

# Cefic proposal to integrate the Bioeconomy & Biotech Act II.

The bioeconomy holds significant importance for the EU's chemical industry as it presents an opportunity to improve competitiveness, achieve circularity, long-term resilience, and net-zero objectives, increase resource security, and support environmental, social, and economic sustainability. While the EU is currently a leader in implementing biomass-derived solutions, it is imperative to establish the right framework conditions to maintain this position.

Scaling-up and increasing the use of biomass-derived chemicals is vital for Europe's bioeconomy growth and for keeping the industrial capacities and high-value jobs in the EU. To compete globally, the advancement of the bioeconomy and biomanufacturing should be put front and centre in the EU's industrial transition. To reinforce the EU's competitive edge in this sector, we call for:

## 1) Present a coherent and cross-sectoral regulatory instrument on bioeconomy

Following years of bioeconomy strategies and action plans, we consider that a communication is not enough to fully deploy the bioeconomy. To achieve a single market for bioeconomy, we ask that the upcoming initiative of Biotech Act II. **goes beyond biotech and biomanufacturing and addresses the whole bioeconomy**. Extending the scope to a wider range of sectors and all technologies contributing to biomass conversions would fully enable innovation and investment opportunities in a field where the EU can still be a leader in the world market.

## 2) Put forward market pull measures and incentives

To create demand for biomass-derived products, it is key to provide incentives for placing products on the market by incorporating dedicated, realistic targets for biomass-derived products into sector-specific legislation (PPWR, ELVR) and **favour biomass-derived products in public procurement policies** (Green Public Procurement). One of the most crucial enablers of market pull would be the **introduction of biomass-derived targets at the product level**. Similarly to how the introduction of binding targets in RED III encouraged higher use of bioenergy, we ask for binding targets that would support higher use of biomass in products.

## 3) Secure the availability and sustainability of feedstock

To ensure that the chemical industry can continue to provide biomass-derived solutions, we need diversified, sustainable, and affordable feedstock, and duty-free quotas for essential raw materials like sugar and bioethanol. We ask to **develop sustainability criteria for biomass sourcing** to ensure it is sourced sustainably within the planetary boundaries, and to ensure its continuous availability. This could be done by applying the provisions of RED III Art 29 (2-7) and extending them to all products, not just energy. Finally, our industry needs access to biomass, which could be boosted by **implementing the cascading use principle**, aiding in achieving the highest efficiency of biomass use and the lowest possible environmental impact through the design of incentives.

This document further details policy suggestions that would help grow and advance the bioeconomy and biomanufacturing sectors within the EU. It offers practical and implementable strategies and concrete provisions that would foster industrial bioeconomy and biomanufacturing.

## Cefic proposals for the bioeconomy, biomanufacturing & biotechnology

The chemical industry produces biomass-derived chemicals<sup>1</sup>, which cover a wide range of molecules from platform chemicals and intermediates to fine and specialty chemicals, plastics, and polymers. These are produced through various technologies like chemical synthesis, thermochemical or biological conversion, and extraction. They have diverse applications, from home and personal care products, agrochemicals, pharmaceuticals, and textiles to packaging. To fully deploy the EU bioeconomy and biomanufacturing, the policy instruments should address the following:

### I. Regulatory coherence, standardized terminology, and the expansion of the Biotech Act II

The Biotech Act II should explicitly recognise the strategic importance of securing Europe's capacity in the bioeconomy, biomanufacturing, and biotechnologies, and **create the right conditions to keep industrial capacities on European soil**. Cefic shares the overall objective of the Act to improve the size and competitiveness of the biotechnology and biomanufacturing sector in the EU while maintaining high safety standards, but we highlight that biotechnology serves as a multi-sectoral tool and that regulatory differences and investment profiles are unique to each sector. Furthermore, other technologies are used to convert biomass to products and should also be recognized.

The proposal should therefore recognise all technologies contributing to the advancement of the whole bioeconomy. We call for a **clear harmonisation in the wider framework** regulating bioeconomy, circular economy, and life sciences to ensure coherence and coordination.

The goal of the Act should be to create a framework able to **accommodate continuously evolving frontiers of knowledge and understanding**, without being too prescriptive. Any new or updated regulatory requirements should be proportional to the actual risks involved, based on scientific and technical evidence, and take into account economic factors, thereby maintaining a balance between fostering innovation, increasing competitiveness, and ensuring safety.

