

Chemical Safety Report Tips

ECHA's Fourth Stakeholders' Day
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ECHA – Helpdesk and Guidance

Chemical Safety Report

Key Messages

- Required information:
 - Substance properties
 - **Practical conditions of safe manufacture and safe use.**
 - Exposure estimation and risk characterisation
- Environmental exposure assessment needs more attention.
- Don't assume, the lead registrant will do the job for you. **Every** registrant needs to understand what is required for a CSR.

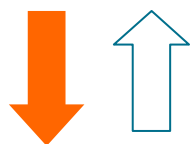
When is a CSA required?

- It is required when a substance is manufactured or imported at 10 tonnes or more per year.
- The assessment shall be documented in a CSR to be submitted as part of the registration dossier.
- Annex I of REACH sets out the general provisions for assessing the substances and preparing CSRs.

Technical Dossier and CSR

Information Requirements (Annex VI-XI)

Technical Dossier



Chemical Safety Assessment

Hazard Assessment

Exposure Assessment*

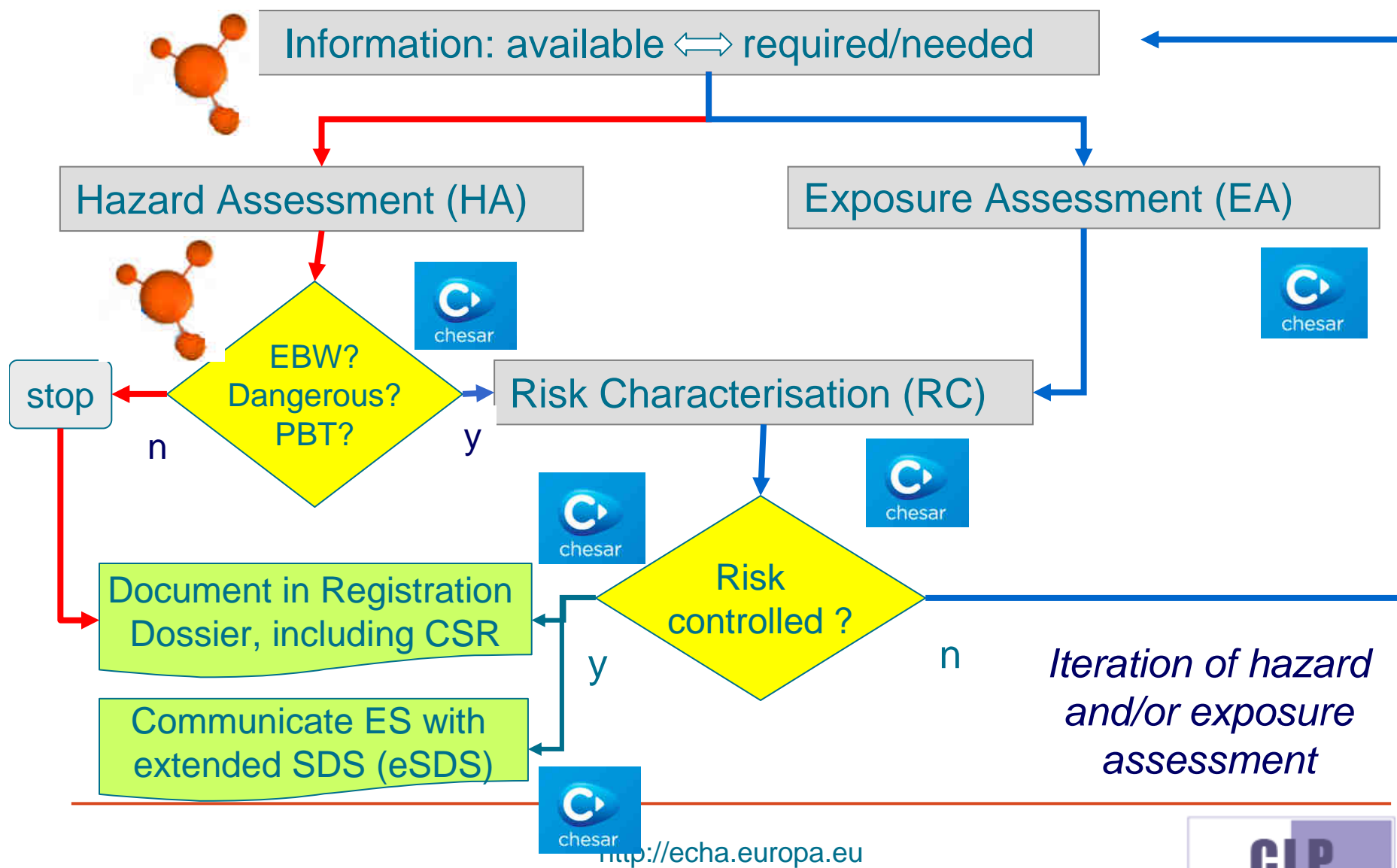
Risk Characterisation*



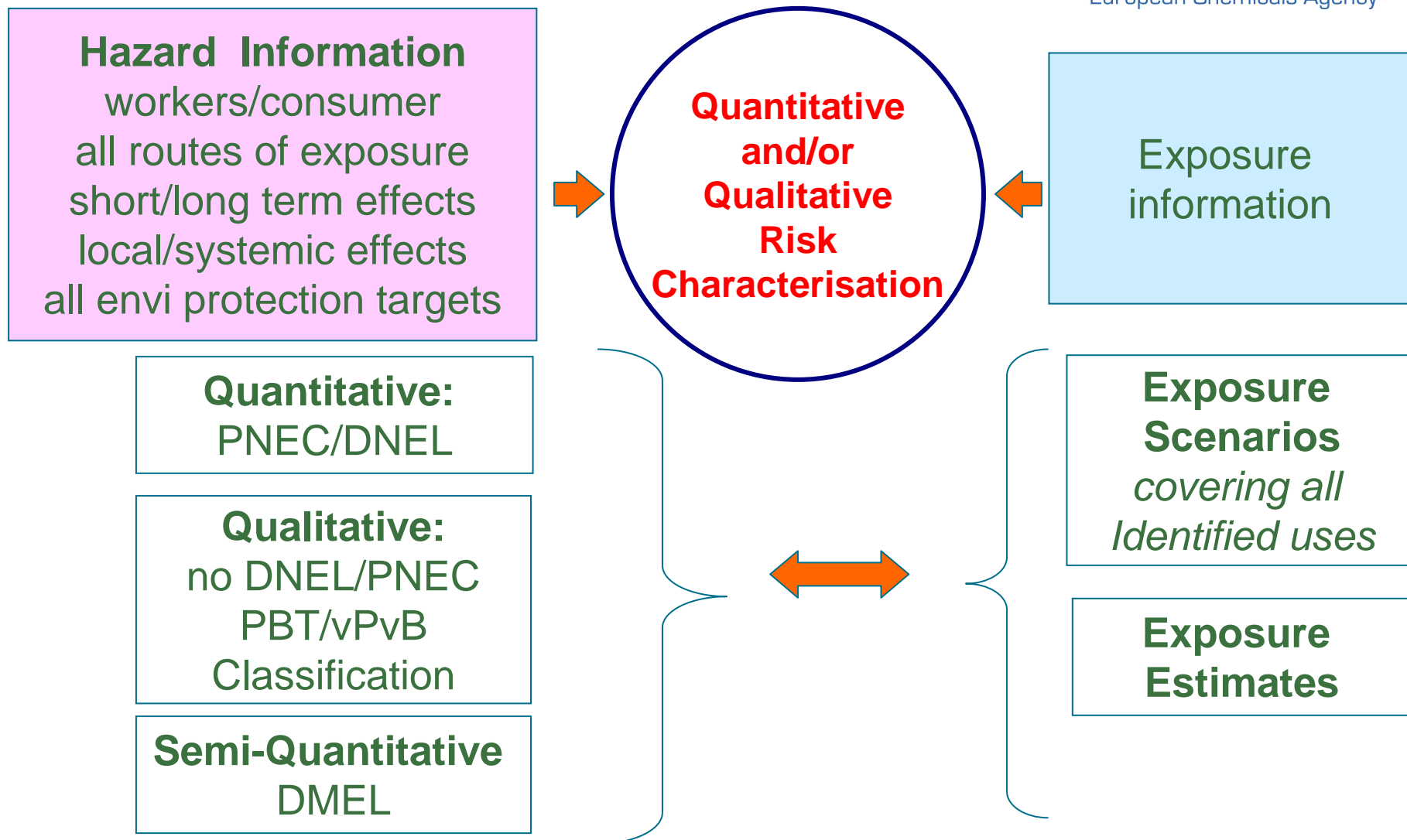
Chemical Safety Report

* If substance meets the criteria for classification as dangerous, or is assessed to be a PBT/vPvB.

