

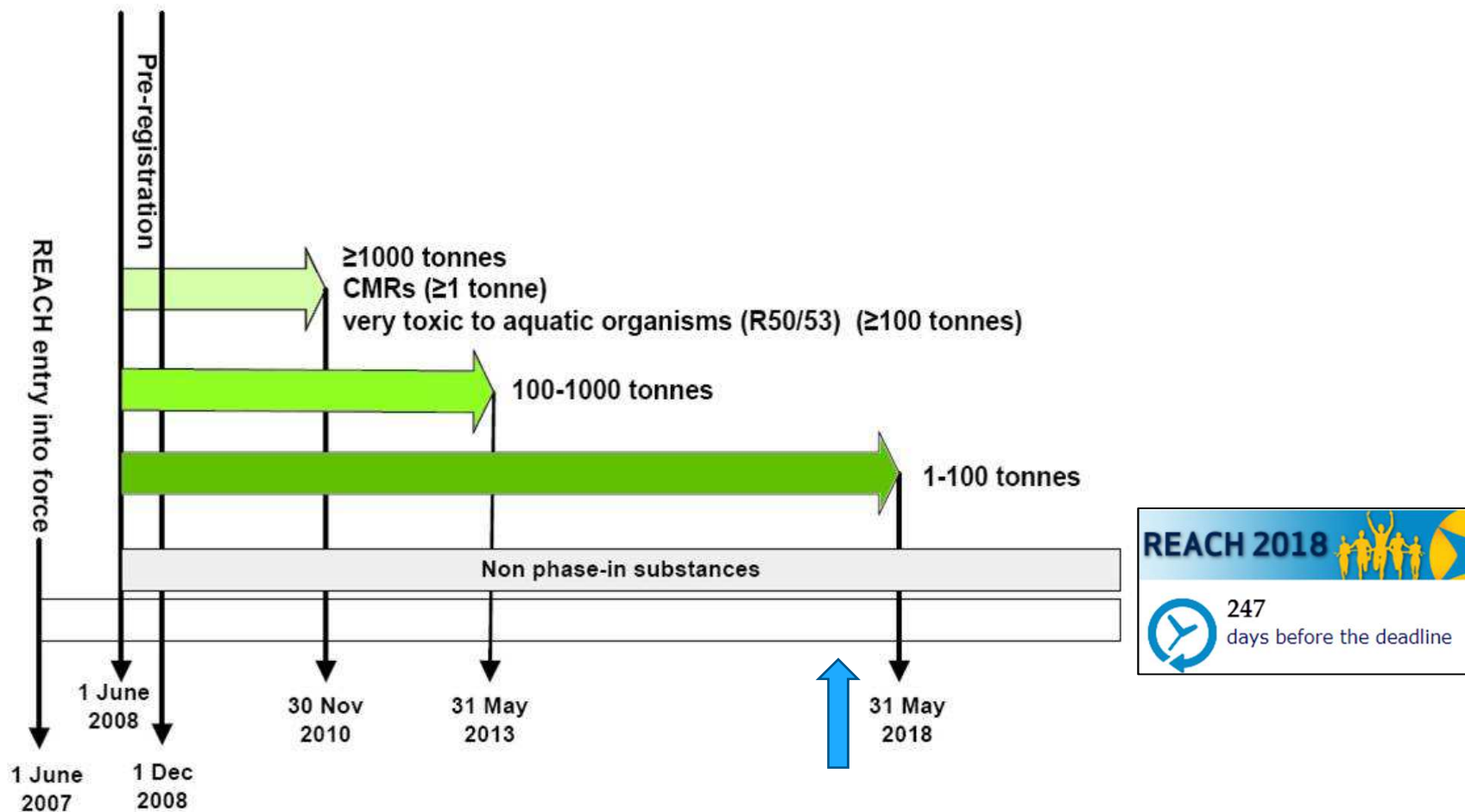


## REACH Guidance:

Lead Component Identification (LCID) and Safe Use of Mixtures Information (SUMI)

[KBull@sphasolutions.com](mailto:KBull@sphasolutions.com)

# REACH registration deadlines



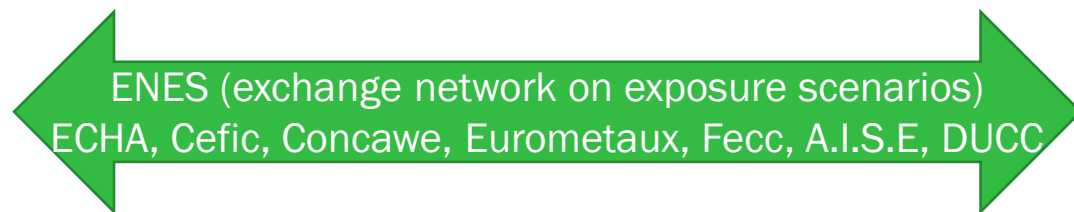
# Communication of safe use information



Safe use of mixtures from ESs of substances

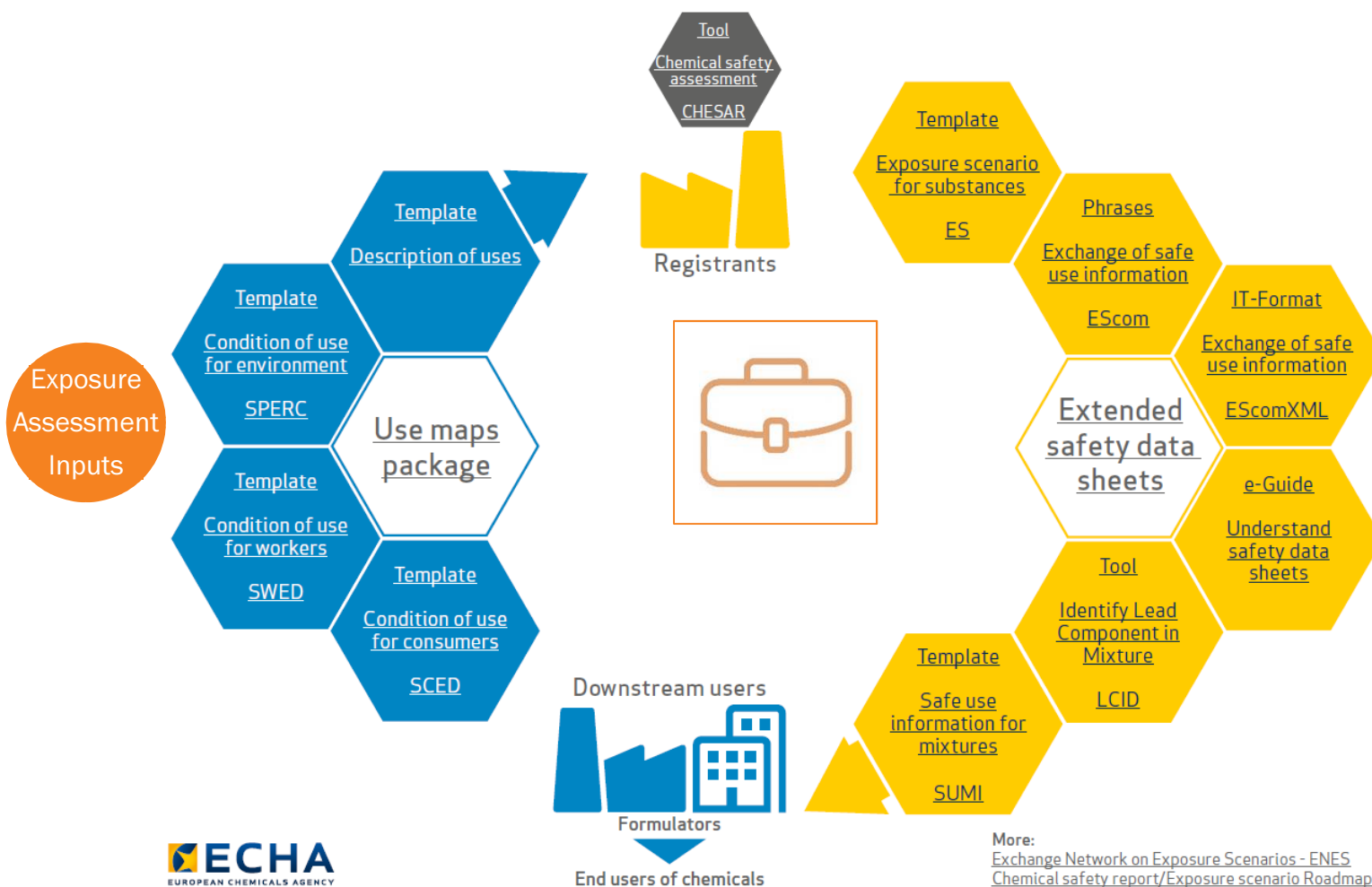


ESs  
Safe use of substances



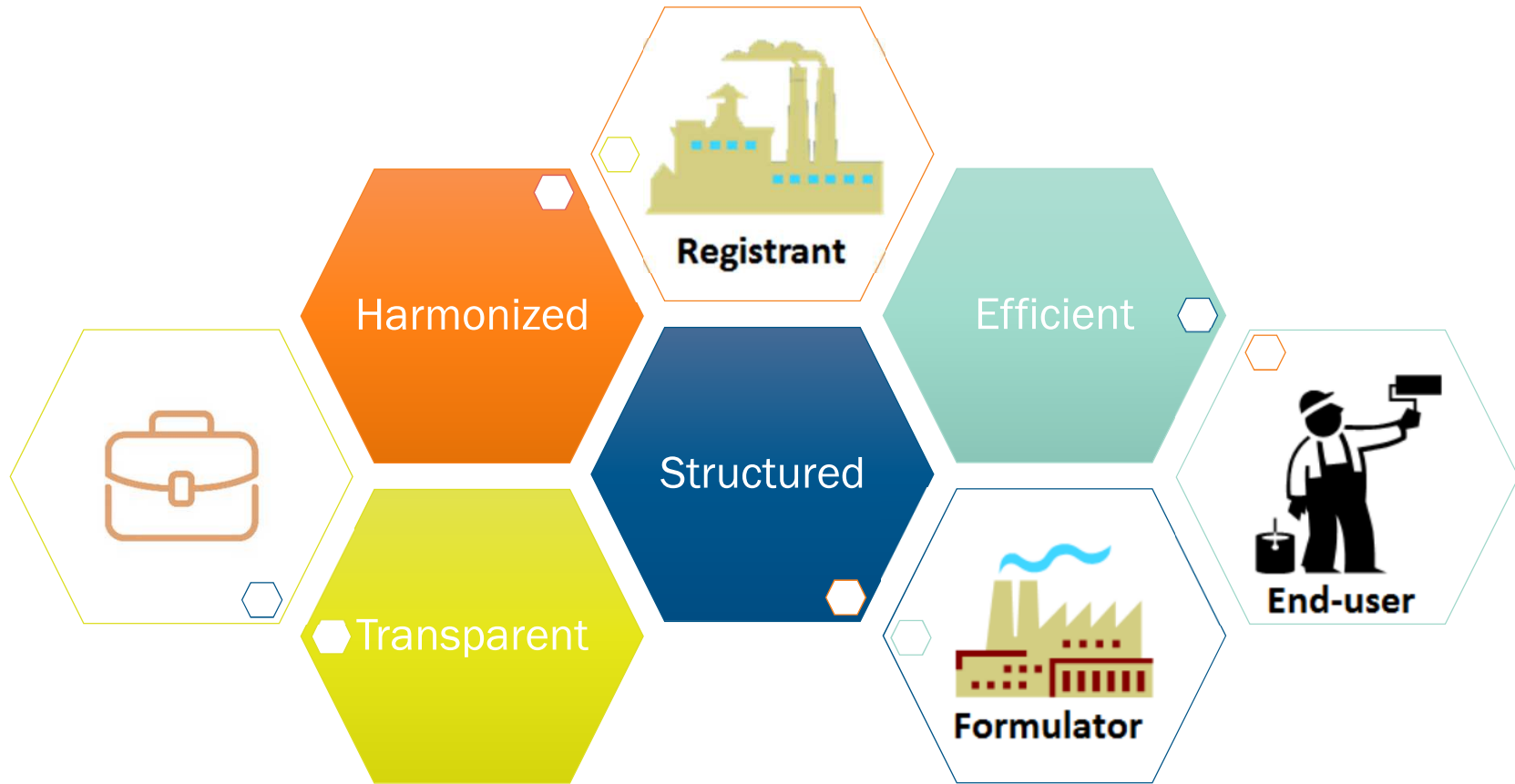
# Chemical safety report/Exposure scenario roadmap

