



Overview on experiences with exposure scenarios – a reflection of practice so far at company level

Dr. Angelika Langsch, Dr. Christian Bögi, BASF SE
Exchange network on exposure scenarios (ENES), 24/25-11-2011, Brussels



Topics today



BASF and REACH

Chemical Safety Assessment - BASF's approach

Extended Safety Data Sheets

IT support

Outlook

REACH in BASF – An Overview



BASF – The Chemical Company



- **BASF is one of the most affected company by REACH worldwide**
- **BASF is manufacturer, importer and downstream user of chemicals and has to fulfill the requirements set by REACH for a lot of substances**
- **Overall, more than 4500 substances have to be registered by BASF**
- **Ca. 680 substances have been registered under Tier 1**
- **Nearly 950 dossiers have been prepared**

(figures include Cognis data)



- 90 Legal Entities (LE) in the EU und 40 non-EU LE
- 23 REACH Management Team members
- 33 REACH Coordinators
- 120 Substance Coordinators in the operating divisions
- > 100 experts:
toxicologists, ecotoxicologists, phys-chem experts, lawyers
- Additionally: external technical consultants
- ... and thousands of products, customers and uses of products

!! COMPLEX ISSUE !!

Extensive Coordination and training of all people involved is crucial

The REACH networker



Topics today



BASF and REACH

Chemical Safety Assessment - BASF's approach

Extended Safety Data Sheets

IT support

Outlook

Information about uses: specific versus generic



Case A



Single use, one customer



In-depth knowledge of exposure conditions at the customer(s) are available

Case B



Numerous uses, numerous (even anonymous) customers



No detailed knowledge of exposure conditions at individual customers available



Proposed iterative process (customer contact): too time consuming

How to cope with both cases?

"3-step approach": introducing pragmatism



Step-in possible
at all levels

1. Step
Basic exposure assessment
(e.g. ECETOC TRA)



2. Step
Generic exposure assessment



3. Step
Specific exposure assessment

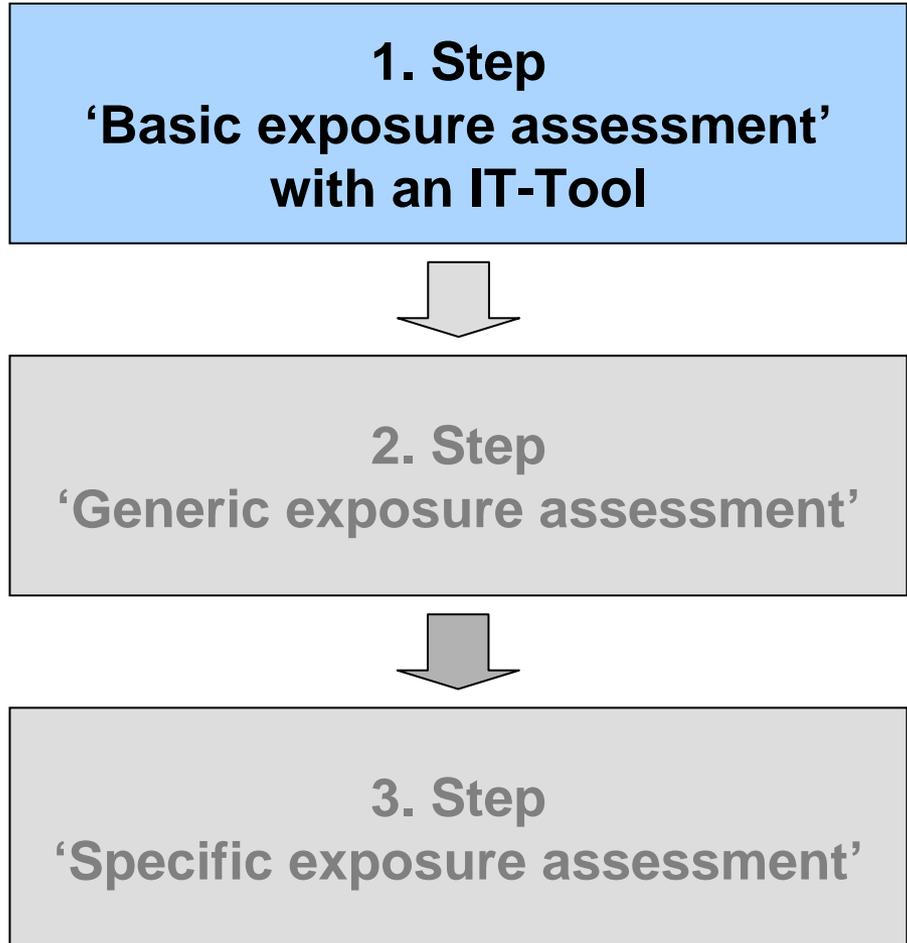
Selection of a tool

- To be applied for all target groups
- Easy to use
- Quick results through automation

Dialogue with Sector Groups

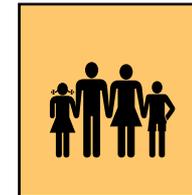
Dialogue with Customer

1st Step: Use of an IT tool



Which tool?

