Cefic/DUCC pilot project on Exposure Scenarios and communication in the supply chain: Registrant Phase (ENES action 2.4)

Summary Report

Table of Contents

1. Introduction

The present report aims at summarising the main observations/learnings from the exercise undertaken by a number of volunteering companies having tested Sector use maps and Generic Exposure Scenarios, from the perspective of registrants.

The exercise was organised under the lead of Cefic and is described as Action 2.4 in the ENES work programme[1].

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 use and harmonising it at sector level will benefit all actors in a supply chain. It needed to be checked that the current structure, the extent of harmonisation, and the guidance available for the Use maps published are suitable for bringing the expected benefits to registrants and formulators.

For the purpose of this 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 Generic Exposure Scenario (GES) from the European Solvents Industry Group (ESIG) have been tested.
The focus was primarily on worker exposure and secondarily on the environmental exposure. Consumer exposure was not considered.

Ten volunteering companies carried out chemical safety assessments and generated Exposure scenarios for communication for seven substances presenting different hazard profiles. The exercise was carried out with the Chesar tool for both the assessment and the generation of the exposure scenarios.

The exercise had been designed so that each use map was tested with different substances and each substance was assessed by at least two testers.

The feedback received by individual testers was consolidated and then confirmed in a de-briefing web-conference on 16/11/2018. The feedback was further analysed by ECHA and registrants' representatives in a workshop of the Core Team on 28/01/2019, followed by various web-conferences. The detailed analysis of selected key issues has been collected in 6 Annexes. These Annexes are available on request at Cefic (sja@cefic.be).
The results were discussed with testers and representatives from the sector organisations during a technical workshop at Cefic offices in Brussels on September 3 and 4, 2019.

The present report is a synthesis of the observations, the related root cause analysis and suggestions for improvement of sector Use Maps and GESs. A particular focus is on the cases where

1. registrants deviated from the use maps inputs for their assessment;
2. registrants assessing the same substance and the same use, with the same input information, came nevertheless to different conclusions.

In other words, the report focusses on cases where the application of the use map approach **does not lead** to the expected output. It needs therefore to be stressed that not all observations reported by

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

testers are documented here, including those related to electronic communication of e-SDS Annexes (as this was not part of the pilot).

The analysis differentiates between observations/solutions with regard to the workability of the sector use map approach (Chapter 2 and 3), and issues more related to exposure estimation methodology and the applicability domain of exposure estimation tools (Chapter 4). The latter are to be dealt with outside the scope of the Cefic/DUCC testing exercise, however they form a relevant learning and therefore have been included into this report.

2. Key observations

2.1. Introduction

For large parts of the chemicals market, industry has developed Downstream Sector Use Maps and/or Generic Exposure Scenarios (GES). This is thought to be a big achievement towards supporting registrants' safety assessment and towards consistency of the information communicated in the supply chain.

The feedback received from testers confirms that the current use maps (in combination with Chesar) appear to be a very efficient solution for carrying out tier I exposure assessment. For most exposure scenarios generated, the assessment outcome across registrants was similar, and hence the exercise demonstrates that harmonisation/consistency can be achieved. However, several specific issues have been identified where further work is needed to prevent registrants from (i) deviating from information provided in the use-maps (and hence break the link to SWEDs and SUMIs) or (ii) generating different assessment outcomes for the same substance in the same use.

The issues identified point to a few underlying **root-causes**: It appears that there is still too much room for interpretation (or choices to make) by assessors on how to demonstrate safe use, leading to inconsistent CSR and ESs for communication across registrants, difficult to interpret/use for the recipients of the information. The main root-causes for the inconsistencies observed in the framework of the current exercise include:

- There are differences in approaches how CLP driven exposure controls should be expressed in the use-maps, to prevent registrants' assessors to modify use-map information in order to address qualitative hazards in their exposure scenarios.

- The use maps do not include yet more stringent exposure controls (such as containment or closed systems) allowing in a Tier 1 assessment to demonstrate safe use for substances with higher hazards. Except for EFCC, the use maps do not include input parameters required to carry out the assessment with higher Tier tools.

- There is a lack of clear rules/tiers for iterating the assessment towards more stringent exposure controls (in particular regarding concentration, target RCR and for duration in the GES.)

- Some input parameters in the use maps are considered missing/ambiguous or unrealistic by registrant's assessors, and thus prompted registrants to deviate from the use map information.

- The mismatch between Generic Exposure Scenarios and Sector Use Maps may cause differences in exposure scenarios for the same substance in the same use.

From a more general perspective, another root-cause could be that the objective of demonstrating safe use in a Consortium's CSR for the purpose of registration does not necessarily match the purpose

of exposure scenarios in an extended SDS provided by a single registrant, which means enabling the users of the substance to take the necessary measures related to health, safety and environment (taking into account the needs and experience of the user audience).[2]

The main observations related to use maps can be categorised according to five main themes. In chapter 3 of this document, corresponding actions/solutions are proposed.

