



INDUSTRIAL END USER OF CHEMICALS: CHEMICAL PLANTS RISK ASSESSMENT & EXPOSURE SCENARIOS

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ENES 12

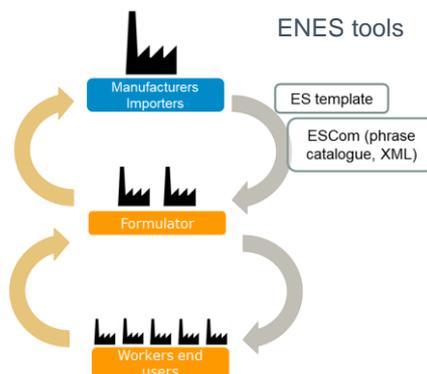
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REGULATORY REQUIREMENTS IN SCOPE

- **REACH (article 37) requires users to check in substance Safety Data Sheet whether:**
 - Their use is covered as an identified use
 - They comply with the measures (RMM) and conditions (OC) in the Exposure Scenario (ES)

- **Directive 98/24/EC - risks related to chemical agents at work**
 - The employer must determine whether any hazardous chemical agents are present at the workplace and assess any risk to the safety and health arising from their presence.



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REACH AND EXPOSURE SCENARIOS: DOWNSTREAM USER PERSPECTIVE

Advantages:

- More information available, improved quality of Safety Data Sheets (SDS) and labels
- Availability of Derived No Effect Levels (DNELs), when there are no regulatory or company Occupational Exposure Limits (OELs).
- Assurance that the risks have been assessed for Identified Uses
- Exposure Scenario information is helpful for screening risks for introduction of new chemicals
- Sector organisations provide more guidance on how to use chemical products in a safe way

Disadvantages:

- Overlap with Occupational Safety and Health (OSH) regulation, where OSH regulation is much more dedicated to workplace risk assessment (including generated hazards), considers complex chemical environments and the hierarchy of control is mandatory
- Administrative duties

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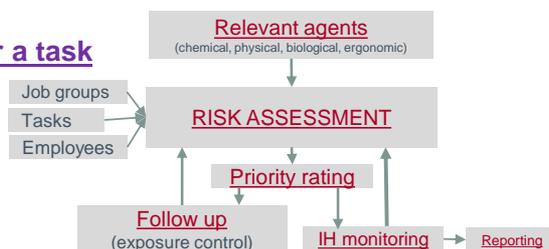
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COMPANY WORKPLACE RISK ASSESSMENT (SEMI-QUANTITATIVE)

For **each task**, a risk assessment is performed to prioritize risk, both for inhalation and dermal exposure based on:

- Health Effect Rating (HER) (1= low hazard, 4 = high hazard), based on GHS
 - ✓ Example: H350 = high hazard
- Degree of exposure (either % of OEL or qualitative assessment)
 - ✓ Qualitative: spraying or high Vapour Pressure=high; work in fume hood or Local Exhaust Ventilation=low)
- Duration of exposure (duration + frequency considered)
 - ✓ Example: 1- 4 hours a day; monthly
- HER x Degree x Duration = Priority Rating for a task**
- Priority Rating ranges from 1 (High) to 5 (Low)
 - Priority 1: immediate action to control exposure
 - High priority (P1, 2 and 3): IH monitoring required



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SLIC CHEMEX GUIDANCE FOR NATIONAL LABOUR INSPECTORATES

Action by Inspectors if use not covered by downstream user

Management of deadlines for ES compliance are 12 months to implement per substance/per supplier upon receipt of the extended SDS incl. registration number and ES. Use should always be safe based on control measures identified by the user's risk assessment.



What if the downstream user has achieved adequate control under CAD/CMD but has not followed the REACH risk management measures?

Just because the downstream user has achieved adequate control under CAD/CMD, it does not mean that the REACH requirements can be ignored. **However, the downstream users might be able to demonstrate that their existing control measures achieve an equivalent level of protection, and that the REACH controls are not appropriate for them.** Downstream users will need to justify any such position with reference to their risk assessment.

LEARNING POINTS FROM THE DETAILED ES CHECKS AT CHEMICAL PLANTS

- The full Exposure Scenario (ES) checks done did not lead to changes in the workplace conditions.
- In most cases, the conclusion was that the actual situation was of a higher protection level than described in the Exposure Scenario.
- List with possible industrial activities (in understandable wording) and related PROC numbers was helpful for doing the full ES check at plant level
- A workplace risk assessment as required under the Chemicals Agents Directive, is considered sufficient to control workplace hazards by trained occupational hygienists and labour inspectors in several European countries.

EXAMPLE of some industrial activities	
Version October 2017	PROC
PRODUCTION facilities	
General measures	n.a.
storage	1
sampling (closed system)	3
sampling (open or semi-open system)	9
transport of chemicals (completely closed system)	1
transport of chemicals (dedicated, mainly closed system)	3
transport of chemicals (non-dedicated, open or semi-open system)	8a
(un)loading/bulk transfers/ material transfers, dedicated system, mainly closed system	8b
etc.....	

