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Cell-based Vaccine Production: Improving the Environmental Footprint

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DPS Group

A leading global architectural, engineering and consulting company with an advanced therapeutics focus.

Sartorius

Mission: To empower scientists and engineers to simplify and accelerate progress in the life science and bioprocessing, enabling the development of new and better therapies and more affordable medicine.

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Agenda

- Single-use (SU) technologies enable today’s industry’s sustainability objectives in vaccine production
- The new plastic economy provides opportunities for SU technologies to become a better option in the future

The UN's sustainable development goals context

Triple bottom line: People ● Planet ● Profit

17 Interconnected goals

Corporate Challenge

- Identify THE driving goal
- As we can, contribute to others
- Activities must be transparent
- Can't be achieved alone

Pharma driving goal

Collaboration imperative

Bioprocessing transitions to SU technologies

Stainless-steel facilities

Image courtesy of Sartorius

Ecosystem quality

Natural resources

Human health

Single-use facilities

Image courtesy of Sartorius

- Industry continues a shift to SU technologies in cell-based vaccine production
- How does SU technology support sustainability goals?
- What are environmental trade-offs associated with the shift?

Many SU product categories / operational criteria

3 GOOD HEALTH AND WELL-BEING

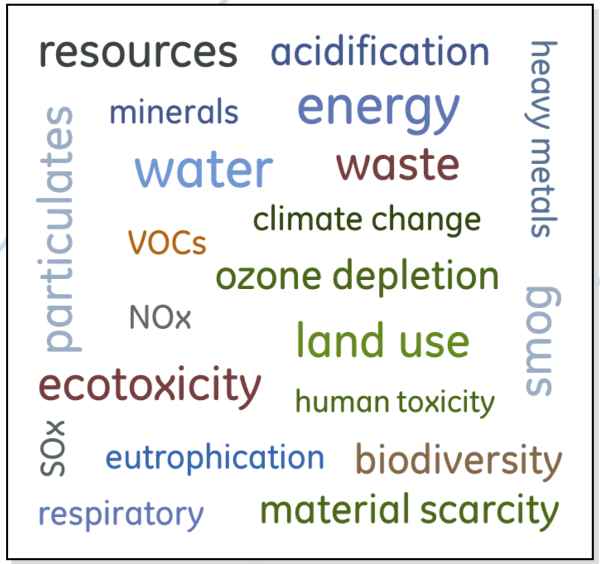
Consumer Convenience
- Foam food containers
- Plastic grocery bags
- Straws and spoons
- Cans and pouches

Medical / Pharma Needs
- Entity flexibility
- Platform flexibility
- Build time
- CapEx
- OpEx
- Total output
- Sterility assurance
- Manufacturing sustainability

Business / Regulatory
- War powers act
- Shortages of filters / bags
- Change control processes for SUS
- SU material shipping / storage
- Operational geography

LCA: Impacts through the vaccine mfg. life cycle

More than just carbon footprint



Ecosystem quality

Natural resources

Human health

Areas of protection (damage categories)

LCA: Life Cycle Assessment

Understanding impact of products / services across value chain

- Support decisions
- Evaluate alternatives
- Prioritize opportunities
- Mitigate environmental issues

Comprehensive LCA study

Traditional stainless-steel facilities

Image courtesy of division of Industrial Biotechnology, KTH/Biotechnology

From Cytiva.com: Single-use technology and sustainability: quantifying the environmental impact in biologic manufacturing

Stainless-steel
Single-use / Hybrid
Protein and Vaccines

Single-use facilities (retrofit)

