ENES Action 2.4. Cefic Pilot project on Exposure Scenarios and communication in the supply chain– Phase 2

Project plan

Contents

1. Introduction

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. The underlying idea of the use maps concept is that structuring the information on uses and conditions of uses and harmonising it at sector level will benefit all actors in a supply chain.

It needs now to be checked that the current structure, harmonisation level, and guidance available bring the expected benefits both for registrants and formulators. Where further improvements are identified, this needs to be addressed.

In 2017 Cefic organised a pilot exercise in collaboration with two downstream sectors. The scope of the pilot exercise and its complexity had been deliberately limited. It was agreed that this first phase of testing would be followed by another one, more extensive and more representative of real (more complex) situations. As for the phase 1, it is critical that formulating companies take part in the activities as they are the primary recipients of the ES generated from the registrant's CSA and they need to be able to process them.

The present document aims at describing the proposed second phase of the pilot.

The pilot is described as Action 2.4 of the ENES work programme but also cover aspects from Actions 4.1[1]. The outcome of this pilot is planned to be reported to ENES 12 meeting planned for end November 2018.

The outcomes of this second pilot is only applicable for a limited range of tested mixtures from the sectors mentioned. The outcome will not imply that the use map approach for mixtures is applicable for all mixtures.

1.1. Summary of pilot phase 1

The phase 1 of the pilot did consist in asking registrants to carry out workers exposure assessments based on SWEDs for 2 predefined substances and some preselected uses from the FEICA and EFCC use maps. The ES generated by registrants were looked at by formulating sectors for understanding the differences and see whether the selection of an appropriate SUMI was supported.

The tables below describe in more details the scope of the testing performed (by registrants and formulators respectively), highlighting also what was explicitly not covered in the exercise.

Use of use maps by registrants	
Tested	Not tested
One substance type (hydrocarbons, liquid, with only quantitative hazard (DNEL))	Solid substances Substances with qualitative hazard (i.e. classification but no DNEL)
Pre-selected use maps (FEICA & EFCC use maps)	Selection of relevant use maps(s) from the library Assessment based on multiple use maps (overlapping use maps, sectors with different approaches)
Pre-selected uses from the use maps	Selection of the uses relevant to a given

[1] ENES Work programme 2020:

act.4.1 "Text or exemplify the available methods to generate safe-use-information for mixtures based on exposure scenarios coming down the supply chain (SUMI).

	substance and registrant
Tier 1 assessment; TRA only	-How should registrants decide to move to tier 2 (e.g. instead of suggesting "unrealistic concentrations", …….) -How use map inputs support assessment with Tier2 tools
Workers assessment (SWEDs)	Environmental assessment (SPERCs) Consumer assessment (SCEDs) Service-life assessment

Processing of Exposure Scenarios by formulators	
Tested	Not tested
Compare the ESs for communication received from different registrants for the same substance in the same use	-Processing of ESs for different types of substances (different hazard profiles, solids and liquids in the same mixture)
Find the appropriate SUMI based on ESs received from different substances in a mixture (EFCC use map only)	-Processing of ESs when both sector Use maps and GES are used (or different sector use maps for 'same mixture')

2. Organisation of pilot phase 2

The aim of this second phase of the pilot is to collect feedback and experience from using use maps in more real situations than in the phase 1.

The methodology to be followed in the second phase of the pilot project proposes to cover the different activities by testing via hands-on exercises aimed at registrants and formulating companies. The downstream sector use maps from AISE, EFCC and FEICA, as well as the ESIG Generic Exposure Scenario (GES) will be tested.

The essence of the activities will be the same as in the first phase, that is, the registrants will have to create the exposure scenarios for the communication and the formulating companies will have to evaluate the information prepared by the registrants.

