



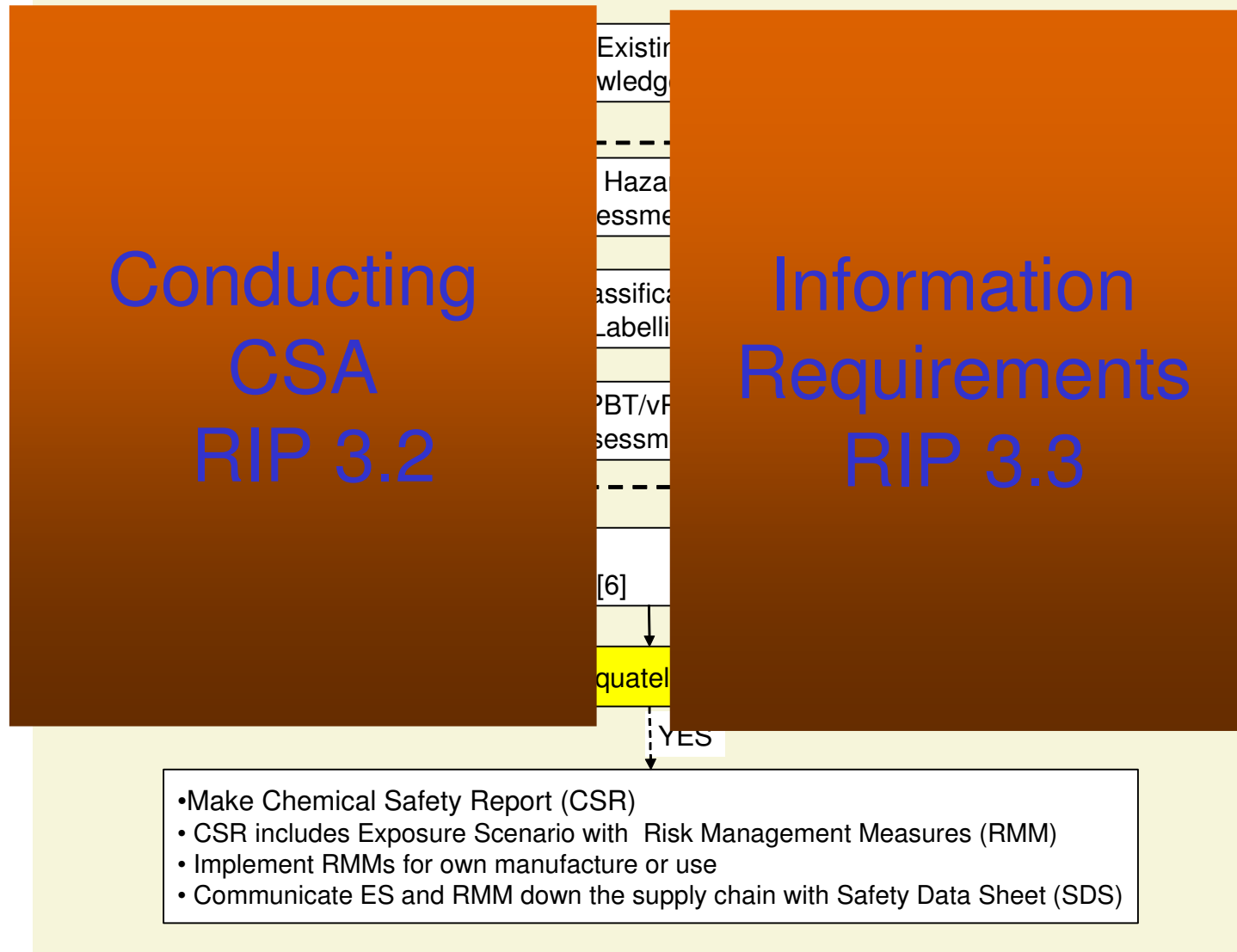
# **CSA/CSR and information requirements**

**Train the trainer on REACH and RIPs  
05 – 06 Mar 2008, Cracow, Poland**



Leo Heezen

# Process of chemical safety assessment





## RIP 3.3

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# Information requirements

# RIP 3.3: Guidance on information requirements for REACH

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To enable Industry:

- ✓ To do the hazard assessment
- ✓ To do the PBT and vPvB assessment
- ✓ To determine the classification and labelling
- ✓ To establish the DNEL (s)
- ✓ To establish PNEC

Under the condition of:

- ✓ Minimal use of animal testing

# Information requirements as defined in REACH



Annex VI	General information, C&L, Guidance on safe use, Exposure info for volume 1-10t/y/M,I
Annex VII	Substances in quantities of 1 ton or more
Annex VIII	Substances in quantities of 10 ton or more
Annex IX	Substances in quantities of 100 ton or more
Annex X	Substances in quantities of 1000 ton or more
Annex XI	Adaptations of the standard Testing regime

## RIP 3.2

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# Guidance on conducting a CSA/CSR

# What is in the guidance?



- 
- Chemical safety assessment process
  - Exposure scenario's,
    - **What are they**
    - **When are they needed (lifecycle)**
    - **Steps in the development**
  - ES format and examples
  - Identified Use and Use Descriptor system
  - Making of ES, some practical examples
  - Communication process
  - Concluding remarks
  - Next steps

# Chemical safety assessment Process



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Risk assessment is the „new“ part of the chemicals legislation as the focus of REACH moved from „hazard assessment“ to „risk assessment“:

