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Federal Institute for Occupational  
Safety and Health

# REACH2SDS Workshop

**MIND THE GAP**

## The REACH2SDS Project

Nicoletta Godas

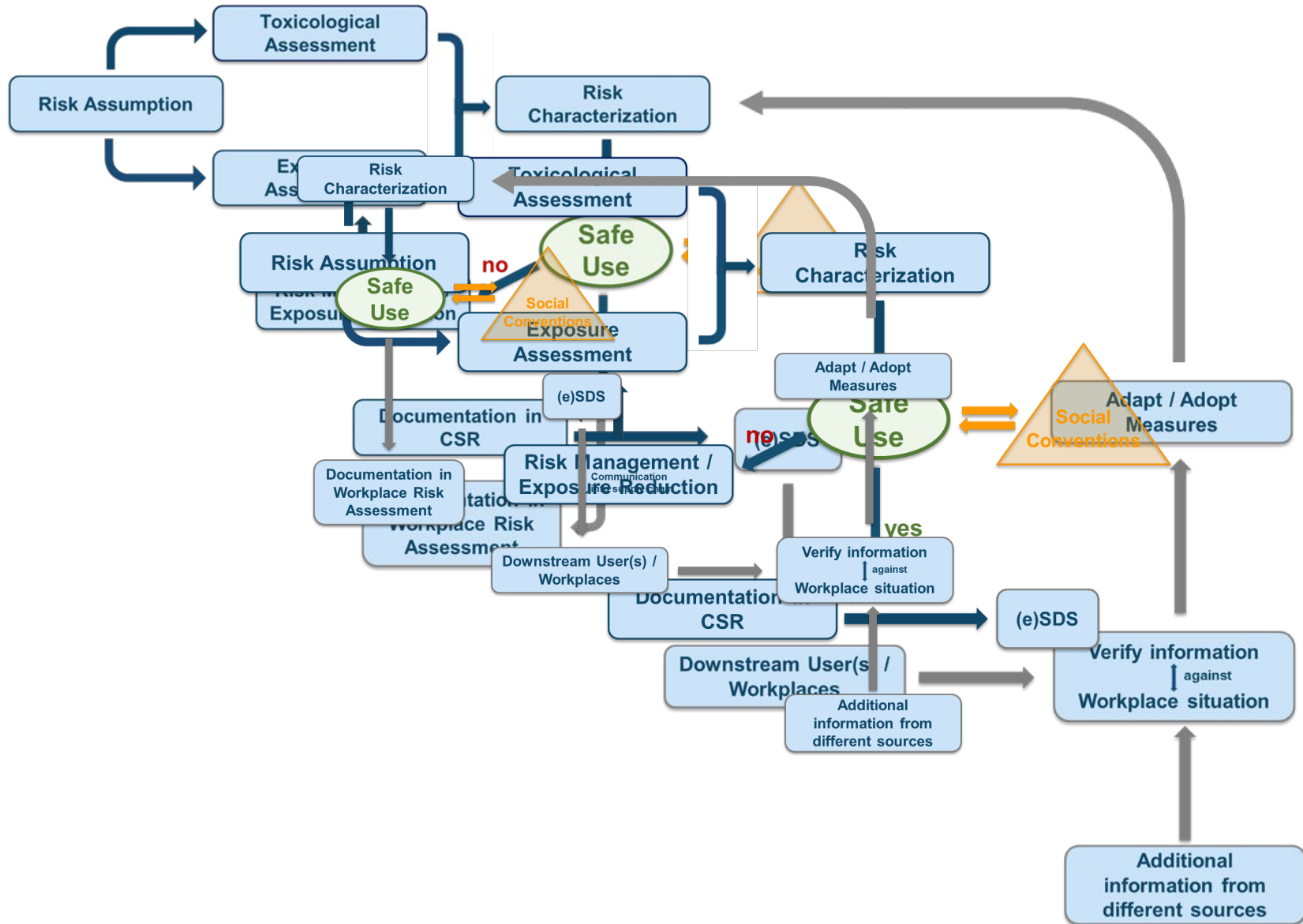
# Project Team

**b a u a :**  
Federal Institute for Occupational  
Safety and Health

