



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

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Exchange network on exposure scenarios (ENES), 24/25-11-2011, Brussels



# Topics today

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## 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



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# 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**

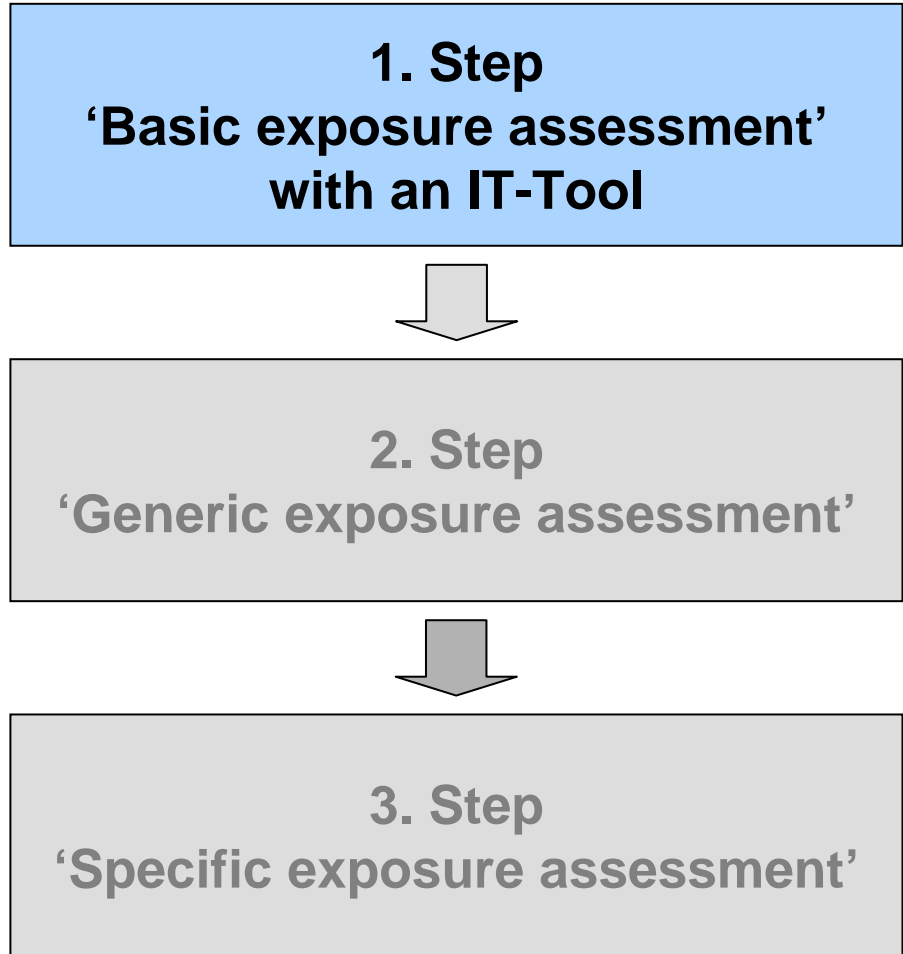
- To be applied for all target groups
- Easy to use
- Quick results through automation

