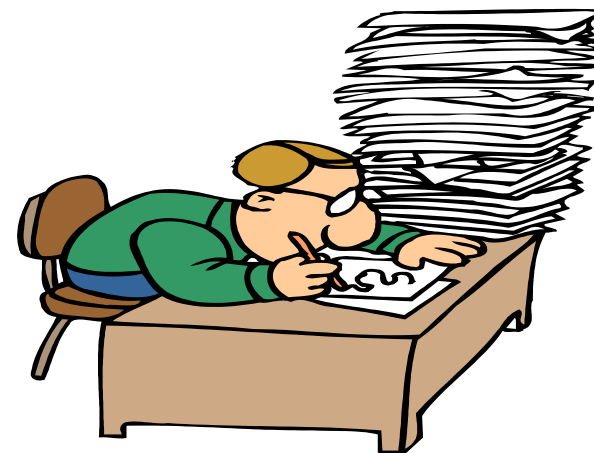




**REACH: The clock started
ticking on 1st June 2007
Today: 314 days have passed!**

Preparation for REACH in The Dow Chemical Company

**Dr. Jan Wilmer
Dow Europe GmbH
Horgen, Switzerland**



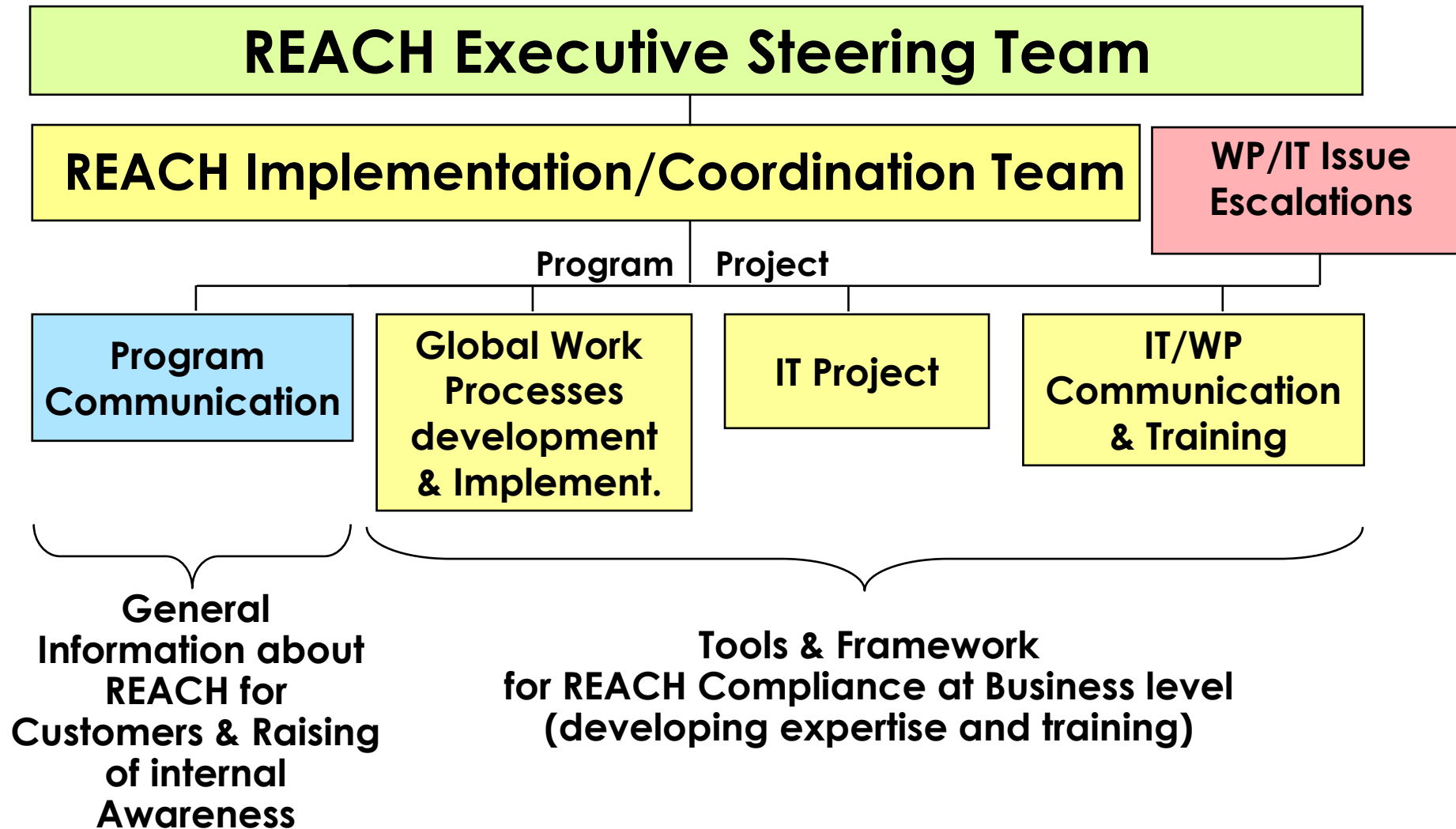


Contents

- **Organisation for REACH in Dow**
- **REACH Preparation – what experts do you need?**
- **REACH pilot projects – what did we learn?**



REACH - Project Organization

