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SUSTAINABLE PLASTICS AND THEIR POTENTIAL TO

REDUCE CARBON FOOTPRINT

THE ALLIANCE TO ZERO



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Blue box means this word is contained within our glossary

0 Executive summary

The carbon footprint of an injection device is largely attributable to plastic components.

The carbon footprint of an injection device for subcutaneous injections of liquid drugs is largely attributable to plastic components. Therefore, sustainable plastics offer a significant decarbonisation potential for the Alliance to Zero members. However, various concerns slow down the implementation of sustainable plastics in the medical device industry.

"Bioplastics" can be either biodegradable or bio-based or both.

For injection devices, biodegradable material generates no benefit, as the devices are contaminated after use and not suitable for composting. But bio-based plastics can be a very interesting option to reduce carbon footprints.

There are several generation methods for producing bio-based plastics, and it's important to understand these. To avoid food competition or any negative impacts on other sustainability categories such as land use or water pollution, the use of bio-plastics originating from edible (also called first generation) feedstock, such as corn or sugar cane, is not recommended. However, a good alternative is to use second generation feedstock, which is feedstock produced from the by-products of other processes like used cooking oil, agricultural waste or inedible biomass such as straw.

Product Carbon Footprint (PFC) data plays a crucial role in relation to biopolymers, as some biomass-based processes require a lot of energy. In addition, fuels, such as Sustainable Aviation Fuel (SAF), are made from the same sources as biopolymers. This could lead to a shortage of sustainable feedstock and price increase in the future.

Bioplastics can be totally new polymer types, but many conventional technical plastics can also be produced from biofeedstock instead of fossil oil or gas. Bio-feedstock undergoes the same conversion process as fossil oil or gas for the production of plastics. The chemistry of the pre-processed oil that enters the production plant is no different and fulfils the same specification. The resulting polymer cannot be distinguished and there are no different impurities, as tests results show.

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0 Executive summary cntd.

Another option for sustainable materials is recycled plastics.

Another option for sustainable materials is recycled plastics. Mechanical recycling is always the best option if feasible, for simplicity, availability of technology, cost and energy required. However, for the outer elements of medical devices, recycled materials are not suitable so far.

For this reason, chemical recycling can be an option. In chemical recycling the polymer chains are broken down and new polymers are built. Depending on the technology, chemical recycling can transform polymers back to monomers or even oil. The further it goes back towards its original state, the more energy is needed. This high energy demand can cause a high carbon footprint, so a case-bycase assessment is needed.



A relatively new feedstock for commercially-available plastics is the carbon capture technology. This captures carbon dioxide from industrial fumes and builds polymers from it. This technology seems to have a good potential for the future.

To avoid building new expensive plants for producing bio-plastics or chemically recycled plastics, plastic producers often mix different feedstock together in one process.

It is possible to allocate the renewable content to only some of the batches produced. To prevent double-counting, certification systems such as ISCC ensure transparency along the whole value chain. As a consequence, one might buy a bio-plastic batch that does not physically contain any bio-feedstock.

Instead, the allocated bio-based feedstock might have been used in a batch that is sold as conventional plastic. For the environment this makes no difference. The respective amount of bio-based feedstock was sourced and the use of fossil feedstock avoided by buying the bio-plastic.

A higher demand in bio-plastics directly causes a higher input of sustainable feedstock in the plant even if not all of it is used for the material it was allocated to.

In this paper, the Alliance to Zero seeks to clearly explain the role that bioplastics can play in the pharmaceutical and biotech sector's transition to net zero.

The first step on this path is to accelerate acceptability and address industry concerns on their implementation within decarbonization strategies.



ISCC:

The International Sustainability and Carbon Certification (ISCC) is a globally applicable sustainability certification system. It covers all sustainable feedstocks, including agricultural and forestry biomass, bio-based and circular materials, and renewables.



1 Introduction

Sustainable plastics are critical in decarbonizing our footprint

At the Alliance to Zero, our mission is to guide the pharmaceutical and biotech sectors toward achieving net-zero emissions. **Plastics represent one of the largest emission categories** for our member companies, but they also offer **significant mitigation potential**. For example, in producing an automated disposal injector device—a collaborative effort among all our member companies—more than half of the total cradle-to-grave product carbon footprint (PCF) is attributable to plastic components and packaging along the value chain. Sustainable plastics can significantly reduce this footprint.

However, **considerable confusion** surrounds them, slowing industry acceptance and implementation. This whitepaper looks at alternatives to fossil-based plastics for the production of medical devices with a focus on decarbonization. Different replacement options are discussed regarding suitability, availability, and sustainability.



2 Overview of alternatives for conventional plastics

While various alternatives exist to reduce plastics' environmental impact, the most promising strategies from a material perspective fall into **two categories**: **bioplastics** and **recycled plastics**. Bioplastics take advantage of low-emission renewable feedstock. Recycled plastics usually have a lower material footprint than virgin plastics and gradually reduce the need for new materials.

Additionally, plastic can also be produced from carbon dioxide, removing greenhouse gasses from the atmosphere. However, the technical and economic feasibility of large-scale applications is yet to be determined. By using or combining different material mitigation strategies, a comprehensive approach to optimizing plastics' footprint and waste production can be achieved.





Plastics:

Plastics are polymers originating from synthetic manufacturing.

Examples of plastics include:

- Nylon synthesized from any source
- Polyolefins synthesized from any source.

Examples of plastics do not include:

- Cellulose (found in woods)
- Silk (produced by silk worms).

Bioplastics:

Bioplastics are plastics synthesized from a biomass source or produced by a biological organism or degrading via biological processes. Note: The term "bioplastic" should not be used for fossil-based biodegradable plastics.

Examples of bioplastics include:

- Nylon when synthesized from biomass
- Polyolefins when synthesized from biomass

Examples of biopolymers do not include:

- Nylon when synthesized from fossil sources
- Polyolefins when synthesized from fossil sources
- Cellulose (found in woods)
- Silk (produced by silk worms)



2.1 Bioplastics

The definition of bioplastic

According to the definition by European Bioplastics, which is adopted by most countries:

bioplastics encompass a broad range of materials that are either biobased, biodegradable, or both.

