

CSR/ES Roadmap Updated Second Implementation Plan

TOWARDS GOOD QUALITY INFORMATION ON THE SAFE
USE OF CHEMICALS IN THE REACH CHEMICAL SAFETY
REPORT AND THE EXTENDED SAFETY DATA SHEET



The CSR/ES Roadmap. Updated Second implementation plan.

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Acronyms

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)
COSHH	Control of Substances Hazardous to Health
CSA	Chemical safety assessment
CSR	Chemical safety report
DU	Downstream user
DUCC	The Downstream Users of Chemicals Coordination Group
ECETOC	European centre for ecotoxicology and toxicology of chemicals – targeted risk assessment (TRA)
ECHA	European Chemicals Agency
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
GISBAU	Das Gefahrstoff-Informationssystem der BG BAU
Inspectie SZW	Inspectie van Sociale Zaken en Werkgelegenheid
IUCLID	International uniform chemical information database
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
SUMI	Safe Use Mixture Information
TUKES	Turvallisuus- ja kemikaalivirasto

The CSR/ES Roadmap

Second Implementation Plan (Q1/2014 to Q2/2015): Updated to Q1/2016

EXPLANATORY NOTE

The CSR/ES Roadmap¹ is a cross-stakeholder plan of actions. It builds on the experience drawn from many actors toward achieving the goals of the REACH Regulation for the safe use of chemicals. Continuous improvement and the importance of good quality information on the safe use of chemicals in the REACH chemical safety report and the extended safety sheet are essential. The Roadmap sets out a series of discrete actions to help that process. These actions form part of rolling programme to 2018 through which good practice examples, methods, guidance and tools will evolve by means of implementation plans.

In January 2015, the CSR/ES Roadmap-ENES Coordination Group reviewed progress on the Roadmap and the second implementation plan². As a result, the Group has prepared a revised document. This document extends the period covered by the second implementation plan to Q1/2016 to reflect the progress on individual actions and that a number of new steps are required for the delivery of certain key actions, as well as highlight progress in 2014.

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).

It is also crucial to pay attention to the communication of the developed solutions, tools, and support material to promote their use. If the Roadmap outputs are not known or not used in the supply chain, the common objective of ensuring that actual risks are managed will not be achieved.

The main lines of activity and the priorities, as set out in the April 2014 edition of the second implementation plan, are not affected. These remain as:

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 communicated in the supply chain will improve.
2. Support to formulators who have immediate obligations under REACH. Not least to enable formulators to transpose the information they receive in substance exposure scenarios into safe use information for their mixtures.

Activities covering 19 of the total of 22 Roadmap actions are actively underway in 2015. Of the remainder, two actions are not scheduled to commence until 2016 and for a third, on Monitoring existing assessment tools (Action 3.2), and for whom the action rests largely with the owners of the exposure estimation tools, the Coordination Group agreed to monitor tool developments and to reflect them in Roadmap actions, when necessary. So, as a result, this action has been removed.

¹ http://echa.europa.eu/documents/10162/15669641/csr_es_roadmap_en.pdf

² http://echa.europa.eu/documents/10162/15669641/csr_es_second_implementation_plan_en.pdf

Substantive progress is expected in 2015 on items supporting registrants and downstream users covered by the main lines mentioned above. In particular:

- Template and Guidance to support the subsequent generation of improved sectors use maps (Q4/2015).
- Updated input templates/data sets for providing the realistic conditions of use to better support the exposure assessment for the environment (SpERCs), consumers (SCEDs) and workers (SWEDs); this involves a new template (SWED) populated by sectors, the newly developed SCEDs and updates of the existing SpERCs.
- An improved, streamlined catalogue of standard phrases and software standard (XML) to support the electronic communication of the exposure scenario communicated (ESCom) with the safety data sheet (Q2/2015).
- Methods to help formulators determine and provide the safe use information for their mixtures (Q4/2015).
- Means by which estimated tonnage per use can be gathered from the supply chain (Q4/2015).

Coupled to these outputs are enhancements to IUCLID and Chesar for registrants to improve the reporting of their chemical safety assessment in their registration dossiers. Updated versions of these tools will be published by ECHA in 2016.

ECHA is also updating a number of CSA-related Guidance documents. These updates reflect the good practices and agreements identified in the context of the Roadmap activities and the ENES community is kept informed on the Guidance consultation progress. For example, the update of the Guidance on use description (R.12) is ongoing at the time of the publication of this plan.

