

Environmental sustainability assessment of batch versus continuous manufacturing: Lessons learned in primary and secondary pharmaceutical manufacturing of Small Molecules

Wouter De Soete^{1,3*}, Ana Gabriela Renteria Gamiz¹, Steven De Meester¹, Bert Heirman² and Jo Dewulf^{1,3}

(1) Ghent University, Department of Sustainable Organic Chemistry and Technology

(2) Janssen Pharmaceutica NV, Johnson and Johnson PRD

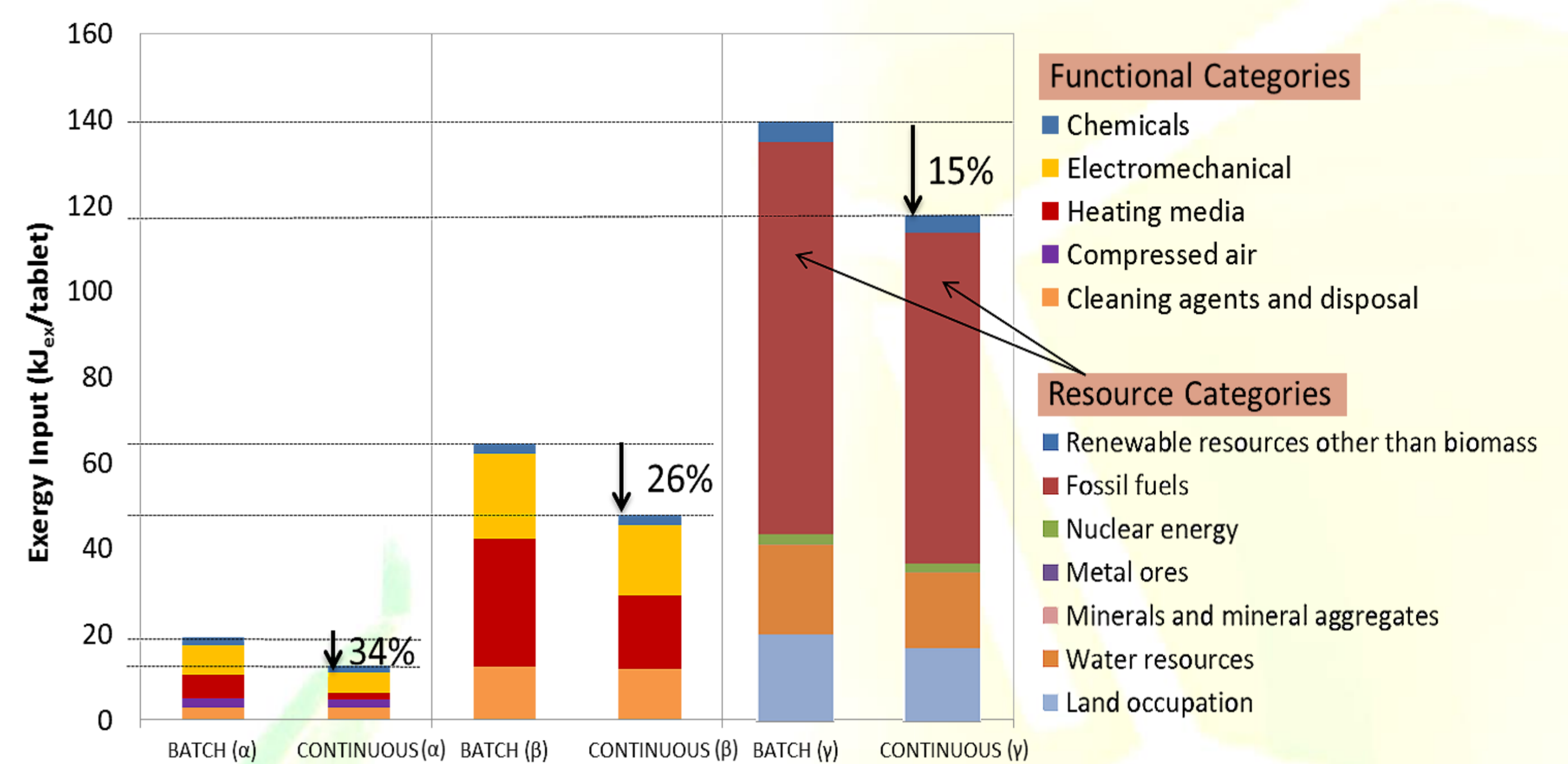
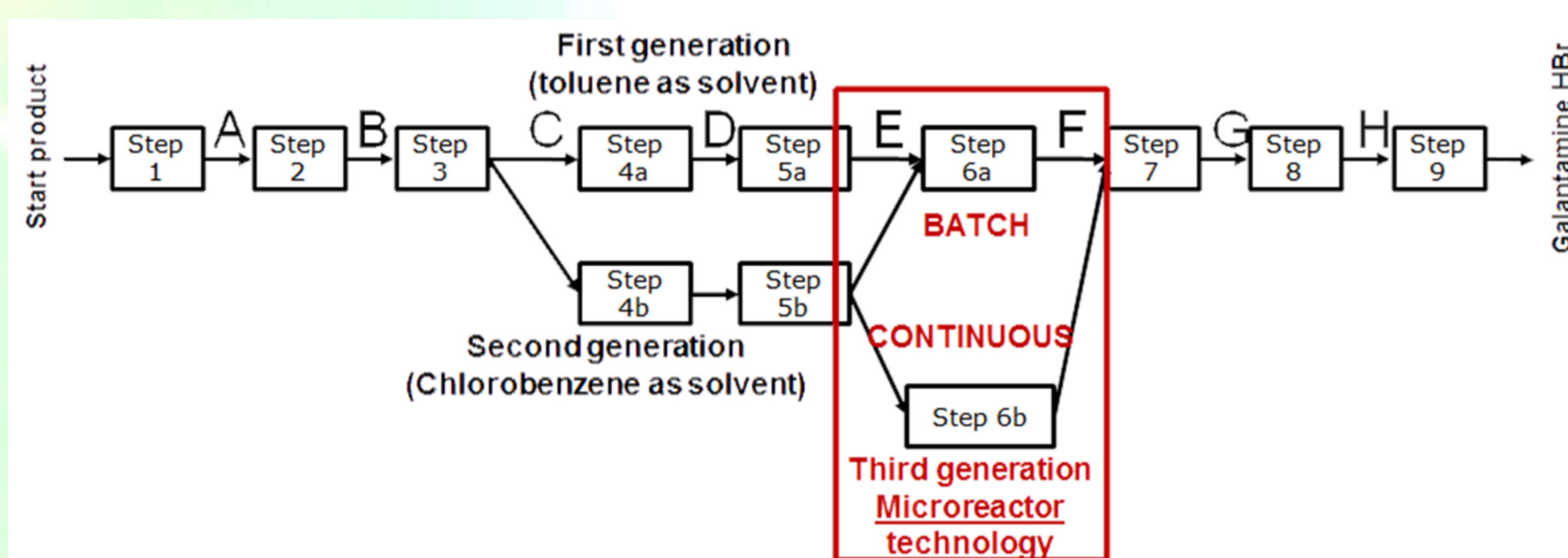
(3) European Commission, Joint Research Centre, Institute for Environment and Sustainability (IES)

Finite supply of fossil fuels, resource efficiency, carbon footprint. All of them are *megatrends* within international production environments. But how to **measure environmental sustainability**? What is the **environmental impact** of your **Supply Chain**?