**Hazardous properties + exposure estimate = risk characterisation**

**Exposure estimation is an area that is less developed than hazard assessment and will pose significant challenges**

**“Safe use” is demonstrated:** exposures are evaluated against:

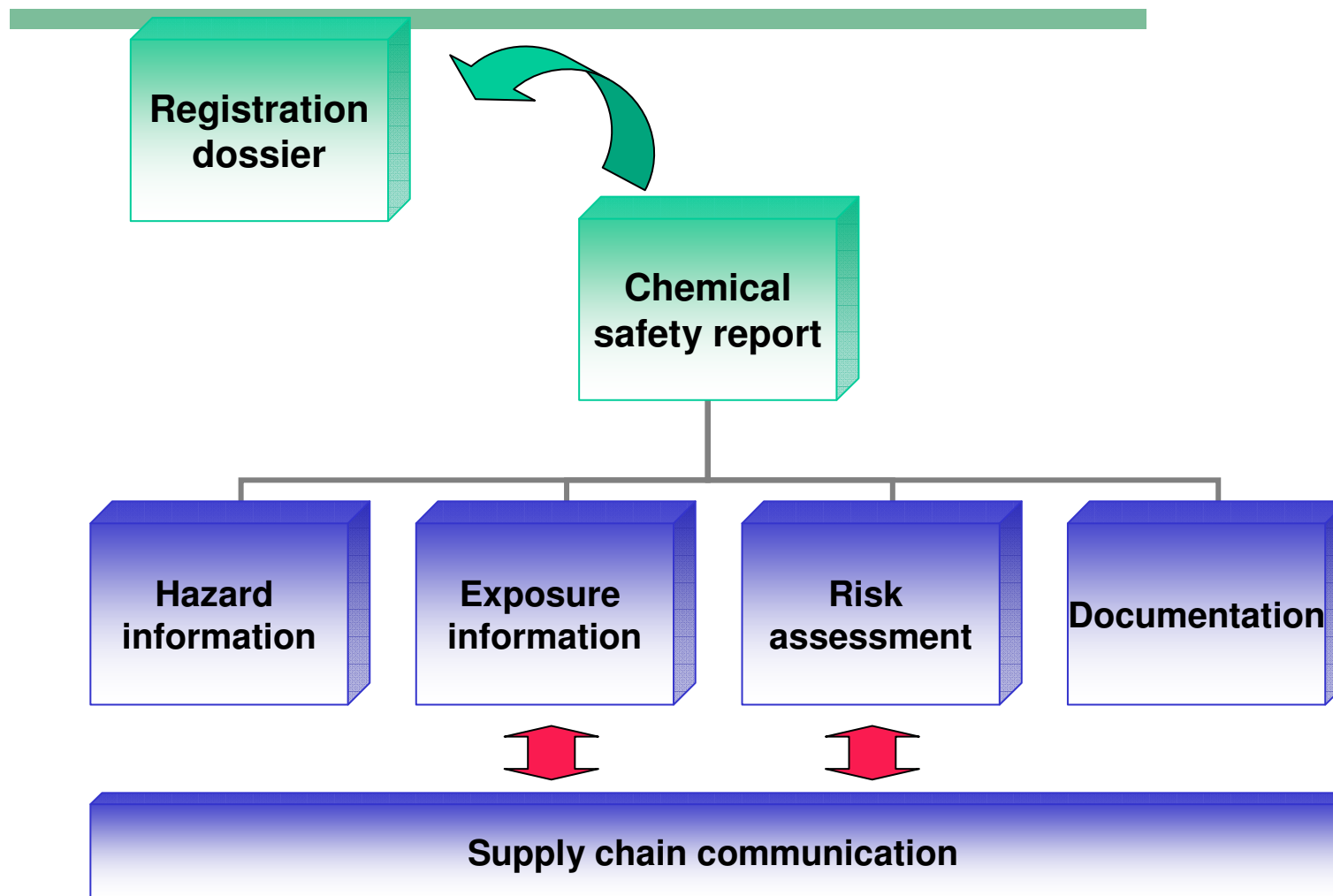
- **DNEL** = derived no effect level (human health)
- **PNEC** = predicted no effect concentration (environment)

workers: well established health based Occupational Exposure limit values can be used to set DNEL's

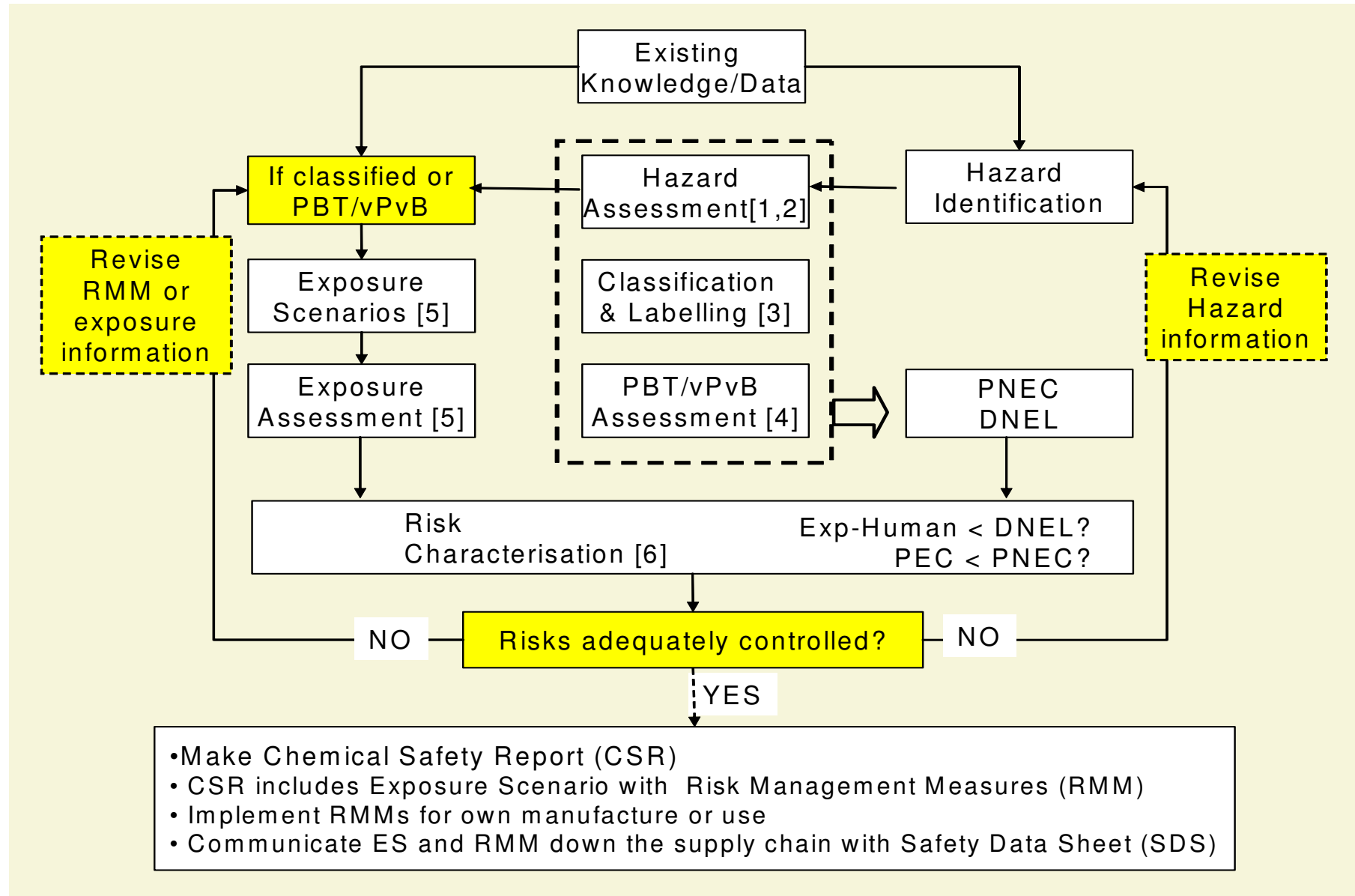
**Safe use will be documented and communicated through Exposure Scenario's**



