SINGLE-USE PULSE 2021

A WEBINAR SERIES EXPLORING THE BUSINESS OF SUTS

THURSDAY, JULY 15

10:30-11:30 AM EDT

SUSTAINABLE RECYCLABLE FLEXIBLE SYSTEMS: IMPROVING THE ENVIRONMENTAL FOOTPRINT

BILL WHITFORD
DPS GROUP

SADE MOKUOLU
WATSON-MARLOW FLUID TECHNOLOGY GROUP

BPSA

BPSA Single-Use Pulse Series Brought to You By

BPSA Sustaining Sponsors

AdvantaPure

Broadley James

bürkert FLUID CONTROL SYSTEMS

CHEMIC LABORATORIES, INC.

CPC

cytiva

Entegris

MilliporeSigma

Nordson MEDICAL

PALL Biotech

PENDOTECH Adding Value To Your Process

RENOLIT Rely on it.

SAINT-GOBAIN

SaniSure Be sure.

SARTORIUS

ThermoFisher SCIENTIFIC

Created in Cooperation With…

socma
SOLUTIONS FOR SPECIALTIES

BAHP
CENTER FOR BABY AND ADULT HYGIENE PRODUCTS

BPSA
Bio-Process Systems Alliance
Advancing Single-Use Worldwide

CPMA
Color Pigments Manufacturers Association

INFORM · ADVOCATE · ACT
Flexible Vinyl Alliance

IPA

Ott Consulting Group LLC

Sustainable Recyclable Flexible Systems: Improving the Environmental Footprint

Article series team members:
W. Whitford, M. Barbaroux, B. Horowski, D. Young, M. Petrich, M. Baillie, M. Snyder & S. Mokuolu
with the support of BPSA Sustainability Subcommittee

Agenda

- Single-use (SU) technologies enable sustainability objectives in bioproduction
- The BPSA's published reviews elucidate the current status and ways of improving

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 entity production
- How does SU technology support modern sustainability goals?
- What are environmental trade-offs associated with the shift?
- How can we make SU an even greener choice?

UN 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

Many SU product categories / operations criteria

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 Demands

- Shortages of filters / bags
- Change control processes for SUS
- SU material shipping / storage
- Operational geography

Desire to improve

BPSA members had an initial article published in 2009

- Update required

Suppliers & manufacturers

- Volunteer on this workstream to provide information on how Single-Use Technologies support biomanufacturing's call for sustainability and takes actions to prove that BPSA seriously tackles sustainability concerns.
- It allows members to be informed on environmental sustainability tools and trends in the biomanufacturing industry and in the polymer industry, to share ideas and best practices.
- Join us in discovering effective, science-based approaches

The Green Imperative: Part One

BPSA's first paper in a series of three

- Assessment of SU systems status / implications on the environment
- Assessment provided is relative to traditional, durable systems
- Composed by the BPSA Sustainability Subcommittee
- BioProcess Int. 18(6) June 2020

