

Pre-registration and Data Sharing - Challenges to Industry

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REACH Workshop, Thursday 21 June 2007, Bonn - Germany



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Outline Data Sharing

- Information requirements
- Chemical safety assessment
- Concluding remarks



What is 'information'

- Physicochemical properties
- Health (toxicological) data
- Environmental (ecotoxicological-fate-behaviour) data

- Compositional data
- Chemical identity
- Volume of production
- Uses
- Exposure data



REACH Information and Timetable

Volume tonne/year	1-10	10-100	100-1000	> 1000
Pre-registration	12 - 18 months after EIF (June – Nov 2008)			
Information	Identity manufacturer/importer Contact person Substance identifier Tonnage band			
Registration				
Information - Annex	VII	VIII	IX	X
CSR	No	Yes	Yes	Yes
Time after EIF	11 years (2018)	11 years (2018)	6 years (2013)	3.5 years (end 2010)
CMR's Cat 1 and 2 & >100 tpa for N; R50/53	3.5 years (end 2010)			

Challenge 1: Product Compositional Data

REACH deals with substances

- Tens of thousands of substances

Industry works primarily with products

- Millions of products
- Use of products in products
- Product safety driven

REACH requires the development of approaches to deal with substances in products

- Substance inventories

Challenge 2: Sameness of substance

Pre-registration list

- CAS or EINECS-identifier

Substances (RIP3.10)

- Well-defined substances
 - Mono-constituent substances
 - Multi-constituent substances
- Substances with Unknown or Variable composition, Complex reaction products or Biological materials (= UVCBs)

Pre-registrants will have to:

- share more detailed substance constituent information
- agree upon sameness of their substance
- establish the SIEF (a virtual organisation in REACH) based on the sameness of the substance
- find ways to manage all this without REACH providing legal certainty

SIEF – Substance Information Exchange Forum

Forced membership

- But no formal process to identify initial members
- 9.5 year duration

Aim:

- Exchange of information
 - data sharing (voluntary & forced)
 - testing proposals
- Agree C&L

Possibilities/Issues:

- Non-registrants with data/information can join after start SIEF (but cannot make use of phase-in status)
- Non-registrants (< 1 tonne/annum) not involved in the C&L process
- Validity of shared information (applicability & cost)

Registration – Technical Dossier

- Identity, address, contact person, etc. of manufacturer / importer
- Identity of the substance
- Tonnage and exposure information
- Information on the manufacture and use(s)
- Proposed classification and labelling
- Summary of standard information acc. to Annexes VII - X
- Robust study summaries if required acc. to Annex I
- Proposal for testing under Annexes IX - X , adaptations to standard testing regime
- Safe use guidance
- CSR > 10 tonnes

Pre-registrant

Registrant

SIEF

Choice (Registrant / SIEF)

CSR: Chemical Safety Report;

SIEF: Substance Information Exchange Forum

Challenge 3: SIEF Operation

Staffing

- For each substance appropriate communication and interaction within the SIEF has to be ensured at the legal entity level
- Information on substances within a company is not organised in legal entities but often in business units

Process description

- No clarity in REACH text on the SIEF process
- Each SIEF will use separate private law agreements
 - general SIEF operations and registration consortia

Practicalities of project management

- Workflows, data sharing requirements and timelines need to be carefully managed to meet the REACH legal requirements
- An “industry standard” IT-system to support SIEF/registration consortia management is not yet available

Challenge 4: SIEF Communications



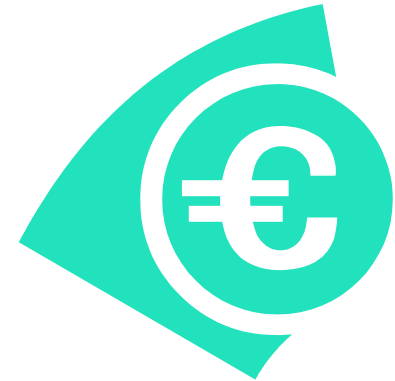
‘Information exchange’ on:

- Chemical identity
- Volume of production (tonnage band)
- Uses (in registration consortia)?
- Exposure data (in registration consortia)?

