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Demonstrating safe use of chemicals under REACH

Frans M. Christensen

European Commission, DG JRC
Institute for Health and Consumer Protection (IHCP)
European Chemicals Bureau (ECB)

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ihcp

Outline

- Starting point: REACH Registration
- Prime actors:
  - Manufacturers / Importers
  - (and Downstream Users –> presentation by Jens Tørsløv)
- How is safe use of chemicals demonstrated?
  - Registration dossier
  - Chemical Safety Assessment / Chemical Safety Report
  - Exposure Scenarios –> Extended Safety Data Sheets
  - Supply chain communication
- Guidance: RIP 3.2 (and RIP 3.5)

Registration

AIM:

è manufacturers and importers obtain information on their substances and

è use this knowledge to ensure responsible and well-informed management of the risks these substances may present throughout their life cycle

Registration Dossier = Documentation

è Technical Dossier: starting at 1 tonnes per year

è Chemical Safety Report: starting at 10 tonnes per year

No formal acceptance - industry retain responsibility

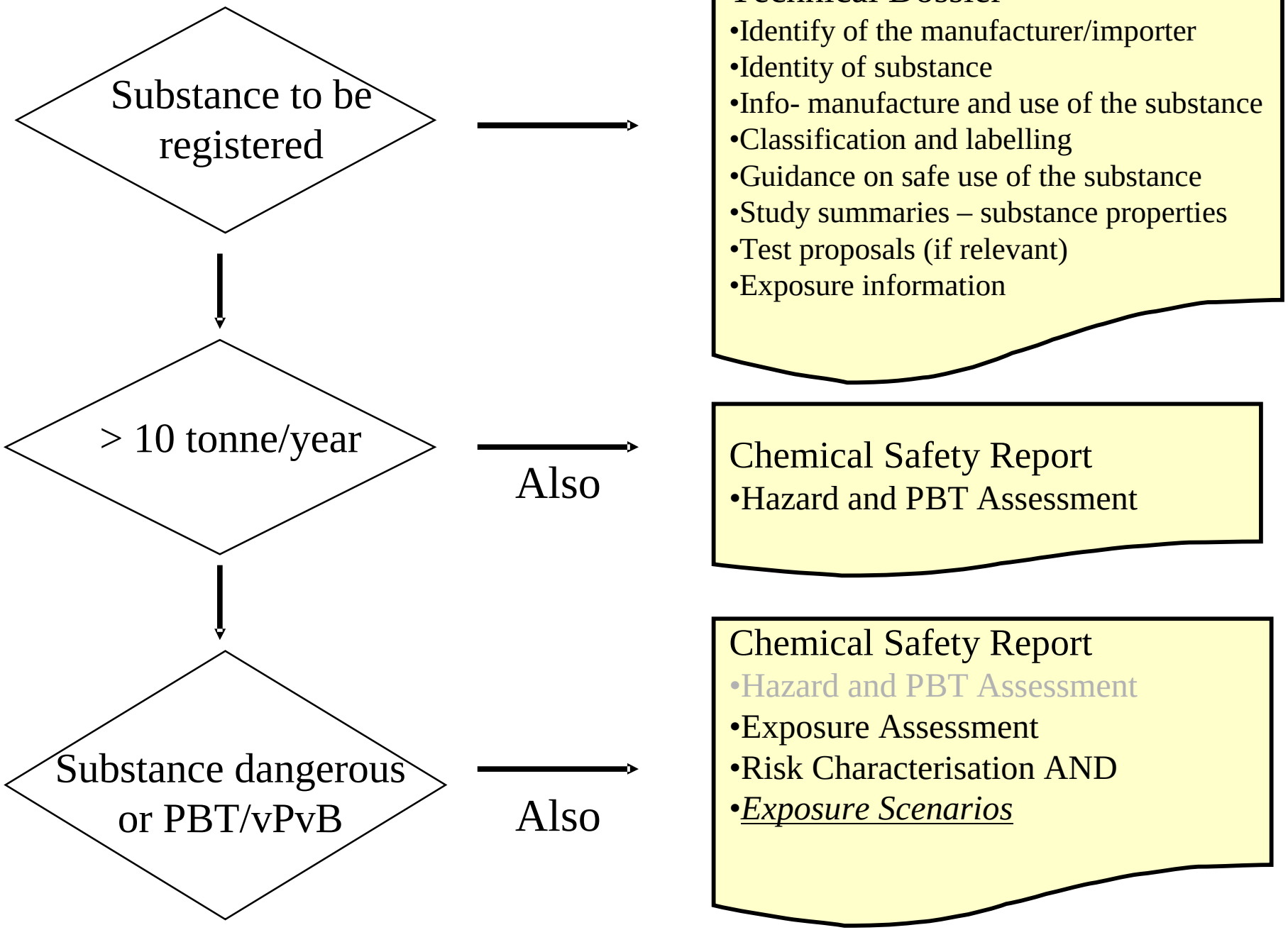
What is the Chemical Safety Report (CSR) ?

