

Sustainability : Green Imperative

Magali Barbaroux, Sustainability Committee Chair



Thank You

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Active contributors :

Burkert, Corning, Cytiva, DPS, DuPont, Entegris, GEA, Gore, KrystalBio, Merck MSD, NewAge, Nordson Medical, Pall, Qosina, Repligen, RubiusTherapeutics, Saint-Gobain, Sartorius, Sealed Air, Solvay, Thermo Fisher, Wood



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



Bioprocessing transitions to SU technologies



Stainless-steel facilities

Image courtesy of Sartorius



Reduced cross contamination
Lower CAPEX
Higher speed to market

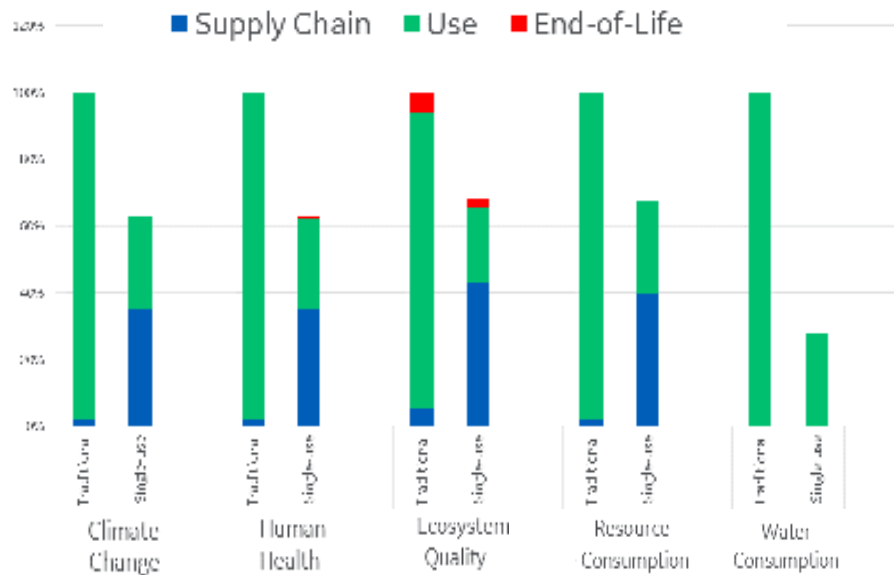


Single-use facilities

Image courtesy of Sartorius



Impact comparison traditional vs SU - THE reference



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



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

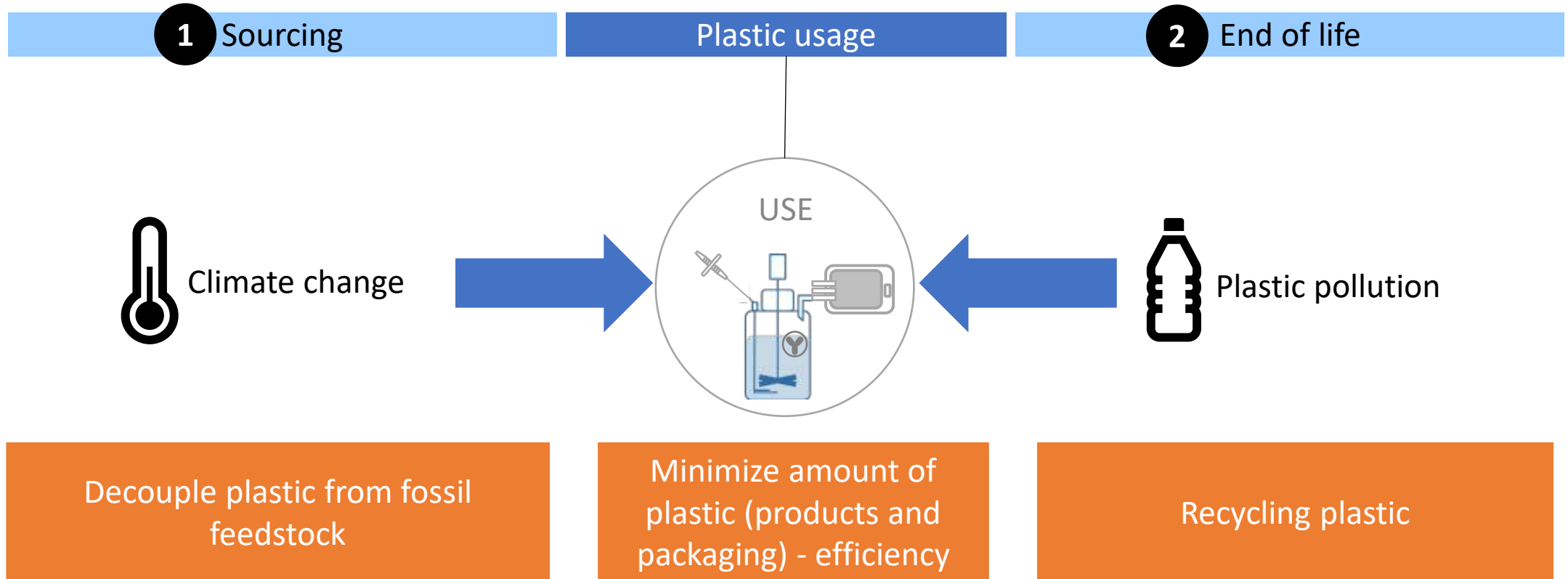


No sensitivity to end-of-life disposal

- Disposal of SU materials is not a significant factor



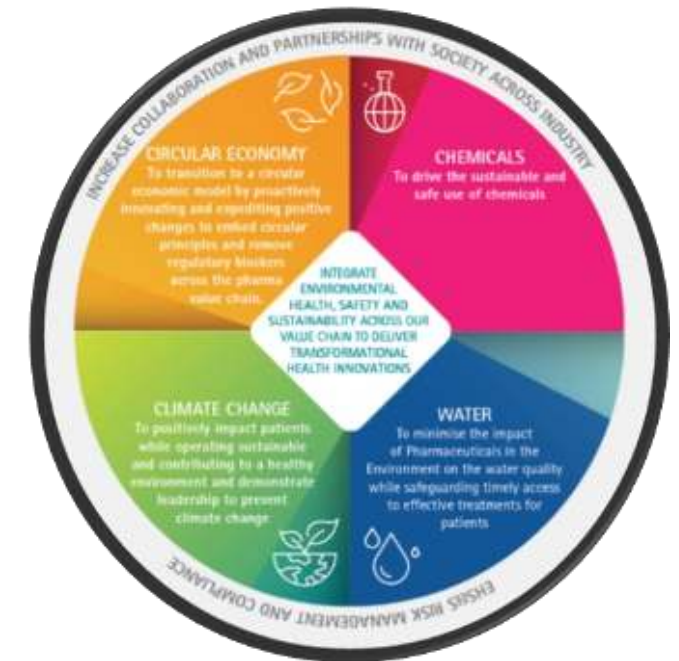
Plastic usage is currently undergoing different environmental pressure⁽¹⁾



⁽¹⁾ Source Carbone 4 – consulting firm for low carbon strategies

Biotech industry environmental landscape

- Pandemic has raised healthcare and pharma industry visibility