BIOPROCESS TECHNICAL

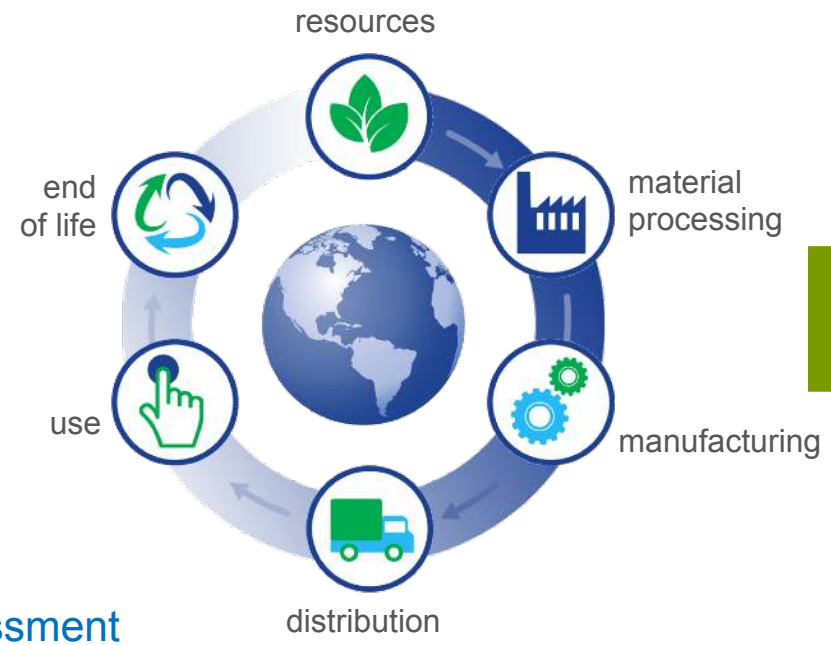
The Green Imperative

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

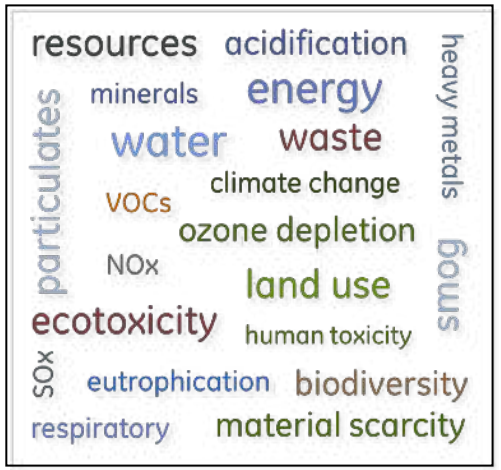
Magali Barbaroux, Brian Horowski, Sade Mokuolu, Mark Petrich, and William Whitford; with the BPSA Sustainability Subcommittee and Bill Flanagan

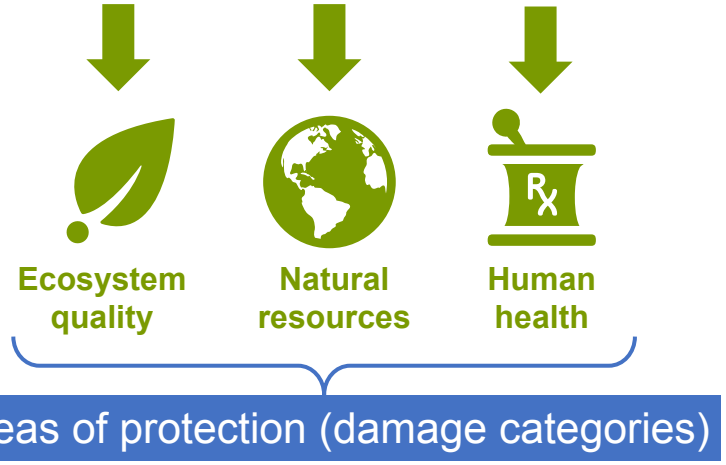
Much has changed since large-scale single-use biomanufacturing equipment was introduced some 15 years ago. Since then, these materials have become accepted and established in production and downstream bioprocessing. Concerns about the environmental impact of single-use (SU) biomanufacturing equipment have become more prevalent as our environmental awareness has increased and related concerns have become more urgent (1). For example, many recommendations and even laws have emerged regarding plastic convenience

