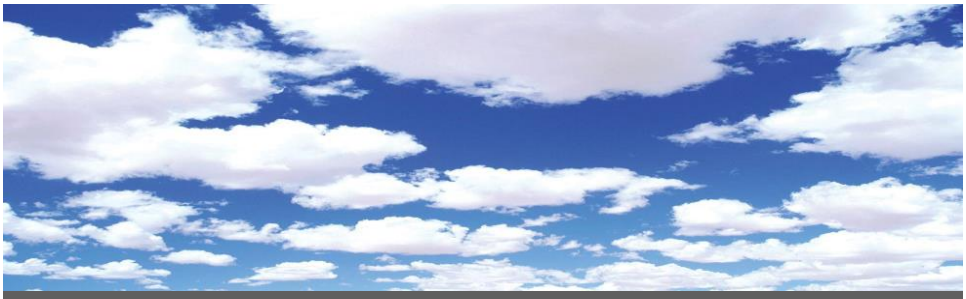

Lead Component Identification (LCID) Methodology

Donna Seid, Ashland Services BV
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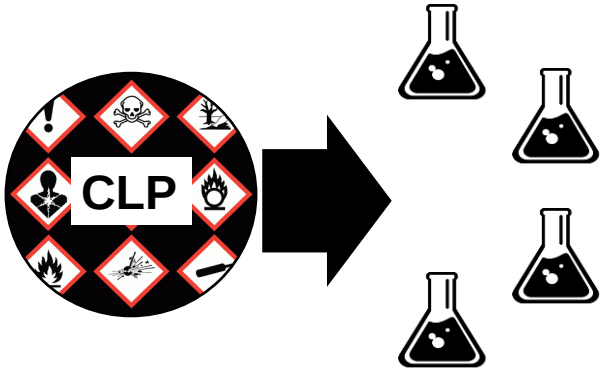
Christian Boegi, BASF
Angelika Hanschmidt, VCI

19 November 2014

COMMON SENSE

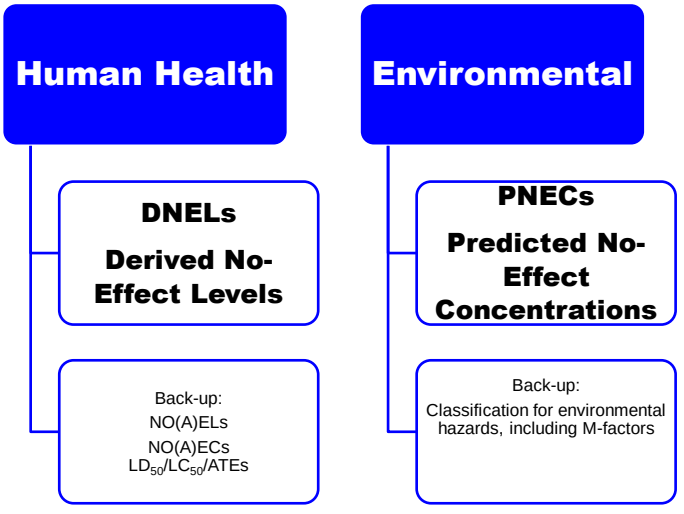
Methodology uses CLP classification



to identify relevant components that drive the hazard classification of the mixture

3

DNELs and PNECs from Exposure Scenarios of relevant components



4

and the basic premise . . .

If the risks are controlled for the most hazardous component, then the risks from the other substances in the mixture are also likely controlled.

5

Agenda

1. Deliverables
2. General workflow and information
3. Human Health (HH) LCID
4. Environmental (ENV) LCID
5. Examples
6. Next steps
7. Questions and answers

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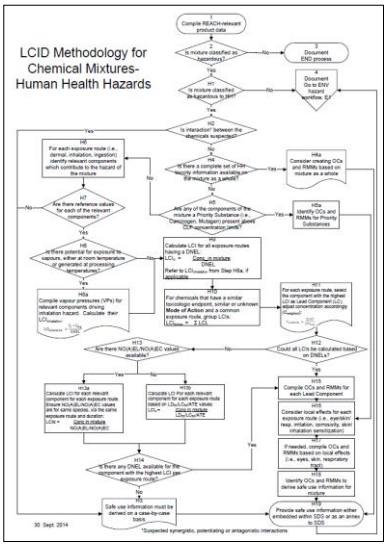
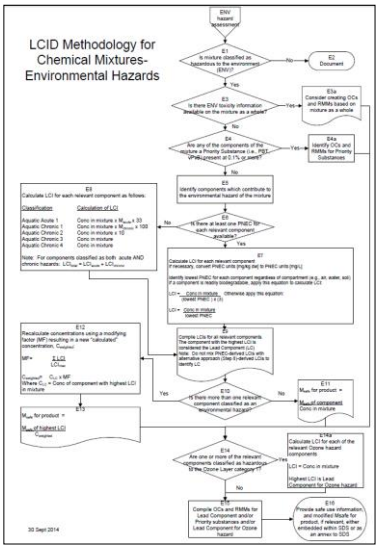
Deliverables: Detailed LCID workflows





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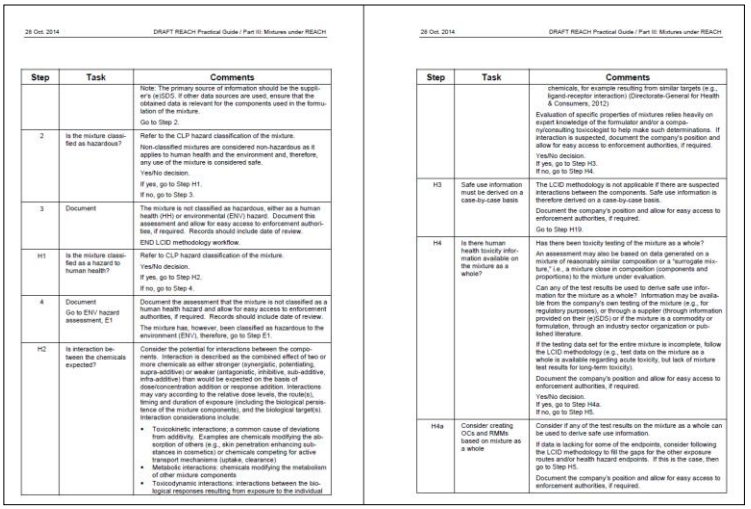
Practical guide



