



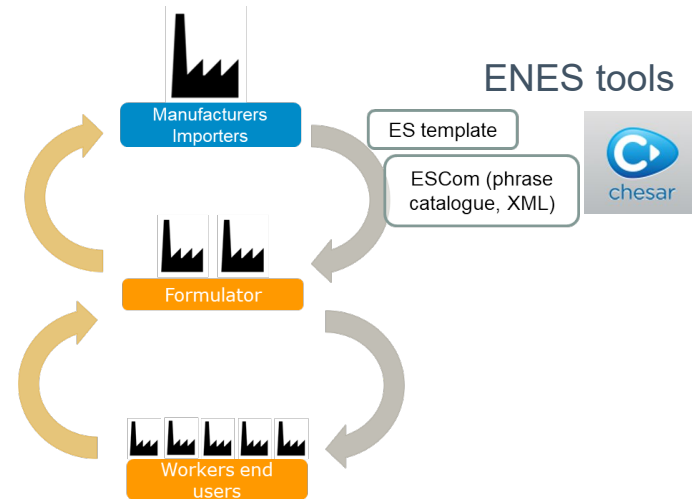
# INDUSTRIAL END USER OF CHEMICALS: HOW TO DEAL WITH REACH & WORKPLACE RISK ASSESSMENT

DR. IR. EVELYN TJOE NIJ  
*OCCUPATIONAL HYGIENIST & REACH RISK ASSESSOR*

*September 28, 2021*

# 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 hazardous chemical agents are present at the workplace and assess any risk to the safety and health arising from their presence.



**Note:** You need chemicals to make chemicals. Manufactures and Formulators are also end users

# REACH AND EXPOSURE SCENARIOS: DU PERSPECTIVE

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## 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

# REACH AND EXPOSURE SCENARIOS: DU PERSPECTIVE

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## Challenges:

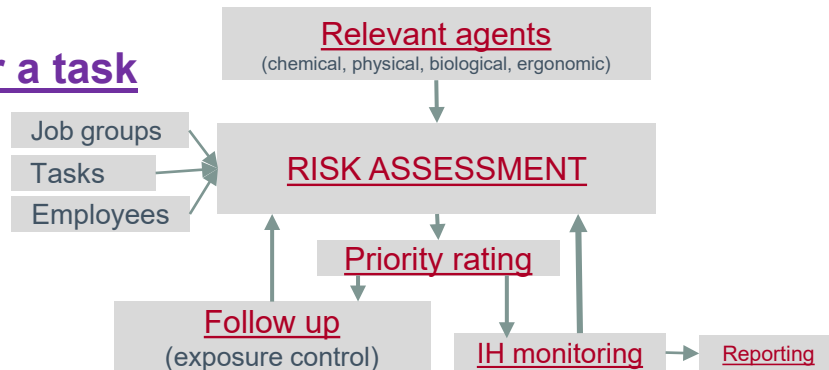
- Exposure Scenarios developed per activity, for substance manufactured above a certain volume only
  - Majority of supplier SDS do not contain an annex, as this is not always required
- Overlap with Occupational Safety and Health (OSH) regulation, where OSH regulation is much more dedicated to workplace risk assessment (including process generated hazards), considers complex chemical environments and the hierarchy of control is mandatory
- Exposure Scenarios are intended to describe safe use in a generic way
- REACH vocabulary and the use descriptor system is not easy to understand
- Significant administrative duties



# 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



# 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 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 ES check at plant level
- A workplace risk assessment as required under the Chemicals Agents Directive, is considered sufficient to control workplace risks by trained occupational hygienists and labour inspectors in several European countries.

<b>EXAMPLE of some industrial activities</b>	
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.....	

# CEFIC KEY POINTS ON REACH/OSH COEXISTENCE

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- REACH and OSH risk assessments can co-exist in the workplace and can complement each other.
- When the use is covered (section 1 of the SDS) & risks are controlled based on an OSH risk assessment, a more pragmatic approach should be allowed.
- When risks are adequately controlled, it should be considered compliant with the ES without the need to prepare a downstream user CSR and notify ECHA in case of deviation from the exact content (Operational Conditions/Risk Management Measures) of the Exposure Scenario.
- Exposure Scenarios should be considered as in information source / screening tool in the context of Workplace Risk Assessments

## Consequence of this approach:

1. Better incorporation of the REACH information into the OSH risk assessment
2. Would allow more clarity on the obligations arising from both legislations and the actions that need to be taken at the workplace level

<https://cefic.org/app/uploads/2021/02/Cefics-views-on-the-interplay-between-REACH-and-OSH-legislation.pdf>



## PROPOSED ES CHECK WHEN ALREADY COMPLYING WITH OSH REQUIREMENTS

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For 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 in the SDS
- 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 process for “introduction of new chemicals”.

## DISCUSSION POINTS FROM INDUSTRY AS DOWN STREAM USER - 1

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- 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 more high-level ES check by all stakeholders (Member States)?
  - Who are the stakeholders and what role do they have?
- What would be conditions 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

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- 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
  - ✓ Harmonized lay out
  
- Further improvements (relevant for all Downstream Users):
  - ✓ Create sector specific/company specific translation lists from PROCs to understandable language.
  - ✓ Merge the output of the qualitative risk assessment in section 8.2 of the SDS (e.g. engineering controls, face shields, goggles). Qualitative risk assessment results in unnecessary repetitive information.





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### 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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GUIDANCE for National Labour Inspectors on the interaction of the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) (Regulation (EC) No. 1907/2006), the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD)

Similar Labour Inspector's Committee (SLIC)