Improving communication on the safe use of chemicals

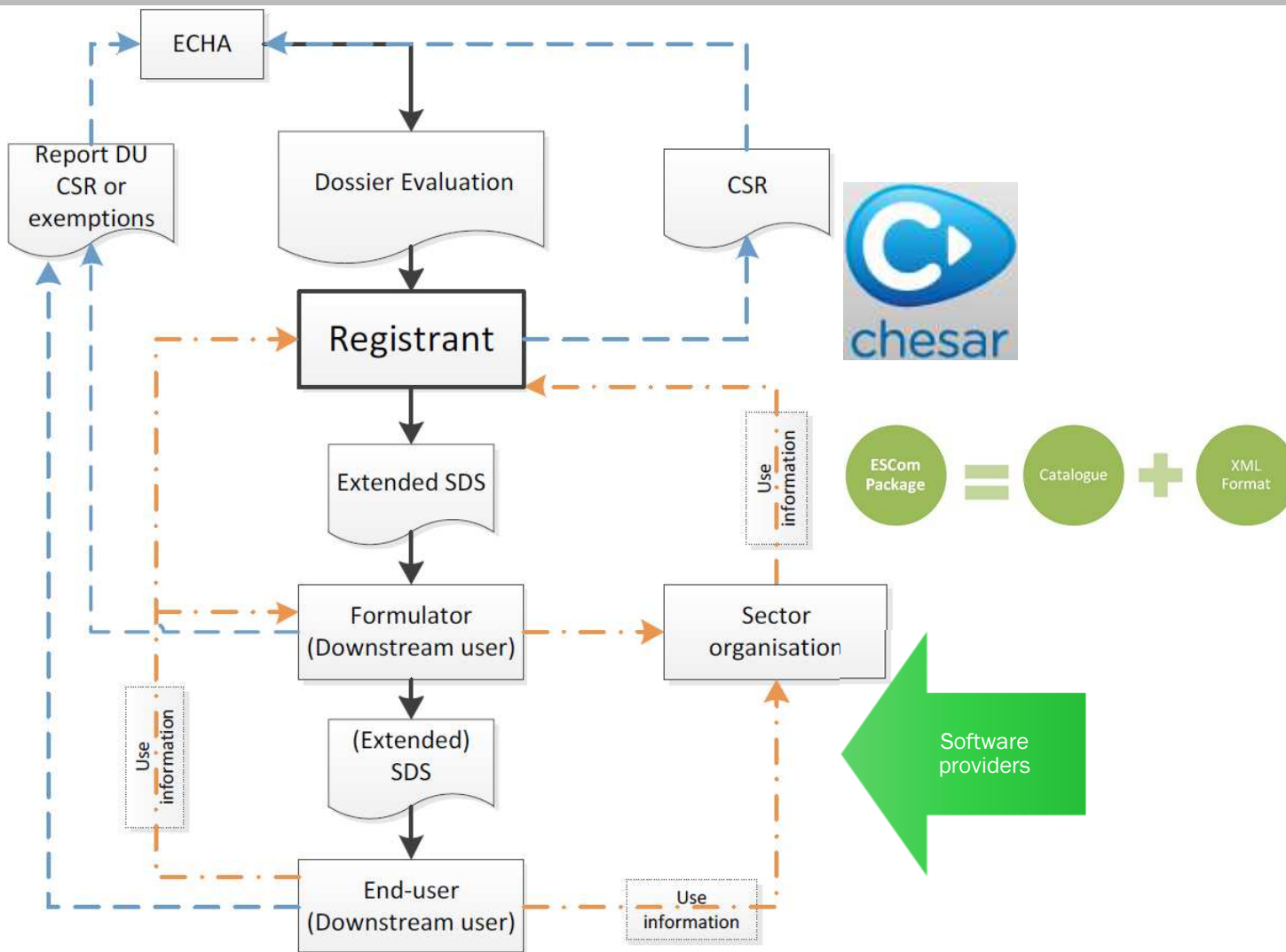


More:  
[Exchange Network on Exposure Scenarios - ENES](#)  
[Chemical safety report/Exposure scenario Roadmap](#)

# Communication in the supply chain



# Communication flows under REACH



# CSR/ES roadmap – Action areas

## Action area 4: Support to formulators



› Action area 1: Increase common understanding among stakeholders

Achieve a common understanding among stakeholders of the information in the chemical safety report scenario for communication.



› Action area 2: Information inputs for the chemical assessment

Identify the information that registrants need from so that the uses can be assessed, and helpfully communicated down the supply chain.



› Action area 3: IT tools and standardisation

Develop IT tools to support the efficient generation of consistent information on safe use.



› Action area 4: Support to formulators

Harmonise the exposure scenario and develop and consolidate the information from single substance to the conditions of safe use for their products effectively.



› Action area 5: Support to end-users

Identify the needs of the various industrial and public of chemicals relating to safety advice, and promote

› Action 4.1: Harmonisation of the safety advice among co-registrants

› Action 4.2: Harmonised layout for the ES for communication

› Action 4.3: Understanding the formulators' options when receiving an extended SDS

✓ Action 4.4: Converting substance exposure scenarios into advice on the safe use of a mixture

This action seeks an agreement on the high level principles for linking the exposure scenario information on substances to the safe use advice for mixtures.

Status: Completed

Agreed general principles were incorporated into the 2013 version of the ECHA Guidance for Downstream Users. The two main approaches identified, referred to as top-down and bottom-up approaches, have been further developed since then.

### Top-down approaches

A methodology has been developed to identify the components that determine the risk management measure, termed lead component identification (LCID). The Practical Guide was published by Cefic/VCI in April 2016.

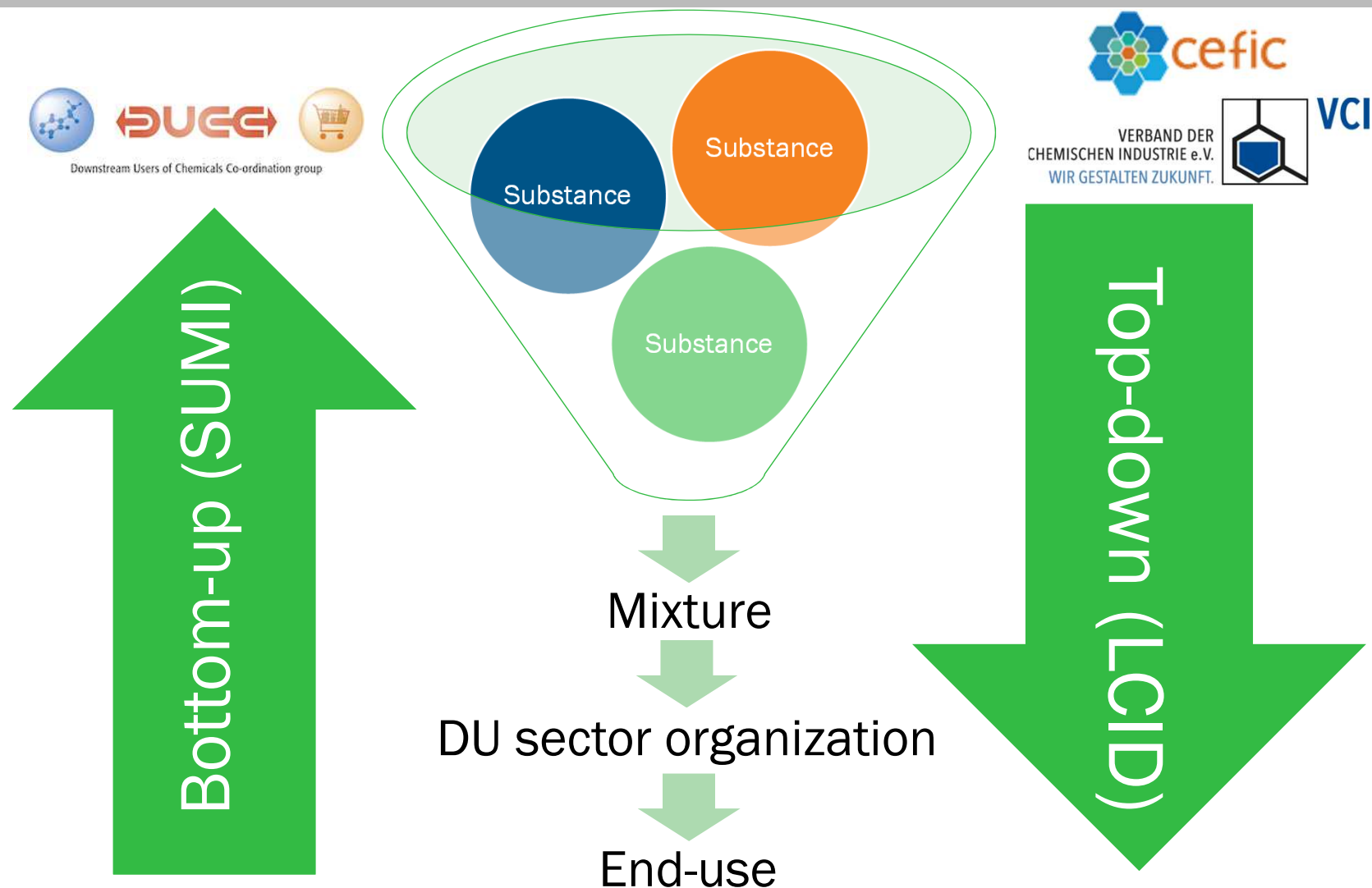
› REACH Practical Guide on Safe Use Information for Mixtures under REACH. The Lead Component Identification (LCID) Methodology (Cefic)

### Bottom-up approaches

A safe use of mixtures information (SUMI) template has been developed which presents safe use advice information for mixtures in an easy to read format. Guidelines on the methodology were published by DUCG in December 2015. A library of SUMIs, containing sector-specific advice for common uses, is expected to be finalised in 2015. This work is closely connected to sector-specific worker exposure descriptions (SWEDs, see action 2.3.A).

