CARRYING OUT CHEMICAL SAFETY ASSESSMENTS (CSA) USING THE ENES TOOL SET

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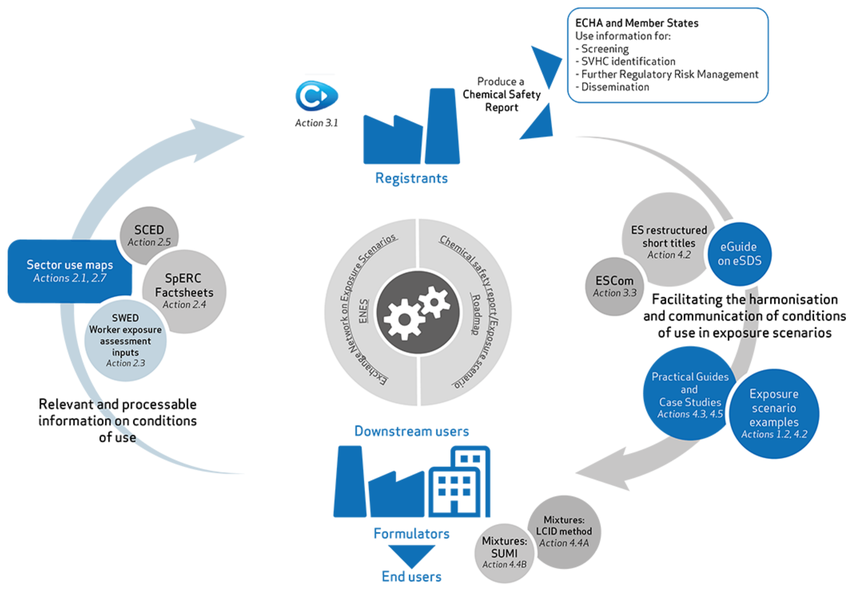
ENES
EXCHANGE NETWORK ON EXPOSURE SCENARIOS



How do develop a Chemical Safety Assessment (CSA)

Step 1: Determine all hazards that require an exposure and/or risk assessment

Step 2: Create the Life Cycle and determine the respective Use Descriptors

Step 3: Carry out the exposure and/or risk assessment for all identified hazards
Apply ENES tools and other recourses to determine the exposure and/or risk of all identified hazards and for all Life Cycle stages.

Available ENES tools for Registrants include:

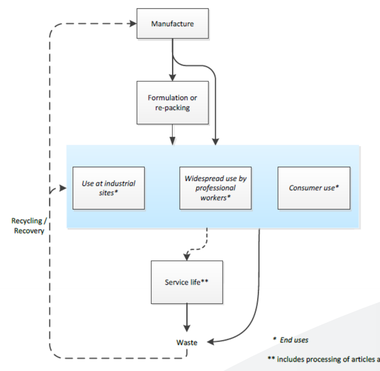
- **Chesar:** Database which can be used to organise CSA, to communicate CSA to ECHA and to share safe use information with Downstream Users
- **Use Maps:** Contain SpERCs, SWEDs and SCEDs that define the typical Conditions of Use (CoU) for the environment, workers and consumers, respectively
- **ESCom phrase library:** Standardised set of phrases that can be used to communicate safe use (the intention is also that in the future this library is available in all official EU languages)
- **ESComXML:** Enables the electronic communication of Exposure Scenarios that contain safe use information

Step 1: Determine all hazards that require an exposure and/or risk assessment

	Environment	Workers	Consumers
Part D – Framework for exposure assessment Part E – Risk Characterisation	R.16 – Environmental exposure assessment	R.14 – Occupational exposure assessment	R.15 – Consumer exposure assessment
Phys-chem hazards	n.a.	Flammability, Explosivity, Oxidising potential	Flammability, Explosivity, Oxidising potential
Qualitative hazards	Remote marine areas, Ozone depleting, Absence of short-term toxicity for low water solubility and/or high hydrophobicity substances,…	Aspiration, Skin/Respiratory Sensitizer, Eye/Skin/Lung Irritants, Eye damaging, Skin corrosion, Drowsiness/Dizziness, Skin Sensitizer…	Aspiration, Skin/Respiratory Sensitizer, Eye/Skin/Lung Irritants, Eye damaging, Skin corrosion, Drowsiness/Dizziness, Skin Sensitizer…
Semi-quantitative hazards	PBT, vPvB	CM, Respiratory Sensitizer	(CM), Respiratory Sensitizer
Quantitative hazards	Acute toxicity, Chronic toxicity	Reprotoxicity, Specific organ tox, Acute toxicity,…	(Reprotoxicity), Specific organ tox, Acute toxicity,…

