

# The Exposure Scenario in General

- Format and content
- Major terms used in ESs
- Understanding ESs

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## What is an Exposure Scenario?



The exposure scenario is a document generated by the registrant during REACH registration. The exposure scenario:

- Describes the conditions that ensure adequate control of risk when a substance is manufactured and used
- Addresses the risk to workers, consumers and the environment, as appropriate

**Exposure Scenarios (ESs) are attached to the Safety Data Sheet (SDS)**



**e-SDS (extended Safety Data Sheet)**



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## Exposure Scenario standard format

| Exposure scenario format*   |
|---|
| 1. Title  |
| 2. Operational conditions and risk management measures                      |
| 2.1 Control of workers exposure   |
| 2.2 Control of environmental exposure                                       |
| 2.3 Control of consumer exposure  |
| 3. Exposure estimation and reference to its source                          |
| 4. Guidance to downstream user to check own conditions                      |
| Additional good practice advice beyond the REACH chemical safety assessment |

\* REACH does not define a specific format, but a standard format helps to streamline the communication in the supply chain.



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## What is in an Exposure Scenario?



- **Table of contents**
  - ✓ It helps to find the ES(s) related to a use/group of uses
- **Section 1 : Title**
  - ✓ Short title / Tasks & Activities covered (Use Descriptors)
- **Section 2: Conditions of Use affecting exposure**
  - ✓ Environment / Workers / Consumers - (Contributing Scenarios)
- **Section 3: Exposure estimation**
  - ✓ Method / Exposure estimates / Risk Characterisation Ratio
- **Section 4: Guidance to DU's**
  - ✓ How to verify that use is covered (Scaling Options)



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## Example for an industrial cleaner

| Exposure Scenario Format (1) addressing uses carried out by workers  |  |
|--|--|
| 1. Title   |  |
| Free short title   | Industrial Cleaner I   |
| Systematic title based on use descriptor   | SU3 (Industrial Manufacturing), PROC4, PROC8, PROC9, PROC10<br>ERC4  |
| Processes, tasks activities covered  | Metal cleaner (degreaser, descaler, etch);<br>Manual process, Semi-Automatic process,<br>Automatic process (according to A.I.S.E.) |
| Assessment Method*   | ECETOC TRA, DPD +  |
| 2. Operational conditions and risk management measures   |  |
| Brief description of overall operational conditions referring to process categories (PROC) and environmental release categories (ERC)  |  |
| Number of sites using the substance supplied by the registrant (potentially required to demonstrate strictly controlled conditions, in order to justify waiving of information according to Annex XI of REACH) * |  |
| 2.1 Control of workers exposure  |  |
| Product characteristic   |  |
| Amounts used   |  |
| Frequency and duration of use/exposure   |  |
| Human factors not influenced by risk management  |  |
| Other given operational conditions affecting workers exposure  |  |
| Technical conditions and measures at process level (source) to prevent release   |  |
| Technical conditions and measures to control dispersion from source towards the worker   |  |
| Organisational measures to prevent /limit releases, dispersion and exposure  |  |
| Conditions and measures related to personal protection, hygiene and health evaluation  |  |



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## Use descriptors

1. **SU** – Sector of Use e.g. construction products
2. **PC** – Product Category e.g. adhesive
3. **PROC** – Process Category e.g. industrial spraying
4. **AC** – Article Category e.g. batteries
5. **ERCs** – Environmental Release Categories

❖ spERCs – sector specific Environmental Release Categories

Some use descriptors support identification of the suitabel exposure estimation used in Tier 1 exposure estimation tool.

See ECHA Guidance Information requirements and CSA, Part D, Chap. 4.3.1, p. 25, + chapter R12 for an overview of Use Descriptors with standardized emission rates.0



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## Example for sectors of use

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Appendix R.0-1: Descriptor-list for sectors of use (SU)