— European Bioplastics, 2024b

Biodegradable:

that is capable of being decomposed by bacteria or

other living organisms and thereby is avoiding pollution. The substance or object needs to be capable of being broken

down especially into harmless products by the action of living

As a result, bioplastics are not necessarily **biodegradable**, and not all biodegradable plastics are **biobased** (Table 1). While bioplastics can have environmental benefits compared to virgin plastic, they do not reduce the amount of waste generated.

	Non-biodegradable	Biodegradable
Bio-based	Bioplastic	Bioplastic
Fossil-based	Virgin plastic	Bioplastic

Table 1: Different types of bioplastics (European Bioplastics, 2024b).

Based on this, bioplastics can be broken down into three distinct classifications:

- Non-biodegradable and fully or partially bio-based (e.g., bio-based PET, bio-based PE)
- Biodegradable and petroleum-based (e.g., PCL)
- Both biodegradable and fully or partially bio-based (e.g., PLA)

Bio-based feedstock

Bio-based implies that the plastic is derived at least partially from **biological matter**. Depending on the source, bio-based feedstocks are classified into **different generations**, from 1st to 4th generation.

1st generation



1st generation feedstock is sourced from edible **biomass**. Although the production process is **well-established** and relatively **straightforward**, using 1st generation feedstock presents significant sustainability challenges.

In addition to **competing with food supplies** and requiring substantial **freshwater resources**, converting land with high carbon stocks in its soil or vegetation for cultivation can result in **significant carbon dioxide emissions**. In some cases, these emissions can significantly outweigh the greenhouse gas reduction benefits typically associated with bio-based feedstocks (RED II 2018). For this reason, RED II explicitly lists what kind of land can be used for the production of 1st generation feedstock.ED II: renewable Energy Directive is the legal framework for the development of clean energy across all sectors of the EU economy.

Bio-based:

"Bio-based" classifies materials or products to be either derived wholly or partially from biological sources, composed of renewable resources or originate from living (or once-living) organisms.

Biomass:

Biomass refers to organic materials or materials of biological origin, excluding fossil materials or those embedded in geological formations.

Feedstock:

Feedstock is a raw material going into a chemical process or plant as input to be converted into a product.



More specifically, "Biofuels, bioliquids and biomass fuels produced from agricultural biomass (...) shall not be made from raw material obtained from land with high-carbon stock, namely land that had one of the following statuses in January 2008 and no longer has that status:

- (a) wetlands, namely land that is covered with or saturated by water permanently or for a significant part of the year;
- (b) continuously forested areas, namely land spanning more than one hectare with trees higher than five metres and a canopy cover of more than 30 %, or trees able to reach those thresholds in situ;
- (c) land spanning more than one hectare with trees higher than five metres and a canopy cover of between 10 % and 30 %, or trees able to reach those thresholds in situ" (European Union, 2018).

2nd generation



2nd generation feedstock is derived from non-edible biomass, including waste from 1st generation feedstock and industrial waste. Although its **supply is limited** and requires **more costly pretreatment** than 1st generation feedstock, 2nd generation feedstock offers significant sustainability advantages. It **repurposes waste streams, does not compete with food supplies, and generally has a lower carbon footprint** than fossil-based feedstock.

Since 2nd generation feedstock is derived from waste, feedstock emissions are attributed to the primary material or original use. **Table 2** below outlines average CO equivalents of 1st and 2nd generation feedstocks that could potentially be used to produce plastics² (Alalwan, Alminshid, & Aljaafari, 2019; Mülhaupt, 2013).

Biofuel and bioliquid production pathway	Feedstock generation	Greenhouse gas emissions - typical value (g CO2eq/MJ)
Rape seed biodiesel	lst	32.0
Sunflower biodiesel	lst	26.1
Soybean biodiesel	lst	21.2
Palm oil biodiesel	lst	26.2
Waste cooking oil biodiesel	2nd	0
Animal fats from rendering biodiesel	2nd	0

Table 2: Selected 1st and 2nd generation feedstock emissions, including soil N2O emissions according to RED II (European Union, 2018).





Table 3 below provides a comprehensive overview of feedstock sources across 1st and 2nd feedstock generations, along with their respective advantages and disadvantages. Newer feedstock called 3rd and 4th generation are not listed because the definition varies and there are no known commercial applications for plastics.

Table 3: Advantages and disadvantages related to 1st and 2nd generations of bio-based feedstock.

Feedstock generation	Feedstock source	Advantages	Disadvantages
lst	Edible Biomass	 + Simple processes + High yield per hectare + Cost efficient + Well established + No intensive pretreatments 	 Food competition Potential high indirect release of CO₂ High land use High freshwater use Fertilization
2nd	 Non-edible Biomass: Wood, straw, grass Waste from 1st generation feedstock and industrial waste (e.g., waste cooking oil, agricultural waste) 	+ Footprint reduction + Valorization of waste streams + No food competition	 Limited supply More expensive pretreatment (complex feedstocks)







Bio-based drop in solutions

The same plastic can be produced from different sources such as fossil oil, talloil or used cooking oil. To reduce the carbon footprint of existing injection devices a switch to these chemically identical bioblastics is a good and easy solution that does not require any retesting, as will be shown in this chapter.

Frequently heard concerns for such a switch to bio-based plastics relate to:

- Perceived impurities in plastics from renewable sources
- Ability to fulfil requirements in Medtech industry
- Potential changes to plastic properties when made from biomass

These concerns are often unfounded as the properties of a plastic are based on its chemistry, whereas the source of the chemical elements does not change the properties.

Figure 1 below illustrates how feedstock for POM can be fossil or biomass-based. Because the refined oil/petrochemicals are chemically identical, they can even be mixed with their fossilbased counterparts as desired, still resulting in the same plastic (Figure 2).