Indicative table: Some endpoints may fall into different hazard categories, depending on the available (eco)toxicological information. E.g. threshold carcinogens, acute toxicity, lung irritation

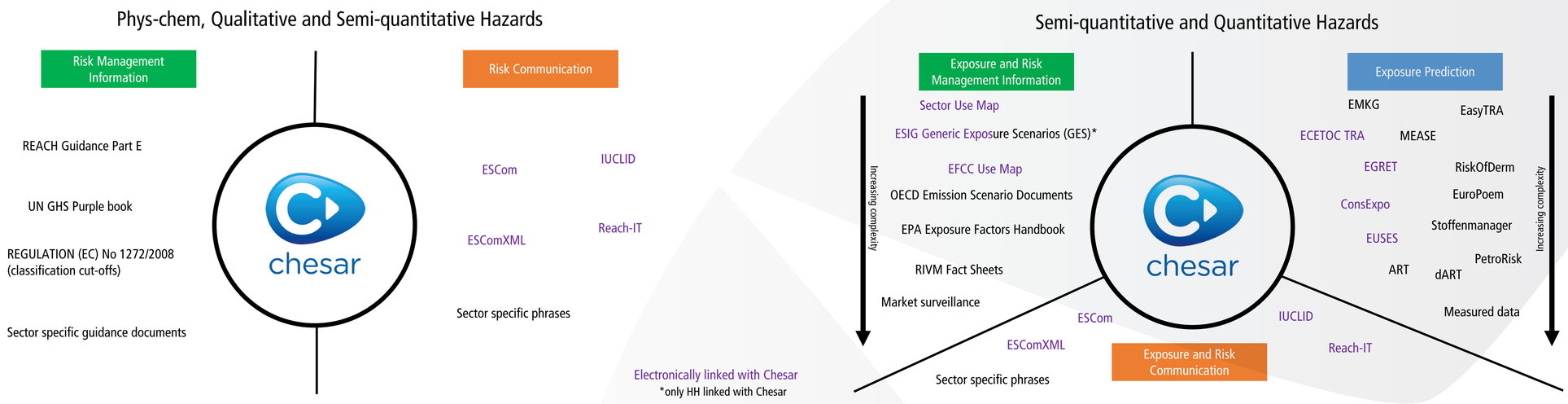
Step 2: Create the Life Cycle and determine the respective Use Descriptors



Manufacture	Tonnage			ERC 1	PROC 0-28	
Formulation or re-packing	Tonnage	Technical function		ERC 2-3	PROC 0-28	PC 0-42
Use at industrial sites	Tonnage	Technical function	SU 0-24	ERC 4-7	PROC 0-28	PC 0-42
Widespread use by professional workers	Tonnage	Technical function	SU 0-24	ERC 8-9	PROC 0-28	PC 0-42
Consumer use	Tonnage	Technical function		ERC 8-9		PC 0-42
Service life (worker at industrial site)	Tonnage	Technical function		ERC 12	PROC 0/21-25	AC 0-13
Service life (professional worker)	Tonnage	Technical function		ERC 10-11	PROC 0/21-25	AC 0-13
Service life (consumers)	Tonnage	Technical function		ERC 10-11		AC 0-13

Figure taken from: ECHA (2015) Guidance R.12 – Use description

Step 3: Carry out the exposure and/or risk assessment for all identified hazards



Applicability of the ENES tools

		Chesar	Sector Use Map	EFCC Use Map	ESIG GES Use Map	ESCom	ESComXML
Phys-chem	Phys-chem hazards	✓	×	×	✓	✓	✓
Qualitative	Aspiration hazard	✓	×	×	✓	✓	✓
	Skin irritation/corrosion	✓	×	×	✓	✓	✓
	Eye irritation/damage	✓	✓	✓	✓	✓	✓
	Drowsiness/dizziness	✓	×	×	✓	✓	✓
	Skin sensitisation	✓	×	×	✓	✓	✓
	Other HH qualitative hazards	✓	×	×	✓	✓	✓
	Other env qualitative hazards	✓	×	×	✓	(✓)	(✓)
Semi-quantitative	Respiratory sensitisation	✓	×	×	✓	(✓)	(✓)
	CMR	✓	×	×	✓	(✓)	(✓)
	PBT/vPvB	✓	×	×	✓	(✓)	(✓)
Quantitative	HH: TRA based assessments	✓	✓	✓	✓	✓	✓
	Env: EUSES based assessments	✓	✓	✓	✓	✓	✓
	HH: non-TRA exposure tools	✓	×	✓	✓	✓	✓
	Env: non-EUSES tools*	✓/×#	✓/n.a.#	✓/n.a.#	✓/n.a.#	(✓)/n.a.#	(✓)/n.a.#
	Measured data	✓	×	×	✓	(✓)	(✓)
Other considerations	Solids in liquids	✓	×	×	✓	✓	✓
	Low volatile liquids-Aerosols	✓	×	×	✓	✓	✓
	UVCB	✓	(×)	(×)	✓	✓	✓