# Chemical Safety Assessment, the registration dossier



# Process of chemical safety assessment



# What is an exposure scenario?



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A description of safe use by describing

- **Conditions of use**
- **Risk management measures**
- **“Algorithm” to be used by DU for validating safe use**

ES covers all activities and processes within the value chain

- **Production: chemical synthesis of the substance and use as intermediate**
- **Formulation: mixing and blending into a preparation**
- **Industrial, professional use**
- **Consumer exposure and private use**
- **Service life**
- **Waste Life stage**

# When are Exposure Scenario's needed?



Exposure Scenarios and CSAs need to be included in the CSR if

- The substance is classified as dangerous **or**
- The substance is a PBT or vPvB **and**
- Produced or imported in excess of 10 t/a
- In a preparation in a concentration below limits indicated in article 14

DU can choose to do his own CSA/CSR **unless**

- no SDS needs to be provided
- The supplier is not required to develop a CSA
- The tonnage limit is < 1 t/a
- The uses downstream should also be taken into account
- **Exposure scenarios need to be developed for all identified uses**

# CSA endpoints & tools



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## Health, Occupational

- Ecetoc TRA, COSHH-BAuA (under development: EASE future, Stoffenmanager)

## Health, Consumers

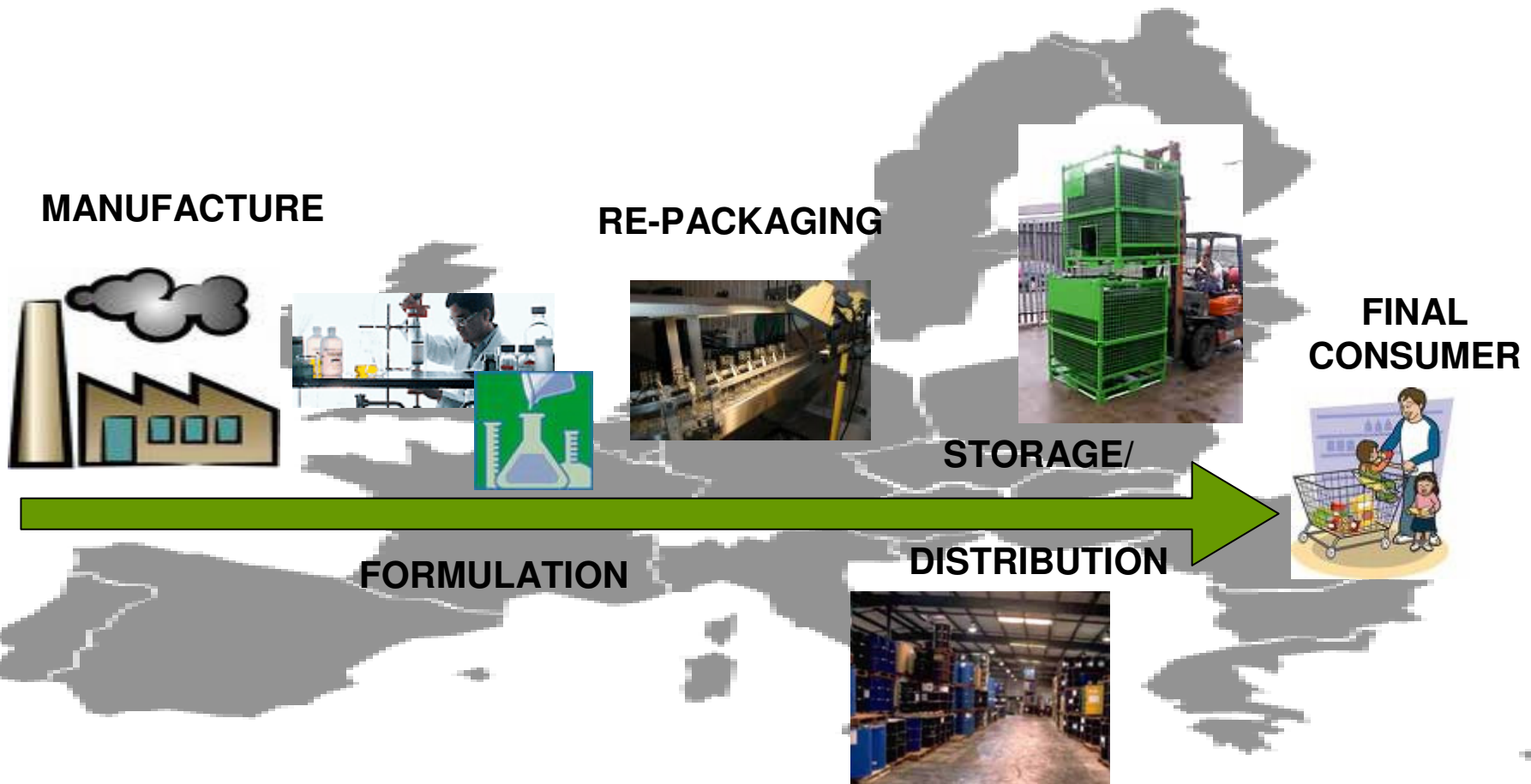
- Consexpo, EUSES

## Environment:

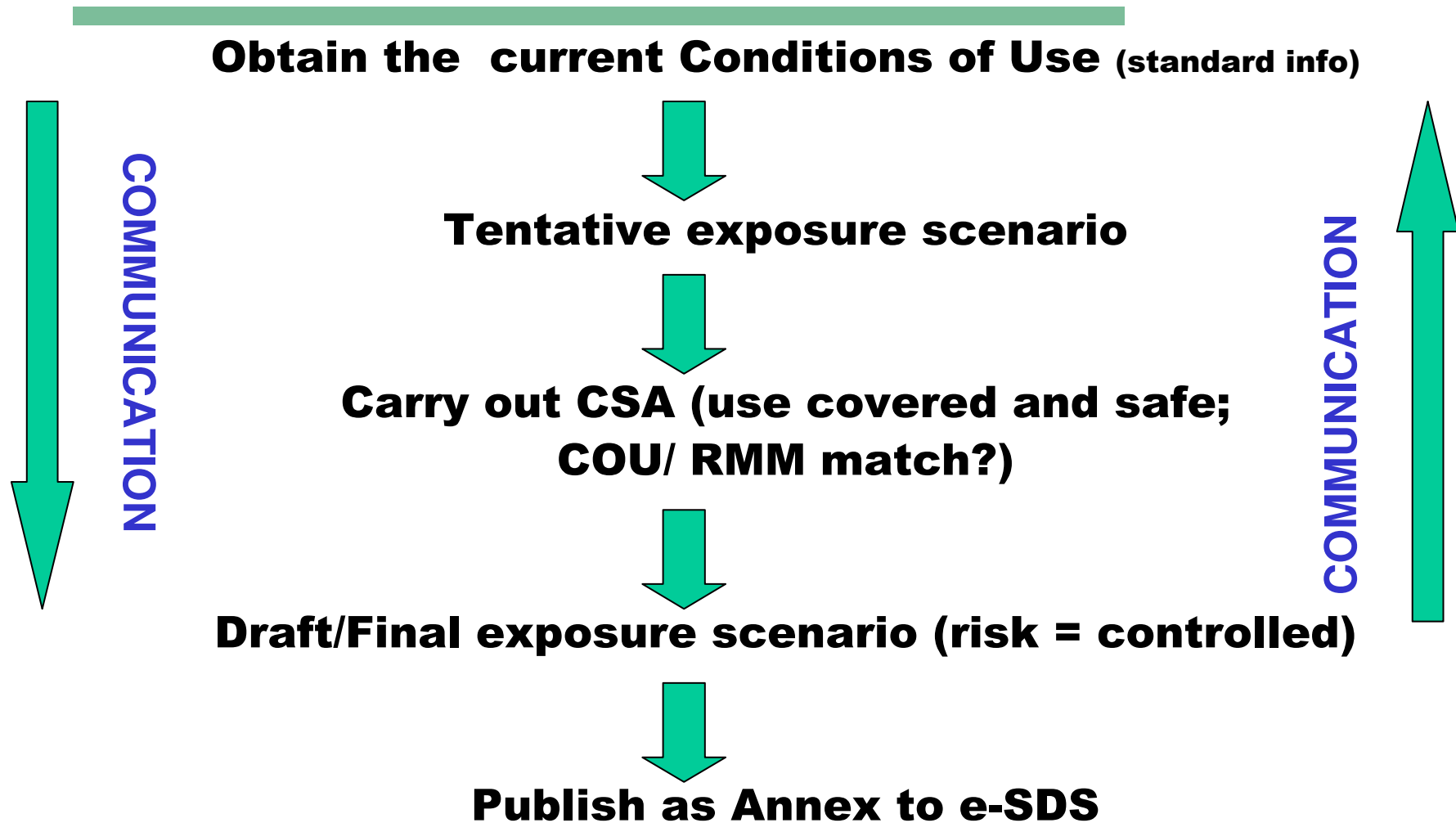
- EUSES, Ecetoc TRA

Input data: use of local ventilation, duration of activity, phys chem properties, concentration of substance in product etc..