- Applicable for all target groups
- Easy to use
- Fast results through automation



BASF experience with the approach (step 1)



- No refinements or specifics where applied in this first step
- Calculation using ECETOC TRA worked well with 'bulk' upload and did save time
- Results showed a good overview
- However, default 'worst case'-assumptions led to "unsafe" uses
- Therefore, calculation resulted in less finalized assessments than expected
- Late availability of input parameter (e.g. DNELs, PNECs) due to intensive discussions in SIEFs retarded the process

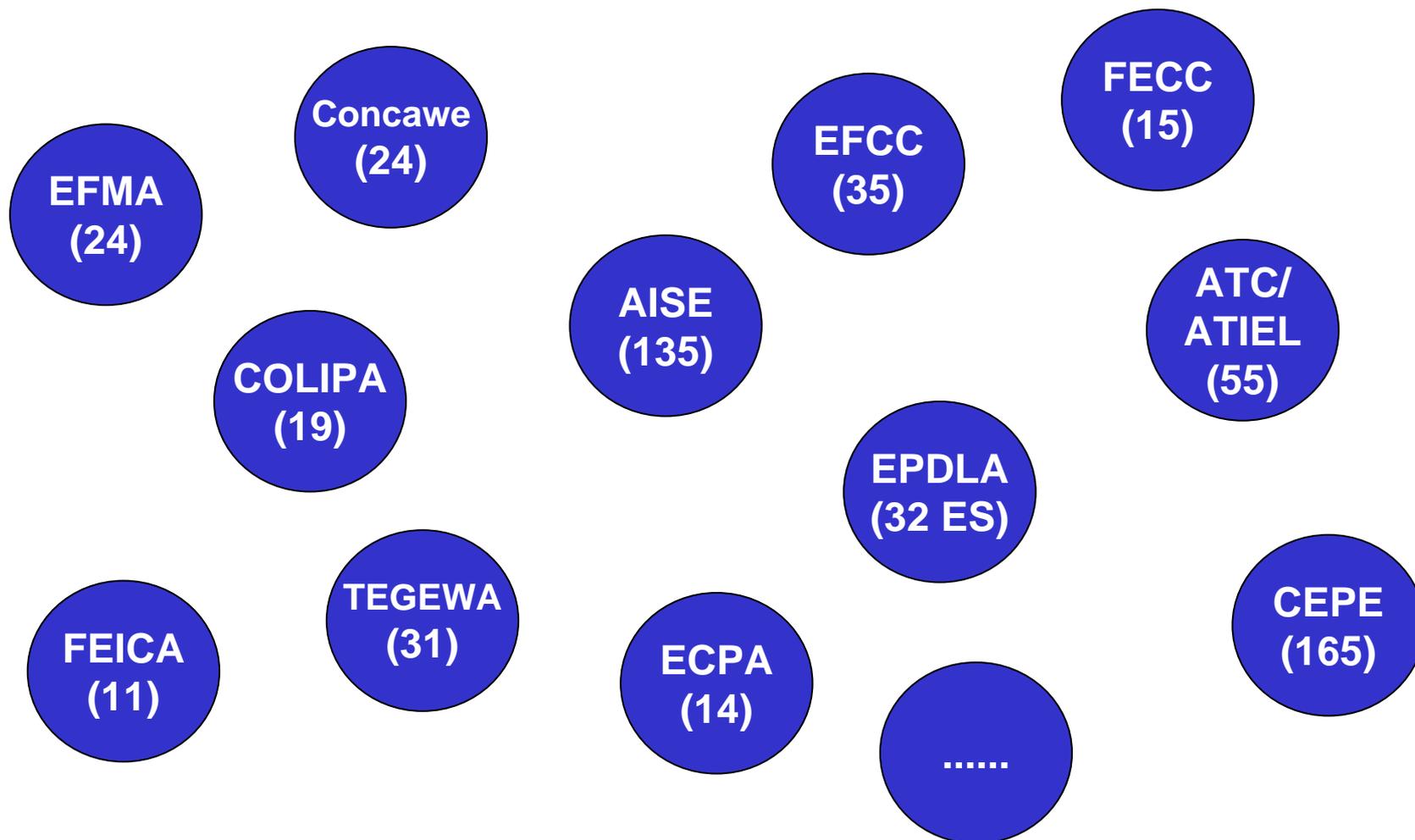


BASF experience with the approach (step 2)