GE Healthcare FlexFactory™ biomanufacturing operations, Marlborough, MA, USA

200 L
500 L
2000 L
2 × 2000 L

50 L
200 L
500 L

200 L
500 L
2000 L
2 × 2000 L

200 L
500 L
2000 L
2 × 2000 L

50 L
200 L
500 L

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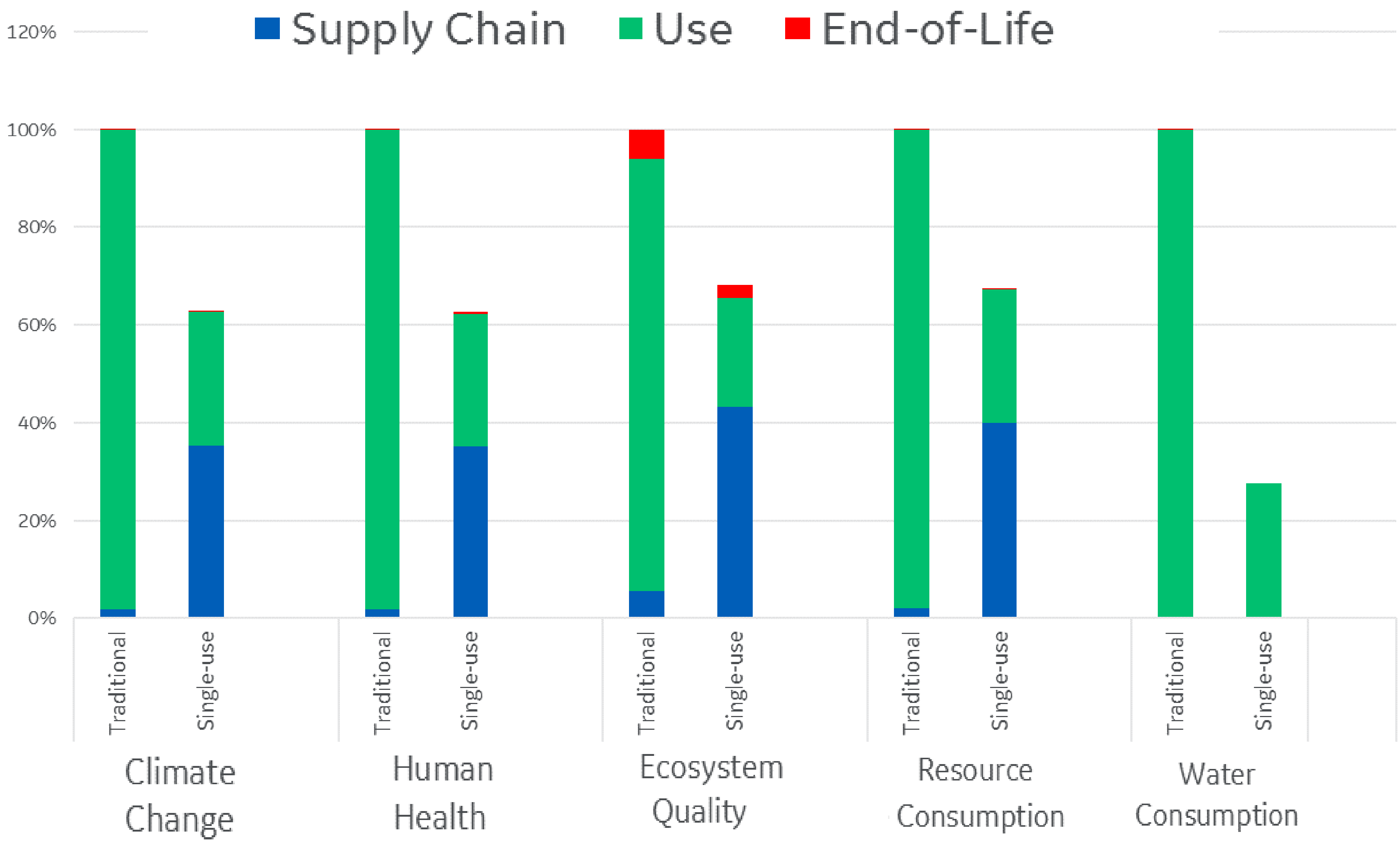
Impact comparison: traditional vs SU

	mAb
Process	Traditional
	Single-use
	Hybrid
Location	Boston
	LA
	Sao Paolo
	Istanbul
	Cork
	Dortmund
	Shanghai
Scale	200 L
	500 L
	2000 L
	2 × 2000 L

From Cytiva.com Single-use technology and sustainability: quantifying the environmental impact in biologic manufacturing



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Strategic environmental insights

Results are sensitive to geography

- Traditional process highly sensitive to “clean vs dirty” electrical grid
- SU process sensitive to both electrical grid and transport logistics

Results are sensitive to process scale

- Impacts (per unit mAb) decrease with increasing production volume

No sensitivity to end-of-life disposal

- Disposal of SU materials is not a significant factor

Trend in biopharma

- Sustainability considered a key process design criteria alongside cost, yield, robustness & quality of assurance.
- Need to combine sustainability goals and circularity.