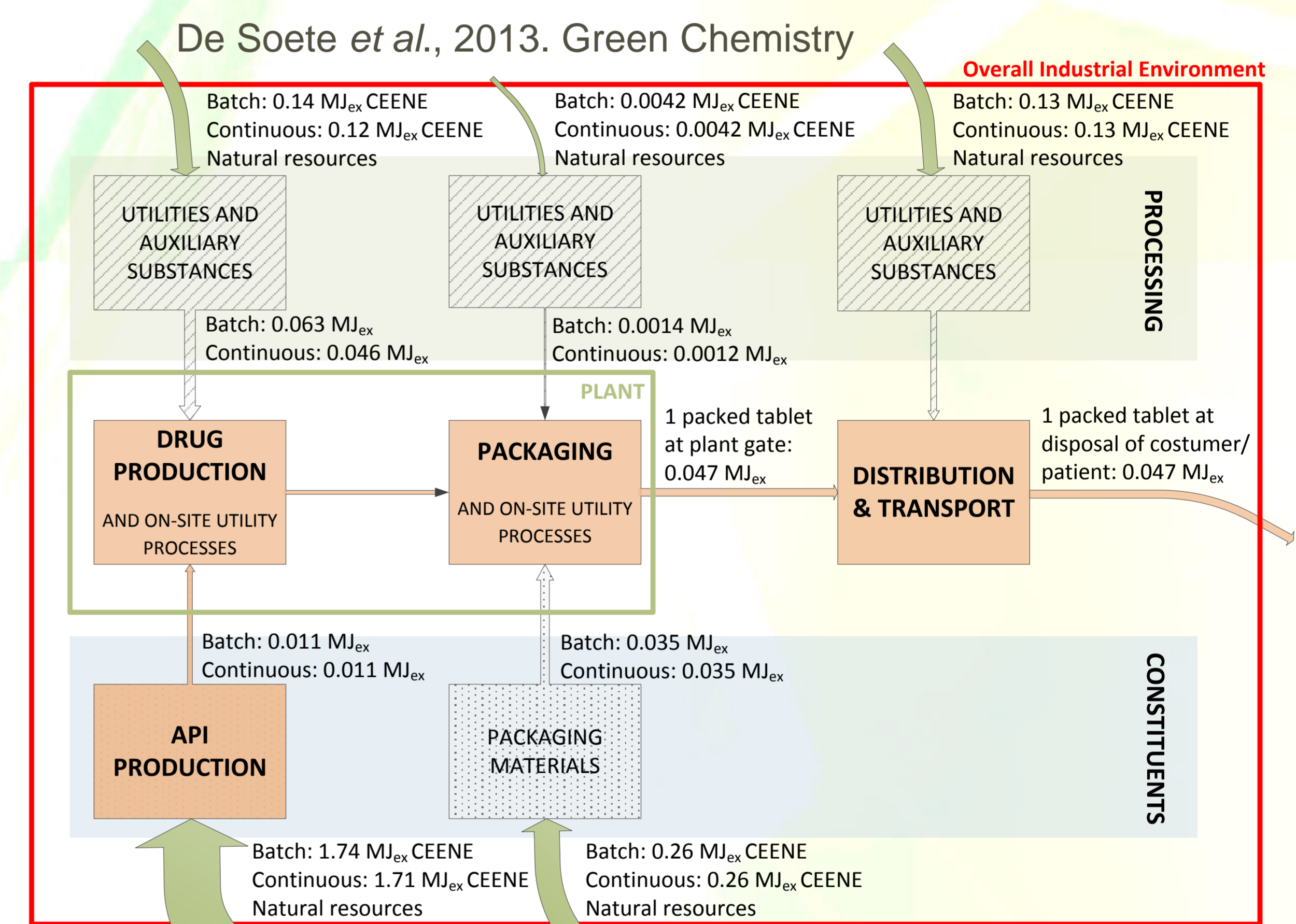
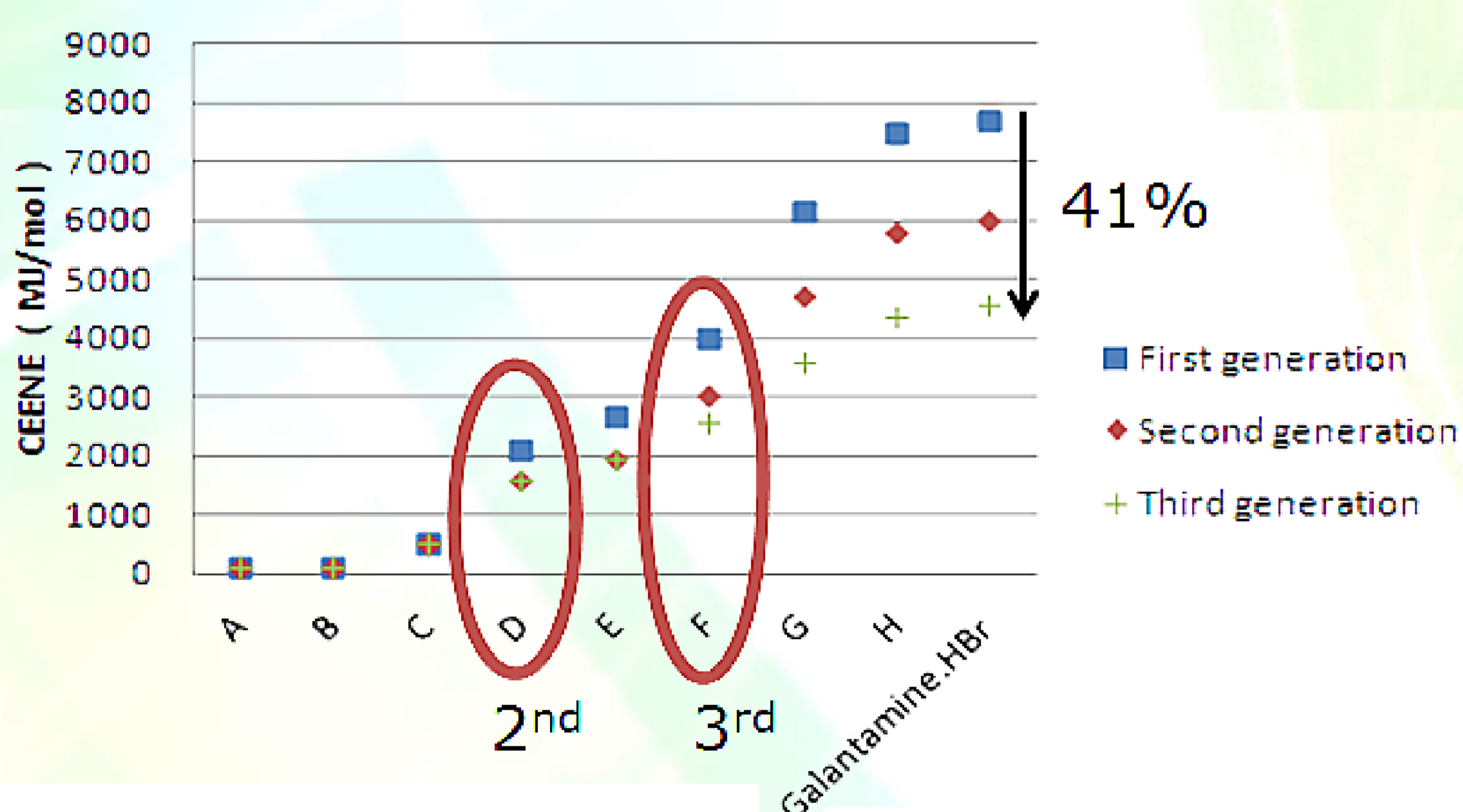
Innovative production technologies require cutting edge resource consumption assessment methods, e.g. based on thermodynamics.