- **Appropriate ES-information from sector groups**
- **Sometimes difficult, as sector groups had few experience with use descriptors in the beginning**
BASF initiated information meetings and supported sector groups with trainings
- **Information is now available (e.g. DUCC, ca. 170 spERCs), this is essential for ‘refinement’ of the risk assessment**
- **Online libraries with ES information of the sector groups with late availability (Cefic web page)**
- **In case consortia and SIEF were familiar with the information, discussions and agreements were much easier**

Currently: great variety of sector specific ES



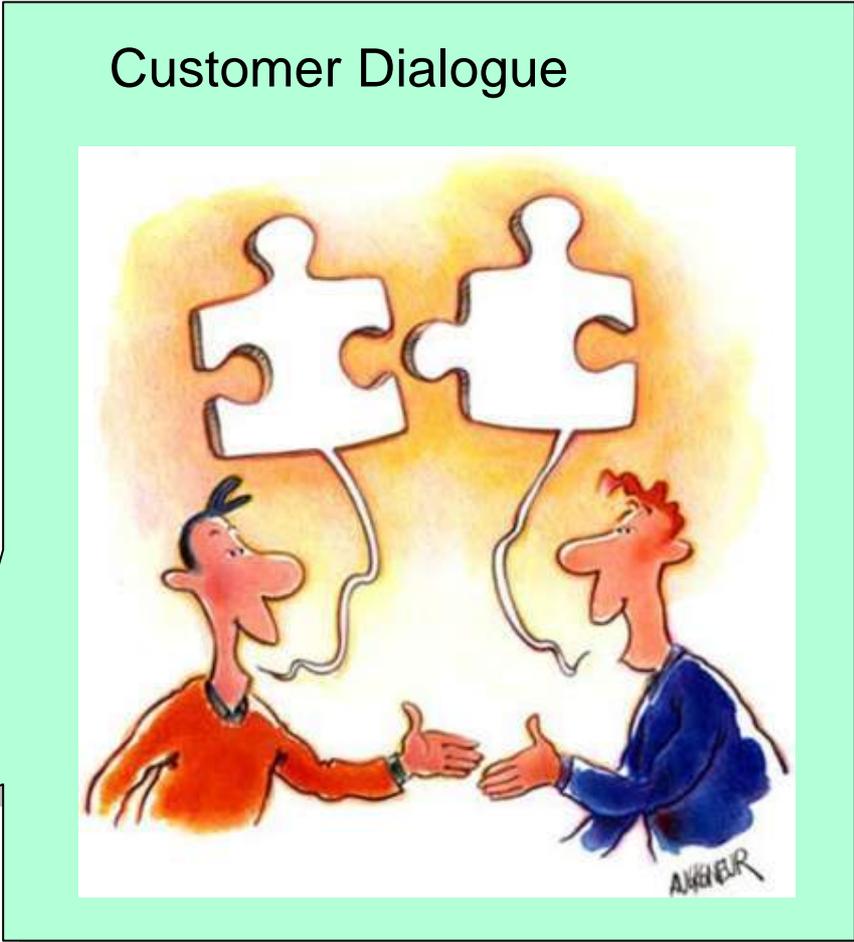
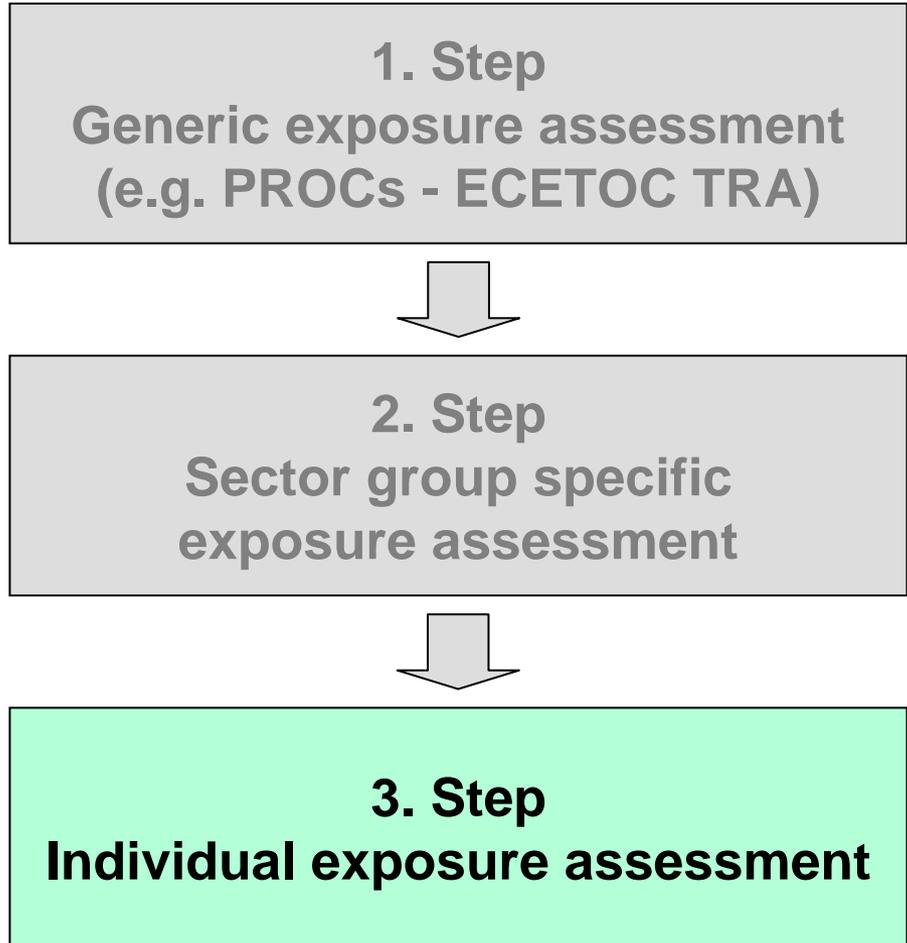
Challenge for assessors, consolidation of information possible??

