REACH Exposure Scenario Check

Industry experience and Proposal for a pragmatic approach

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Background

REACH (article 37) requires users to check in substance SDS whether:

- Their use is covered as an identified use
- They comply with the measures (RMM) and conditions (OC) in the Exposure Scenario (ES)

Meeting these requirements is difficult and cumbersome:

- Interpretation of the legal requirements is not clear
- New concepts and terminology (ES, use descriptor system) is incomprehensible for many end-users
- Quality of current ES's is still insufficient – e.g. models used outside their boundaries, applied by non experts, quality of models debated in scientific literature
- Scepticism to comply with OC/RMM when risks are already managed and controlled by OSH approach
- ECHA DU Guidance is not realistic

Exchange of experiences during Industrial Hygienist (IH) meeting in February – April 2018

- Presentation of approaches/systems/processes
- Discussion on issues with the execution of the ES check
- Workshop at DOHS Conference on pragmatic approach of ES check

Conversion REACH regulation to ES check

- Is this a REACH registered hazardous substance, for which a Chemical Safety Assessment (CSA) has been performed?

YES

In principle SDS should have ES attached for uses assessed

- Check whether your own application is described in one of the ES's

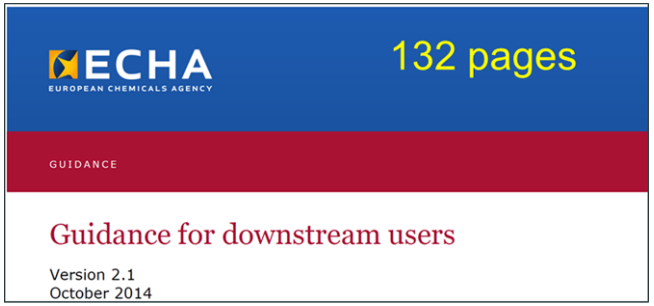
NO

Contact supplier to include own application as identified use

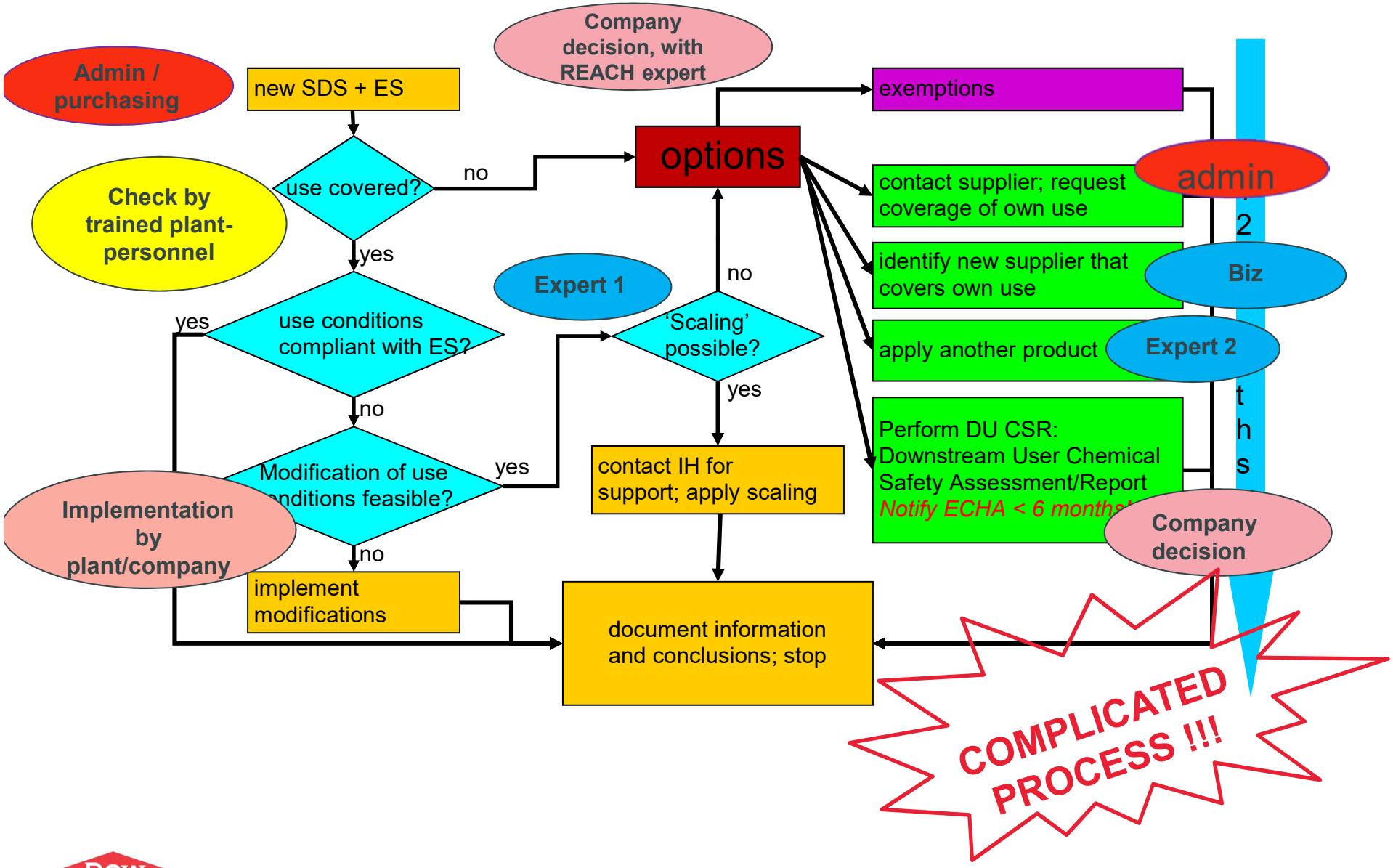
- Check whether own RMM and OC are compliant with the ES