→ **Exergy Analysis (EA)** at process (α) and plant (β) level

→ **Exergetic Life Cycle Analysis (ELCA)** at overall industrial level (γ)



Van der Vorst *et al.*, 2013. Green Chemistry



Results:

- **Continuous processing** has proven to be an effective approach for process intensification; **reducing resource consumption** in the production site and throughout the overall supply chain
- For low dose drugs, the **primary packaging phase** is an important resource contributor. Assessing complex primary packaging processes like it is the case of **lyophilization** can lead into significant resource savings

Potential valorisation:

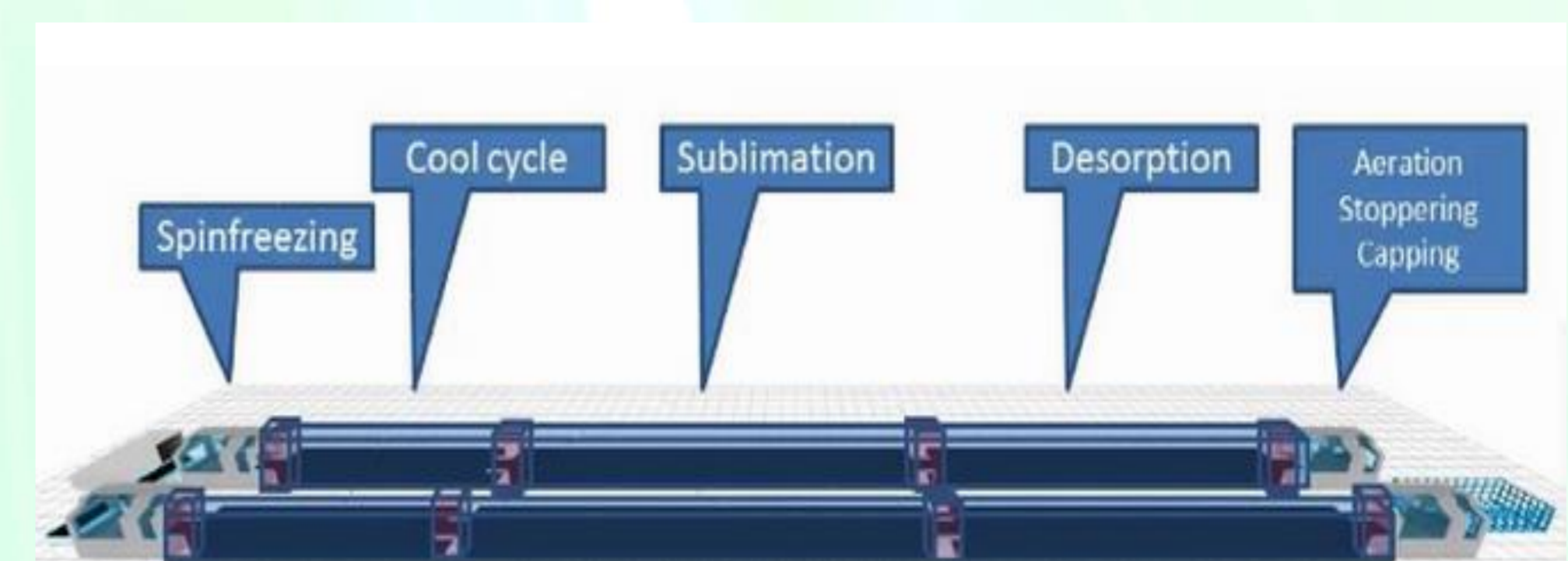
- **Direct cost reduction** (26% resource consumption reduction) → Lean Manufacturing
- **Corporate Sustainability Reporting**
- **Marketing**, communications
- Meeting (European) legislations and voluntary initiatives

Future outlook:

- Environmental assessment of a batch lyophilization technology versus a (new) continuous lyophilization technology



VS



Sustainability indicators can facilitate the improvement of technologies such as lyophilization by quantitatively supporting decision making; leading to new, more efficient and more sustainable pharmaceutical production processes. These indicators should look further than the process level, taking into consideration the whole life cycle production chain