



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL  
**Joint Research Centre**

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# **Chemical Safety Assessment and Report**

## **“Guidance on Information Requirements and Chemical Safety Assessment”**

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**REACH Workshop: Final countdown**

**14 April 2008, Brussels**





## Overview - issues

- Starting point: **REACH Registration**
- Generation of information
- Control of risks
- Documentation
- Downstream User (DU) perspective and supply chain communication
- Guidance and supporting IT tools



# Registration

AIM:

- manufacturers and importers obtain information on their substances and
- use this knowledge to enable well-informed management of the risks these substances may present throughout their life cycle

Registration Dossier = Documentation

- Technical Dossier: starting at 1 tonnes per year
- Chemical Safety Report: starting at 10 tonnes per year

**No formal acceptance - industry retain responsibility**



## Aims of the Chemical Safety Assessment process

- Collect/generate/assess information on uses, exposures and intrinsic properties. Based on this:
- Identify the conditions under which the risks arising from manufacture and use(s) of a substance are controlled.
- Prepare a set of corresponding information on operational conditions and risk management measures (= Exposure Scenarios) to be communicated to the users of the substance (for dangerous substances).
- Document the assessment in a Chemical Safety Report (CSR) for the companies' own documentation.
- Submit CSR to the authorities as part of the registration.



# What is the Chemical Safety Report (CSR) ?

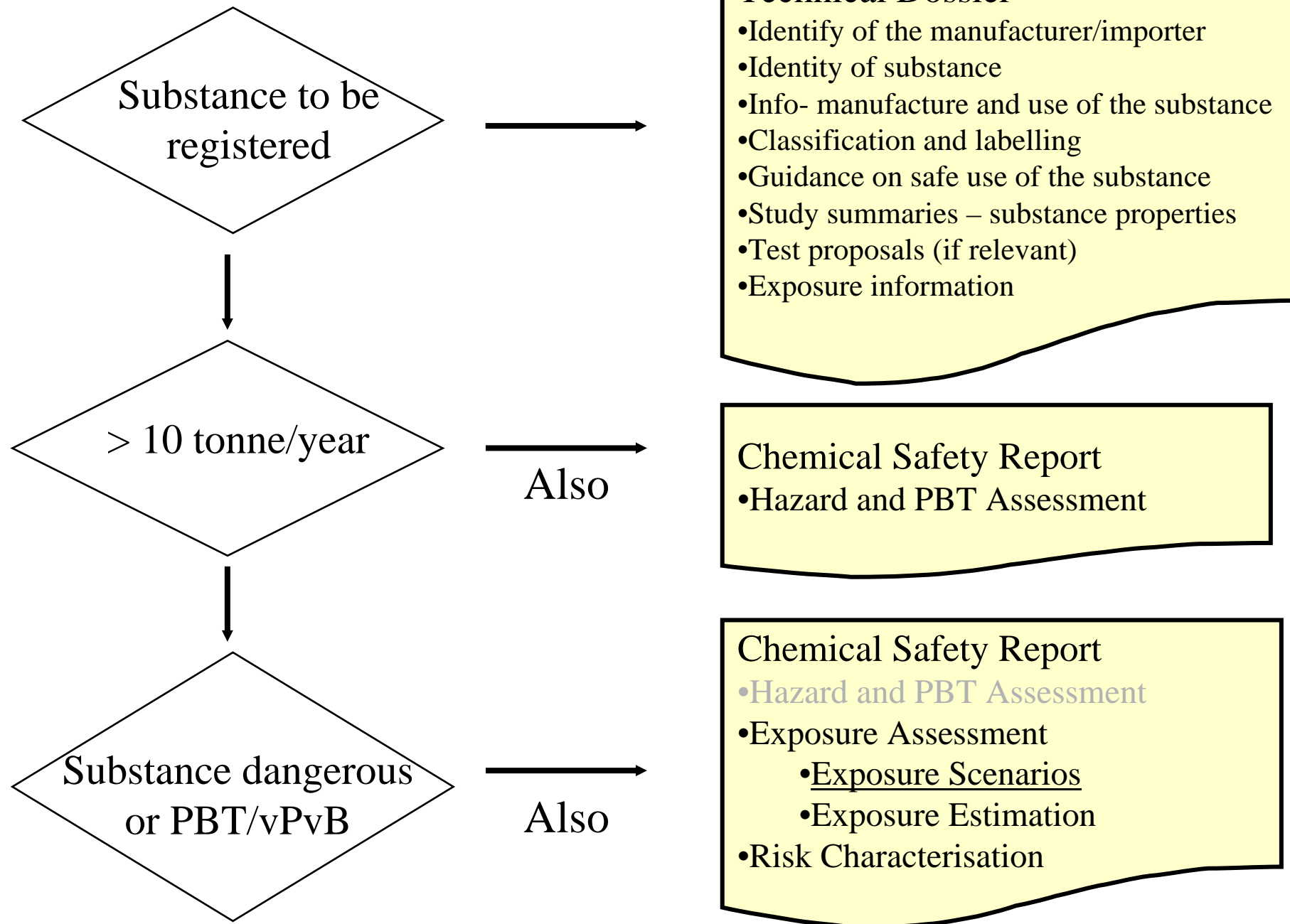
- The CSR is the documentation of the Chemical Safety Assessment (REACH Annex I) covering:
  - Hazard Assessment of the inherent properties
    - Human Health
    - Physicochemical
    - Environmental
  - PBT and vPvB assessment\*
- and when substance is dangerous or PBT/vPvB
  - Development of Exposure Scenarios for controlling risks
  - Exposure estimation quantifying human and environmental exposure levels
  - Risk Characterisation