# COMPLEX SUPPLY CHAINS



# Steps in the development ES



# Elements of an Exposure Scenario

**Table D- 2: Standard format of a final Exposure Scenario**

	ES Entry	Information
1	Short title of the exposure scenario	
2	Processes and activities covered	
3	Duration and frequency of use	
4.1	Physical form of substance or preparation; surface to volume ratio of articles;	
4.2	Concentration of substance in preparation or article	
4.3	Amount used per time or activity	
5	Other relevant operational conditions of use	
6.1	Risk management measures related to human health (specified for workers or consumers)	
6.2	Risk management measures related to the environment	
7	Waste management measures	
8	Exposure prediction and reference to its source	
9	Guidance to DU to evaluate whether he works inside the boundaries set by the ES	



# Use and identified use



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**Use: any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization.**

Identified use:

**If an actor in the supply chain (intends to) use(s) a substance on or places it on market for certain use(s) (directly or via distributors) or is informed by one of his immediate downstream users on a use existing or intended.**

- then registrant may include identified use in registration dossier

Descriptor system (not final yet)

**Sectors of Use, 22 options, example, SU1 Agriculture, forestry, fishery,**

- Product Category, 39 options , PC1 Adhesives
- Process Category, 20+ options, PROC1 use in closed systems, no likelihood of exposure
- Article Category,
  - Not intended release 20, options, AC02 Passenger cars and motor cycles
  - Intended release (in development)