2.1. Participants

The project is set up with the following organisation

- Lead: Cefic (Alejandro Garabatos)
- Core group (in charge of the organisation of the pilot): Cornelia Tietz (ESIG), Divina Gomez (FEICA), Martin Gloeckner (EFCC), Evelyn Tjoe Nij (Cefic Chesar WG Lead), Gerald Bachler (Consultant representing Concawe), Laure Anne Carton (ECHA), Hélène Magaud (ECHA) and Laura Portugal (DUCC).
- Participants: Based on the expression of interest following the call for participation. It is critical to have both registrants and formulating companies.

2.2. Organisation/Timing

The following steps are expected

What	Who	When
Expression of interest by participants	Volunteers	Mid July
Testing exercise >>>Registrants Kick-off meeting with the registrants >>> explain the tasks to be carried out, substances to be used >>> fix deadline to carry out exercises	Core group/Registrants	Early September (webex)
Debrief with Registrants	Core group/Registrants	Mid September (webex)
Testing exercise >>> Formulators Kick-off meeting with the formulators >>> fix deadline to carry out exercises	Core group/Formulators	End September Beginning October (webex)
General meeting to comment on the results obtained by the registrants and formulators.	Core group/Registrants/Formulators	Mid-End October (F2F meeting)
Preparation for ENES 12 reporting	Core group	Early November (webex)

2.3. Objective of the testing and high level overview of the elements to be tested

For registrants: The objective is to collect the feedback on the added value and difficulties encountered when preparing a CSA (generating CSR and Exposure scenarios for communication) on the basis of a use maps (DUs sector Use maps or ESIG GES) in the "various situations" described in section 3 Test cases).

For formulators: the main focus will be on testing the processing of the ES received (in order to generate safe use information for mixture) from (or being consistent with) the ES received in particular for the following cases:

- When ESs for substances in a given mixtures are derived from one use map (WP1 and WP3)
- When ESs for substances in a given mixtures are derived both from a sector use map and the ESIG use map (called GES) (WP2)

Compared to phase 1 of the pilot the idea is to extend the testing, for example:

- Use use-maps from other sectors than FEICA and EFCC (note that the pilot is expected to run using Chesar. Therefore, only use maps developed by sectors having made a Chesar file available can be tested)
- Based on the above, use AISE, EFCC, FEICA DU sector use maps and ESIG GES.

- Test additional use maps elements (SPERCs, in addition to SWEDs) [note that no test cases have been developed with SCEDs[2], see explanations in foot-note]
- Test situation with a wider range of substance types (in terms of hazard profiles and physical form).
- Test additional elements covered by EFCC use maps (see WP3 below) such as use of Tier 2 exposure tools for workers or the systematic use of various CAs for different level of Risk management

3. Test cases

3.1. WP1: ESs for a giving mixture having been generated on the basis of the same use map.

Note 1: for some of (or all) the test cases described below it would be useful to have several registrants carrying out the same assessment (for the same substance) to observe whether the assessment generated are the same (differences were observed in phase 1 of the pilot but no analysis had been made to understand the root cause of such observation).

Note 2: it is suggested that the default format for ES generated by Chesar is used by all registrants in this WP (i.e. ES subheading NOT included; template with common conditions of use for workers NOT used; Section 3 of the ES containing exposure estimates and RCR included).

Test Case 1

Objective: Test environmental aspect, based on SPERCs, and in particular cases where different SPERCs are used for substances in the same mixture (in FEICA or EFCC use maps it means for example a volatile and a non volatile substance).

Setting:

It is suggested to work with three substances, two of them assessed on the basis of the same SPERC (in FEICA or EFCC use maps it means that both should be either volatile or non-volatile).

- Substance A and B: liquid volatile; Hazardous for environment
- Substance C: non volatile (liquid or solid); Hazardous for environment
- Use: professional end uses and at least 1 industrial end use

Test Case 2

Objective: Test quantitative human health assessments when the following combinations (physical state) of substances are part of the same mixture (simple case only systemic hazard, i.e. systemic DNELs available).

