European Commission

Enterprise and Industry
Directorate-General

REACH Exposure Scenarios and Exposure assessment

Elina Karhu

DG ENTR / G1 - REACH

Brussels, 19 September 2006

What is REACH?

- Single, coherent system for new and existing chemicals
- Elements:
  - Registration of substances ≥ 1 tonne/yr
  - Information in the supply chain
  - Evaluation of some substances
  - Authorisation only for substances of very high concern
  - Restrictions - the safety net
  - Agency to manage system

Registration

AIM

- →Manufacturers and importers
- →Obtain information on their substances and
- →Use this knowledge to ensure responsible and well-informed management of the risks the substances may present throughout the supply chain

Registration Dossier

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

Core tools under REACH

- The Chemical Safety Assessment (CSA) is the tool used to determine
- The Chemicals Safety Report (CSR) is the tool used to document
- The Safety Data Sheet (SDS) is the tool used to communicate

Conditions for use (for sufficiently protecting human health and the environment):

- risk management measures
- operational conditions

Exposure Scenario

The Chemical Safety Assessment
Annex I

1. Human health hazard assessment
2. Human health hazard assessment of physicochemical properties
3. Environmental hazard assessment
4. PBT and vPvB assessment

---------- if dangerous or a PBT or vPvB ---------

5. Exposure assessment incl **exposure scenarios**
6. Risk characterisation

Exposure Scenario (ES)

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

-> Factors affecting the exposure level

Exposure Scenario (ES) and Exposure Estimation

Exposure scenario(s) and exposure estimation need to cover

- Manufacture
- Manufacturers / importers own use(s)
- All identified uses
- All life cycle stages resulting from the manufacture, own uses and identified uses

Exposure Scenario (ES) and Exposure Estimation (cont.)

Exposure scenario(s) and exposure estimation need to address, where relevant,

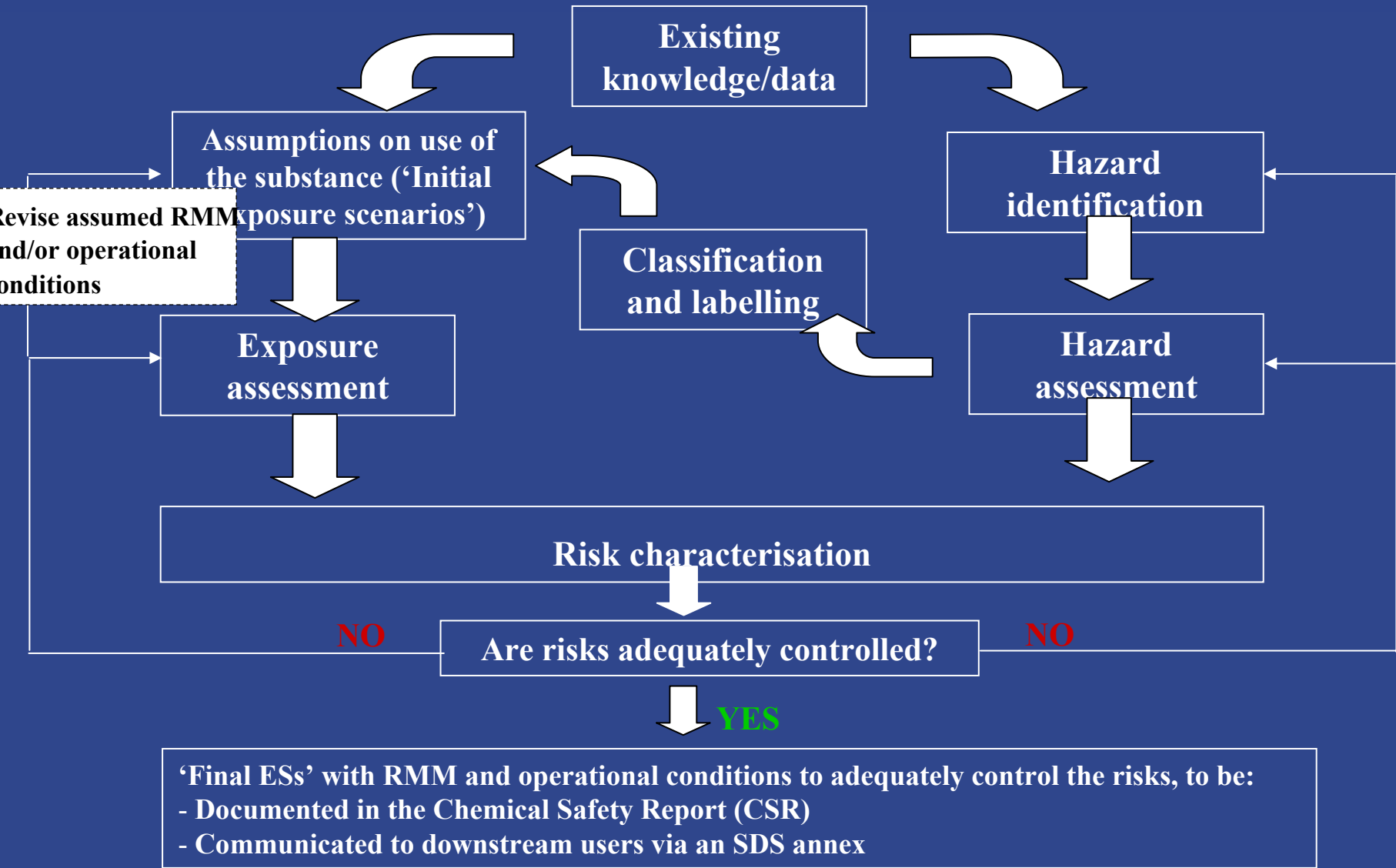
- Human health
  - Workers
  - Consumers
  - Humans exposured via the environment