2.2. Qualitative and quantitative hazard characteristics

Risk management related to qualitative hazards is not systematically integrated into use-maps. How to perform/report a qualitative assessment is left quite open in all existing guidance so far. The approaches in the use-maps for addressing use conditions triggered by classification (rather than DNEL) are diverse, and some registrants' assessors have added their own approaches on top of the use maps.

2.2.1. Hazard categories without assessment on extent of exposure

Even when a CSA is foreseen, some types of hazards (in particular physical-chemical hazards) do not require an assessment of the extent of exposure as defined in Annex I, but just the determination of measures to prevent accidents. In ECHA guidance, it is therefore recommended to include the necessary measures into the CSR but to keep the advice for safe handling in Section 7 of the SDS, instead of integrating it into the exposure scenarios. The approach for physiochemical hazards (H225, H226) could also be applied to aspiration hazard (H304)[3] and potentially even to eye and skin irritation/corrosion (H314, H315, H318, H319)
During the pilot, some registrants limited concentrations to prevent classification of the mixture for such hazards instead of determining the highest safe concentration based on the quantitative assessment for (systemic long-term) toxic effects. Again, with the consequence of creating difficulties for formulators to interpret the exposure scenario information they receive.

The traditional place for measures to prevent accidents/incidents related to these hazards is Section 7 of the SDS, and it is confusing when some registrants include such information in the ES (possibly as a response to requests by inspectors) and others do not. Systematic inclusion of this information into use-maps would inflate the information content without much added value. In addition, the physical hazards of a mixture in any case need to be fully re-assessed by the formulator, as these hazards are largely driven by the behaviour of the mixture as a whole.

2.2.2. Similar control measures for qualitative and quantitative hazards

Sector use-maps have been built to provide input for exposure assessment related to long-term systemic hazards (with DNELs). The corresponding RMM, however, partly overlap with the RMM suitable for short-term and/or local hazards for skin and inhalation (often without DNELs). This can lead to confusion for assessors when generating the exposure scenarios for communication. In addition, due to the non-integration of certain RMM driven by classification only, some registrants have complemented their use-map based assessments with measures for such hazards, resulting in a broken link to the SWED code, and hence blocking automated processing by the formulator.
The current use maps follow different approaches regarding control measures beyond the DNEL-based TRA assessment. For example:

[2] See REACH Annex II, point 0.2.1 and 0.2.3
[3] Note: In ECHA Guidance there is no explicit recommendation yet to treat aspiration hazards in a similar way as physicochemical hazards.

- A.I.S.E.: No guidance provided to registrants as to whether 'qualitative hazard' needs to be considered for selecting the appropriate SWEDs or whether it should be done only on the basis of quantitative hazard characteristics (i.e. the DNELs).
    - Skin: 2 permutation of SWEDs defined for given activities: one without gloves, the other one with gloves.
    - Eye protection: always set to "no", with the following standard text for communication 'Suitable eye protection might be recommended in the SDS by the formulator depending on the product'
- EFCC: No guidance provided to registrants as to whether 'qualitative hazard' needs to be considered for selecting the appropriate SWEDs, or whether it should be done only on the basis of quantitative hazard characteristics (i.e. DNEL).
    - Skin: gloves (90% effectiveness) advised by default in all SWEDs[4]
    - Eye protection: eye protection (goggles) advised by default in all SWEDs
- GES: Guidance explicitly stating that *'Tox end points for Long Term Systemic Inhalation and Dermal DNELs only have been used in GES assessments and RCR determinations. If the substance has DNELs for other hazards or another qualitative hazard, these substance effects must be additionally addressed by Users.*[5] 'Standard phrases for skin and eye irritants added by default in all workers Contributing scenarios. It is up to the registrant's assessor to remove it if not relevant.
    - Skin/eye irritants: qualitative RMM phrases generically added to all CAs for each GES as a CoU ('General measures'). When not applicable, the assessor must bulk delete the phrase. The guidance provides illustration of the outcome of the qualitative and quantitative assessment in the CSR and in the ES for communication.
    - Appendix provided with the description of how to document qualitative risk assessment for eye and skin irritants (Appendix 3 of the ESIG GES guidance)[6]

<u>For skin and eyes:</u> This concerns skin and eye irritation and corrosion, skin sensitisation (H314, H317, H315, H318 and H319) and possibly acute toxicity through dermal exposure (H311 and H312).