Setting:

	Substance 1physical state	Substance 2 physical state
Mixture1	Power	Powder
Mixture2	Powder	Liquid
Mixture3	Liquid	Liquid
Industrial and/or professional end use		

[2]Consumers (SCEDs): as there is an ENES action 4.5 on-going related to the ES for consumer uses and it was felt that it would be better, for optimisation of resources, to first await for the outcome of that work.

Test Case 3[3]

Objective:

Better understand whether and how registrants' assessment related to HH local effects on eye and skin (qualitative hazard) is identifiable in ES and can be "reused" by formulators (as the mixture composition plays a big role in whether a given hazard is still relevant or not for the mixture). This should also enable to define the rules (for Chesar) whether conditions of uses defined in use maps should be modifiable by registrants or not (note that currently all are fixed with the exception of eye protection [4]).

Setting:

- Substance A and B, both have to be at least classified for dermal local effects (no systemic effects, i.e. no DNEL available in the dossier).
- SWED considering no need for gloves
- Mixture contains the 2 substances with concentration below the CL for each but the sum of the concentrations for the 2 substances is above the CL

3.2. WP2: ESs for a given mixture having been generated on the basis of a sector use map and a GES

Objective:

- Test whether it is possible for a formulator to "recognise" the various ES generated from DU Sectors use maps (e.g. FEICA, AISE or EFCC) and GES (ESIG) which are relevant for his type and composition of mixture.
- Analyse the differences between ES received relevant for the same use but generated for different substances or from different use maps (sectors use map and ESIG GES).
- Collect feedback/ideas from formulators on how to process the information received to generate information for safe use of the mixture.

Setting:

One or several mixtures should be defined by formulators containing both solvents and non solvents. Ideally, registrants will systematically assess the full sector use map (for non solvents) and ESIG GES (for solvents).

If possible, several registrants should carry out the assessment using the ESIG GES for the same substance to see whether they iterate their assessment in a same way (on the basis of the

[3] Consider that this exercise is only targeted to the AISE use maps.

[4] Note that

- The conditions of use are fixed in SWED (cannot be modified), so the registrants have to set the concentration of the substance in a mixture to ensure that quantitative effects are controlled. If even at the lowest relevant concentration the safe use cannot be ensured than the SWED cannot be used for generating the ES for communication
- If conditions of use are modified by the registrant (thus, no SWED-based), then the registrant has to decide on whether he would lower the concentration of the substance in a mixture or set more stringent measures.

In the current version of Chesar it is possible to modify the "eye protection" characteristics even if SWED based. Therefore, the registrant has to decide for an eye irritant substance whether he sets the contributing scenario with a % of substance in a mixture below the concentration limit without Eye protection or % of substance in a mixture above the concentration limit but use of Eye protection

instructions from ESIG).

3.3. WP3[5]: Testing use Tier 2 (ART) for workers/risk management levels in EFCC use map

Objective:

- Better understand what are the triggers for registrants[6] to decide to move to Tier 2 assessment (also in view of the different risk management levels available peer contributing activity in the EFCC use map).
- Confirm that the information available in EFCC use map well supports the assessment with ART or give indications which information is missing.
- Compare ES by formulators when generated for some substances on the basis of ECETOC TRA assessment and for other substances part of the same mixture on the basis of ART.

Setting:

The test cases will be defined possibly partly similarly to what is in WP1. EFCC use maps will be used.

One (or more) mixture should be tested containing at least 2 substances with different level of hazard (systemic DNELs available).

4. Tasks

Participants to the pilot will work on the basis of the DU sector use maps from FEICA, AISE and EFCC, ESIG GES, SUMIs where available, and all support material/guidance currently available (ECHA and sector's support materials).