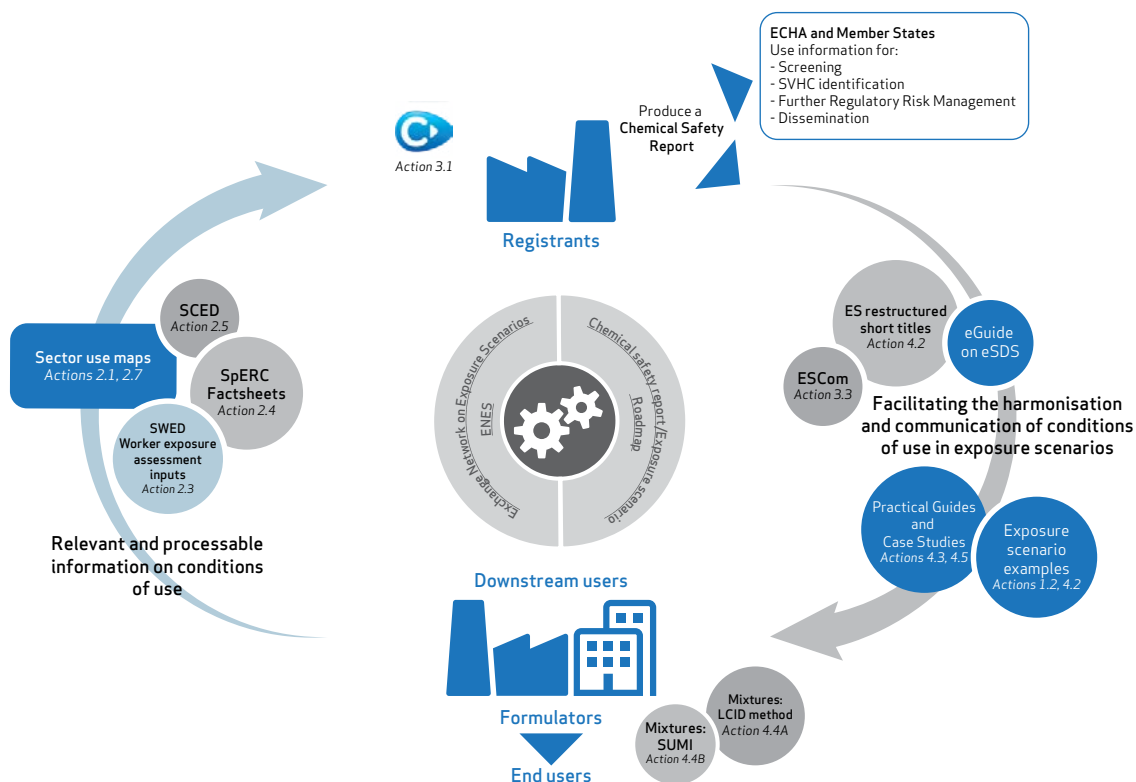


Figure 1: Illustration of where these various Roadmap outputs support REACH actors in the supply chain communication cycle.

The elements of Action Area 2 (Actions 2.1 to 2.5) remain combined into the concept of improved use maps to ensure consistency as well as increase efficiency. The improved use maps are a concrete output of the Roadmap Action 2.7.

The use maps are meant to structure and harmonise 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 may need to be reviewed to reflect the updated format agreed. Where necessary, there may be the need 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 (SWED), environmental exposure (SpERC) and consumer exposure (SCED)³. 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.

Some actions, especially under Action Area 4 should produce the final solutions in 2015. 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.

In this update/revision to the second implementation plan, certain Roadmap actions remain merged or regrouped, as published in the April 2014 edition. Therefore, their titles may differ from those expressed in the original Roadmap⁴. 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 15 months from Q1/2015 to Q1/2016. 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.

³ Assessment input for workers' exposure may be based on existing GES, if available.