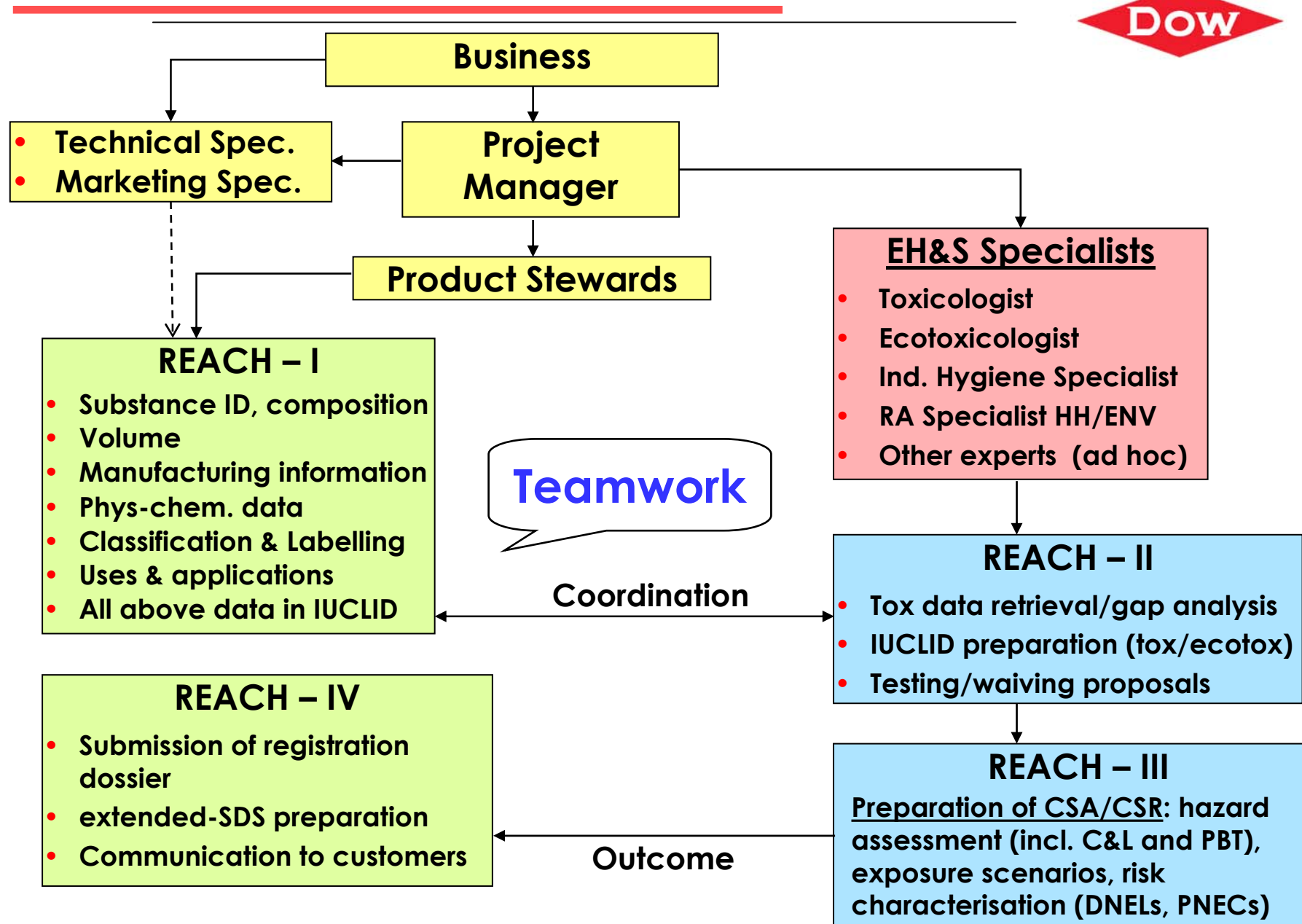




The various steps in preparing a REACH dossier

- Step 1: Substance inventory/substance identity
- Step 2: Data availability/gap analysis – get ready for the SIEF!
- Step 3: IUCLID 5.0 preparation (the core document!)
- Step 4: Hazard Assessment (including classification and labelling, PBT/vPvB assessment and DNEL & PNEC derivation)
- Step 5: Uses, Exposure Scenarios/Exposure assessment
- Step 6: Risk characterisation
- Step 7: Preparing the extended SDS

