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

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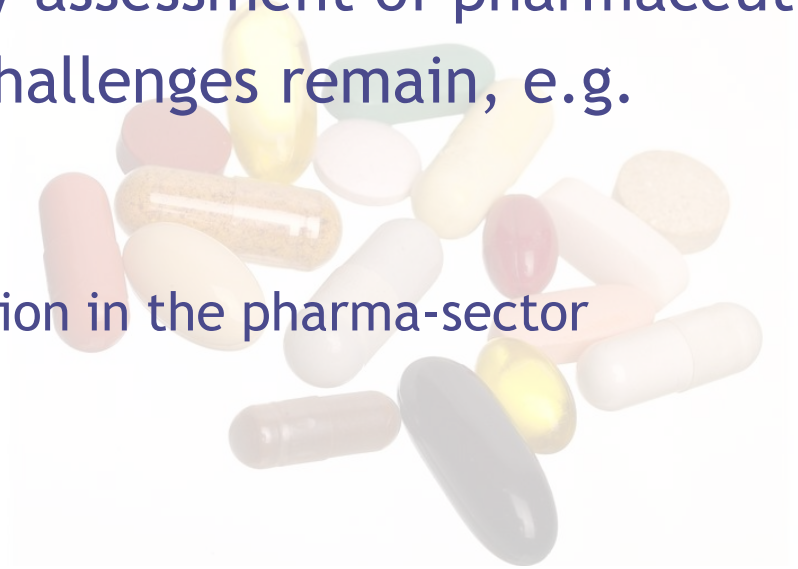
- A growing and ageing human population have led to a significant global rise in the consumption of pharmaceuticals…

  …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

What did we do so far?

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

PCR draft – scope / granularity level

– Generic rules for the sector

Generic “Frame-PCR” for the pharmaceutical industry

– More specific rules

PCRs for pharmaceutical products (e.g. on ATC level III)

- Specific PCR for migraine drugs (N02C)
- Specific PCR for Thyreostatica (H03B)
- ...

PCRs for drug manufacturing processes

- Specific PCR for chemical synthetis of an API
- ...
- ...

ATC: Anatomical therapeutical chemical classification system

PCR-draft – structure & content

- 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 classfication
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