For workplaces where chemicals are handled, a minimum industrial hygiene standard regarding skin protection is needed. Needs for extended skin protection, including chemical resistant gloves, may be driven by classification for local hazards (triggered by irritation, corrosion, skin sensitisation). At the same time, 'gloves' can be required to control long-term systemic exposure through the skin. Both types of hazard trigger exactly the same requirements related to design/material of equipment and the handling of it. The TRA defines three glove management levels; to differentiate glove efficiency (80 to 95%), such "RMM-Levels" may implicitly also exist for hazards without DNELs (see the banding approach for skin hazards in BAuA's EMKG tool).

However, due to the lack of integration between TRA-based quantitative assessments and the qualitative assessment for other hazards on the dermal route, gloves are mentioned twice in many ES without being clear what the difference is.

Another complication lies in the fact that glove type/material needed for a mixture is to be specified by the formulator in Section 8 of the SDS and can be different from the material for the substance as such. Hence, the reference in the ES to the glove specification in Section 8 of the substance SDS may potentially no longer be valid when the substance has become a component in a mixture.

The general requirement to apply protective gloves/clothing/face shield/goggles is triggered by

[4] with the following standard phrases for communication 'Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training; If skin contamination is expected to extend to other parts of the body, then these body parts should also be protected with impervious garments in a manner equivalent to those described for the hands; For further specification, refer to section 8 of the SDS.

[5] Section 2 of the guidance available in the Use maps library: https://www.echa.europa.eu/documents/10162/23966702/ESIG_Worker_GES_Chesar_Technical_User_Guide_V1.1_en.pdf/45e9b423-9153-2c42-2640-1472467f8058

classification for skin local effects driven by the concentration of a substance in the mixture (independent of the use conditions). When using the TRA however, the requirements for gloves[6] are also triggered by the activity type and the DNEL for systemic effects via dermal exposure. In the context of the use-maps, this leads to two different triggers for largely the same measures, i.e. to various permutations in terms of SWED conditions.

In addition, skin protection requirements in SWEDs can also be driven by other workplace agents (e.g. to protect against biological agents during toilet cleaning) or to protect against skin damage due to working with water for long duration.

For inhalation hazards: Low hazards (acute toxicity cat 4, irritation, drowsiness) related to inhalation (H332, H335, H336)

For some short-term inhalation hazards without DNELs, '*outdoor use or well-ventilated areas'* is foreseen by default via assignment of the relevant P-statement (independent of the activity type and other use-conditions). This may overlap with the ventilation conditions determined by quantitative assessment for the long-term exposure[7]. Again, in the context of the use-maps, this leads to two different triggers for largely the same measures, i.e. to various permutations in terms of SWED conditions (i.e. with or without ventilation conditions for these hazards).

2.3. Specification for containment and/or higher Tier tool input

Use maps aim to provide realistic information on conditions of use (for the majority of substances and products in a sector), and they refer to Tier 1 assessment based on the TRA. With the exception of the EFCC use map, the current use maps do not contain the input parameters required to perform higher tier assessment (e.g. with ART). This may leave registrants with too limited information on which conditions of use to consider where safe use cannot be demonstrated with the TRA, and another tool or measured data sets need to be used. Whether such situations are relevant to the sectors at hand, and whether it might be useful to further develop the use maps accordingly, is to be discussed within the sectors.

2.4. Diversity in target-setting for demonstrating safe use

Downstream sectors expect registrants to determine the highest safe concentration (or use rate at site) of the substance at the risk management levels defined in the use maps for the different contributing activities of a use. Registrants, however, have followed different approaches for concluding the risk characterisation.

This diversity of approaches creates difficulties for downstream users to understand the advice communicated to them, in particular if registrants of the same substance have followed different approaches.

Risk characterisation concluded at RCR significantly below 1

Some assessors concluded the assessment if the RCR was somewhere below 1, even when 0.1 or less, while still advising risk management measures in the ES for communication. This happened, for

[6] The TRA PROC definition includes an implicit assumption on the extent of dermal contact with hands and forearms, over a span of factor 8; other body parts not considered for protection measures). The TRA assumes even for PROC 1-3 a dermal contact by one/two hands face (possibly related to sample taking, coupling/uncoupling, …). For PROC 1, the logic of one hand dermal contact may need some re-evaluation.

[7] The TRA assigns the same exposure modifying factor of 0.7 to i) good (indoor) general ventilation (3-5 ACH) and ii) to outdoor use.

example, where registrants used indicative values from sectors or in the GES for mixture concentrations or site tonnage as a starting point for their assessment. Also limiting the concentration to avoid the substance triggering the classification of the mixture for physicochemical or health hazards (for example skin sensitisation) may result in an RCR for systemic effects clearly below 1. Another reason may be that registrants add the same CoU (e.g. ventilation with certain efficiency) over all CS, because in practise it is often not possible to have variable ventilation for each CS.

Other registrants 'normalised' their assessments to the highest safe concentration or highest safe amount in which a substance can be used, while still being below an RCR of 1. However, some registrants use an RCR benchmark of 0.8 (or lower) to allow for an additional margin of safety.