NO

Demonstrate that safe use is ensured with other RMM/OC or contact supplier



Workflow for execution of full REACH ES check



Example: use of PMDETA

Pentamethyldiethylenetriamine

CAS: 3030-47-5

REACH reg.no: 01-2119979537-18

Liquid

Vapour pressure: 27 Pa

Harmonized Classification: H302 (acute tox 4); H311 (acute tox 3); H314 (skin corr 1B)

Technical function: additive/catalyst in Polyurethane products

Use: formulation in polyols at Polyurethane formulation plant (Dow, Terneuzen)

Supplier information

2 suppliers: A and B

Information	Supplier A (SDS 2016)	Supplier B (SDS 2014)
Classification	H302, H311, H314, H318, H331, H412	H302, H311, H314
OEL	Not available	Not available
DNEL inhalation (longterm, systemic)	1.058 mg/m^3	0.529 mg/m^3
DNEL dermal (longterm, systemic)	0.3 mg/kg bw/day	0.15 mg/kg bw/day

Incorrect!

Executing the check on use coverage

Use title plant: formulation, industrial

Use descriptor combination plant:

- Sector of Use: SU3, SU10
- Environmental Release Category: ERC2
- Process Categories Worker => contributing activities:
  - Storage & in-line charging (from storage tank into mixing tank, fully closed system): PROC1
  - Mixing in tank (fully closed system, batch operation): PROC3
  - Dedicated transfer from tanktruck into storage tank; fully closed except coupling/decoupling operation): PROC8b

	Plant	ES Supplier A	ES Supplier B	Check
Use title	Formulation	ES 2B: formulation and (re) packing of substances and mixtures	ES1: formulation and (re) packing of substances and mixtures	✓
SU	SU3, SU10	SU3, SU10	SU3	✓
ERC	ERC2	ERC2	ERC2	✓
PROC	PROC1, 3, 8b	PROC1, 3, 4, 5, 8a, 8b, 9, 15	PROC1, 3, 4, 5, 8a, 8b, 9, 15	✓

Example: Executing check on OC and RMM for PROC3

OC/RMM for PROC 3	Conditions Plant	Supplier A	Supplier B
Containment	Closed process	Closed process	(PROC title)
Location	**Outdoor**	Indoor	Indoor
Duration/Frequency	**Duration 1 hr/5 days/week**	Duration 8 hrs/5 days/week	Duration 8 hrs/5 days/week
Concentration	**< 1%**	100%	100%
General Ventilation	**Outdoor**	No	No
Local Exhaust Ventilation	**No LEV**	LEV (90% effective)	LEV (90% effective, also for dermal)
Respiratory Protection	**No**	Yes (95% effective)	Yes (95% effective)
Dermal Protection	Yes	Yes (95% effective)	Yes (95% effective)
Eye Protection	Yes	Yes	No
Exposure calculations (ECETOC TRA)			
Inhalation exposure (RCR)	***0.303 (RCR=0.57)***	*0.108 (RCR = 0.205)*	*0.108 (RCR = 0.205)*
Dermal exposure (RCR)	***0.003 (RCR=0.02)***	*0.034 (RCR = 0.23)*	*0.0034 (RCR = 0.023)*

In red: deviation in OC/RMM between suppliers

In red/bold: deviation in OC/RMM between plant and both suppliers

Exposure calculations demonstrate safe use for OC/RMM applied in plant (in green)

Both suppliers request for LEV and Respiratory Protection, which is not implemented at the plant

Example: Executing check on ERC 1

	Plant	ES Supplier A	Check
Tonnage	5100 ton/year	35 ton/year	X
M safe value	-	1,9E+07 kg/d or 19000 ton/d	✓
RMM to water	Site permitting	Ensure a waste water removal efficiency of 96.2 %	Requires risk assessor to review information

- High level information on the “Tonnage” does not indicate that the use in under scope
- Following an indepth review by a risk assessor, the scenario proves to be applicable for the given use.