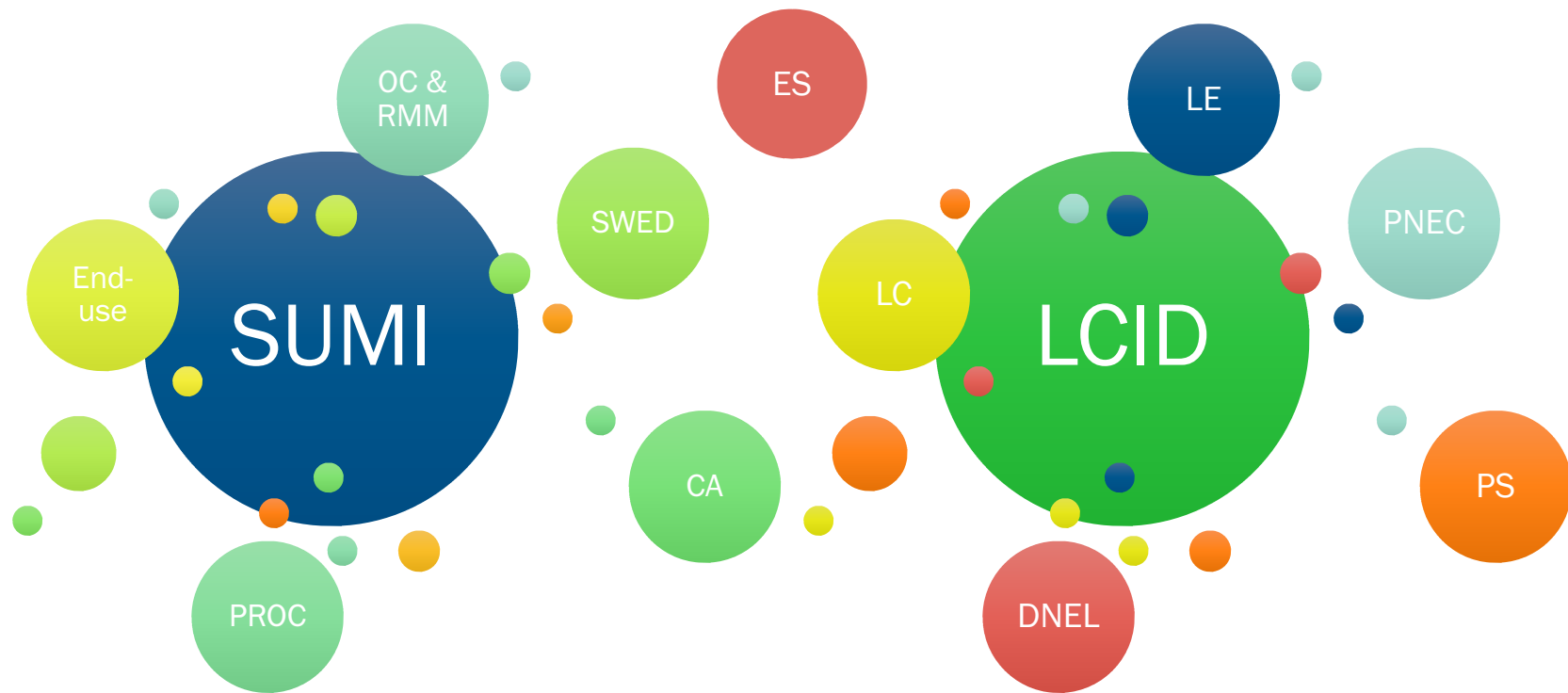
SUMIs/SWEDs aim to define the existing conditions of use for mixtures as the

# Approaches: UP and DOWN



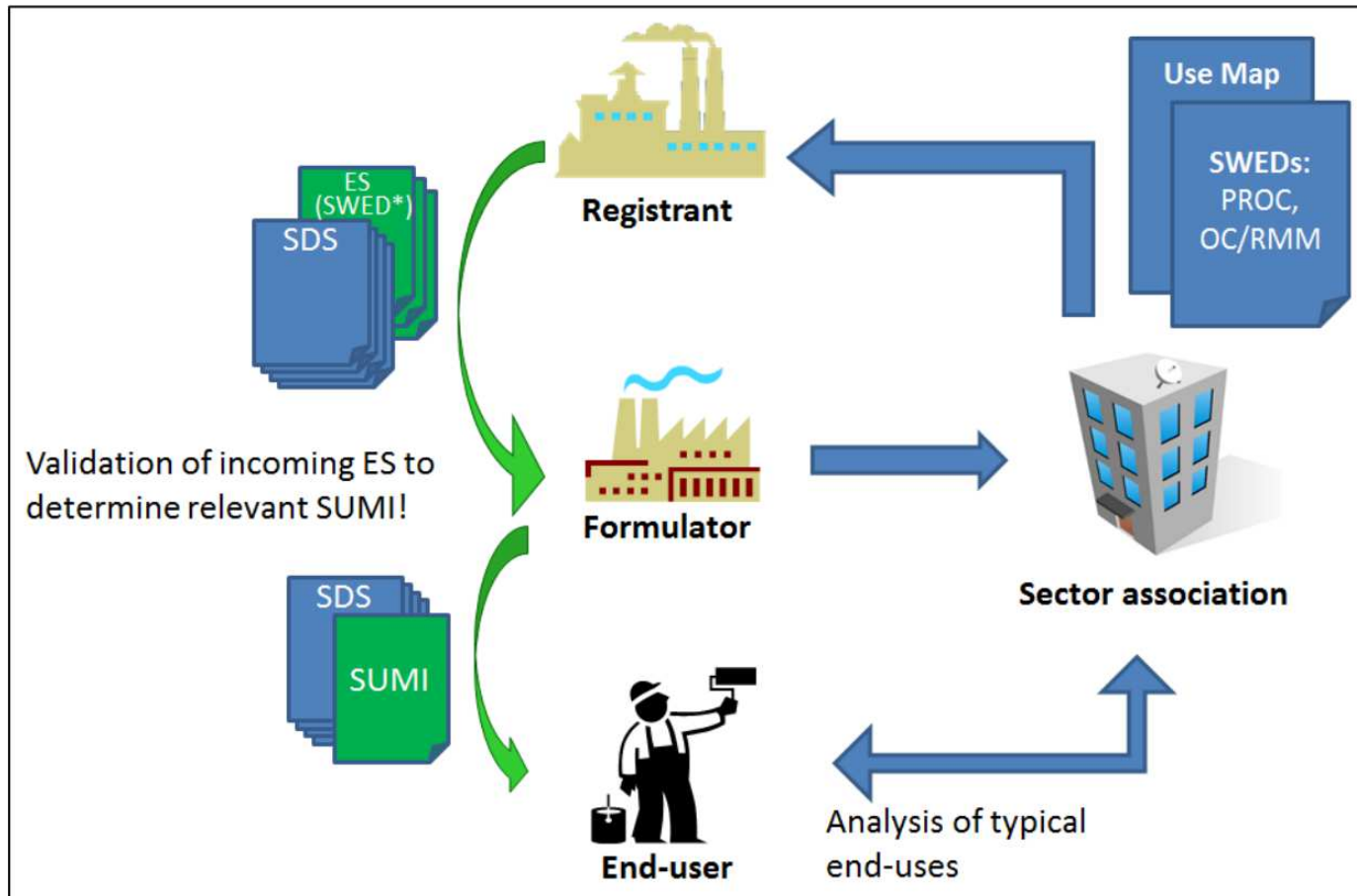


$$\Delta G = \Delta H - T\Delta S$$



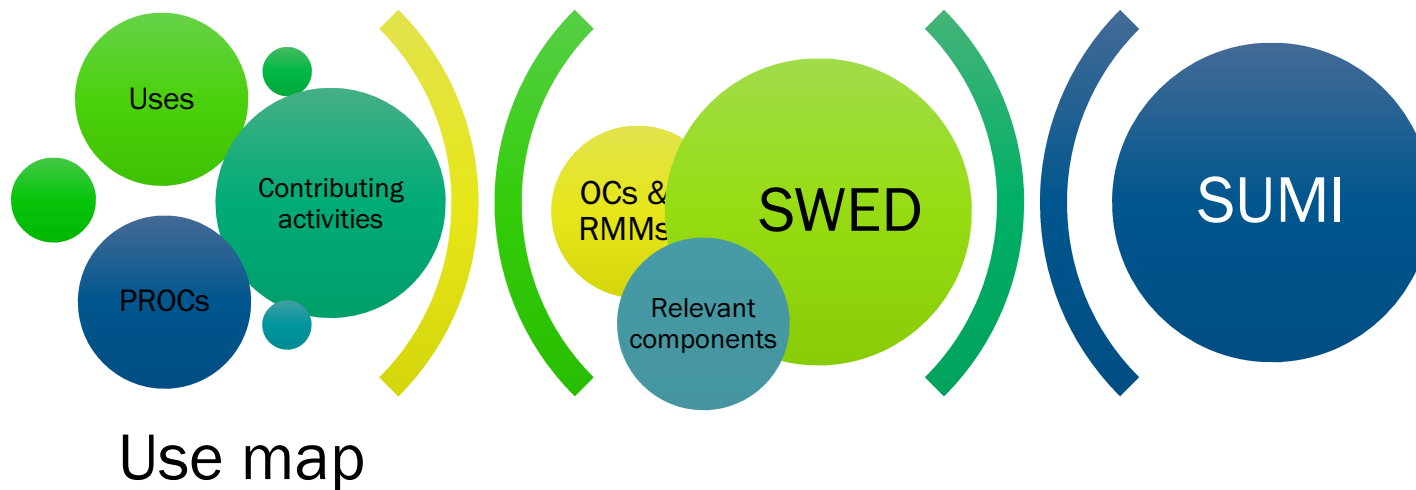
# Bottom-up: SUMI (safe use of mixtures information)