Risk characterisation ratio leaving room for aggregated (combined) exposure from different activities

The Tier 1 assessment based on TRA addresses exposure and risk per contributing scenario (activity). The exposure time per activity can be selected, from full shift down to less than 15 minutes, and a worker can perform various activities (corresponding to various process categories) per day.

For the assessment, it creates a particular issue if the contributing scenarios is limited to less than 4 [1] [0.25] hours per day, based on use map information. The assessor may calculate a reduced exposure (TRA supporting this) and determine the highest safe concentration in the mixture against the RCR in two ways:

a. RCR of 1
b. RCR below 1, proportional to the assumed exposure time (to take into account that other activities during the rest of the shift may be still associated with contact to the substance).

Both approaches are defendable in practice, however, they have different consequences for the recipients of the ES, and thus require corresponding communication. Approach a) logically means that the person having carried out the contributing activity for the limited time should not be exposed to the substance for the rest of the shift. Approach b) leaves room for safely working with the substance also during the rest of the shift. Both approaches add complexity to the understanding of the exposure scenario generation and communication.

Removing contributing activities for which safe use could not be demonstrated

Some registrants removed uses or contributing activities where it was not possible to demonstrate safe use even in low concentration range. Other registrants instead introduced conditions different from the conditions in the use-map.

2.5. Completeness/clarity of information input for TIER 1 assessment

Current sector use maps aim to provide at least the full set of information on activities and conditions of use enabling Tier 1 assessments. Assessors reported that in general all assessment inputs required to perform an assessment with TRA are present in the use map for the activities and RMM levels currently described. However, some assessors found that certain activities/ RMM levels are missing, unrealistic (according to their own market knowledge) or not sufficiently specified. They modified the use map information, with the consequence that the benefit of use map is lost (introduction of non-harmonised uses/contributing activities, link to SWED code broken). In the current testing, assessors flagged the following use map elements as missing or deficient:

- Life Cycle stage not covered (service life),
- conditions of use not sufficiently differentiated (e.g. A.I.S.E. SPERC for industrial use of cleaners assumes 100% emission down the drain, which was deemed not representative for all industrial

uses by some assessors, for example with regard to dipping and washing processes in the metal industry),

- lack of harmonisation and understanding across use maps for example regarding
    - physical form of the product (what to communicate to DU),
    - dealing with "solids in liquids" and exposure assessment for aerosol forming activities in a Tier 1 assessment with the TRA (to overcome the limitations of the tool with pragmatic work arounds),
    - default-value and meaning for "ambient temperature" (and what this triggers for the TRA assessment in Chesar).

2.6. Discrepancies between GES and Sector Use Maps

The uses and contributing activities addressed in GES and in sector use-maps have been mapped to each other[8]. However, there is still a lack of convergence between the GES and SWEDs in terms of (i) a common starting point for the assessment of the same use and (ii) the options available for adapting the level of control. The use-maps define the existing conditions of use (potentially with different levels on control [RMM levels] for some activities) and registrants are expected to determine the highest safe concentration under these conditions. The GES also defines typical conditions of use for various industry sectors as a starting point (partly different from those in the use-maps), but then leaves it to the assessor to adapt the conditions of use (for increasing or decreasing the RCR) following the hierarchy of control concept. This resulted in differences among assessors: not all assessors adjust the concentration/conditions of use if the RCR is low. If the RCR was above 1, some assessors increased ventilation or lowered duration, irrespective of the existing conditions described in the use-map.

The GES were developed by ESIG in 2010 in consultation with various industry sector organizations to help substance manufacturers and importers to prepare CSAs in the 1st REACH registration phase. However, in many instances the GES-based safe use advice communicated down supply chains in the form of extended SDS was not well received/understood by downstream users (DU). The complaints often related e.g. to inconsistent RMMs recommended by different suppliers of the same substance or mismatch between the RMMs for different substances formulated in a mixture. Therefore, several DU sector groups decided to develop sector specific Use Maps that would outline typical RMMs employed in a sector handling specific types of mixtures (e.g. adhesives, paints, cleaning agents), thus helping the DUs to overcome the problems associated with GES-based exposure scenarios.

[8] https://echa.europa.eu/documents/10162/23966702/ESIG_ESVOC_usemap-overviewtemplate_showing_DU-UseMapMapping_v1.2_25092018_en.xlsx/b6fe1b12-b4f8-5e01-cbcb-714a016e69f3

3. Working towards solutions

3.1. Introduction

From the workshop of the core-team in January, and in the subsequent more in-depth analysis of the key issues, a number of initial proposals for improvements/solutions emerged. These are briefly described in the sections below. Where relevant, it is indicated whether the action would be directed to use-map developers, registrants' assessors, ECHA or Member States.
Once the proposed solutions have been discussed and agreed, there are various means available to support the implementation. This includes updating the ECHA Guidance for clarification or modification of principles, practical guides on how to handle particular assessment challenges, update of Chesar, submission of phrases to the ESCom group[9], update guidance for use-map developers, or update of single use-maps.

