

The CSR/ES Roadmap

Second Implementation Plan

Q1/2014 to Q2/2015



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List of abbreviations

BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
Cefic	European Chemical Industry Council
Chesar	Chemical Safety Assessment and Reporting tool
CONCAWE	The oil companies' European association for environment, health and safety in refining and distribution (Conservation of clean air and water in Europe)
CSA	Chemical safety assessment
CSR	Chemical safety report
DU	Downstream user
DUCC	The Downstream Users of Chemicals Co-ordination Group
ECHA	European Chemicals Agency
ECETOC	European centre for ecotoxicology and toxicology of chemicals – targeted risk assessment (TRA)
ENES	ECHA-stakeholder Exchange network on exposure scenarios
ES	Exposure scenario
ESCom	Exposure scenario for communication (ESCom) standard project
Fecc	The European Association of Chemical Distributors
GES	Generic exposure scenario
Inspectie SZW	Inspectie van Sociale Zaken en Werkgelegenheid
OC	Operational condition
OECD	Organisation for Economic Co-operation and Development
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measure
SCED	Specific consumer exposure determinant
SpERC	Specific environmental release category
TUKES	Turvallisuus- ja kemikaalivirasto
IUCLID	International uniform chemical information database
UBA	Das Umweltbundesamt

The CSR/ES Roadmap

Second Implementation Plan Q1/2014 to Q2/2015

The CSR/ES Roadmap-ENES Coordination group has created an implementation plan for Q1/2014 to Q2/2015. The plan reflects previous experience from the Roadmap and addresses how to achieve its objectives in the foreseen timeframe.

Two main lines of activities are proposed:

- 1) Improving the quality of information at the top of the supply chain. This way, the quality of the CSRs in the registration dossiers as well as the subsequent information in the supply chain will improve.
- 2) Support to formulators who have immediate obligations under REACH.

The challenge will be to find the correct balance between these tasks.

When preparing the Roadmap, both authorities and industry agreed that it is important for the registrants' chemical safety assessments to be based on realistic assumptions. The resulting conditions of safe use should also be realistic for downstream users to implement. The most crucial pieces of information for carrying out the CSA are: the brief description of identified uses, and the exposure assessment inputs (for workers, environment, consumer), in particular the need to further develop the existing tools such as generic exposure scenarios (GESs), specific environmental release categories (SpERCs) and specific consumer exposure determinants (SCEDs).

To ensure consistency as well as increase efficiency, the elements of Action Area 2 have been combined into the concept of "extended use maps". This will improve the information from the downstream users as an input to the registrants' chemical safety assessments. In practice, this will mean that existing industry sector use maps will need to be reviewed once an updated format is agreed. Where necessary, they will be extended to improve the description of the uses, the information on substances present and to connect the uses to the relevant assessment input for worker exposure (based on GES), environmental exposure (SpERC) and consumer exposure (SCED). The exposure assessment inputs should characterise the conditions of use (OC/RMM) so that registrants are able to carry out exposure assessments and risk characterisations for their substances.

In the CSR/ES Roadmap, this means that Actions 2.1 to 2.5 will form a tight package with interlinks to be made throughout the extended use map development. As such, the extended use maps would be a concrete output for Roadmap Action 2.7.

Some actions, especially under Action Area 4, are foreseen to continue and should produce the first solutions in 2014. The goal is to support formulators and other downstream users to fulfil their legal obligations: to understand and react to exposure scenario information received from their suppliers and to forward meaningful information on the safe use of their own products. It is expected that these solutions will be implemented in the supply chains. Experience on their practical applicability will be gathered. After a reasonable period, the Roadmap Coordination group will decide on a review and potential follow-up actions. The foreseen improvement of the communicated exposure scenario (ES) over time may also refocus these activities.

