Creating a Sustainability Index Framework to Support the Bioprocess Sustainability Goals of the Next Decade

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Insights on environmental sustainability applied to the implementation of single-use technology in the biopharmaceutical industry.

SUSTAINABILITY ISSUES AND DRIVERS

The 17 United Nations Sustainable Development Goals (SDGs) for 2030 (1) constitute a commonly approved starting point for any reflection around sustainability and its "people, planet, and profit" triple bottom line. Interconnections between these goals highlight the complexity of taking sound sustainable decisions in a multivariate world. Indeed, the challenge is first to identify the driving sustainable development goal and then to contribute as much as possible to the other goals. Many signals show that today the healthcare sector is expected to deliver critical health services (SDG3), and, like any other industry, grow the economy, while, even in time of pandemic, producing less waste, using less resources, and reducing the negative impacts on the environment and human health (2) (i.e., more or less all remaining SDGs).

Single-use technologies (SUT) are one of the enabling technologies that have the potential to positively contribute to the sustainability challenge. Indeed, SUT is simplifying and accelerating progress in bioprocessing, decreasing cost per dose, and supporting wider access to treatment. In addition, significant benefits of SUT over re-usable stainless-steel process technology have been recognized. For example, SUT impacts on climate change, energy consumption, or natural resource depletion have the potential to be between 50% and 80% lower than the conventional re-usable alternative existing today (3, 4).

At the same time, ocean pollution has triggered public opinion. Debate around the environmental impact of plastics is controversial and highly emotional. Despite recognized benefits in carbon footprint, food waste, and energy reduction (5), the use of plastics is under increasing scrutiny and is pushing governments and policy makers to take action (6, 7) and drive the plastic industry, especially for packaging, to transition from a linear to a circular economy (8). Large corporations in the packaging and consumer goods industries have committed to plastic sustainability goals and thus drive innovation (9), which creates sustainability opportunities for other industries such as biopharma.

A BUSINESS IMPERATIVE

A majority of the biopharma industry members have established sustainability goals, and it is clear that environmental impact is an important consideration as biopharmaceutical manufacturing continues to evolve. The healthcare plastics represent less than 2% of the plastic market,[1] and biotech plastic waste is estimated to contribute to less than 0.01% (10) of the total plastic waste. Its use is well controlled and therefore such waste should never be found in the ocean. It is our business imperative, as an industry, to question and improve our practices around the complete life cycle of products from cradle to grave: raw materials, design, manufacture, use, recycle, and end of life. Front runners in biomanufacturing are expected to act responsibly and seize opportunities raised by the new plastic economy. These include the review of biopharma practices and impacts, to foster circularity without worsening climate change impact, to enhance collaboration between end users, suppliers, and academia, and to boost the development of smarter practices throughout the plastic product and packaging life cycle. This requires a significant scientific, pragmatic approach to define and use relevant tools to report, track, and act transparently.

Investors, collaborators, suppliers, and customers are now increasingly interested not only in the economic performance of a company, but also in its commitment to Corporate Responsibility. They expect to find sustainability ratings provided by independent third parties such as EcoVadis.[2] As we have seen, sustainability goals are interconnected and there is no “one size fits all” or “off-the-shelf” sustainability strategy. In addition, the success of a sustainability strategy relies on its understanding and adoption by everyone.

In Sartorius, sustainability has been part of the company’s DNA since its foundation 150 years ago, and is currently one of the key core values. As one of the leading partners in the biopharmaceutical industry, Sartorius is committed to supporting a future where more people gain greater access to better medicine while responsibly treating natural resources. How to support the biomanufacturing industry to reach their goals while combining the environmental benefit of SUT, global warming challenge and circular economy is a cornerstone of Sartorius’ sustainability strategy.

ENGAGING THE BIOPHARMA INDUSTRY

The objective of this paper is to give visibility and share insights on environmental sustainability applied to the implementation of SUT in the biopharma industry. This is an outcome of a collaboration between Sartorius and Aspire Sustainability on how to build on the environmental benefits brought by the replacement of standard stainless-steel equipment and at the same time encourage the circularity of SUT. The reflection is still evolving, more theoretical than practical at this stage, however we think it is the right time to engage the industry in contemplation and call for collaborative thinking.