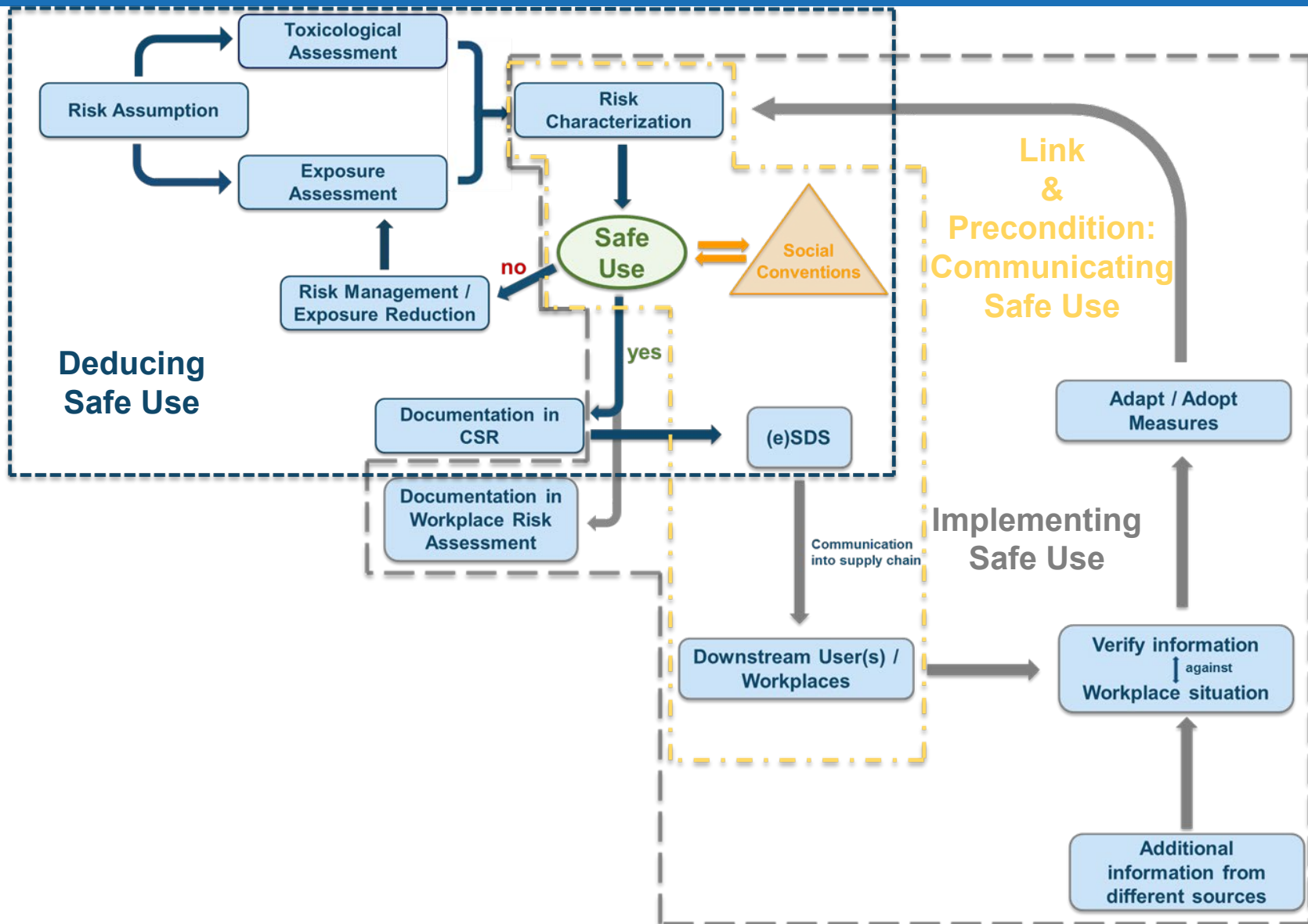
**Angela Kämpfer  
Susann Wothe  
Charlotte Haase  
Elina Wolf**

**MIND THE GAP**

# Risk management: REACH & OSH



# Risk management: REACH & OSH



Registration  
dossier

```
graph TD; A[Registration dossier] --> B[Safety Data Sheet]; B --> C[Workplace risk assessment];
```