Biocompatible:

Biocompatibility refers to the ability of a material to come into contact with living tissue without causing a harmful reaction. It is an important aspect in the development of medical implants, prostheses and other products that are used in or on the human body.

Chemically identical:

Chemically identically implies that the compounds are identical, having the same chemical and physical properties (and other properties too).

Input levels for selected bio and fossil-based polymers:



Figure 1: Input levels for selected bio and fossil-based polymers



Biocompatibility of bio-based feedstock

The equivalency of plastics made from different feedstocks can be proven by testing the feedstock or the monomers or the polymers.

LyondellBasell has the CirculenRenew Portfolio that offers polyolefins from renewable feedstock. They conducted a series of tests on their final product and compared it to the properties of the fossil based counterpart. All tests including infrared spectroscopy, molecular weight distribution, viscosity, volatiles and extractables showed no significant difference.



Borealis also offers Polyolefins made from renewable feedstock. They compared the spectrum of the monomers produced from renewable and fossil feedstock in gas chromatography. As can be seen below, monomers produced from fossil and non-fossil feedstock have identical composition, disregarding concerns about additional impurities when produced from bio feedstock. Notably, in this instance, the plastic made from renewable sources and fossil sources cannot be distinguished (lines in Gas chromatography completely overlap) and is chemically identical.

Monomer feed to polymerisation with the Bornewables™



Gas chromatograms of monomer – fossil vs renewable-based feedstock, before entering polymerisation process

All curves from renewable-based feedstock; several samples taken over longer time period (9 days) vs reference (fossil): 63103_2021_1_7



The fact that the bio-based plastics are chemically identical to their fossil-based counterparts also addresses concerns that bio-based feedstock cannot fulfill requirements from the Medtech industry. It also shows that biocompatibility tests do not have to be repeated with bio-based feedstock if they have been conducted with fossil feedstock and equivilancy of the two feedstocks have been proven.

When bio-plastics from fossil- and bio-based feedstocks are identical, no change requests are required for their use in existing applications. Considering that medical devices are extensively tested and registered in each country, making material change very time-consuming, bio-plastics have gained popularity in Pharma.

The extract below illustrates a typical supplier equivalency statement, which guarantees the material parity between a bio-plastic and its virgin counterpart.

Example of a typical bioplastic equivalency statement:

Equivalency Statement for Material X (fossil-based) and Material X (virgin-based)

In the matter mentioned above, we refer to the technical and regulatory compliance equivalency of Material X (fossil-based) and Material X (virgin-based).

The materials Material X (fossil-based) and Material X (virgin-based) are produced following the same recipe and under the same manufacturing process, and therefore share the same specifications. These materials have identical technical properties and medical regulatory status.

If you have further questions on that subject, please contact your local sales representative.



Figure 3: Example of a typical bioplastic equivalency statement

Biodegradability

Biodegradable plastics represent a relatively small subset of bioplastics that decompose into carbon dioxide, water, and biomass through the natural action of microorganisms (European Commission, 2024). The biodegradability of a plastic is determined by the chemical properties of its polymer, irrespective of the polymer's origin. As a result, biodegradable plastics can be derived from either bio-based or petroleum-based feedstock sources. **Compostable** plastics, a further subset of biodegradable plastics (Figure 1), are certified by third-party organizations to meet international standards, such as ASTM D6400 (U.S.) or EN 13432 (Europe), for biodegradation under specific conditions and timeframes. Consequently, while all compostable plastics are biodegradable, not all biodegradable plastics qualify as compostable (Ellen MacArthur Foundation, 2024; European Commission, 2024a).

Compostable:

Compostable materials are organic matter that can be broken down into nutrient-rich soil. This includes things like food scraps, eggshells, manure, grass clippings, leaves, fruit and vegetable peels, coffee grounds, and tea bags

Compostable plastics can be categorized as either home-compostable, which decomposes at ambient temperatures with natural microbial activity, or industrially compostable, which requires elevated temperatures, higher humidity, and specialized microbial conditions.

It is important to note that oxo-degradable plastics form a distinct category (Figure 4). These are conventional plastics combined with additives that mimic biodegradation. Unlike biodegradable and compostable plastics, oxo-degradables fragment into smaller pieces, known as microplastics, but do not decompose at the molecular or polymer level (European Commission, 2022).

Different types of biodegradable and non-biodegradable plastic:



Figure 4: Different types of biodegradable and non-biodegradable plastic (Green Dot Bioplastics, 2024)

While bio-based plastics (particularly those derived from 2nd, 3rd, or 4th generation feedstocks) offer clear environmental benefits—most notably in terms of reducing CO_2 emissions—the standalone environmental merits of biodegradability are highly debated. The key concerns are as follows:

Incineration and composting of biodegradable plastics both generate equivalent amounts of CO₂.

- Most biodegradable plastics do not contribute to soil enrichment or produce fertilizer as part of the degradation process.
- Certain biodegradable plastics can negatively impact soil health, making them unsuitable as a remedy for poor waste management or littering practices.
- Incineration and composting of biodegradable plastics both generate equivalent amounts of CO₂.
- Incineration in high-efficiency plants can yield greater CO₂ savings through heat and electricity generation compared to biogas production via industrial composting.
- Many plastics labeled as biodegradable fail to fully break down even in industrial composting facilities and must be removed (Deutscher Bundestag, 2016).
- Biodegradable plastics are often mistaken for conventional plastics, and when they enter the standard recycling stream, they can degrade the quality of recycled materials.



Biodegradability is generally unsuitable for medical devices

due to the presence of drug residues, frequent attachment to needles, and potential contamination. Components in direct contact with patients or medications can be classified as medical waste, requiring incineration by law. However, even medical device parts that are not medical waste require strict safety protocols and handling procedures. Consequently, approaches such as reuse and chemical recycling, which involve thorough sterilization or material heating, are significantly more appropriate than composting.