- The CSR is the documentation of the Chemical Safety Assessment (REACH Annex I) covering:
  - Hazard Assessment of the inherent properties; physicochemical and toxic properties
  - PBT and vPvB assessment*
- and when substance is dangerous or PBT/vPvB
  - Exposure Assessment quantifying human and environmental exposure levels
  - Risk Characterisation
  - Development of Exposure Scenarios

* PBT: Persistent, Bio-accumulative and Toxic

* vPvB: very Persistent and very Bio-accumulative

Registration dossier - content



Why Exposure Scenarios ?

To protect humans and the environment….

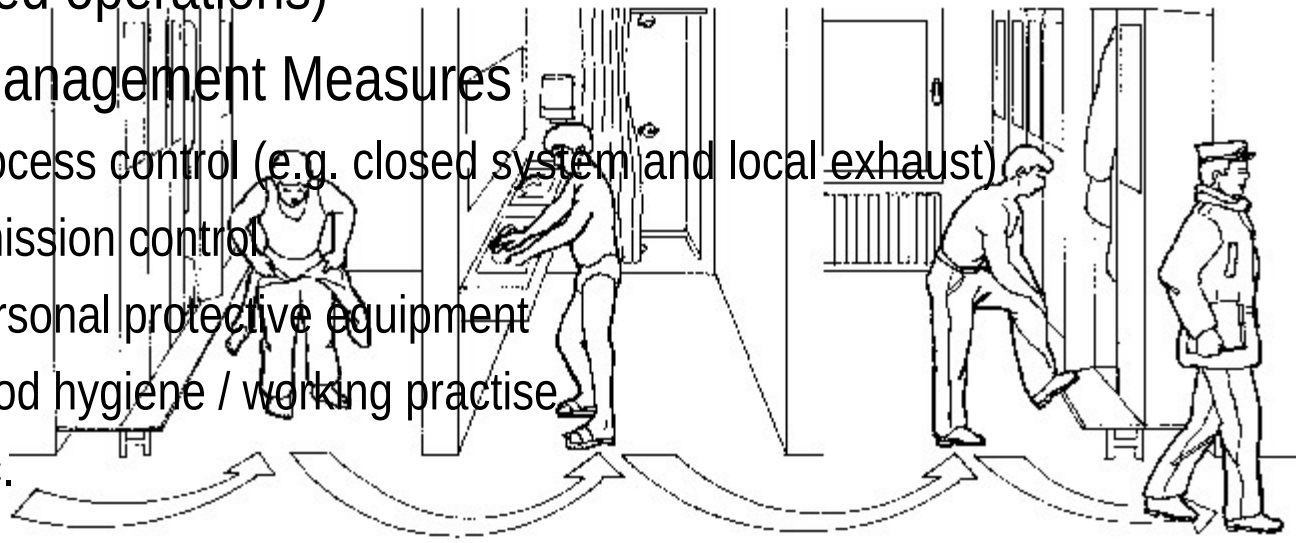
- …..by guiding the user of the chemical…
- …..on how to control risks

The exposure scenarios are developed by using…

- …all available and generated information on the use of the chemical, and related exposures
- …all available and generated information on properties and toxicity of the chemical

What is an Exposure Scenario (ES) ?

- Conditions for use:
  - Process description (incl. quantity used)
  - Operational conditions (incl. 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.

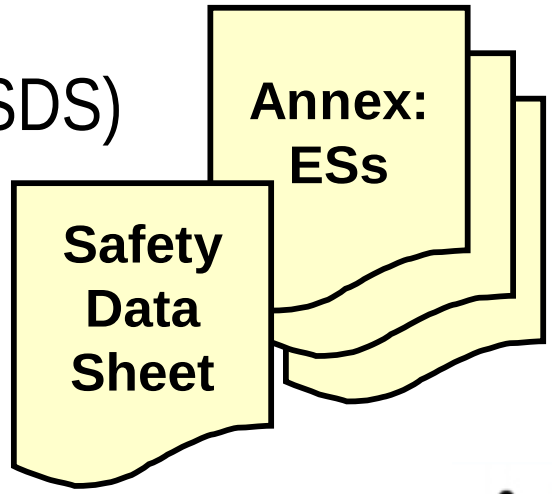


- Other relevant information

How will the user know?

