



Federal Institute for Occupational
Safety and Health

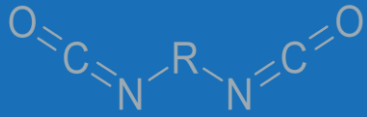
Improving Occupational Safety and Health when Working with Diisocyanates

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Background – Diisocyanates (DI)

- Important substance in industry for polyurethanes products
- Production > 2.5 million t/y
- Widespread use in specialty and everyday products
- 5 million potentially exposed workers

- Respiratory and skin sensitiser
- Number of work-related DI asthma cases in the EU/year is in the four-digit range



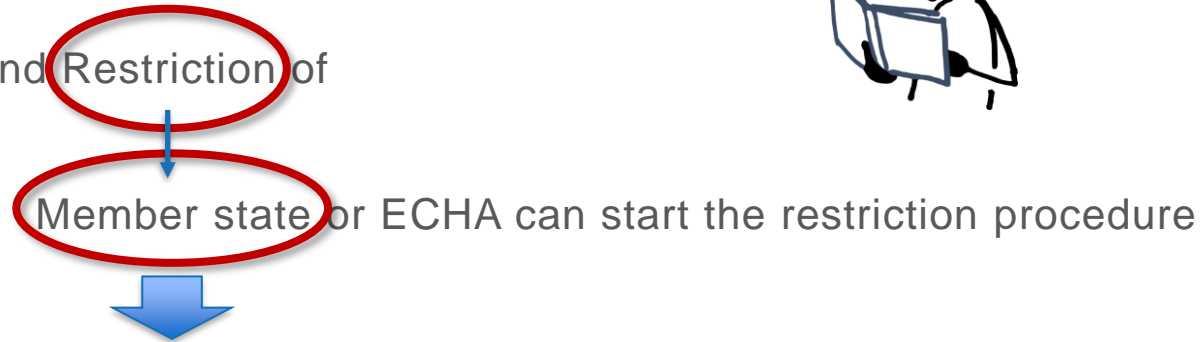
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Restriction under REACH

Regulation concerning the
Registration,
Evaluation,
Authorisation and Restriction of
Chemicals



BAuA Germany in 2016:
New concept: no ban, but requirements instead → Teaching safe handling of DI through specific trainings
→ Regulation of DI by the EU Commission in 08/2020

Feasibility study

Feasibility study,
Preparation main cohort study

Main cohort study: 5 years
incl. intervention study

2018

2019

2020

2021

2022

2023

2024

2025

Aims

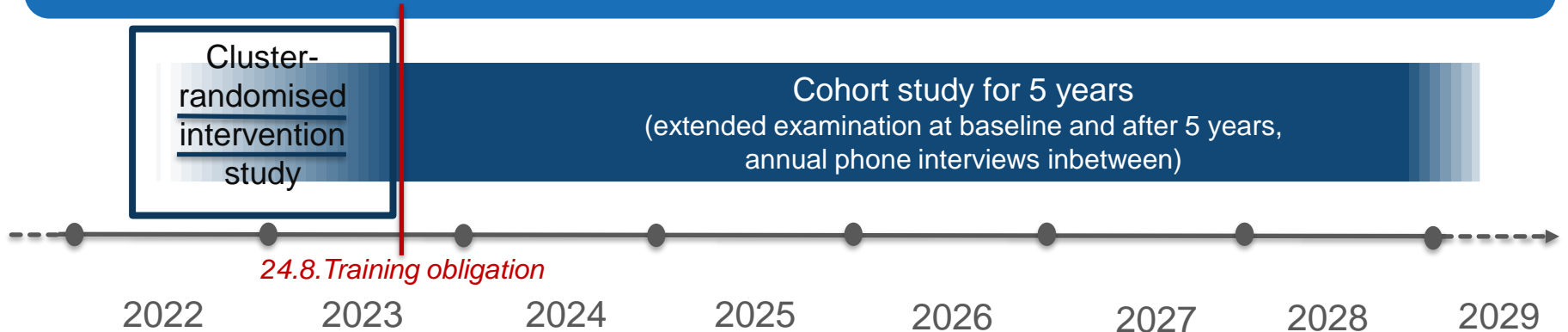
- Recruiting enough companies with DI-exposed workers for cohort study + controls (~1 500 + 200) → Resulted in provisional commitment of 35 companies with >1.300 exposed employees
- Design of the main study

Funded by:

- Federal Institute for Occupational Safety & Health (BAuA)
- European Associations of Isocyanate Producers (ISOPA/ALIPA)
- Selected Statutory Accident Insurance Institutions (BG RCI, BGHM, BG BAU, BG ETEM, BGHW)



Main study: cohort and intervention study



Aims

- Record number of DI-related respiratory and lung diseases (prevalence, incidence)
- Determine DI exposure (external exposure, biomonitoring)
- Describe the relationship between exposure and lung function (dose-response)
- Check effectiveness of the trainings under REACH-restriction (exposure reduction)

Intervention study: Cluster randomised controlled trial

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7
Intervention group	Baseline	Training			Biomonitoring 2		
Waiting control group		Baseline				Biomonitoring 2	Training

- Questionnaires
- Blood and urine samples for biomonitoring
- FeNO (fraction of exhaled nitric oxide)
- Spirometry (Lung function test)
- Methacholine challenge test
- Photo documentation of skin (hands)
- Air monitoring

- According to REACH
- Trainer from ISOPA/ALIPA + standardised training materials
- Part of the study
- Process evaluation

Air Monitoring – Sampling Strategy

Each activity with DII:



Personal air sampling
(1-3 workers)