3 GOOD HEALTH AND WELL-BEING — Sustainability driving goal

+

CO_2 — Climate strategy

+

Plastic strategy

The New Plastic Economy triggered innovation

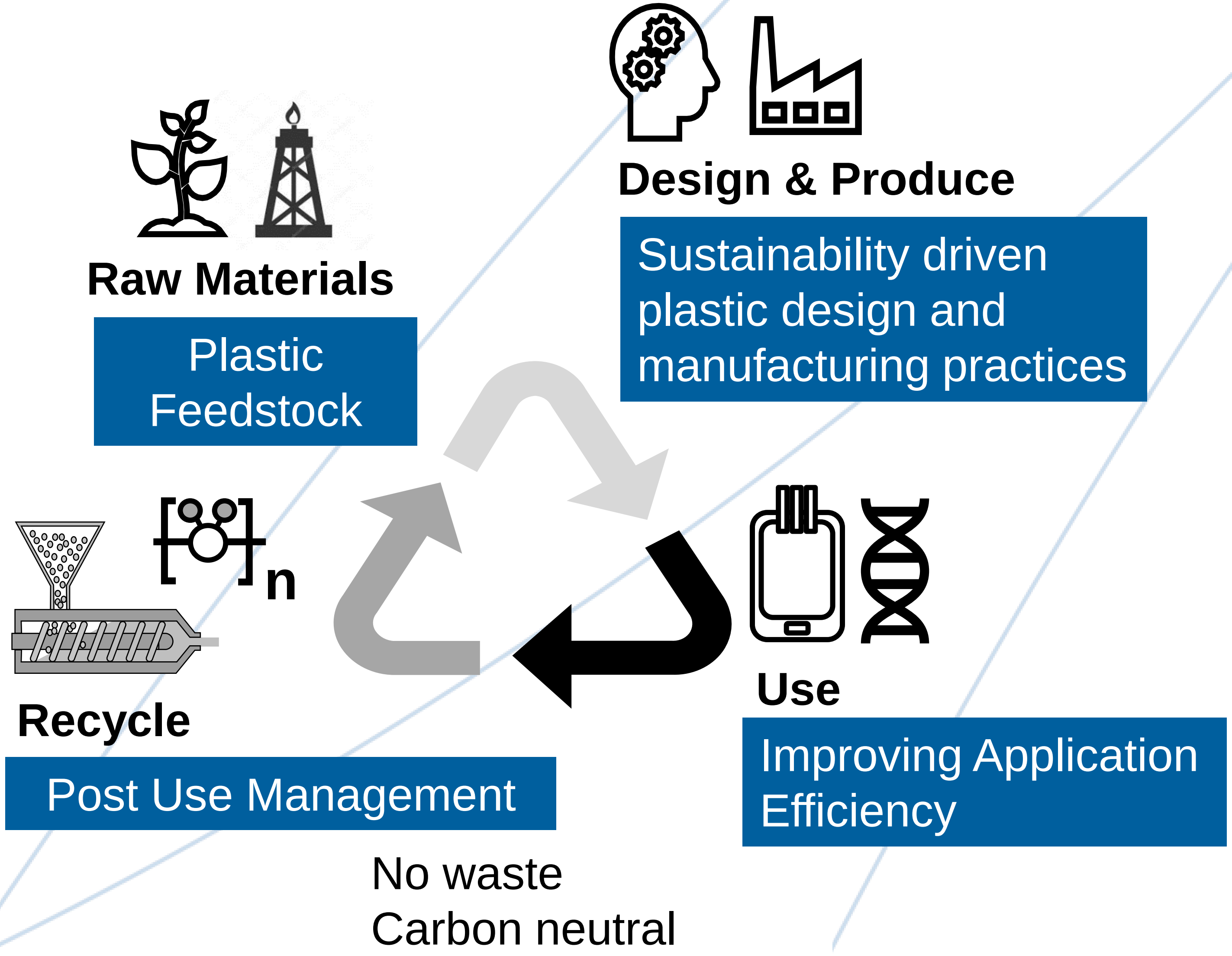
Plastic dilemma

- Innovation engine
- Light, robust, hygienic, economic
- Plastic pollution : esthetic, ethical, emotional

New Plastic Economy

ELLEN MACARTHUR FOUNDATION

- Rethink
- Reduce
- Reuse
- Recycle
- Renewable feedstock



Sustainability as a design criterion in vaccine mfg.