\* PBT: Persistent, Bio-accumulative and Toxic

\* vPvB: very Persistent and very Bio-accumulative



## Registration dossier - content

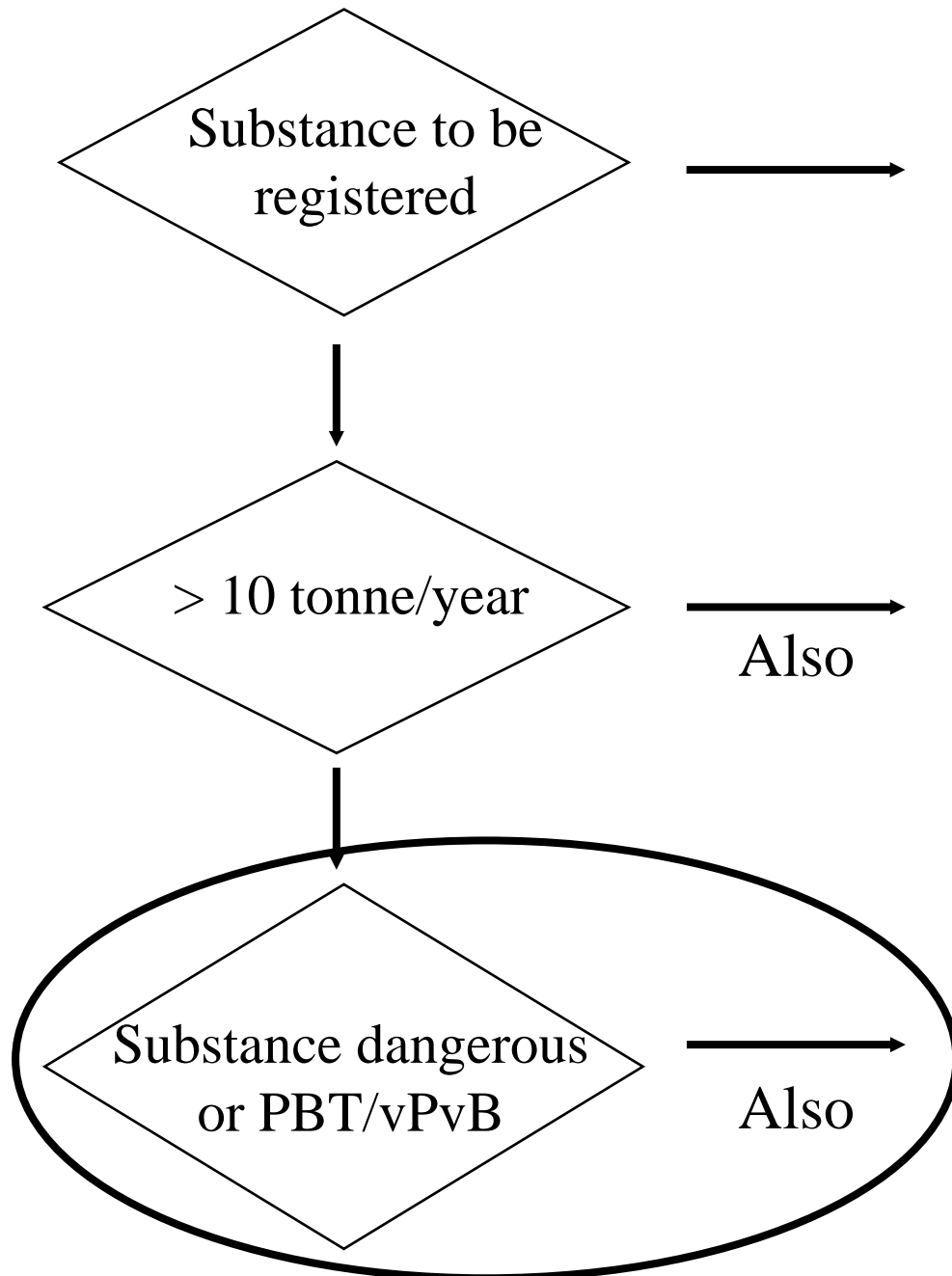




## Generation of information on intrinsic properties Hazard and PBT assessment

- Generation of information on inherent properties
  - Collect all available information
  - Compare with standard information requirements (tonnage dependant) and identify information gaps
    - Consider adaptations (triggering or waiving of test)
  - Generate further information or make a testing proposal
- Hazard Assessment
  - Classification and labelling (C&L)
  - Dose/concentration-response; No-effect levels (Derived or Predicted no-effect levels/concentrations DNELs/PNECs) or other measure of potency
- Assess whether substance has PBT or vPvB properties

