



# LCID Methodology Guide Update and Preliminary Test Results

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Cefic/VCI Mixtures Task Force  
Brussels 06.11.2015



## LCID team

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### LCID sub-team created:

- **Steven Van de Broeck, Cefic**
- **Angelika Hanschmidt, VCI**
  
- **Christian Bögi, BASF**
- **Marc Brulport, Merck**
- **Sophie Letouzé, formerly of Brenntag**
- **Thomas May, Axalta**
- **Frank Schnöder, DuPont**
- **Donna Seid, Ashland**
- **Stefanie Welz, BASF**

# Agenda

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1

Background of Cefic/VCI project on mixtures

2

Test run of LCID methodology

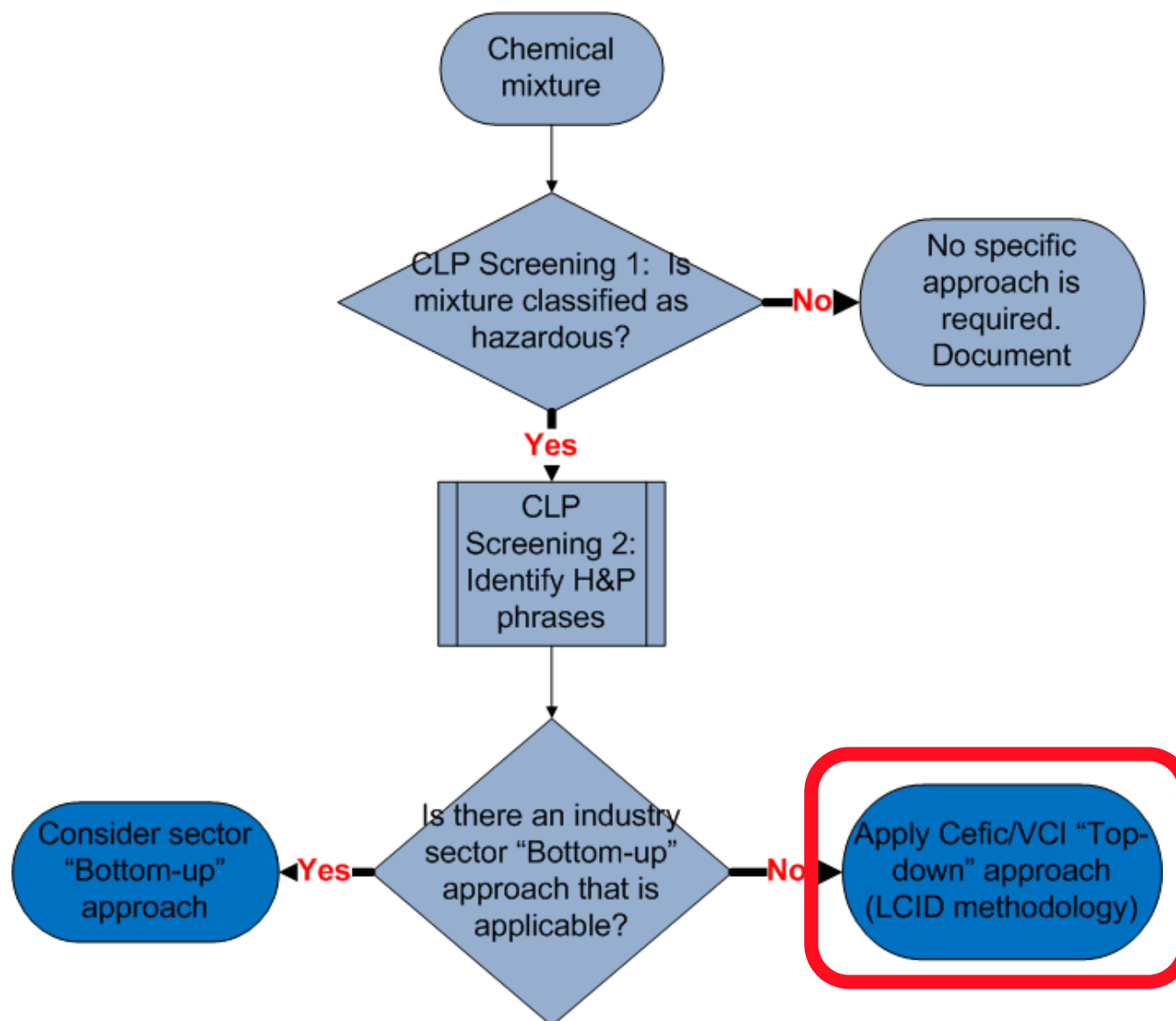
3

Preliminary results

4

Next steps