# Identified use (Example 1)



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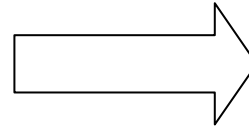
**Substance X is used in building and construction work (SU19) and in the general public domain (SU22) in Coatings and Paints, Fillers, Putties, Thinners (PC9) by professional spraying outside industrial settings and/or applications and roller or brushing application (PROC)**

# Examples of Process categories

Table D-A.3: Descriptor for process categories [PROC]		
	Process categories based on TRA categories for workers <sup>21</sup> ;	Examples and explanations
PROC1	Use in closed process, no likelihood of exposure Industrial ;	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems.
PROC2	Use in closed, continuous process with occasional controlled exposure (e.g. sampling) Industrial;	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions  It is not high integrity and occasional expose will arise e.g. through maintenance, sampling and equipment brakings
PROC3	Use in closed batch process (synthesis or formulation) Industrial;	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises Industrial;	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during the charging, the sampling or discharge of material, and when the nature of the design is likely to result in exposure.
PROC5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) Industrial;	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage.
PROC6	Calendering operations Industrial;	Processing of product matrix Calendering at elevated temperature an large exposed surface

# Identified use (Example 2)

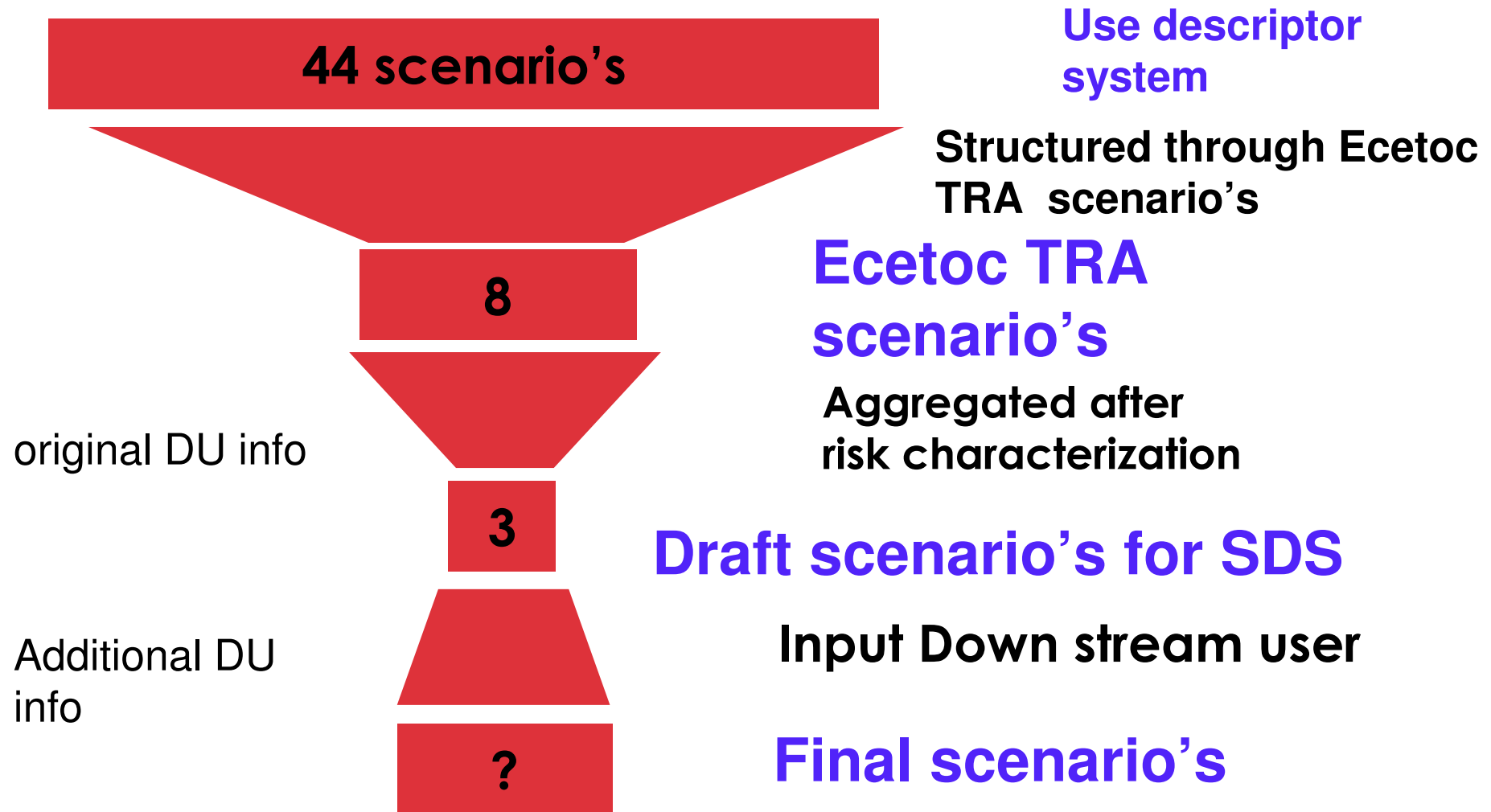
10 product category +  
8 process category



44 combinations

Preparation category Process Category for industrial and professional use		Inter media to PC19	Texti le dyes PC 34	Adhesiv es Sealants PC 1	Aut o. Car PC 6	Coatin gs Paint PC 9	Building constru ct. PC 10	Ink& Toner s PC 18	Polish es &Wax PC 31	Washin g Cleanin g PC 35	Lubri - cant sPC 24	Hobb y Artis t PC 5
<b>PROC 2</b>	<b>Continuous processing operations/occasionally controlled exposure</b>	X	X	X		X		X	X	X		
<b>PROC 5</b>	<b>Mixing/blending in batch process; multi-stage, significant contact</b>	X	X	X		X		X	X	X		
<b>PROC 9</b>	<b>Transfer to small containers (dedicated filling line)</b>	X	X	X	X	X	X	X	X	X	X	
<b>PROC 10</b>	<b>Handling, cleaning of treated surfaces</b>		X		X	X	X	X	X	X		
<b>PROC 13</b>	<b>Immersion operations</b>		X	X	X	X				X		
<b>PROC 11</b>	<b>Air dispersive techniques</b>		X		X	X	X					
<b>PROC 10</b>	<b>Low energy spreading</b>		X		X	X	X	X	X	X		
<b>PROC 15</b>	<b>Laboratory operations</b>	X	X			X		X	X			