## Registration dossier - content



### Technical Dossier

- Identify of the manufacturer/importer
- Identity of substance
- Info- manufacture and use of the substance
- Classification and labelling
- Guidance on safe use of the substance
- Study summaries – substance properties
- Test proposals (if relevant)
- Exposure information

### Chemical Safety Report

- Hazard and PBT Assessment

### Chemical Safety Report

- Hazard and PBT Assessment
- Exposure Assessment
  - Exposure Scenarios
  - Exposure Estimation
- Risk Characterisation



## What is an Exposure Scenario (ES) ?

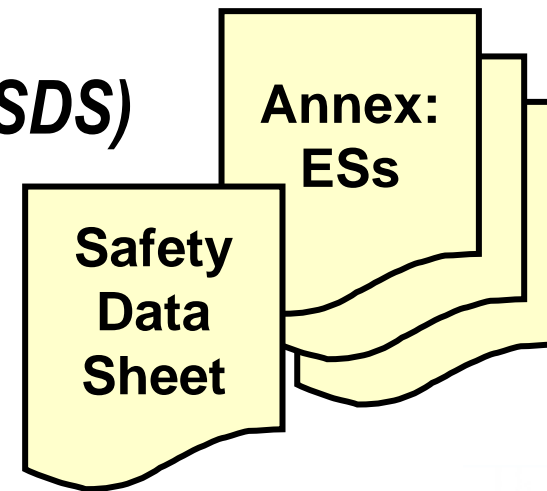
- Conditions for use:
  - Process description
  - Operational conditions (incl. quantity used, frequency and duration of specified operations)
  - Risk Management Measures
    - process control (e.g. closed system and local exhaust)
    - emission control
    - personal protective equipment
    - good hygiene / working practise
    - etc.
  
- Other relevant information



## How will the user know?

Exposure Scenarios will be attached to the Safety Data Sheet (SDS)

-> ***Extended Safety Data Sheets (e-SDS)***





# Exposure Scenario Content/Template

Title and covered activities	
1	Short title of the exposure scenario
2	Processes and activities covered
Operational Conditions	
3	Duration and frequency of use
4.1	Physical form of substance or preparation;
4.2	Concentration of substance in preparation or article
4.3	Amount used per time or activity
5	Other relevant operational conditions of use
Risk Management Measures	
6.1	Risk management related to human health (workers, consumers)
6.2	Risk management measures related to the environment
7	Waste management measures
Reference to exposure prediction	
8	Exposure prediction and reference to its source
9	Guidance to DU to check whether he is working within ES



# Overview of CSA process

**Information: available ⇔ required/needed**

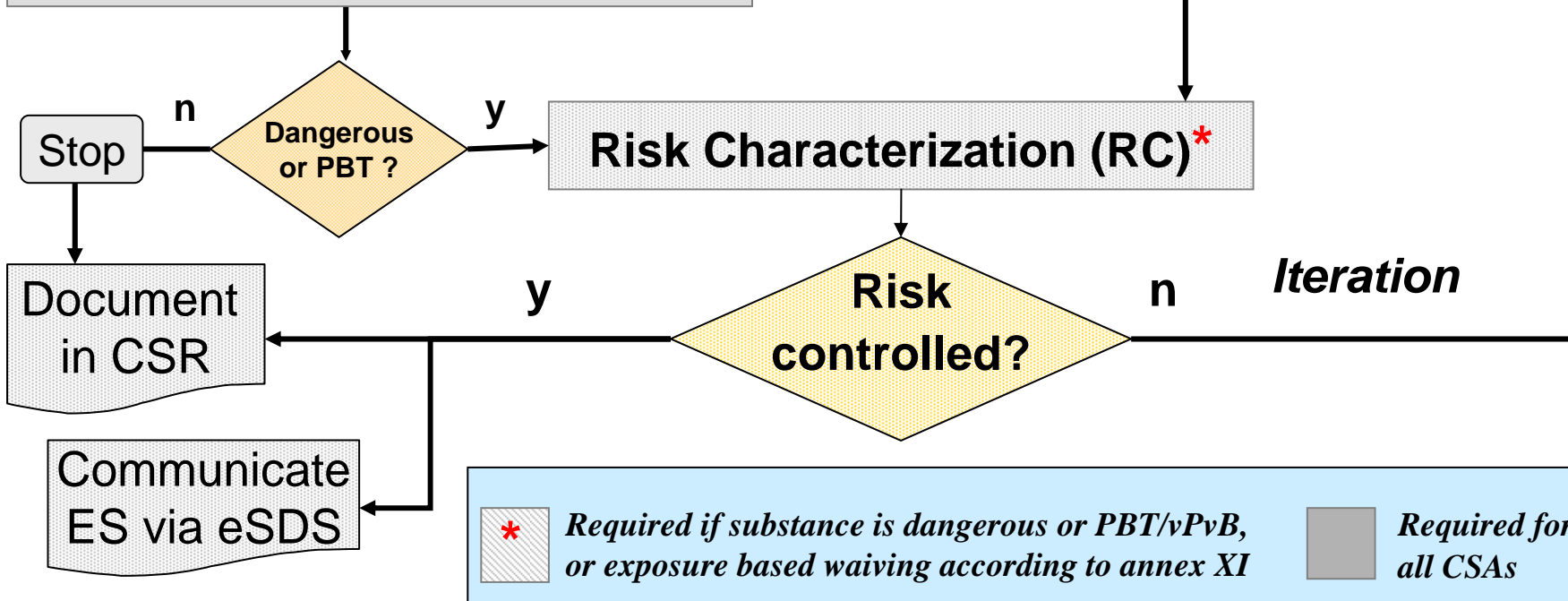
- substance intrinsic properties
- manufacture, use, tonnage, exposure, risk management