Extract from ECHA presentation

3. Use/conditions not covered

You can take any of the following options

1. Contact your supplier to have the ES updated with your use covered
2. Change your process to implement the ES
3. Substitute with another substance or process or stop the activity
4. Find a supplier providing ES that covers your conditions
5. Prepare downstream user chemical safety report (DU CSR) to establish safe conditions for the use not covered in ES and report unsupported use to ECHA

Time consuming; experience: will take long to get updated eSDS

Costly, time consuming, may technically not be feasible; secondly: not needed, as safe use can be demonstrated!

Time consuming; experience: not easy to find other supplier

Administrative burden

Question: Is there evidence that this administrative process increases worker safety and health?

Extracts from ECHA presentation+website

Reporting to ECHA

You need to report to ECHA if you:

- Prepare a downstream user chemical safety report

  OR

- Are exempted from preparing the chemical safety report

Submitting a DU Report

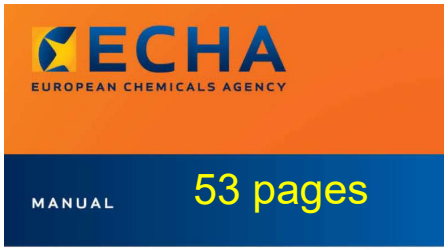
There are two ways to submit a downstream user report to ECHA for any unsupported uses, via REACH-IT.

Downstream User Report

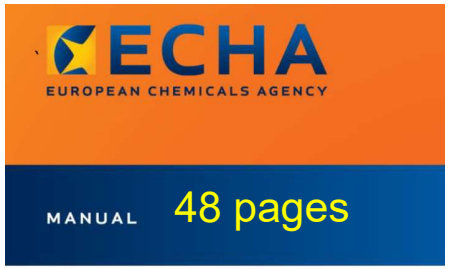
REACH-IT

Here's how to get started

1. Register a company
2. Manage company and users
3. Login
4. Submit and follow up your process



ECHA Accounts Manual for Industry Users



How to prepare a downstream user report

Fill template for reporting unsupported uses and submit via REACH-IT

DOWNSTREAM USER REPORT DESCRIPTION OF CONDITIONS OF USE			
Company		**Date**	
Substance		**Ref**	
Environmental Exposure[1]			
Use not covered			
Reason why use is not covered in supplier Exposure Scenario	☐ Title/Activity ☐ Own ☐ Downstream ☐ Quantity ☐ Own ☐ Downstream ☐ Oth ☐ ___ ***Tick all***		
Substance quantity[2]	Annual Maximu Substa		
Operational Conditions and Risk Management Measures (OC/RMM)[3]	·		

To be repeated for each not covered contributing activity

Human Exposure[1]	
Use not covered	
Reason why use is not covered in supplier Exposure Scenario	☐ Title/Activity ☐ Own ☐ Downstream ☐ Concentration ☐ Own ☐ Downstream ☐ Other OC/RMM ☐ Own ☐ Downstream ☐ _____ ☐ Own ☐ Downstream ***Tick all not covered or matched in ES***
Substance concentration[2]	Concentration range in own processes _____%__ Concentration range in supplied product _____%__ Substance supplied downstream ☐ Yes ☐ No
Operational Conditions and Risk Management Measures (OC/RMM)[3]	· *Operational conditions* · *Technical and organisational risk management measures* · *Product form/design/composition aspects that influence exposure*

Conclusions

- The ES check and required follow up actions lead to a high administrative burden for companies, with little confidence that this results in a higher level of worker safety.
- ES check does not consider OSH risk assessment, which is normally already in place.
- There is a clear need for clarity on the overlap/inconsistencies between OHS and REACH legislation
- ES's are incomplete, only partly standardized and the quality can be significantly improved
- In particular for professional and smaller industrial users the ES concept, REACH vocabulary and the use descriptor system is difficult to understand.
- Communication in the supply chain is only effective when a use has not been included as an identified use and is not described in section 1 of the SDS
- **Poor quality ES, complicated process and guidance, and difficulty in interpretation of the legal text reduces motivation, credibility and trust**

Proposal for pragmatic approach

Prerequisite: a system is in place to evaluate SDS and ES

1. Review date, language, 16 sections, signal words and H phrases
2. Use covered (section 1 or annex)?
3. Tonnage or Msafe covered?
4. Section 8: review OELs and use of correct PPE
5. Check if product label is consistent

→ Communicate if SDS is not correct or use/tonnage not covered

→ DU to decide if details in ES should be used as source for safe use information in addition to OSH risk assessment.

<u>Gradual implementation of other ES requirements:</u>

- OC/RMM check initiated when quality of ES and ECHA Guidance for DU has been improved.

Guidance SLIC CHEMEX for national labour inspectorates

5.4 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 users risk assessment.

https://circabc.europa.eu/w/browse/4f2025c8-2256-422c-b09d-3b551cb7149d

SLIC CHEMEX guidance, *page 30*:

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.

Downstream users should remember that there may still be circumstances in which they must nevertheless prepare a CSR (for uses outside the conditions described in an exposure scenario, or uses that are against the advice of the supplier).

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.

Thank You