Safety Data  
Sheet

Workplace risk  
assessment

**Data availability**, workplace exposure, risk management measures

**Quality of information transfer**

**Usability for workplace risk assessment**

<https://www.baua.de/reach2SDS-en>

# REACH2SDS → Research Project

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REACH2SDS:

REACH Exposure Assessment of Chemicals to  
Safety Data Sheets

Identifying problem  
areas

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Compliance Check

or

Enforcement Activity

# Registration Dossier Analysis

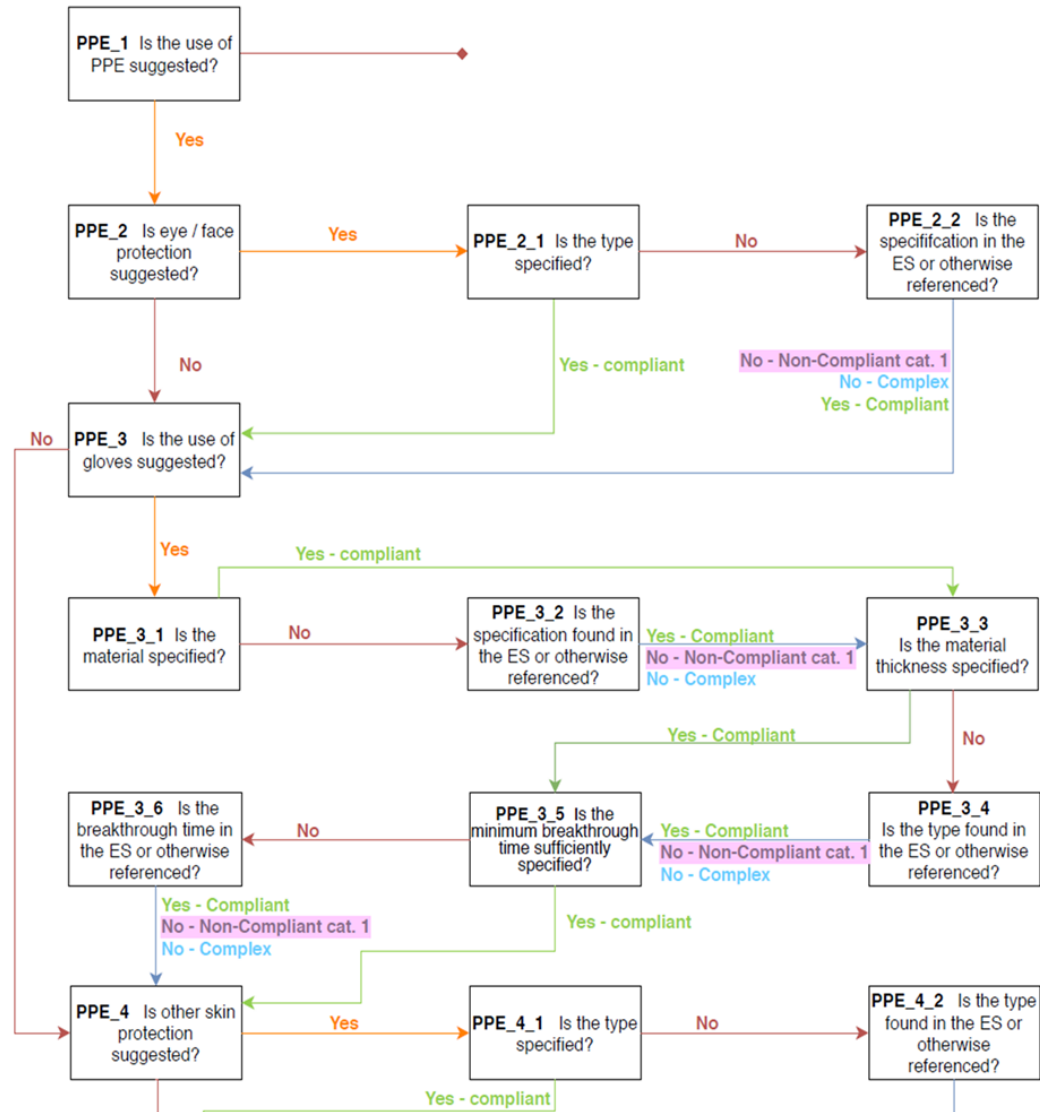
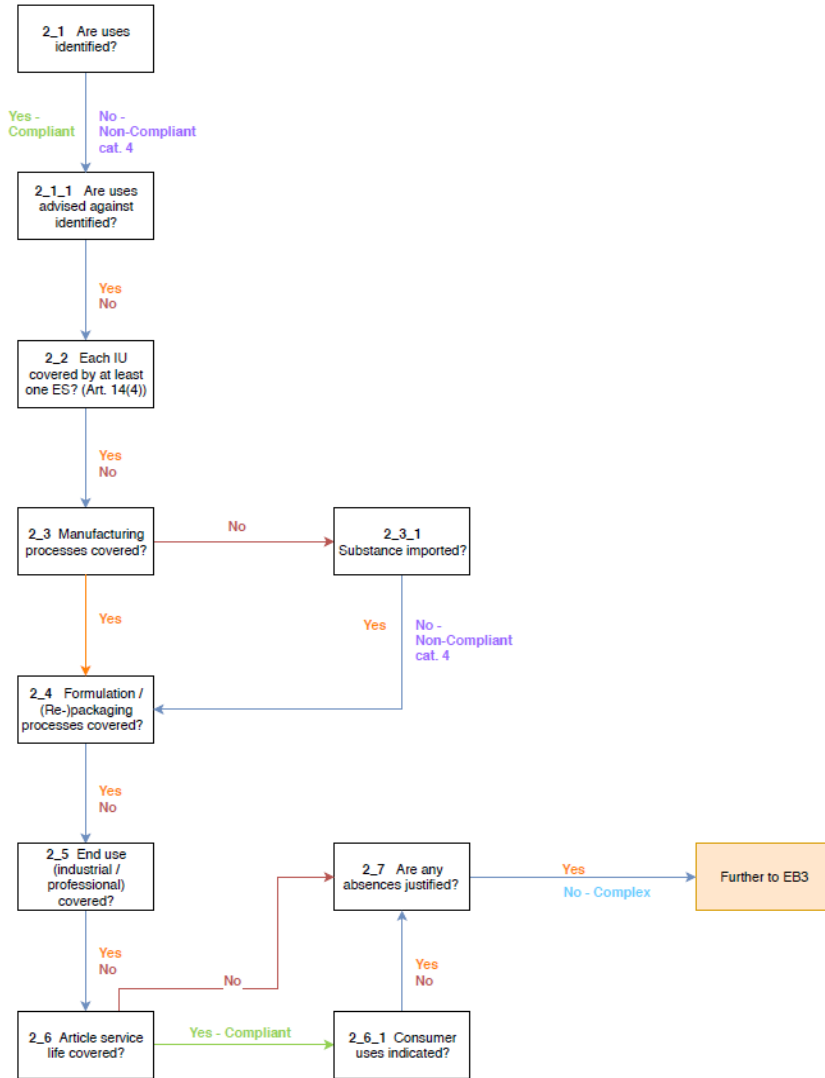
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Analysis of data availability of exposure and use related information:

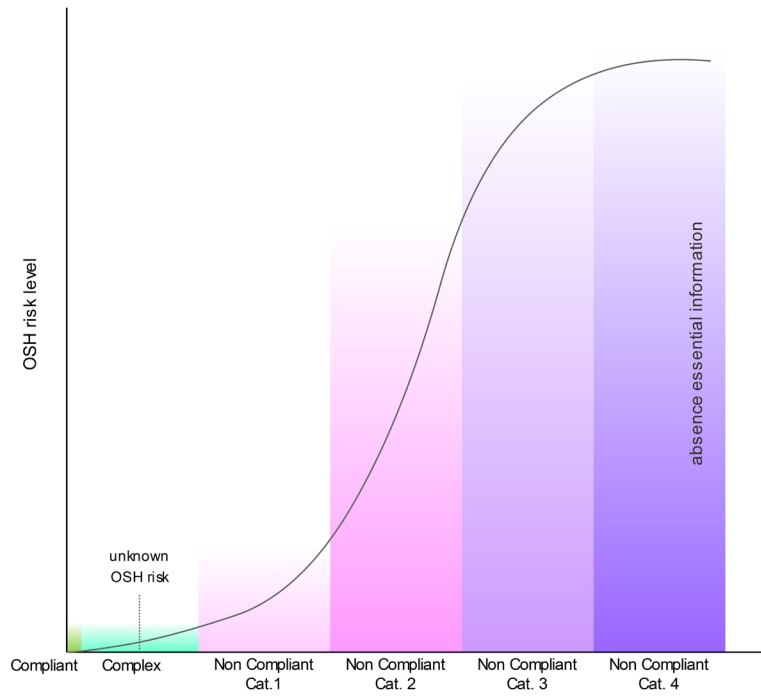
- planned 1690 Lead-Dossiers for chemicals of the 100 – 1 000 tpa band
- definition of relevant markers
- development of decision trees