### Hazard Assessment (HA)

- Hazard Classification and PBT conclusion
- Dose/Concentration-Response Characterisation

### Exposure Assessment (EA)\*

- Build Exposure Scenarios (RMM and OC)
- Estimate Exposure Level





# Exposure Scenarios from the Downstream User point of view

# The Downstream User



## Must:

- Implement Operational Conditions and Risk Management Measures communicated to him via the exposure scenarios in the SDS Annex
- If he uses the chemical outside the conditions described in the exposure scenario(s)
  - Inform his supplier of this use to make it an identified use
  - Alternatively:
    - Conduct a safety assessment for his own use (and for his downstream uses if he is a supplier)
      - and implement ES from own safety assessment
      - and report to the Agency
    - Switch to another supplier
- Communicate further down the supply chain if he is supplier



## Guidance



- Guidance on Information Requirements and Chemical Safety Assessment (first version to be published on the ECHA web-site before 1 June 2008)
  - Guidance was, between others, developed based on an array of exposure scenario case studies conducted by industry organisations and companies
  - Chemicals industry (CEFIC in cooperation with downstream user organisations) is working on making exposure scenarios examples based on the case studies available
  - Risk Management Measures (RMM) library developed as part of the guidance development project is made available via the CEFIC web-site
- Guidance on Downstream User requirements (available via the ECHA web-site)



## Who will use the CSA Guidance ?

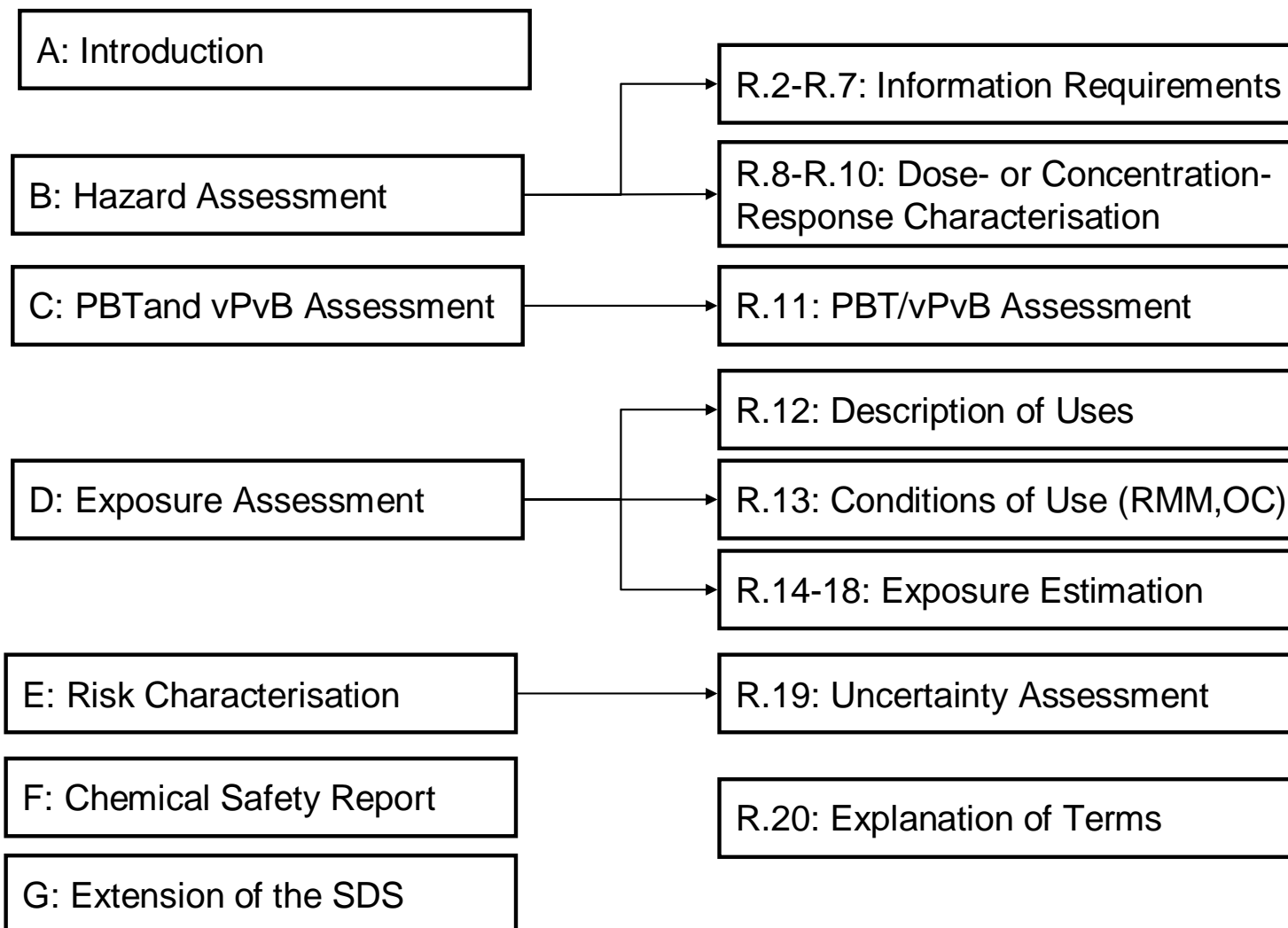
- Manufacturers of substances > 10 t/a
- Importers of substances (> 10 t/a) as such (or as part of preparations)
- Downstream users who need or want to make their own chemical safety assessment
- Producers and importers of articles when they have to register substances intended to be released
- Manufacturers, importers and downstream users preparing or updating a CSA/CSR as part of applying for an authorisation
- Authorities using the Guidance as a reference for activities related to assessment and control of risks under evaluation, authorisation or restriction procedure.