# Communication in the supply chain



SWED: sector-specific worker exposure description

# SUMI approach





# Use maps – A.I.S.E.

End-use: industrial → tab: AISE INDUSTRIAL USES

Use maps template - Last updated: April 2016

Sector Name: A.I.S.E. Date: October 2016

## Use identification and general description

Use code	Link to entry in previous use maps	Life Cycle Stage	Life Cycle Stage code	Use name	ESCom standard phrase code(s) for use name	Further description of use	Sectors of use (SU)	Product categories (PC)	Article categories (AC)	ES short title for communication	This use leads to subsequent service life (Y/N)	Reference to subsequent service life use and relevant substances (if Y in previous column)
AISE_IS_002_v1		Use at industrial sites	IS	Industrial uses; Metal surface treatment products			SU17	PC14		Use at industrial sites; Metal surface treatment products (PC14); General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment (SU17)	no	

↑  
Use name

# Use maps – A.I.S.E.

Use maps template - Last updated: April 2016

Sector Name: A.I.S.E. Date: October 2016

## Use identification and general description

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Use name

## Link activities to exposure assessment inputs

Contributing activity (CA) type	CA name	ESCom standard phrase code(s) for CA name	CA descriptor	Exposure assessment input code for this CA	Additional information (optional) Generic composition by technical functions; maximum concentration per technical function; tonnage information; other
Workers	Transfer and dilution of concentrated product by using dedicated dosing system; medium RMM	-	PROC8b - Transfer of substance or mixture (charging and discharging) at dedicated facilities	AISE_SWED_IS_8b_1	
Workers	Brushing; Automated task; medium RMM	missing	PROC10 - Roller application or brushing	AISE_SWED_IS_10_1	
Workers	Industrial uses; Treatment of articles by dipping or pouring; medium RMM	11133165901; 11133170157; missing	PROC21 - Low energy manipulation and handling of substances bound in/on materials or articles PROC13 - Treatment of articles by dipping and pouring	AISE_SWED_IS_21_1 AISE_SWED_IS_13_1	
Workers	Industrial spraying; Automated task; Open systems; Long term; with LEV	11133170150; 11133170578; 10133334557	PROC7 - Industrial s		
Workers	Industrial spraying; Automated task; Open system; Long term; high RMM	11133170150; 11133170578; 10133334557	PROC7 - Industrial s		
Environment	Use at industrial site leading to inclusion into/onto article	11133170200;	ERC5 - Use at industrial site leading to inclusion into/onto article		
Environment	Use at industrial site leading to inclusion into/onto article	11133170200;	ERC5 - Use at industrial site leading to inclusion into/onto article	AISE SPERC 5.1b.v2	

Contributing Activity name

SWEDs (sector-specific worker exposure descriptions)

# SWEDs – A.I.S.E.

Link activities to exposure assessment inputs					Additional information (optional)
Contributing activity (CA) type	CA name	ESCom standard phrase code(s) for CA name	CA descriptor	Exposure assessment input code for this CA	Generic composition by technical functions; maximum concentration per technical function; tonnage information; other
Workers	Transfer and dilution of concentrated product by using dedicated dosing system; medium RMM	-	PROC8b - Transfer of substance or mixture (charging and discharging) at dedicated facilities	AISE_SWED_IS_8b_1	
Workers	Brushing; Automated task; medium RMM	missing; 11133170578; missing	PROC10 - Roller application or brushing	AISE_SWED_IS_10_1	
Workers	Low energy manipulation and handling of substances bound in/on materials or articles				
Workers	Industrial uses; Treatment of articles by dipping or pouring; medium RMM				
Workers	Industrial spraying; Automated task; Open systems; Long term; with LEV				
Workers	Industrial spraying; Automated task; Open system; Long term; high RMM				
Environment	Use at industrial site leading to inclusion into/onto article				
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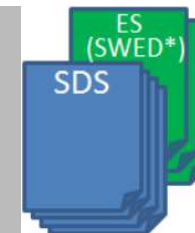
A.I.S.E. SWEDs					
Version October 2016					
Row No.	Field name	AISE_SWED_IS_8b_1		AISE_SWED_IS_10_1	
		Field content	Information for communication	Field content	Information for communication
<b>1</b>	<b>SWED identifiers</b>				
1.1	SWED title*	Transfer and dilution of concentrated product by using		Brushing; Automated task;	
1.2	SWED code*				IS_10_1
1.3	Short description of process/activity covered*				
1.4.1	Short description of the applicability domain (in terms of substance properties)				
1.4.2	Short description of factors during use that may influence selection of modelling tool				
1.6a.1	name*	dedicated dosing system; medium RMM		Brushing; Automated task; medium RMM	
1.6a.2	Corresponding PROC*	PROC8b		PROC10	
1.7	Last Revision date	10/1/2016		10/1/2016	
<b>2</b>	<b>Conditions of use for workers (input to CSA)</b>				
2.1	Percentage (w/w) of substance in mixture*	The risk assessor using this SWED should indicate the maximum concentration for the relevant substance that can be used safely considering the conditions of use indicated in this SWED.		The risk assessor using this SWED should indicate the maximum concentration for the relevant substance that can be used safely considering the conditions of use indicated in this SWED.	

SWEDs (sector-specific worker exposure descriptions)

Conditions of use



# Validation



## 2.2.9. Control of worker exposure: Roller, spreader, flow application; Printing (PROC 10)

Product (Article) characteristics	Covers concentrations up to 2.0 %
Am	2.2.4. Control of worker exposure: Raw material receipt and transfer (PROC 8b)
Cov	
Tec	Product (Article) characteristics
Loc	Covers concentrations up to 2.0 %
Prov	Amount used (or contained in articles), frequency and duration of use/exposure
Sup	Covers use up to 1.0 h/day
ope	Technical and organisational conditions and measures
Oth	Provide a basic standard of general ventilation (1 to 3 air changes per hour).
Indc	Supervision in place to check that the risk management measures in place are being used correctly and operation conditions followed.; Ensure control measures are regularly inspected and maintained.
Ass	
Add	Other conditions affecting workers exposure
We	Indoor use
Use	Assumes process temperature up to 40.0 °C

Use

## 2. ES 2: Use at industrial sites; Coatings, Thinner, paint removers (PC 9a)

### 2.1. Title section

ES name: General Industrial use of coatings and inks  
 Product category: Coatings and Paints, Thinners, paint removers

<b>Environment</b>
1: Industrial application of coatings and inks involving water
2: Industrial application of coatings and inks involving water
3: Industrial application of coatings and inks. Water free
<b>Worker</b>

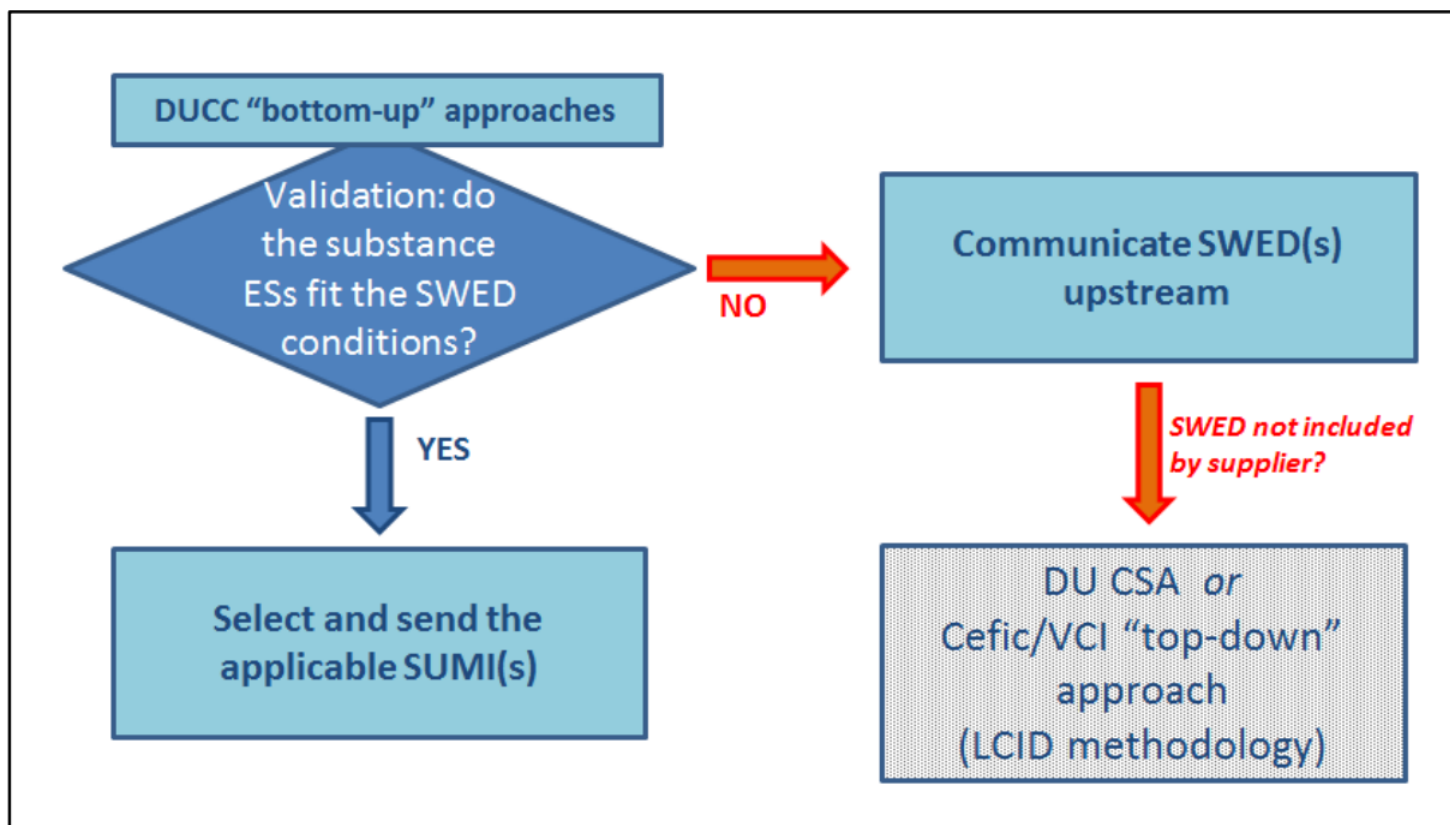
PROCs

4: Raw material receipt and transfer	
5: Mixing operations; Open systems	PROC 5
6: Batch loading of equipment (manual, non dedicated)	PROC 8a
7: Spraying	PROC 7
8: Printing closed automated machinery	PROC 10
9: Roller, spreader, flow application; Printing	PROC 10
10: Dipping, immersion and pouring	PROC 13
11: Film formation - force drying, stoving and other technologies; Elevated temperature	PROC 2
12: Equipment cleaning and maintenance; Manual	PROC 28

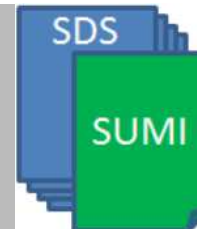
OCs & RMMs

All the conditions of use (OCs, RMMs) in a SWED (e.g. PROC 8b, PROC 10) are covered by the ESs of all the substances contributing to the mixture classification

# SUMIs



# SUMIs – A.I.S.E.



Use,  
SWED,  
PROC

OCs

RMMS

<b>SUMI: Safe Use of Mixtures Information for end-users</b>	
<b>AISE_SUMI_13.1.b.v1: Professional use of drain unblockers</b>	

<b>General description of the process covered</b>	
Use of drain unblocking products by professional end-users	
<i>This information is linked to AISE_SWED_13.1.b.v1</i>	
Sector of use (SU): 22	Professional
Process Category (PROC) 13	Dipping & pouring

<b>Operational conditions</b>	
Maximum duration	10 minutes per day.
Process conditions	Process is carried out at room temperature. In case of dilution, tap water at a maximum temperature of 45 degrees Celcius is used. No LEV needed; good general ventilation at workplace is sufficient.