✓	applicable
(✓)	applicable, but typically specific phrases are needed that may not be supported by EScom
×	currently not applicable, but solutions are being developed by ECHA and Sector Groups
(×)	depending on the complexity of the assessed UVCB substance
×	not applicable

* Electronic communication with Chesar is currently not possible
\# MvE must be based on EUSES in Chesar

Additional considerations

Sector Use Maps currently do not consistently apply EScom phrases

➜ Electronic communication along the supply chain is not possible

Service Life is currently not covered by any Use Map

➜ e.g. substances that may remain in dried coatings, adhesives or comparable mixtures after application in/on the article or substances incorporated in buildings, constructions and parts of them

Screening step of the LCID method is hazard driven

➜ Substances that do not contribute to the classification of the mixture are not considered by the formulators, but may be the constituent with the highest risk (e.g. enzymes, alkoxysilanes)

Indicative boundaries quantitative risk assessment using ECETOC TRA

		VP @30°C	AISE – Ind	AISE – Prof	EFCC – Prof	FEICA – Ind	FEICA – Prof
Transfers – PROC8	High	>10 kPA	123	410	615/144/41	87	n.a.
	Moderate	500 Pa - 10 kPa	21	82	123/29/9	15	n.a.
	Low	0.01 Pa - 500 Pa	4.1	21	25/6/1.7	2.9	n.a.
	Very low	<0.01 Pa	0.082	0.082	0.25/0.058/0.016	0.058	n.a.
	Dermal	n.a.	13.71/2.74	13.71/2.74	1.37	1.37	n.a.

		VP @30°C	AISE – Ind	AISE – Prof	EFCC – Prof	FEICA – Ind	FEICA – Prof
Mixing – PROC5	High	>10 kPA	n.a.	n.a.	2050/861/173	144	123
	Moderate	500 Pa - 10 kPa	n.a.	n.a.	410/173/35	29	25
	Low	0.01 Pa - 500 Pa	n.a.	n.a.	41/18/3.5	2.9	2.5
	Very low	<0.01 Pa	n.a.	n.a.	0.4/0.018/0.033	0.06	0.025
	Dermal	n.a.	n.a.	n.a.	1.37	1.37	1.37

How to read the tables:

Minimum systemic, long-term DNEL needed to apply the respective Use Maps with ECETOC TRA

- Inhalation route: mg/m3
- Dermal route: mg/kg/day

Assumption:

- Liquid (100%) is transferred and mixed
- Indoors
- 100 g/mol

Does not consider exposure via aerosols

Indicative boundaries quantitative risk assessment using ECETOC TRA when also considering combined exposures

		VP @30°C	AISE – Ind	AISE – Prof	EFCC – Prof	FEICA – Ind	FEICA – Prof
Transfers – PROC8	High	>10 kPA	1970	6600	2500/2300/660	1400	n.a.
	Moderate	500 Pa - 10 kPa	340	1300	500/460/145	240	n.a.
	Low	0.01 Pa - 500 Pa	66	340	100/95/28	48	n.a.
	Very low	<0.01 Pa	1.3	1.3	1.0/0.95/0.26	1.0	n.a.
	Dermal	n.a.	27.4/5.5	27.4/5.5	2.74	2.74	n.a.

		VP @30°C	AISE – Ind	AISE – Prof	EFCC – Prof	FEICA – Ind	FEICA – Prof
Mixing – PROC5	High	>10 kPA	n.a.	n.a.	4100/1750/700	2300	500
	Moderate	500 Pa - 10 kPa	n.a.	n.a.	820/350/140	460	100
	Low	0.01 Pa - 500 Pa	n.a.	n.a.	82/36/14	48	10
	Very low	<0.01 Pa	n.a.	n.a.	0.8/0.04/0.14	1.0	0.1
	Dermal	n.a.	n.a.	n.a.	2.74	2.74	2.74

Assumptions:

- Combined route:
  The inhalation and dermal route contribute each 50% to the combined systemic, long-term, RCR
- Combined exposure (full-shift exposure)
  Applying an RCR benchmark of 0.5 and of 0.125 for the inhalation route and for activities that are limited to less than 4 hours and 1 hour, respectively.
  (this is a possibly approach on how to consider combined exposure that was discussed during the ECHA/Cefic Use Map Pilot)