Dialogue with Sector Groups

Dialogue with Customer

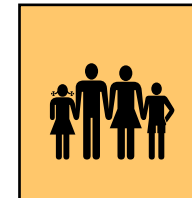


# 1st Step: Use of an IT tool



## 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



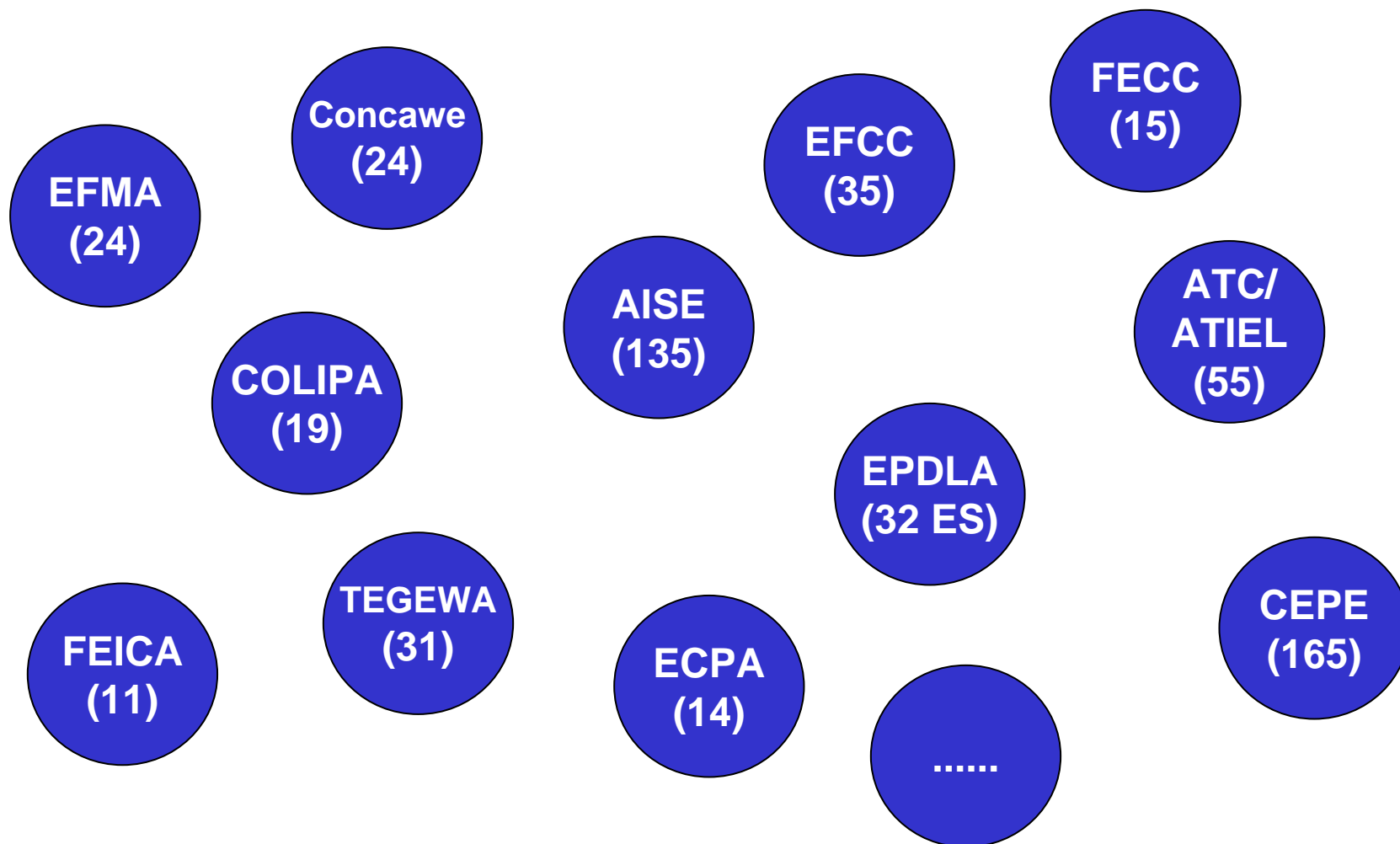


# BASF experience with the approach (step 2)



- **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. DUCG, 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??