Applicability to upcoming EU waste regulations

To combat the alarming pace of global warming and accommodate growing consumer awareness, governments are tightening up their regulation, even as players in some key industries (such as FMCG) voluntarily self-regulate (Roland Berger, 2024). In the European Union, the primary policy framework influencing material usage is the **EU Green Deal**, which gives rise to a range of related laws and regulations (Anthesis 2024).



EU Green Deal:

The EU Green Deal is a strategic initiative of the European Union that aims to become climate-neutral by 2050. It includes measures to reduce greenhouse gases, promote renewable energies, improve resource efficiency and protect biodiversity in order to promote the transition to a sustainable economy.

EU Emerging Policy:

OVERARCHING POLICY	MAIN PILLARS	ASSOCIATED LEGISLATION	ASSOCIATED REGULATION	ASSOCIATED
		Packaging and Packaging Waste Regulation	Extended Producer Responsibility	Material classification and reporting, fees now and how this may differ leading up to 2025
	Circular Economy	Single-Use Plastics Directive	Recycled Content	Requirements for % of recycled content in packaging
	Action Plan	Eco-Design Directive	Plastic Taxes	Taxes on plastic packaging waste that is not recycled 2021/2
		Waste Framework Directive	Single-Use Plastic Bans	Material bans and material restrictions now and until 2025
EU Green	Climate Policy	Associated legislation	Eco-Design	Design requirements for packaging to be recyclable/reusable
Deat	Farm to Fork	Associated legislation	Disposal and Recycling	Improve waste management, stimulate innovation in recycling and limit landfill.
	Clean Energy	Associated legislation		****
	Smart Mobility	Associated legislation		*****
	Forestry Strategy	Associated legislation		







Regarding bioplastics, significant uncertainty surrounds the recycled content regulation, which mandates that a specific percentage of packaging, varying by plastic type, must be composed of post-consumer recycled content.

While it has been confirmed that materials produced through chemical recycling will be classified as "recyclates" (Roland Berger, 2024), ongoing discussions are determining whether certain biopolymers will also qualify as recycled content.

Notably, limited exemptions for the pharmaceutical sector regarding the recycled content regulation have been established until January 1, 2035. During this period, the minimum recycled plastic content requirements will not apply to the immediate packaging of human or veterinary medicinal products or to the outer packaging in cases where the packaging must "comply with specific requirements to preserve the quality of the medicinal product." The requirements will also not apply to contact-sensitive plastic packaging of medical devices or in vitro diagnostic medical devices.

While it has been confirmed that materials produced through chemical recycling will be classified as "recyclates", ongoing discussions will determine whether certain biopolymers will also qualify as recycled content.

However, the Pharma industry will still be affected by the EU Green Deal. By January 1, 2028, packaging must display EU-harmonized sorting and reusability symbols, along with mandatory QR codes providing consumers with detailed information on packaging reusability and recycling points.

Additionally, packaging must be minimized, with no more than 40% of its total volume consisting of empty space. <u>Pharma impacted by new EU packaging and packaging waste proposals - Lexology</u>.





Commercialization

Today, the share of bioplastics is very small compared to fossil-based plastics. In 2023, global bioplastic production was estimated at 2.18 million tonnes, accounting for approximately 1% of the total production volume of fossil-based polymers. **Figure 6** illustrates global bioplastic production capacities by material type for that year.

Notably, as reported by Borealis (2022), thirdgeneration bio-based plastics are only commercially available at an industrial scale for specialty chemicals and have yet to enter large-scale commodity production. According to McKinsey & Company (2023), 2050 global biomass demand could outgrow sustainable supply two times over. In turn, as demand continues to grow, so does the risk of price increases and supply shortages (McKinsey & Company, 2023).







Figure 6: Global production capacities of bioplastics in 2023 by material type (European Bioplastics, 2024a)

2.2 Recycled plastic

According to the European Waste Framework Directive, recycling is "any recovery operation by which waste materials are reprocessed into products, materials or substances, whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and reprocessing into materials that are to be used as fuels or for backfilling operations." Departing from this general definition, plastic recycling can be further categorized into open and closed-loop recycling, as well as mechanical and chemical recycling.

Open-loop and closed-loop recycling

Open-loop recycling involves recycling a product into a different form, often referred to as downcycling or reprocessing. During this process, the material loses value and cannot be reused for its original purpose. Closed-loop recycling, on the contrary, refers to the process of recycling a product while maintaining its material properties, allowing it to be reused in the production of the same product.

Mechanical recycling

Mechanical recycling, which has been around for decades, involves processing plastic materials without altering their chemical structure. While mechanical recycling can vary slightly, it typically involves shredding, washing, and sorting. Mechanical recycling is especially well suited to pre-sorted rigid plastic waste with limited contamination. From an environmental as well as economic perspective, mechanical recycling is always preferable to chemical recycling whenever feasible (Waste Management World, 2023).

From an environmental as well as economic perspective, mechanical recycling is always preferable to chemical recycling whenever feasible.

Figure 7 indicates typical CO_2 emissions of mechanically recycled plastic types compared to alternative treatment.





Figure 7: CO₂ emissions of different recycled plastics compared to virgin plastics from pdf:https://plasticsrecycling.org/wp-content/uploads/2024/08/APR-Recycled-vs-Virgin-LCA-May2020.pdf

Mechanical recycling and biocompatibility

Unfortunately, mechanically recycled plastic is currently unsuitable for the outer components of automated injection devices. These devices must adhere to ISO 10993, "Biological Evaluation of Medical Devices," which mandates that all materials in contact with the patient or drug must be proven safe for their intended use. Compliance requires a thorough analysis of material data provided by manufacturers and may involve additional toxicological testing or animal studies to identify any harmful chemical leaching. Notably, VDI 2017 for Medical Grade Plastics (MGP) ensures that plastics meet specific criteria to comply with ISO 10993.