Materials development → Product design → Mfg. practices[9] → Waste management

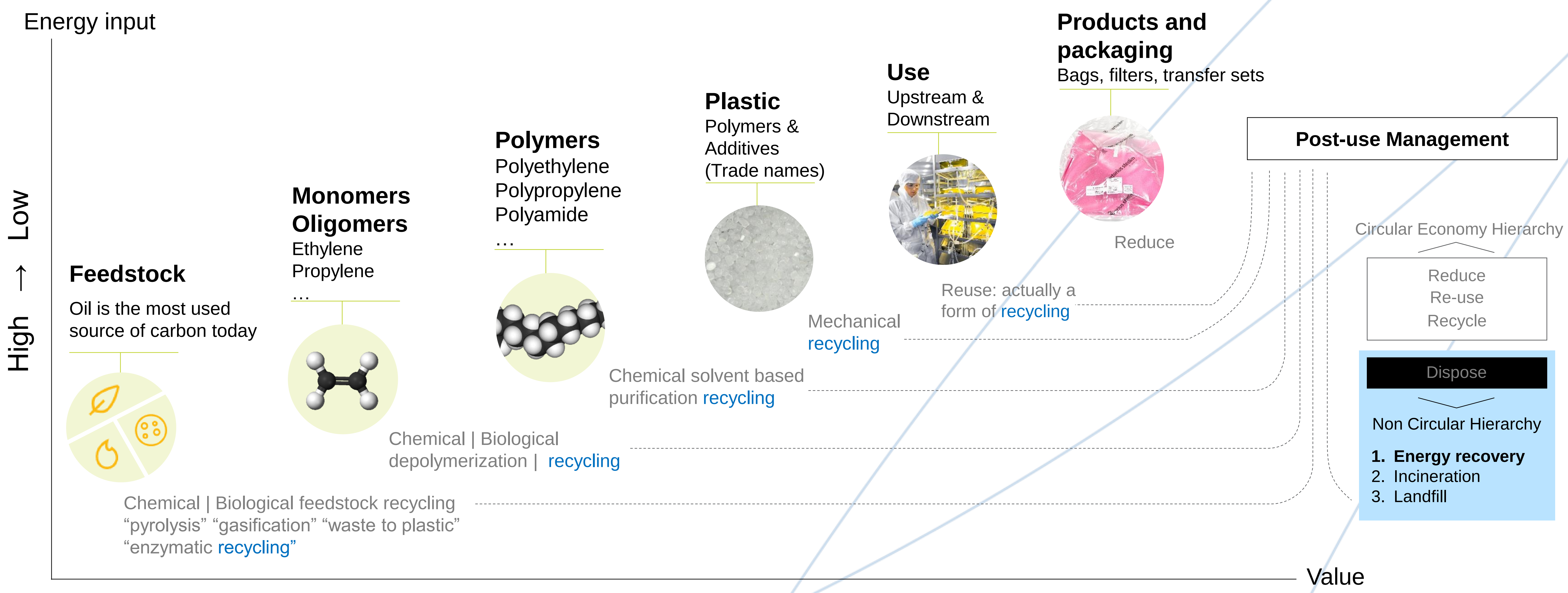
- Reduce mass per process
- Design to include recyclability
- Reduce waisted ”safety” excess
- Waste reduction in manufacturing
- Extend shelf life / reduce other loss

- Function, safety and quality first
- Packaging provides ~10% of weight (protective function)
- Less-harmful polymers and additives
- “Sustainable” polymers contact vs non-contact risk analysis
- Mono-polymer components where possible

Improving application efficiency in vaccine mfg.