3.2. Streamline use map information related to qualitative hazards

It is proposed to systematically map the CLP hazard classes (including high hazard) and the related P-phrases, to harmonised workers conditions of use as resulting from the application of exposure modelling tools (see ENES 3.2 project). Such mapping could serve as guidance to registrants so that they can see in which cases they need to complement the conditions of use resulting from the quantitative assessment with conditions resulting from qualitative assessment. Find below a number of initial proposals.

3.2.1. Physico-chemical hazards and aspiration hazards

Measures to ensure safe handling regarding physico-chemical hazards as well as aspiration hazards should be reported under Section 7 of the safety data sheet. This is in line with the existing ECHA Guidance E, agreed with industry and the Member States. The existing guidance does not mention aspiration hazards explicitly, but the same logic can apply (no measures foreseen to control exposure rather than measures to prevent accidents). Action: **ECHA** and **Member States** to confirm this approach. Chesar to ensure that a reference to section 7 can be included into the SDS for communication without breaking the link to the SWED.

3.2.2. Control of exposure to skin

For the **qualitative** assessment, ECHA guidance part E differentiates low, medium and high hazards according to H phrases and assigns generic control measures. Also, the COSSH control banding approach (also applied in BAuAs EMKG tool) defines three skin protection levels, driven by the hazard of the chemical (expressed as H phrases) combined with the extent of contact, depending on duration and body surface area exposed (which is related to the type of activity):

- General hygiene measures to protect the skin (no engineering controls; no chemical resistant gloves);
- Extended skin protection
    - Engineering controls (containment, extract ventilation)
    - Chemical resistant gloves, protection suits;
- Closed system (e.g. glove box).

For the **quantitative** assessment, the TRA defines three RMM-levels for the dermal route, which can

[9] Exposure Scenario Communication working group led by Cefic responsible for developing and maintaining the Catalogue of standard phrases for the Exposure Scenario to be annexed to a Safety Data Sheet of a substance

also be extended to protection measures for other body parts. The effectiveness is related to the handling of the gloves rather than the material.

Dermal RMM level	Phrases associated
Level 1 (80% effectiveness)	Wear suitable gloves tested to EN374; If skin contamination is expected to extend to other parts of the body, then these body parts should also be protected with impervious garments in a manner equivalent to those described for the hands; For further specification, refer to section 8 of the SDS.
Level 2 (90% effectiveness)	Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.; If skin contamination is expected to extend to other parts of the body, then these body parts should also be protected with impervious garments in a manner equivalent to those described for the hands.; For further specification, refer to section 8 of the SDS.
Level 3 (95% effectiveness)	Wear chemically resistant gloves (tested to EN374) in combination with specific activity training.; If skin contamination is expected to extend to other parts of the body, then these body parts should also be protected with impervious garments in a manner equivalent to those described for the hands.; For further specification, refer to section 8 of the SDS.

In addition, the TRA provides the option to apply local exhaust ventilation to control dermal exposure, and for some processes also containment.

The measures to prevent/control exposure for the dermal route are the same, regardless whether local effects (irritant and corrosive substances) or systemic effects are to be avoided.

Use-map developers can therefore define the skin protection package(s) (RMM levels) for each contributing activity, which may be triggered either by a DNEL based assessment (and the related highest safe concentration) or by classification-concentration bands for mixtures. This would prevent registrant's assessors adding measures beyond use-map information, and by this breaking the link to the SWED code and the corresponding SUMI.

The **registrant** would choose from the use-map the RMM level for skin protection required for the hazard profile of the substance, corresponding to a maximum safe concentration. **Chesar** can support such further integration of qualitative and quantitative assessment with H-statement-triggered rules.

3.2.3. Control of exposure to eyes

For irritant or corrosive substances also standard measures for eye and face protection would be defined per activity in the use map, again different RMM levels may apply depending on hazard and type of activity. As an alternative, eye protection measures could be disregarded in use-maps at all, and registrants could add eye protection measures in their exposure scenarios without breaking the link to the SWED (current solution in Chesar).

3.2.4. Control of inhalation exposure for low hazards

For acute toxicity cat 4, irritation and drowsiness related to inhalation (H332, H335, H336), often no DNEL is available. The corresponding P-statement claims *use in well ventilated areas or outdoor only.* This condition could possibly be mapped to good general ventilation (3-5 ACH; 30% effectiveness), as defined in the determinants for exposure modelling with the TRA. The **registrant** would choose from

the use-map the RMM level required for the hazard profile of the substance, corresponding to a maximum safe concentration.

