

LCM in the pharmaceutical industry using an applicable and robust LCA-based environmental sustainability assessment approach

Marc-William Siegert, Yasmine Emara, Annekatriin Lehmann, Matthias Finkbeiner

LCM Conference

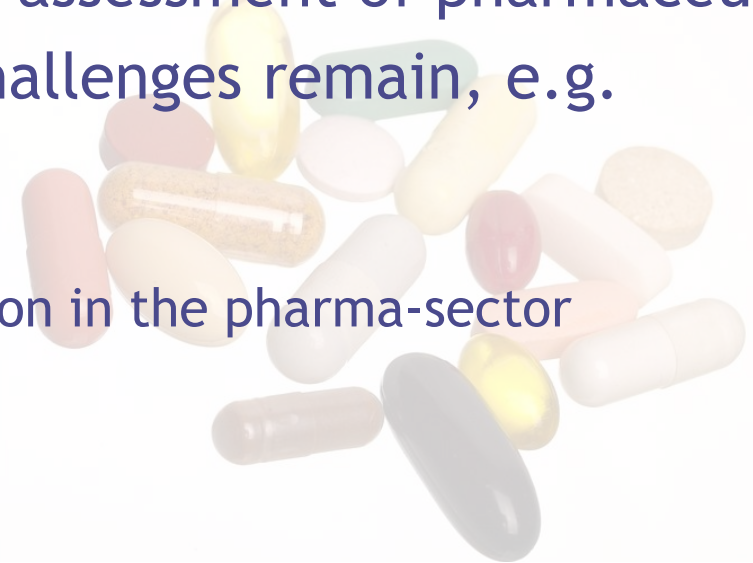
Luxembourg, 03-06 Sept 2017



Technische Universität Berlin
Department of Environmental Technology
Chair of Sustainable Engineering



- A growing and ageing human population have led to a significant global rise in the consumption of pharmaceuticals...
...and also to increasing environmental impacts
- Efforts regarding environmental and sustainability assessment of pharmaceutical products and processes already exist, but many challenges remain, e.g.
 - Missing consideration of the whole life cycle
 - Methodological and practical challenges of LCA-application in the pharma-sector



Our goal & approach

- 2016-2019: project “SERUM” (Fund: German Federal Environmental Foundation)

• **Goal: *Sector-specific methodology for environmental assessment in the pharma industry***



- **Objectives:**

- Develop product category rules (PCRs) for pharma processes and products
→ to facilitate and harmonize future pharma-LCAs
- Enhance existing / develop new impact assessment (LCIA) methods
→ to consider missing pharma-specific impacts
- Case studies → to test and refine the PCR and the LCIA methods