# Safe use information for mixtures



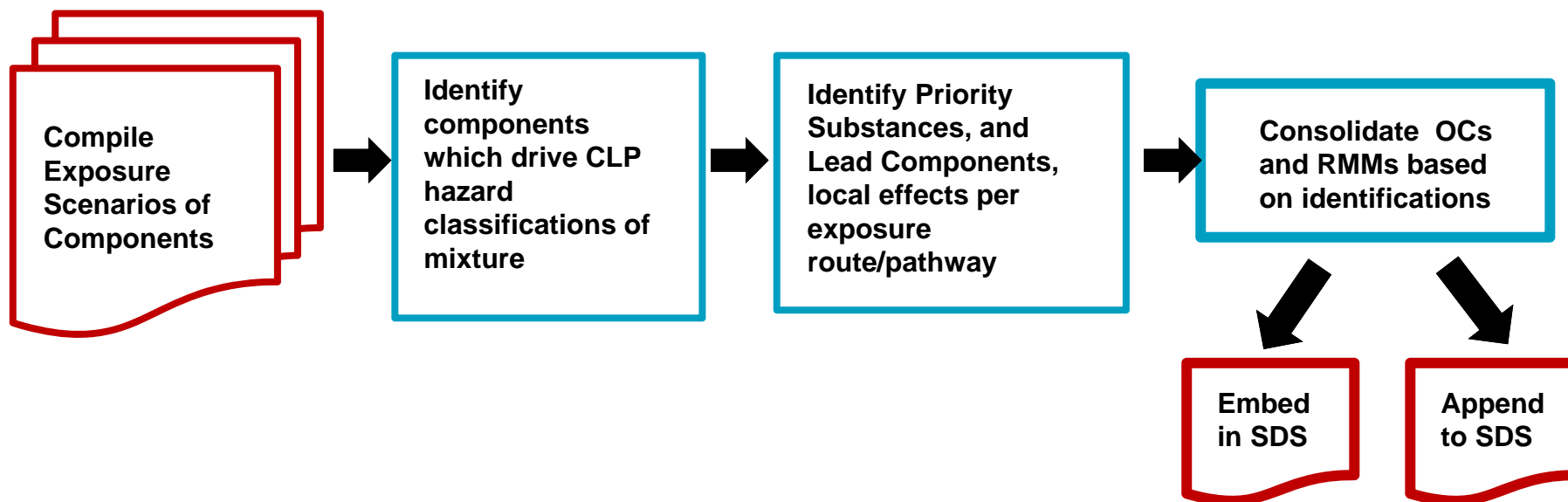
# LCID methodology

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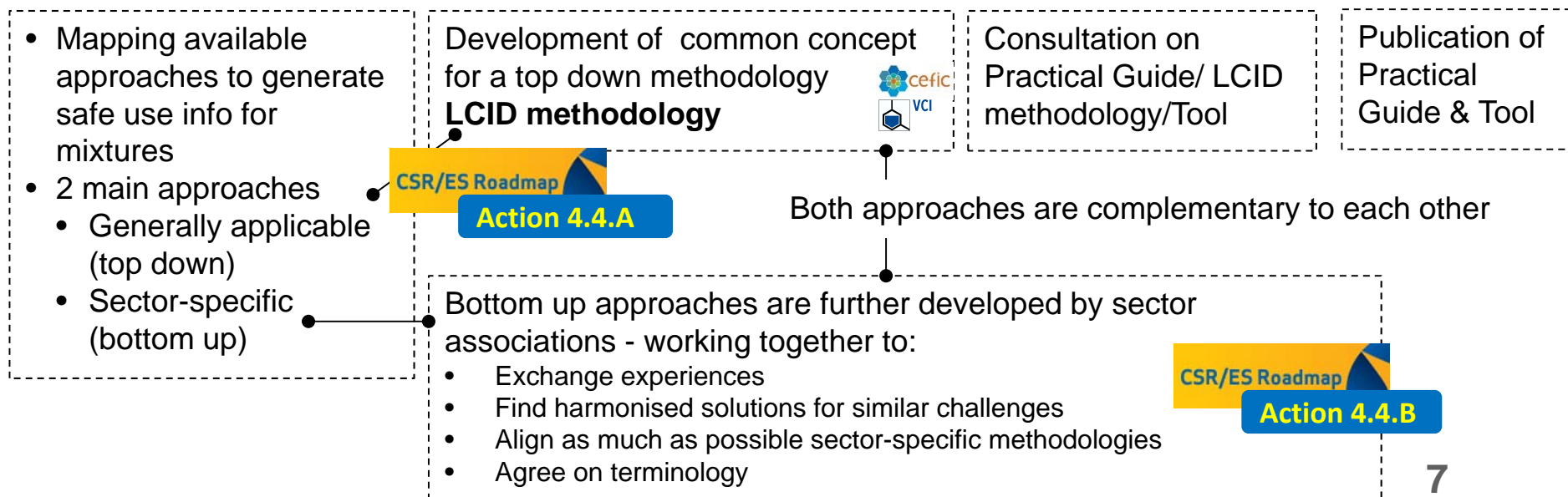
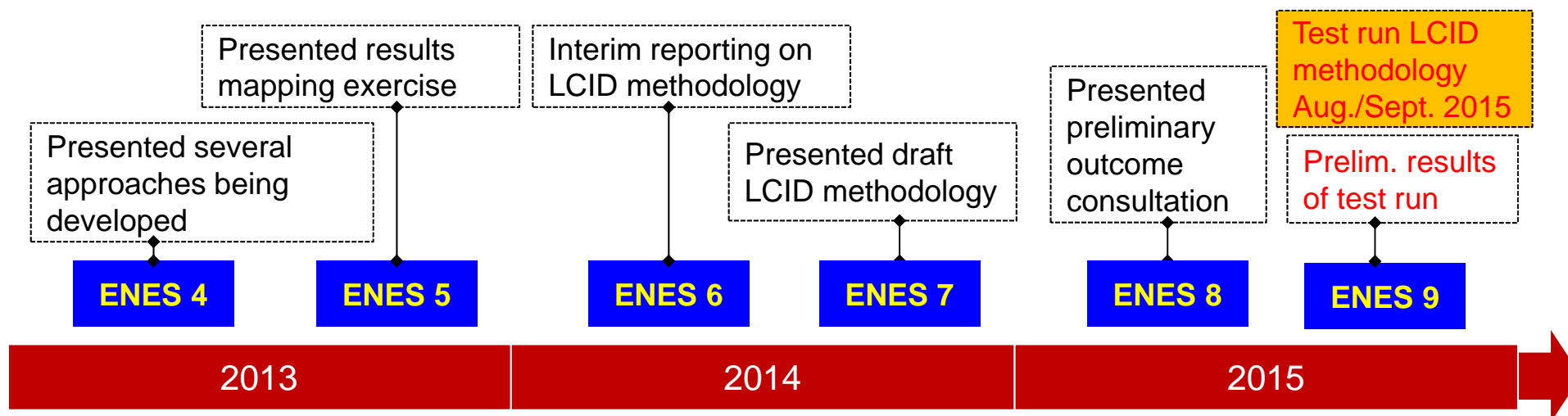
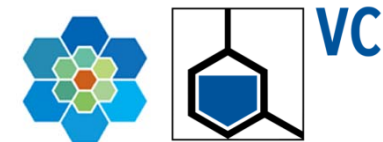


If the risks are controlled for the most hazardous component, then the risks from the other substances in the mixture are also likely controlled.

