



Exposure Scenario related activities by ECHA

***CEFIC – DUCG Workshop on Exposure
Scenario***

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ECHA – Risk Management Identification



Content

- Duties and challenges for registrants and formulators of mixtures
- Support initiatives targeted to exposure scenario building and exposure scenario communication
- Details on selected examples
 - Support to build a computation infrastructure
 - The Practical Guidance for formulators to “read” exposure scenarios
 - Exchange network on exposure scenario experience (ENES)
- Key messages



Communication in the supply chain

- ❑ Step 0: Manufacturers/importers (M/I) and Downstream Users (DU) communicate on uses before registration
- ❑ Step 1: Substances are registered by M/I. Updated Safety data Sheets (SDSs) are sent to DUs. When required, exposure scenarios (ES) are attached.
- ❑ Step 2: DUs receive updated SDSs (and ESs) and
 - check (and document) if uses and use conditions are covered (art 31.7 and 37.3)
 - keep documentation available for authorities (art 36)
- ❑ Step 3: DUs take appropriate actions if uses are not covered (art 37)
- ❑ Step 4 DUs communicate safety information (and ESs) to customers (art 31.7)



Challenges for registrants

- Mind set: Risk management to become integral part of the assessment process
- Organising the communication up and down the supply chain well before each registration deadlines
- Linking the “safety assessment” focus under REACH to traditional exposure assessment
- Identification of exposure estimation methodology allowing high throughput without being overly conservative
- Converting exposure scenarios used in registration into guidance for safe use of substances



Challenges for producers of mixtures

- Converting exposure scenarios for substances into guidance for safe use of mixtures
- Complexity of the mixture: a mixture can be made of large number of substances with different properties and different registration requirements. Raw materials are often already mixtures
- Timing: clock start ticking when SDS is received. SDS are not received all at the same time
- Length and complexity of (extended) SDS. Relevant information hard to find.
- No electronic exchange format yet – processing of info fully manual
- DU CSA and/or reporting to ECHA: When to report and what to report?



ECHA support to registrants

- Guidance and practical guides
 - Publication of guidance documents on ES building and ES format
 - Publication of practical examples of ES and CSR
- Developing IT tools for computational support
 - Development of a tool to perform CSA and generate harmonised ESs in electronic exchange format (CHESAR);
 - Cooperation with industry groups to build the interfaces with CSA related tools and formats
- Cooperation and communication
 - Exchange network launched for exchange of experience related to exposure scenarios (ENES), in cooperation with various industry organizations;



ECHA supports developing the “system” infrastructure

- In the framework of the Chesar development, dialogue with various initiatives under the lead of industry:
 - Development and maintenance of a catalogue of standardized phrases for communication of exposure scenarios
 - Development and maintenance of Specific Environmental Release Categories (SpERCs)
 - Development and maintenance of Generic Exposure Scenarios and other forms of generic starting points for Chemicals Safety Assessment.
 - IT format for exchange of exposure scenario information (EScomXML)
- ECHA sees the responsibility for these “system” elements on industry but supports the development process as resources allow.



ECHA support to producers of mixtures

- DUs obligation on ES
 - Leaflet with explanation of obligations (May 2011)
 - practical guidance for producers of mixtures how “to read” exposure scenarios (December 2011)
- Reporting uses to ECHA
 - Online tool for reporting to ECHA (December 2011)
 - Webinar for DU on how to report to ECHA (Dec 2011)
 - Publication of Q&A document on DU report
- Cooperation and communication
 - Workshop on ES for mixtures
 - ENES



Cooperation on ES for mixtures 1

ECHA's objectives

- Promote common understanding within industry and between industry and enforcement authorities on the long-term process towards implementation of REACH mechanisms in the supply chain
- Support development of practical examples illustrating
 - how exposure scenarios for mixtures could look like
 - which processes and methodologies are available to generate exposure scenario information for mixtures



Cooperation on ES for mixtures 2

Working process

- Gathering information on the approaches being under development in industry (short term and long-term)
 - June workshop
 - Bilateral exchange process with sector organisations and single companies October/November
 - ENES 1 workshop 24/25 of November
 - Review existing guidance
- Describe the state of play and the medium term perspective in a sort of “roadmap” towards implementation of REACH supply chain mechanisms
- Work out illustrative examples (in co-operation with industry)
- Present and discuss these examples at ENES 2 or 3
- Publish examples with practical guidance



The practical guide for formulators

- Advice to formulators on how to check if conditions of use are covered by the ESs
- Situations are described through practical examples
- It explains the purpose and the boundaries of scaling and some practical examples of scaling options
- For each examples analysis and options are provided
- Examples cover
 - Exposure to environment (site settings)
 - Exposure to workers
 - Exposure to consumers
 - Examples for Scaling
- “Living document”, meant to include more examples in future



The practical guide : timeline

- initial draft : developed by ECHA
- review and additional inputs :
 - experts from industry
 - National helpdesk
- publication expected : Dec of 2011
- Current status (Oct 2011): initial review by industry experts



Exchange Network on Exposure Scenario

- What?
 - cross-sector collaborative network
 - improvements in consistency and understanding
 - overcome obstacles to development and implementation.
 - Who?
 - Coordination Group: ECHA + AISE, Cefic, Concawe, FECC, Eurometaux
 - ECHA + Stakeholders (includes Member State competent authorities / enforcing authorities)
 - When?
 - First meeting 24-25 November 2011, Brussels
 - Further meetings to follow in 2012/2013
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Conclusions and way forward

- For ECHA the functioning of the mechanisms for the communication in the supply are key to the success of REACH.
- Good practical examples are needed to illustrate how useful exposure scenarios could look like.
- Infrastructure to build, communicate and process exposure scenario in the supply chain is still to be put in place (procedures, harmonisation, IT based exchange)
- ECHA has its focus on providing support for a better quality of exposure scenarios generated at the top of the supply chain.

Thank you for your attention!



Links



Guidance on ES

ECHA guidance on IR and CSA Part D

- Exposure Scenario building
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_d_en.pdf
- Exposure Scenario format
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_ESformat_en.pdf?vers=27-05-10
- Guidance Fac sheet on ES building
http://guidance.echa.europa.eu/docs/fact_sheets/inforeq_d_en.pdf



Examples and tools on ES

- Examples of ES for industrial use of substances
http://guidance.echa.europa.eu/docs/other_docs/es_project_document_v5.pdf
- Example of ES for professional use of substance
http://guidance.echa.europa.eu/docs/other_docs/es_professional_use_20110829.pdf
- Example of ES for consumer use of substances
http://guidance.echa.europa.eu/docs/other_docs/es_for_consumer_20110829.pdf
- ECHA Software tools (and manuals) on CSA and CSR
CHESAR (**CHE**mical **S**afety **A**ssessment and **R**eporting tool)
<http://chesar.echa.europa.eu>



Information for DUs

TIPS

- Checking if use and conditions of use are covered
 - Practical Guide on How to compare downstream user's use against supplier's exposure scenarios (Under development)
- Actions to take if use is not covered
- Support to Downstream Users
 - ECHA DUs web page
http://echa.europa.eu/reach/du_en.asp
 - Checking DUs' uses
http://echa.europa.eu/reach/du/du_use_repring_en.asp
 - Fac sheet on SDS and exposure scenario
http://echa.europa.eu/doc/reach/du_fs/du_fact_sheet_en.pdf
 - Data Submission Manual 21
http://echa.europa.eu/doc/reachit/dsm21/dsm21_how_to_sunmit_dur_v1.0_en.pdf