CSA Framework and Tools



Demonstrating “control of risk”



Exposure scenarios

Examples for content

- Concentration of the substance in the relevant categories of chemical products or articles
- Substance amounts applied in relevant categories of uses
 - amount at a typical industrial site (daily and annually)
 - amount in products for consumer or professional use
- Measures to be applied for limiting or preventing
 - **releases** to the environment
 - **exposure** to workers and/or consumers
- Other conditions driving exposure

Two Exposure Scenarios

- **Exposure scenario for the CSR**
- **Exposure scenario for the extended safety data sheet**
 - extract from the ES in the CSR, potentially phrased as (target group specific) advice
 - extract of information on exposure estimates and risk characterization
 - advice to DUs on how to establish whether or not they are working within the boundaries assessed to be safe by the registrant

TIPS

CSR Submission

- Each registrant needs to know when a CSR is required, and ii) which information is required.
- The lead registrant should communicate whether or not he intends to prepare a joint CSR.
- A member registrant mandating the lead registrant to prepare a joint CSR needs
 - to provide all necessary information on the conditions of manufacture and use to the lead
 - to identify which uses and exposure scenarios in the joint CSR are relevant to him (own conditions and supply chain)
 - to ensure transparency and consistency when submitting a separate, complementary CSR part.

Exposure Assessment

- To be addressed:
 - all relevant populations, routes and types of effects; all protection targets for the environment;
 - all identified hazards, not just those leading to classification and labelling.
- Exposure scenarios are meant to describe **conditions and measures** suitable to ensure safe use (control of risk).
- Exposure estimates needed for each exposure scenario.
- All uses are to be covered in the exposure scenarios.

Environmental exposure

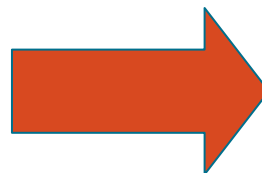
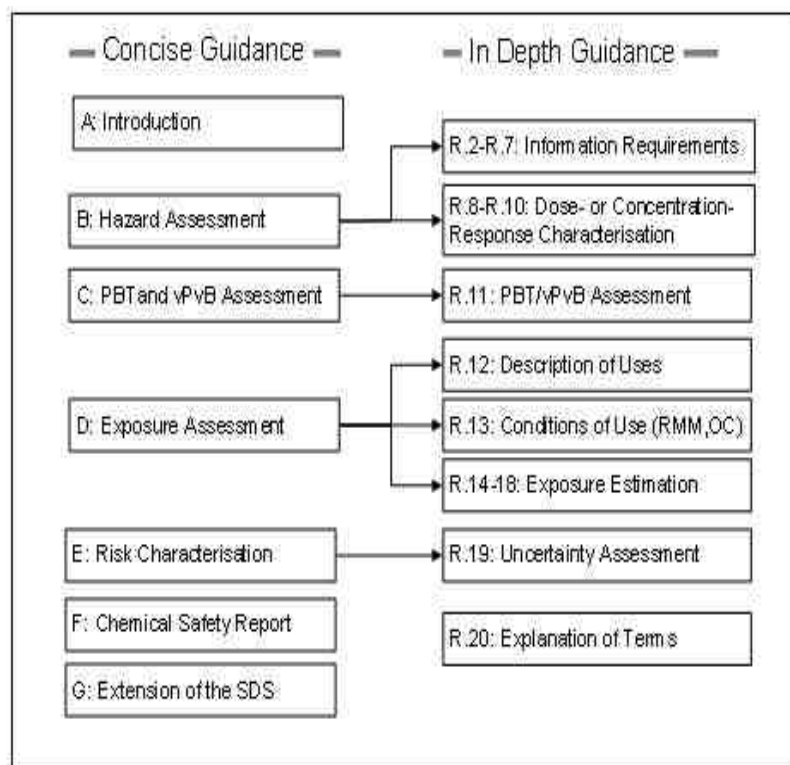


- Determination of tonnage break down into the different uses needed.
- Exposure scenarios should describe conditions and measures, not just a release rate or emission factor.

Updated Guidance on CSA

- **Publication before June 2010**
 - Use descriptor system (R.12)
 - Exposure scenario format (Part D and F)
 - Exposure estimation for workers (R.14)
 - Exposure estimation for consumers (R.15)
 - Exposure estimation for the environment (R.16)
- **Continued consultation, publication only Q1/2011**
 - “Strictly controlled conditions” and “no release” (R.5)
 - Exposure assessment for waste life stage (R.18)
 - Scope of exposure assessment (B)
 - DNEL derivation from human data (R.8)

From Guidance to Chesar



Chemical Safety Report - Tips



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