LCA: Impacts through the mfg. life cycle



More than just carbon footprint





LCA: Life Cycle Assessment

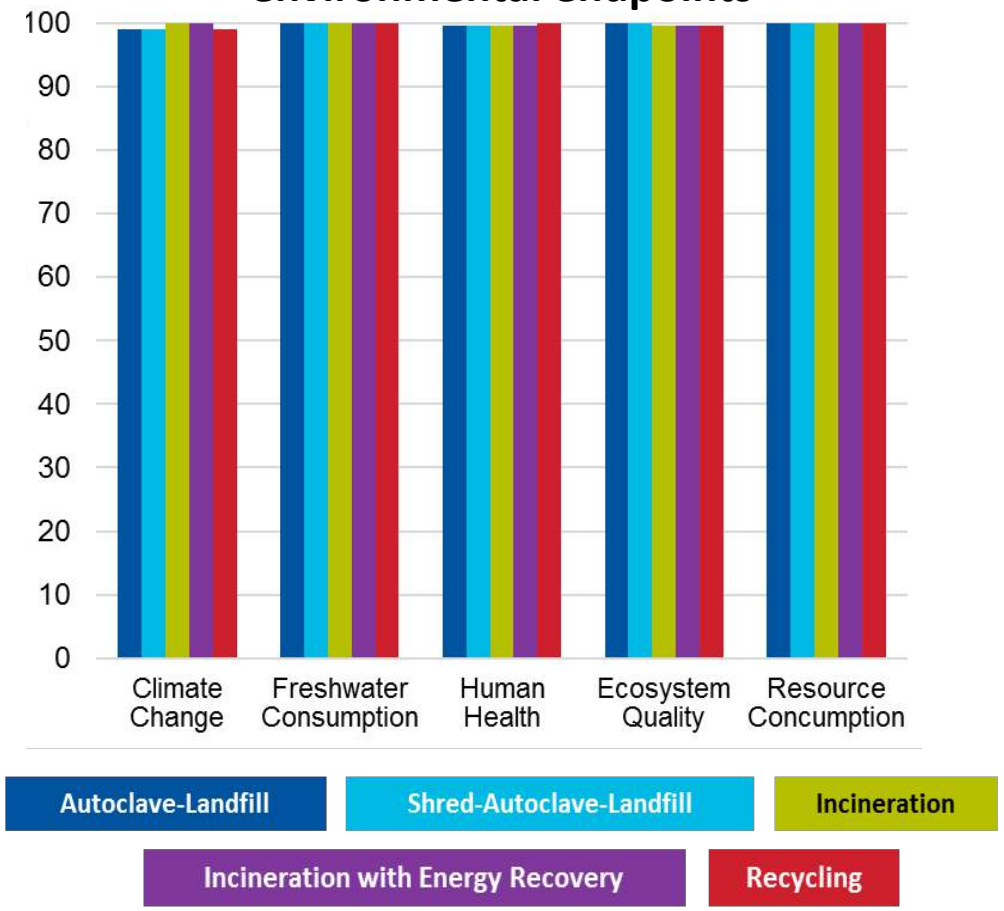
Understanding impact of products / services across value chain

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

LCA study findings

- SU: lower environmental impacts over life cycle
- Greatest impact for both methods in use stage
- SU fractional end-of-life impacts are negligible
- SU carbon impact is higher in the supply-stage
- CIP, SIP, and WFI energy demands are the greatest burdens with traditional, durable systems
- No significant differences were observed among entity types, production scales or mixed modes
- Facility geographical location is the greatest determinate of environmental impact through
  - Transportation energy and carbon burden
  - Differential water supply cost and sensitivity
  - Differential burden of the power grid types

Effect of SU end-of-life options upon environmental endpoints

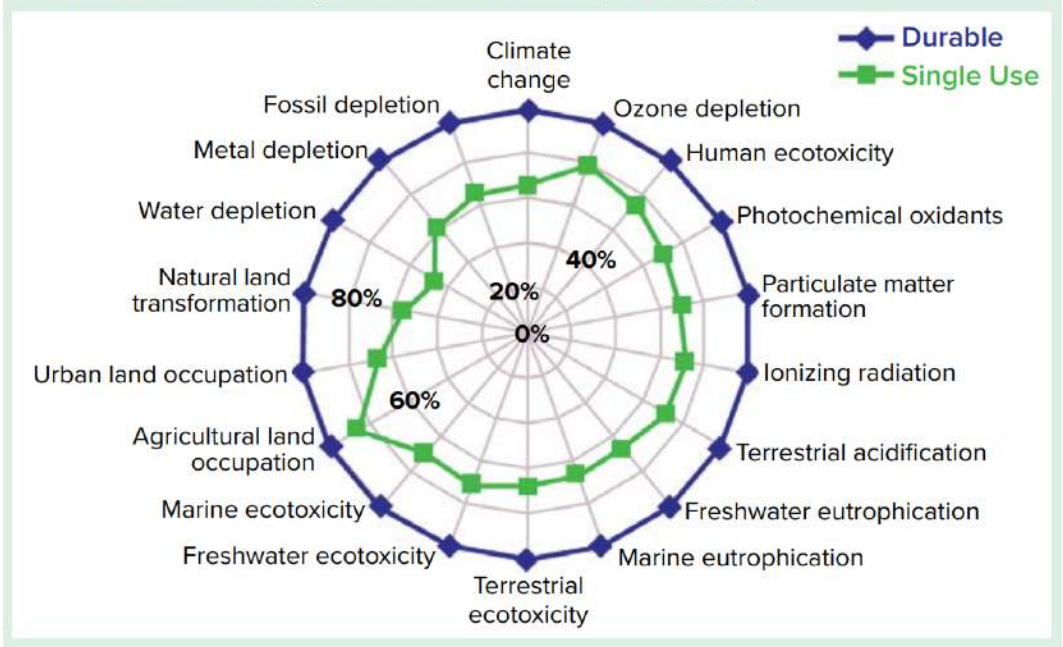


Pietrzykowksi M. *et al*, An Environmental Life Cycle Assessment Comparison of Single-Use and Conventional Process Technology for the Production of Monoclonal Antibodies, *J. Clean. Prod.* 41, 150-162 (2013).