<b>Risk management measures</b>	
Conditions and measures related to personal protection equipment (PPE), hygiene and health evaluation and the environment	Use gloves and safety goggles. See Section 8 of the SDS of this product for specifications.
	Training of the worker in relation to proper use and maintenance of the PPE must be ensured.
Environmental measures	Prevent that the undiluted product reaches surface waters.

Note: This example is a draft and subject to change.

<b>Good practise advice</b>	
Don't eat or drink, don't smoke, no open flame	
Wash hands after use Avoid contact with damaged skin Do not mix with other products	
Spillage instructions	Dilute with water and mop up.
Additional good practise advice	Follow the product instructions as specified on the label or in the product information sheet and use good occupational hygiene practices as specified in Section 7 of the SDS of the used product.

<b>Additional information on product composition</b>	
In Section 2 of the SDS of products and on the label the classification of the undiluted product is provided.	
The classification of a product is based on the classified ingredients in the products. All ingredients contributing to the classification of the mixture are mentioned in Section 3 of the SDS.	
Relevant limit values of the ingredients on which the exposure assessment is based, are stated in Section 8 of the SDS.	
This product may contain sensitizing ingredients, that may cause an allergic reaction in certain people. Section 15 of the SDS states these ingredients, when applicable to the product.	

*Disclaimer: This is a generic document for communicating conditions of safe use of a product. If a GEIS code is mentioned in Section 1 of the SDS of a product, the formulator of that product declares that all substances in the mixture are present in such concentration, that the use of the product within the conditions of the GEIS CSP documents is safe, according to the GEIS Formulator Guidance. When available, this safe use is ensured by evaluating the results of the chemical safety assessments as performed by the raw material suppliers. When no chemical safety assessment has been carried out by the supplier for an ingredient that contributes to the classification of the mixture, the formulator has performed a safety assessment himself.*

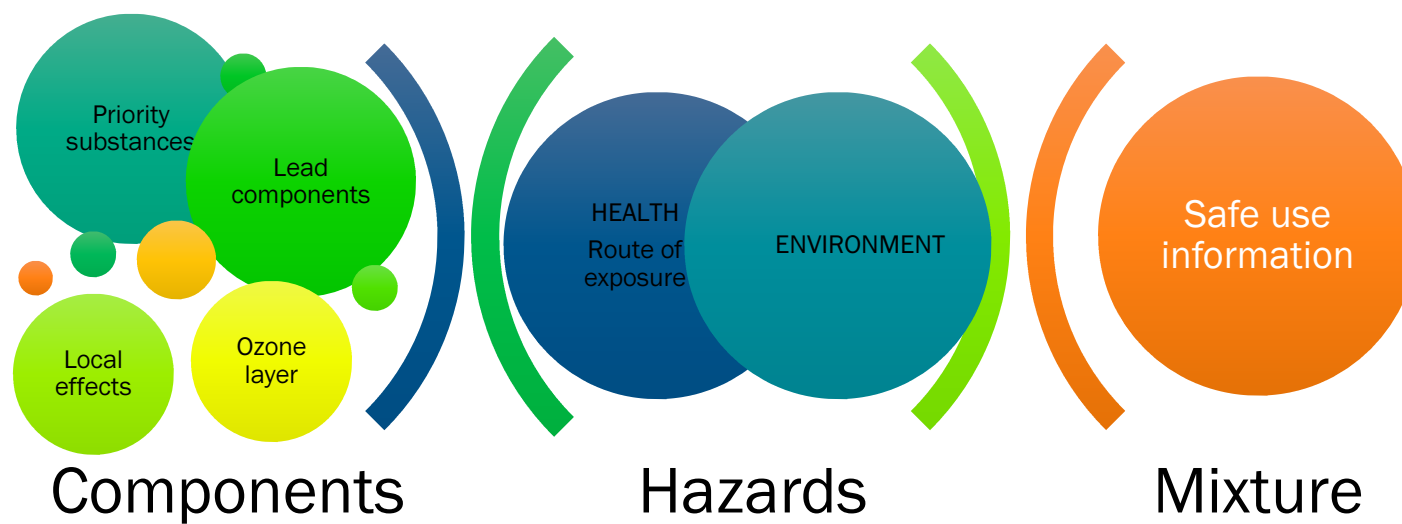
*Following Occupational Health legislation, the employer of workers that use products that are assessed as safe following GEIS conditions remains responsible for communicating relevant use information to employees. When developing workplace instructions for employees, Generic Exposure Information Sheets should always be considered in combination with the SDS and the label of the product. The GEIS Guidance for End Users provides more information.*

*The A.I.S.E. is under no conditions liable for any damage, no matter of what kind, which is the direct or indirect consequence of acts and/or decisions (partly) based on the contents of this document.*

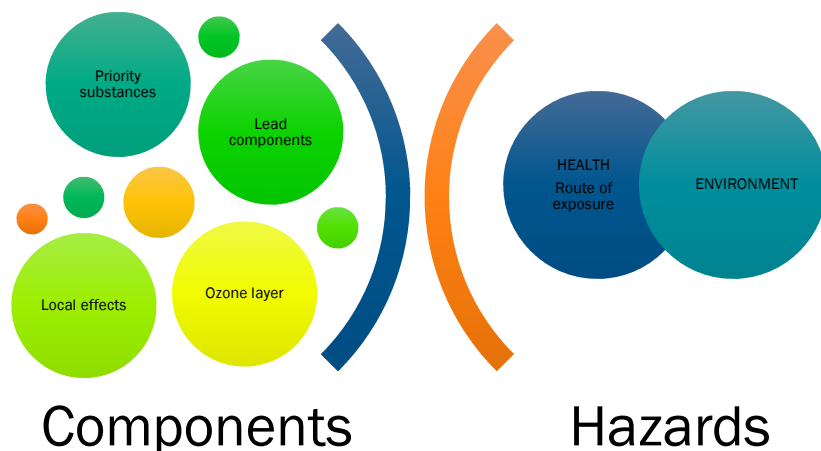
Version: 2.0, May 2015

# Top-down: LCID (lead component identification)

# LCID methodology



# LCID methodology



Not addressed:

- Physical hazards
- Aspiration hazards

**Relevant components**

- Contributing to mixture classification
- **Health:** OELs

**Priority substances**

- **Health:** carcinogen, mutagen
- **Environment:** PBT, vPvB

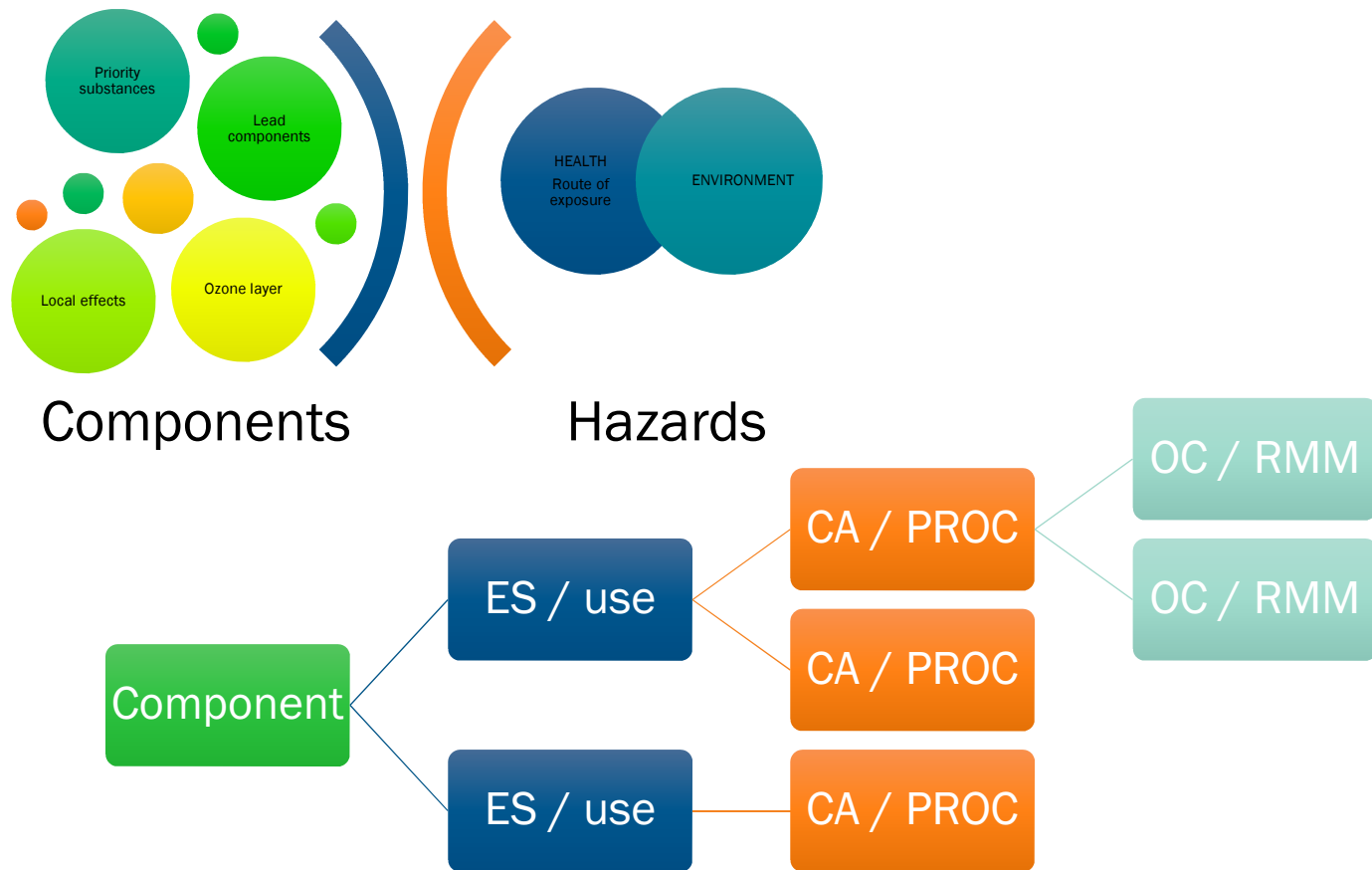
**Lead components**

- **Health:** systemic effects (DNELs)
- **Environment:** environmental hazards (PNECs), ozone layer