PROPOSED HIGH LEVEL EXPOSURE SCENARIO CHECK

Companies that already have a good workplace risk assessment, regular updates and effective actions plans + Environmental permit

- Requirement on checking if the (Identified) Use is covered = high-level ES check
- Requirement on checking Msafe?

- Companies' responsibility to choose the best combination of control measures, in agreement with the hierarchy of control. Engineering controls are preferred.
- Companies' decision on how to integrate content of ES information into workplace risk assessment – e.g. integrate in the procedure for "introduction of new chemicals".

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Long Range Research Initiative



cefic

User interface: RMM Library
[https:// prod-diamonds.tno.nl](https://prod-diamonds.tno.nl)

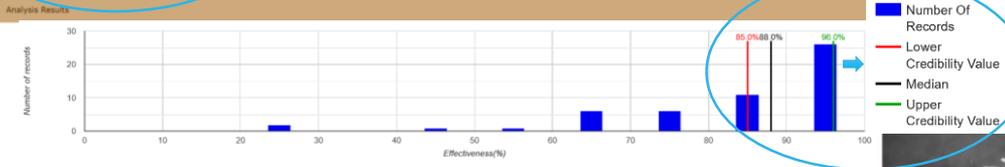


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Reference: Akbar-Khanzadeh F, Milz S, Ames A, et al. Crystalline silica dust and respirable particulate matter during indoor concrete grinding - wet grinding and ventilated grinding compared with uncontrolled conventional grinding. J Occup Environ Hygiene. 2014;11(10):1111-1119.

Example: wetting at point of release

Effectiveness: 88.0%
 Credibility interval: 85.0%-96.0%
 Records: 53 Studies: 14

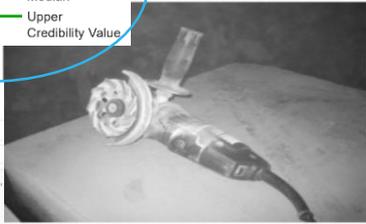


Legend: Number Of Records (Blue), Lower Credibility Value (Red), Median (Black), Upper Credibility Value (Green)

E-card	RMM-group	RMM-subgroup	Route	Substance-Class	Proc-Nr	PROC	Activity-class	Activity-subclass	Sector	Agent	Activity
Suppression	Wetting at point of release	Wetting at point of release	Inhalation	High (mechanical) energy workup of substances bound in materials and/or articles	24	High (mechanical) energy workup of substances bound in materials and/or articles	Fracturing and abrasion of solid objects	Fracturing and abrasion of stone	Construction	Silica crystalline - quartz (in respirable particulate)	Demolition, wrecking, scraping
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Example of grinder used for uncontrolled grinding



reduction method) and ventilated grinding (local exhaust systems of respirable crystalline silica dust (quartz) and respirable particulate matter) compared with that of uncontrolled (no dust reduction method) set up to simulate concrete surface grinding using handheld grinders. A total of 34 personal samples (16 pairs side-by-side and 2 pairs top-to-bottom) were collected during 18 concrete grinding sessions ranging from 10 to 30 minutes. The results show a statistically significant effect on operator's exposure to dust. Overall,

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DISCUSSION POINTS FROM INDUSTRY AS DOWN STREAM USER - 1

- What should an ES check look like for companies already complying with requirements under the Chemicals Agent Directive (CAD)?
 - How can we prove compliance with article 37(4) by a company risk assessment as required under the Chemicals Agent Directive.

- How can we get acceptance of an agreed method for a high-level ES check by all stakeholders (Member States)?
 - Who are the stakeholders and what role do they have?

- What are circumstances that make a Downstream User Chemical Safety Report necessary?
 - How and why this is helpful for the end user?

DISCUSSION POINTS FROM INDUSTRY AS DOWN STREAM USER - 2

- Ext SDS improvements relevant for Industry as Downstream User:

As discussed within ENES projects:

- Improvement of layout of the Exposure Scenario:
 - ✓ Table of Content
 - ✓ Improvement of Title Section

- Further improvements (relevant for all Downstream Users):
 - ✓ Create sector specific/company specific translation lists from PROCs to understandable language
 - ✓ Exposure control measures to be applied to all activities with the substance should be only specified once (e.g. in section 8.2 of the SDS), and not multiply repeated within and across all the exposure scenarios

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BACKUP: SLIC CHEMEX GUIDANCE, PAGE 29:

What if it is not possible or impractical to apply the risk management measures in a safety data sheet?

This will need to be considered as part of the CAD/CMD assessment. There is a clear expectation in REACH that downstream users should apply the full range of control measures identified in the SDS. But if there are clear and justifiable reasons for not doing so (i.e. the risk management measures are not 'appropriate'), then it is not a contravention of REACH to take other measures. In such circumstances, the downstream user should be able to demonstrate how the other measures taken provide for an equally effective level of protection and should document in their risk assessment the reasons for not applying the REACH controls. Downstream users should also report any inappropriate risk management measures to their supplier.



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