28 Oct. 2014 DRAFT REACH Practical Guide / Part III: Mixtures under REACH

Step	Task	Comments
		Note: The primary source of information should be the supplier's (e)SDS. If other data sources are used, ensure that the obtained data is relevant for the components used in the formulation of the mixture. Go to Step 2.
2	Is the mixture classified as hazardous?	Refer to the CLP hazard classification of the mixture. Non-classified mixtures are considered non-hazardous as it applies to human health and the environment and, therefore, any use of the mixture is considered safe. Yes/No decision. If yes, go to Step H1. If no, go to Step 3.
3	Document	The mixture is not classified as hazardous, either as a human health (HH) or environmental (ENV) hazard. Document this assessment and allow for easy access to enforcement authorities, if required. Records should include date of review. END LCID methodology workflow.
H1	Is the mixture classified as a hazard to human health?	Refer to CLP hazard classification of the mixture. Yes/No decision. If yes, go to Step H2. If no, go to Step 4.
4	Document Go to ENV hazard assessment, E1	Document the assessment that the mixture is not classified as a human health hazard and allow for easy access to enforcement authorities, if required. Records should include date of review. The mixture has, however, been classified as hazardous to the environment (ENV), therefore, go to Step E1.
H2	Is interaction between the chemicals expected?	Consider the potential for interactions between the components. Interaction is described as the combined effect of two or more chemicals as either stronger (synergistic, potentiating, supra-additive) or weaker (antagonistic, inhibitive, sub-additive, infra-additive) than would be expected on the basis of dose/concentration addition or response addition. Interactions may vary according to the relative dose levels, the route(s), timing and duration of exposure (including the biological persistence of the mixture components), and the biological target(s). Interaction considerations include: • Toxicokinetic interactions; a common cause of deviations from additivity. Examples are chemicals modifying the absorption of others (e.g., skin penetration enhancing substances in cosmetics) or chemicals competing for active transport mechanisms (uptake, clearance) • Metabolic interactions; chemicals modifying the metabolism of other mixture components • Toxicodynamic interactions: interactions between the biological responses resulting from exposure to the individual

28 Oct. 2014 DRAFT REACH Practical Guide / Part III: Mixtures under REACH

Step	Task	Comments
		chemicals, for example resulting from similar targets (e.g., ligand-receptor interaction) (Directorate-General for Health & Consumers, 2012) Evaluation of specific properties of mixtures relies heavily on expert knowledge of the formulator and/or a company/consulting toxicologist to help make such determinations. If interaction is suspected, document the company's position and allow for easy access to enforcement authorities, if required. Yes/No decision. If yes, go to Step H3. If no, go to Step H4.
H3	Safe use information must be derived on a case-by-case basis	The LCID methodology is not applicable if there are suspected interactions between the components. Safe use information is therefore derived on a case-by-case basis. Document the company's position and allow for easy access to enforcement authorities, if required. Go to Step H19.
H4	Is there human health toxicity information available on the mixture as a whole?	Has there been toxicity testing of the mixture as a whole? An assessment may also be based on data generated on a mixture of reasonably similar composition or a "surrogate mixture," i.e., a mixture close in composition (components and proportions) to the mixture under evaluation. Can any of the test results be used to derive safe use information for the mixture as a whole? Information may be available from the company's own testing of the mixture (e.g., for regulatory purposes), or through a supplier (through information provided on their (e)SDS) or if the mixture is a commodity or formulation, through an industry sector organization or published literature. If the testing data set for the entire mixture is incomplete, follow the LCID methodology (e.g., test data on the mixture as a whole is available regarding acute toxicity, but lack of mixture test results for long-term toxicity). Document the company's position and allow for easy access to enforcement authorities, if required. Yes/No decision. If yes, go to Step H4a. If no, go to Step H5.
H4a	Consider creating OCs and RMMs based on mixture as a whole	Consider if any of the test results on the mixture as a whole can be used to derive safe use information. If data is lacking for some of the endpoints, consider following the LCID methodology to fill the gaps for the other exposure routes and/or health hazard endpoints. If this is the case, then go to Step H5. Document the company's position and allow for easy access to enforcement authorities, if required.

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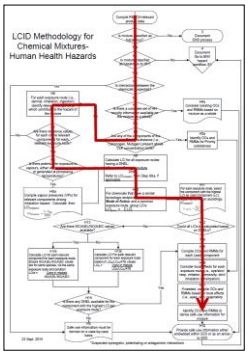
Technical document

Human Health – Underlying principles of and rationale for the steps for generating safe use information regarding human health hazards for chemical mixtures

Step	Task	Justification
1	Compile REACH-relevant product data	Analysis begins by gathering all available and relevant information on both human health and environmental data for all individual components of the mixture as well as on the mixture itself. This information forms the basis for identifying what the hazards are associated with the components, their potential contribution to the hazards of the mixture, and the potential health and environmental risks for which Operating Conditions (OCs) and Risk Management Measures (RMMs) would constitute safe use for the mixture under various exposure and contributing scenarios.
2	Is the mixture classified as hazardous?	Non-classified mixtures are considered non-hazardous as it applies to human health and the environment and, therefore, any use of the mixture is considered safe. This is in alignment with REACH, where no exposure assessment or risk management measures have to be defined for non-classified substances. The same logic is used for mixtures. For classification criteria, refer to the CLP hazard classification of the mixture. The EU regulation on classification, labelling and packaging ("CLP Regulation") uses internationally agreed classification criteria and labelling elements to contribute towards global efforts to protect humans and the environment from hazardous effects of chemicals.
3	Document	Documentation of this assessment should be readily available both internally and to enforcement authorities, if required.
H1	Is the mixture classified as a hazard to human health?	The lead components are derived separately for human health (HH) and the environment. Following the reasoning behind Step 2, all uses of the mixture are considered safe for HH, if it is not classified as hazardous for HH. In this case, the assessment would only be performed for the environmental hazard(s).
4	Document Go to ENV hazard assessment, E1	Documentation of this assessment should be readily available both internally and to enforcement authorities, if required.
H2	Is interaction between the chemicals expected?	Interactions between different components of the mixture are not covered by the LCID method and require a case-by case-assessment. Interaction is described as the combined effect of two or more chemicals as either stronger (synergistic, potentiating, supra-additive) or weaker (antagonistic, inhibitive, sub-additive, infra-additive) than would be expected on the basis of dose/concentration addition or response addition. Interactions may vary according to the relative dose levels, the route(s), timing and duration of exposure (including the biological persistence of the mixture components), and the biological target(s) (Directorate-General for Health & Consumers, 2012).