➤ Supported by an advisory committee

Method



Objectives

PCR draft



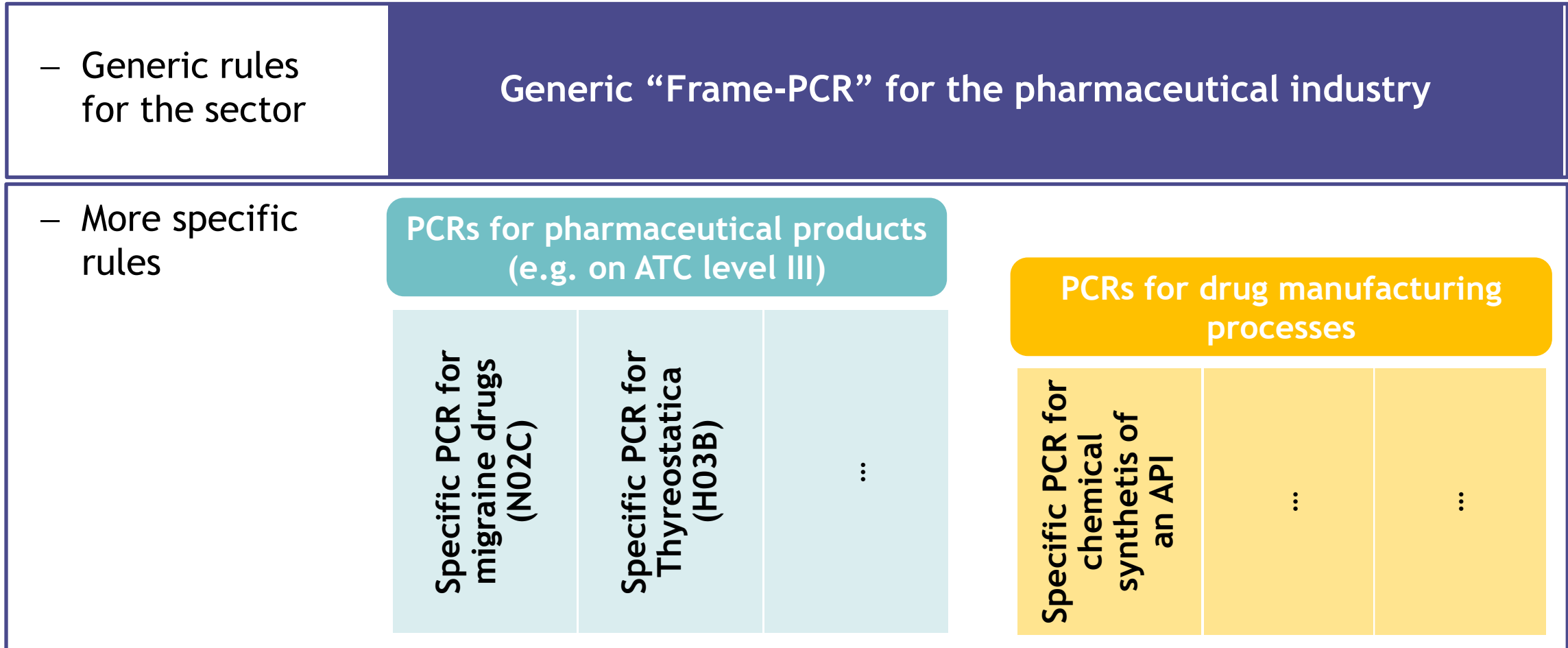
LCIA

Research steps

- Review of standards (e.g. ISO), specific guidelines (e.g. LC metrics for chemical products) & existing PCRs/pharma LCAs
 - Define the scope/granularity
 - First recommendations for the LCA requirements
- Review of pharma impacts, pharma & wastewater/sewage sludge LCAs, databases and LCIA models
 - Analyse if/how active pharmaceutical ingredients (APIs) and metabolites are currently considered in LCA (inventory & impact assessment)
 - Identify existing approaches & develop ideas for considering APIs in LCIA

Results

- PCR-draft
- Impact assessment



ATC: Anatomical therapeutical chemical classification system

- Structure acc. to ISO 14040/44 and GPCRD
- Methodological LCA requirements are specified acc. to:
 - Generic rules
 - Specific rules for products & processes
 - Intended application (internal use vs. external use)

1	General information
2	PCR Review and background information
3	Goal and scope
4	Inventory
5	Impact Assessment
6	Results & interpretation
7	Additional information

1	General information
1.1	Validity (temporal, geographic)
1.2	Conformity with other standards/PCR
1.3	Product category
1.4	Product description and classification
1.5	Stakeholder participation (consultation)
2	PCR Review and background information
2.1	Existing PCR for product category
2.2	Reasons for developing the PCR
2.3	Underlying LCAs
3	Goal and scope
3.1	Goal of the study
3.2	Functional unit
3.3	Content Declaration
3.4	Product system
3.5	Zeitraum (optional)
3.6	Data quality requirements
4	Inventory
4.1	Data collection
4.2	Secondary data
4.3	Primary data
4.4	Data calculation
4.5	Assumptions
4.6	Use phase
4.7	End of Life (EoL)
4.8	Allocation
5	Impact Assessment
5.1	Impact categories
5.2	Impact assessment methods
6	Results & interpretation
6.1	Results
6.2	Interpretation
6.3	Hot Spots (optional)
6.4	Assumptions and limitations
6.5	Uncertainties
7	Additional information
7.1	Tolerability
7.2	Side effects