⁴ http://echa.europa.eu/documents/10162/15669641/csr_es_roadmap_en.pdf

PRIORITY ACTIONS



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

Developing improved use maps as a basis for good quality chemical safety assessment (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 improved 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). Alignment with the development of the IT tools (see Action 3.1) and Guidance update is also crucial.</p> <p>Test with case studies the practical usability and the realisation of the added value expected for the CSA and the related exposure scenarios for communication generated by the improved use map in a number/range of uses and supply chains. Develop and publish guidance that supports the review and extension of existing industry sector use maps will be done in parallel.</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 improved use map (both format and content). Encourage those sectors that have not yet mapped their uses to do so following the improved use maps approach.</p> <p>Communicate the role of use maps towards achieving realistic exposure assessment and subsequent advice on safe use of chemicals.</p>
Planned events	<p>Presentation at ENES8 (May 2015) and agreement on the template and guidance for publication.</p> <p>Testing phase, including supply chain aspects, organised by throughout 2015 to test how the links to the exposure assessment inputs function (as this was not feasible to test in the phase 1 testing stage in Q3/2014). Extended tests to be done in cooperation with the related Action Areas 2.3, 2.4, and 2.5 on exposure assessment inputs and the development of Chesar3 to ensure the possibility to import the information from the use maps to an exposure assessment. Promotion and communication (e.g. sectorial workshops) in Q1/2016 to encourage sectors to develop improved use maps.</p>
Expected outcome	<p>Template and supporting guidance for the improved use maps, including the link to exposure assessment inputs, published in Q4/2015.</p> <p>Improved use maps are developed by downstream user sectors. Both first time registrants and registrants updating the CSAs can use them once available.</p> <p>Process established during Q4/2015 to track implementation of use maps.</p>
Lead and contact point	ECHA: Laure-Anne Carton de Tournai (laure-anne.cartondetournai@echa.europa.eu)
Working Group	<p>Improved Sector Use Maps Working Group</p> <p>[DUCC sector members (AISE, FEA, FEICA, EFCC, CEPE, ECPA, Cosmetics Europe); Cefic; VCI; Eurométaux; Fecc; Concawe; Member State competent authorities (DE, NL); ECHA]</p>

Exposure assessment inputs for workers

Roadmap action: 2.3A

Activities foreseen	<p>Analysis of current format and content of the GESs and of the worker exposure assessment related parts of existing use maps largely limited to Tier 1 assessments as starting point. Identification of potential improvements/additional information that may be relevant. Develop format for the exposure assessment input i.e. via a sector-specific worker exposure description (SWED) template - see also Action 4.4B beneath - in connection with the work on improved use maps based on the above.</p> <p>Testing the format and scope within sectors. After validation of the concept, encouraging sectors to develop/update the exposure assessment input for workers in that format within their sector.</p> <p>Provide input to the development of Chesar3 to enable it to support SWEDs.</p> <p>Analyse and take account of ongoing related initiatives concerning the input parameters for worker exposure assessment e.g. downstream sector information on mixtures (SUMIs; see Action 4.4B beneath), the Eteam project⁵ findings, the development of libraries for risk management measures⁶. The interim results of the BAuA project (see next Action 2.3B) are expected to help sectors in identifying suitable risk management packages which can be communicated via the SWEDs.</p>
Planned events	<p>Introduction to and preliminary agreement on the concept and corresponding SWED format at ENES8 (May 2015).</p> <p>Workshop on results of testing (proof of concept) and final agreement on format (Q4/2015).</p>
Expected outcome	<p>Concept paper prepared Q2/2015 for discussion among stakeholders.</p> <p>Format for the exposure assessment input for workers agreed (Q4/2015) at ENES9 (November 2015).</p> <p>Exposure assessment inputs to estimate worker exposure from identified use(s) of substances/ mixtures are developed within downstream user sectors as appropriate. They can be applied by both first time registrants and registrants updating their CSAs.</p>
Lead and contact point	<p>Concawe: Jan Urbanus; jan.urbanus@shell.com</p> <p>ECHA: Bridget Ginnity; bridget.ginnity@echa.europa.eu</p>
Working Group	<p>Working Group on Workers' Exposure Assessment Input [Concawe; DUCC sector members (A.I.S.E., CEPE, EFCC, FEICA) Cefic; Member State competent authorities (DE, NL); ECHA]</p>

⁵ See <http://www.eteamproject.eu/>

⁶ See Cefic Long Range Initiative <http://cefic-lri.org/projects/b15-ucran-developing-a-robust-method-of-allocating-efficiency-measures-to-regulatory-instruments-in-the-chemicals-industry/>

Connecting existing risk management measure packages for worker exposure to the REACH chemical safety assessment (CSA)

Roadmap action: 2.3B

Activities foreseen	<p>Collect information on existing use-specific risk management advice formerly elaborated to comply with occupational legislation (e.g. COSHH control sheets, GISBAU safety advice for construction chemicals).</p> <p>Try to assign exposures/ exposure bands to these packages so that they can be used as input to the CSA.</p> <p>Analyse whether existing use-specific management advice may be added/ linked to existing exposure estimates, related conditions of use and RRM that are already communicated for registered substance in their eSDS.</p> <p>Preliminary results of this project will also contribute to the action on the exposure assessment input for workers and on improved use maps (see previous action box).</p> <p>Analysis of existing packages by BAuA, the interim results and the proposals for the way forward to be discussed in Q3/2015.</p> <p>Use/integrate RMM packages as (part of) input data in future exposure assessment models.</p>
Expected outcome	<p>Publication of project report on existing risk management measure (RMM) packages (mid-2015)</p> <p>Collection of established risk management advice for particular sectors, product/substance types to support to the registrant's exposure assessment under REACH.</p> <p>Application of control banding approach to identify necessary risk management measures in the REACH CSA.</p>
Lead and contact point	BAuA: Eva Lechtenberg-Auffarth; lechtenberg.eva@buaa.bund.de