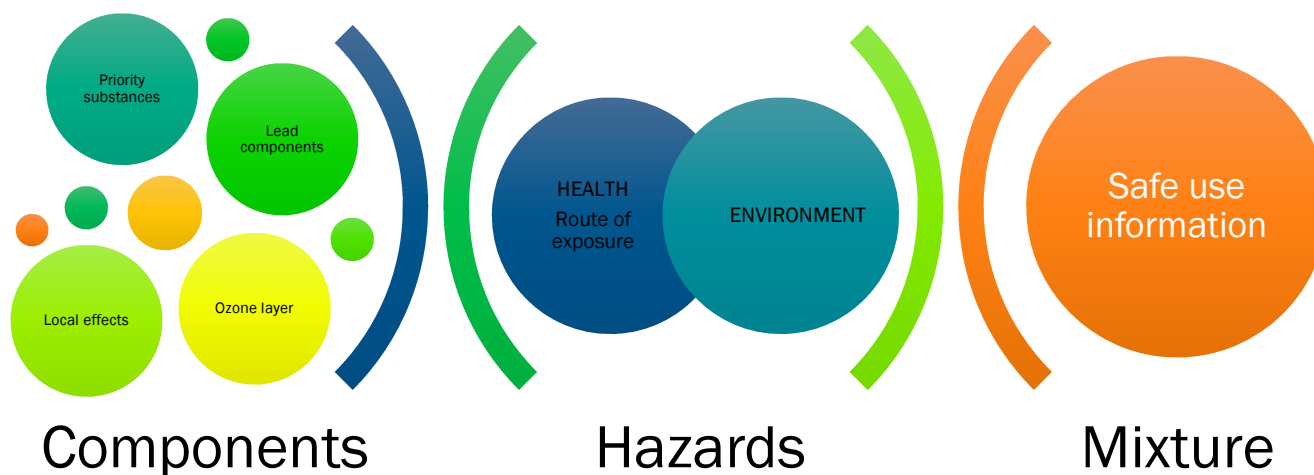
**Local effects**

- **Health:** irritation, corrosion/damage, sensitization, drying and cracking of the skin

# LCID methodology



# LCID methodology



## Mixture

- Worst-case assumption... but coverage checks of OC, RMM for PS, LC, LE
  - All components and/or exposure pathways
  - Components with specific properties not reflected by classification
  - End-uses of mixture



# LCID vs. DPD+ methodology

Use of concentration ~~limits of hazards~~ reference values (DNELs, PNECs, etc.)

- DNELs take into account the assessment factors used to derive them

Grouping of additive hazards

- Gives endpoints more weight

Consideration of local effects and ozone layer

# Lead component indicator (LCI) – Health

Component with highest LCI = LC

$$LCI_{\alpha} = \frac{\text{Conc in mixture}}{\text{DNEL}}$$

$$LCI_{\text{inhalation}} = \frac{C_i \times C_{\text{fug}}}{\text{DNEL}}$$

Not addressed:

- Component interactions (synergistic/potentiating/antagonistic effects)

Additive effects

Acute toxicity (oral, dermal and inhalation) – Categories 1, 2, 3 and 4

STOT SE 3 (dermal and inhalation) – Narcotic effects

$$LCI_{\text{group}} = \sum LCI_i \quad C_{\text{weighted}} = \sum_{i=1}^n \frac{C_i \times \text{DNEL}_{\text{LC}}}{\text{DNEL}_i}$$

# Lead component indicator (LCI) – Environment

Ozone layer

LCI = Conc in mixture

Environmental hazards

$$\text{LCI} = \frac{\text{Conc in mixture}}{(\text{lowest PNEC}) \times 3}$$

for readily biodegradable component

$$\text{LCI} = \frac{\text{Conc in mixture}}{\text{lowest PNEC}}$$

for **not** readily biodegradable component

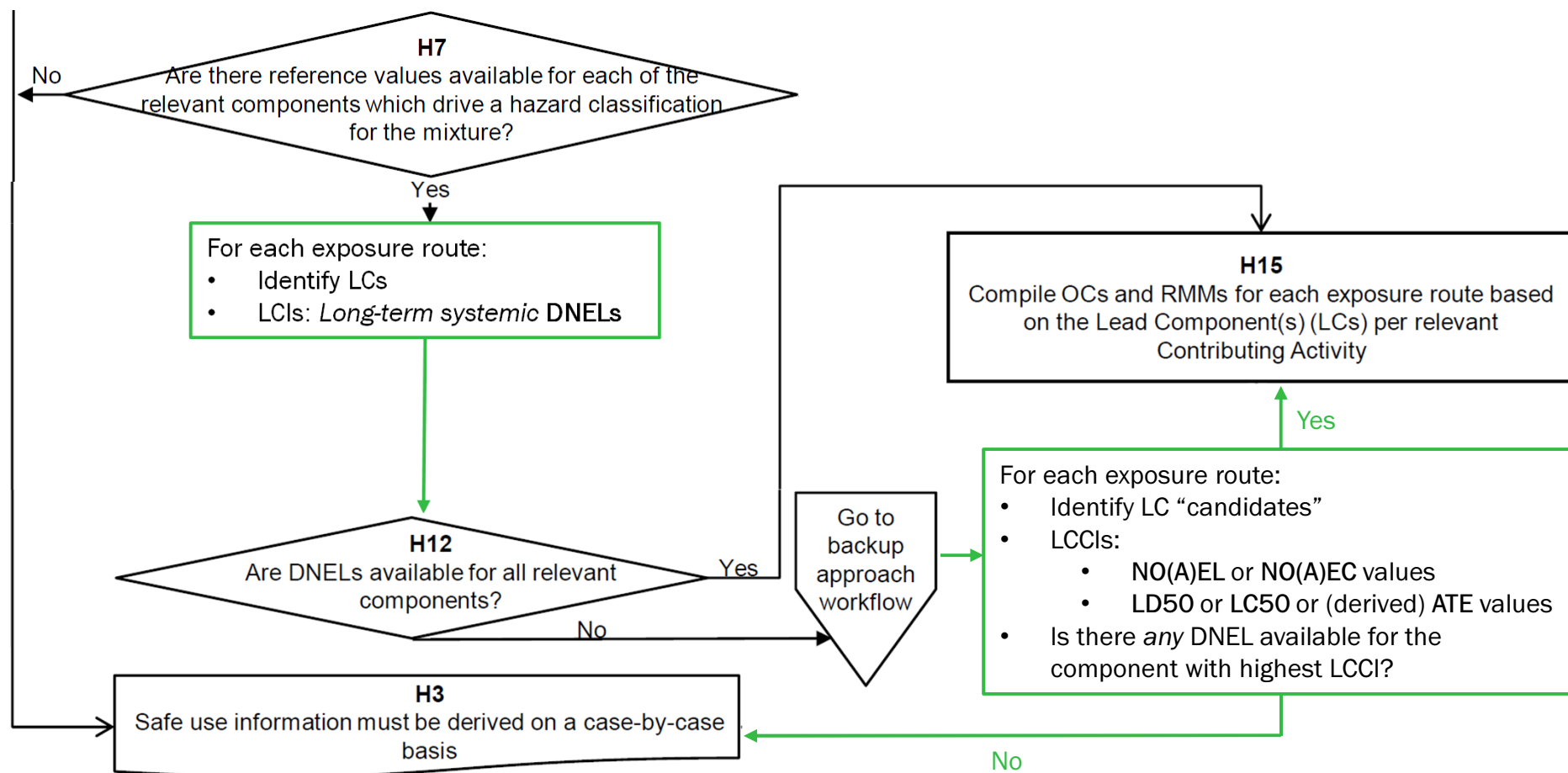
# LCID calculation

“Calculation according to LCID is possible as long as at least one of the above mentioned values is available for all relevant components”

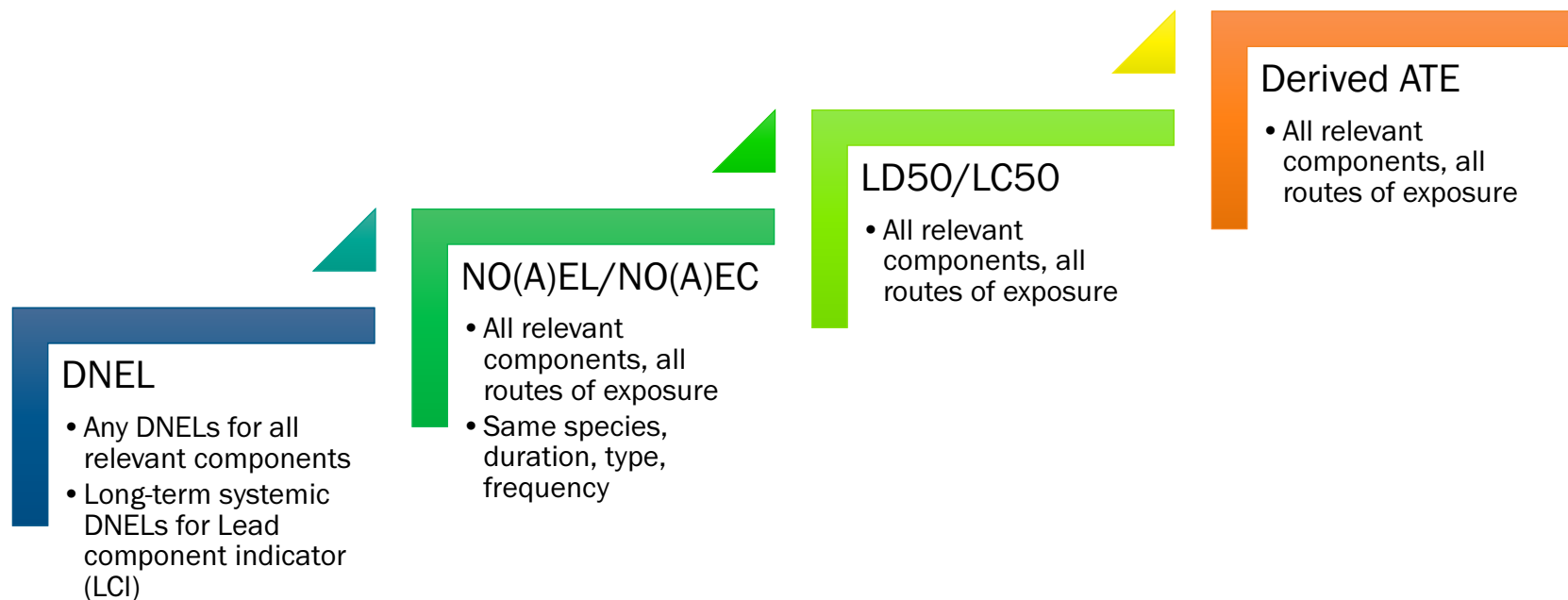
DNEL, NO(A)EL, NO(A)EC, LD50, LC50, (derived) ATE



