CSR/ES Roadmap Action 4.4A

The Cefic/VCI Project on Mixtures under REACH

Cefic/VCI Workshop on the LCID methodology

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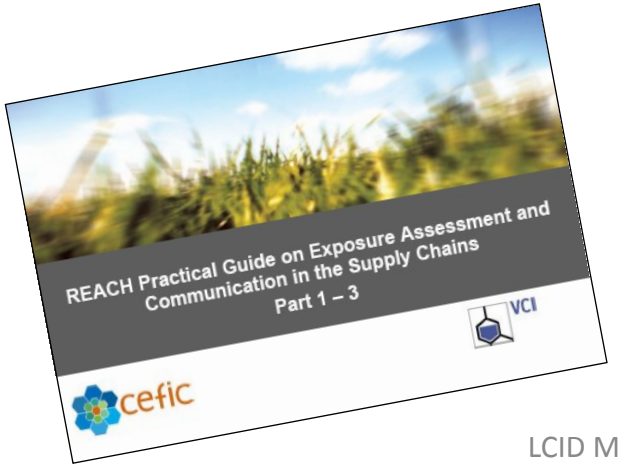
Content

- Cefic/VCI Activities and Exposure Scenarios
- Action 4.4. on Mixtures/LCID Methodology under the CSR/ES Roadmap
- The Practical Guide Project