GPCRD: Global Initiative for PCR Development

PCR-draft – LCA requirements: examples

	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		

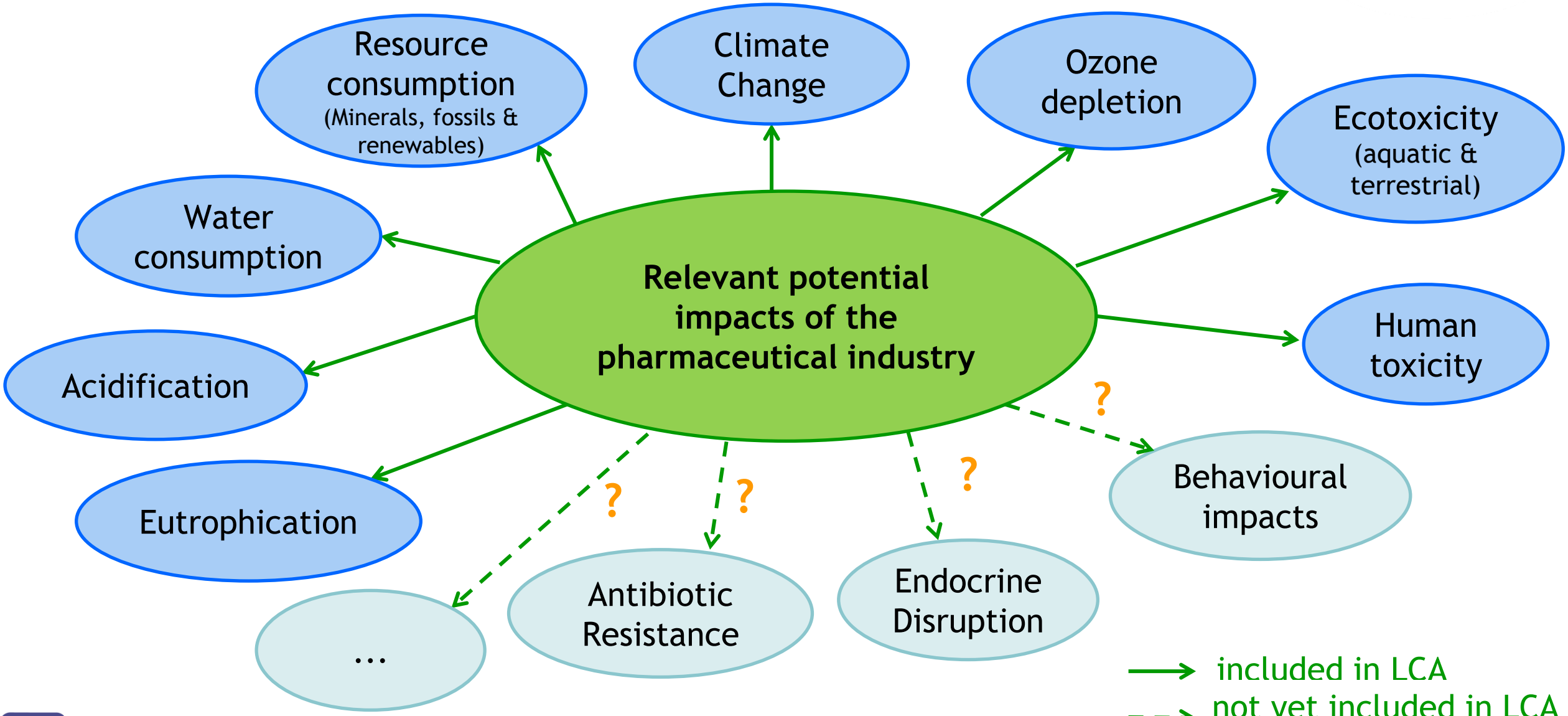
e.g.

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

Results

- PCR-draft
- **Impact assessment**

Potential environmental impacts in the pharma industry



How are APIs currently considered in LCA (LCI & LCIA)

SUSTAINABLE ENGINEERING

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

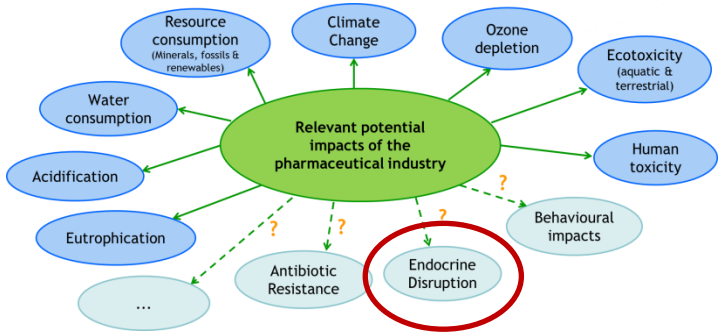
- So far ~60 CFs were identified in studies considering APIs

API: active pharmaceutical ingredients

SUSTAINABLE ENGINEERING

- **Existing approach***
  - Integrates ED in *ecotoxicity*

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



→ expands the characterization factor (CF) in USETox by adding an ED-related toxicological endpoint to the effect factor (EF)

- **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*

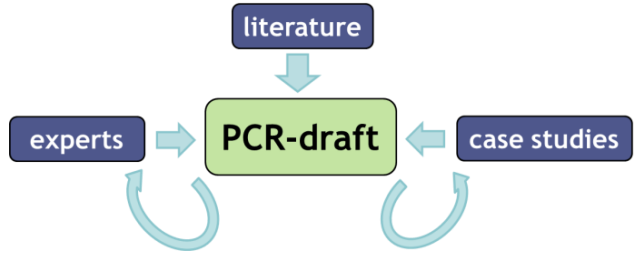
* Larsen et al. (2009): New sustainable concepts and processes for optimization and upgrading municipal wastewater and sludge treatment. Deliverable 4.2. Methodology for including specific biological effects and pathogen aspects into LCA. NEPTUNE · Contract-No. 036845 (FP6 project). Technical University 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!

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