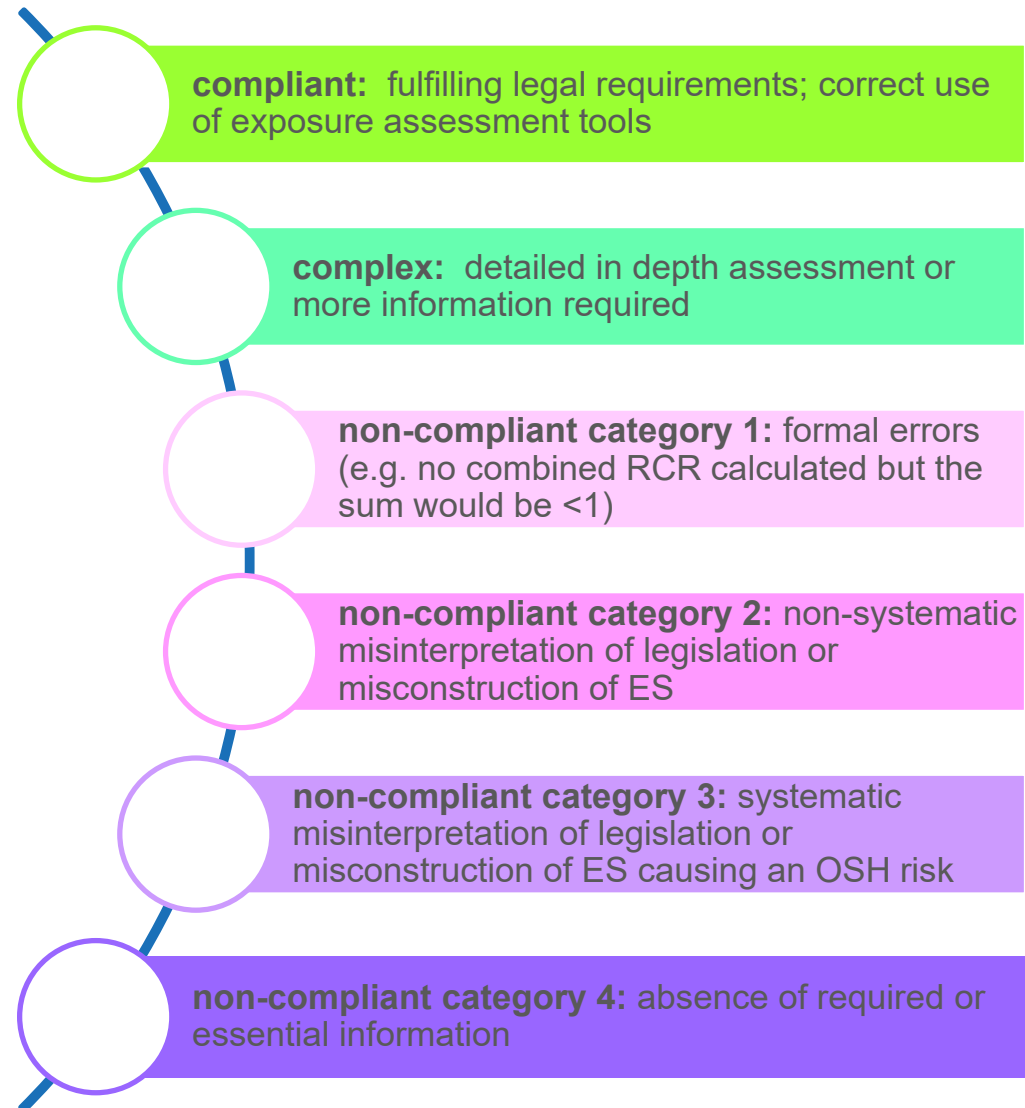
# Decision Tree Examples



# Banding Approach for decision tree evaluation



→ Depending on the severity of the information gap for safety at work



# Preliminary results

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→ ~ 600 completed analyses

significant quality differences between CSRs

missing information:

- **personal protective equipment**
- lack of information on the manufacturing process for non-imported substances
- CSR

# Preliminary results

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Critical observations:

- stretching model limitations
- models used: so far only Tier1
- use of inappropriate reduction factors
- discrepancies between process and RMMs

# Comparison of data availability & quality between registration dossier and eSDS

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1907/2006 Art. 31(2):

“Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the **information** in the safety data sheet **is consistent** with the information in this assessment.”

# Safety Data Sheet (SDS)

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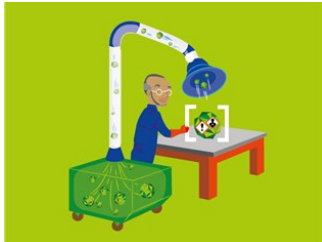
The communication tool in the chemical supply chain!

enables the employer to determine:

- are there hazardous substances at the workplace?
- are there risks?
- serve as a basis for assessing risks

enables the user:

- to implement necessary protective measures



**REACH Regulation: Annex II**

# Extended Safety Data Sheet (eSDS)

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SDS + annexed **Exposure Scenarios (ES)** = eSDS

## **Exposure Scenarios:**

part of the Chemical Safety Report (CSR)

Set of:

**Operational conditions & Risk Management Measures** that describe how the substance is manufactured or used during its life-cycle

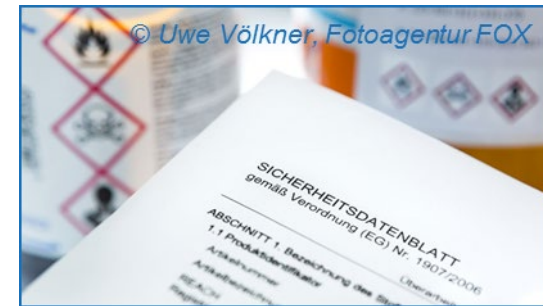
→ Safe Use

→ Controlled Risk

**Art. 3 No. 37 REACH-Regulation**

# Comparison of data availability & quality between registration dossier and eSDS

- definition of relevant eSDS-related markers
  - classification
  - use advised against
  - RMM
  - PPE details
  - ...
- development of decision trees
  - eSDS required
- questionnaire designed to maximize query value