} CSA/
CSR





Start Early!

Experiences from Pilot Projects



Participation in REACH Pilot Projects

I. November 2004 - February 2005:

- Pilot project to test the entire draft REACH legislation
- Project led by CEFIC (10 companies participating)
- Involvement of Member States and Commission
- Dow participated with category of solvents
- Go & Do team: Marketing/Business, Technical Specialist, Product Steward and Toxicologist



REACH Pilot Project – 2004/2005

- **Hazard assessment**
- **Use information collected - via questionnaire - from:**
 - Dow internal sources (business, sales/marketing, technical specialists)
 - 4 major direct customers (coatings, detergents, metal working fluids, consumer products)
 - One distributor, handling a large volume in a number of member states
- **Building of “exposure scenarios” based on above information**
- **ECETOC TRA Tool (Targeted Risk Assessment) used to estimate exposure for professional workers and consumers**
- **EUSES to estimate environmental exposure**
- **Risk Characterisation: described in a CSA/CSR**
- **Extended Safety Data Sheet (a kind of)**



REACH Pilot: approach for CSA/CSR

Common exposure scenarios derived from input on the use and exposure questionnaire:

1. Manufacturing of the substance (closed system)
2. Discharging to/from vessels
3. Filling of containers
4. Formulating
5. Reagent/solvent use in laboratory
6. Spray painting
7. Roller application or brushing of paints

* Scenario of concern: Spray painting ----- > Risk Reduction



Major Issues

Use information

- In-house knowledge on use of substances – important source
- Direct customers – good information obtained
- Distributors – improvement needed

Risk Assessment/Risk Characterisation for classified substances

- Do we need a full exposure assessment when a substance is only classified for phys-chem. properties?
- Do we need an environmental exposure assessment if a substance is only classified for human health endpoints?
- How to conduct a CSA/CSR for a category of substances?