Test examples

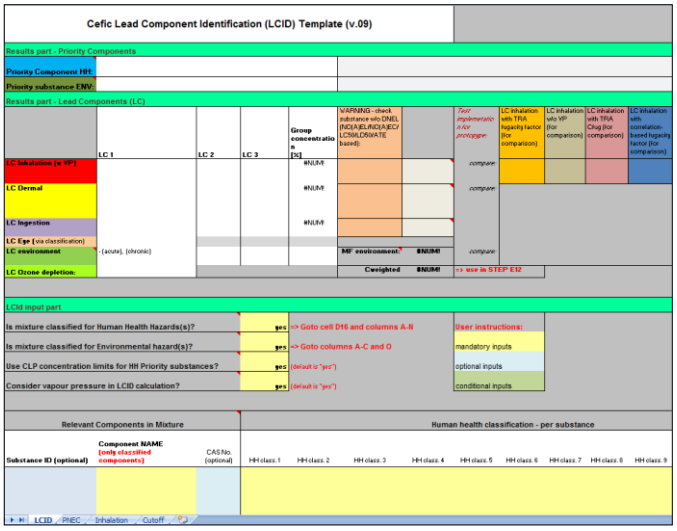


Test Example 3

Name of Product	Test Example 3			Comments
Classification	Ac. Tox. 3 (oral, derm.), STOT RE 2, Skin corr. 1B, Eye dam. 1			
Relevant components	Component 1	Component 2	Component 3	
Relevant CAS Nos. (if available)				
Concentration of relevant component	45	25	10	
Health Hazard CLP classification of relevant component	Ac. Tox. 3 (oral)	STOT RE 2	Ac. Tox. 2 (dermal) Skin corr. 1B Eye dam. 1	
Priority Substance (yes/no)	No	No	No	
DNEL inh (mg/m³)	100	30	45	
DNEL derm (mg/kg bw day)	10	4	2	
LCI (DNEL) - oral (if applicable, e.g., consumer)	N/A	N/A	N/A	
Vapour Pressures @ 25°C (hPa)	N/A, mixture of solids	N/A, mixture of solids	N/A, mixture of solids	
LCI (DNEL) - inh	45 / 100 = 0.45	25 / 30 = 0.8	10 / 45 = 0.2	LCI = Conc / DNEL
LCI (DNEL) - derm	45 / 10 = 4.5	25 / 4 = 6.3	10 / 2 = 5.0	LCI = Conc / DNEL
LCI (DNEL) - oral	N/A	N/A	N/A	
Lead Component for relevant exposure routes		Lead Component for inhalation and dermal routes of exposure		Highest LCI-inhalation is Component 2 (0.8); Highest LCI-dermal is Component 2 (6.3)
Relevant local effects	None	None	Skin corr. 1B Eye dam. 1	Local effects come from Component 3 (Skin Corr. and eye damage)
Exposure Scenario				
Contributing Scenario				
Operating Conditions (OCs)	> 4h, 5 days a week	**> 4h, 5 days a week**	> 1h, 5 days a week	Exposure duration for Component 3 is not relevant to assessment of local effects, so the OCs were taken from the Lead Component (Component 2)
Risk Management Measures (RMMs)	Enhanced general ventilation Gloves tested to EN 374	**Local exhaust ventilation** **Good general ventilation** **Gloves tested to EN 374**	**Gloves tested to EN 374** **Goggles**	
Modified OCs for the Mixture	**> 4h, 5 days a week**			From Component 2 as Lead Component-inhalation
Modified RMMs for the Mixture	**Local exhaust ventilation** **Good general ventilation** **Gloves tested to EN 374** **Goggles**			From Component 2 as Lead Component-inhalation, - dermal and Component 3 - local effects on skin and eyes

Example when DNEL values are available for all relevant components

LCID excel-based tool



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Automation

Primary focus was to develop an approach based on science and logical assumptions

Once methodology is validated; make available to IT system developers to create algorithms/rules sets

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Practical considerations

LCID methodology may be applied:

When the identity of the Lead Component(s) is less obvious

To support your intuitive conclusions

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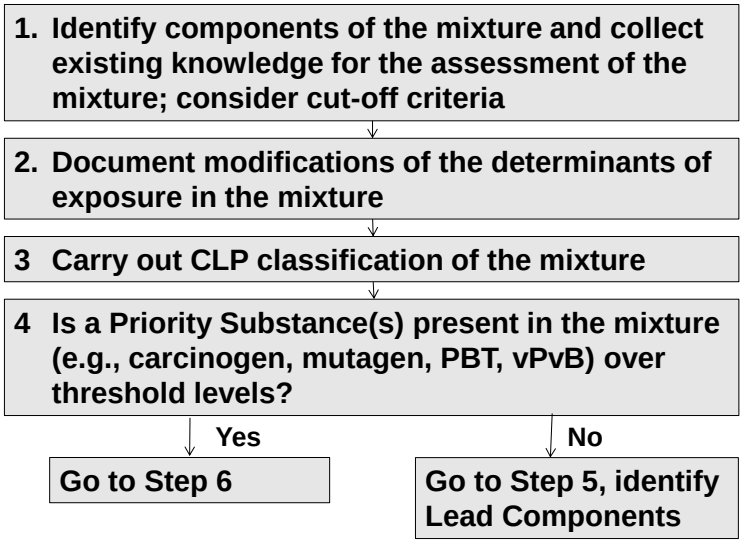
High level LCID workflow