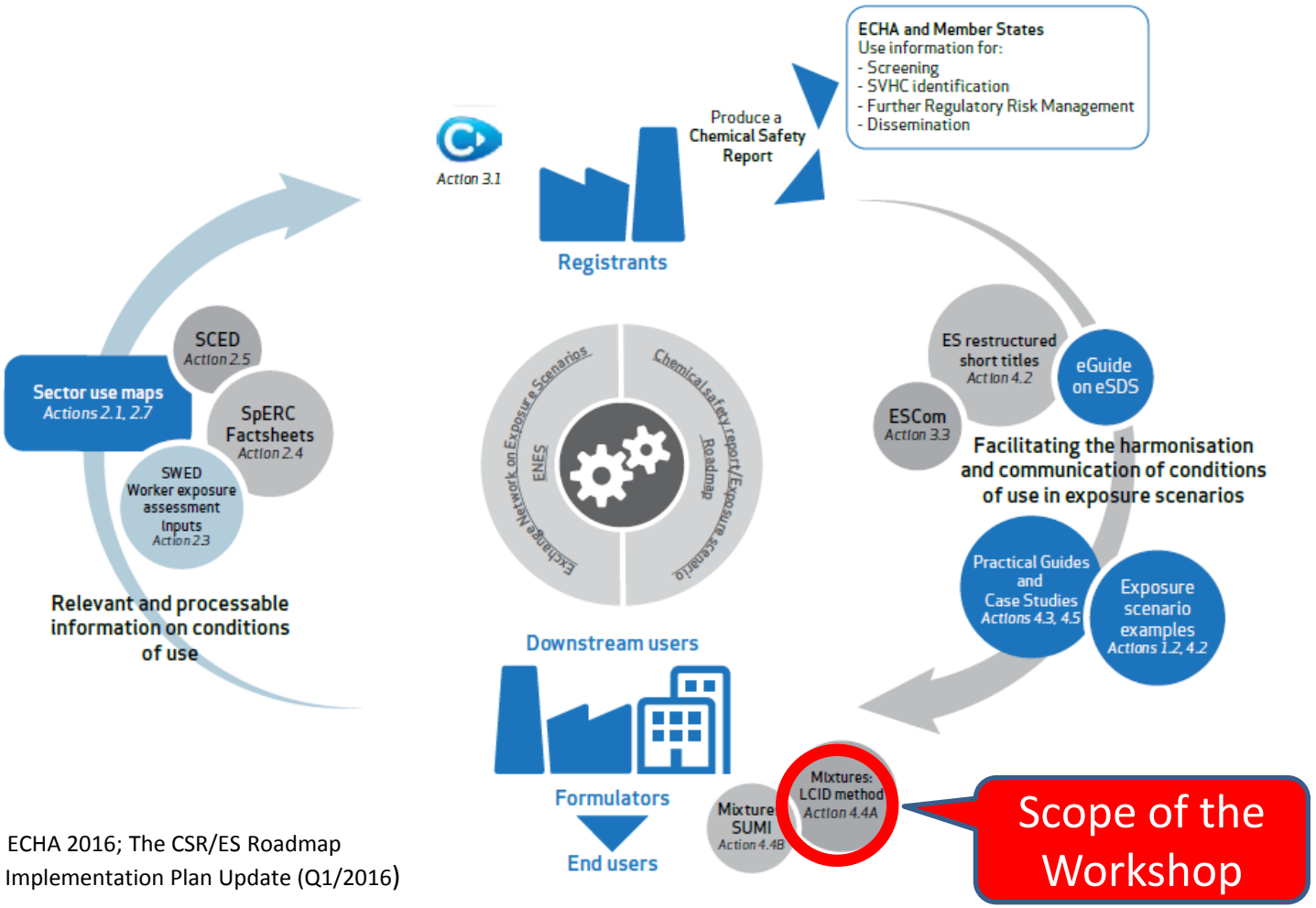
Exposure Scenarios introduced by REACH

CSR/ES Roadmap

- **Exposure Scenario (ES) is a new REACH element**
  - Chemical Safety Report (CSR) for substances produced/imported ≥ 10 tonnes/year: ES required, if substance is classified as hazardous under CLP or is PBT/vPvB
  - Extended Safety Data Sheet (eSDS): ES Annex(es) for all relevant identified uses of a substance registered (and requiring CSR/ES); consideration of ES information when drafting SDS for mixture
- **Cefic & VCI developed early support for members**, e.g.:



The CSR/ES Roadmap



Source: ECHA 2016; The CSR/ES Roadmap Second Implementation Plan Update (Q1/2016)