3.3. Support for containment and inclusion of Tier 2 parameters

Completion of use-maps regarding Tier 1 input seems in particular needed where sector specific description of containment (closed conditions) and the corresponding reference to an exposure estimation method is missing (i.e. no evidence based on which the registrant's assessor can apply a TRA PROC 1-3 exposure estimate as a proxy for contained conditions).

In the framework of ENES action 3.2, the input parameters for current tools for worker exposure assessment have been mapped to each other (for determining the similar parameters across the tools), and proposals for harmonization have been made (including harmonised phrases for communication). The consolidated assessment input for modelled occupational exposure across all tools (core determinants) has been made available to use-map developers for commenting (no major concerns were raised). The containment determinants (not available in all tools) and the specific inputs to ART and MEASE are still under consideration and will be made available to use map developers soon. Based on this, use-map developers can then decide whether and to which extent additional conditions of use should be integrated into the SWEDs.

3.4. Normalise assessments to control bands [levels] and RCR of 1

To overcome the diversity in target-setting for demonstrating safe use, the following approach could be standardised (same logic and same terminology across use maps; consistent link to control-banding tools) as a baseline through guidance:

- **For use-map developers**: Define (in SWEDs) for the relevant uses/activities of **workers** the existing use conditions at different risk management levels (provided such levels can be differentiated in practice). For activities usually carried out for short duration only, define the duration. The generic RMM levels are:
    - (1) No RMM beyond good (industrial) hygiene practice (including basic/good ventilation) and dermal/eye protection when working with chemicals.
    - (2) Enhanced ventilation conditions to control hazards via inhalation and/or enhanced dermal protection using particular management.
    - (3) Closed systems/containment preventing contact with the substance except for short, strictly controlled manual interventions.
    - The role of respiratory PPE in relation to the presence or absence of engineering controls is to be defined in the use-map, taking into account the hierarchy of controls as mandatory in OSH legislation.

- **For registrants**: Express the outcome for **workers exposure assessment** as maximum concentration at which the substance can be used while applying the defined levels of RMM [control] from the use map and not exceeding an RCR of 1.
    - When it can be demonstrated that the pure substance (100%) can be safely used at RMM level 1 or 2, the next RMM level does not need to be assessed anymore.
    - If all the risk management levels fail to control the risk at a concentration level reasonably meeting the users' technical needs, (i) apply higher Tier exposure assessment or (ii) remove the use from the exposure scenarios (if one of key contributing activities cannot be demonstrated to be safe even at concentration < 1%, which is the lowest concentration band of the TRA).
    - To avoid receiving ES with unrealistically low concentrations, DU sector organisations may provide indicative concentration values for the functional components in their mixtures. These values should be used as benchmarks to compare the outcome of the assessment,

rather than as an input to the assessment. If the GES guidance provides indicative values different from information by DU sectors in context of use-map, streamlining would be desirable.

- **For use-map developers**: Define (in SPERCs) for the different uses/activities the existing conditions (driving the **environmental release**) at different risk management levels. The generic risk management levels are:
  - (1) No onsite treatment of exhaust air or wastewater before discharge
  - (2) Onsite treatment of exhaust air or wastewater at least xyz % effectiveness; alternatively, dispose of aqueous residues as waste rather than emission to waste water;
  - (3) Closed system and/or no contact to water and therefore no release.

- **For registrants:** Express the outcome of an **environmental site assessment** as the maximum amount of substance [mixture] that can be used per day (without and with onsite RMM if relevant) to arrive at an RCR at < 1 (Msafe).
  - To avoid receiving ES with unrealistically low safe amounts per site, DU sector organisations may provide indicative daily use rates for the industrial use and for the wide spread use of the chemical. These values should be used as benchmarks to compare the outcome of the assessment rather than as an input to the assessment.

3.5. Reality check and completion of use-maps for Tier 1

For the issues identified, the following solutions are proposed:

- Where relevant, extend the use maps to cover conditions of use during service life.
- Update use maps where conditions of use are not sufficiently differentiated or where relevant activities are not covered at all.
- Update use maps with more specific information on the type of LEV in place/required
- Amend guidance, Chesar manual and possibly EScom phrases[10]regarding
  - the communication to DU regarding the physical form of the product
  - default value and meaning for “ambient temperature”.

3.6. Approach to manage the differences between GES and sector use-maps

The GESs applicable for the uses and contributing activities covered in existing sector use-maps might be further aligned, though the scope (in terms of substance types) and the concept regarding safe use information is different. In particular, the default conditions in the GES (before iteration) could be the same as defined in the sector use-maps. Ideally, the conditions at RMM-levels 2 and 3 as defined in the use maps should be included as iteration logic into the GES guidance. However, this would require further differentiation between GESs, if a 1:1 match with sector use maps and SUMIs would be the goal. In may be therefore more realistic for time being to concentrate on

- developing incentives for registrants to base their assessments on sector use map information (if available)
- facilitating the processing of heterogeneous ES information by formulators

For market areas where no DU sector use maps have been published, the GES remain a valuable source of information for consistent exposure assessment. However, learnings from the current exercise can also be valid for GES (e.g. how to deal with normalized assessments and the duration of the activity).