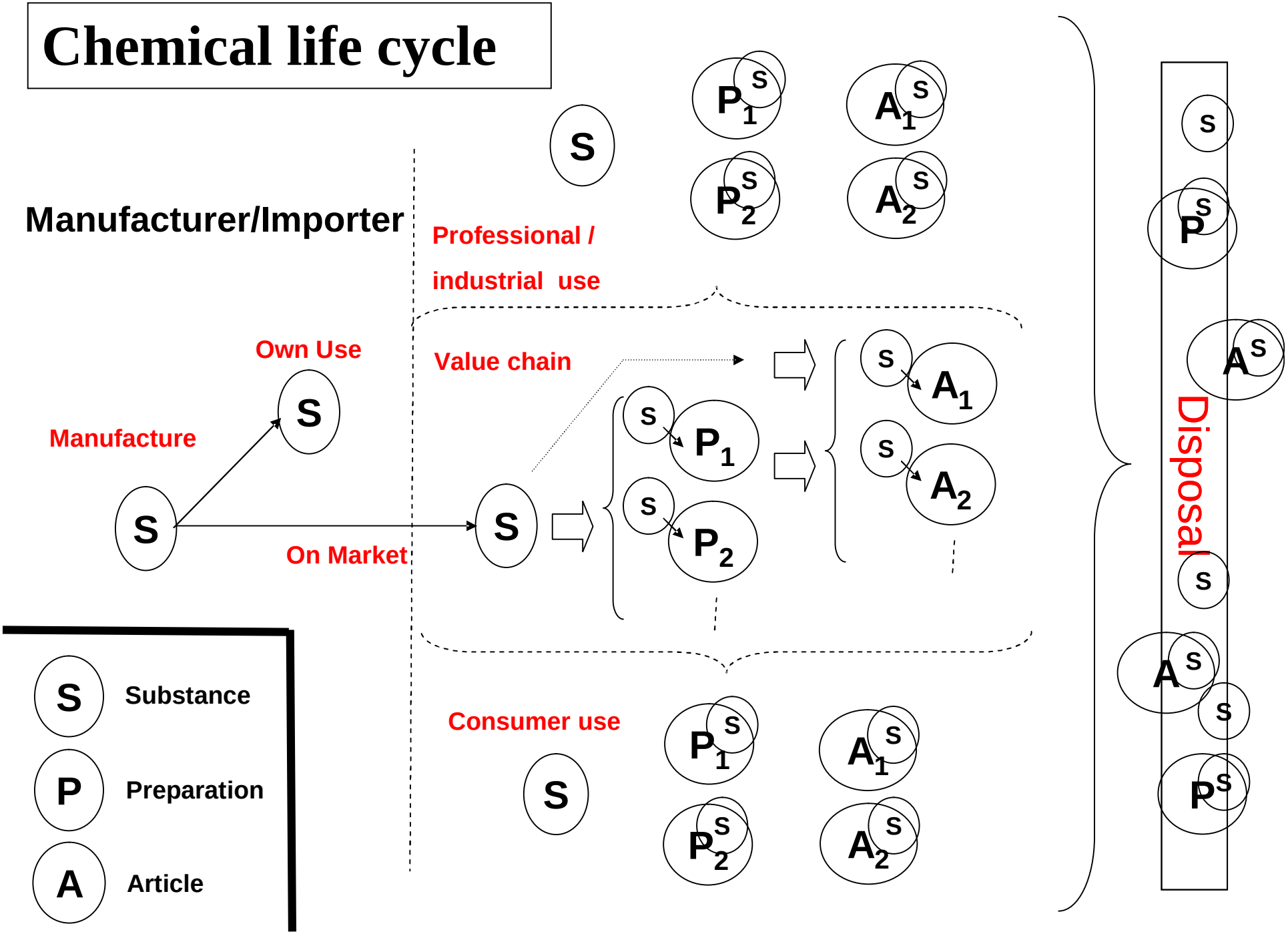
Exposure Scenarios will be attached to the Safety Data Sheet (SDS)

-> Extended Safety Data Sheets (e-SDS)



For which uses/processes are ESs required?