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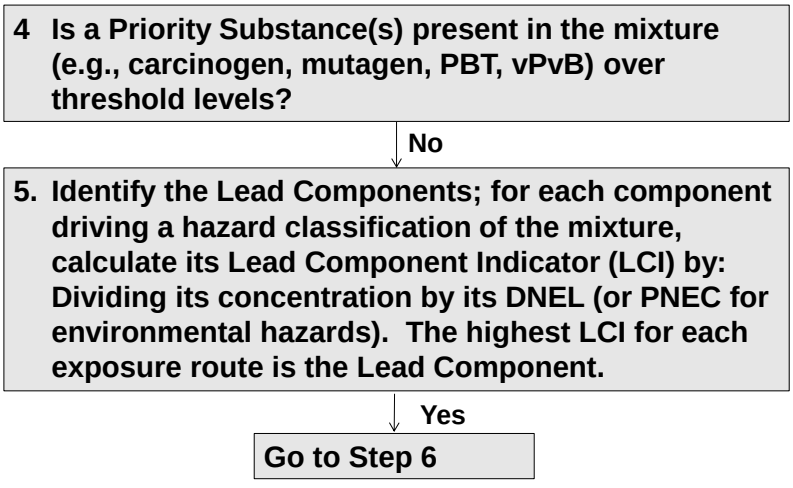
High level LCID workflow cont'd



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High level LCID workflow cont'd

6. **Identify components which contribute to any local effect classifications (for Human Health) or ozone depletion (for the Environment)?**

7. **Collect required information OCs and RMMs for Priority Substances/Lead Components/ components driving local effects/ozone layer hazard; consolidate to derive safe use information for the mixture**

8. **Generate safe use information. Decide whether to include it in Sections 1- 16 or to develop an annex to the SDS**

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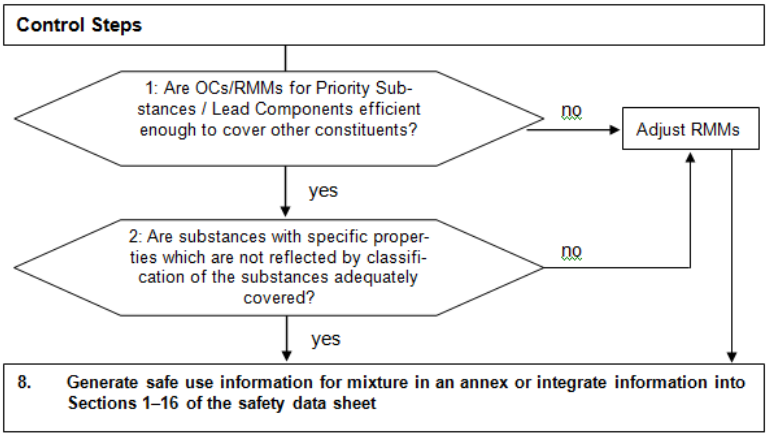
Advanced evaluation



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Control steps

Control Step 1

Ensure that RMMs for Lead Components and Priority Substances cover protection against the other hazardous substances in the mixture

- The substance-specific measure removes the Lead Component very efficiently (e.g., precipitation of remaining sulphide concentration in the waste water with iron hydroxide), however, RMM for that component has no effect on any remaining hazardous components
- Priority Substances which are classified for a certain route of exposure (e.g., nickel dioxide-carcinogenic by inhalation) might only control for one route and disregard other relevant routes of exposure
- Migration potential through glove barriers may have to be considered in recommending glove type and thickness

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Control steps cont'd

Control Step 2

Address components causing risks to humans or the environment that do not meet the CLP classification and labelling criteria for the mixture

- Chemicals present below the threshold levels but for which there is relevant information, such as community workplace exposure limits, DNELs or PNECs are provided by the supplier(s) (e.g., gloves to protect against local effects of a component not leading to the classification of the mixture as a whole)

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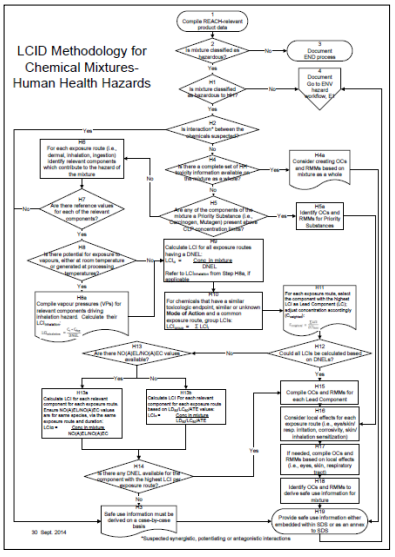
Derivation of safe use

Classification	Ac. Tox. 3 (oral, derm.), STOT RE 2, Skin corr. 1B, Eye dam. 1		
Relevant components	Component 1	Component 2	Component 3
Lead Component for relevant exposure routes		Lead Component for inhalation and dermal routes of exposure	
Relevant local effects	None	None	Skin corr. 1B Eye dam. 1
Exposure Scenario			
Contributing Scenario			
Operating Conditions (OCs)	> 4h, 5 days a week	**> 4h, 5 days a week**	> 1h, 5 days a week
Risk Management Measures (RMMs)	Enhanced general ventilation Gloves tested to EN 374	**Local exhaust ventilation** **Good general ventilation** **Gloves tested to EN 374**	**Gloves tested to EN 374** **Goggles**
Modified OCs for the Mixture	**> 4h, 5 days a week**		
Modified RMMs for the Mixture	**Local exhaust ventilation** **Good general ventilation** **Gloves tested to EN 374** **Goggles**		

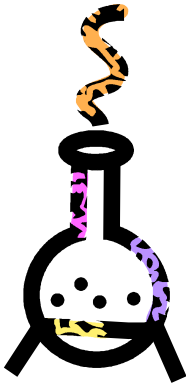
Agenda

Human Health (HH) LCID



Vapour pressure considerations

Is there a potential for exposure to vapours?



For each relevant component associated with the hazardous inhalation classification for the mixture, a Lead Component Indicator (LCI) is calculated.