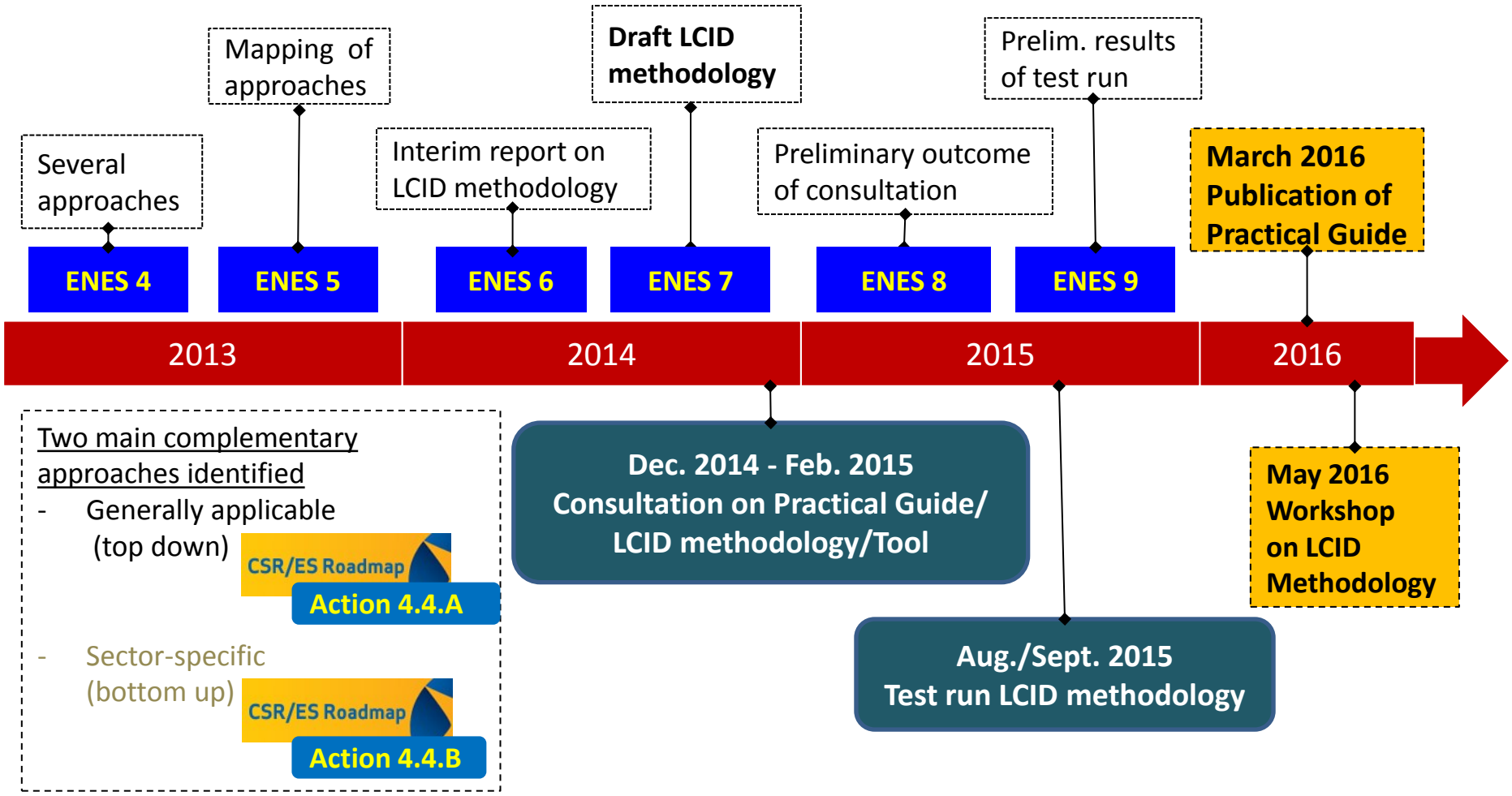
The CSR/ES Roadmap Action 4.4A (I)

- **Scope of Cefic/VCI Mixtures project**
  - Refine and merge available top-down approaches that consider exposure information from substances to compile SDS for mixtures
  - Consider CLP classifications and components' DNELs & PNECs
  - Define best choice of lead/priority substance identification steps based on rationales given and scientific evidence for method/ prioritisation decisions taken
  - Test and validate identified best practices using realistic examples
  - Publish description of project results:
    introduction to formulator's tasks and options, prioritisation method, workflow including principles and decision tree

The CSR/ES Roadmap Action 4.4A (II)

- **Starting Point of Cefic/VCI Mixtures Project**
  - Top-down approaches presented during ENES 5 in Nov. 2013 (inter alia DPD+, CLP+, CCA)
  - Previous Cefic/VCI experience
    - Exposure assessment and communication in the supply chains practical guide project
    - DPD+ project
- **Objective of Cefic/VCI Mixtures Project**
  - Develop a generally applicable top-down approach to derive safe use information for mixtures based on ES(s) received from suppliers of component substances

Safe Use Information for Mixtures
Development of the LCID Methodology



Cefic/VCI Mixtures Project - Consultations

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Consultation on LCID Methodology, Practical Guide, Excel Tool

- Internal, then ENES consultation

Received ≅ 150 comments from ENES attendees by Feb 2015

- From industry, authorities, trade associations and ECHA
- Overall supportive of structure and content
- Sought clarification and further elaboration of workflow
- Recommended inter alia test run, training

Gave responses to commenters by Nov 2015

Restructured workflows, included clarifications/amendments

Cefic/VCI Mixtures Project - Test run

CSR/ES Roadmap

Scope: LCID methodology reproducible irrespective of user?
LCID Guide and Tool sufficiently developed?

