Demonstrating safe use of chemicals under REACH

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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:
- manufacturers and importers obtain information on their substances and
- use this knowledge to ensure responsible and 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
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

Substance to be registered

> 10 tonne/year

Substance dangerous or PBT/vPvB

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
- Risk Characterisation AND
  * Exposure Scenarios*
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?
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

Exposure assessment
- PECs
- Human exposures

Risk characterisation
PEC < PNEC? ; Hum-EXP < DNEL?

Are risks adequately controlled?
YES

Exposure Scenarios (Risk Management Measures, etc.)

To (downstream) users as annexes to Safety Data Sheet
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.
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
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/documenting 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
- 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