Mechanically recycled plastic is currently unsuitable for the outer components of automated injection devices



2.5

2.2 Recycled plastic cont.

Injection devices for liquid drugs, such as the autoinjector shown in **Figure 8**, are classified as medical devices. Therefore, they must be evaluated for biocompatibility according to ISO 10993, necessitating the use of medical-grade plastics. Mechanically recycled materials, however, can be contaminated with various substances throughout their lifecycle, requiring batch-by-batch testing to ensure biocompatibility. Additionally, there are currently no established standards or approved processes for producing Medical Grade Plastics through mechanical recycling. While recycled PET has demonstrated viability in consumer products such as drinking bottles (food grade), achieving similar standards for medical applications will require further development.

Autoinjector for the automatic administration of a fixed dose of drug



Figure 8: Autoinjector for the automatic administration of a fixed dose of drug

Conversely, the inner components of the injection device, which do not come into direct contact with the drug, could theoretically be made from any material as long as it meets mechanical requirements and maintains consistent quality as specified in the technical specification.

Chemical recycling

Chemical recycling breaks down plastic waste into its chemical building blocks. While various chemical recycling technologies exist for different types of plastic waste, they can be broadly categorized into thermochemical, depolymerization, and solvent-based technologies, with outputs ranging from pyrolysis oil to syngas, monomers, and polymers (Figure 9). Depending on the type of plastic waste, some technologies are more suitable than others (Figure 10).

Thermochemical recycling can be subdivided into pyrolysis and gasification and uses heat to break down plastic waste into smaller chemical compounds. Pyrolysis involves the thermal decomposition of organic materials into pyrolysis oil at relatively low temperatures and in the absence of oxygen. Gasification, on the other hand, converts feedstock into syngas using high temperatures and a controlled, limited amount of oxygen or steam.

Depolymerization involves applying heat, chemicals, or enzymes to break down plastics into their monomer units or smaller molecules using chemical reactions.

In solvent-based recycling, plastic waste is entirely dissolved and purified. By removing the solvent, the polymer is recovered. Solvent-based recycling can be further divided into solvolysis and dissolution. While solvolysis breaks down plastic waste into monomers, dissolution breaks down plastic without breaking down its molecular structure. Notably, chemical recycling via solvent purification currently does not produce sufficiently pure material to qualify as Medical Grade Plastic.

2.2 Recycled plastic cont.





Figure 9: Overview of plastic recycling processes (Roland Berger, 2024)

Suitability of common plastics for chemical recycling technologies



Figure 10: Suitability of common plastics for chemical recycling technologies (Roland Berger, 2024)

While all forms of recycled plastics help reduce waste, not all offer significant CO₂ savings.

While all forms of recycled plastics help reduce waste, not all offer significant CO₂ savings. The further down the value stream the recycling technique, the more energy-intensive it becomes, with pyrolysis being particularly energy-demanding compared to mechanical and solvent-based recycling methods. For example, if solvolysis is employed, then the plastic is broken down to monomer level, which requires significantly less energy as a process compared to pyrolysis, which brings the plastic back to feedstock level and is extremely energy intensive. Existing life cycle assessments (LCAs) for chemical recycling can be misleading, and decision-makers should exercise caution when interpreting them (Zero Waste Europe, 2020). Zero Waste Europe (2020) advises against accounting for avoided emissions from alternative waste disposal methods and recommends that only recycling options with a lower carbon footprint than virgin plastic production should receive EU government support.



2.2 Recycled plastic cont.

Similarly, a study by Quantis (2020) found that the production carbon footprint of chemically recycled LDPE exceeds that of virgin LDPE. The overall environmental impact of chemically recycled LDPE only appears lower when "environmental credits" for avoided waste are included. In contrast, mechanical recycling is consistently shown to have the lowest environmental footprint, when only considering the emissions that occurred during production as well as when taking into account environmental credits (**Figure 11**).

Notably, the carbon footprint of chemical recycling could be reduced in the future by increasing efficiencies and transitioning to renewable energy sources.

Product perspective scenarios impact and benefits, for 1kg of mixed plastic waste treated, climate change indicator



Figure 11: Product perspective scenarios impact and benefits, for 1kg of mixed plastic waste treated, climate change indicator (Quantis 2020)

Commercialization

Despite its long history, only about 12% of global plastic waste currently gets recycled. However, due to increased regulation, this figure is expected to nearly double to 20% by 2030 and reach 45% by 2050. With more plastic in circulation, the volume of plastic waste entering the recycling chain is projected to grow from 44 million tons (MT) in 2023 to 85 MT in 2030 and 230 MT by 2050, reflecting a compound annual growth rate of nearly 6%. Volume growth will be faster in APAC and North America compared to Europe, with dynamic growth also seen in developing economies, particularly African countries. Notably, almost 40% of capital investment in chemical recycling will occur in Asia Pacific, followed by North America and Europe. These trends will create significant opportunities for suppliers of recycling technologies and equipment (Roland Berger, 2024).

Mechanical recycling, predominant in developed countries, currently accounts for around 75% of global recycling capacity. Waste-to-X applications, common in developing nations, contribute about 20% of global recycling capacity, using waste for construction materials and furniture. Chemical recycling handles just 3% of global plastic recycling today but is expected to grow to nearly 25% by 2050. Pyrolysis, capable of processing most polymers and fibers, is projected to dominate the chemical recycling market with a 65% share by 2050. Depolymerization technologies will capture about 15% due to their narrower material focus. The remaining 20% will be shared by gasification, solvolysis, and dissolution technologies by 2050 (Roland Berger, 2024).



2.3 Plastics from carbon dioxide

Carbon dioxide is an abundant, low-cost resource that occurs naturally and can be captured from sources such as exhaust fumes using **carbon capture** technology. Once recovered, CO_2 can be converted into chemicals, which in turn can be used to produce plastics. These plastics help reduce the reliance on fossil fuels and directly decrease atmospheric CO_2 levels. While this conversion process is energy-intensive, future developments could make it more sustainable by using renewable energy (Cormier, 2024).

After more than a decade of research, the first CO₂-based plastics are now commercially available.