During the strategy framing process within Sartorius, contradictions popped up, making

[1] Medical plastic market is estimated to be 7.7 million tons in 2020 (https://www.grandviewresearch.com/industry-analysis/medical-plastics-market) for a global market of 400 million tons (UNEP SINGLE-USE PLASTICS A Roadmap for Sustainability Figure 12), e.g., 1.9%.

[2] https://ecovadis.com

obvious the need for measurement and decision tools to improve transparency and consistency, and to support decision processes in all of Sartorius' projects with regards to the environmental impact of products. Indeed, we feel it is mandatory to have a holistic understanding to approach our product development. This includes how products are designed, what raw material(s) they are made of, and how they are manufactured, packaged, transported, used, and managed post-use. This should enable the setting of meaningful and relevant environmental goals with the hope of preventing senseless and often environmentally adverse "greenwashing." A key part of this strategy is to develop a toolset that includes so-called "sustainability index," that could be used by all Sartorius stakeholders around the life cycle of the product to measure, track, and report environmental impacts of products and processes.

The question arises as to how one should understand and address the environmental sustainability of products. It is tempting to think in terms of conventional metrics such as energy efficiency, water consumption, carbon emissions, or wastes. While these are convenient and easy to grasp, they may not capture the full range of intricacies and trade-offs that can be involved when comparing complex technology options (11). Environmental life cycle assessment (LCA) is a well-established, robust methodology that can provide insight into the environmental benefits and trade-offs of competing technologies to support informed decision making. LCA is internationally standardized (12, 13) and is increasingly becoming the foundation to measure and communicate product sustainability performance. LCA is used across a wide range of industries to quantitatively measure and manage environmental impact across the full life cycle of products and technologies. LCA provides a holistic perspective across multiple life cycle stages that allows one to understand any burden shift from one life cycle stage to another. In addition, multiple environmental indicators provide a comprehensive perspective including awareness of any trade-offs among different environmental impact categories.

In fact, LCA has already been employed to compare and quantify the environmental performance of SUT vs. traditional durable biopharmaceutical process technologies (14–19). The LCA studies have revealed the surprising and counterintuitive insight that switching to SUT can significantly reduce the use stage impacts. This is primarily due to reduction or elimination of the need for cleaning and sterilization between batches. Although adoption of SUT involves adding a supply chain of single-use consumables and the accompanying increase in post-use solid wastes, the added environmental burdens are low and are significantly offset by the reduced use-stage impact. This typically results in overall environmental impacts across the life cycle compared to traditional durable process technology.

With this in mind, a focus on further improving the environmental performance of SUT becomes the next goal. How can we make the single-use platform as sustainable as possible? With innovation and collaboration, we need to find the best solutions for many factors. Such examples include selecting materials of lower environmental impact, applying greener chemistries, more efficient waste management, optimizing packaging and transport, expanding renewable and reusable approaches, and integrating circularity in all aspects across the life cycle.

With additional biopharma industry engagement, research, and innovation, a more thoughtful understanding of the industry's role in sustainable development and the circular

LCA and circularity aspects should be equally considered to gain balanced perspectives. LCA approaches should be used to complement circular economy-based strategies (20), and circularity should be better integrated into LCA (21, 22).

economy can be achieved.

ALIGNING THE EXISTING INITIATIVES

While LCA has many advantages, it also has limitations. LCA excels at evaluating a holistic range of impacts but it does not always successfully highlight or prioritize opportunities to improve materials circularity. Meanwhile, a sole focus on materials circularity can potentially lead to unintended consequences if recommended materials strategies lead to increased impacts in other environmental impact categories such as through increased fossil energy usage related to transport or materials processing. In our view, both LCA and circularity aspects should be equally considered to gain balanced perspectives. LCA approaches should be used to complement circular economy-based strategies (20), and circularity should be better integrated into LCA (21, 22).