Increased risk of:

- Infringements of Anti-competition law, and
- Loss of CBI (Confidential Business Information)

REACH – Information requirements



Annex VII

- ❖ Physicochemical properties (non-GLP)
- ❖ Human health: *in vitro* irritation, sensitisation, mutagenicity, acute toxicity (one route)
- ❖ Environmental: acute aquatic toxicity (daphnia, algae), biodegradation

Annex VIII

- ❖ Human health: including *in vivo* irritation, and 28-day repeat dose studies
- ❖ Environmental: acute toxicity fish, fate studies (hydrolysis, adsorption/desorption)

Annex IX and Annex X (Testing proposal)

- ❖ Long term, repeat dose, chronic, fate etc

Annex VII - X

- ❖ Specific exemptions rules (Column 2)

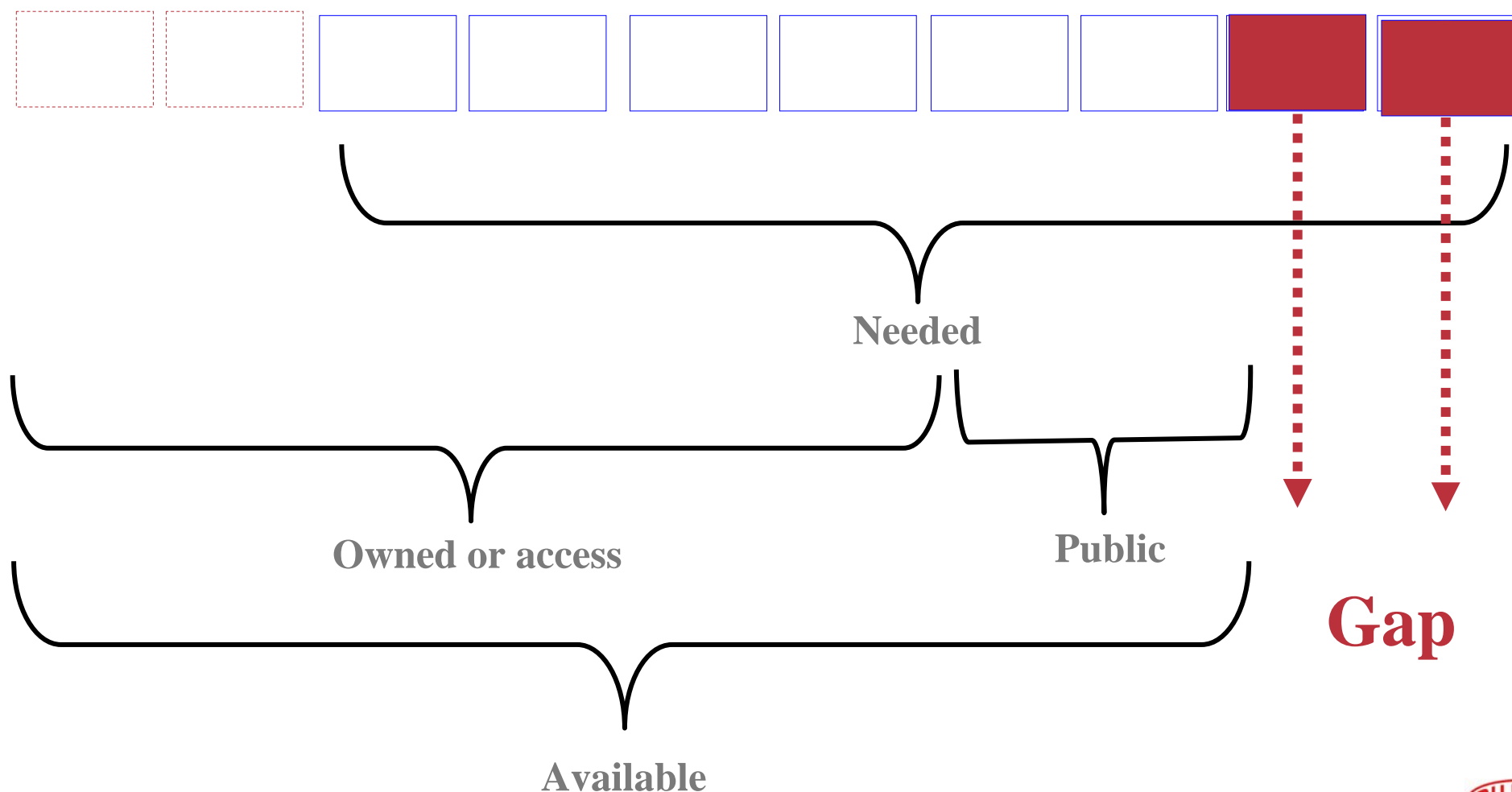
Annex XI

- ❖ Generic testing exemption rules

Challenge 5: Data/Information Gap Analysis

Per substance manufactured or used:

- Determine data/information needed
- Run analysis of available data



Challenge 6: E-evaluation available information

Reliability

- evaluating the **inherent quality** of a test report or publication relating to preferably standardized methodology and the way the experimental procedure and results are described to give evidence of the clarity and plausibility of the findings;

Relevance

- covering the extent to which data and tests are **appropriate** for a particular hazard identification or risk characterization; and

Adequacy

- defining the **usefulness** of data for hazard/risk assessment purposes.

Quality criteria system