Chemical life cycle



Steps in development of Exposure Scenarios - 1

1. Identification of uses
   - in-house info
   - supply chain communication
   - information from branch organisations, literature, etc.
2. Description of use (manufacturing or use process)
3. "Tentative ES" – describe situation today
   - Process description (from step 2)
   - Operational conditions
   - Risk management measures
   - Other 'determinants of exposure'

Steps in development of Exposure Scenarios - 2

4. Assessment of exposure and risk
   - Estimate exposure based on the tentative ES
   - Risk Characterisation

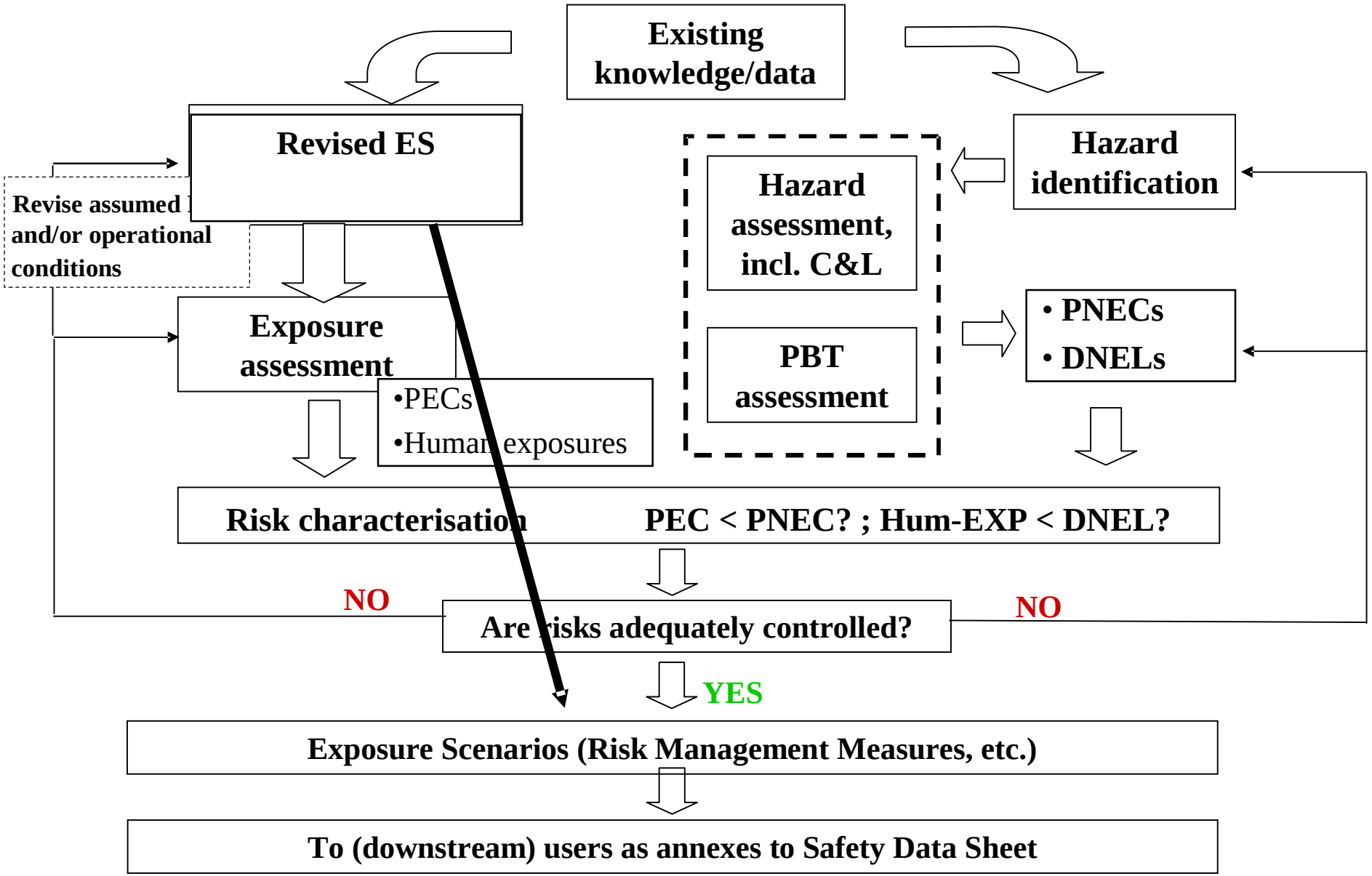
   Environment: Exposure < Predicted No Effect Concentration (PNEC)?