While LCA is thought of as the most comprehensive methodology for quantifying the environmental sustainability of products and technologies, there is also a need for less exhaustive tools and approaches that have the potential for providing accurate directional guidance. The American Chemical Society's (ACS's) Green Chemistry Institute Pharmaceutical Roundtable (GCIPR) has been developing process mass intensity (PMI) approaches that leverage materials flows as proxies for environmental impact (23, 24). Further work is needed to verify whether a PMI approach is well calibrated or if it could potentially miss important environmental trade-offs or burden shifts, but efforts are underway to understand any cross-implications.

The Bio-Process Systems Alliance (BPSA)[3] sustainability committee has started the publication of a series of three articles called "The Green Imperative." The first paper (10) aims to introduce major themes arising in the study and implementation of single-use technology for a more sustainable manufacturing environment. The second article in this series will outline current thinking on how to design materials, platforms, and processes supporting the "reduce, reuse, and recycle" paradigm of the circular economy for plastic and packaging principles and faced challenges. The final paper will illuminate current and future post-use handling methods and reprocessing technologies.

BPSA is connected to the BioPhorum Operations Group (BPOG)[4] through a collaboration to survey a broad range of suppliers and end users.

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)[5] has launched an intensified/integrated program that includes a 10-year vision to design and build bioprocesses to be carbon neutral (25). Sustainability is considered a key

3 https://bpsalliance.org/

4 https://www.biophorum.com/

5 https://niimbl.force.com/s/

process design criterion alongside cost, yield, robustness and quality of assurance. Future intensified bioprocesses should be designed for low carbon footprint, reduced water use, low energy, and recycling of raw materials.

A TIERED APPROACH TO ASSESSING SUSTAINABILITY OF SUT

Sartorius hopes to help the industry inform decisions around the sustainability of SUT and other technology development activities by using a life cycle perspective. This allows for the identification of tradeoffs between different stages of the product life cycle as well as from one environmental impact category to another.

Sartorius, with support from Aspire Sustainability, has begun conceptualizing a sustainability index concept to offer awareness and insights into sustainability opportunities and challenges from a life cycle perspective. The aspirational intent is to gain wide-spread adoption of such an index across the industry in an effort to collectively proliferate sustainability in the bioprocess marketplace.

An effective sustainability strategy should provide breadth as well as depth. We envision a tiered methodology involving three levels of application:

- **Tier 1: Sustainability Awareness**
  - Qualitative or semi-quantitative with low data requirements
  - Easily applicable across entire product portfolios
- **Tier 2: "Screening" LCA or PMI**
  - "Light" quantitative to provide more focused insights
  - Applicable to targeted products or product categories
- **Tier 3: Comprehensive LCA**
  - The most rigorous approach targeted at key or market-leading products and technologies
  - Supports public messaging and stakeholder engagement

The Tier 1 Sustainability Awareness level is intended to allow for insights early in the design process without the need to gather extensive data. This provides the opportunity to perform high-level sustainability assessments of many products with efficient use of time and resources. Tier 2 would allow for screening life cycle assessments or process mass intensity (PMI) approaches to be performed, and Tier 3 would involve selective application of comprehensive life cycle assessments, which do require additional data but that can provide detailed insights into product and technology benefits and impacts.

During this early stage of conceptualizing the sustainability index concept, the core attributes of the approach should be enlightening/informative, easy-to-use, and integrable. As such, the Tier 1 Sustainability Awareness tool would use simple rank ordering perhaps supplemented with "light data" collection to assess an array of sustainability concepts (e.g., dematerialization, reusable packaging, renewable energy, water scarcity, hazardous chemicals, materials recovery, etc.). The awareness-building questions would align with topics addressed in EcoVadis and other corporate green ranking surveys/indices, customer requests, and supply chain sustainability questionnaires.