RIP 3.2 – Testing Project Exposure Scenarios

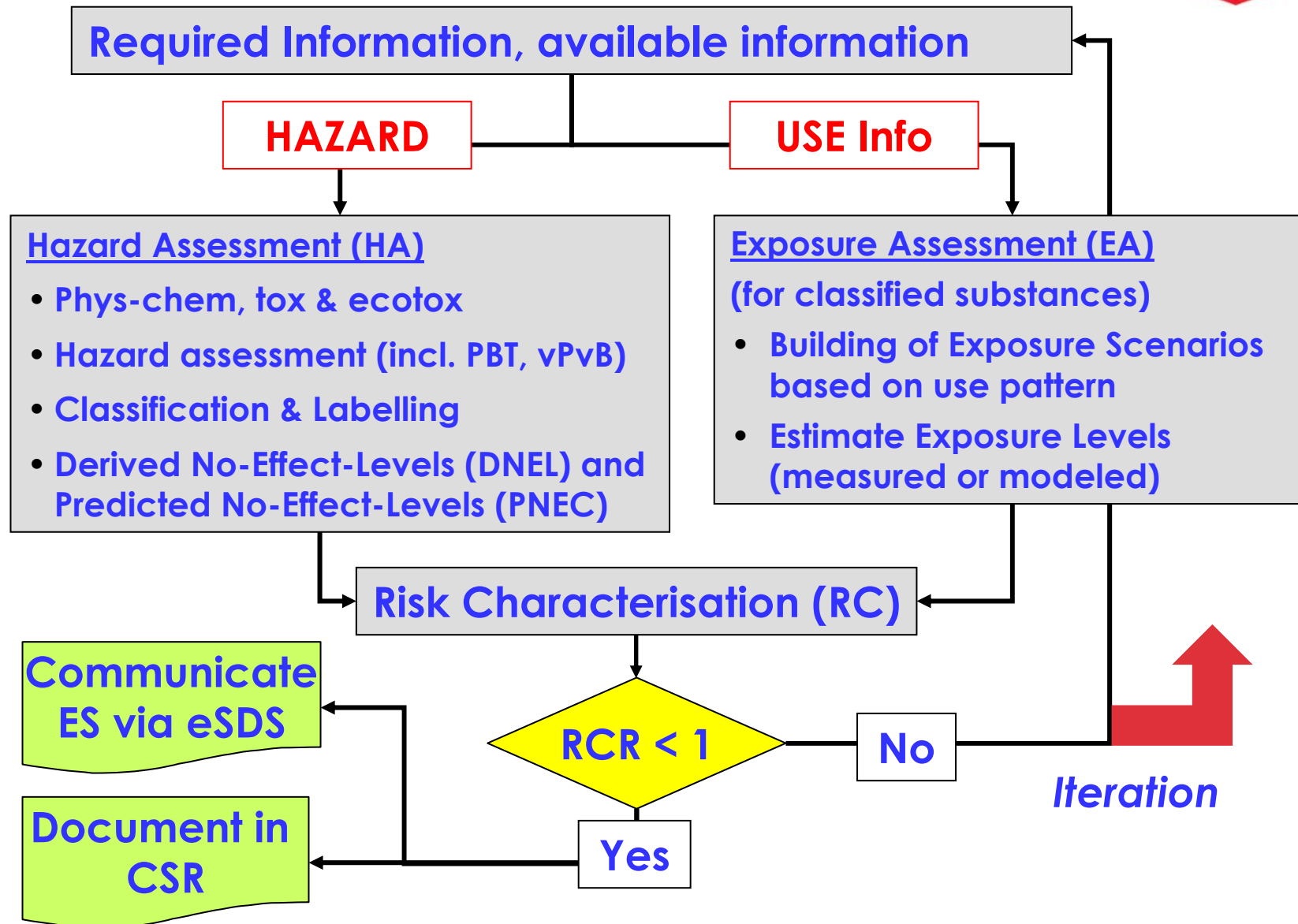


REACH Pilot Projects

II. June - September 2007:

- Testing of draft RIP 3.2 – guidance for CSA/CSR:
- Focus on the preparation of the Chemical Safety Report:
 - » DNEL (for each route of exposure) and PNEC derivation
 - » Map out the uses (“use descriptor system”)
