (e.g. Generic Exposure Scenarios)?
- Fix a number of issues and/or provide guidance for **exposure estimation** with the TRA (in Use Maps, Chesar and/or the TRA itself): this concerns for example estimation of exposure to aerosols (in particular for low volatile substances as such or in liquids), exposure estimation for maintenance and repair, and the convention for operating at ambient temperature.
- **Additional remarks** on improvement possible:
 - for some Use Maps, more alignment is needed with standard ECom phrases (it is necessary that all Use Map content is covered by standard phrases);
 - environmental aspects to be covered via the SUMIs¹²;
 - collaboration between ECHA and assessment tools owners (e.g. ART, Petrorisk) to facilitate integration of assessment into Chesar.

The proposals for improvement will be fed into the **2020 action/work plans** of various stakeholders and their fora: REACH Review Action 3 and 12 (lead by Commission and ECHA) and ENES work program 2020; ECom; Chesar; DUCC and its sector groups; Cefic and its sector groups; REACH Exposure Expert Group of the Member States (REEG).

¹² DUCC is already discussing internally about inclusion of environmental considerations in the SUMIs for professional and industrial uses.