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 improved use maps and the use of SpERCs in that context. Completion of ECHA's Best Practice project for SpERCs with the view to improve the documentation and justification of SpERC-based estimation of environmental exposure. Agree on the potential involvement of Member States during the further development and implementation phases.</p> <p>Based on the conclusions on both format- and content-related update needs, all sectors to review their SpERCs in the light of this. Encourage those sectors that have not yet developed SpERCs for their uses to do so in the revised format. Provide input to development of Chesar3-SpERC format to ensure the possibility to import a SpERC to an exposure assessment for the environment.</p>
Planned events	Presentation at ENES8 (May 2015) and discussion on applicability of format across sectors and how to develop SpERC best practice further in collaboration with industry and Member States (May 2015).

Exposure assessment input for the environment

Roadmap action: 2.4

Expected outcome	<p>Format for the exposure assessment input for the environment (improvements and format for SpERCs) agreed (Q3/2015).</p> <p>Consensus on the documentation for SpERCs (taking into account findings from the ECHA best practice project) (Q3/2015).</p> <p>Inputs to Chesar3 development by Q3/2015.</p> <p>Sets of harmonised SpERC Factsheets available to registrants (Q1-Q2/2016).</p> <p>Improved SpERC contents are developed within downstream user sectors so that they can be applied by both first time registrants and registrants updating their CSAs.</p>
Lead and contact point	DUCC: Johannes Tolls; johannes.tolls@henkel.com
Working Group	<p>CSR/ES SpERC Task Force</p> <p>[Representatives and member companies of DUCC sector associations A.I.S.E., Cosmetics Europe, FEICA, CEPE, EFCC); Eurométaux; Cefic; ESIG/ESVOC; ETRMA; and ECHA.]</p>

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.</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 the light of this. Encourage those sectors that have not yet developed SCEDs for the consumer uses of their substances to do so in the revised format.</p>
Planned events	<p>Discussion on role of Member States in SCED review (in 2015).</p> <p>Promotion and communication (e.g. sectorial workshops) to encourage sectors to develop own SCEDs (in 2015).</p> <p>Registrants to make use of them, when available (as of Q1 2016).</p> <p>Workshop with authorities to review content-related findings on SCEDs in mid-2016.</p>
Expected outcome	<p>SCEDs published by sectors by starting in Q4/2015.</p> <p>References to SCEDs included in the improved sector use maps for consumer use description as soon as use maps and SCEDs are available⁷.</p> <p>SCEDs are developed within, and promoted by, downstream user sectors so that they can be applied by both first time registrants and registrants updating their CSAs.</p>
Lead and contact point	DUCC : Laura Portugal ; laura.portugal@aise.eu

⁷ Depending on the availabilities of sector SCEDs.

Exposure assessment input for consumers

Roadmap action: 2.5

Working Group	SCED Working Group [Representatives and member companies of DUCC sector associations (A.I.S.E., FEA, CEPE, FEICA, EFCC); Concawe.]
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Information gathering on methods for registrants to estimate volumes per use within supply chains

Roadmap action: 2.6

Activities foreseen	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 2015. The approach may vary from sector to sector; an analysis of the essential elements that make it work may be useful. For example availability of market studies and non-CBI information play a role. The first step will focus on a collection of methodologies that have been followed by registrants in 2010 and 2013. Continue to illustrate how this information is used by authorities. . After the information gathering period, the outcome is analysed and the Roadmap Coordination Group agrees on the way forward.
Planned events	Workshop to discuss findings in Q4/2015.
Expected outcome	Overview on the practical means (available to registrants) to estimate the volume supplied to the different end-uses of their substance by end of 2015, with an analysis of the strengths and limitations. Project findings published in Q4/2015.
Lead and contact point	Cefic/VCI: Petra Weber; petra.weber@clariant.com Jean-Christophe Dewart; jcd@cefic.be Angelika Hanschmidt; hanschmidt@vci.de
Working Group	Cefic-VCI Task Force (Companies representing manufacturer and downstream user industries associations and sectors: CIA, Fecc, UIC, VCI).