Currently: great variety of sector specific ES

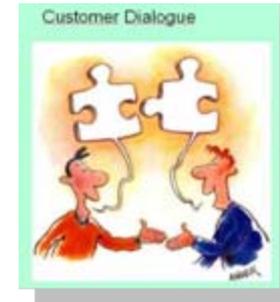


- **Possibility 1: assessment of all individual ES**
 - complex and laborious
 - addition of all ES to CSR and eSDS makes documents large and unmanageable
 - redundancies possible due to similar ES from different sectors
 - allows for the DU to search the specific DU scenario (by sector code) of his needs without having to figure which combination of use descriptors is appropriate
- **Possibility 2: consolidation of ES**
 - reduction of number of assessments
 - CSR and eSDS shorter and more concise
 - DU needs to identify appropriate ES and do adaptation (e.g. scaling, DU-CSR, notification to supplier) if necessary

3rd Step: detailed customer communication



BASF experience with the approach (step 3)



- Step 2 often served as basis for step 3, additional refinements were applied
- For 'refinement' often more detailed information is necessary than available in the sector groups
- BASF internally collected the uses of their customers in a data base and tried to consolidate uses
- Customer notification of uses: the dialogue starts ...
- Varying quality of use notifications
- No harmonised information, e.g. due to change of guidance for use descriptors during preparation phase of Tier 1
- Variety of tools available and used

Topics today



BASF and REACH

Chemical Safety Assessment - BASF's approach

Extended Safety Data Sheets

IT support

Outlook

Extended Safety Data Sheets



- Compilation and preparation of SDS requires expertise
- BASF ships worldwide > 1 Mio safety data sheets per year
- Implementation of ES as annex in December 2010: Time pressure due to late availability of Annex II and guidance documents
- Requirements:
 - Generation in IT-system
 - Training of people involved
 - To be provided in several languages
 - Assure management of SDS versions

BASF
The Chemical Company

Safety data sheet

Page: 1/96

BASF Safety data sheet according to Regulation (EC) No. 1907/2006
Date / Revised: 00.00.0000
Product: Hexamethylenediamine

Version: 0.0
//SDS_GEN_EU/EN/
Date of print 08.11.2011

1. Identification of the substance/mixture and of the company/undertaking

Product identifier

Hexamethylenediamine

Chemical name: hexamethylenediamine
CAS Number: 124-09-4
REACH registration number: 01-2119473901-25-0002, 01-2119473901-25-0011

Relevant identified uses of the substance or mixture and uses advised against
Recommended use: for the production of homopolymerisates and copolymerisates, initial product for chemical syntheses

For the detailed identified uses of the product see appendix of the safety data sheet.