# ECETOC TRA approach



Set of standard core information on conditions of use contained in an Exposure Scenario (Draft)

<b>1. Short title of Exposure Scenario</b> <sup>[1]</sup>	<b>Water soluble solvent MANUFACTURE AND FORMULATION in Industrial and professional use</b>
<b>2. Description of activities/process(es) covered in the Exposure Scenario</b>	<ul style="list-style-type: none"> <li>• <b>Use in a continuous systems with process sampling</b></li> <li>• <b>Formulating via batch processes</b></li> <li>• <b>Dis/charging</b></li> <li>• <b>Filling of containers</b></li> <li>• <b>Use as laboratory agent (for QA purposes).</b></li> </ul>
<b>3.Operational conditions</b>	<b>Process is carried out under room temperatures at atmospheric conditions</b>
<b>3.1 Duration and frequency of use for which the RMM ensure adequate control of risk</b>	<b>&gt;4 hrs/day, 200 days per year</b>
<b>3.2 Max amount used</b>	
<b>•Concentration</b>	<b>100% v/v</b>
<b>•Temperature</b>	<b>Room temperature, unless handled in a closed system</b>
<b>4. Physical form of product</b>	<b>Liquid</b>
<b>5. Product specifications (Concentration or percentage of substance in preparation or article applied)</b>	<b>See section 2 of SDS</b>

<p><b>6. Risk management measures determining exposure</b></p>	
<p><b>•Occupational measures following the hierarchy of Directive 98/...; impact of single options or combination of options on exposure to be quantified; options to be phrased as instructions</b></p>	<p><b><u>Use in closed system:</u></b>  <b>W7.01 Closed dosing, transfer, sampling and application system including connectors</b>  <b><u>Apply local exhaust ventilation</u></b>  <b>W15 ex2 Ventilated process enclosures or</b>  <b>W15 ex3 Fume cupboard or</b>  <b>W17 ex1 Local Exhaust Ventilation - with captor hood or</b>  <b>W18 ex1 Local Exhaust Ventilation - with receptor hood for dust</b>  <b><u>In case of skin contact:</u></b>  <b>CW29.01 Use Protective Gloves - Chemical resistant (see for more detail on type of glove section 8)</b>  <b>In case of eye contact:</b>  <b>CW31.02 Use Goggles - Not specified</b>  <b><u>General RMM's</u></b>  <b>W27.02 Personal hygiene</b>  <b>W27.01 Apply General good hygiene and housekeeping</b></p>

<p><b>•Environment related measures; impact of single options or combination of options on exposure to be quantified; options to be phrased as instructions;</b></p>	<p><b>To be developed</b></p>
<p><b>•Consumer related measures</b></p>	<p><b>Not applicable</b></p>
<p><b>7. Waste related measures needed to ensure adequate control of risk at the different life cycle stages (including articles at the end of service life)</b></p>	<p><b>For worker protection see RMM's as defined for Manufacture and Formulation</b></p>
<p><b>8a Prediction of exposure resulting from the conditions as described above</b></p>	<p><b>Predicted worker inhalatory exposure based on ECETOC TRA:</b>  <b>For closed systems : 0.5 ppm</b>  <b>For batch processes: 1.8 ppm</b>  <b>For discharging: 3 ppm</b>  <b>For Filling containers:0.6 ppm</b>  <b>For use as lab agent: 0.1 ppm</b>  <b>Worker dermal exposure is not predicted as the expo-sure should be minimized to prevent irritation effects.</b></p>
<p><b>8 b Derived control thresholds</b></p>	<p><b>none</b></p>
<p><b>9. Set of variables which together indicate safe use</b></p>	<p><b>ECETOC TRA scenario's:</b>  <b>-closed continuous process</b>  <b>-batch process</b>  <b>-dis/charging</b>  <b>-filling</b>  <b>-use as lab agent</b></p>