The LCI is then calculated as follows:

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

Where:
$LCI_{inhalation}$: LCI for inhalation
C_i: Concentration of the component i in the mixture
C_{fug}* = Factor representing the potential effect of the vapour pressure (VP)
DNEL: Derived no-effect level long term systemic

Dose/conc addition approach

- Group chemicals that have similar mode of action and/or common toxic endpoints
- For the chemicals that have been grouped by their common toxic effect, sum their individual LCIs and this total, LCI_{group} represents the LCI for the group
- If this "LCI_{group}" represents the highest LCI of the components:

The component of the grouped chemicals having the highest LCI becomes the Lead Component

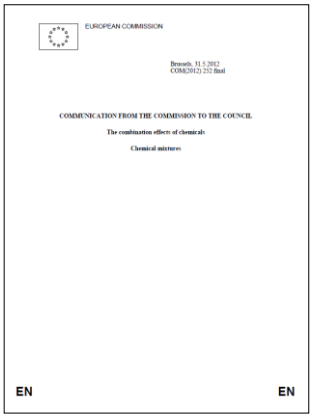
Dose/conc addition approach

- Apply a weighted calculation for the Lead Component (based on the individual LCI and its concentration in the mixture, called $C_{weighted}$):

$$C_{weighted} = \sum_{i=1}^{n} C_i \times \frac{LCI_i}{LCI_{max}}$$

The RMMs for the Lead Component would be based on the $C_{weighted}$ value

Basis for approach


EUROPEAN COMMISSION

Brussels, 31.5.2012
COM(2012) 252 final

COMMUNICATION FROM THE COMMISSION TO THE COUNCIL

The combination effects of chemicals

Chemical mixtures

EN EN


Directorate-General for Health & Consumers

Scientific Committee on Health and Environmental Risks
SCHER

Scientific Committee on Emerging and Newly Identified Health Risks
SCENIHR

Scientific Committee on Consumer Safety
SCCS

Toxicity and Assessment of Chemical Mixtures

Scientific Committees

Approved opinions of 3 scientific EU bodies

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Indicating these considerations:

Mode of action (MoA)	Groupings	Interactions
• Common MoAs act jointly to produce combination effects • Difference in potencies • LCID methodology	• Group based on structural similarities • Group by toxicologic response • LCID methodology	• **Synergism/ Potentiation**- stronger combined effects • **Antagonism**- weaker combined effects • Outside of LCID methodology

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Mode of action (MoA)

2. Chemicals with common modes of action will act jointly to produce combination effects that are larger than the effects of each mixture component applied singly. These effects can be described by dose/concentration addition.

6. With regard to the assessment of chemical mixtures, a major knowledge gap at the present time is the lack of exposure information and the rather limited number of chemicals for which there is sufficient information on their mode of action. Currently, there is neither an agreed inventory of mode of actions, nor a defined set of criteria how to characterise or predict a mode of action for data-poor chemicals.

7. If no mode of action information is available, the dose/concentration addition method should be preferred over the independent action approach. Prediction of possible interaction requires expert judgement and hence needs to be considered on a case-by-case basis.

Reference: Directorate-General for Health & Consumers, Toxicity and Assessment of Chemical Mixtures. European Union, 2012.

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Default common endpoints

ECHA, Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, 2013

Inhalation	Dermal	Oral
• Acute categories 1,2,3 and 4 • H330 H331 H332	• Acute categories 1,2,3 and 4 • H310 H311 H312	• Acute categories 1,2,3 and 4 • H300 H301 H302

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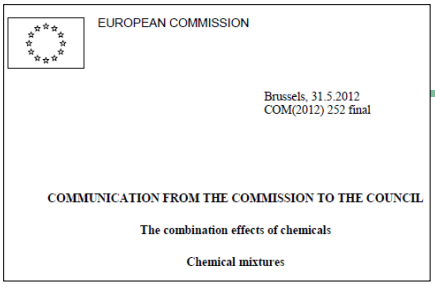

EUROPEAN COMMISSION

Brussels, 31.5.2012
COM(2012) 252 final

COMMUNICATION FROM THE COMMISSION TO THE COUNCIL

The combination effects of chemicals

Chemical mixtures

By June 2015 – the Commission will be publishing a report on the assessment of chemical mixtures to review progress and experience on, among other items:

Opportunities for addressing knowledge gaps, in particular relating to:
(i) the mode of action of chemicals,
(ii) grouping chemicals into categories or assessment groups;
(iii) predicting interactions; and
(iv) Identifying chemical substances that are the main drivers of mixture toxicity

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Backup Solutions: (1) NO(A)ELs

- If one of the relevant components lacks a DNEL, then use NO(A)ELs/NO(A)ECs to ensure the appropriate comparisons

- **DO NOT** mix DNELs and NO(A)ELs within one route of exposure
- When using **NO(A)ELs ONLY** make comparison with studies that are using same species via the same exposure route and duration
- If applying NO(A)ELs to calculate LCI use:

$$LCI = \frac{Concentration\ in\ mixture}{NO(A)EL}$$

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(2) LD_{50}/LC_{50} or ATEs values

If there are no NO(A)ELs then use LD_{50}/LC_{50}/ATE* values and calculate LCI with this equation:

$$LCI_a = \frac{C_i}{LD50/LC50/ATE}$$

As with NO(A)ELs/NO(A)Ecs, make like comparisons: LD_{50}s with LD_{50}s, LC_{50}s with LC_{50}s, ATEs with ATEs

Consider these reference values when making an interpretation to ensure that a potentially more toxic component is not missed when developing safe use information for the mixture

* Acute toxicity estimates (ATEs)

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Agenda

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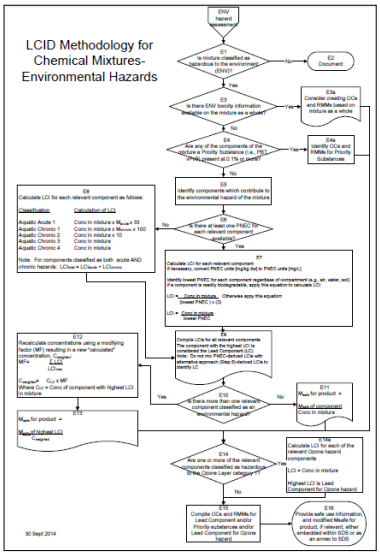
Environmental (ENV) hazard LCID