This idea has been integrated into a prototype tool (FIGURE 1) in which the topics and questions are arranged by life cycle stage of the product or technology including: Product Design & Application, Materials & Packaging, Manufacturing & Assembly, Transportation & Storage, Use & Maintenance, and End of Life.

Figure 1: Prototype Sartorius Sustainability Awareness Tool.

Product Life Cycle | Eco-Points	Product A	Product B	Product C	Product D
Total Life Cycle	26.6	19	13	5.3
Product Design & Application	5	3.3	2.3	1
Materials & Packaging	3.5	2.5	1.7	0.7
Manufacturing & Assembly	4.3	3.3	2.1	0.9
Transportation & Storage	5	3.0	2	1
Use & Maintenance	4.6	3.6	2.7	0.9
End of Life	4.2	3.3	2.2	0.8

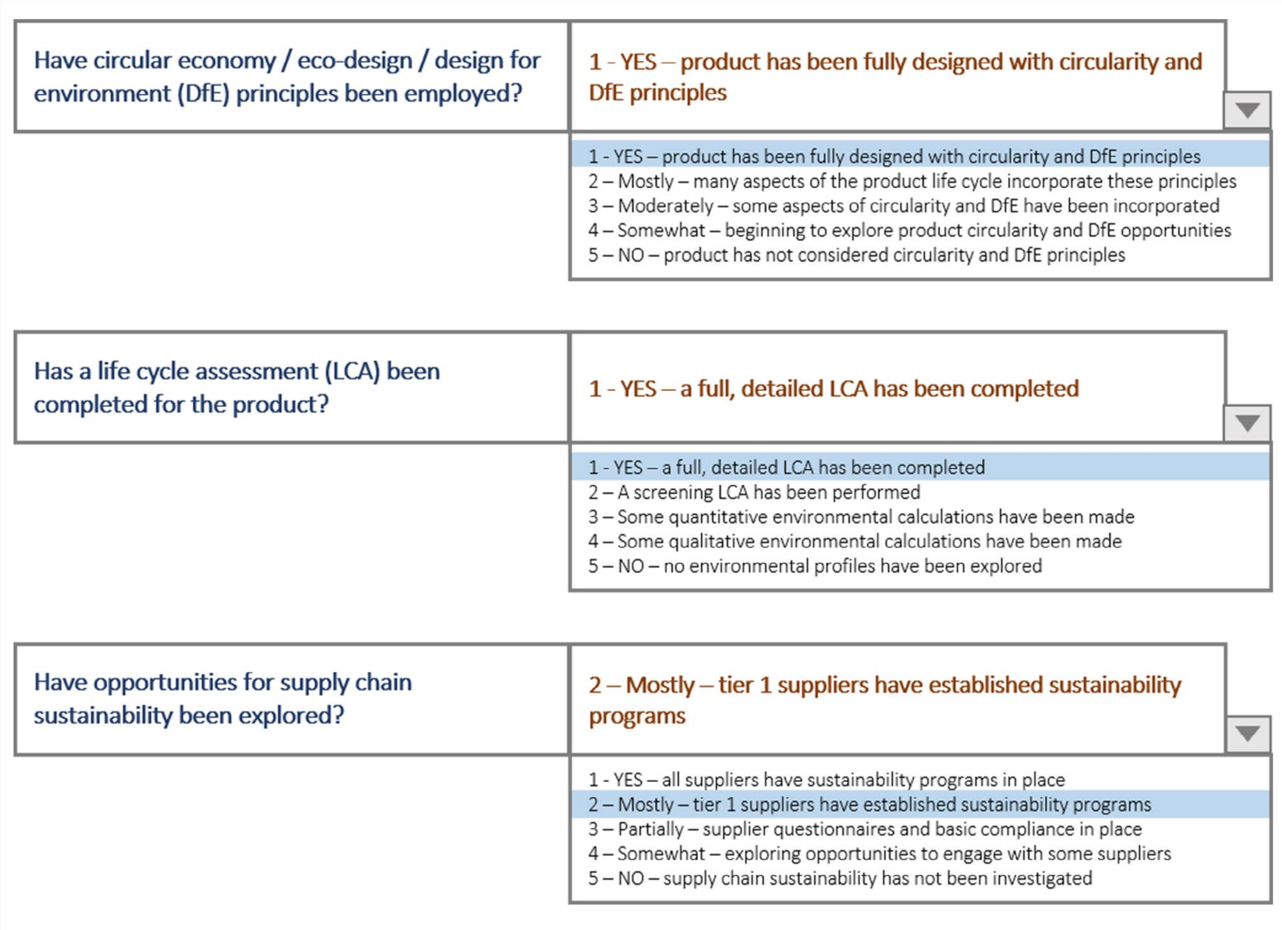
Product Life Cycle | Indicators	Product A	Product B	Product C	Product D
Climate	24.2	17.0	11.4	4.8
Water	25.0	17.1	12.7	5.0
Health	25.8	18.9	12.9	5.2
Circularity	28.9	20.3	14.0	5.8
Eco-Design	29.2	21.9	14.3	5.9