# LCID methodology (high level)



# Background



# Comments on LCID guide and tool

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## Received

- **12** contributions
- **> 140** comments by Feb. 2015
- Nordic working group comments

## Reviewed

- Filtered (e.g., by content, clarification, Guide/Tool)
- Grouped like comments
- Incorporated changes, as appropriate

## Responded

- Delivered responses to commenters by the beginning of November 2015



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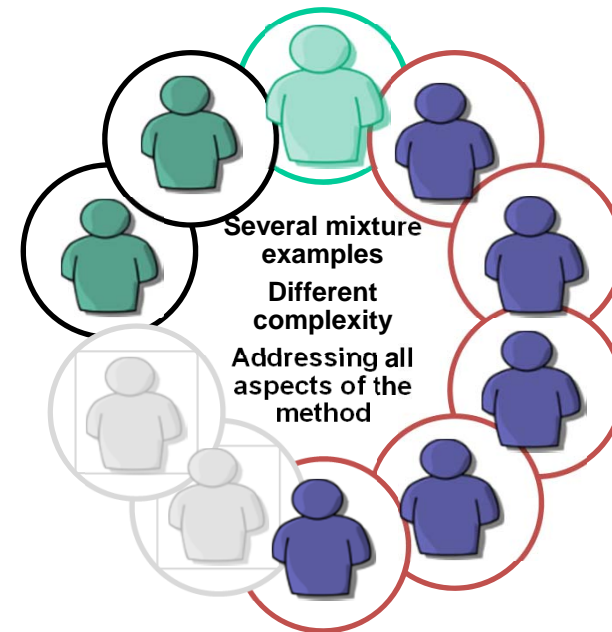
Next steps

# Testing comprehension of LCID methodology



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- Objective:
  - Is outcome of the LCID methodology reproducible, independent of user?
  - Is the LCID Guide and tool sufficiently elaborated to enable the user to apply the methodology in an appropriate way?
- How?
  - Different people apply the LCID methodology independent of each other for the same examples.

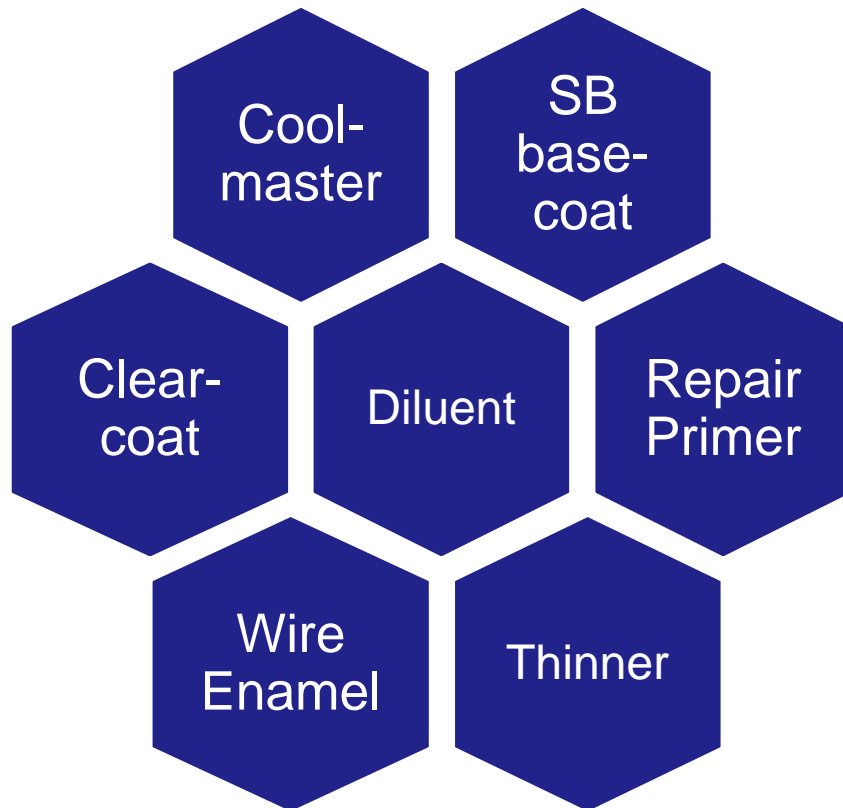


# Examples

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- **Realistic formulations as possible**
- **Demonstrate understanding of various scenarios:**
  - **Priority Substances present**
  - **DNELs available**
  - **Back-up approach**
  - **Groupings**
  - **Case-by-case basis**