Overall SU manufacturing conclusions

In general, SU Systems'

- Total waste is much less than consumer convenience items
- Provide unique benefits in critical / vital societal functions
- Fulfill high functional criteria for protecting health / safety
- Provide the safe, effective and, overall, less polluting option



https://www.bioprocessonline.com/doc/environmental-life-cycle-assessment-of-single-use-technologies-0001

The Green Imperative: Part Two

BPSA's second paper in a series of three

- Outlines thinking on the design of materials / systems / processes for a new plastics economy
- Define the circular-economy paradigm concept for plastic materials and their packaging
- Introduce the 6Rs: Rethink and reengineer drive application of reduce, reuse, recycle, rubbish
- Present how engineering will soon make SU an even more sustainable manufacturing option
- BioProcess Int. 19(1–2) Jan–Feb 2021

FOCUS ON... DISPOSABLES

The Green Imperative

Part Two — Engineering for Sustainability in Single-Use Technologies

Magali Barbaroux, Brian Horowski, Sade Mokuolu, Mark A. Petrich, Mitchell Snyder, and William Whitford, with the BPSA Sustainability Subcommittee

In BPI's June 2020 issue, the first installment of this series introduces the study and implementation of single-use (SU) technology to provide a more sustainable manufacturing environment (1). We presented evidence showing that the economic and social benefits of SU systems currently outweigh the residual environmental risks. Not only is SU technology often a better environmental choice than traditional biomanufacturing options, it also is sometimes the only choice for rapid process design and facility start-up. In situations such as the