ACTION AREA 3: FURTHER DEVELOP IT TOOLS AND STANDARDISATION

ECHA in consultation with industry and Member States via various channels (see above).

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

Activities foreseen	<p>Develop IUCLID so that (i) it provides better opportunities to enter the information required for registration purposes in a consistent and useful way and (ii) it can contain the information on use and exposure which the authorities may need to carry out their tasks under REACH</p> <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 improved 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>In particular, to extend the scope of IUCLID and Chesar to better support the reporting of "more complex cases" where more than one set of substance properties may be needed to carry out the assessment (assessment entity concept).</p>
Planned events	<p>Workshop for Member States on IUCLID6 (Q1/2015).</p> <p>Consultations on the technical specification requirements for Chesar 3 within the Chesar consultation group.</p> <p>Workshops and bilateral work with industry and/or Member States regarding the assessment entity concept (Q1/2015, Q2/2015 (SETAC))</p>
Expected outcome	<p>Release of IUCLID 6.1 where some key CSR related information (on use and exposure) can be reported in a newly structured format (Q2/2016).</p> <p>Release of Chesar3 for a wider range of substances, and where the CSR extract can be directly exported into the technical dossier (Q2/2016).</p>
Lead and contact point	<p>ECHA</p> <p>IUCLID: Andreas Ahrens; andreas.ahrens@echa.europa.eu;</p> <p>Chesar: H�el�ene Magaud; helene.magaud@echa.europa.eu</p>
Working Group	<p>ECHA in consultation with industry and Member States via various channels (see above).</p>

ESCom package	
Roadmap action: 3.3	
Activities foreseen	<p>An ESCom package governance structure has been set up and the project is currently foreseen to continue at least until the end of 2015. This includes the mechanism for proposing new phrases for the phrase catalogue.</p> <p>Review and update the ESCom Standard Phrases catalogue v.1.4 for the exposure scenario for communication to ensure meaningful, consistent and concise information is communicated and to achieve full alignment with the structure of the electronic exchange format, ESCom XML. Modify the ESCom XML data model to ensure full alignment with the ESCom standard phrases catalogue and alignment with the structure of the exposure scenario (ES) for communication.</p>
Planned events	<p>Publication of the ESCom package (Q2/2015)</p> <p>Awareness raising on the ESCom package within sectors and companies (Q2-Q4/2015).</p>
Expected outcome	<p>An improved, harmonised catalogue of standard phrases and electronic exchange format (ESComXML) that can be implemented by registrants/suppliers for the generation and sending (electronically) of exposure scenarios with their safety data sheets for substances, from mid-2015 onwards:</p> <ul style="list-style-type: none"> • Publication of an improved standard phrase catalogue v.2.0 by removing redundant or duplicate phrases, by Q2/2015. • Publication of an up-to-date, harmonised XML format v.2.0 that supports the electronic exchange of the standard phrases between different company IT systems in the supplier-customer supply chain. <p>A mechanism established for the continuous inclusion of new, relevant phrases.</p> <p>The creation a sustainable structure for the continued maintenance of the ESCom package by Q4/2015.</p>
Lead and contact point	Cefic: Dook Noij; dook.noij@dow.com
Working Group	ESCom Working Group on Standard Phrases (Member companies of Cefic and ECHA). This Group works in close collaboration with an ESCom Working Group for IT Providers, and an ESCom Steering Committee (Cefic-DUCC-ECHA-IT providers).



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: 4.2, 1.2

Activities foreseen	Raising awareness and common understanding on the format and content of the exposure scenario, with reference to annotated templates and an illustrative example of an exposure scenario for communication published by ECHA in Q2/2014.
Planned events	Workshop to raise awareness and gain feedback of the practical implementation and usefulness of the various tools and practices identified in the context of the Roadmap regarding the exposure scenario for communication in Q1/2016.
Expected outcome	Improved understanding on the information essentials for the exposure scenario for communication. Growth in the frequency by which the standard format and content are communicated in the supply chain. Feedback from implementation of relevant Roadmap outputs on this subject.
Lead and contact point	ECHA: Mercedes Viñas; mercedes.vinas@echa.europa.eu