 CO_2 -to-chemical conversion offers greater output potential per unit of land than biomass, positioning it as a promising alternative to biomass in the long term (McKinsey & Company, 2023). After more than a decade of research, the first CO_2 -based plastics are now commercially available, with new production facilities being developed. Notable examples include:

- Covestro, which produces polyurethane foams containing 20% carbon dioxide under the brand "cardyon," used in mattresses and upholstered furniture (Covestro, 2024).
- Celanese, which manufactures polyoxymethylene (POM) and other plastics from carbon dioxide (Čučuk, 2024).
- SABIC, which is constructing a large-scale carbon capture and utilization plant, positioning it as a leader in this emerging field (Sabic, 2024).



Types of Sustainable Plastic	Advantages	Disadvantages
Biopolymer	+ Identical material properties to virgin plastics	 CO₂ emissions potentially higher than virgin plastics Potential pollution of waste streams and environment No reduction in waste generation Feedstock limited
Mechanical Recycling	 + Most economical recycling method + Significant CO₂ reduction + Reduction in waste generation 	- Decreasing quality (downcycling) - Not suitable for all waste types - Limited input material
Chemical Recycling	 + High-quality output + Suitable for most plastics and contaminated waste + Reduction in waste generated 	 Very energy intensive (much higher than mechanical recycling) Expensive Low yield
Carbon Capture	 + Identical material properties to virgin plastics + Reduces atmospheric CO₂ + Abundant feedstock 	 Energy intensive Large-scale technical and economic viability uncertain

Table 4: Most important advantages and disadvantages of sustainable plastic alternatives



3 Which alternatives to conventional plastic are truly sustainable?

The most sustainable plastic alternative depends on the sustainability criteria applied and the intended application. While carbon footprint is often the primary factor considered, other crucial dimensions to assess the sustainability of plastic alternatives are gaining importance:

- Water consumption
- Energy intensity
- Use of renewable resources
- Impacts on biodiversity and water quality
- Food competition
- Health and environmental hazards
- Controlled product lifecycle
- Recyclability²



Under favorable conditions, bio-based plastics can offer a lower carbon footprint while maintaining the same material performance as conventional plastics. From an ecological perspective, the production of bio-based plastics conserves fossil resources compared to traditional plastics. To avoid negative environmental impacts and reduce waste, feedstock should not be sourced from 1st generation crops but waste biomass or by-products from other processes (e.g., tall oil, bio-methanol from composting, waste cooking oils). Conducting a life cycle assessment (LCA) on a case-by-case basis is essential to verify whether a particular bio-based plastic is more sustainable than its fossil-based counterpart. Notably, improper disposal of biodegradable bioplastics may contaminate waste streams or the environment. Due to their sensitive nature, biodegradable bioplastics are generally unsuitable for medical devices.

Recycled materials can significantly reduce CO₂ emissions and mitigate waste generation compared to conventional plastics. However, their material properties are often not fully equivalent to those of virgin plastics. Moreover, depending on the waste type, not all recycling methods are suitable. Given the wide variation in recycling technologies and their environmental impact, sustainability must be evaluated on a case-by-case basis against virgin plastics. Additionally, producing high-quality recycled plastics relies on well-sorted waste streams, which can limit production capacity and scalability.

Lastly, plastics derived from carbon dioxide hold promise for substantial CO₂ savings while maintaining material properties like conventional plastics. However, these materials do not address waste reduction, and their large-scale economic and technical feasibility remains uncertain.

Conducting a life cycle assessment is essential to verify whether a particular bio-based plastic is more sustainable than its fossil-based counterpart.



4 Methodological aspects

4.1 Mass-balance approach: forwarding sustainable feedstock

Plants for plastic production are very complex. Since the amount of plastic from renewable sources is still low compared to the fossil based plastics, buildings new plants for them would be time consuming and very expensive. It is much easier to mix fossil and renewable pre-products such as methanol and use them in the same production plant. However, it is important to ensure that the accounting of renewable feedstock is done correctly.

The Mass Balance Approach (MBA) is a Chain of Custody (COC) model that ensures transparency in the supply chain. By tracking inputs and outputs, claims about product composition can be verified. In practice, MBA is most commonly used for tracking the use of chemically recycled or bio-based feedstock. Thereby, MBA applies to situations where the use of sustainable feedstock is indistinguishable from conventional feedstock in the final product, supporting the circular economy without needing new infrastructure (Open LCA, 2024). An example of mass balance applied in practice can be seen in **Figure 12**.

MBA applies to situations where the use of sustainable feedstock is indistinguishable from conventional feedstock in the final product, supporting the circular economy without needing new infrastructure.



Figure 12: Mass balance example (ISCC, 2024).



4.1 Mass-balance approach cont.

To ensure credibility, certification schemes like ISCC PLUS, REDcert, RSB Advanced Products, and Ecoloop verify companies' adherence to MBA principles. Each scheme has a different methodology, accounting unit, and levels (material batches, company, site-specific, across sites with physical connectedness or none) at which mass balance is verified (Open LCA, 2024). Increasingly, ISCC is becoming the most used MBA certification scheme for plastics. To forward ISCC-certified material, each company in the supply chain (apart from the end-user) needs to be ISCC-certified (**Figure 13**), annually audited, and pass forward a self-declaration/ sustainability declaration.

Step-by-step traceability of ISCC-certified material



Figure 13: Step-by-step traceability of ISCC-certified material (ISCC, 2023).

4.2 CO₂ footprint calculation

An increasing number of feedstock, granulate, and component suppliers are now providing Product Carbon Footprint (PCF) calculations for their products. To ensure meaningful comparability, it is crucial that all materials and components are evaluated using consistent methodologies (European Commission, 2024b).

Numerous standards and guidelines have been developed to improve PCF comparability, though they generally differ only in minor aspects. One of the most comprehensive frameworks is the "Life Cycle Assessment (LCA) of Alternative Feedstocks for Plastics Production," created by the Joint Research Centre (JRC) and based on the EU Product Environmental Footprint (PEF) method. The "Product Carbon Footprint Guideline for the Chemical Industry," developed by Together for Sustainability, also offers valuable direction (European Commission, 2021, 2024b). Additionally, the Alliance to Zero has also published a PCF guideline to ensure uniform calculation across its member companies along the value chain.