# Templates for manual calculations



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Template-Description of Data Fields		Fields to be pre-populated for mixture	
		Fields to be completed by Test Panel	
Name of Product	Coolmaster Deep Zero	Comments	
CLP Health Hazard Classification of mixture	Not classified for human health hazards, H420 (Hazardous to the ozone layer 1)		
(Relevant) components	Dichlorodifluoromethane XY2 1,2-Dichlorotetrafluoroethane		
Relevant CAS No. (if available)	76-71-0 1234 56-7 76-14-2		
Concentration of component	16,20 62,50 22,3		
Health Hazard CLP classification of relevant component			
Relevant local effects			
Health Hazard Priority Substance (pss/no)			
DNEL inh (mg/m <sup>3</sup> )			
DNEL derm (mg/kg bw day)			
DNEL oral (mg/kg bw day) (if applicable, e.g. consumer)			
Vapour Pressure @ 25 C (hPa)			
LCI (DNEL) - inh			
LCI (DNEL) - derm			
LCI (DNEL) - oral			
Grouping: by route of exposure			
LC <sub>50</sub> (DNEL) by route of exposure			
C <sub>max</sub> of LC - by route of exposure (%)			
Are there DNELs available for all the relevant components? (pss/no)			
NOAEC inh (mg/m <sup>3</sup> )			
NOAEL derm (mg/kg bw day)			
NOAEL oral (mg/kg bw day)			
LCCL (NOAEC) - inh			
LCCL (NOAEL) - derm			
LCCL (NOAEL) - oral			
LD50 (inhalation) (mg/m <sup>3</sup> )			
LD50 (dermal) (mg/kg bw)			
LD50 (oral) (mg/kg bw)			
LCCL (LD50) - inh			
LCCL (LD50) - derm			
LCCL (LD50) - oral			
Lead Component for relevant exposure routes			
Exposure Scenario (ES)			
Contributing Scenario (CS)			
Operational Conditions (OCs)			
Risk Management Measures (RMMs)			
OCs for the Mixture			
RMMs for the Mixture			



	Fields pre-populated for mixture
	Fields to be completed by Test Panel
	Name of Exposure Scenario/Contributing Scenario
	Derived safe use information



# Instruction form



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**Test Run of LCID Methodology: Instructions and Evaluation Form**

Introduction

Thank you for volunteering for participating in this test run of applying the LCID methodology to sample mixtures. Please familiarize yourself with the underlying principles and rules of the LCID methodology as documented in detail in Chapter 7 of the 'DRAFT REACH Practical Guide on Exposure Assessment and Communication in the Supply Chains – Safe Use Information for Mixtures under REACH (DRAFT Version 5.1, 24 August 2015).

Anticipated tasks of and feedback from testers of the methodology

You are requested to identify the safe use information for 7 mixtures as provided via the attached excel file [4\_150824\_TestRun\_Mixtures\_LCID]. The excel file contains 8 spreadsheets: a template spreadsheet which describes the data fields and formulas to calculate certain results, and 1 spreadsheet for each mixture. Please save this excel file as [LCID\_testrun\_companyname\_date].

The data provided for each mixture is complete and contains all that is necessary to apply the LCID methodology (data contained in blue color-coded cells).

*In order to ensure a common basis for all testers, the pre-filled data may not be changed nor may other data be added or referenced.*

Each spreadsheet also contains a set of empty fields (color-coded in pink). These empty fields need to be completed by the tester to document the final results and rationales (e.g., relevant calculations).

*You are only required to complete those fields that are relevant for documenting the results of applying the LCID methodology. For example if you apply the LCID methodology and you come to the conclusion that grouping is not relevant, you don't need to complete the fields referring to  $LC_{50}$  and  $C_{align}$ .*

The completed excel files should be returned by **25 September 2015**.