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	Note: The format and guidelines for building the table of contents for the exposure scenarios which is annexed to the safety data sheet was concluded in November 2014. Details can be found on the DUCC web page . A small number of follow-up activities are foreseen: Address the practical experience and feedback on the 3rd Identifier for the structured short title during 2015. Identification of potential update needs to the Guidelines for review by the end of 2015. Implement the rules for building structured short titles in the ESCom package of standard phrases and XML data model (see Action 3.3 above) by Q2/2015. Improve certain use descriptors, as defined in the revised ECHA Guidance R.12 on description of use, in 2015.
Planned events	Promotion of the approach within sectors. Include structured short titles' experience in workshop mentioned in previous Action (Q1/2016).
Expected outcome	Implementation of the table of contents for the exposure scenario annex to the safety data sheets within the substance supply chains.
Lead and contact point	DUCC: Sylvie Lemoine; sylvie.lemoine@aise.eu

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

Roadmap action: 4.2

Working Group	ES Structured Short Titles Working Group Companies representing manufacturer and downstream user industry associations and sectors: DUCC, Cefic; IT providers; ECHA.
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Support for formulators in understanding their obligations and options

Roadmap action: 4.3

Activities foreseen	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 that is annexed to the substance safety data sheet. The examples will be developed together with the stakeholders and be linked to discussions on how scaling can be implemented. Further actions to be decided by the Coordination Group in 2015.
Planned events	Webinar to support the DU CSR Practical Guide (see Action 4.5) in Q4/2015.
Expected outcome	Practical Guide 13 with additional examples on the application of scaling at downstream user sites. Update to ECHA's eGuide on the extended safety data sheet in Q3/2015.
Lead and contact point	ECHA: Bridget Ginnity; bridget.ginnity@echa.europa.eu

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

Roadmap action: 4.4A: "Top-down approaches" based on lead component identification

Activities foreseen	The mixtures working group will continue its work on consolidating advice on safe use of mixtures, based on discussions first held at ENES5. The focus is to provide a harmonized and generally applicable top-down approach for deriving safe use information for mixtures from exposure scenario information related to components of a mixture, with supporting guidelines. This methodology will consider CLP classifications and available DNELs and PNECs. Strengths and weaknesses of previous approaches (e.g. DPD+ method) are considered in order to develop this generally applicable methodology. In those cases where a suitable bottom-up approach is applicable (see Action 4.4B beneath) it might be preferable to apply a bottom-up approach as it will be more straight forward.
Planned events	On the ENES8 and 9 agendas, May and November 2015 respectively. Conduct round robin testing of the "top-down" approach.

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

Roadmap action: 4.4A: "Top-down approaches" based on lead component identification

Expected outcome	<p>Consultation on a draft Practical Guide – Safe Use Information for Mixtures under REACH containing workflows and worked examples in Q1/2015.</p> <p>A tested, generic framework for the identification of the risk driving substance(s) published in a Practical Guide, in Q4/2015, after which it can be promoted within sectors.</p>
Lead and contact point	<p>Cefic/VCI: Steven Van de Broeck; sva@cefic.be Jean-Christophe Dewart; jcd@cefic.be Angelika Hanschmidt; hanschmidt@vci.de</p>
Working Group	<p>Cefic-VCI Mixtures Task Force (Member companies of Cefic and VCI representing manufacturers, importers and downstream users, representatives of DUCC and Fecc)</p>

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

Roadmap action: 4.4B and 5.1: Downstream user sector approaches to generating safe use information ("bottom-up" approaches based on sector use maps)

Activities foreseen	<p>DUCC will look at the methodology commonalities between the different 'bottom-up' approaches of its member sectors to define a common framework and supporting guidelines. The focus will be on agreeing templates (format and content) for implementation by sectors that provide information on the conditions of use of mixtures to the registrants as input information for their substance CSAs. These are termed Sector-specific Worker Exposure Descriptions (SWEDs) and will be covered by Action 2.3A above; and their corresponding Safe Use Mixture Information (SUMIs) that formulators can use to convey "safe use" information as part of a mixture SDS.</p> <p>The development of environmental aspects will be considered in early 2016.</p>
Planned events	<p>On ENES8 agenda (May 2015).</p>
Expected outcome	<p>Agreed template for DUCC sector (A.I.S.E., CEPE, FEICA, EFCC) SUMIs and the development of explanatory note (guidance) by Q3/2015.</p> <p>Sectors publish SWEDs and SUMIs together with Explanatory Note by Q1/2016.</p> <p>Inputs to Chesar3 development in the form of a SWED specification by Q4/2015. (Refer also to Action 2.3A).</p> <p>Updating of sector use maps to include relevant SWED references for registrants (Q1/2016). They can be applied by both first time registrants and registrants updating their CSAs. (Refer also to Action 2.3A).</p>
Lead and contact point	<p>DUCC: Laura Portugal; laura.portugal@aise.eu</p>
Working Group	<p>DUCC Mixtures Task Force DUCC member association representatives from: IFRA, A.I.S.E., CEPE, FEICA, FEA, EFCC, Fecc, I&P and Cosmetics Europe. DUCC Members' companies representing downstream users.</p>