Details of the supplier of the safety data sheet

Company:
BASF SE
67056 Ludwigshafen
GERMANY

Telephone: +49 621 60-0
E-mail address: global.info@basf.com

Emergency telephone number

International emergency number:
Telephone: +49 190 2273-112

2. Hazards Identification

Label elements

According to Regulation (EC) No. 1272/2008 (CLP)

Annex to the eSDS – Result of a long process



- 4-section format for the ES was implemented as given in the updated ECHA guideline
- Depending on variety of uses the annex may be large => but provides information in a structured way
- Table of content facilitates an easier identification of the exposure scenario relevant to the DU
- Need to get used to a common language => standard phrases
- Making ES info available in EHS IT systems still requires manual typing => Electronic transmission is needed

Page: 15/96

BASF Safety data sheet according to Regulation (EC) No. 1907/2006
 Date / Revised: 00.00.0000
 Product: Hexamethylenediamine

Version: 0.0
 (SDS: GEN_EUWEN)
 Date of print 08.11.2011

Annex: Exposure Scenarios

Index

1. Manufacture of substance
 SU3; SU8, SU9, ERC1, PROC1, PROC2, PROC3, PROC8a, PROC8b, PROC9, PROC15
2. Use as Monomer
 SU3; SU12; ERC6c; PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC15; PC32
3. Use as Monomer
 SU3; SU12; ERC6c; PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC15; PC32
4. Use as an intermediate
 SU3; SU8, SU9, ERC6a; PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC15; PC19
5. Formulation, (solid)
 SU3; SU10; ERC3; PROC5, PROC8a, PROC8b, PROC9, PROC15; PC32
6. Use in/as Formulation, (solid), Industrial applications
 SU3; SU11; ERC6a; PROC5, PROC6, PROC8a, PROC8b, PROC14; PC32
7. Formulation & (re)packing of substances and mixtures, (liquid)
 SU3; SU10; ERC2; PROC3, PROC8a, PROC8b, PROC9, PROC15; PC34
8. Use in/as Formulation, (liquid), Industrial applications
 SU3; SU5; ERC5; PROC5, PROC8a, PROC8b, PROC13, PROC15; PC34

1. Short title of exposure scenario
 Manufacture of substance
 SU3; SU8, SU9, ERC1, PROC1, PROC2, PROC3, PROC8a, PROC8b, PROC9, PROC15

Control of exposure and risk management measures

Contributing exposure scenario	
Use descriptors covered	ERC1: Manufacture of substances
Operational conditions	
Daily amount per site	300,000 kg
Minimum emission days per year Continuous	300
Emission factor air	0.01 %
Emission factor water	0.30 %
Emission factor soil	0.01 %
Releases based on A&B-tables taken from TGD 2003	
Process optimized for highly efficient use of raw materials	
Dilution factor coast	1,500

Topics today



BASF and REACH

Chemical Safety Assessment - BASF's approach

Extended Safety Data Sheets

IT support

Outlook

IT support



Implementing REACH into practice requires enormous efforts. Therefore, IT support is indispensable for:

- Management of use notifications, consolidation
- Exposure estimation: GESs, SPERCs etc. need to be available in assessment tools
- Electronic exchange of ES information from and to companies' IT systems is required
 - ECom XML
- A common and agreed ES language
 - standard phrases
- Electronic support for the processing of information
 - compilation of the annexes of eSDSs
 - support of the DU compliance check under REACH
- Scaling

Necessary prerequisites are under development, but still have to be finalized and implemented

Topics today



BASF and REACH

Chemical Safety Assessment - BASF's approach

Extended Safety Data Sheets

IT support

Outlook

Conclusion



- **Even one year after Tier 1 registration, companies have to struggle with a lot of unclear issues**
- **Approaches and understanding still varies a lot**
- **Alignment of stakeholder views requires further training for all players (everyone needs to understand the subject)**
- **Supplier eSDS are a challenge**
 - **Understanding of the chosen approach**
 - **Maintenance of the data**
 - **Internal compliance check**
 - **Processing of ES data for compounds to make information available for SDS of mixtures**
- **Scaling needs clarity and expertise**
- **IT tools need to be developed (further) and implemented**
- **Management of expectations: all players in the REACH arena are still on a learning curve, making the legislation smoothly running in practice still requires time and effort**

Recommendations



- **Communication of identified uses: early and clear**
- **Consolidation of uses where possible (e.g. for substance groups or similar activities across sectors)**
- **Focus on relevant uses only**
- **Avoidance of redundancies leading to overloaded SDSs**
- **Continued training and dialogue on the issue**
- **Share experiences**

Thank you for your attention!