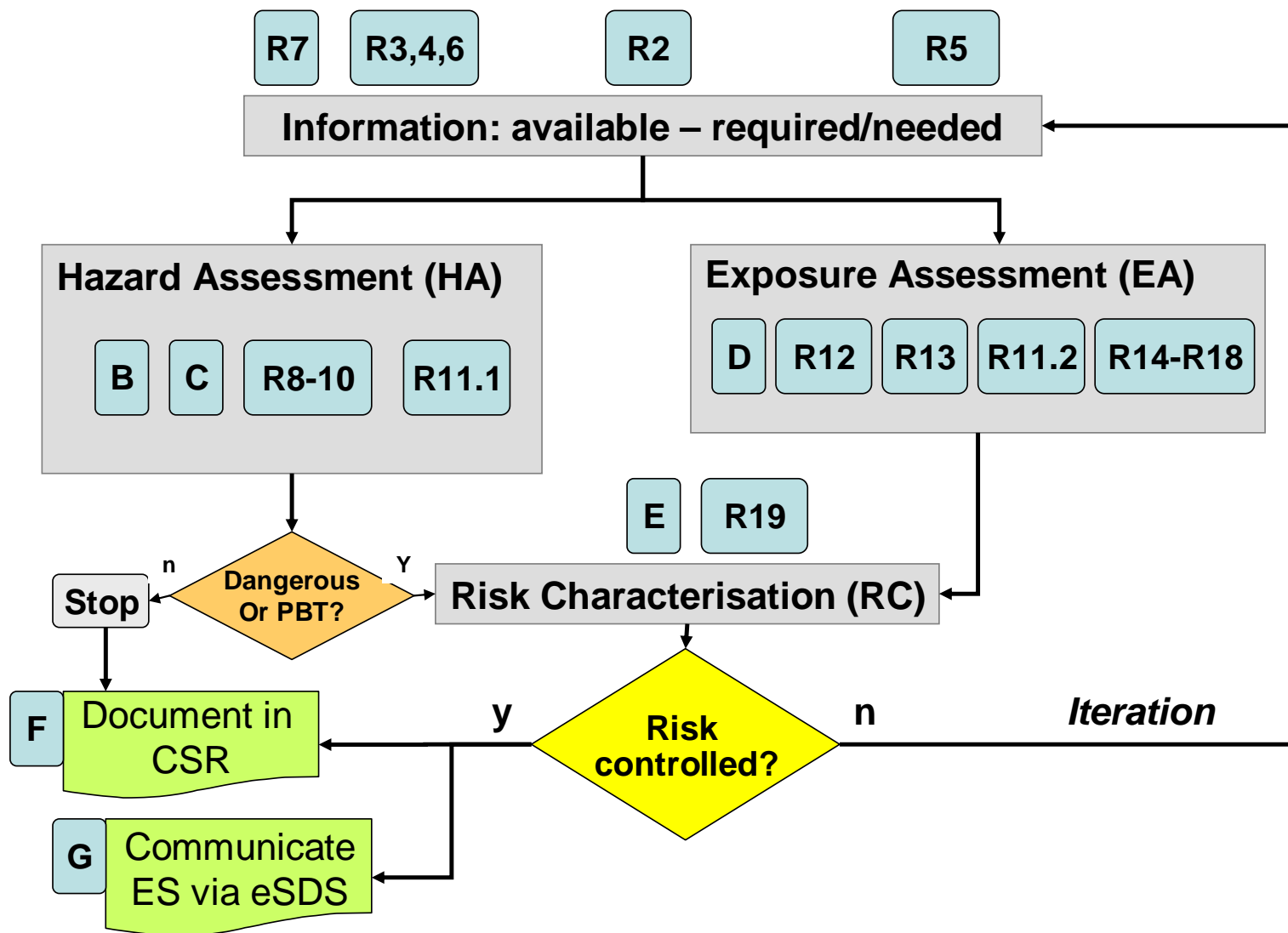
# Guidance on Information Requirements and Chemical Safety Assessment