# Preliminary results

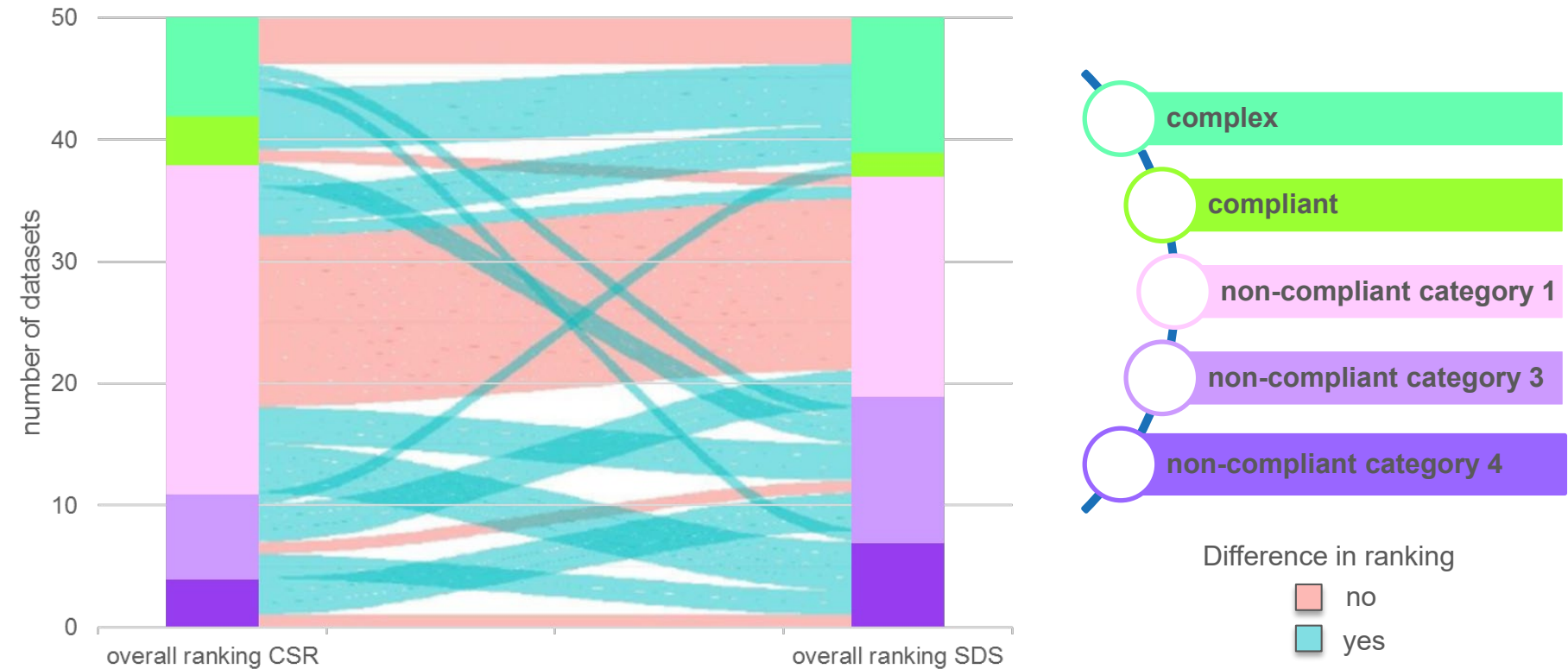
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300 eSDS planned for representative statement

received: ~ 200 eSDS

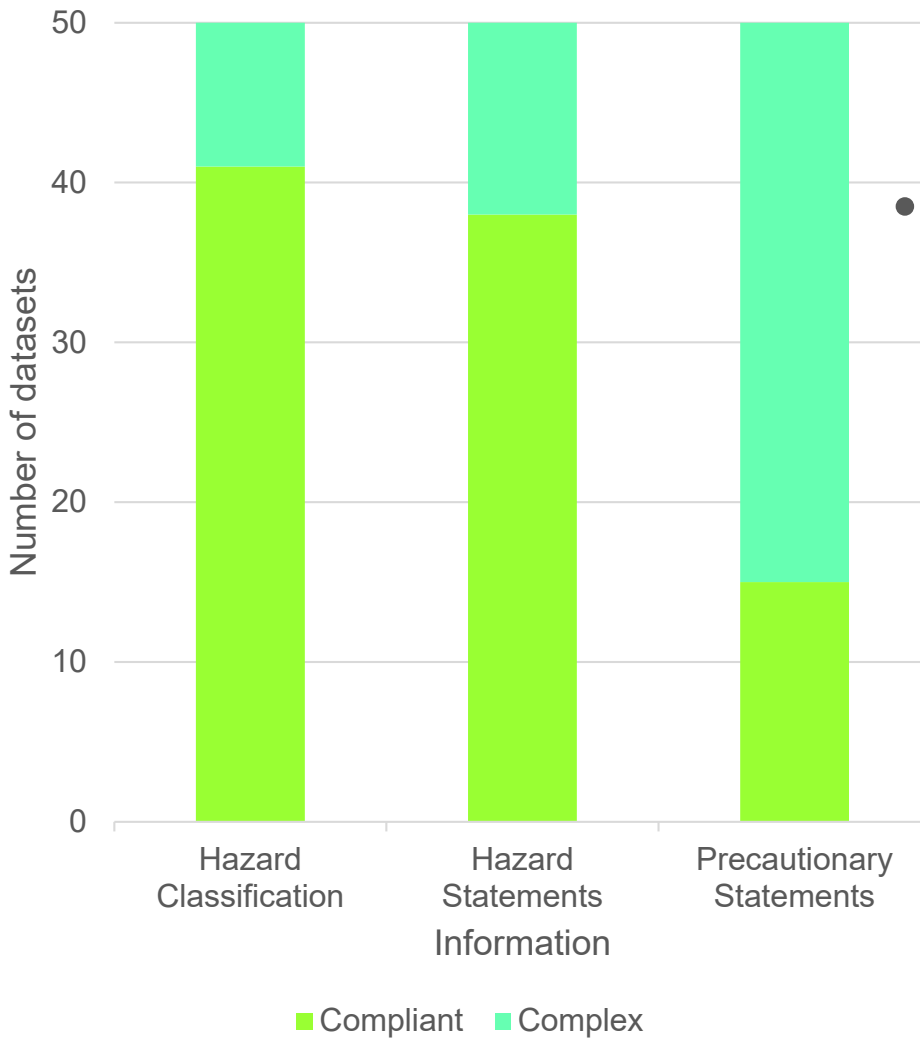
- half out of scope
- lead registrants hesitant to share the eSDS
- additional SDS acquisition
- current status eSDS: ~ 160 evaluable