- Klimisch H-J, Andrea M and U Tillmann (1997) A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. *Regulatory Toxicology and Pharmacology* **25**: 1-5

Challenge 7: Valuation of available studies

- **In a fair, transparent, non-discriminatory way (Art 27.3)**
 - Detailed guidance in RIP3.4 – Data sharing
- **Proof of cost (Historical or replacement value)**
 - Preliminary testing for determining test concentrations;
 - Substance testing according to the standard protocol;
 - Development of suitable analytical methods;
 - Supplementary analyses;
 - Substance characterization; Stability in test medium; Concentration in test medium;
 - Administrative expenses;
 - Processing and professional support by the commissioning party (may include study design and /or preparation of test material);
 - Travel expenses;
 - Archiving of the test substance and raw data;
 - Preparation of IUCLID data set and robust study summary.
- **Proportionality or equal shares**

RIP 3.3 – Intelligent Testing Strategies - Information assessment and testing proposals

Elements (in line with Annex XI of the REACH proposal):

- How to use existing information (including human data and non GLP studies)
- How to apply a weight of evidence approach
- When and how to use SARs and (Q)SARs
- When and how to use in-vitro methods
- When and how to apply grouping and read-across
- When testing is technically impossible
- When testing can be omitted based on exposure considerations
- Further guidance on implementation of the rules for adaptation as provided in the different annexes, especially for substances manufactured/imported in higher tonnages.