# Health hazards – Two approaches



# Data requirements – Health



# Data requirements – Environment

## PNEC

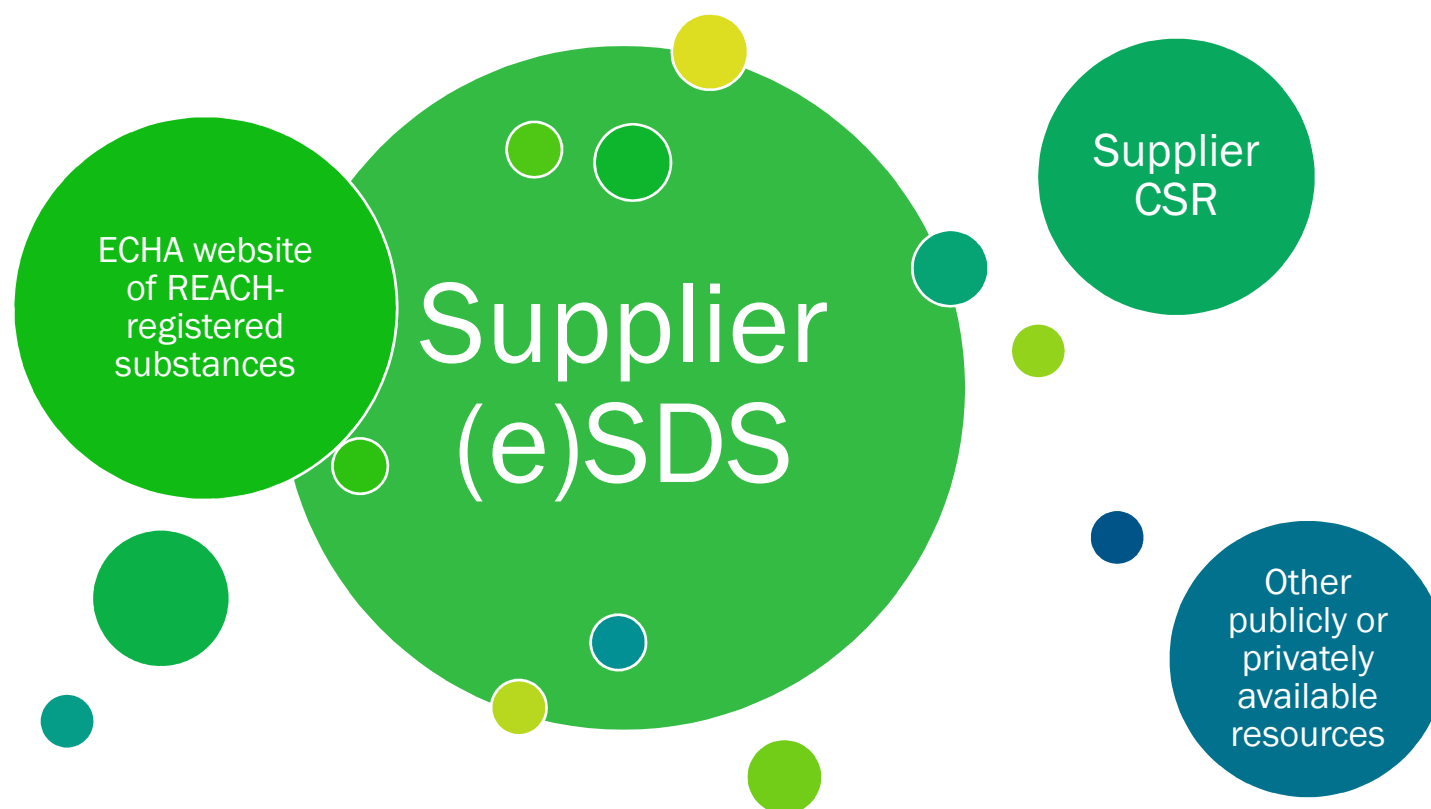
- Any PNECs for all relevant components, any compartment
- Convert to mg/L

## Aquatic environment

- Acute/chronic category and M-factor

# Data sources

“The primary source of information should be the supplier’s (e)SDS”





# ECHA website of REACH-registered substances

ECHA > Information on Chemicals > Registered substances



## Registered substances

The data comes from registration dossiers submitted to ECHA by the date indicated as last update. The Total Tonnage Band is compiled from all the dossiers with two exceptions: any tonnage deemed confidential and any quantity used as an intermediate to produce another substance. The data does not necessarily reflect the registered substances.

[IUCLID](#) > [Support](#) > [Get IUCLID data](#) > REACH study results



Please note that some of the information on chemical substances is directly accessible via [eChemicals](#). Such information may therefore require the [Legal Notice](#) for further information.

### Get IUCLID data

- IUCLID inventories
- REACH substance substances
- REACH study results

## REACH study results

REACH study results is a collection of non-confidential substance data that was submitted to ECHA under the REACH regulation. ECHA believes that making this data downloadable will be yet another step forward towards the goals of REACH - both in terms of improving the safe use of chemicals, for example through improved safety data, and the development and use of alternative methods. The REACH Regulation stipulates that data is available, free of charge.

1 substance at a time, dossier

15000 substances in a single database, results

Last updated 25 August 2017. Database contains 15000 substances.

- Substance identity
  - Substance name:
  - EC / List number:
- Administrative data
- Substance data
- Uses and exposure

The data is available in a single database, which can be downloaded in bulk, using the IUCLID 6 Desktop application (1 MB). Before using the data, you are advised to read carefully the terms and conditions because it states, among other things, the conditions under which the data may be used. For example, the data may not be used for registration under the REACH Regulation. Moreover, it should be recalled that the data derives from REACH registration dossiers, and as such there are no guarantees/warranties pertaining to its quality and fitness for purpose.

REACH study results can be downloaded in the following forms:

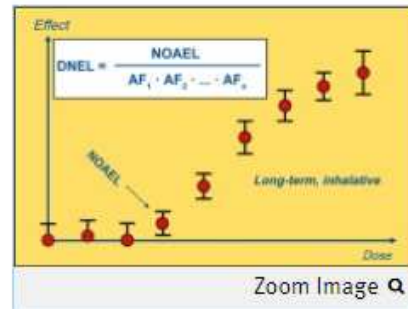
1. An Oracle database archive. This requires an installation of proprietary database software provided by Oracle.  
[REACH study results for an Oracle database](#) (829 MB)
2. Inside a default installation of IUCLID 6 Desktop, which does not require the purchase of any additional software.  
[REACH study results in IUCLID 6 Desktop](#) (3.4 GB)

# Other publicly or privately available resources

Home > GESTIS > GESTIS DNEL list

## GESTIS DNEL List

Hazardous substance information system of the German Social Accident Insurance



[GESTIS DNEL List \(XLSX, 595 kB\)](#)

4800 substances,  
industry-specific

### Contents

For the registration of each substance under the European chemicals regulation REACH, manufacturers or importers have to quote assessment benchmarks on which the protective measures are based. Among these assessment yardsticks are Derived No-Effect Levels (DNELs). The REACH regulation defines them as exposure levels beneath which a substance does not harm human health.

The GESTIS DNEL list of the German Social Accident Insurance (DGUV) is based on a compilation conducted by the social accident insurance institution for the construction industry which makes available workplace-related DNELs that have been established by manufacturers and importers on their own responsibility and are published in this form by the European Chemicals Agency (ECHA).

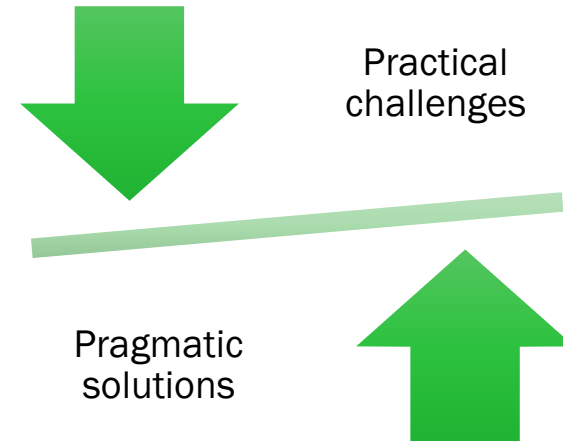
# LCID Methodology Guide Update and Preliminary Test Results