Understanding the issues and providing support for conducting downstream user chemical safety report (CSR)

Roadmap actions: 4.5

Activities foreseen	Developing an ECHA Practical Guide.
Planned events	Webinar (Q4/2015)
Expected outcome	ECHA Practical Guide for downstream users who want to conduct their own CSR published in Q3/2015. Supported by webinar and other promotional materials. Identification of unresolved issues by Q4/2015.
Lead and contact point	DUCC: Laura Portugal; laura.portugal@aise.eu For Practical Guide, ECHA: Bridget Ginnity; bridget.ginnity@echa.europa.eu
Working Group	DUCC DU CSR Task Force [Representatives and member companies of DUCC sector associations: A.I.S.E., CEPE, Cosmetics Europe, ECPA, EFCC, FEA, FEICA; Eurométaux; Fecc; Cefic; VCI; Member State competent authorities (DE, IT, NL, PL); ECHA.]

Understanding what authorities can do with downstream users reports

Roadmap action 4.6

Activities foreseen	Clarify how authorities (ECHA and the Member States) currently use or could use the information received in REACH Article 38 reports and, based on the results, consider whether changes in the reporting format are necessary.
Planned events	None (at time of publication).
Expected outcome	Report on the amount and nature of downstream user reports submitted to ECHA in Q3/2015. Identification of unresolved reporting issues by Q4/2015.
Lead and contact point	ECHA: Laura Walin; laura.walin@echa.europa.eu

APPENDIX 1. Progress and main outcomes from the CSR/ES Roadmap second implementation plan (edition April 2014) for Q1/2014-Q4/2014

The following paragraphs summarise the progress and outputs achieved in 2014 across the main actions in the CSR/ES Roadmap. Progress on most actions was reported at one or both of the meetings of the Exchange Network on Exposure Scenarios⁸ in 2014, ENES6 and ENES7.

MAIN ACHIEVEMENTS

Actions related to increased common understanding among stakeholders on the practical use of the information in the CSR and in the exposure scenario for communication (Action Area 1).

ECHA initiated through the OECD Task Force on Exposure Assessment (TFEA) adaptations to the OECD template covering use and exposure. European industry sectors and Member States competent authorities provided input. These adaptations will also be reflected in the technical specification for IUCLID6 (due for release in Q2 2016). A key driver is the identified need to provide an opportunity to registrants to report some information in their registration dossier as this may convince efficiently the authorities that there is no need for further scrutiny or regulatory action on their substance.



To emphasise the “content essentials” in the exposure scenario communicated with the safety data sheet, two new documents were published⁹ in August 2014 to provide practical guidance to those who generate and receive exposure scenarios:

1. an illustrative example of an exposure scenario for communication; and
2. a set of annotated templates covering environmental, occupational and consumer exposure controls.

These publications illustrate the 4 main sections in an exposure scenario, their “essential” content and its purpose.

Actions to further develop the methods and processes for generating the key information inputs for the chemical safety assessment (Action Area 2).

A priority for 2014 was to build on the current downstream sector use maps as a means by which downstream users can provide registrants with realistic information on:

- the uses of their substances,
- the typical conditions of use (operational conditions and risk management measures).

In so doing, registrants then have a higher quality of information on which to undertake their chemical safety

⁸ <http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios>

⁹ <http://echa.europa.eu/regulations/reach/downstream-users/exposure-scenarios>

assessments for the identified uses.

To this end, an improved use maps format was prepared by a cross-stakeholder Working Group and discussed at ENES6 (May 2014). Thereafter, the format and content were piloted by a number of downstream user sector associations and companies. The results were shared at ENES7 (November 2014). Finalisation of the improved sector use maps is now underway for publication in 2015 (see revised second implementation plan) with supporting guidelines.

Coupled to an improved description of use, the principle of referring in the sector use maps to more specific data sets, which reflect good practice for conditions of use to aid the registrant's CSA for the environment and human health, is acknowledged in many sectors. The development of an improved format for the specific environmental release categories (SpERCs) continued. ECHA commissioned a study Assessment of the reliability of SpERCs to support ECHA and REACH stakeholders in ensuring a high quality of environmental emission estimates. The study report has been published¹⁰ in early 2015 and its findings will be taken into account in the Roadmap's action on SpERCs in 2015.