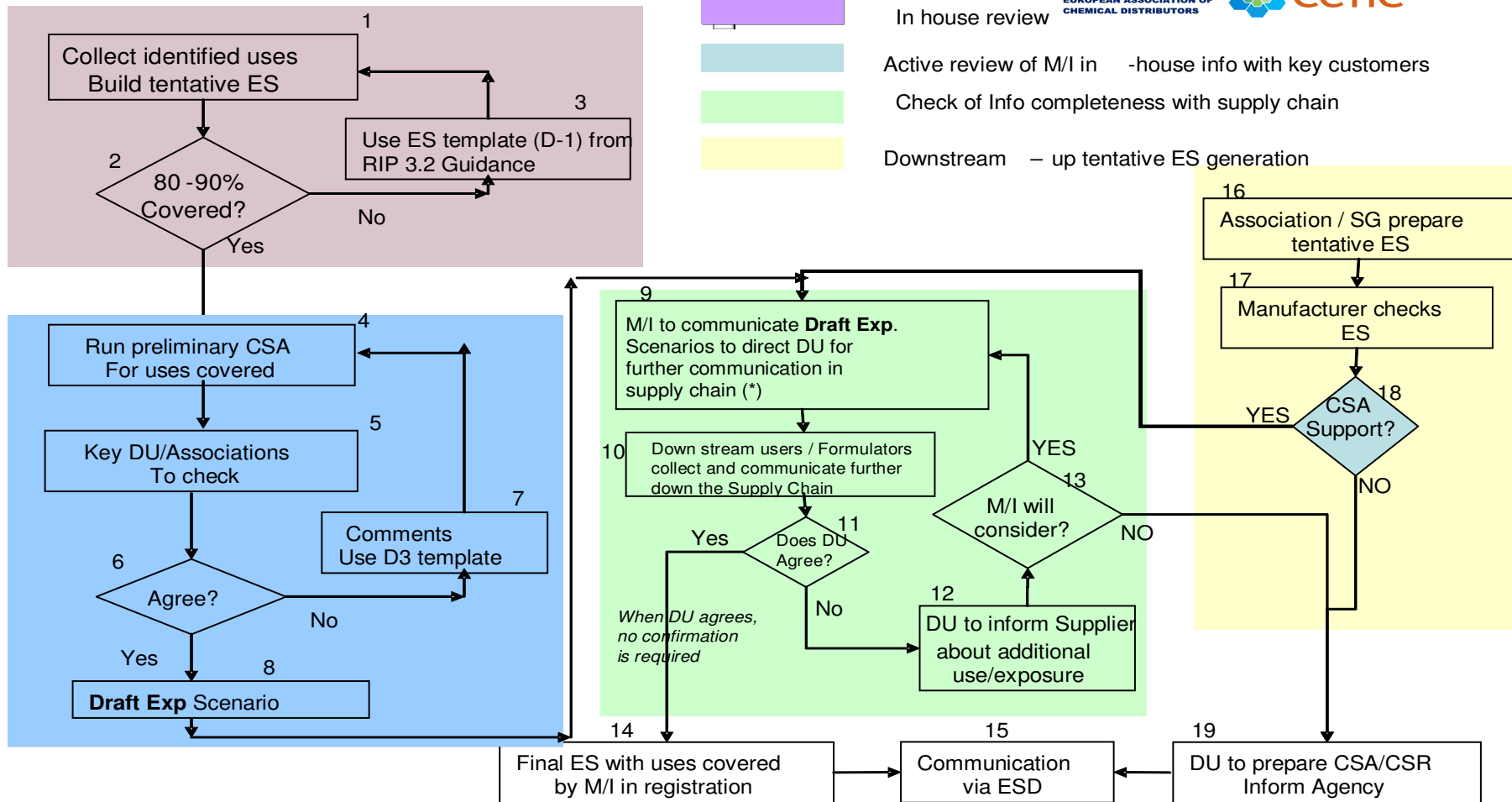
# Exposure scenario's and Communication



- 
- Coding System for Use Applications
  - Top – Down Approach by M/I
  - Tentative Exposure Scenarios tested with first line key customers
  - Draft ES Communication in the supply chain
  - Feedback system
  - Realistic deadlines for feedback
  - No feedback needed if agreement
  - Final Exposure Scenario in eSDS
  - Bottom-up input by Associations, Sector groups etc

# CEFIC Workflow Use & Expose Scenario Communication

## Workflow Use & Expose Scenario Communication



(\*) M/I intends to register by (Registration date). Uses that have been communicated before date x will be included in the Registration process

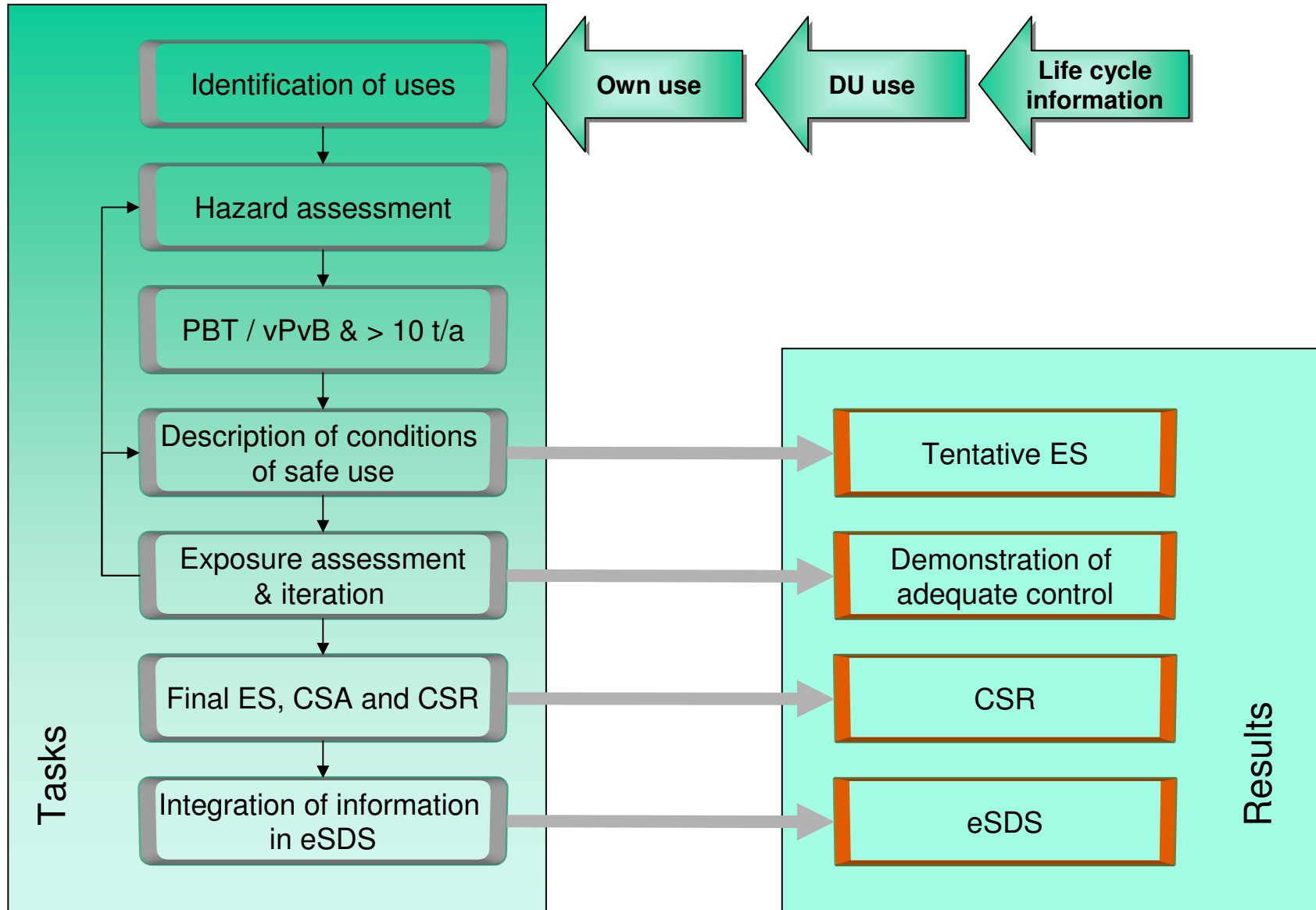
# What will CEFIC develop for communication ?