- Pharma environmental priorities reduction GHG, energy, water, waste, PIE⁽¹⁾
- Recent biotech study - American Chemical Society Pharma showed :
 - Electricity for cleanroom = major contributor to all impact categories
 - 90% PMI = water (although cleaning not considered)
 - Recycling all SUT = 10% \searrow CO₂ footprint/kg of BDS expected
 - Recycling benefits allocated when recycled materials are used
 - Process intensification = significant reductions in environmental impact
- Climate, water and circularity are interconnected : no one fits all metric.
- Multiple industry groups have a “(SUT) sustainability” stream

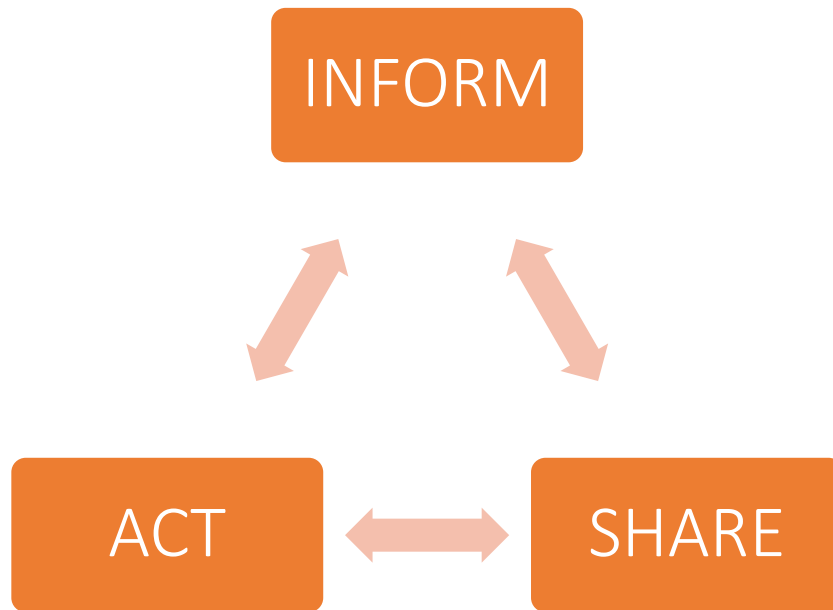


European Federation of Pharmaceutical Industries and Association⁽²⁾

(1) PIE = pharmaceutical in environment -<https://www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/environment-health-safety-and-sustainability/>

BPSA Sustainability Committee

Board Sponsor : Mark Petrich, Krystal Biotech | *Committee chair* : Magali Barbaroux, Sartorius



Mission

- Provide members **information** on how **SUT support biomanufacturing call for sustainability** & takes **actions** to prove BPSA seriously tackle sustainability concerns.
- Allow members to be informed on environmental sustainability tools and trends in the biomanufacturing and polymer industry, to **share** ideas and good practices.