4.1. Registrants' tasks

Generate CSR and ES for communication on the basis of the selected DU sector Use Maps and/or GES as provided by the Chesar use map file for the selected substances using Chesar. For that:

- Generate the relevant IUCLID file (substance properties, all registrants will receive the same IUCLID file)
- Upload the Chesar use map and keep the relevant uses
- Complement the use information by including the technical function as a minimum and use tonnage when environment is considered[7]
- Select the relevant Contributing activities when relevant
- Carry out the assessment:
    - Set the % substance in mixture/site tonnage appropriately to ensure quantitative RCR <1. Note that when carrying out an assessment on the basis of a GES, iteration of the assessment by the registrant can be done beyond modifying the concentration.
    - Carry out qualitative exposure assessment
- Generate CSR: observations

[5] Consider that the outcome of this exercise is currently only applicable to the EFCC use maps.

[6] It is essential that the participating registrants have a certain expertise in exposure assessment.

[7] Note that the use tonnage is also used for priority setting by the authorities even for substances without environmental hazard.

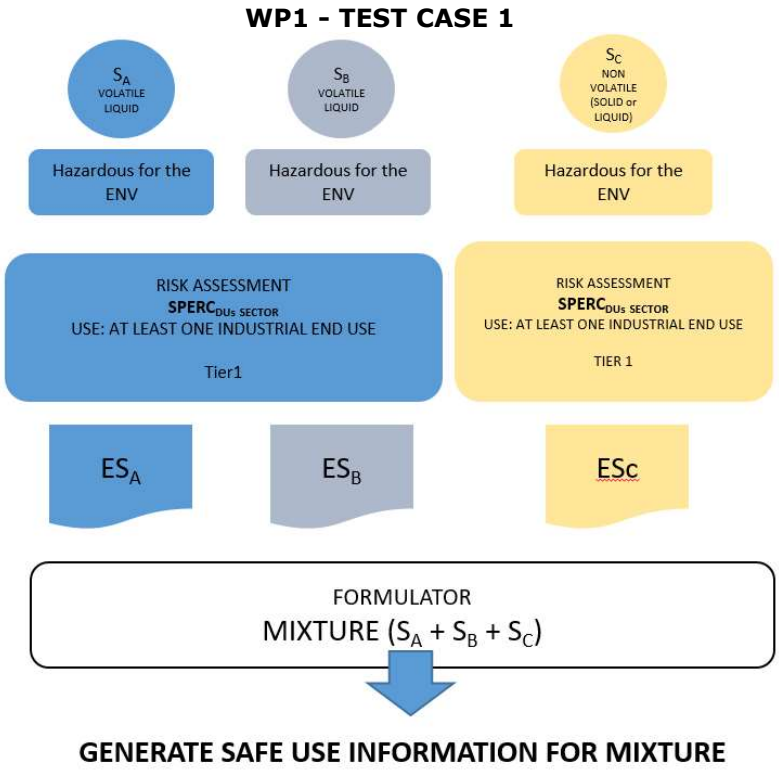
- Generate ES for communication : observations
- Discuss internally the outcome with the Product Steward of the relevant business and the implications for the SDS generating systems with the HazCom organisation.