*If you should not be able to complete the spreadsheets for each mixture before the deadline, please send us whatever data you do have available.*

We are also providing an Excel-based LCID tool that has been designed to assist users in identifying the Lead Components for the relevant exposure routes and pathways. By entering input data, such as mixture formulation, hazard classifications, and associated reference values (e.g., DNELs, PNECs, vapour pressure, ... taken from the mixture examples provided), the tool can support you in identifying the Priority Substances/Lead Components necessary to derive the safe use information for the mixture. It's your choice whether you apply the LCID methodology manually and/or with support of the tool. If you use the tool in your testing, please save each test mixture spreadsheet under its own file name [LCID\_toolrun\_testmixturename\_companyname\_date] for each mixture and submit these also for our review and evaluation regarding problems or improvements required for the tool.

Feedback

In addition to forwarding your test result files to us we ask you to complete the following form to help us improve the comprehension and usability of the LCID methodology tool which has been developed.

Thank you for your participation in this test program.

Contacts for test run and feedback:

- Steven Van de Broeck (Cefic): [sva@cefic.be](mailto:sva@cefic.be)
- Jean-Christophe Dewart (Cefic): [jcd@cefic.be](mailto:jcd@cefic.be)
- Angelika Hanschmidt (VCI): [hanschmidt@vci.de](mailto:hanschmidt@vci.de)

• Description of templates



• No need to gather further information

• Save spreadsheets using a given naming convention

# Evaluation form



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**Evaluation Form for Test Run of LCID Methodology**

Name: \_\_\_\_\_  
Affiliation: \_\_\_\_\_  
Address: \_\_\_\_\_  
Phone No: \_\_\_\_\_  
E-mail Address: \_\_\_\_\_  
Date: \_\_\_\_\_

1. Which group of testers do you belong to (check all that apply)?  
 Manufacturer/Importer  
 Downstream User  
 Distributor  
 Consultant  
 Competent Authority/Regulatory Agency  
 Other, please describe: \_\_\_\_\_

2. Did you derive safe use information for all the examples?  
 Yes  
 No, I focused on examples (please specify number): \_\_\_\_\_  
If checked No, why not? \_\_\_\_\_

3. Did you run the examples you tested manually or by using the tool?  
 All just manually  
 All just using the tool  
 All both manually and using the tool  
 Partly by using the tool and partly manually  
If you did not use the tool, why not? \_\_\_\_\_

4. Was there an example(s) you could not finalize?  
 No  
 Yes

• Identification information

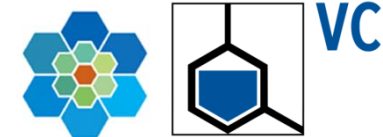
• Able to run the methodology manually? using the tool?

• Able to derive Lead Components?

• Feedback on instructions, example results, manual/tool calculations

# Delivered on 25 August 2015

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**1**

Updated  
Practical  
Guide and  
LCID Tool with  
examples

**7**

Test examples  
with templates

**25.9.15**

Deadline for  
response

**>40**

Volunteers  
representing  
industry,  
consultants,  
Competent  
Authorities,  
ECHA



# Agenda

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1 Background of Cefic/VCI project on mixtures

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# Respondents



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27

- Total
- 12 manufacturers, importers, downstream users, distributors
- 6 consultants
- 7 authorities
- 1 software supplier
- 1 N/A

12

- Did all examples
- 13 partial
- 2 N/A

5

- Calculated manually and with tool
- 7 manually only
- 2 used tool only
- 11 partial tool/manual
- 2 N/A

Main reason for not completing—time constraints

## General comments: a selection

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*“We really like this whole study and approach. Congratulations! Its very helpful and I hope I can work further to have this implemented in our IT system. It’s the best approach (for us) from several others that we have ‘evaluated ‘ until now.”*

*“...powerful tool, more clear arrangement of the end result wishful...”*

*“...the guidance and the tool provided for the most part make intuitive sense and meet the intended purpose. The biggest problem in applying this guidance is the vast increase in complexity and technicality...”*

*“LCID tool is a good tool for assistance, especially in proofing the results of calculations. However, it does not substitute expert judgment.”*

*“...workshop would be preferable...”*

## General comments: summary



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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

## Human health: preliminary results



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**Test run  
was  
successful**