AND

- Environmental spheres for which exposure is known or reasonably foreseeable

-> Integrated approach for human health and the environment

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

Note that ES communicated to the user must be based on an assessment showing that risks are controlled

Downstream users

- Exposure Scenarios (ES) will be communicated to DUs as an annex to Safety Data Sheets (SDS)

- A DU needs to ensure that his use is covered by the ES and to implement at least as effective risk management measures and operational conditions as in the ES

OR

- If he uses the substance outside the ES (other uses or other conditions), he may either
  - Inform his supplier to make his use an identified use, OR
  - Conduct a DU chemical safety assessment for his use(s) (and for his downstream uses if he is a supplier)

Exposure scenarios – level of detail?

- Broad ESs may cover a range of processes, uses and/ or be applicable to many substances
- An ES shall be as detailed as needed
  - To ensure that risks are adequately controlled upon implementation of the ES
  - ES is practical and proportional to the risk

Guidance

RIP 3.2: TGD for preparing the CSR

- Guidance for preparing the Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR)
  - Scoping study: RIP 3.2-1 available
  - Second phase: RIP 3.2-2 ongoing, to be finalised in first half of 2007
- The current RA TGD one of the main starting points for the project

IT tools to assist the development of CSR

- Project on analysis and design in 2007

Guidance (cont)

RIP 3.5: TGD for Downstream users

Develop guidance for DU on how they can fulfil their obligations:

- Use of chemicals and exposure scenarios
- Which information shall be available
- Communication up- and downstream, including proactive communication of the currently applied conditions of use to suppliers

Scoping study: RIP 3.5-1 available

Second phase: RIP 3.5-2 ongoing, to be finalised in first half of 2007

Conclusions

- **Exposure scenario**
  - defines under which conditions the risks related to a substance are adequately controlled
  - Exposure scenario is a key tool in REACH safety assessment and in communication in the supply chain
- **M/I responsible for preparing CSR and**
  - Implement RMMs and OCs needed to control risks related to manufacture and own uses
  - Recommend RMMs and OCs needed to control DUs' risks
- **DU can either communicate his use to the supplier (if not already covered by the ES) or take the responsibility himself**

Conclusions (cont.)

REACH will provide for downstream users

- More information hazard properties of substances
- Clear guidance on risk management
- Framework for supply chain communication
- Integrated way to implement the requirements related to occupational health and the environment

Further information

REACH proposal:

http://europa.eu.int/comm/enterprise/reach/index.htm
and
http://europa.eu.int/comm/environment/chemicals/index.htm

REACH Implementation Projects (RIPs):

http://ecb.jrc.it/REACH/ > Documents > public access > RIP final reports

http://ecb.jrc.it/REACH/ > Documents > restricted access > SEG (UserID: segr and password: segr07)