The tool also offers comparability between several different product scenarios allowing evaluation of a variety of different design features or activities. Comparability is a key feature as it will allow for rapid, directional insight into the impacts of different choices across the product or technology life cycle. FIGURE 2 provides example questions with drop-down answers ranked one to five (one being better, five being worse).

This Tier 1 Sustainability Awareness tool connects the sustainability concepts to a variety of environmental indicators such as climate change, water, benefits to health, circularity, and ecodesign, ultimately deriving a single "eco" score to easily illustrate overall sustainability performance. These concepts and indicators can be weighted to emphasize the more critical aspects of the life cycle for a particular application. A brief description of the indicators is as follows:

- **Climate:** The climate change indicator encompasses the greenhouse gas emissions (carbon emissions) associated with the various activities across the life cycle of the product or technology
  - For example, energy use during manufacturing or transportation of raw materials to the facility
- **Water:** The water indicator considers direct water use across the life cycle
  - For example, water consumption during use or manufacturing in water

Figure 2: Example questions for the sustainability awareness assessment.



stress regions

- **Benefits to Health:** The Benefits to Health indicator reflects life cycle activities that amplify the advantages in productivity, safety, efficiency, and ease-of-use of the product or technology
  - For example, safety, productivity, and ease of use
- **Circularity:** The circularity indicator considers activities across the life cycle that increase the circularity of the product or technology related to recyclability, reusability, materials sustainability, and end-of-life opportunities
  - For example, reuse and recovery of manufacturing scrap or use of renewable materials
- **Ecodesign:** The Ecodesign indicator encompasses elements of product and technology design that optimize efficiency and reduce life cycle impacts
  - For example, dematerialization of SUT components or design for ease of disposal

STRATEGIC APPLICATION OF THE SUSTAINABILITY INDEX

The sustainability index is intended to be useful for both manufacturers and users of SUT. From a manufacturer's perspective, the sustainability index would be applied to SUT products that are sold to manufacturers. From a user's perspective, the sustainability index would be applied to the SU process itself. The difference in perspective can be understood by comparing how the life cycle stages would be defined for an SUT manufacturer vs. an SUT user as shown in TABLE 1.

Clearly the life cycle stages and perspectives of manufacturers and users of SUT are

Table 1: Life Cycle Stages from Manufacturer and User Perspectives

Life Cycle Stage	SUT Manufacturer Perspective *focus = SUT component*	SUT User Perspective *focus = bioprocess*
Product Design & Application	SUT component design	Bioprocess design (e.g., SU vs. SS, green chemistry)
Materials & Packaging	SUT component materials and packaging, including supply chain transport	All bioprocess materials inputs (e.g., SUT components, media & buffers, etc.) including their supply chain impacts
Manufacturing & Assembly	SUT component manufacturing and assembly	All SUT component mfg and assembly impacts (inherit from SUT manufacturer)
Transportation & Storage	Transport of SUT component to biopharma manufacturing facility	Transport of all SUT components to biopharma facility
Use & Maintenance	SUT performance characteristics and/or benefits during biopharma manufacturing	Bioprocess energy and water consumption; process chemicals
End of Life	SUT component implications at end of life (recyclability or disposal requirements of component or packaging)	Wastewater treatment, solid wastes (disposal or recycling of SUTs and packaging)