Challenge 8: Technical expertise required for testing proposals

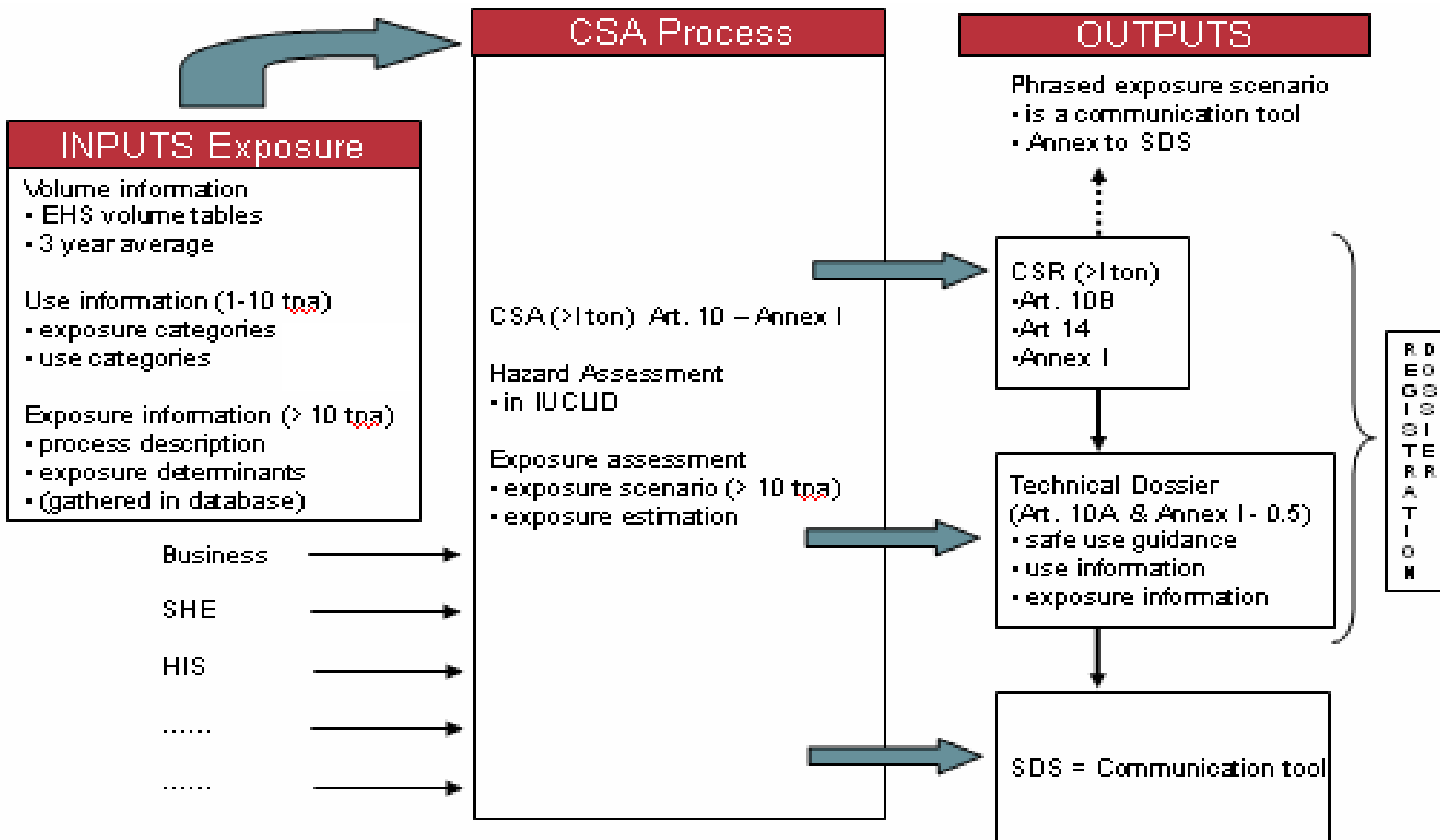
11 years since 1st Technical Guidance Document

- TGD 2nd edition in 2003 – 4 parts – 944 pages in total
- Hazard assessment and exposure assessment elements