 - » Exposure scenarios and exposure estimates
 - » Develop information for the extended Safety Data Sheet
- CEFIC project – 10 companies participating
- Dow participation with a widely used solvent
- Dow team: Toxicologist, Industrial Hygiene Specialist, Exposure and Risk Assessment Specialists

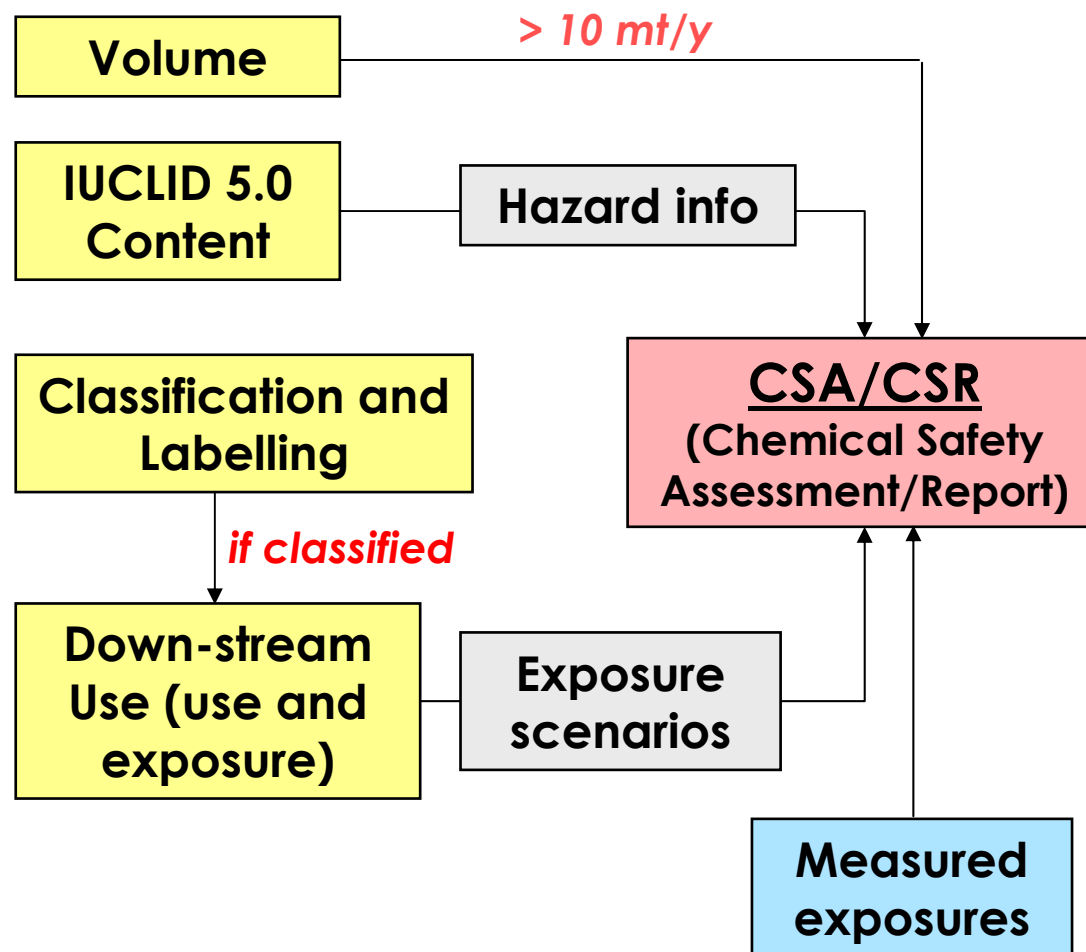
REACH – a simple process!?