— Concise Guidance —

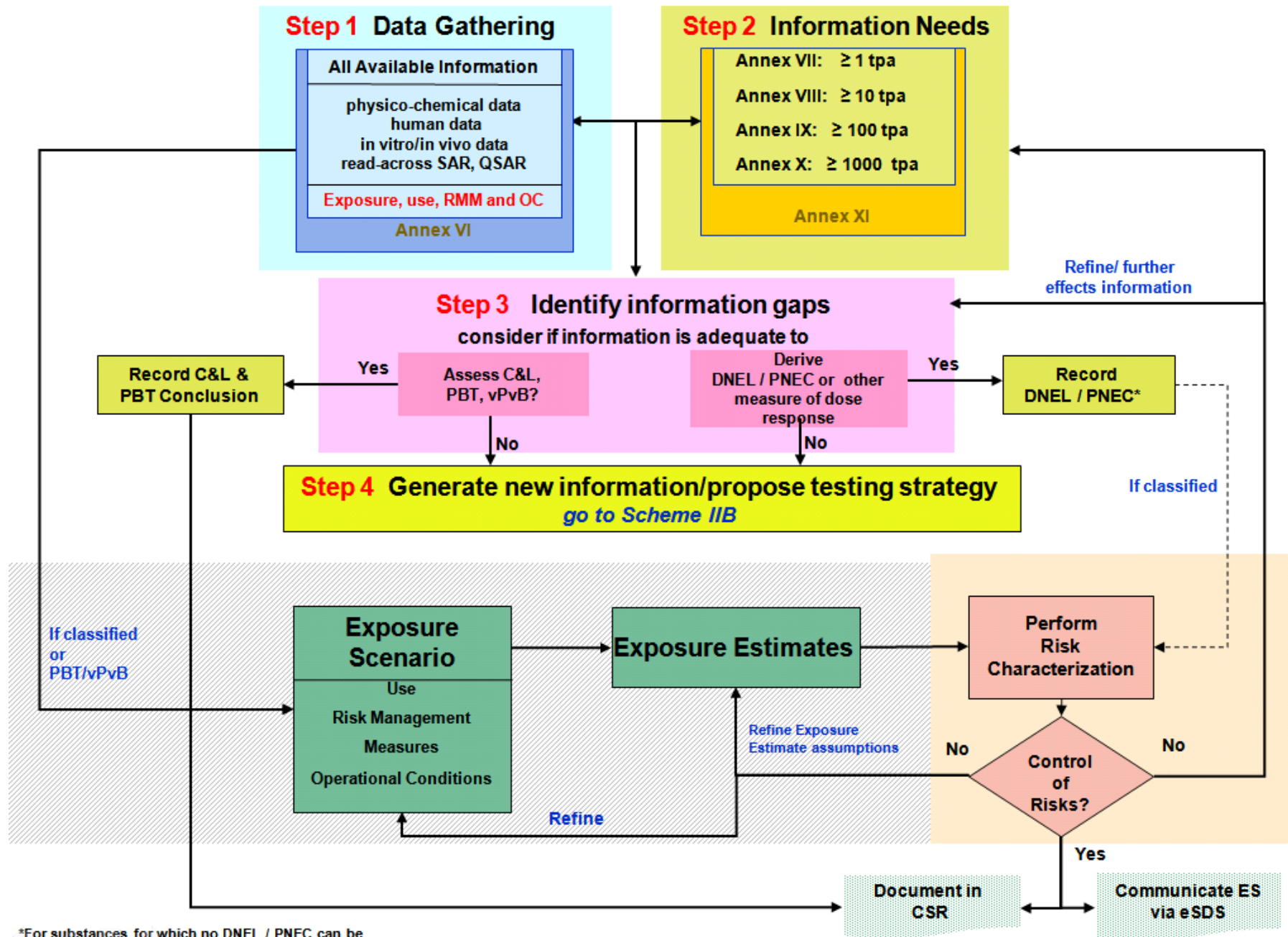
— In Depth Guidance —



# Guidance on Information Requirements and Chemical Safety Assessment

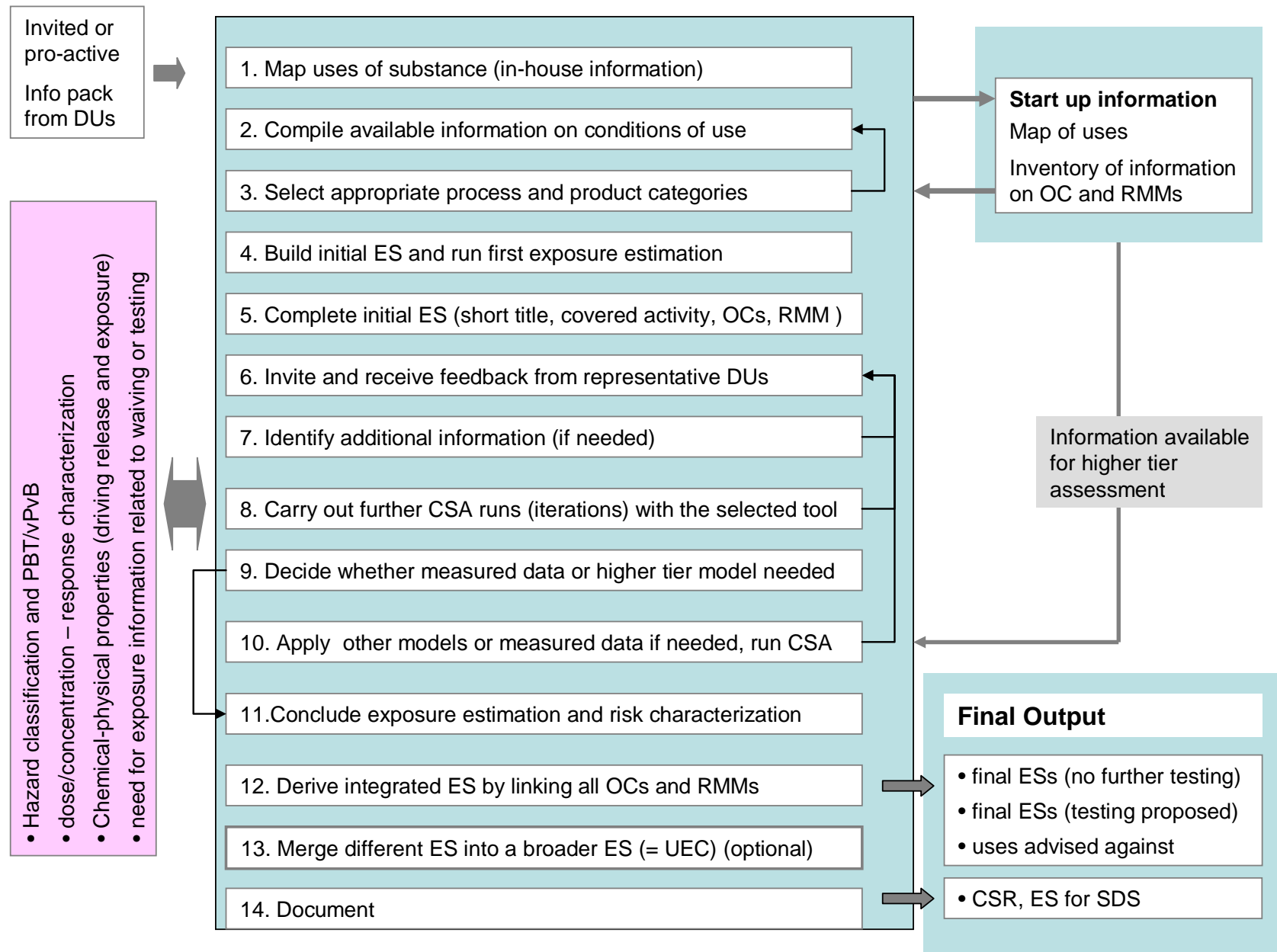


# Info on intrinsic properties and hazard assessment



\*For substances for which no DNEL / PNEC can be derived – perform a qualitative risk characterisation

# Workflow for generation of Exposure Scenarios





# Building Exposure Scenarios



## Initial Exposure Scenarios

- Short title
- Operational conditions (OC)
- Risk management measures (RMM)



## Final Exposure Scenarios

- Short title
- Operational conditions (OC)
- Risk management measures (RMM)



If risks are not controlled



## Decisions by M/I

- Refine hazard assessment
- Refine exposure estimate
- Modify RMM or OC
- Advise against use