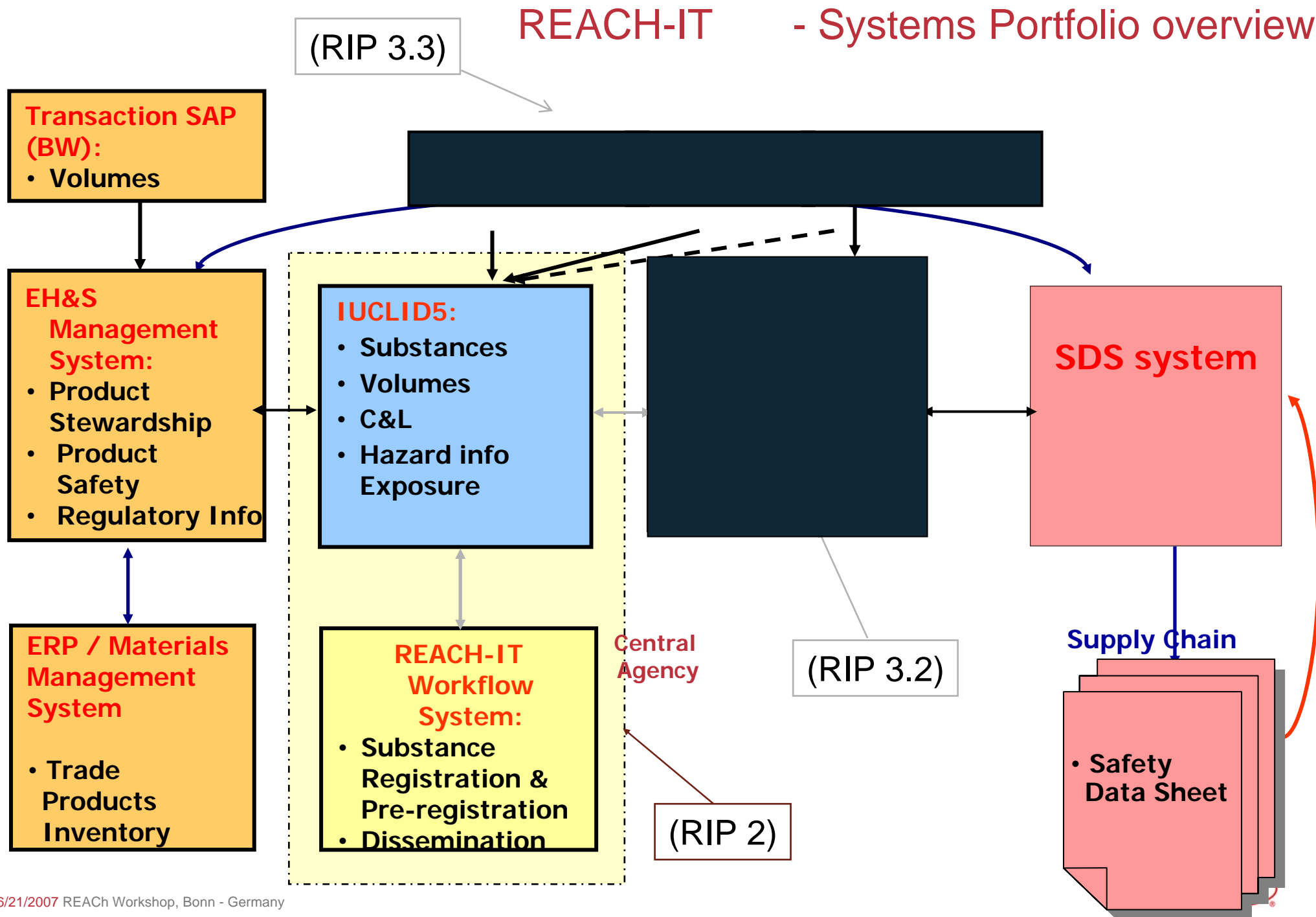
RIP 3.3 (version 4 May 2007)

- Hazard information only – 4 parts - 1154 pp in total
 - Part 1: General issues 250 pp
 - Part 2: Phys-Chem and Human Health Endpoints 413 pp
 - Part 3: Aquatic Toxicity, Degradation & Bioaccumulation 347 pp
 - Part 4: Appendices 44 pp
- Experts knowledge required for information assessment and testing proposals