HTTPS://STOCK.ADOBE.COM

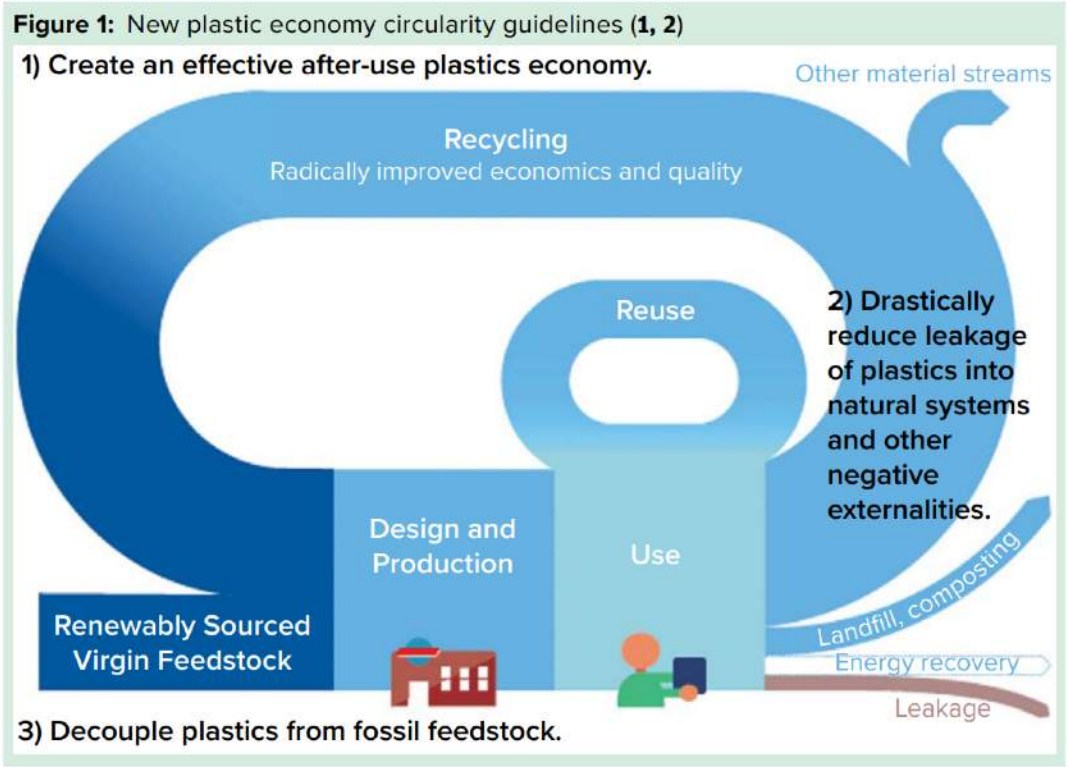
PLASTIC AND HEALTHCARE

Even though SU applications in healthcare are rarely criticized — and despite the fact that plastic packaging used in healthcare products represents under 2% of total plastics produced each year — circularity guidelines for packaging do not exclude pharmaceutical packaging from their scope (4). As the World Health Organization has stated, "Of the total amount of waste generated by healthcare activities, about 85% is general, nonhazardous waste" (5). A significant amount of plastic used in

The new plastics economy

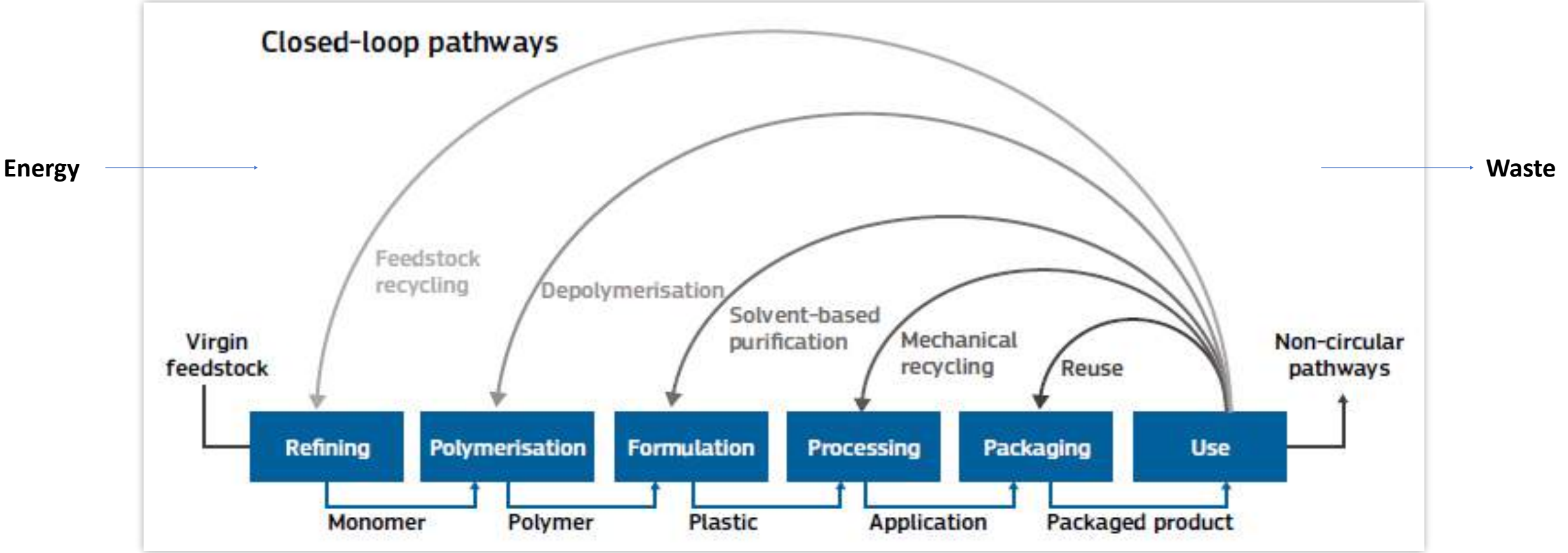
The New Plastics Economy: Rethinking the Future of Plastics

- Create an effective post-use economy
- Decrease plastics leakage into the environment
- Decouple plastics from fossil feedstock



The New Plastics Economy: Rethinking the Future of Plastics. Neufeld L, et al., Eds. World Economic Forum: Geneva, Switzerland, January 2016; http://www3.weforum.org/ docs/ WEF_The_New_Plastics_Economy.pdf.