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Lead Component Indicator (LCI)

PNECs available

E7

Calculate LCI for each relevant component
If necessary, convert PNEC units [mg/kg dw] to PNEC units [mg/L]

Identify lowest PNEC for each component regardless of compartment (e.g., air, water, soil)
If a component is readily biodegradable, apply this equation to calculate LCI:

LCI = Conc in mixture Otherwise appy this equation:
(lowest PNEC) x (3)

LCI = Conc in mixture
lowest PNEC

PNECs not available (back-up solution)

E8

Calculate LCI for each relevant component as follows:

Classification	Calculation of LCI
Aquatic Acute 1	Conc in mixture x M_{acute} x 33
Aquatic Chronic 1	Conc in mixture x $M_{chronic}$ x 100
Aquatic Chronic 2	Conc in mixture x 10
Aquatic Chronic 3	Conc in mixture
Aquatic Chronic 4	Conc in mixture

Note: For components classified as both acute AND chronic hazards: $LCI_{total} = LCI_{acute} + LCI_{chronic}$

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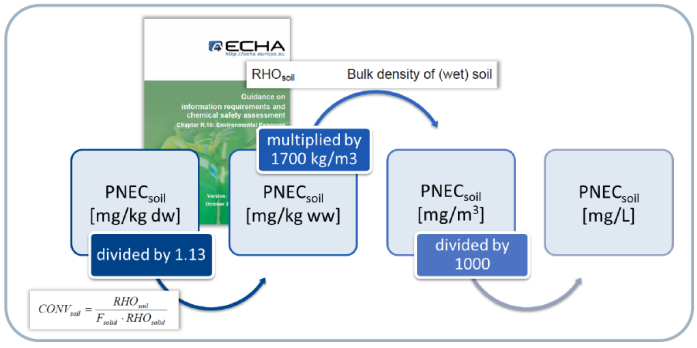
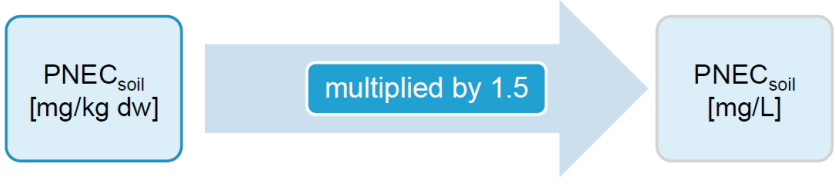
$PNEC_{soil}$ mg/kg ww to mg/L





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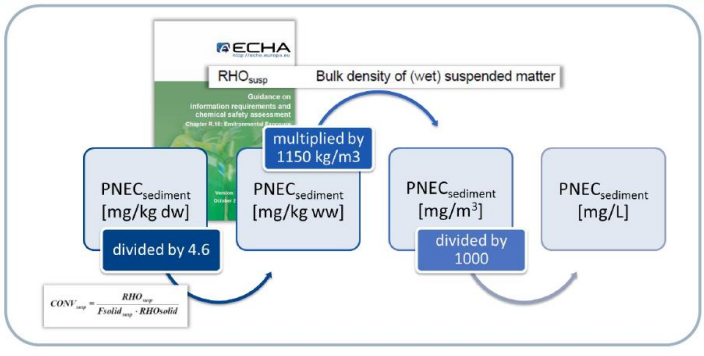
$PNEC_{sediment}$ mg/kg ww to mg/L



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PNECs and back-up solution

- **There is at least one PNEC for each relevant component that drives the environmental classification of the mixture; if not then calculate LCI using the alternative approach**


- **Do not compare:**
  PNEC-derived LCIs with alternative approach-derived LCIs, to identify the Lead Component

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If more than one environmental hazard

E12

Recalculate concentrations using a modifying factor (MF) resulting in a new "calculated" concentration, $C_{weighted}$:

$$MF = \frac{\Sigma\ LCI}{LCI_{max}}$$

$$C_{weighted} = C_{LC} \times MF$$

Where C_{LC} = Conc of component with highest LCI in mixture

A modifying factor gives increased weight to substances classified as hazardous to the environment

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M_{safe} for product

Maximum daily tonnage of the substance guaranteeing safe use for a specific application

1 environmental hazard	$M_{safe}\ product = M_{safe}\ component\ /\ C$
>1 environmental hazard	$M_{Safe}\ product = \frac{M_{safe}\ LC}{C_{weighted}}$

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Ozone layer hazard

Calculate LCI for each of of the Ozone hazard components

LCI = Conc in mixture

Highest LCI is Lead Component for Ozone hazard

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Examples

Health	Environment
• DNELs • No DNELs • Grouping	• PNECs • No PNECs • Ozone layer hazard

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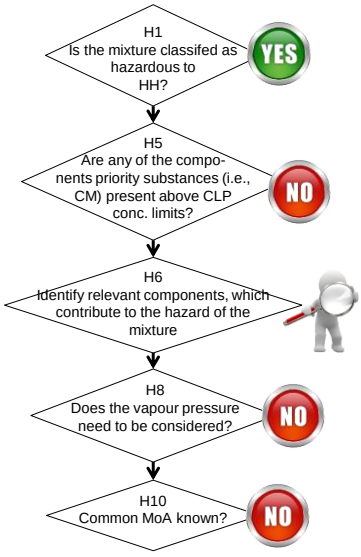
Health examples



Health example: DNELs available

Relevant component	Comp. 1	Comp. 2	Comp. 3
Concentration	45%	25%	10%
DNEL inhalation (LT, systemic)	100mg/m³	30mg/m³	45mg/m³
DNEL dermal (LT, systemic)	10mg/kg	4mg/kg	2mg/kg

LCI = Concentration / DNEL (per RoE)

LCI (inhalation)	0.45	**0.8**	0.2
LCI (dermal)	4.5	**6.3**	5.0
local effects	none	none	**Skin corrosion Eye damage**