To reflect the above, the Roadmap actions have been merged or regrouped in the implementation plan. In addition, the relatively wide actions described in the Roadmap will sometimes be taken forward as smaller sub-tasks. Therefore, their titles may differ from those originally expressed in the Roadmap. To maintain the

connection to the original document, the related actions in the Roadmap document are given for each action in the implementation plan. The actions are also grouped under the headings of the original Action Areas.

This implementation plan covers 18 months from Q1/2014 to Q2/2015. The Coordination group will review the plan twice a year to react to new developments and to steer the work accordingly. The updated implementation plan will be available on the CSR/ES Roadmap web page.



ACTION AREA 2: FURTHER DEVELOP INFORMATION INPUTS FOR THE CHEMICAL SAFETY ASSESSMENT

Developing extended use maps as a basis for good quality CSA

Roadmap actions: 2.1, 2.2, 2.7; strong interlinks to Actions 2.3-2.5 as explained in the introduction.

Activities foreseen	<p>Building on the current use maps and harmonised exposure assessment inputs, develop and establish an agreed approach, i.e. format and content, for the extended use maps. These indicate the necessary elements for description of use as well as the links to the exposure assessment inputs (Actions 2.3-2.5), which can also be included in the development of the IT tools implemented there (see Action 3.1).</p> <p>Test with case studies the practical usability and realisation of the added value expected in the CSA and related ES for communication generation by the extended use map in a number/range of supply chains. After this, develop and publish guidance that supports the review and extension of existing industry sector use maps.</p> <p>If the method proves valuable, encourage the sectors to review their existing industry sector use maps and amend as necessary to align with the extended use map (both format and content). Encourage those sectors that have not yet mapped their uses to do so following the extended use maps approach.</p>
Planned events	<p>Introduction and preliminary agreement to the concept and corresponding formats at ENES6 in mid-May 2014.</p> <p>Workshop on results of testing (proof of concept) and final agreement on formats (Q4/2014).</p>
Expected outcome	<p>Agreed format for an extended use map by Q2/2014.</p> <p>Agreed content for extended use maps by Q4/2014, input coming from actions 2.3-2.5.</p> <p>Draft guidance for developing an extended use map within a sector by Q4/2014.</p>
Lead and contact point	<p>DUCC</p> <p>Laura Portugal; laura.portugal@aise.eu</p> <p>ECHA</p> <p>Laure-Anne Carton de Tournai; laure-anne.cartondetournai@echa.europa.eu</p>

Exposure assessment inputs for workers

Roadmap action: 2.3

Activities foreseen	<p>Analysis of current format and content of the GESs and of the exposure assessment related parts of existing use maps (including exemplification for one sector/product category).</p> <p>Develop format for the exposure assessment input in connection with the work on extended use maps based on the above.</p> <p>Testing the format and content within sectors. After validation of the concept, encouraging sectors to develop/update the exposure assessment input for workers. The interim results of the BAuA project (see next block) is expected to help sectors in identifying suitable risk management packages.</p>
Planned events	<p>Working meeting between ECETOC and ECHA to discuss update needs/plans for TRA worker (Q2/2014).</p> <p>Workshop with GES authors and potentially owners of worker exposure estimation tools to discuss options for a harmonised exposure assessment input for workers.</p>
Expected outcome	<p>Format for the exposure assessment input for workers agreed (Q2/2014).</p> <p>Improved exposure assessment inputs to estimate worker exposure from identified use(s) of substances are developed within downstream user sectors. They can be applied by both first time registrants and registrants updating the CSAs from 2016 onwards.</p>
Lead and contact point	<p>Lead - tbd</p> <p>Interim contact point: Andreas Ahrens; andreas.ahrens@echa.europa.eu</p>

Connecting existing risk management measure packages for worker exposure to REACH CSA