Stationary air sampling
at emission source



Material sample of
emission source



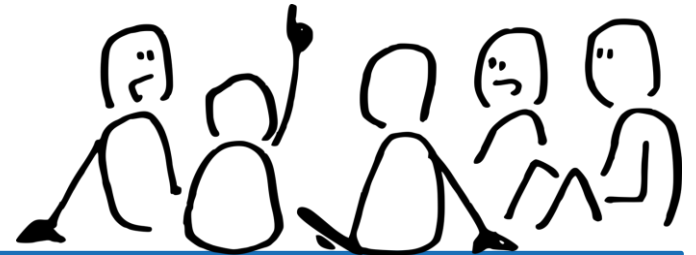
- Impregnated filters (1,2-MP)
- 2 h with 3,5 L/min
- Quantification of monomeric DII, TRIG and poly isocyanates

Summary

- **REACH restriction on diisocyanates is scientifically monitored**
 - Combination of epidemiological, analytical and medical research
 - Investigation of exposure, health, effectiveness of training
 - Different study designs (observational study + intervention study)
- **Large-scale cooperation project**
 - Various scientific disciplines, different stakeholders involved
 - Including companies throughout Germany
- **Findings can be used directly for occupational safety and health in companies**
- **Example for evaluation of new EU-wide chemicals regulation**

b a u a :

Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin



Thank you for your attention!



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Back-Up

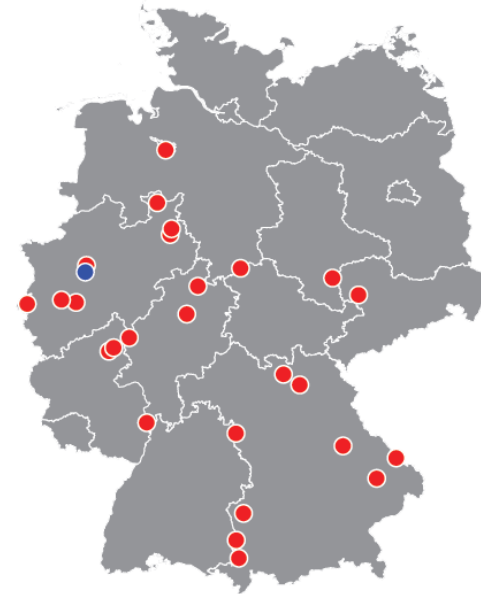
Results: Recruited Companies

Flow Chart about the recruitment of the companies for the cohort and intervention study

35 Companies with provisional commitment to the cohort study during feasibility study, incl.
>1.300 exposed employees (potential study participants)

26 Updated company locations with confirmed commitment to the intervention and cohort study

Locations of the companies participating in the intervention study in Germany (red), study centre IPA (blue)



Distribution of used Diisocyanates and Industrial Sectors

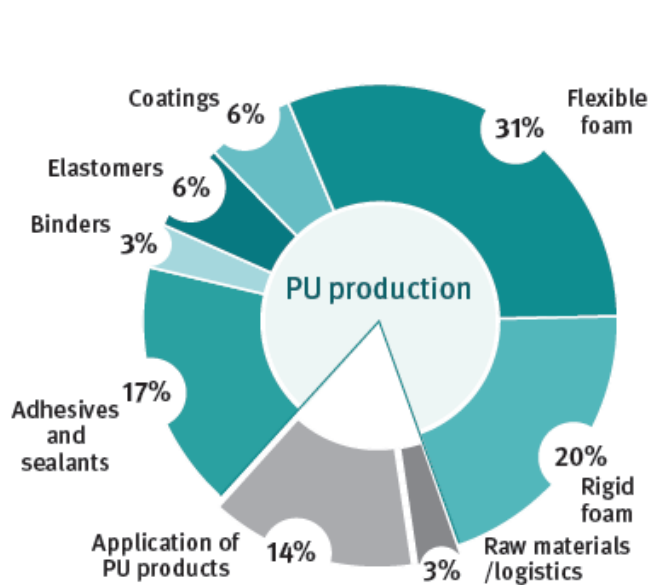


Fig. 2: Sectors of the 35 companies with provisional commitment during the feasibility study, divided into PU-producing companies (29), PU-using companies (5) and raw materials/logistics (1)

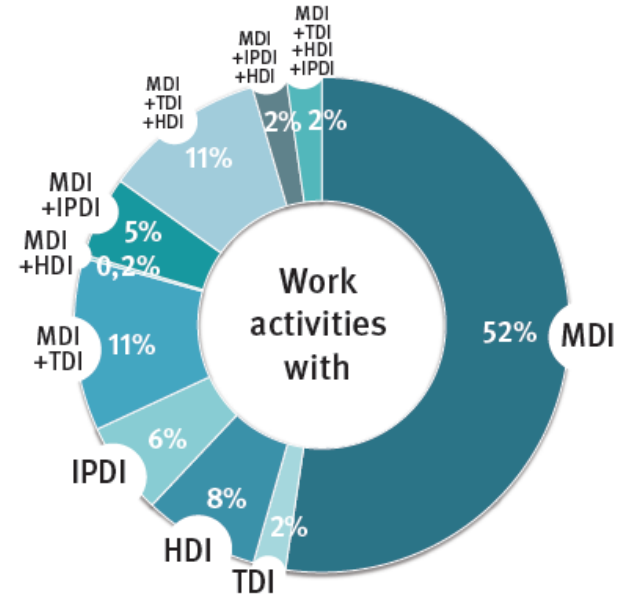


Fig. 3: Distribution of the > 1.300 employees in the companies with preliminary commitment with regard to the DII MDI, HDI, TDI or IPDI used in their work activities