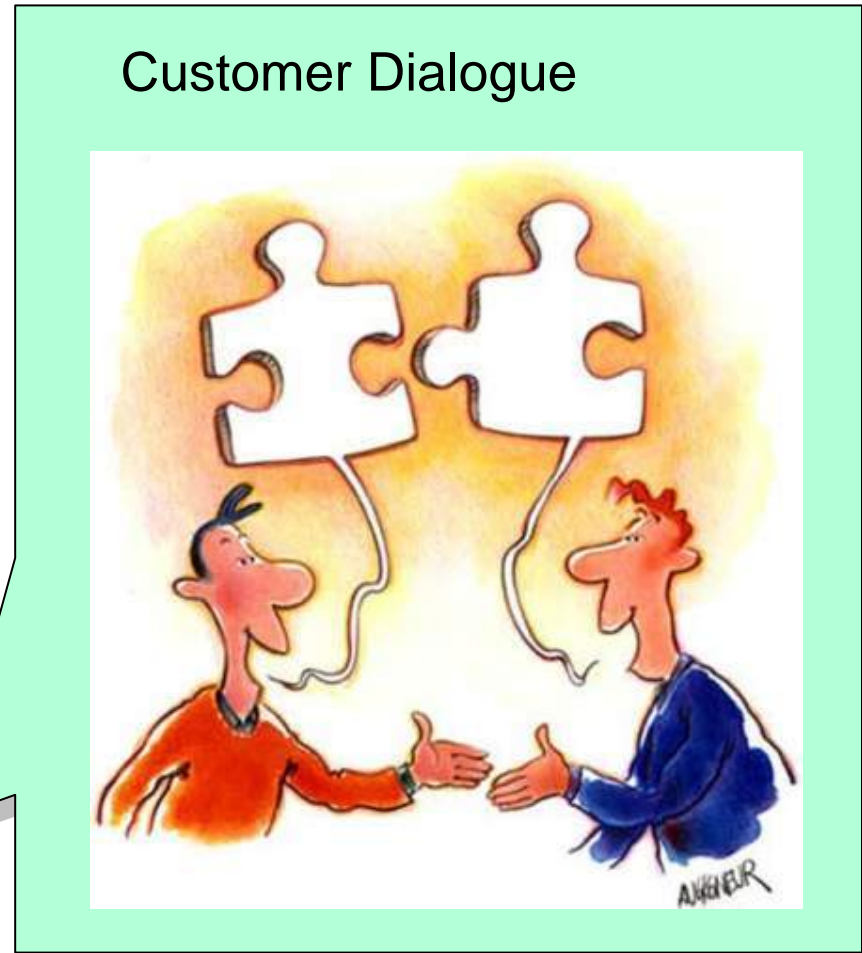
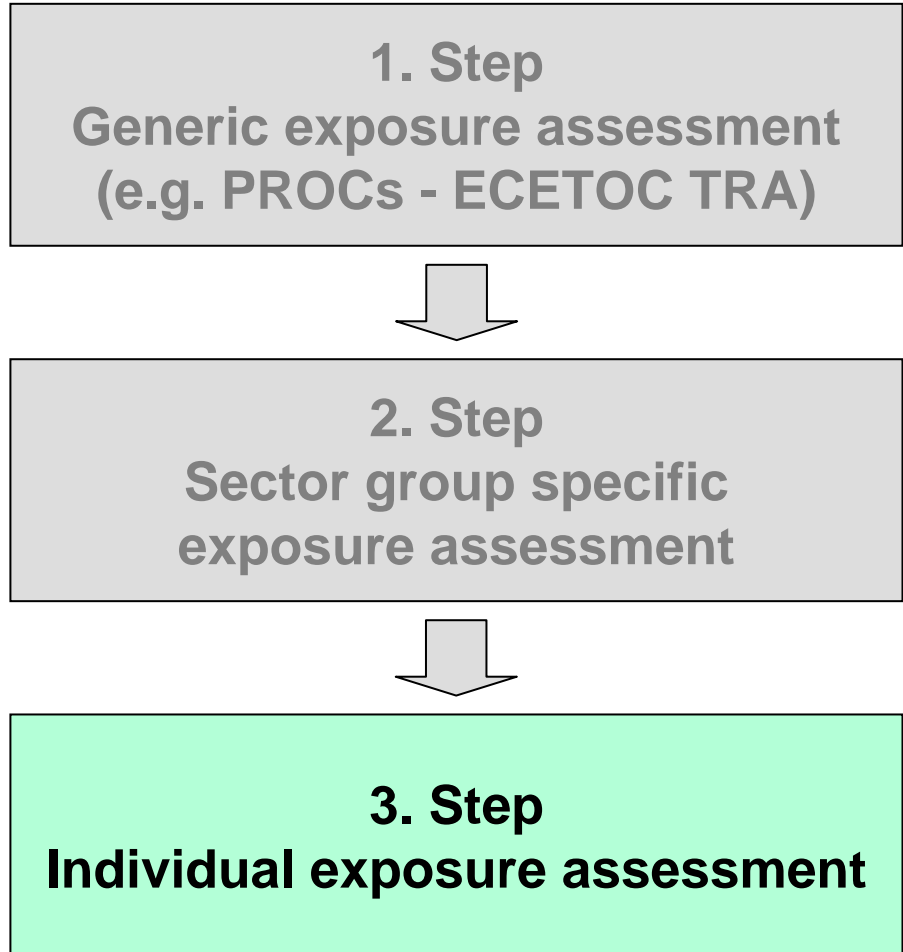
# Currently: great variety of sector specific ES

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- **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

# 3<sup>rd</sup> 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

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# 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**

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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

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**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

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**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

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

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**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

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**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
<b>Operational conditions</b>	
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

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# IT support

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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**

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# Conclusion

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- **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

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- **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!**

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