Even “circular” approaches have degrees of sustainability



Adapted from BPSA, Engineering for Sustainability in Single-Use Technologies, BPI, *In Press* 2020

Example approaches

Reuse of SU materials

- Buffer/media mixers for consecutive batches
- Top-off of buffer/media bags
- Reuse buffer bags for collecting liquid waste
- Inlet air/gas and exhaust/vent filters for mixer and storage bags.
- Reuse chromatography paths, TTF, and prepacked columns
- Reuse polymeric non-product contact pinch clamps, tri-clamps
- Adapt contactless instrumentation

Polymer feedstocks not made from petroleum or coal

- Materials from artificially captured CO_2 and methane
- Biobased polymers made from biomass and derivatives
- Materials from biological processes derived CO_2/ methane
- Biobased plastics technically equivalent to their fossil-based counterparts
  - A commercialized PE is made from biobased ethylene
  - A corn-sourced isosorbide replaces BPA monomer to manufacture biobased polycarbonate

Science-based and life-cycle approach recommended to assess ideas.

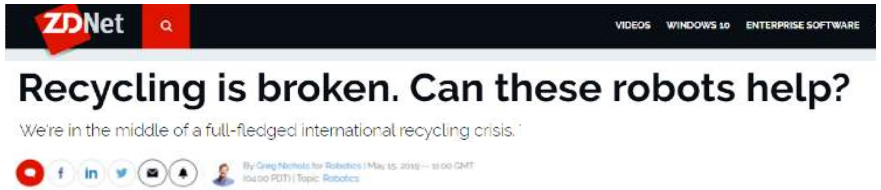
Traceability and supply chain challenges to be overcome

The Green Imperative: Part Three

BPSA's third paper in a series of three

- Provides a summary of the three-part series
- Outlines the current options available to handle post-use plastics
- Identifies the benefits and drawback of each
- Provides method-organized references for further pursuit
- Is currently in press: BioProcess Int. XXX, 2021

Courtesy AMP Robotics com/
WWW . https://www.amprobotics.



AMP Robotics is another example of a company combining robotics, machine vision, and AI to make recycling faster and cheaper, raising the possibility that we can onshore our waste disposal.

Post-use handling of SU vaccine mfg. material

Many parameters considered

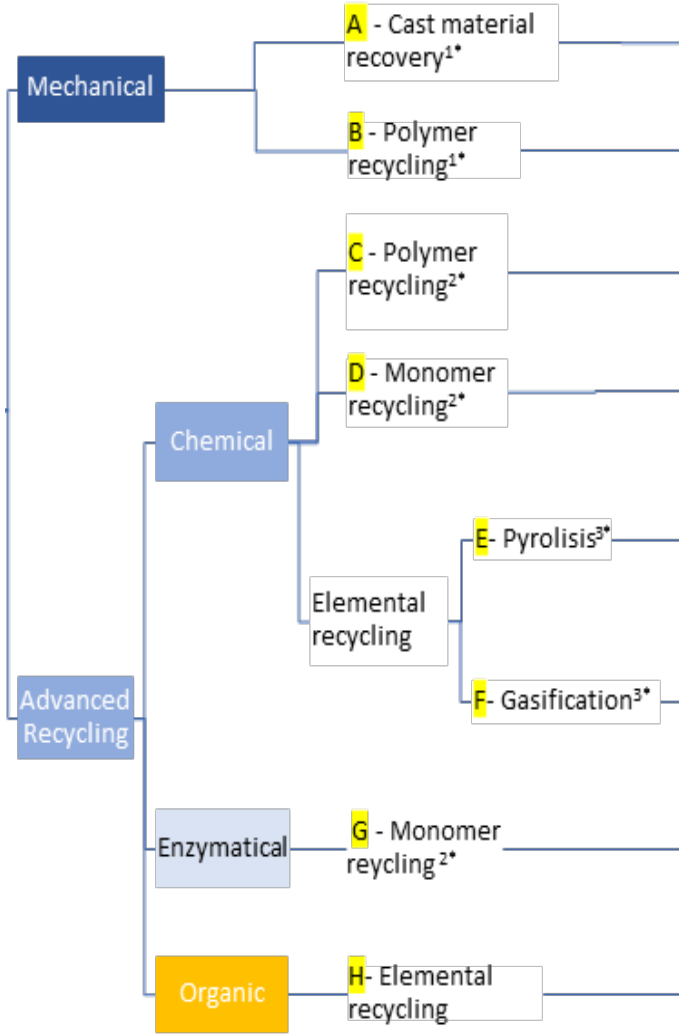
- Type of plastics employed
- Used materials at location
- Environment burden type
- Cost of standard disposal
- Better solutions available
- Cost of green alternatives
- GMO DNA contamination
- Traces of active ingredient
- Distance to recycling plant
- National/regional/local law
- Corporate goals/obligation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

Example: Types of recycling

- The concept of recycling is composed of many different approaches
- Mechanical recycling reuses the actual cast piece or it's plastic polymer
- Chemical recycling reuses the polymer, monomer or constituent H, C and N.
- Enzymatic and organic approaches use natural means of de-polymerization.