- Support heightened standards
- Create intensified bioprocesses
- Low carbon footprint, reduced water use, low energy design
- Model processes test ideas and integrate sustainable features
- Process Mass Intensity (PMI) design feeds into LCA fulfillment
- Processes optimized for sustainability, efficiency and cost structure

Approaches to SU post-use management



Post-use handling of SU vaccine mfg. material

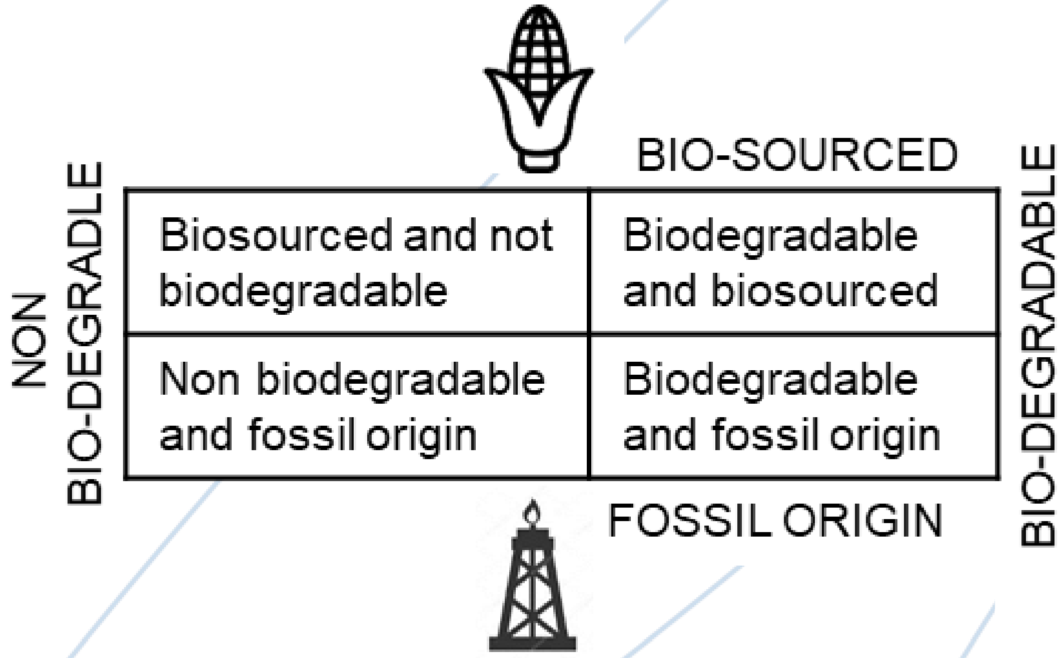
Many parameters considered

- Type of plastics employed
- Used materials at location
- Environment burden type
- Cost of standard disposal
- Better solutions available
- Cost of green alternatives
- GMO DNA contamination
- Traces of active ingredient
- Distance to recycling plant
- National/reginal/local laws
- Corporate goals/obligation
- Customer/societal demand

Assessing sustainable options

- Science-based and life-cycle approach recommended
- Chemistries and options are not generally understood
- There is much progress in the field currently occurring
- Many circular chemistry options theoretically available
- Few options are available now, but are in development

Considerations for plastics feedstock in vaccine mfg.



- Oil is the most used source of carbon today
- “Biopolymers” is not a specific enough term
- Biocompatible ≠ Biosourced ≠ Biodegradable
  - Biocompatible refers to the application of the polymer
  - Biodegradable refers only to the end of life of the polymer
  - Bio-sourced refer to the origin of carbon in the polymer backbone
- Existing commercial applications from vegetable feed-stock
- 2nd generation of bio-sourced polymers: better environmental footprint & less ethical issue
- Emerging technology : Bioprocessing of living cells to capture | convert carbon to monomers

Conclusions for SU in vaccine manufacturing

3 GOOD HEALTH AND WELL-BEING

SUT contributes to develop and make innovative therapies faster, safer and cheaper

Biopharma accounts for **~0.01%** of total plastic waste

Virtually none
of our plastic ends up in the oceans

Industry imperative to drive circular economy and recycling

Further improvement by customer, supplier, academia and industry cooperation

For development of smarter techniques and practices throughout products' life cycle

- Opportunities offered by the new plastic economy
  - Foster circularity of materials
  - Improve sorting and recycling
  - Reduce virgin materials fraction
  - Reduce absolute amount of plastics used
  - Minimize the part of waste incinerated or landfilled
  - All to reduce plastic and carbon in the environment

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Thank you