## General comments: summary

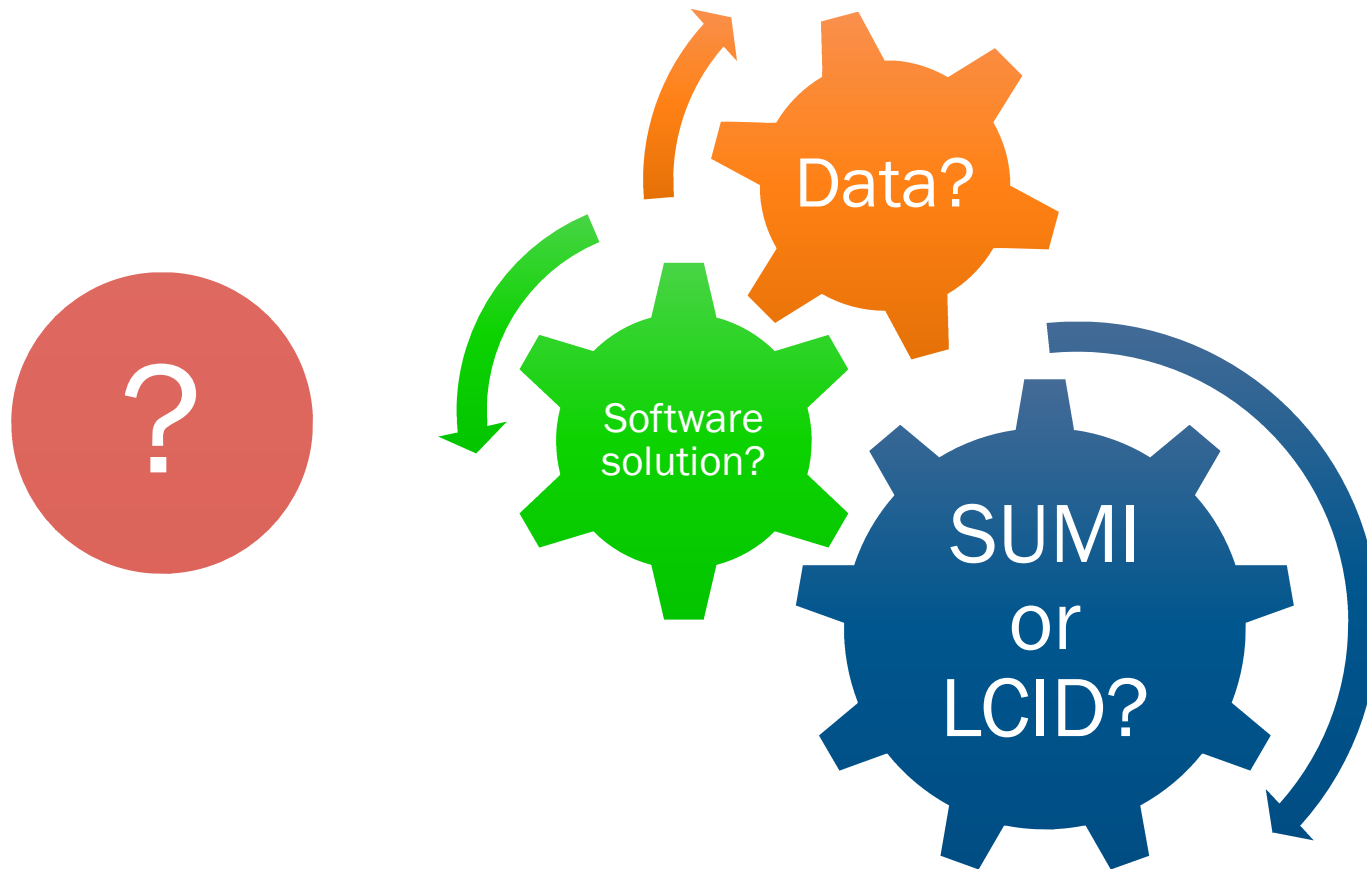


**No show  
stoppers!**

- Both guidance and tool are comprehensive and easy to use
- Application of the methodology is challenging if needed for a large number of mixtures
- Ease of use and results strongly depend on data availability
- Expert judgment is still necessary
- Need for further IT support of the calculation tool or the separate development of software solutions
- Training workshops would be appreciated



# Approaches: UP or DOWN?



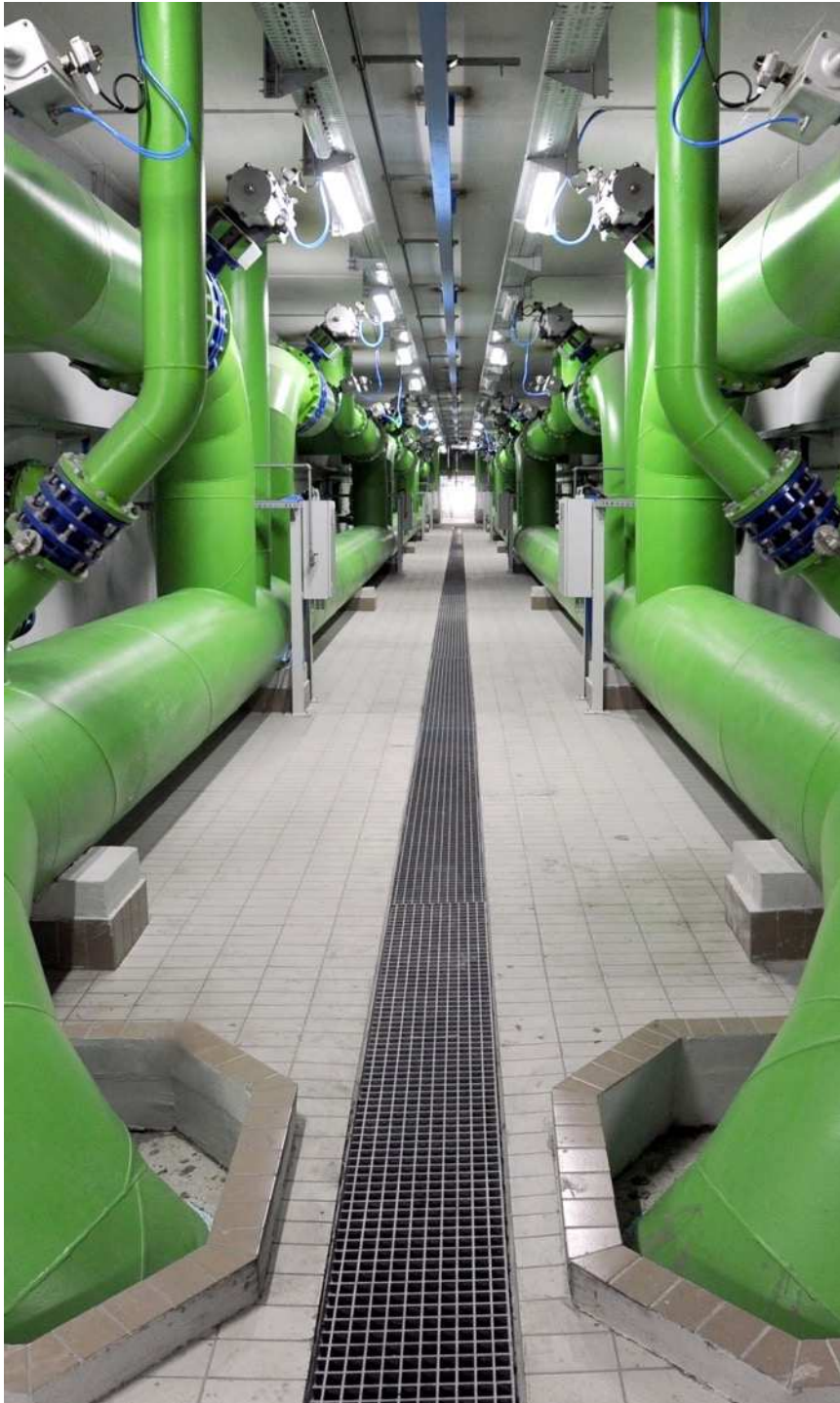
# Acronyms

<b>A.I.S.E.</b>	International Association for Soaps, Detergents and Maintenance Products
<b>ATE</b>	Acute Toxicity Estimate
<b>CA</b>	Contributing Activity
<b>Cefic</b>	The European Chemical Industry Council
<b>CEPE</b>	European Council of the Paint, Printing Ink and Artists' Colors Industry
<b>Chesar</b>	Chemical safety assessment and reporting tool
<b>CSA</b>	Chemical Safety Assessment
<b>CSR</b>	Chemical Safety Report
<b>DNEL</b>	Derived No-Effect Level
<b>DU</b>	Downstream User
<b>DUCC</b>	Downstream Users of Chemicals Co-ordination group
<b>ECHA</b>	European Chemicals Agency
<b>ENES</b>	Exchange Network on Exposure Scenarios
<b>ES</b>	Exposure Scenario
<b>ESCom</b>	Exposure Scenario Communication
<b>eSDS</b>	extended Safety Data Sheet
<b>IUCLID</b>	International Uniform Chemical Information Database
<b>LC</b>	Lead Component
<b>LCI</b>	Lead Component Indicator
<b>LCCI</b>	Lead Component Candidate Indicator

<b>LCID</b>	Lead Component Identification (methodology)
<b>LC50, LD50</b>	Lethal Concentration, Dose 50
<b>LE</b>	Local Effect
<b>NO(A)EC, NO(A)EL</b>	No Observed (Adverse) Effect Concentration, Level
<b>OC</b>	Operational Condition
<b>OEL</b>	Occupational Exposure Limit
<b>PBT</b>	Persistent, Bioaccumulative and Toxic substance
<b>PNEC</b>	Predicted No-Effect Concentration
<b>PROC</b>	Process Category
<b>PS</b>	Priority Substance
<b>REACH</b>	Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (EC) No 1907/2006
<b>RMM</b>	Risk Management Measure
<b>SCED</b>	Specific Consumer Exposure Determinant
<b>SDS</b>	Safety Data Sheet
<b>SpERC</b>	Specific Environmental Release Category
<b>SUMI</b>	Safe Use of Mixtures Information
<b>SWED</b>	Sector-specific Workers Exposure Description
<b>VCI</b>	Verband der Chemischen Industrie e.V. (the German chemical industry association)
<b>vPvB</b>	very Persistent and very Bioaccumulative substance

# References

ECHA	<a href="https://echa.europa.eu/regulations/reach">https://echa.europa.eu/regulations/reach</a> <a href="#">An illustrative example of the exposure scenarios to be annexed to the safety data sheet</a>
ENES	<a href="https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios">https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios</a>
CSR/ES roadmap	<a href="https://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap">https://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap</a>
IUCLID 6	<a href="https://iuclid6.echa.europa.eu/">https://iuclid6.echa.europa.eu/</a>
Chesar	<a href="https://chesar.echa.europa.eu/">https://chesar.echa.europa.eu/</a>
ESCom	<a href="http://www.cefic.org/Industry-support/Implementing-reach/escom/">http://www.cefic.org/Industry-support/Implementing-reach/escom/</a>
DUCC	<a href="#">Sector-specific approaches towards developing and communicating information for the safe use of mixtures</a> <a href="#">SUMI template</a>
Use maps	<a href="https://echa.europa.eu/csr-es-roadmap/use-maps/concept">https://echa.europa.eu/csr-es-roadmap/use-maps/concept</a>
Cefic	<a href="http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/">http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/</a>
LCID methodology	<a href="#">REACH Practical Guide on Safe Use Information for Mixtures under REACH: The Lead Component Identification (LCID) Methodology</a>
Registered substances	<a href="https://echa.europa.eu/information-on-chemicals/registered-substances">https://echa.europa.eu/information-on-chemicals/registered-substances</a>
REACH study results	<a href="https://iuclid6.echa.europa.eu/reach-study-results">https://iuclid6.echa.europa.eu/reach-study-results</a>
GESTIS DNEL List	<a href="http://www.dguv.de/ifa/gestis/gestis-dnel-liste/index-2.jsp">http://www.dguv.de/ifa/gestis/gestis-dnel-liste/index-2.jsp</a>



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