Roadmap action: 2.3

Activities foreseen	<p>Collect information on existing risk management measure (RMM) packages and try to assign an exposure band/level to these packages.</p> <p>Make a link to existing exposure estimates and propose a way to integrate the RMM packages into the registrant's CSA and subsequently into (existing) extended safety data sheets and IUCLID.</p> <p>Preliminary results of this project will contribute to the action on the exposure assessment input for workers and on extended use maps (see previous blocks).</p> <p>Analysis of existing packages by BAuA, and interim results and the proposals for the way forward to be discussed in spring 2015 with an expert group of industry and authorities.</p> <p>Use/integrate RMM packages as (part of) input data in future exposure assessment models.</p>
Planned events	<p>Workshop to discuss interim results of the BAuA project in Q2/2015.</p>
Expected outcome	<p>Connection of established risk management for particular sectors, product/substance types to the registrant's exposure assessment under REACH.</p> <p>Application of control banding approach to specification of risk management measures in the REACH CSA.</p>
Lead and contact point	<p>BAuA</p> <p>Eva Lechtenberg-Auffarth; lechtenberg.eva@baua.bund.de</p>

Exposure assessment input for the environment

Roadmap action: 2.4

Activities foreseen	<p>Analysis of the SpERC format update needs with regard to the linking of SpERCs to the extended use maps and the use of SpERCs in that context.</p> <p>When published, analysis of the content update needs based on the SpERC review conducted by UBA.</p> <p>Based on the conclusions on both format and content related update needs, all sectors to review their SpERCs in light of this. Encourage those sectors that have not yet developed SpERCs for their uses to do so in the revised format.</p>
Planned events	<p>Expert meeting to discuss the enhancement needs for the SpERC format (Q2/2014).</p> <p>Workshop to discuss UBA's SpERC review findings in Q3/2014.</p>
Expected outcome	<p>Format for the exposure assessment input for the environment (improved and format for SpERCs) agreed (Q2/2014).</p> <p>Improved SpERCs contents are developed within downstream user sectors so that they can be applied by registrants in updating the CSAs from 2016 onwards.</p>
Lead and contact point	DUCC

Exposure assessment input for consumers

Roadmap action: 2.5

Activities foreseen	<p>Publication of the specific consumer exposure determinants (SCEDs) developed so far by sectors, and the industry guidance that explains how to develop and apply them. Publication of Chesar v.2.3 which contains the functionality to import a SCED to an exposure assessment for consumers.</p> <p>Analysis of the SCED format with regard to the extended use map concept and identification of the improvement needs by Q2/2014.</p> <p>Review period of the SCED content involving Member State authorities on the published material, and discussion on their findings and potential improvement needs organised.</p> <p>Based on the conclusions on update needs, industry sectors to review their SCEDs in light of this. Encourage those sectors that have not yet developed SCEDs for the consumer uses of substances to do so in the revised format.</p>
Planned events	<p>Expert meeting to discuss the enhancement needs for the SCED format (Q2/2014).</p> <p>Workshop with authorities to review content related findings on SCEDs in Q1/2015.</p>
Expected outcome	<p>Format for exposure assessment input for consumers agreed (Q2/2014).</p> <p>(Improved) SCEDs are developed within downstream user sectors so that they can be applied by registrants in updating the CSAs from 2016 onwards.</p>
Lead and contact point	<p>DUCC</p> <p>Sophie Mathieu; sophie.mathieu@aise.eu</p>

Information gathering on methods for registrants to estimate volumes per use within supply chains

Roadmap action: 2.6

Activities foreseen	<p>A systematic information gathering on potential existing sources and methodologies that could be used as such or as proxies for giving estimates on volumes per use within the supply chain; an overview available by the end of 2014. A first step will focus on a collection of methodologies that have been followed by registrants in 2010 and 2013. Any preliminary findings may feed into the extended use map format development.</p> <p>The authorities further explain for what this information is needed.</p> <p>After the information gathering period the outcome is analysed and the Coordination group agrees on the way forward.</p>
Planned events	<p>Workshop to discuss findings in Q1/2015.</p>
Expected outcome	<p>Overview on practical means (available to registrants) to estimate the volume supplied to the different end-uses of their substance.</p>
Lead and contact point	<p>Cefic Jean-Christophe Dewart; jcd@cefic.be</p>



ACTION AREA 3: FURTHER DEVELOP IT TOOLS AND STANDARDISATION

Further development of the IT tools, IUCLID and Chesar to take account of experience and needs

Roadmap actions: 3.1, 1.1; also strong links to extended use maps Actions.