2022 – Objectives Update

INFORM, SHARE & ACT

Objectives

Status

Monthly opening sustainability spotlights

5 opening spotlights done and more scheduled
Thank you to Nordson, Saint-Gobain, RubiusTherapeutics, NewAge, Pall

1-2 webinars

No webinar organized yet
Options : SUT communication or Opening sustainability spotlights

Publications, E-book, Glossary, LinkedIn

LinkedIn site revived
Next on the list – E-book with the “green imperative” BPSA paper series / generic article to answer plastic bashing ?

Create & clearly state an industry message inside and outside linked to SDGs goals

Work in progress
Requires quantified “plastic” data for credibility - consultancy



SUT industry narrative today

- SUT contributes to develop and make innovative therapies faster, safer and cheaper
- Converting from SS to SUT in biopharma improve environmental footprint
- Most of the post-used SUT are incinerated because hazardous (none in the oceans)
- Biopharma plastic waste is negligible compared to total amount of plastic
- Industry imperative to collaborate and drive circular economy

The Green Imperative: Part One – Life-Cycle Assessment and Sustainability for Single-Use Technologies in the Biopharmaceutical Industry

by Megall Samarou, Brian Horowitz, Sade Mokuolu, Mark A. Petrich, William Whitford and with the BPSA Sustainability Committee
Thursday, Ji

Much has single-use equipment years ago. have become establishe downstream about the single-use equipment prevalent awareness concerns laws have become pressures resolve, a

The Green Imperative: Part Two – Engineering for Sustainability in Single-Use Technologies

by Megall Samarou, Brian Horowitz, Sade Mokuolu, Mark A. Petrich, Mitchell Smol, William G. Whitford and with the BPSA Sustainability Committee
Thursday, February 4, 2021, 8:45 pm

[View PDF](#)

The Green Imperative: Part 3 – Postuse Management of Single-Use Bioprocessing Materials, Today and Tomorrow

by William Whitford, Sade Mokuolu, Megall Samarou, Mitchell Smol, Mark Petrich, Megan Seltie, Brian Horowitz and Don Young
Wednesday, December 3, 2021, 5:01 pm

[View PDF](#)

The world desires a more sustainable economy in which resources can be saved, products can be profitably used, and at the end of their useful life, component materials can be recycled into other useful products. The bioprocessing industry has made efforts to meet those goals and has learned a great deal about the role of plastic components in sustainable manufacturing. The most important lesson might be that a science-based



Modern waste-to-energy plant in Oberhausen.

Published in bioprocess International 2020/2021

general, processes using single-use technologies (SUTs) often have smaller environmental footprints than processes based on durable systems (1, 2).



2022 BPSA Members' Roundtable

GETTING BACK TO BUSINESS

People • Production • Planet • Profit • Post-Pandemic

Challenges and opportunities we need to face collaboratively as an industry

- No reliable data measuring the amount of plastic for bioprocessing
- No robust waste mapping - landfilling still exists
- Increasing cost of hazardous waste management is a concern
- Impact of plastic will increase with intensified processing.
- Need to combine emissions, circularity and water goals.
- WHO “85% of healthcare waste are general waste” (not hazardous)
- No internal or external guidelines indicating not using recycled plastics – only quality constraint : consistency and traceability.



« Plastic » data collection

The industry needs data – transparent, consistent, complete

- For a credible narrative
- To identify circularity opportunities
- To monitor progress
- To support the implementation of SUT

Today, each industry group leads its own initiative



Let's join forces for efficiency, quality and credibility

Short term

- Accurate data on plastic waste volumes and post-use treatment mapping
- Powerful industry alignment on communication around SUT

And if successful

- Identification of waste streams as candidates for industrial symbiosis
- Common goals on circularity / packaging / both
- Collaborate to an industry assessment for LCA assessment



How to make it happen

- Use of a third party (consultant) to support and lead
- Board approval for each industry group to give momentum
- Create a “spinoff” for plastic data out of the industry groups
- Defined and common scope, milestones, methodology, goals, assumptions, confidentiality, boundaries, etc.
- Coordinated surveys for all industry groups with targeted SPOC
- Next step : joint call with BioPhorum, BPSA, NIIMBL and ISPE “plastic” data stakeholders to define the project.

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8. Whitford, William; Petrich, Mark; Flanagan, William. “Environmental Impacts of Single-Use Systems.” Single-Use Technology in Biopharmaceutical Manufacture, 2nd Edition, edited by Regine Eibl and Dieter Eibl, John Wiley & Sons, 2019, 271-285.
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12. European Commission : A circular economy for plastics, Insights from research and innovation to inform policy & funding decisions
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*Last access to web sites – June 29th, 2022



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