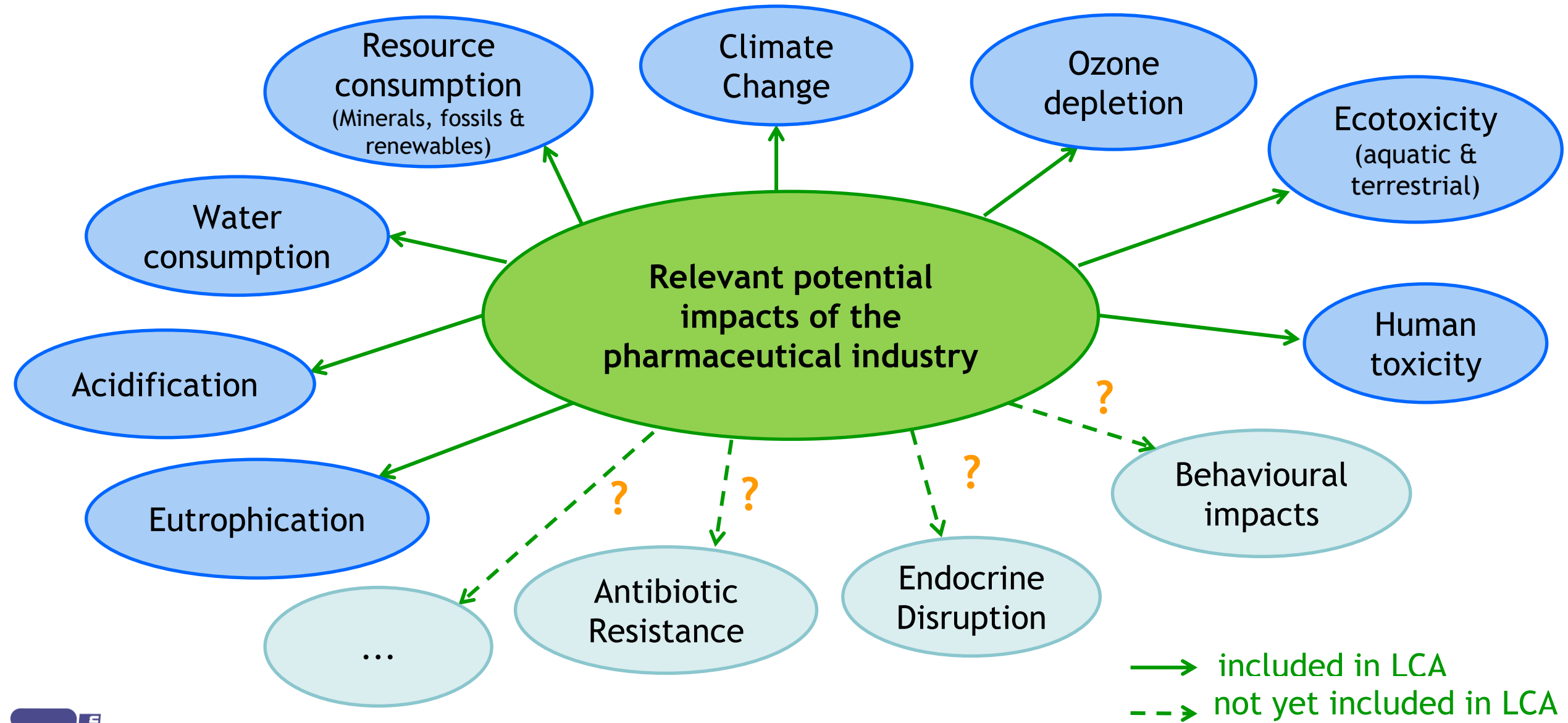
	Generic/ horizontal rules	Specific rules		
		Product		Process
		horizontal	vertical	
Geographic scope	Germany	No specification needed		
Functional Unit		Treatment of one average patient	Specification of disease/ indication	Production of 1 kg API
Primary data use	e.g. for API production	No specification needed		
Impact assessment	Set of categories & methods	Specification may be needed		

Note: further specification may be needed depending on the intended application

← e.g.