For consumers, a new template and supporting guidelines for the exposure assessment input was published¹¹, the specific consumer exposure determinant (SCED).

For workers, the Federal Institute of Occupational Safety and Health (BAuA) commissioned a study to establish clearer connections between the risk management measures that exist in occupational health and safety good practice and those recommended in the REACH exposure scenario. These findings were reported at ENES7 and a report will be published early in 2015. The main output foreseen is a library of control sheets on risk management measures that can be used by registrants and downstream users alike when evaluating what are the appropriate risk management measures for the control of risk from substances, in practice. These connections will be taken forward in 2015 as part of the development of an updated exposure assessment input for workers.

Actions to further develop IT tools and standardisation for generating, processing and exchanging CSR and exposure scenario information (Action Area 3).

Work done to enable the reporting of certain key CSR-related information on use and exposure in a structured format is explained under Action Area 1 above.

Chesar is continuously developed to support the harmonisation/standardisation of the assessment approach (and harmonised reporting in the CSR and ES for communication). The developments follow closely the work on improved sector use map information and the related assessment input data sets (see Action Area 2 above), so that this information can be fed into the chemical safety assessment (CSA) generated by Chesar.

Furthermore, extending the scope of Chesar to better support the reporting of "more complex assessment cases" has been actively explored where more than one set of substance properties may be needed to carry out the assessment – the so-called "assessment entity concept". This work will continue in 2015.



In May, the exposure scenario for communication (ESCom¹²) standard phrases catalogue was updated with new content, supported by a new industry web page.

¹⁰ http://echa.europa.eu/documents/10162/13628/assessment_of_reliability_of_sperc_final_report_annexes_en.pdf

¹¹ <http://www.ducc.eu/Activities.aspx>

¹² <http://www.cefic.org/Industry-support/Implementing-reach/escom/>

The aim of the ESCom action is to provide good quality phrases on the safe use of chemicals in the exposure scenario for communication and the means by which this information can be shared efficiently and electronically between substance suppliers and their customers (the ESComXML).

Work continued throughout 2014 to improve the content and structure of the phrase catalogue. Alignment with the ESCom XML data model has been done in parallel with IT providers in advance of a major new release of the catalogue and XML in spring 2015. Both catalogue and XML can be used with Chesar.

Actions to support understanding and processing of exposure scenario information at formulators' level (Action Area 4).



Guidelines¹³ for building the table of content for the exposure scenarios which are annexed to a safety data sheet were published in November.

Publication was preceded by a series of development and testing exercises in 2014, involving companies drawn from different industry sectors to agree upon the essential elements for a structured short title that then goes to make an entry in the table of contents.

Work on determining and presenting safe use information for mixtures for formulators and end-users took two routes in 2014, based on discussions first held at ENES5 (November 2013). An industry Task Force developed an approach for the identification of the lead components (i.e. the risk-driving substances) based on CLP classification criteria and DNELs/PNECs (or alternative limits values where these do not exist). A cross-stakeholder consultation was launched at the end of 2014 on the so-called "top-down approach" and publication of a Practical Guide, after further testing, is planned in 2015.



In parallel, a number of downstream user sectors compared their 'bottom-up' methodologies for conveying safe use information on mixtures for workers at the end-user level of the supply chain, in order to identify the commonalities between them. One sector approach was published by the detergents sector (A.I.S.E./NVZ¹⁴) in May.

A common framework that can be applied by sectors has been defined and pending further work, the framework and its supporting guidelines will be published in 2015.



Finally, a new web page for formulators¹⁵ was created by ECHA to provide relevant and useful information to help formulators fulfil their obligations under REACH and CLP.

Actions to support understanding and processing of exposure scenario information at the end-users' level (Action Area 5).

The downstream user sectors' work on safe use information for mixtures (see Action Area 4 above) also supports Action Area 5 and aims to improve the presentation and to tailor the information on safe use of mixtures in the safety data sheet for the benefit of end-users. Furthermore, a case study presented at ENES7 (November 2014) served to illustrate how the different elements of the extended safety data sheet can support end-users in meeting their obligations under other European Union legislations on chemicals at industrial sites. Further development on both activities will continue in 2015.

13 http://www.ducc.eu/documents/StructuredShortTitles_for_publication_041114_final.pdf

14 http://www.aise.eu/documents/document/20140617113855-geis_guidance_for_formulators_final_version1_0_may_2014.pdf

15 <http://echa.europa.eu/en/regulations/reach/downstream-users/who-is-a-downstream-user/formulators>

APPENDIX 2. COMPOSITION OF THE CSR/ES ROADMAP - ENES COORDINATION GROUP

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