- 7 test cases (realistic formulations) elaborated
- 40 volunteers for test run identified

Testing package shared with testers in Aug 2015

- Test case templates with all relevant input data
- Optional manual & tool runs, updated draft guide/tool
- Instructions and evaluation form

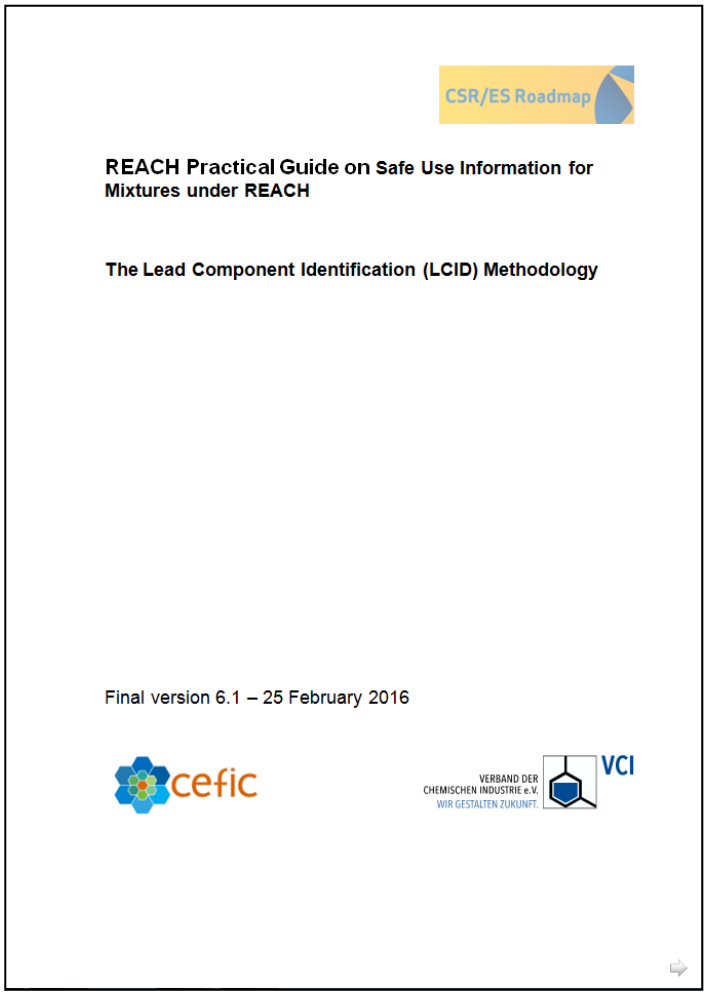
27 Parties provided test run feedback by Sept 2015

- Test run was a success, results reproducible

LCID Methodology, Practical Guide and Excel tool finalised

- Further improvement of project deliverables

Practical Guide on Safe Use Information for Mixtures under REACH



The Practical Guide

Introduction/Formulator's Tasks (Ch. 1 - 6)

- Supply chains & mixtures, REACH and Formulators
- Safe use information for mixtures: options, approaches
- Determining safe use information for inclusion in an SDS of a mixture: main steps

Identification of Lead Components (Ch. 7)

- Workflow figures for human health and environmental approach
- Step-by-step descriptions

Further relevant aspects (Ch. 8-10)

- Extended evaluation of mixtures
- Additional options for DUs, IT support

Glossary (Ch. 11)

Annexes

- III: Test examples applying the LCID methodology
- IV: Underlying principles and rationales of the LCID Methodology

More Information

Cefic Website – REACH Guidance and Tools

http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

VCI Website – REACH

http://www.vci.de/vci-online/themen/chemikaliensicherheit/reach/cefic-vci-issue-practical-guide-on-safe-use-of-mixtures-under-reach-lead-component-identification-methodology.jsp

VCI Platform „REACH&CLP“ (Login required)

https://www.vci.de/reach