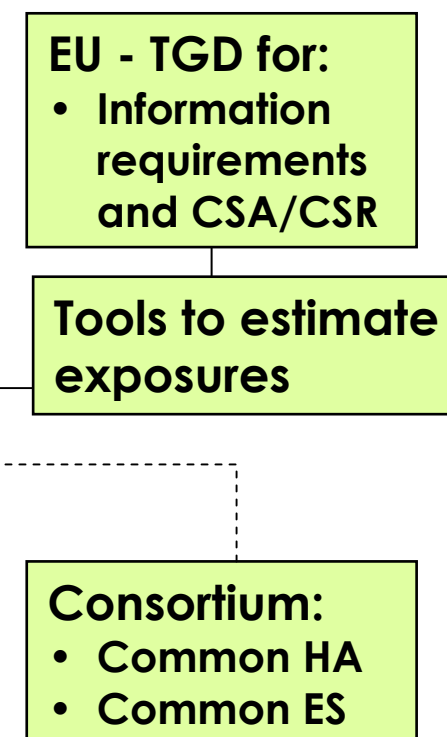


Leverage-in from other “Work Processes”

Internal

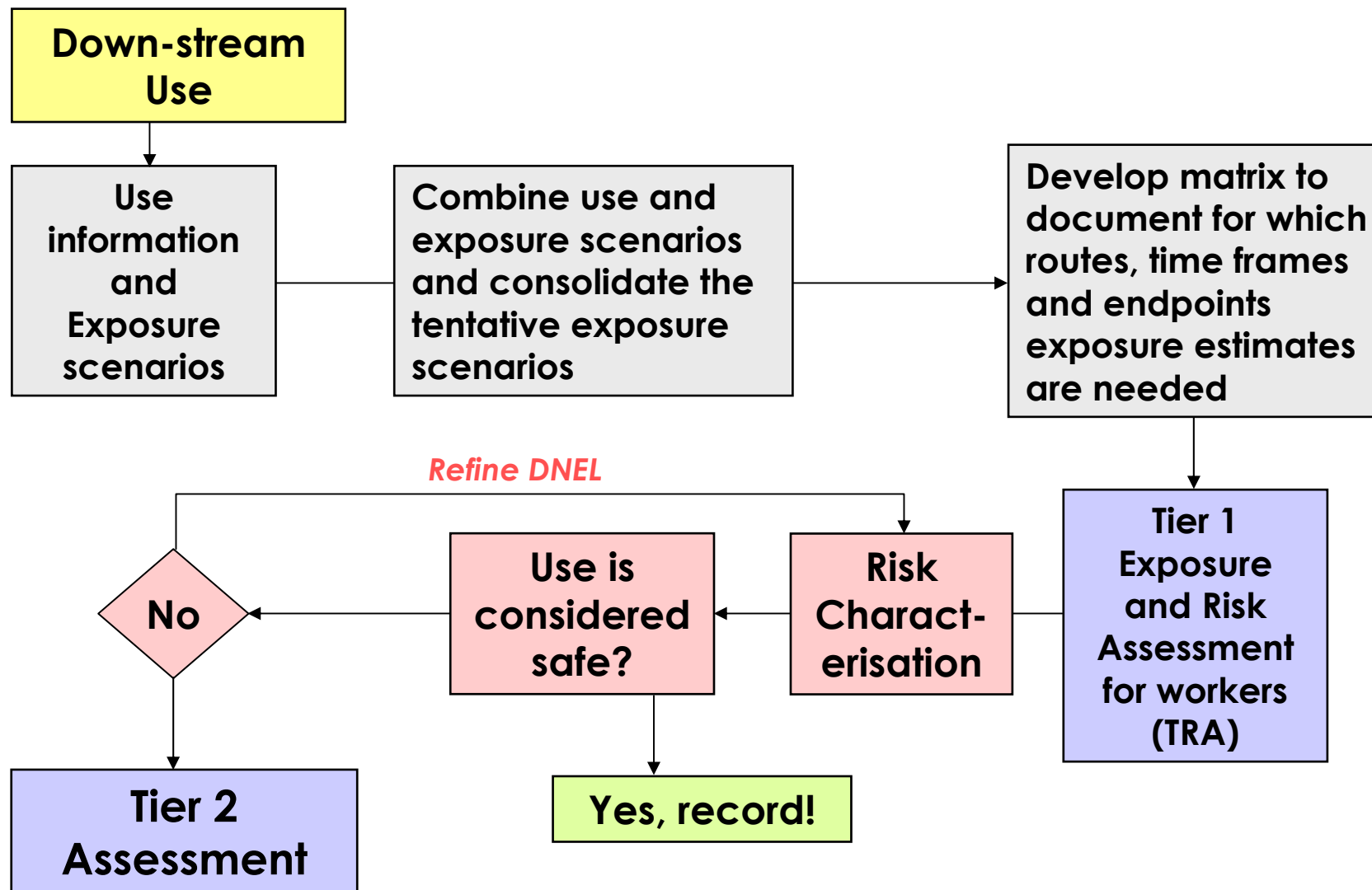


External