4.2 CO footprint calculation cont.

Negative CO₂ emissions

A material will never achieve a negative carbon footprint over its entire life cycle, including its degradation or incineration. However, from a cradle-to-gate perspective—where end-of-life emissions are excluded—a material can theoretically have a negative carbon footprint. For example, when feedstock is derived from biomass, the carbon captured during the biomass or plant growth is stored within the material. If the emissions from sourcing the biomass and the polymerization process are lower than the amount of carbon stored in the biomass, the carbon footprint of the resulting plastic granulate can appear negative (**Figure 14**). However, during end-of-life treatment, the stored carbon is eventually released back into the atmosphere, resulting in a net positive carbon footprint. Therefore, when selecting materials or products, it is crucial to consider emissions across the entire life cycle—including outbound transportation, usage, and end-of-life—rather than focusing solely on cradle-to-gate emissions, which encompass only raw material extraction, inbound transport, and processing.

In a cradle-to-gate analysis for materials or products, the captured CO_2 (also called biogenic content) shall be included and expressed separately (see also ISO 14067) as this information may be relevant for the remaining value chain.

In a cradle-to-gate analysis the captured CO₂ shall be included and expressed separately.

Negative emissions from stored carbon



Figure 14: Negative emissions from stored carbon



5 Conclusion

100% Biodegradable



This paper aims to present a comprehensive overview of key insights, data, and trends concerning sustainable materials, with a particular focus on bioplastics and recycled plastics. As the pharmaceutical industry increasingly seeks to transition toward more environmentally responsible solutions, it is crucial to develop a deep understanding of the fundamental principles and data surrounding sustainable materials. However, beyond the foundational knowledge, there remain several alignment challenges that need to be addressed for the widespread adoption of sustainable material alternatives. These challenges span a wide array of areas, including technical, regulatory, environmental, and economic considerations, which must be tackled collaboratively by all stakeholders in the value chain.

A critical issue is achieving consensus on the chemical equivalence of technical plastics made from renewable sources when used to substitute fossil fuels often applied via mass balance approach, along with associated testing re-validation and biocompatibility. Without such consensus, companies may be reluctant to implement sustainable materials due to concerns over material quality, durability, and compatibility with current systems and products.

Equally important is the standardization of methodologies for evaluating the environmental impact of materials, particularly in terms of carbon footprints in general and with respect to negative emissions, double-counting, and capturing emissions across the entire life cycle, in particular. Establishing transparent and comparable assessments is essential to building trust in the sustainability claims of alternative materials.

From an economic standpoint, for sustainable materials to achieve broader market penetration and ensure their long-term viability and adoption, there must be industrywide agreement on the cost structures, pricing models, and availability of these materials.

> To address these multifaceted alignment challenges and facilitate meaningful progress, the Alliance to Zero will host a collaborative workshop that convenes key stakeholders from across the sustainable materials value chain. This event will provide a critical platform for industry leaders, researchers, policymakers, and manufacturers to exchange insights, explore innovative solutions, and work toward harmonized approaches for the future of sustainable materials.

> We would be honored to have you participate in these vital discussions, as your expertise and insights will play an invaluable role in shaping the future of sustainable material adoption within the pharmaceutical industry and beyond.

6 References

6.1 Glossary

This glossary lists the most important terms and their definitions. Unless otherwise stated, the GHG Protocol Standards and the SBTi were used as sources.









	LDPE (low-density polyethylene) is a low-density thermoplastic. It is		
LDPE	characterized by flexibility, impact strength and resistance to moisture and chemicals. LDPE is often used for plastic bags, films, bottles and cable sheathing.		
Plastics	Plastics are polymers originating from synthetic manufacturing.		
	 Examples of plastics include: Nylon synthesized from any source Polyolefins synthesized from any source 		
	Examples of plastics do not include Cellulose (found in woods) Silk (produced by silk worms).		
Polymers	Polymers are large molecules (macromolecules) made up of many repeating subunits (monomers). Polymers can be a natural occurring material like cellulose or proteins or synthetically produced material.		
	 Examples of polymers include: Nylon when synthesized from biomass Polyolefins Cellulose (found in woods) Silk (produced by silk worms) 		
Pyrolysis	Pyrolysis is a common technique used to convert for instance plastic waste into energy, in the form of solid, liquid and gaseous fuels. Pyrolysis is the thermal degradation of plastic waste at different temperatures (300–900°C), in the absence of oxygen.		
Pyrolysis oil	in the pyrolysis of more than 200 different compounds resulting from the depolymerization of products treated in pyrolysis		
Recycled plastics	Recycled plastics are plastics resulting from a chemical or mechanical recycling process of former waste.		
RED II	The Renewable Energy Directive (RED II) is a regulation for all European Union countries that promotes the use of energy from renewable sources		

 Solar-to-fuel
 Solar energy can be used to convert basic chemical feedstocks such as carbon dioxide (CO₂) and water into clean alternative fuels. (Source: Solar Fuels | Concentrating Solar Power | NREL)

 Solvent
 A solvent is a liquid that dissolves other substances without changing chemically. It is often used in chemical processes, in cleaning, in industry and in the manufacture of products. Well-known solvents are water, alcohol and acetone.

 Syngas
 Synthesis gas or syngas is a gas mixture that can be produced from biomass or natural gas through specific processes. It consists of hydrogen and carbon monoxide. (Source: Synthesis Gas - an overview | ScienceDirect Topics)

6.2 Footnotes

- 1 Notably, the terms polymers and plastics are often used interchangeably. However, they are not quite the same. Polymers are chemical compounds characterized by long, repeating molecular chains. Plastics are a specific type of polymer composed of these chains. Consequently, all bioplastics and recycled plastics are polymers, but not all biopolymers and recycled polymers are classified as plastics.
- 2 Good recyclability means that the material can theoretically be recycled with minimal change in properties in an energy-efficient way, but also that there is recycling infrastructure and collection for that material.