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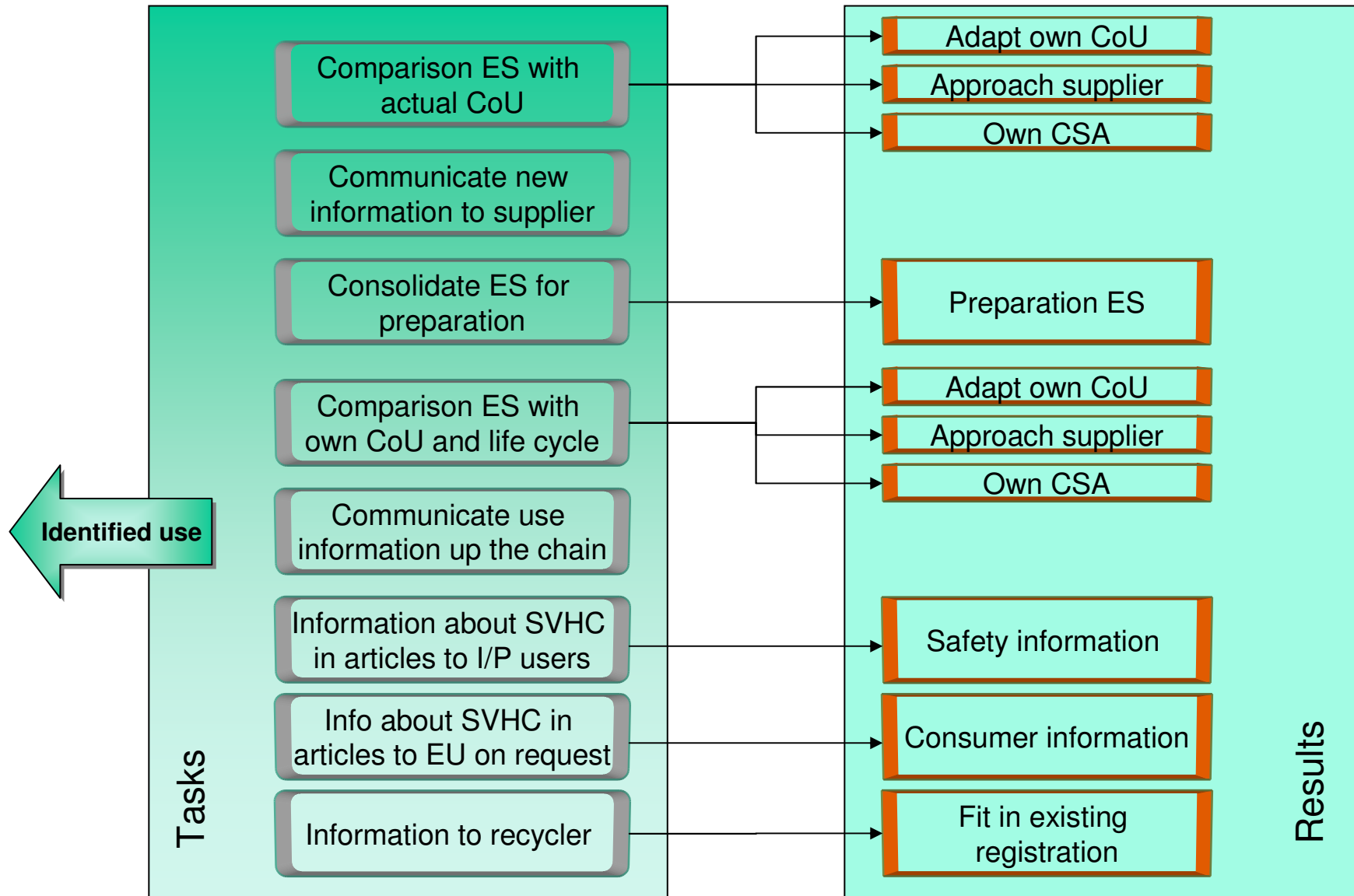


- **Facilitate development of the requirements for IT tools (final outcome RIP processes)**
  - Collection of identified use and input parameters for ES
  - Dialog between M/I and key customers
  - Check completeness with supply chain
- **Development Risk Management Library**

# 15 key tasks – the M/I part of it



# 15 key tasks – the DU part of it



# Conclusion



- 
- Get prepared
    - **Understand work to be done**
    - **Free up resources**
    - **Understand own and/or down stream use and exposures**
  - Consider current work processes
    - **Start dialogue with suppliers and first tier customers.**
    - **Use also standard libraries as developed by RIP 3.2**
    - **Use the Cefic communication tool.**
  - Consider time line
    - **Try to line up with M/I activities**
  - Otherwise it will be chaos!!

# Time line and next Steps



- RIP 3.2 'final' expected early December 2007
- Commercial IT tools available expected early 2008
- Draft Exposure Scenario development 2008-2009, including end use identification
- Tentative Exposure Scenario roll out 2009-2010
  - ❖ **Downstream users to indicate use is covered**
- Final Exposure Scenario, 2010

Note: substances will be on different timelines  
dates are indication only: M/I may consider "early"  
registration, may have its own timeline based on resource  
planning in case many registrations need to be done by  
him.