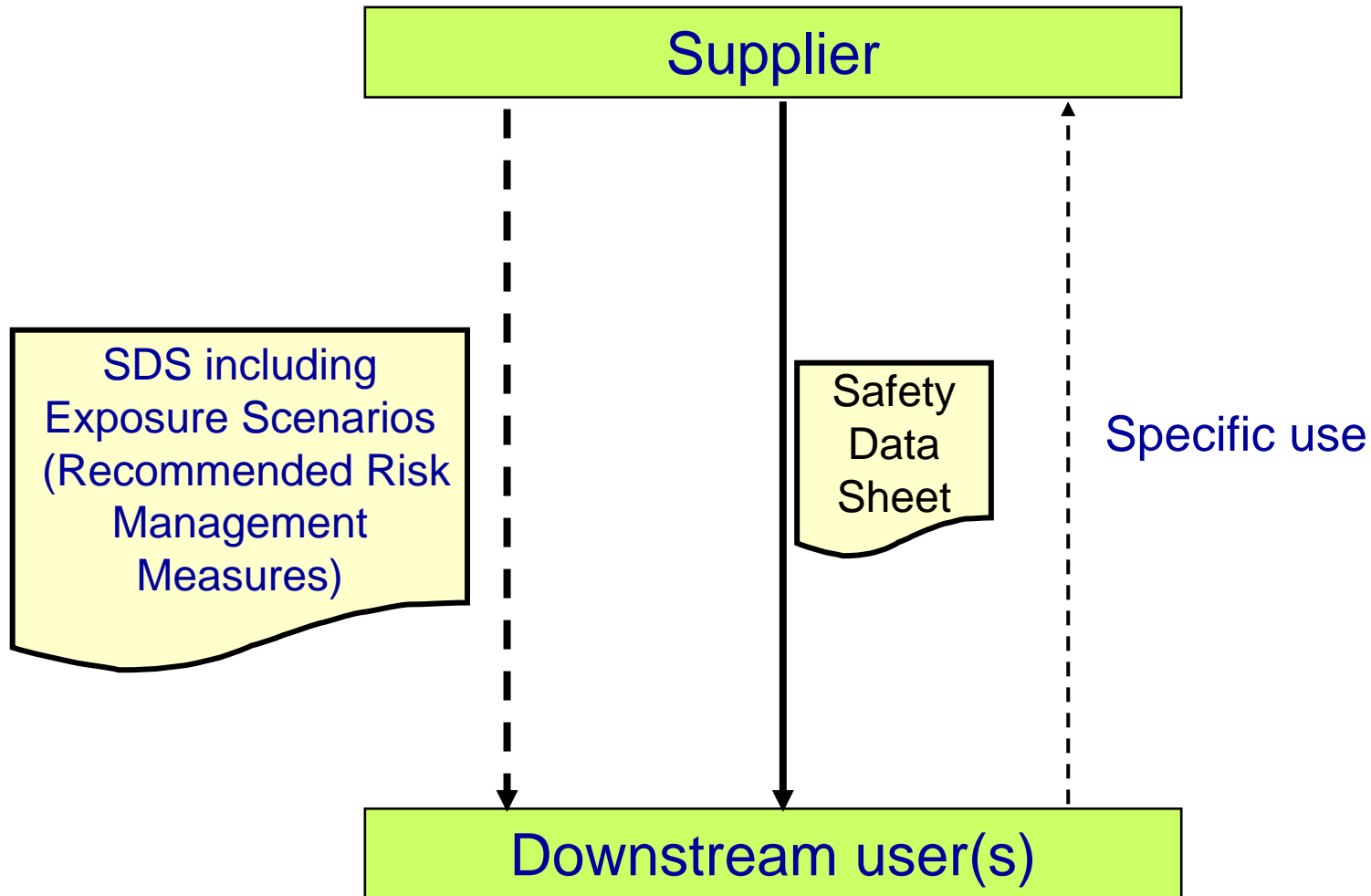
Chemical Safety Assessment



Challenge 9: Communication within the company ¹⁸



Communication through the supply chain*



Challenge 10: Communication through the supply chain



Safety Data Sheets / Chemical Safety Reports

- exposure scenario
- risk management measures
- registration number
- authorization/restriction info