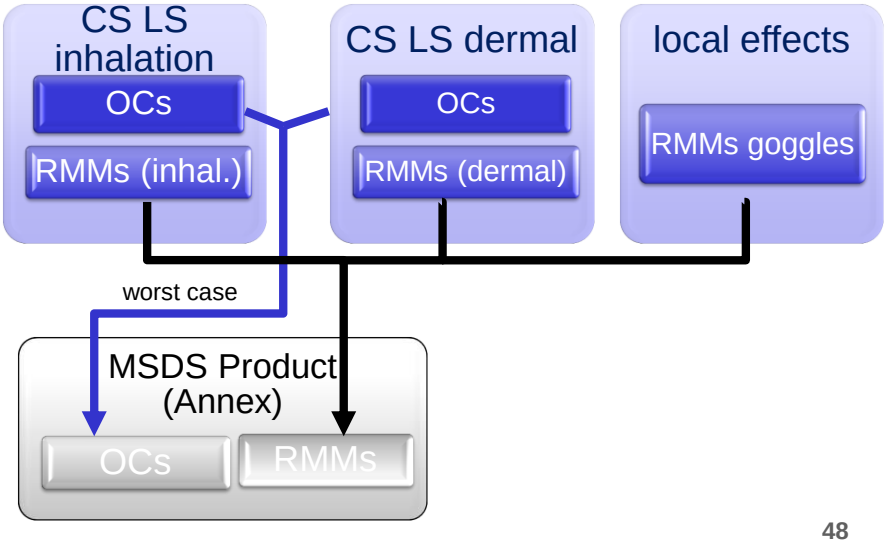
Health example: not all DNELs available

Relevant component	Comp. 1	Comp. 2	Comp. 3
Concentration	20%	40%	40%
DNEL inhalation	not relevant only class. for local effects	26mg/m³	N/A
DNEL dermal		4mg/kg	N/A
LC50		3mg/L	5mg/L
LD50		50mg/kg	300mg/kg

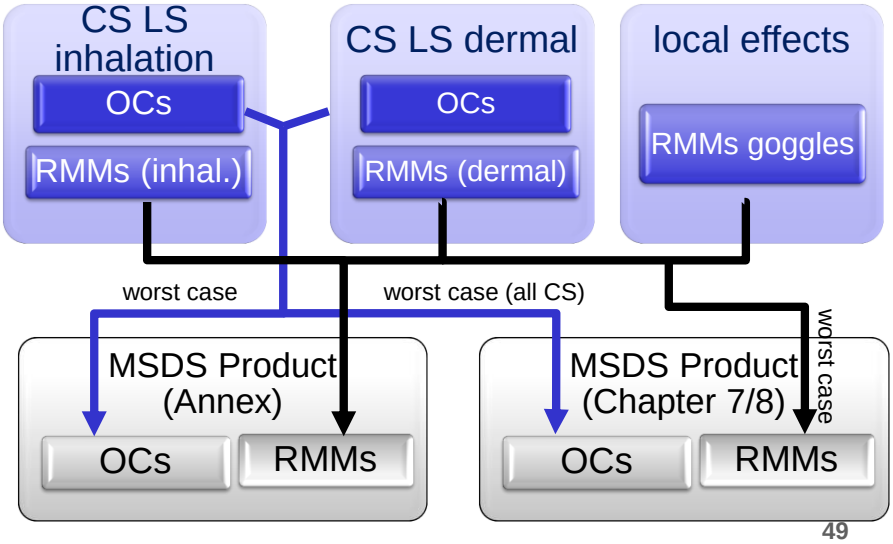
LCI = Conc. / reference value

LCI (inh): DNEL/LC50	-	1.5 / 13.3	- / 8
LCI (der): DNEL/LD50	-	10 / 0.8	- / 0.1
local effects	**Eye irritation**	none	none

Safe use information for mixture



Safe use information for mixture



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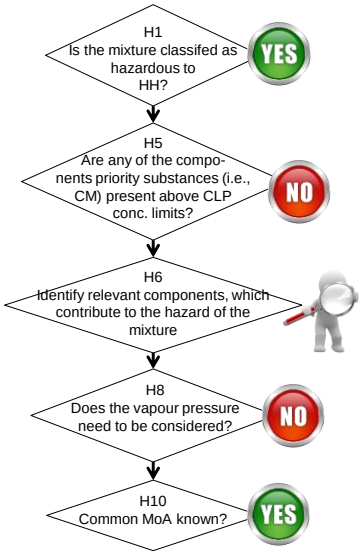
Health example: Common MoA



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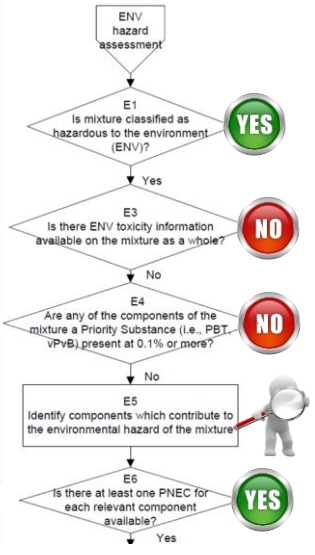
Health example: common MoA

Relevant component	Comp. 1	Comp. 2	Comp. 3
Concentration	50%	30%	20%
DNEL inhalation	3mg/m³	5mg/m³	1mg/m³
DNEL dermal	4mg/kg	10mg/kg	5mg/kg
	common MoA		
LCI (inhalation)	16.7	6	20
LCI (dermal)	12.5	3	4
LCI group (inh.)	22.7		20
LCI group (derm.)	15.5		4
Adjusted conc.	67%	-	-