Results

- PCR-draft
- **Impact assessment**





Pharma-LCAs

- API emissions are not considered in the analyzed LCAs (exclusion of use and EoL phase)

Databases (GaBi, ecoinvent)

- Flows exist for only ~1% of the analyzed „Top 150“ APIs/metabolites measured in the environment
- Process dataset found for only one of the 150 APIs

USEtox

- Characterization factors (CF) exist for ~30% of the APIs

LCAs of waste- water and sewage sludge treatment

- So far ~60 CFs were identified in studies considering APIs



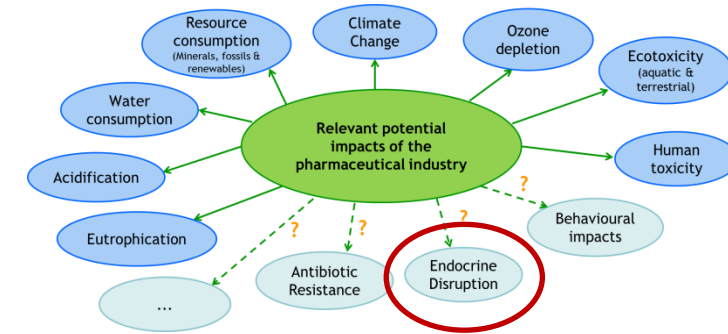
- Existing approach*

- Integrates ED in *ecotoxicity*

- expands the characterization factor (CF) in USETox

- by adding an ED-related toxicological endpoint to the effect factor (EF)

$$CF_i = FF_i \cdot XF_i \cdot EF_i$$



- Currently, we follow 3 new approaches

- All aim either enhancing the current EF or identifying alternative calculation ways

- Depending on this ED can be either addressed under *ecotoxicity* or in a new impact category *endocrine disruption*

* Larsen et al. (2009): New sustainable concepts and processes for optimization and upgrading municipal wastewater and sludge treatment. Deliverable 4.2. Methodology for including specific biological effects and pathogen aspects into LCA. NEPTUNE · Contract-No. 036845 (FP6 project). Technical University of Denmark. <http://orbit.dtu.dk/files/4673998/D4.2.pdf>

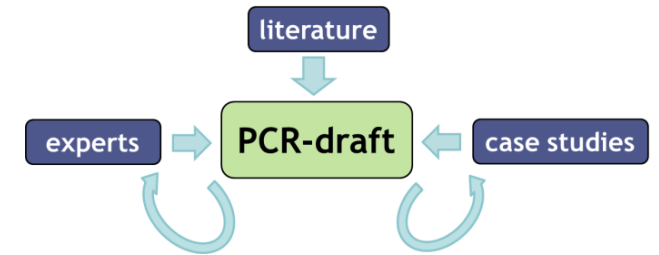
Summary & next steps



- *A long-term goal is...*to achieve a green & sustainable pharmacy
- *Our (mid-term) goal is...*to establish a reliable methodology to monitor and promote the progress towards this goal (→ PCR & LCIA)

Next steps:

- Finetuning of the PCR draft, discussion with experts & testing in case studies
- Update the review and further developing of the ideas to integrate pharma-specific impacts LCIA (*endocrine disruption* and also *antibiotic resistance*)
- Continuing with our case studies



Thank you!

ACKNOWLEDGEMENT:

We would like to thank the German Federal Environmental Foundation (Deutsche Bundesstiftung Umwelt - DBU) for the funding which enabled the work presented here.


CONTACT

Dr.-Ing. Annekatriin Lehmann

 +40 (0)30/314 - 79501


 annekatrin.lehmann@tu-berlin.de

M.Sc. Marc-William Siegert

 +49 (0)30/314 - 28453

 marc.siegert@tu-berlin.de

M.Sc. Yasmine Emara

 +49 (0)30/314 - 26179

 y.emara@tu-berlin.de

TECHNISCHE UNIVERSITÄT BERLIN
Institute of Environmental Technology
Chair of Sustainable Engineering
Office Z1, Strasse des 17. Juni 135
10623 Berlin, Germany
web: www.see.tu-berlin.de