6.3 Bibliography

Alalwan, H. A., Alminshid, A. H., & Aljaafari, H. A. (2019). Promising evolution of biofuel generations. Subject review. Renewable Energy Focus, 28, 127-139.

Cormier, Z. (2024). Turning carbon emissions into plastic. Retrieved from <u>https://www.bbcearth.com/news/turning-carbon-emissions-into-plastic</u>

Covestro. (2024). Cardyon- Brighter use of CO2. Retrieved from <a href="https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://solutions.covestro.com/-/media/covestro/solution-center/brochures/polyurethane/covestro-cardyon-brighter-use-of-co2-fact-sheet.pdf%3Frev%3D595aca44bec0410abafdf017f5947297%26hash%3D25BF04D33316291B577B3231AD4FA701&ved=2ahUKEwi-y_DqhsqIAxX9cvEDHUjCDSsQFnoECBUQAQ&usg=A0vVaw0cfX6tn7F_Jli8uuJHxPXE

Čučuk, A. (2024). Mitsui, Celanese joint venture starts CO2-to-methanol production. Retrieved from <u>https://www.offshore-energy.biz/mitsui-celanese-joint-venture-starts-co2-to-methanol-production/</u>

Deutscher Bundestag. (2016). Ausarbeitung- Biologisch abbaubare Kunststoffe. WD 8-028-15. Retrieved from <u>https://www.bundestag.de/resource/blob/410104/34eca17202ee9d7380e1df34946335c8/wd-8-028-15-pdf-data.pdf</u>

Ellen MacArthur Foundation. (2024). Compostable, biodegradable, and bio-based plastic – what's the difference? Retrieved from <u>https://www.ellenmacarthurfoundation.org/compostable-biodegradable-and-bio-based-plastic-whats-the-</u>

difference#:~:text=Biodegradable%3A%20able%20to%20be%20broken,time%2Dframe%20under%2 Ospecific%20conditions



6.3 Bibliography cont.

European Bio-plastics. (2024a). Bio-plastics market development update 2023 Retrieved from https://www.european-bio-plastics.org/market/#

European Bio-plastics. (2024b). European Bio-plastics represents the interests of the bio-plastics industry and is committed to building and strengthening a supportive policy environment in the EU for bio-based, biodegradable and compostable plastics to thrive. Retrieved from https://www.european-bioplastics.org

European Commission. (2021). Life Cycle Assessment (LCA) of alternative feedstocks for plastics production. Retrieved from https://publications.irc.ec.europa.eu/repository/handle/JRC125046

European Commission, (2022), EU policy framework on bio-based, biodegradable and compostable plastics. Retrieved from https://environment.ec.europa.eu/document/download/14b709eb-178c-40ea-9787-6a40f5f25948 en?filename=COM 2022 682 1 EN ACT part1 v4.pdf

European Commission. (2024a). Bio-based, biodegradable and compostable plastics. Retrieved from https://environment.ec.europa.eu/topics/plastics/bio-based-biodegradable-and-compostableplastics en#:~:text=Biodegradable%20plastics%20biodegrade%20in%20certain,first%20need%20to %20be%20collected.

European Commission. (2024b). Environmental Footprint Methods- Calculating the environmental impact of products and services. Retrieved from <u>https://green-business.ec.europa.eu/environmental-</u> footprint-methods en

European Union. (2018). DIRECTIVE (EU) 2018/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. Official Journal of the European Union. Retrieved from <u>https://eur-lex.europa.eu/legal-</u> content/EN/TXT/PDF/?uri=CELEX:32018L2001

Green Dot Bio-plastics. (2024). Benefits of Bio-plastics. Retrieved from https://www.greendotbioplastics.com/biodegradable-vs-compostable-vs-oxo-degradable-plastics-a-straightforwardexplanation/

ISCC. (2023). ISCC EU 203 Traceability and Chain of Custody. Retrieved from https://www.isccsystem.org/wp-content/uploads/2024/01/ISCC EU 203 Traceability and Chain-of-Custody v4.1 January2024-1.pdf

ISCC. (2024). Mass Balance Explained. Retrieved from https://www.iscc-system.org/news/massbalance-explained/

McKinsey & Company. (2023). Sustainable feedstocks: Accelerating recarbonization in chemicals. Retrieved from https://www.mckinsey.com/industries/chemicals/our-insights/sustainable-feedstocksaccelerating-recarbonization-in-chemicals

Mülhaupt, R. (2013). Green polymer chemistry and bio-based plastics: dreams and reality. Macromolecular Chemistry and Physics, 214(2), 159-174.

Open LCA. (2024). Mass Balance Approach in the chemical industry. Retrieved from https://oneclicklca.com/en/resources/articles/mass-balance-approach-chemical-industry/

Roland Berger. (2024). More plastic means more waste- but also attractive business prospects in recycling. Retrieved from https://www.rolandberger.com/en/Insights/Publications/How-EPCs-andequipment-suppliers-can-capitalize-on-chemical-recycling.html

Sabic. (2024). CREATING THE WORLD'S LARGEST CARBON CAPTURE AND UTILIZATION PLANT. Retrieved from https://www.sabic.com/en/newsandmedia/stories/our-world/creating-the-worldslargest-carbon-capture-and-utilization-plant

Waste Management World. (2023). Mechanical Recycling vs. Chemical Recycling: Rivals or Partners? Retrieved from <u>https://waste-management-world.com/resource-use/mechanical-chemical-recycling-</u> rivals-or-partners/

Zero Waste Europe. (2020). Understanding the Environmental Impacts of Chemical Recycling. Retrieved from https://zerowasteeurope.eu/wp-

content/uploads/2020/12/zwe_jointpaper_UnderstandingEnvironmentalImpactsofCR_en.pdf



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