Activities foreseen	<p>Incorporate the authorities' use and exposure needs into the technical specifications for IUCLID 6.1 development. Consult with authorities and industry.</p> <p>Develop Chesar 3 in collaboration and/or consultation with industry for i) supporting harmonisation/standardisation of assessment approach (and harmonised reporting in CSR and ES for communication) ii) facilitating the extended use map information (and related exposure assessment inputs) to be fed into the CSA and iii) supporting the registrants to carry out/update the CSA in a way that the CSR extract can be directly exported into the technical dossier.</p> <p>Realistic test cases developed by industry in order to be able to test the tool.</p>
Planned events	<p>Consultation of the subgroup of the OECD Task for on exposure assessment (two web conferences in Q1/Q2 2014)</p> <p>Consultations on the requirements for Chesar 3 within the Chesar consultation group.</p>
Expected outcome	<p>IUCLID 6.1 where some key CSR related information (on use and exposure) can be reported in a structured format (Q1/2016).</p> <p>Chesar 3 for a wider range of substances, and where the CSR extract can be directly exported into the technical dossier.</p>
Lead and contact point	<p>ECHA IUCLID: Andreas Ahrens ; andreas.ahrens@echa.europa.eu Chesar: H�el�ene Magaud; helene.magaud@echa.europa.eu</p>

ESCom package	
Roadmap action: 3.3	
Activities foreseen	<p>ESCom package governance structure has been finalised and the project is currently foreseen to continue at least until the end of 2015. As the first step, the mechanism for proposing new phrases to the phrase catalogue has been set up.</p> <p>The existing phrase catalogue is being reviewed with a view to removing duplicate phrase entries. The current XML format is also under a review. Both are expected to be published in 2014.</p> <p>Awareness raising on the ESCom package within sectors.</p>
Planned events	None.
Expected outcome	<p>Improved phrase catalogue by removing redundant phrases and continuous inclusion of new, relevant phrases.</p> <p>An up-to-date XML format to support the exchange of the phrases between different IT systems.</p>
Lead and contact point	<p>Cefic</p> <p>Dook Noij ; dook.noij@dow.com</p>



ACTION AREA 4: SUPPORT PROCESSING OF INFORMATION AT FORMULATORS' LEVEL

Aligning understanding on the purpose of the different information elements in the exposure scenario for communication	
Roadmap actions: 4.1, 1.2	
Activities foreseen	<p>ECHA will consult stakeholders on an annotated template and an illustrative example for the exposure scenario communicated with the safety data sheet. The outcome of the consultation, as published in the final template and example is considered as the current common understanding, both in terms of content and format.</p> <p>Awareness raising within the industry sectors so that the template will be used.</p>
Planned events	On the agenda at ENES 6 (mid-May 2014).
Expected outcome	Publication of an annotated template and an illustrative example on exposure scenario for communication by ECHA.
Lead and contact point	<p>ECHA</p> <p>Mercedes Viñas; mercedes.vinas@echa.europa.eu</p>

Harmonised layout-format for the exposure scenario for communication: Table of content based on exposure scenario short titles for communication