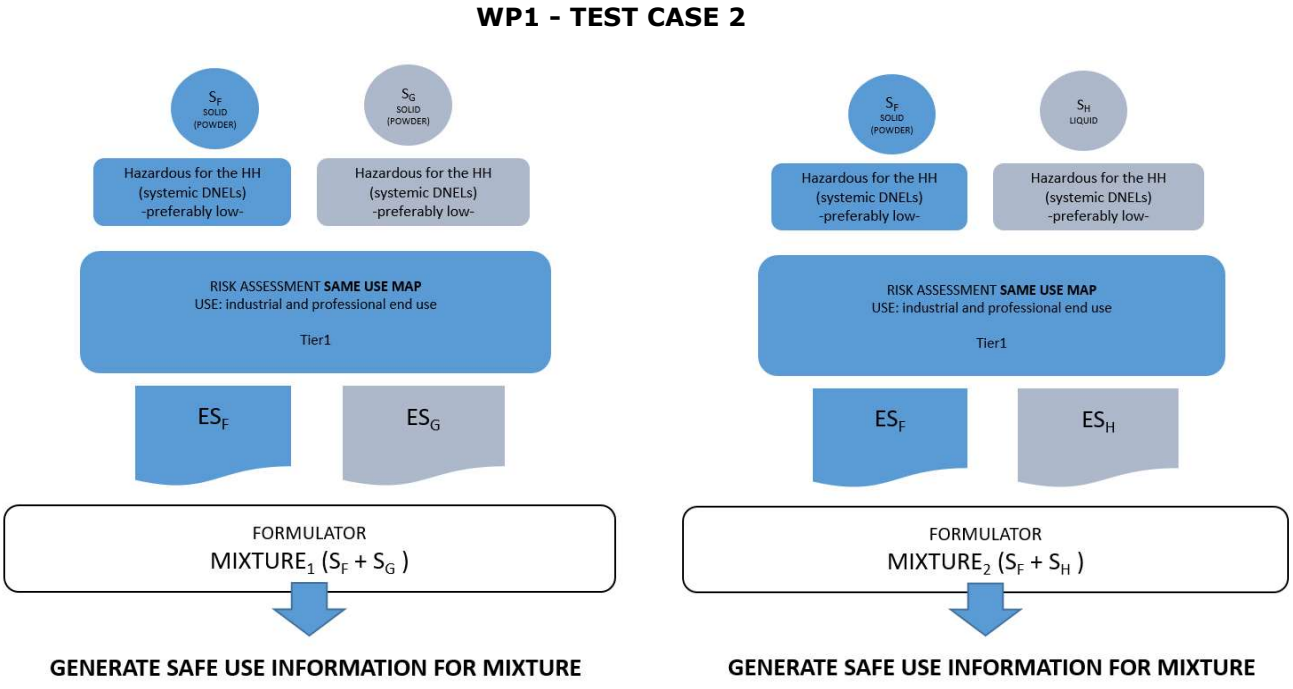
4.2. Formulators' tasks

1. Analysis of the ES:
    - Select the relevant uses for the product and check for correct implementation of the sector use map.
    - In case of ESs that are not SWED/SPERC-based:
        - checking/comparing the Conditions of Use (CoU) in the ES received from the various registrants/ for the various substances:
            - What is the same what is different?
            - Is it easy to find, to understand?
            - Does it fit with my mixture composition and general safety advice?

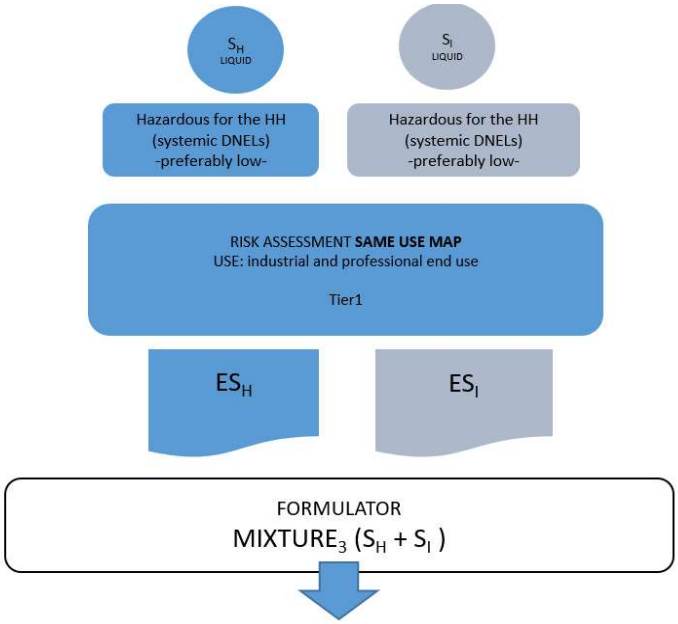
2. Generate the safe use information for the mixture on the basis of the ES for the substances for the relevant end-uses, applying either the
    - SUMI selection method
    - LCID method or
    - other method for example the manual generation of "Safe use information for mixture".