| Key descriptor: Main user groups             |  |                          |
|--|--|--------------------------|
| SU 3   | Industrial uses: Uses of substances as such or in preparations* at industrial sites              |                          |
| SU 21  | Consumer uses: Private households (= general public = consumers)                                 |                          |
| SU 22  | Professional uses: Public domain (administration, education, entertainment, services, craftsmen) |                          |
| Supplementary descriptor: Sectors of end-use |  | NACE <sup>21</sup> codes |
| SU1  | Agriculture, forestry, fishery   | A                        |
| SU2a   | Mining, (without offshore industries)  | B                        |
| SU2b   | Offshore industries  | B 6                      |
| SU4  | Manufacture of food products   | C 10,11                  |
| SU5  | Manufacture of textiles, leather, fur  | C 13-15                  |
| SU6a   | Manufacture of wood and wood products  | C 16                     |
| SU6b   | Manufacture of pulp, paper and paper products  | C 17                     |
| SU7  | Printing and reproduction of recorded media  | C 18                     |
| SU8  | Manufacture of bulk, large scale chemicals (including petroleum products)                        | C 19.2+20.1              |
| SU9  | Manufacture of fine chemicals  | C 20.2-20.6              |
| SU 10  | Formulation [mixing] of preparations and/or re-packaging (excluding alloys)                      | C 20.3-20.5              |
| SU11   | Manufacture of rubber products   | C 22.1                   |
| SU12   | Manufacture of plastics products, including compounding and conversion                           | C 22.2                   |
| SU13   | Manufacture of other non-metallic mineral products, e.g. plasters, cement                        | C 23                     |
| SU14   | Manufacture of basic metals, including alloys  | C 24                     |
| SU15   | Manufacture of fabricated metal products, except machinery and equipment                         | C 25                     |
| SU16   | Manufacture of computer, electronic and optical products, electrical equipment                   | C 26-27                  |
| SU17   | General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment            | C 28-30,33               |
| SU18   | Manufacture of furniture   | C 31                     |
| SU19   | Building and construction work   | F                        |
| SU20   | Health services  | Q 86                     |
| SU23   | Electricity, steam, gas water supply and sewage treatment  | C 35-37                  |
| SU24   | Scientific research and development  | C72                      |
| SU0  | Other  |                          |

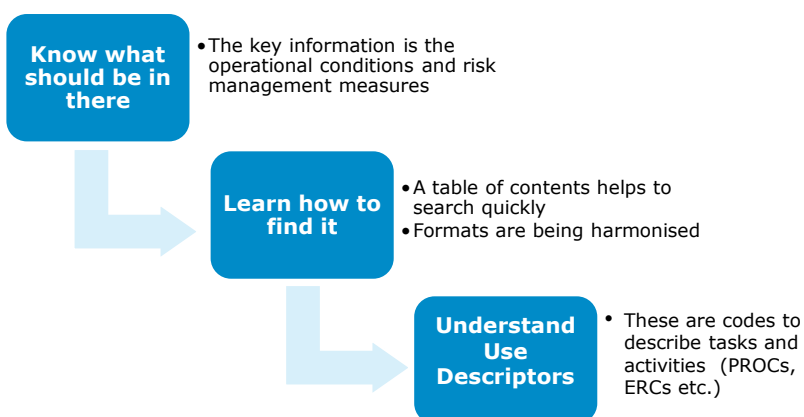


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Regional Accession Network **ECRAN**

## How to read exposure scenarios



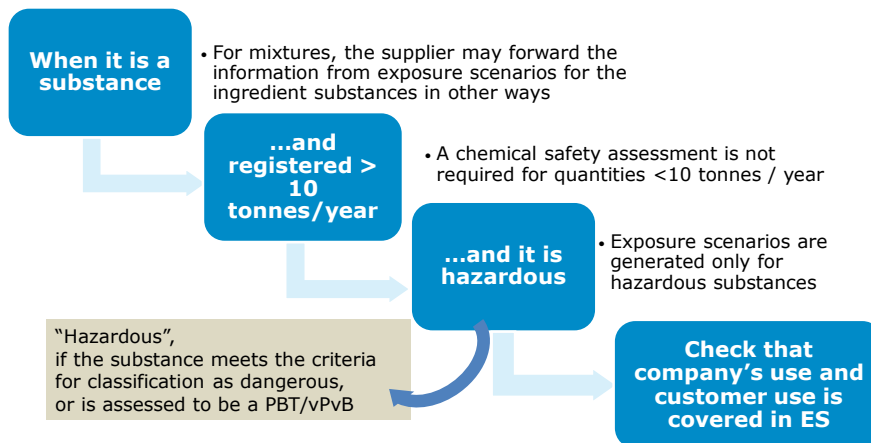
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## When exposure scenarios required

**When a chemical safety assessment with exposure assessment has been prepared, namely:**



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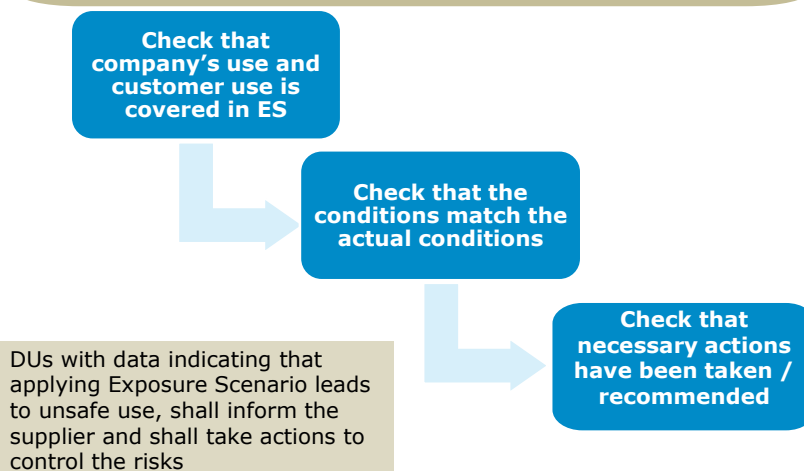