Roadmap action: 4.2

Activities foreseen	<p>Testing of building the table of contents for the exposure scenarios annexed to the safety data sheets. This is based on the preliminary rule set presented at ENES5 with the group of volunteer companies and sectors. Reporting the outcome of testing and recommendations for implementation at ENES6.</p> <p>Plan for follow-up activities, if any (e.g. link to ESCom phrase catalogue update).</p>
Planned events	<p>Workshop to review the test phase findings and agree guidelines for implementation in March 2014.</p> <p>On the agenda of ENES6 (mid-May 2014).</p>
Expected outcome	<p>A rule set for constructing a short title for exposure scenario agreed (for first and second identifier).</p> <p>Promotion of the approach within sectors.</p> <p>Implementation of the table of contents within the supply chains.</p>
Lead and contact point	<p>DUCC</p> <p>Sylvie Lemoine; sylvie.lemoine@aise.eu</p>

Support for formulators in understanding their obligations and options

Roadmap action: 4.3

Activities foreseen	<p>ECHA will update Practical Guide 13 (“How downstream users can handle exposure scenarios”). It will add further examples on how to determine that downstream conditions of use are within the boundaries recommended in the exposure scenario appended to the safety data sheet. The examples will be developed together with the stakeholders.</p> <p>Further actions to be decided by the Coordination Group in early 2015.</p>
Planned events	<p>Webinar related to Practical Guide 13 update and DU CSR (action 4.5) in Q3/2014.</p>
Expected outcome	<p>Practical Guide 13 with scaling examples.</p>
Lead and contact point	<p>ECHA</p> <p>Bridget Ginnity; bridget.ginnity@echa.europa.eu</p>

Producing advice on safe use of mixtures based on REACH substance exposure scenarios

Roadmap action: 4.4

Activities foreseen	<p>The mixtures working group will continue its work on consolidating advice on safe use of mixtures, based on discussions at ENES5.</p> <p>The focus for the ENES6 deadline is on how to identify the risk driving substance(s) in a mixture. The challenge of consolidating risk management measures from different substance exposure scenarios will be addressed later in the year, and integrated with Action Area 2.</p> <p>DUCC will look at methodology commonalities between the different 'bottom-up' approaches of its member sectors.</p> <p>An overview of the information developed and presented at various ENES meetings will be consolidated by the working group and made available on the ECHA website. ECHA will develop and publish a web section targeted to formulators.</p>
Planned events	On the ENES6 agenda.
Expected outcome	<p>A generic framework for the identification of the risk driving substance(s) with guidelines presented at ENES6, after which it can be promoted within sectors.</p> <p>Formulator web section on the ECHA website in Q3.</p>
Lead and contact point	<p>Cefic</p> <p>Steven Van De Broeck; svandebroeck@essencia.be</p>

Understanding the issues and providing support for conducting downstream user CSR

Roadmap actions: 4.5, 4.6

Activities foreseen	<p>Survey for companies who have conducted a DU CSR to better understand the support needs. This will form the basis for establishing a project plan on DU CSR, which integrates the needs/issues identified in the survey.</p> <p>Developing an ECHA Practical Guide.</p>
Planned events	Survey results reported at ENES6.
Expected outcome	<p>Understanding of the difficulties encountered when preparing DU CSR in Q1/2014. A plan of how to resolve these issues in Q2/2014.</p> <p>ECHA Practical Guide for downstream users who want to conduct their own CSR in Q3/2014.</p> <p>Communication activities for disseminating the Practical Guide and related documents.</p> <p>Resolution of outstanding issues by Q2/2015.</p>
Lead and contact point	<p>DUCC</p> <p>Laura Portugal; laura.portugal@aise.eu</p> <p>For Practical Guide, ECHA</p> <p>Bridget Ginnity; bridget.ginnity@echa.europa.eu</p>

APPENDIX 1. COMPOSITION OF THE CSR/ES ROADMAP-ENES COORDINATION GROUP

REPRESENTATIVES FROM MEMBER STATE AUTHORITIES

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	Jean-Christophe Dewart	
CONCAWE	Arlean Rohde	
DUCC	Sylvie Lemoine	
DUCC	Laura Portugal	
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