Novel Coronavirus SARS-CoV-2

Covid has accelerated consumption of SU plastics in healthcare

- Plastics played major roles in the Covid 19 pandemic
  - Most PPE largely composed of, e.g., polypropylene
  - Aided in rapid development/production of vaccines
- Plastic waste has increased greatly, especially in PPE
  - Face masks/shields alone est. at 3.4 billion units/day
  - At 5 grams average for mix, 17 000 tons wasted/day.
  - Biopharma annual SU waste estimated to 90,000 tons/ year(1)

"New York National Guard" The National Guard, March 14 2020 (CC BY) https://creativecommons.org/2020/03/19/now-is-the-time-for-open-access-policies-heres-why/new-york-national-guard-the-national-guard-march-14-2020-cc-by/

(1) Assumption that it has tripled since 2018

Conclusions for SU in biomanufacturing

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 improvements by customer, supplier, academia and industry cooperation

- For development of smarter techniques and practices throughout products' life cycle
- Many 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
- Need for metrics to take sound decisions

Green initiatives endorsed by the BPSA

- Demanding continued progress through improved manufacturing, distribution, use
- Designing out harmful waste by adding green stipulations to material supply contracts
- Establishing dedicated corporate/service positions supporting green initiatives
- Implementing new sustainability programs, personnel, initiatives, and in-service training
- Promoting sustainability through publications, foundation donations, and consortia support

BPSA Elite Sponsors

References*

1. World Economic Forum 2016 – The New plastic Economy
2. UNEP SINGLE-USE PLASTICS - A Roadmap for Sustainability
3. Medical plastic market is estimated to 7.7 million tons in 2020
   (www.grandviewresearch.com/industry-analysis/medical-plastics-market) for a global market of 400 million de tons, e.g.1,9%.
4. www.who.int/news-room/fact-sheets/detail/health-care-waste
5. www.nationalgeographic.com/science/2019/10/can-medical-care-exist-without-plastic/
6. www.the-scientist.com/news-opinion/ucl-to-phase-out-single-use-plastics--including-pipette-tips-66637
7. 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.
8. J. Ignacio, From Single-Use to Re-Use in the MedecineMaker, June 2018
9. Barbaroux, M., et al., "The Green Imperative: Part two – Engineering for Sustainability in Single-Use Technologies" BioProcess Intl, 19(1–2) January–February (2021) p18-25.

Further reading

- W. Flanagan, "Single-use and sustainability: quantifying the environmental impact," BioProcess Online, 2016.
- Barbaroux, M., et al., "The Green Imperative: Part One – Life Cycle Assessment and Sustainability for Single-Use Technologies in the Biopharmaceutical Industry," BioProcess International, June 2020
- European Commission : A circular economy for plastics, Insights from research and innovation to inform policy & funding decisions
- K. Budzinski, et al., "Introduction of a process mass intensity metric for biologics," New BIOTECHNOLOGY 49 (2019) 37-42.

*Last access to web sites – August 26th 2020

Q&A

BPSA Single-Use Pulse Series Brought to You By

BPSA Sustaining Sponsors

AdvantaPure

Broadley James

bürkert FLUID CONTROL SYSTEMS

CHEMIC LABORATORIES, INC.

CPC

cytiva

Entegris

MilliporeSigma

Nordson MEDICAL

PALL Biotech

PENDOTECH Adding Value To Your Process

RENOLIT Rely on it.

SAINT-GOBAIN

SaniSure Be sure.

SARTORIUS

ThermoFisher SCIENTIFIC

SINGLE-USE PULSE 2021

A WEBINAR SERIES EXPLORING THE BUSINESS OF SUTS

FRIDAY, JULY 16

10:30-11:30 AM EDT

FINANCING GLOBAL HEALTH RESILIENCE

NAFISA JIWANI
U.S. INTERNATIONAL DEVELOPMENT FINANCE CORPORATION (DFC)

BPSA