[10] Standard phrases for the Exposure Scenario to be annexed to a Safety Data Sheet of a substance.

As many substances in current CSRs have been assessed with a GES approach, mapping of GES with downstream sector use maps is needed, to facilitate formulators' processing of received exposure scenarios. Adding a SWED code to GES contributing scenarios with a fixed set of CoU would be helpful in that sense. For other approaches and sector/company specific GES, the same type of mapping might be considered.

4. Issues related to exposure estimation and RCR calculation

4.1. Key observations

Assessors flagged a number of issues related to exposure assessment methods and limitations of exposure modelling tools:

- The TRA estimates the exposure to liquids for the vapour phase, and for most activities does not take the formation of aerosols into consideration. For low volatile liquids or solids in liquids applied in aerosol forming activities, the TRA may therefore underestimate exposure. As a workaround, the VP-driven assessment may be replaced or complemented with an assessment for solids, based on dustiness. Assessors claimed that the current use maps do not contain sufficient information for determining where – beyond spraying – aerosols may play a role. Therefore, assessors need to make assumptions on aerosol formation when determining for which Process Categories (PROCs) the work around in the TRA should be applied. Different assessors make different choices for the same use map, again impacting on consistency across assessments. There is a need to align approaches when and to which extent the TRA workaround should be applied, and whether this would require additional information in use maps.
- Adapting the vapour pressure of the substance to the operating temperature is crucial for exposure estimation, but there is still some confusion regarding which "ambient" temperature should be assumed by default (in the range up to 40), and how to take into account elevated process temperatures, including in closed systems (temperature of chemical during the process/task or room temperature in breathing zone of worker)
- Exposure assessment for UVCBs (see *Hydrozed* example in the testing) containing constituents with significantly different vapour pressure may require parallel assessment for these different fractions. Furthermore, the complexity increases when the maximum safe use concentration of a UVCB in a product (for worker or consumer uses) needs to be evaluated. There are different possibilities how to do this in practice, leading to differences in results and hence potentially to inconsistency across assessors.
- Annex I of the REACH regulation, requires registrants to take into account combined exposure to a substance from different sources. There are different approaches in dealing with combined exposure of workers from different activities contributing to a use, and the duration of the contributing activity. The differences of these approaches may lead to difficulties correctly interpreting the exposure scenarios received downstream.
    - Demonstrating control of risk for the full shift per contributing activity helps to avoid the need to anticipate combinations of contributing activities during the shift. Therefore, ECHA Guidance R.14 suggests that shortening exposure time should not be used for bringing down the risk characterisation ratio to below 1.
    - For demonstrating control of risk for activities which are described as short in sector use maps (and hence the TRA exposure reduction factor can be applied), some assessors use an RCR of 1 as a benchmark, others use an RCR of less than 1 for assessing the single activity, in order to leave room for exposure from other sources or activities.
- It is not obvious how to generate the exposure estimate for PROC 28 with the TRA, even though the input parameters are available from the use map, except for the PROC entry for the TRA

estimate. When using another PROC entry as a surrogate (e.g. PROC 8a), Chesar switches to manual assessment and by this the link to the SWED is broken.

The points above are more challenges for exposure estimation and risk characterisation rather than related to the functioning of use-maps. Therefore, these points are set aside for the time being, and no specific solution have been proposed in chapter 3. Nevertheless, there is a need to agree on solutions to these issues, otherwise the diversity of approaches among assessors may undermine the advantages of i) the sector use map concept and ii) the TRA as the tool for Tier 1 assessment related to worker's exposure.

4.2. Working towards solutions

For the five issues below, dedicated guidance and/or an update of Chesar could be the way forward, once existing solutions have been confirmed or further developed.

4.2.1. Exposure to low volatiles and solids in aerosol forming activities

The PROC system includes identification of processes/activities where forming of aerosols is to be taken into account by default. Clarification/confirmation through expert consultation is desirable. For these process/activity categories the workarounds suggested in ECETOC Technical Report 114 could be applied. Solutions to be confirmed/clarified with ECETOC TRA group, possibly in the context of a wider discussion on modelling-based exposure estimates for aerosols (see also work carried out under ENES Action 3.2). In any case registrant's assessors should be explicit on whether exposure to aerosol-form of the substance has been covered in the assessment or not. For aerosol assessment, additional determinants may be added to the use maps and Chesar may be adapted to easily support this.