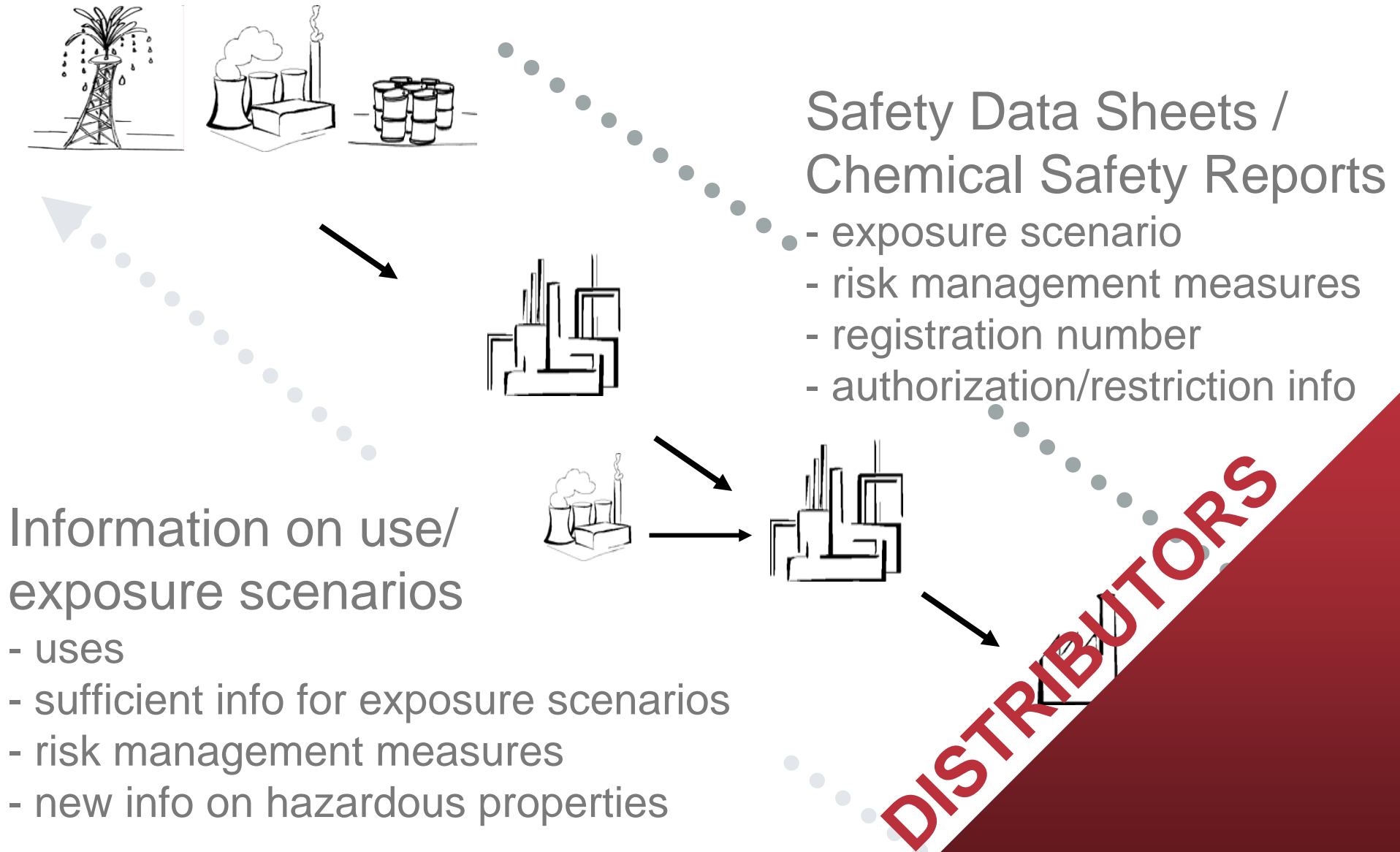


End User

Information on use/ exposure scenarios

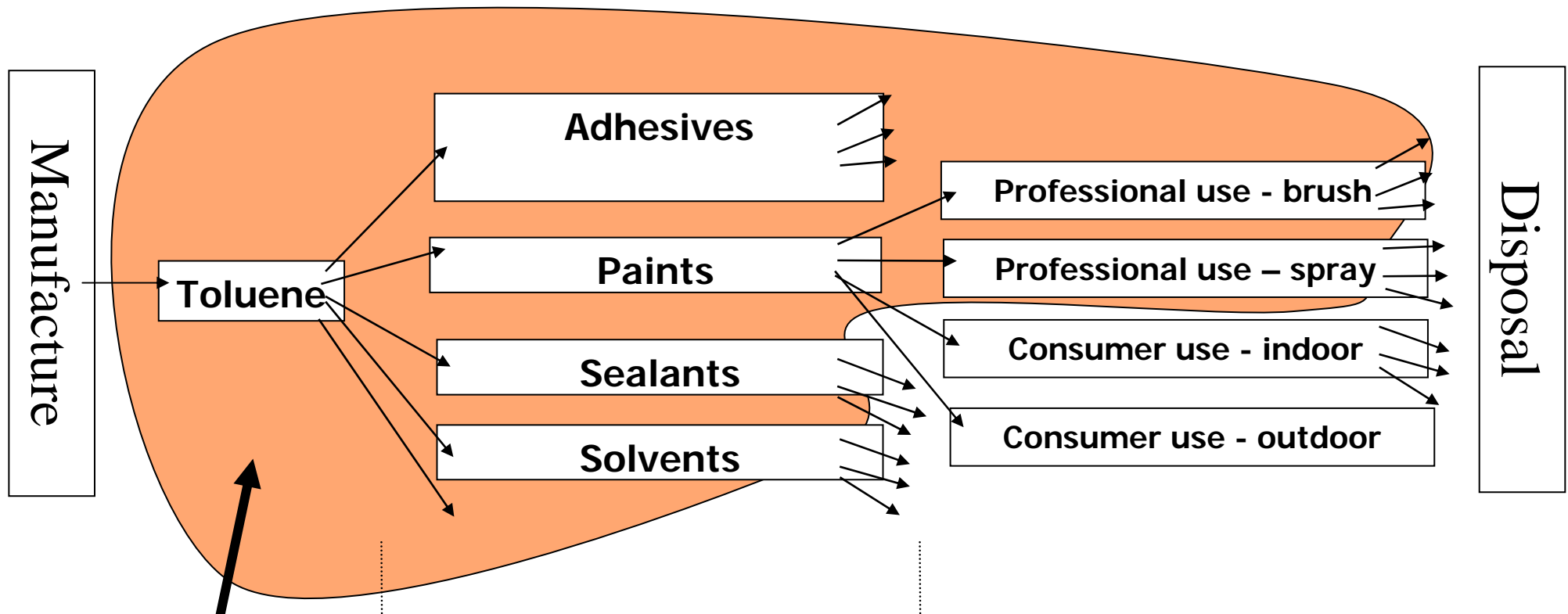
- uses
- sufficient info for exposure scenarios
- risk management measures
- new info on hazardous properties

Challenge 11: Communication Breaks



Challenge 12: Expertise required for the exposure assessment

Must be covered in a Chemical Safety Assessment



Downstream uses = requirements for information exchange

← Identification of uses →

← SDS – Exposure Scenarios →

Challenge 13: Efficiency of the CSA

Existing Substances Regulation (79/793/EEC)

- 4 priority lists for risk assessment with 141 substances
- 28 years since publication of legislation
- 11 years since publication of the Technical Guidance Document
 - TGD 2nd edition in 2003 – 4 parts – 944 pages in total

Approx. **12 to 13** substance risk assessments per year since 1996

REACH (EC/2006/1907)

- Increased scope -> Risk management measures integral part of the safety assessment
- Estimated 30,000 chemicals to be registered by 2018

Approx. **2500-3000** substances to be risk assessed per year

At least 2 orders of magnitude difference

Some challenges: summary

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1. Products
 - Inventory of substances
 - Substance identifier

 2. Management of SIEFs
 - Operation
 - Communication (CBI/Anti-competition)
 - Sameness of the substance
 - Valuation of available studies

 3. Technical expertise
 - E-valuation available information
 - Intelligent testing strategies
 - Exposure assessment

 4. Communication
 - Within the company
 - In the supply chain
 - Breaks in communication

 5. Efficiency
 - Chemical safety assessment
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