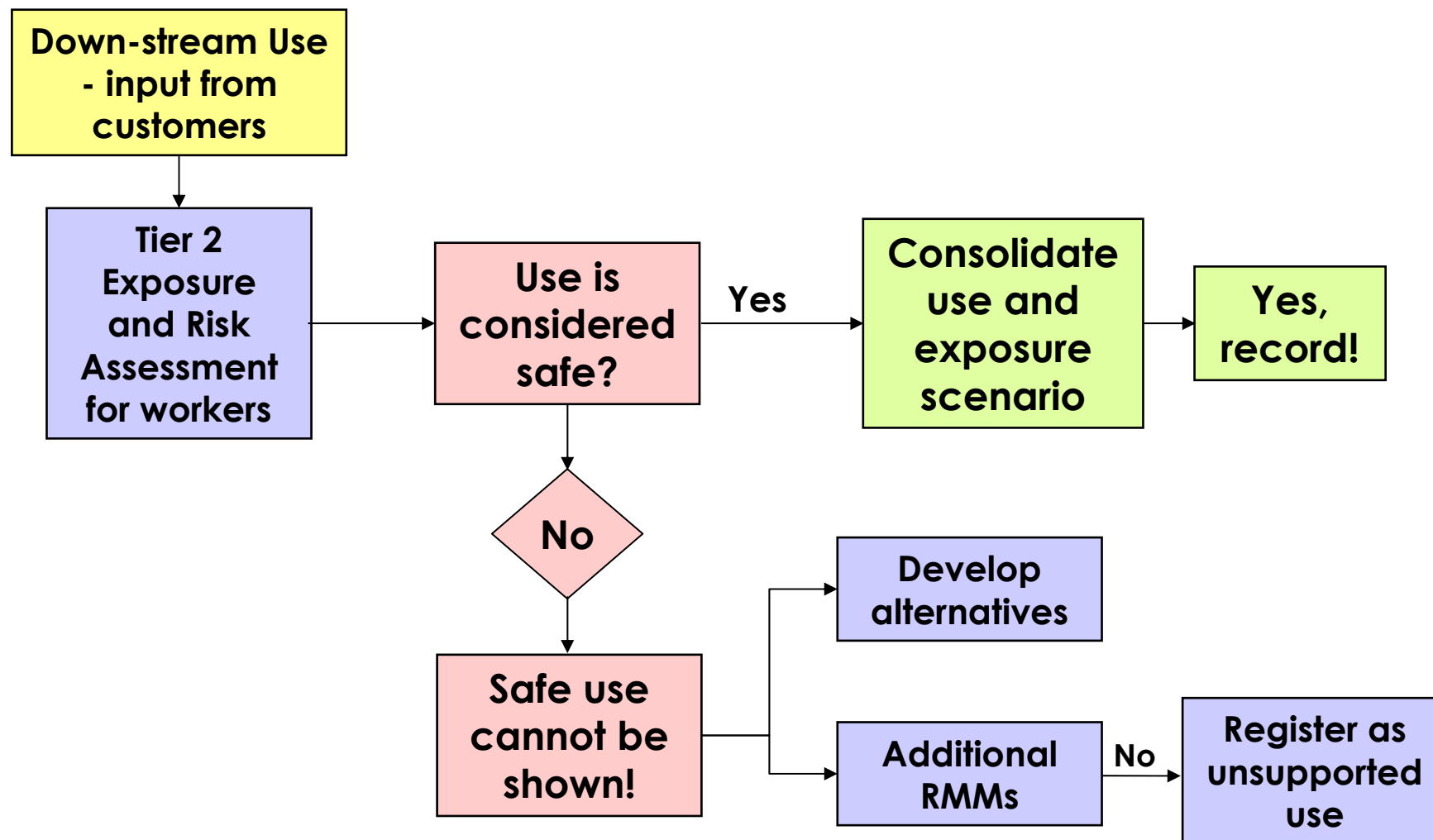


CSA/CSR Process – Example for Workers





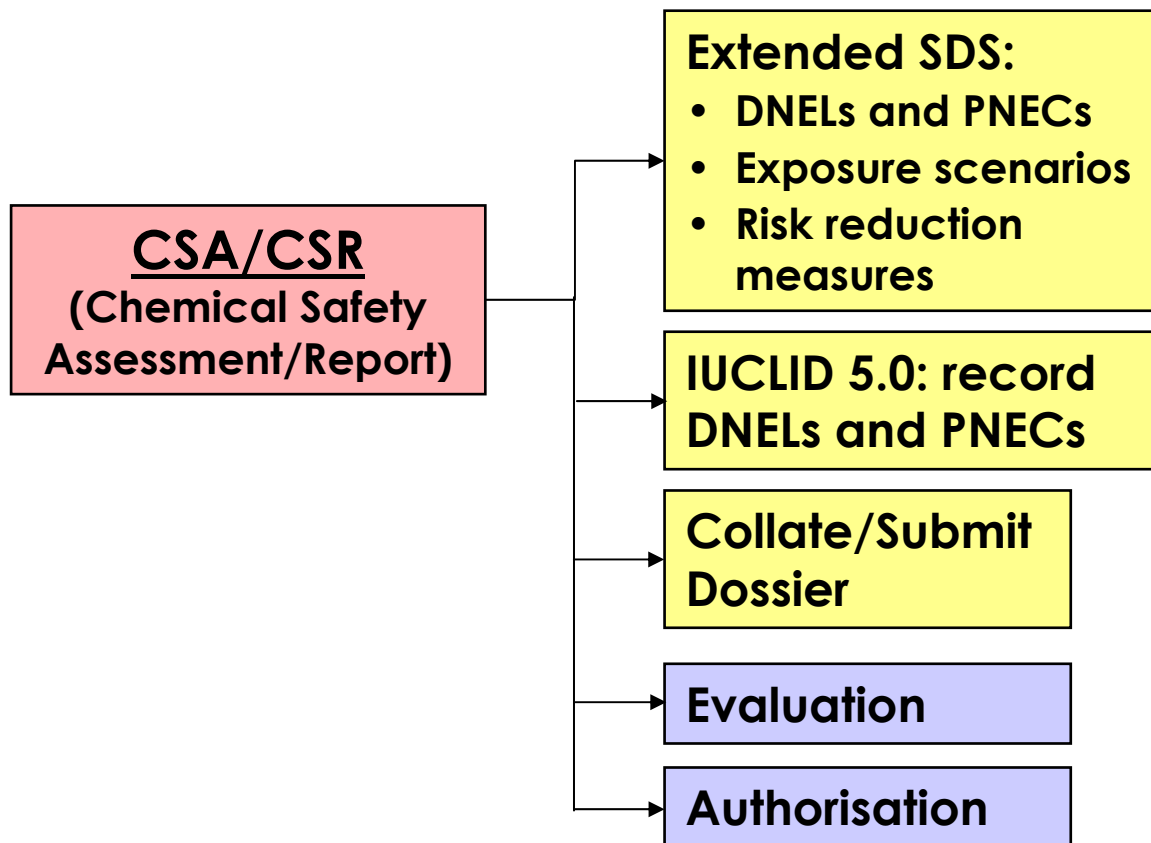
CSA/CSR Process – Example for Workers (cont.)