# IT tools for developing ES, conducting CSA and preparing CSR

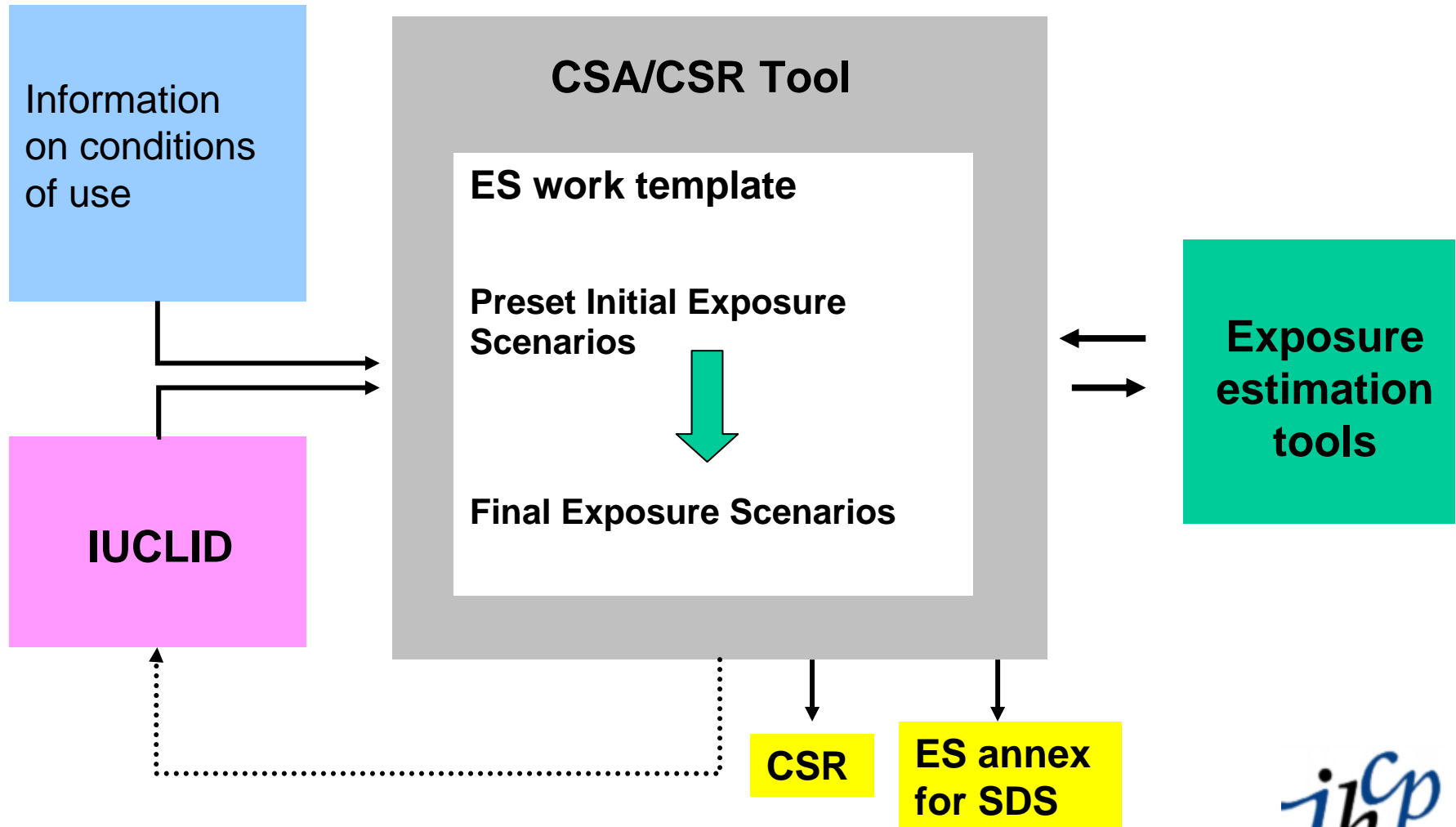


- “Analysis and Design” study April 2007 – March 2008
  - Based on the outcome of RIP 3.2
  - Strong focus on Exposure Scenarios
  - Existing exposure estimation models and tools are taken into account
    - Challenge is that existing tools do not normally (transparently) include or describe how Operational Conditions and Risk Management Measures are included
  - > Further development needed to make tools REACH compliant
- ECHA is currently preparing a call for tender for building the 1<sup>st</sup> generation of CSA-CSR tool
  - CSR template (1 June 2008)
  - IUCLID plug in for CSR generation (summer 2008)
  - First version of ES/CSA/CSR tool (2009)



# IT tools for developing ES, conducting CSA and preparing CSR

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# Conclusions – 1



## REACH Registration

- Manufacturers and importers
- Obtain/generate information on their substances and
- Use this knowledge to enable well-informed management of the risks that substances may cause throughout their life cycle
- Cooperation with Downstream Users



## Conclusions – 2



- Exposure scenarios play a very important role by giving use conditions for controlling risks
- Exposure Scenarios are:
  - developed in the *iterative* Chemical Safety Assessment (CSA)
  - recorded/documentated in the Chemical Safety Report (CSR)
  - communicated to downstream users as annexes to Safety Data Sheets (SDSs)
- Managing risks becomes an integral part of the Chemical Safety Assessment (new mindset!)
- Communication between DU and M/I should take place before registration.
- Guidance: (Soon) available via ECHA web-site
- Supporting IT tools and examples: Under development



**Thank you for your attention !**