interconnected. The SUT manufacturer needs to adopt a life cycle perspective to ensure that they are considering not just materials and manufacturing of their products, but also how their product designs influence the sustainability of biopharma manufacturing operations as well as disposal or recycling of their products at end of life. The SUT user needs to adopt a life cycle perspective around bioprocess design and operation to ensure that the biomanufacturing process is as environmentally sustainable as possible. Many of the insights and data needs are synergistic, which is why it is so important for the biopharma industry to be collaboratively working together to develop common goals, purposes, and metrics to ensure that product and process evolution is properly advancing the sustainability agenda for the industry.

For any sustainability strategy to thrive, it must create business value. Resources (time and funding) must be strategically focused on activities where they make the most difference and where they create value for the company, stakeholder, or society. The approach must be customizable to business context, since the sustainability and business drivers in one company, geography, or product category can be quite different from another. There is no "one size fits all" tool or strategy, but a smartly developed approach can circumvent this problem by being customizable and adaptable. Finally, to the extent possible, sustainability strategies and methods should be integrated such that they are considered "the way of business" or "the way of technology development." A thoughtful, diligent approach to sustainability stimulates innovation, creates and supports business value, enables and energizes new markets, and empowers both the current and next generation of employees and customers.

A CALL TO ACTION FOR COLLABORATION IN THE BIOPHARMA INDUSTRY

A collaborative approach should address the following aspects:

Approach. The biopharma industry should work collaboratively towards agreement on the concepts and elements of a tiered strategy, thus ensuring that the best ideas and experiences are gathered and considered. The goal should be to develop a harmonized approach that is efficient and optimized for the industry and its stakeholders.

Industry harmonized data strategy. Efficient data gathering and harmonization will need smart industry solutions such as the creation of IT workflows for easing the burden of data wrangling and visualization of the large diverse datasets to support LCA and related sustainability assessments. The complexity of weighting of the various topics could be eased by the development and application of algorithmic guided decision tools. Evolving data integrity tools could be applied to manage the accuracy of data used by technology providers assessing products or end users comparing manufacturing processes.

Collaborative Focus Areas

- Industry collaboration to agree on the details of a conceptual tiered approach (Sustainability Awareness, PMI/screening LCA, comprehensive LCA)
- An industry harmonized strategy for data gathering and sharing
- Agreement on how to weigh the various topics, impact categories, and approaches to generate sustainability index values for components and processes
- Agreement on how to ensure comparability and equity in applications of the sustainability index

Weighting. The envisioned holistic sustainability assessment involves various impact categories such as carbon, energy, water, circularity, health, ecosystems and possibly others. We should seek agreement on the categories to include, and how to properly weight them to generate a sustainability index.

Comparability and equity. When developing methodologies and approaches at the industry level, care must be applied to ensure that the results and insights are both comparable and equitable.

There are many opportunities to further evolve the sustainability of the biopharma industry through exploring improved sustainability in materials choices and innovation, productivity and efficiency improvements in manufacturing, increased materials circularity, end-of-life waste minimization/recycling, plastics management, and supplier engagement. Working together, we can better position the biopharma industry, advance sustainability benefits, and maintain focus on the healthcare benefits that this industry provides to so many.

We began this article with a reference to the United Nations Sustainable Development Goals (1, 2), which provide a perspective for reflection. We close by quoting the SDG17 which defines: “A successful development agenda requires inclusive partnerships—at the global, regional, national and local levels—built upon principles and values, of a shared vision and goals, placing people and the planet at the center.” SUT is a powerful enabler to develop and produce new medicines faster and cheaper. Let’s collaborate to achieve BIOPROCESS SUSTAINABILITY GOALS that are transparently shared, harmonized and even standardized using comparable and equitable tools.

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