   Human Health: Exposure < Derived No-effect Level (DNEL)?

   If no: Risk are not controlled -> go to Step 5

   If yes: Risks are controlled -> go to Step 6.
5. Iterate assessment if needed
   - Refine assessment or assume stricter use conditions or risk management measures. Repeat Step 4.
6. Develop annex to the safety data sheet
   - "Translate" the 'final ES' into SDS language

Chemical Safety Assessment



Dual role of ESs !

1. Basis for exposure estimation (in preparing the CSA)
   Exposure Scenarios enable a quantitative release and exposure estimation by describing the determinants of exposure; i.e. the parameters that affect the exposure level

2. Communication (CSA output, annex to SDSs)
   ES is the communication tool to the user on how to use the chemical in a way that risks are controlled, including specifying the necessary Risk Management Measures

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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)
    - Implement ES from own safety assessment
    - Report to the Agency
- Communicate further down the supply chain if he is supplier

Who will do what in the chemical supply chains?

- To which extent will the downstream users inform their suppliers?
- Will downstream users (or DU organisations) develop 'bottom-up' exposure scenarios that can be used by the registrants?
- How do we deal with Confidential Business Information (CBI)?

In any case:

- All evidence so far point to the benefit of being pro-active both as Manufacturer/Importer and as Downstream User

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Some key issues

How detailed ?

- ES shall be as detailed as necessary
- Broad/Generic ES may cover a range of processes and/or be applicable to many substances (with a max. hazard profile)
- Key points are that
  - risks are adequately controlled upon implementation of the ES
  - ES is practical and proportional to the risk

Risk Management Measures

- Description
- Quantification of the efficiency
- Transparent communication

- Guidance development needed

  -> Next presentation (Peter Douben)

ES and preparations

- REACH requires substances to be registered (e.g. toluene, formaldehyde)
- Many substances are used as part of a preparation (e.g. paints, adhesives)

- Guidance needed on preparing ES for preparations

Guidance development

- RIP 3.2 Develops Guidance on how to prepare the Chemical Safety Report (CSR), including exposure scenarios
- RIP 3.5 on Downstream User requirements -> Presentation by Jens Tørsløv

RIP 3.2-1 Scoping study

- Jan-July 2005
- CEFIC lead in consortium with RIVM, DHI Water & Environment, Ökopol, BfR, Baua, TNO and ECETOC
- Reporting:
  - First activities on Exposure Scenario framework
  - IT implications, focus on ES and CSA tool-box
  - Considerations of SDSs and CSAs for preparations
  - Safety Data Sheets requirements under REACH
  - Preliminary TGD (pTGD)
    - Part A (Introduction)
    - Part B ('Concise' TGD)
    - Part C (Reference/Expert TGD)

RIP 3.2-2 Main Study

- Several tasks on-going
- Some tasks lead by Commission and some by external contractors
- “Arona network” on ES

- More RIP 3.2-2 details in next presentation

Conclusions – 1

REACH Registration

- Manufacturers and importers
- Obtain/generate information on their substances and
- Use this knowledge to ensure responsible and well-informed management of the risks that substances may cause throughout their life cycle

Conclusions – 2

- Exposure scenarios play a very important role by giving use conditions for adequately controlling risks
- Exposure Scenarios are:
  - developed in the iterative Chemical Safety Assessment (CSA)
  - recorded/documented 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!)
- Guidance being developed in RIP 3.2 (and RIP 3.5)

Thank you for your attention !

- Back-up slide

RIP 3.2-2 Main Study

TASK I

Preliminary activities - ES and Exposure Assessment
- **Identification of cases for ES exemplification - "Arona network"**
- **Consumer exposure**

TASK II

Drafting groups on hazard assessment and risk characterisation
- **Human Health (incl. Derivation of DNELs)**
- **PBT assessment**
- **Substances of very High Concern**

TASK III

IT tools for CSA/CSR
- **Preliminary working group (Nov 2005 – June 2006)**
- **Further specifications – Call for tender (15 SEP)**

TASK IV

External contract (CEFIC lead consortium)
- **Exposure Scenario cases and guidance**
- **Draft Final Guidance, integrate Task I-III and further issues**

TASK V

Consolidation and integration with other guidance