4.2.2. Adapting of vapour pressure to temperature

The TRA can be used for estimating exposure at elevated temperature, via adaptation of the vapour pressure of the substance[11]. At the same time, the tool limits the predicted exposure to the saturated vapour pressure concentration. For the default Tier 1 assessment regarding processes/activities carried out at ambient (room) temperature, assessors use 20 to 40 C as a reference. In the FEICA and EFCC use maps, 30 C is set as reference. If no specific information is entered (for example via use map information), Chesar provides a re-calculation of the vapour pressure at 40 C as a worst case for "ambient" conditions. Some harmonisation on the approach across use maps would be desirable. Further on, there is a need to clarify with the ECETOC TRA group to which medium (point in space) this temperature should refer: i) temperature of the chemical agent during the activity/process or ii) temperature of the air in the breathing zone of the exposed worker.

4.2.3. Exposure estimates and risk characterisation for UVCBs

Chesar is equipped for such assessment and has been updated for correctly taking into account the concentration of the different fractions of constituents when assessing volatile UVCBs being part of a mixture.
Assessment of UVCBs with a very wide range of vapour pressure (including "solids" becoming airborne only at high temperature) is a specific topic for further discussion between ECHA and industry sector groups.

[11] Not relevant for PROC 1 (exposure estimate independent from vapour pressure) and for PROC 6 (elevated temperature already taken into account in the exposure estimate)

4.2.4. Assess full shift exposure for all activities by default

In general, control of risk should be demonstrated per contributing activity for full shift exposure time. However, sector **use-map developers** may explicitly flag certain contributing activities that are short by definition and are usually not carried out frequently over the day by the same person. Typically, this may be the case for the transfer of chemicals, sampling and mixing. Such time limitation may even be needed for work with PPE to ensure consistency with OSH requirements. It is nevertheless assumed that even when a certain contributing activity is time-limited, the use of the substance (i.e. all contributing activities together) takes place for a full shift. In order to take into account the related potential for aggregate exposure, use map developers may assign a duration of up 1h or up to 4h, even if the activity takes only a few seconds or minutes a day. A case by case determination might be needed. It is recommended to also ask the ECETOC TRA group on their views regarding a sensible approach for working with the duration modifier in the TRA.

4.2.5. Exposure estimate for PROC 28

The solution to this issue includes two elements, i) agree to use the PROC 8a entry to TRA as the best fitting for generating an exposure estimate and ii) enable exposure estimating in Chesar without breaking the link to the SWED.

Glossary/List of acronyms

A.I.S.E.	International Association for Soaps, Detergents and Maintenance Products
ART	Advanced REACH Tool for estimating inhalation exposure
BAuA	Federal Institute for Occupational safety and Health
CA	Contributing Activity
Cefic	Conseil Européen des Fédérations de l'Industrie Chimique – European Chemical Industry Council
Chesar	Chemical Safety Assessment and Reporting tool
CLP	Classification, Labelling and Packaging Regulation ((EC) No 1272/2008)
COSSH	Control of Substances Hazardous to Health
CoU	Conditions of use. They include operational conditions (OC, e.g. duration of activity) and risk management measures (RMMs, e.g. local exhaust ventilation)
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
DU	Downstream User
DUCC	Downstream Users of Chemicals Co-ordination Group
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECETOC TRA	Model for exposure estimation and risk description
ECHA	European Chemical Agency
EFCC	European Federation for Construction Chemicals
EMKG	Easy-to-use workplace control scheme for hazardous substances
EMGK Tool	First tier IT-tool to estimate the inhalation exposure at the workplace to fulfil the obligations arising from REACH
ENES	Exchange Network on Exposure Scenarios
ES	Exposure Scenario
ESCom	Exposure Scenario Communication

eSDS	Extended Safety Data Sheet
ESIG	European Solvents Industry Group
ESVOC	European Solvents Industry Platform
FEICA	Association of the European Adhesive and sealant industry
GES	Generic Exposure Scenario
LEV	Local Exhaust Ventilation
MEASE	Tool for the estimation and assessment of substance exposure which combined approaches from the EASE (Estimation and Assessment of Substance Exposure) expert system, from the ECETOC TRA tool and from the health risk assessment guidance for metals (HERAG – Health Risk Assessment Guidance for Metals)
Msafe	Maximum daily tonnage of the substance guaranteeing safe use for a specific application
OSH	Occupational Safety and Health
PPE	Personal protective equipment
PROC	Process Category
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
SDS	Safety Data Sheet
SPERC	Specific Environmental Release Category
SUMI	Safe Use of Mixtures Information
SWED	Sector-specific Workers Exposure Description
TRA	Targeted Risk Assessment
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
VP	Vapour phase

Annexes

Annex 1: ART discrepancies

Annex 2: Use amount environment

Annex 3: Qualitative assessments

Annex 4: Discrepancies using TRA

Annex 5: GES assessment

Annexes are available on request at Cefic (sja@cefic.be).