- LCID methodology was generally well understood
- Able to identify underlying principles
- Calculation tool delivered reliable results
- Method proved to be robust
- Valuable comments were received for a refinement of the examples and further improvements

## Human health: preliminary results cont'd

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### Reasons for differences when compared to results from LCID group

- Minor mistakes, e.g., mathematical errors
- (Mis)identification of relevant components
- Template was not correctly completed
- (Mis)groupings (e.g., selection of two inhalation lead components)
- A case-by-case assessment was missed
- Not all data needed was entered correctly in tool, e.g., DNELs

# Environment

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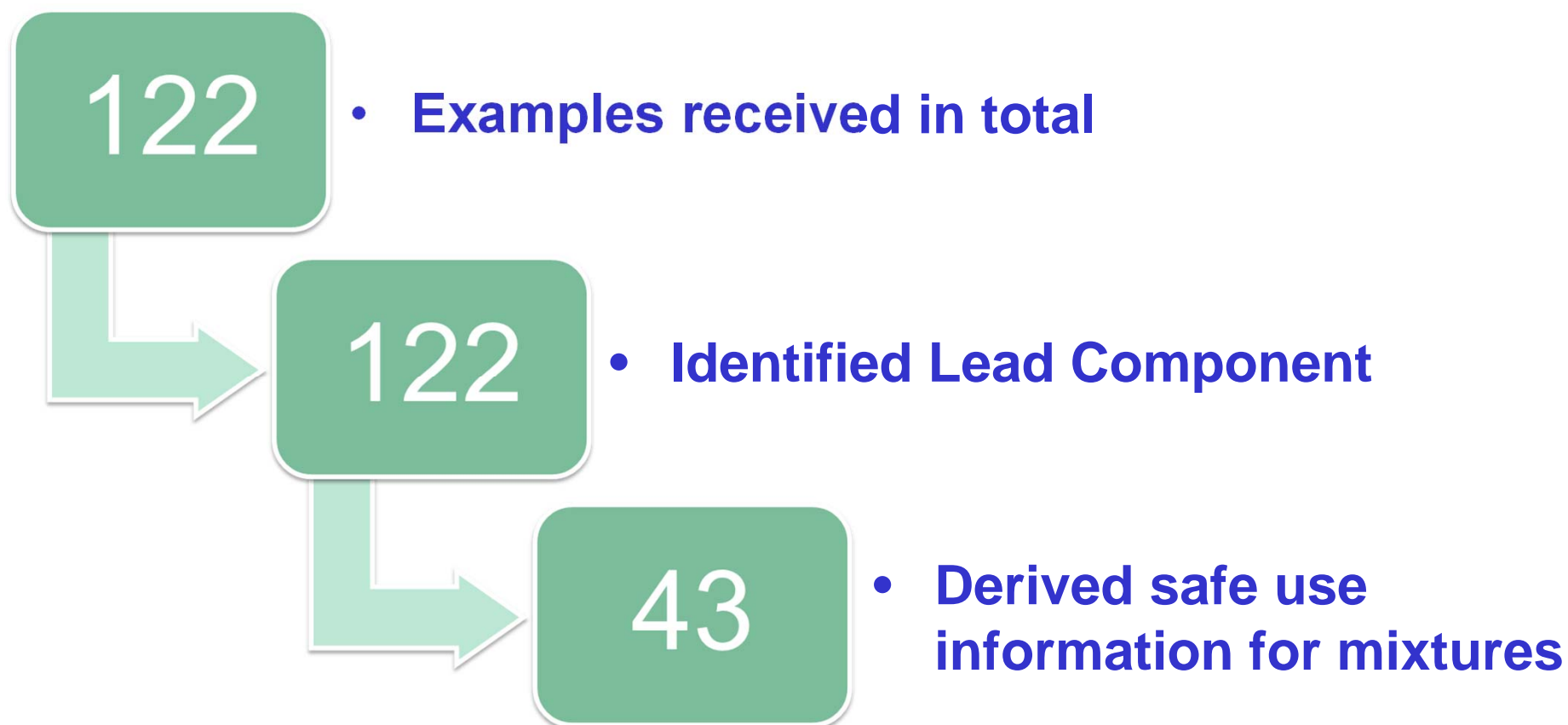
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## Environment: preliminary results