Leverage-out from the CSA/CSR Work Process

Output





Use descriptor system for REACH

Four elements:

1. Sector of use (SU, 22 in total)

SU1 = Agriculture, forestry, fishery

SU8 = Manufacture of bulk, large scale chemicals

SU9 = Manufacture of fine chemicals

SU22 = Public Domain

2. Product Category (PC, 41 in total)

PC1 = adhesives, sealants

PC9 = coatings and paints, fillers, putties, thinners

PC37 = water treatment chemicals



Use descriptor system for REACH

Four elements (cont):

3. Process Category (PROC, 15 in total)

- PROC1 = use in a closed process with no likelihood of exposure
- PROC15 = use as a lubricant (in metal working fluids)

4. Article Category (AC, 40 in total)

- With no intended release
- With intended release



Process Categories (PROC)

Example: activities dealing with a “bulk” solvent

- Manufacturing of the solvent at Dow’s manufacturing site
- Packaging, transport and storage (Dow’s site and customer’s site)
- Storage and handling of the chemical during the formulation of chemical products by customers.

Assumptions:

The processes are enclosed and automated and are under the control of Dow and its immediate customers and occur in the workplace or during transport.



Process Categories

The relevant process categories for REACH are:

- **PROC1: Use in closed system, no likelihood of exposure (closed loop sampling)**
- **PROC2: Use in closed, continuous process with manual intervention e.g. for sampling, maintenance etc.**
- **PROC8: Transfer of substance or preparation into small containers at dedicated filling lines**
- **PROC15: Laboratory operations**

Four Exposure Scenarios performed, one for each Process Category. ECETOC TRA tool used to estimate exposures.



Use of the substance in formulations:

- **Exposure to the solvent occurs as the result of contact with a formulation that contains the substance:**
 - **Occurs in a wide range of industry sectors (professionals) that use the formulations (frequency is usually high)**
 - **Occurs at consumers using formulations containing the substance (occasionally)**
- **44 “scenarios” were identified, based on the use descriptor system.**
- **Refinement/combination resulted in 8 exposure scenarios.**
- **Based on risk characterisation --- > 3 final exposure scenarios communicated via e-SDS.**



Final Exposure Scenarios

Exposure Scenario 1:

Manufacture and Formulation in Industrial and Professional Use

- Use in a continuous systems with process sampling
- Formulating via batch processes
- Dis/charging
- Filling of containers
- Use as laboratory agent (for QA purposes)



Final Exposure Scenarios (cont.)

Exposure Scenario 2:

Applications using air dispersive techniques in professional and industrial use

- **Spraying for Surface Coating, Adhesives, Cleaners**

Exposure Scenario 3:

Low energy spreading in Industrial and professional use

- **Manual or mechanical brushing, smearing, rolling of adhesives, coatings**



What did we learn?

- The REACH process is not designed for the layman.
- Business needs to drive the process – various specialists are needed to conduct the work.
- A very good organisation of the work is needed (teamwork).
- ‘Red-button“ approach is not feasible: guidance documents and associated tools are not intended to provide an “expert system“.
- The chain of events is complex, a number of steps in the REACH process need to be taken carefully.
- Workable mechanisms are needed to ensure reliable and complete use information from and to the entire supply chain.
- The time pressure to comply will increase, increase,



**From today: 2 years, 7 months and 16 days
until
The First Registration Deadline!**

THANK YOU FOR YOUR ATTENTION!

QUESTIONS?



"Disclaimer:

Although the information and any recommendations in this presentation are presented in good faith and are believed to be correct at the time of compilation, neither The Dow Chemical Company nor its affiliates makes any representations or warranties as to the completeness or accuracy of Information contained within it. Information is supplied on the condition that the persons receiving it will make their own determination as to its suitability for their purposes prior to use. In no event will Dow be responsible for damages of any nature whatsoever resulting from the use of or reliance upon Information or the product to which Information refers. Nothing contained in this presentation is to be construed as a recommendation to use any product, process, equipment or formulation in conflict with any patent and Dow makes no representation or warranty, express or implied, that the use thereof will not infringe any patent. No representation or warranties, express or implied, of merchantability, fitness for a particular purpose or of any other nature are made with respect to Information in the presentation or products to which the presentation refers.