# Differences in data availability & quality between CSR and eSDS of 50 datasets



- lack of PPE information
- issues with RCR calculation, e.g.  $RCR > 1$  or national OEL not considered in eSDS

# Consistency of classification & labelling



- identified differences in classification, hazard and precautionary statements between CSR and eSDS indicated by the result category “complex”

# Consistency of PPE information

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- availability on PPE information in (e)SDS was provided at a higher percentage compared to CSRs
- a common issue are information on glove thickness and their breakthrough time

# Questionnaire

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1. **Introduction:** Role under REACH
2. **Development of the eSDS:** Which tools and information are used, who is responsible?
3. **Communication:** use for internal company risk assessment, how will the eSDS and changes be communicated to downstream users?

# Questionnaire

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- 4. Quality management:** eSDS quality and completeness checked? Consistency check with CSR?
- 5. Personal Views:** impact of eSDS, creation effort, usefulness for downstream user
- 6. Personal Views:** changes that may improve ES / eSDS
- 7. Information about the company:** number of employees, country

# Preliminary results

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## Majority of respondents:

- considers the creation and communication of eSDS to be useful
- does not use other tools for risk communication with downstream users



- does not consider the eSDS suitable as a source of information for workplace risk assessment

# Preliminary results

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but:

- uses results from the internal workplace risk assessment for CSR creation
- even more use the eSDS internally to communicate risk and RMM





# Preliminary results

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## Free text fields:

Suggestions for improvement of eSDS format

- increasing harmonisation; mandatory format
- shorter; important information in the main part of the SDS
- less scientific; better applicable for different levels of education

# Comparison of eSDS & CSR information in the context of workplace risk assessment

- consistency check of RMMs communicated via the eSDS using the EMKG



# EMKG Workplace & Chemicals:

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- tool for workplace risk assessment
- combines easily accessible parameters from SDS and site inspections and suggests appropriate measures → Control Guidance Sheets
- enables the determination of an appropriate control strategy for contact with hazardous substances via:
  - inhalation
  - skin contact
  - fire and explosion

# Comparison EMKG output & ES

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Checked if:

- the information provided in the Control Guidance Sheets and RMM matched
- the required RMM were missing or if less/other RMM would have been sufficient

or

- the Control Guidance Sheets and RMM are only consistent up to a certain quantity range

# Comparison EMKG output & ES

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~ 450 ES have been checked

- results show about 50% of RMM from eSDS were inconsistent with the recommended protective measures from EMKG
- inconsistencies may effect risk assessment of the employers
- complicates the employer's duty to implement appropriate measures to protect employees

# Workshop

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- part of the research project
- discuss identified challenges
- set a starting point for solutions



# Summary REACh2SDS

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REACh2SDS evaluates:

- the data availability on workplace exposure, use and on RMM for registered substances
- how this data is communicated in the supply chain via eSDS
- how this data can be used for workplace risk assessment

# Thought starter

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- Is the information you receive via the supply chain sufficient for you to work with?
- Does the information you feed into the supply chain meet your own expectations?

## Contact

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# Copyright information

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