ENV example: PNECs available



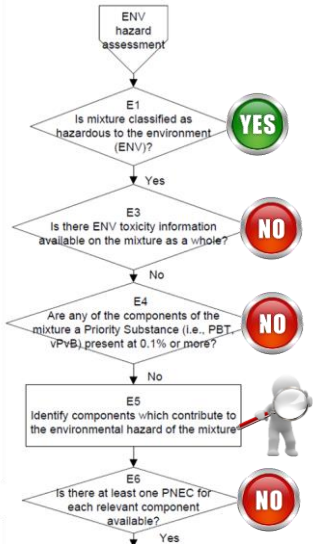
ENV example: PNECs available

Relevant components	Component 1	Component 2	Component 3
Concentration	30	2.5	20
Lowest PNEC	0.0112 mg/L ($PNEC_{freshwater}$)	0.03 mg/kg ($PNEC_{soil}$)	0.004 mg/kg ($PNEC_{sediment}$)
Convert to mg/L	0.0112 mg/L	0.45 mg/L (0.03 x 1.5)	0.001 mg/L (0.004 / 4)
Biodegradable status	Readily biodegradable	Not readily biodegradable	Not readily biodegradable
LCI (PNEC) - env	893.9 (30 / (0.0112 x 3))	5.5 (2.5 / 0.45)	2000 (20 / 0.001)

$$LCI\ (PNEC) = \frac{\text{Concentration in mixture}}{\text{Lowest PNEC (x 3*)}}$$

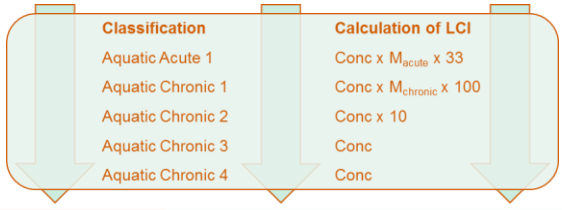
*if readily biodegradable

ENV example: PNECs NOT available



ENV example: PNECs NOT available

Relevant components	Cyclohexane	n-Hexane	Naphtha, hydrotreated light
Concentration	30	2.5	20
Classification	Aquatic Acute 1 Aquatic Chronic 1	Aquatic Chronic 2	Aquatic Chronic 2
M factor(s)	M_{acute} = 1 $M_{chronic}$ = 1	not applicable	not applicable



$LCI = LCI_{acute} + LCI_{chronic}$

LCI (no PNEC) - env	3990 (30 x 1 x 33) + (30 x 1 x 100)	25 (2.5 x 10)	200 (20 x 10)

Safe use information for mixture

Relevant components	Component 1	Component 2	Component 3
LCI	893.9	5.5	2000
Concentration	30	2.5	20
Modifying factor	MF = ∑LCI / LCImax = (893.9 + 5.5 + 2000) / 2000 = 1.45		
$C_{weighted}$	$C_{weighted}$ = Conc LC x MF = 20 x 1.45 = 29		
M_{safe} Lead compound			33000 kg/d
M_{safe} product	M_{safe} product = M_{safe} LC / $C_{weighted}$ = (33000 / 29) = 113793 kg/d*		

*relevant OCs and RMMs of the Lead Component are transferred to the mixture (e)SDS

PBT & Ozone

- **Rare cases**
- **A PBT compound (≥ 0.1%) is considered a "priority substance"**
  Most likely, the same measures as recommended for the pure substance will have to be applied to a mixture containing this substance.
- **The component hazardous to the ozone layer with the highest concentration in the mixture is identified as the Lead Component relating to this effect.**
  Again, the same measures as recommended for the pure substance will have to be applied to a mixture containing this substance.

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Agenda

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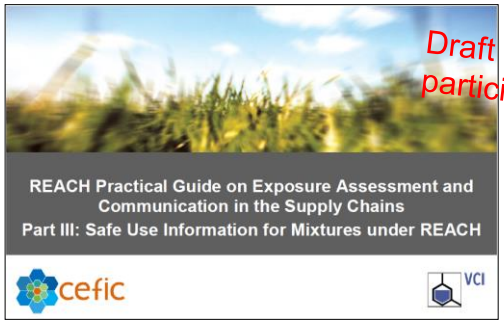
Next steps



Draft to be shared with participants past ENES7

Examples and Testing Tool have been elaborated in Mixtures Task Force

⇒ Update of Practical Guide from 2010
⇒ Support for formulators in their tasks regarding safe use information for mixtures
⇒ New LCID method chapters replace DPD+ approach
⇒ Cefic/VCI contribution to CSR/ES Roadmap Action 4.4

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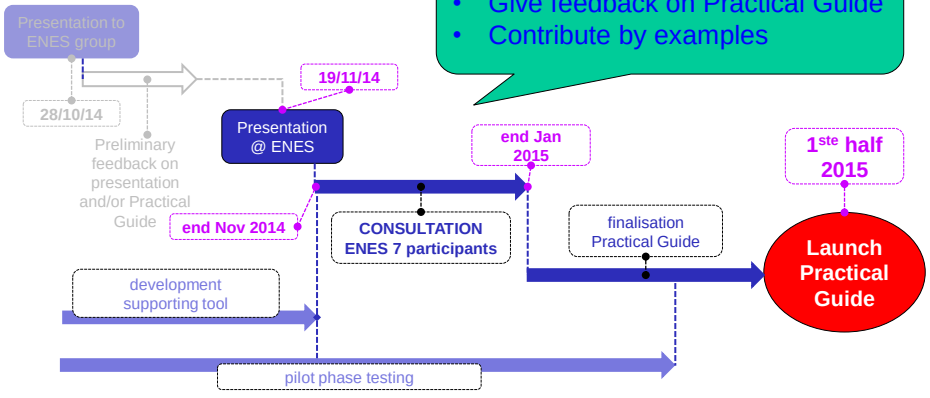
Next Steps

Next steps LCID

- Apply LCID Methodology!
- Give feedback on Practical Guide
- Contribute by examples



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Agenda

1. Deliverables
2. General workflow and information
3. Human Health (HH) LCID
4. Environmental (ENV) LCID
5. Examples
6. Next steps
7. Questions and answers

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Questions

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Mixture containing mixtures

- Often raw materials as provided to a formulator may itself be a mixture.
- Formulators should rely on information provided at the substance-level, not the mixture-level
- Relevant substances and their corresponding concentrations are in Section 3 of SDS
- The formulator should try to identify the relevant components driving the hazard classifications for the raw material mixture, and derive their ultimate concentrations
- Apply LCID methodology
- If OCs and RMMs have has been derived from a bottom-up approach, try to identify “Lead Components” and apply LCID methodology

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