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## What to do when ES(s) present

**It seems like a lot of information, but the key information is the operational conditions and risk management measures**



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## Checking uses and conditions of use

The exposure scenario should be checked by DUs for their own use and any foreseeable customer use



Uses described by supplier



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Actual use

- SDS Section 1.2
  - Identified uses
- ES Section 1 - Title
  - Identified uses
  - Processes/activities covered
- ES Section 2
  - Conditions of safe use

- Own/customer site
  - Processes/activities
  - Conditions of use
- Own /Customer products
  - Product category
  - Article category

Understand use descriptors



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## ES – check if company's use is covered in the title section



### Title section: use name

- Are all uses and foreseeable uses of a product by customers identified in the title section of one or more of the exposure scenarios?
- Is the use title applicable to these uses?

### Title section: scope

- Do the contributing exposure scenarios cover all tasks or processes relevant for own uses in the contributing scenarios? (matching PROCs/ERCs)



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## ES – Check if the technical measures in section 2 will match



### Section 2:

#### Operational conditions.

#### Technical measures

- Do the product/substance characteristics (such as form [liquid/powder/-granular/pellet], volatility and viscosity, concentration of substance in mixture) match those specified in the exposure scenario?
- Are the processes, technologies and the conditions which control the release of the substance into the working environment (such as amount used, transfer system, containment, frequency and duration of use,) in line with the recommendations in the exposure scenario?



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## ES – Check if the organisational measures in section 2 will match



### Section 2:

#### Operational conditions.

#### Organisational measures

- Are organisational measures (such as training and supervision) specified in the exposure scenario included at the location?
- Is training provided as required?
- Is equipment maintained?
- Are measures recommended as a 'good practice' incorporated into the implemented work practices?

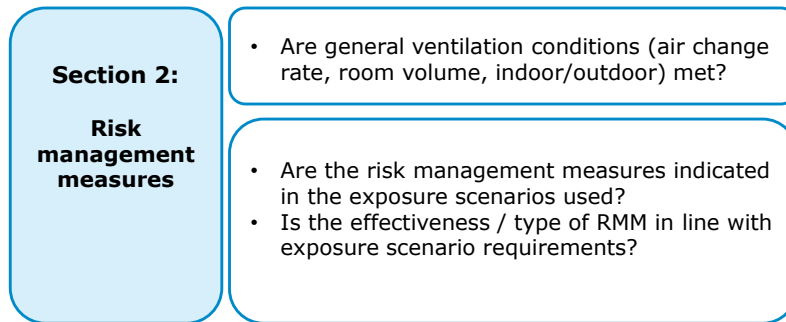


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## ES – check if the RMM in section 2 will match



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## Outcome of the ES check

1. Use and conditions of use are covered
  - No action needed.
2. Conditions of use slightly differ
  - Check if conditions of use may be covered by similar use of broader scope (by scaling, if applicable)
3. Use and/or conditions not covered
  - Company needs to take actions!



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## 2. Conditions slightly differ



### Has the company its conditions of use covered by using "scaling".

- Scaling is a mathematical method to show that the substance is used under use conditions described in the ES, but some parameters are slightly different
- It can be used when:
  - There is an exposure limit (DNEL/PNEC)
  - the supplier (registrant or DU) has used an exposure model for the assessment
  - the supplier provides information for scaling



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## Outcome from the scaling

### ***Scaling shows that the use is covered***

- No further actions required.



### ***Scaling shows that use is not covered e.g.***

- ✓  $R_{CR_{scaling}} > R_{CR_{ES}}$  or
- ✓ parameters are not scalable or
- ✓ scaling is not foreseen as an option
- Have actions been taken for uses not covered



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### 3. Use/conditions not covered

#### Has the company taken any of the following options?

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



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### DU Chemical Safety Report (CSR)



#### ***What it's not***

As extensive as a registrant chemical safety report

#### ***What it is***

A report of the chemical safety assessment for the use not covered. The hazard assessment of the registrant (DNEL's/PNEC's etc.) may be used.



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## Exemptions from DU CSR



- The total use is less than 1 tonne/year



- The substance is used for Process and Product Oriented Research & Development (PPORD)



**No need to prepare DU Chemical Safety Report?**

**.... however, use needs to be reported to ECHA**



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