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# Topics

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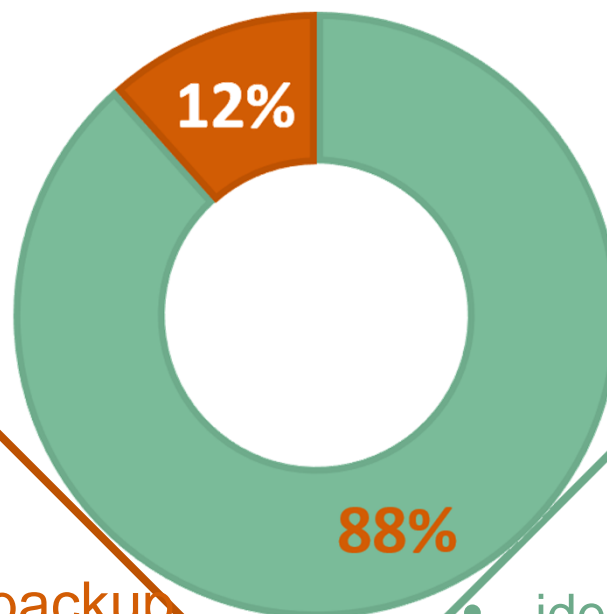


- Identification of Lead Component (LC)  
(both PNEC- and backup/classification approach)
- Ozone hazard
- Priority Substance (e.g., PBT)
- Mixture not classified for environmental hazards
- $M_{\text{safe}}$  for mixture  
(calculation of modifying factor,  $C_{\text{weighted}}$ )
- OCs / RMMs for mixture

# Lead Component Identification



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**12%**  
**Failure**

## Testers did:

- mix up PNEC- and backup approach
- not spot PBT compound and failed to identify LC due to missing data
- claim missing info for non-classified components

**88%**  
**Correct answer**

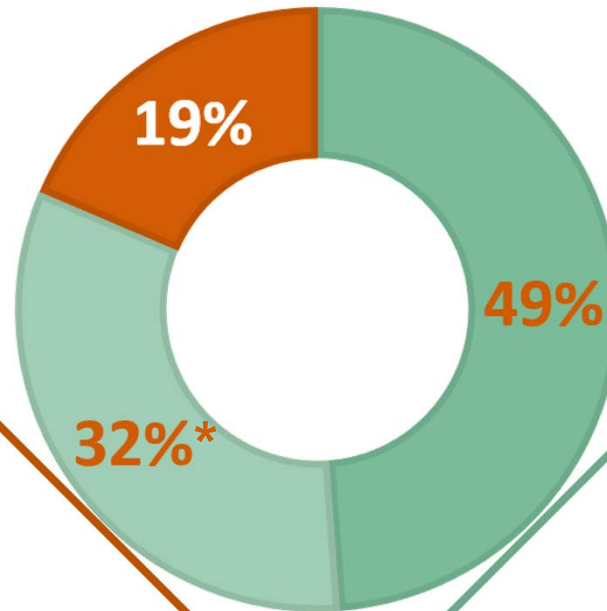
## Testers did:

- identify correct LC (via PNEC- or backup approach, also for ozone hazards)
- spot PBT component
- stop the procedure because of the classification of the mixture

# $M_{safe}$ , OCs/RMMs



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**19%**  
**Failure**

## Testers did:

- calculate modifying factor and  $C_{weighted}$  correctly, but used concentration of LC to derive  $M_{safe}$
- not consider grouping components

**49+32\* = 81%**  
**Correct answer**

## Testers did:

- correctly calculate the modifying factor,  $C_{weighted}$  and  $M_{safe}$  (for the mixture)
- derived appropriate OCs and RMMs for the product

\*division by XY% instead of 0.XY

## Environment: preliminary results



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## Next steps

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Finalize assessment of test results

Update Practical Guide by Q4 2015

Update LCID Tool by Q4 2015

Define and commence execution on communication plan

Involve IT providers in LCID methodology launch

Workshop in 2016

# Questions

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