5. Appendix 1. Illustrative figures on the test cases



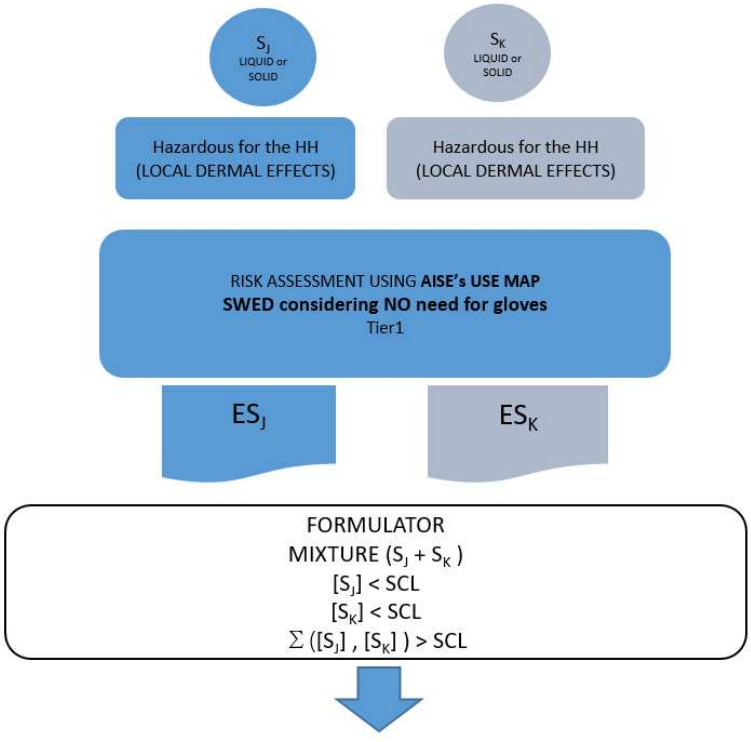


WP1 - TEST CASE 2,cont



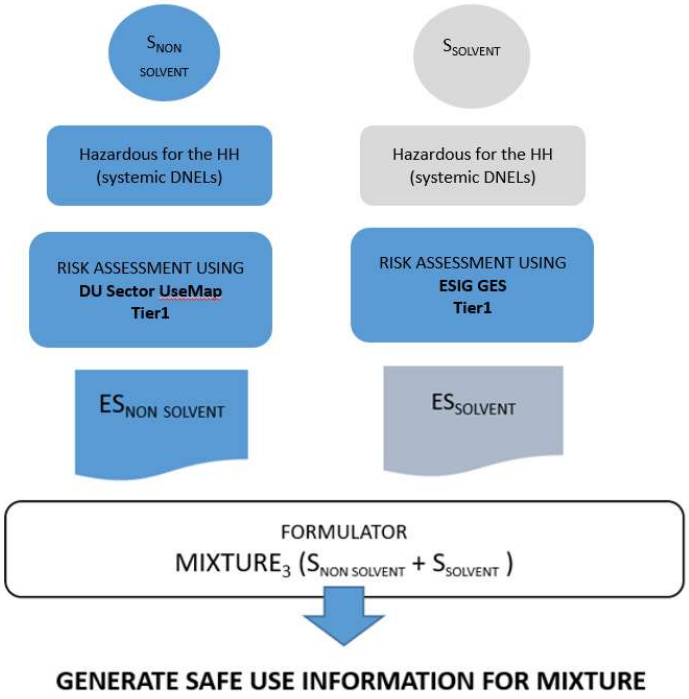
GENERATE SAFE USE INFORMATION FOR MIXTURE

WP1 – TEST CASE 3



GENERATE SAFE USE INFORMATION FOR MIXTURE

WP2: ESs for a given mixture having been generated on the basis of a sector use map and a GES



WP3: Testing use Tier 2 (ART) for workers/risk management levels in EFCC use map