- Avoid overregulation and tackle fragmented policies, **cross-check existing regulations**, and thoroughly analyse potential overlaps or conflicting requirements within a clearly set timeline.
- Future regulatory systems should have a unified point of entry and either a single pathway that considers all potential applications or more pathways that anticipate the much broader range of products that emerge from engineering biology. Further, to decrease the risk of products being passed between multiple regulatory committees, there should be one or more regulatory bodies that could review a full spectrum of options, with input from relevant specialist agencies.
- **Streamline, accelerate, and harmonize the EU's marketing authorization procedures** so that innovations can be efficiently and swiftly placed on the market. Refrain from revising whole permits or market authorizations when introducing a new product, and instead use simplified measures or solely notification systems (for example, simplified approval for biomanufacturing activities which already hold a permit in one Member State).
- Apply product-based instead of process-based risk assessments.
- Assist public authorities in **expediting the permit-granting process** (i.e., financial resources or skill development initiatives), similar to the announced technical support instrument in the Startup and scale-up strategy.
- **Enhance the recently created biotech and biomanufacturing hub** beyond a gateway, extend the portfolio of products covered beyond human health, veterinary medicinal products, food and feed, and finally consider integrating it with the Knowledge Centre for Bioeconomy.

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<sup>1</sup> Biomass-derived chemicals are wholly or partly derived from biomass, including bio-based and bio-attributed chemicals.

- **Enhance the dialogue between industry and authorities** by designating an expert committee or an EU authority to issue nonbinding recommendations to applicants to decide which organisms should be within the scope of the regulation, following the US example of [“Am I regulated?” approach](#).

### Definitions and terminology

Cefic provides definitions to clarify each relevant term, helping create a shared understanding of their meanings.

- **Engineering Biology** is the design, construction, and/or assembly of the components of living systems to achieve an intended function or outcome. It includes approaches such as genetic and metabolic engineering.
- **Synthetic Biology** is the systematic deployment of engineering principles to design (or profoundly redesign) and engineer biological systems, endowing these with novel biological functions that are inaccessible when using conventional genetic engineering methods, or even creating new-to-nature functions.

Furthermore, the EU should adopt a “bio-based materials and products” definition which reflects the existence of different business & manufacturing models, and their related output, namely including bio-based and bio-attributed materials & products, which can be wholly or partly derived from biomass. In particular:

- **Biomass-derived products** are products wholly or partly derived from biomass, encompassing bio-based and bio-attributed products.
- **Bio-based products** are those for which the share of bio-based content can be measured via established radiocarbon methods (<sup>14</sup>C tracing). These may be fully or partially bio-based.
- **Bio-attributed products** are those for which the use of bio-based feedstocks, substituting part of the raw material needed in the manufacturing process, has been attributed to the product via the mass balance method and is certified according to a third-party certification scheme.

## **II. Rapid market deployment and de-risking industrialization**

The development of new value chains, either valorising different feedstocks or introducing new and/or improved chemicals, and the introduction of demand creation measures are essential components of an industry-focused strategy. This addresses the needs of EU biomass-derived businesses as they scale up or convert their business model to a biomass-derived one, aiming to become world-leading firms. This issue is pressing; significant investments are needed; however, there appears to be a reluctance in the market to absorb the green premium independently.

We therefore recommend:

- Favor the bioeconomy industrialization by considering the incorporation into product-specific legislation (such as PPWR, ELVR, etc.), and sector-specific legislation addressing the biomass-derived value chains, of measures such as:
  - Dedicated targets for biomass-derived products, not competing with other circular carbon sources (recycled and carbon capture). Such targets should aim to increase the use of biomass as feedstock in products (e.g., in plastic packaging as foreseen in the Packaging & Packaging Waste Regulation - PPWR) and should consider the contribution of both bio-based<sup>2</sup> and bio-

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<sup>2</sup> Bio-based products are those for which the share of bio-based content can be measured via established radiocarbon methods (<sup>14</sup>C tracing). These may be fully or partially bio-based.

attributed<sup>3</sup> products, thus allowing all technologies to contribute to the transition towards circular carbon sources. Targets should be set at a realistic level based on a comprehensive impact assessment, considering (sustainable) biomass availability, technical and economic feasibility of biomass conversion to chemicals and products, market development, existing national legislations, and broader socio-economic factors.

- Incentivise the use of biodegradable and compostable plastics, where it proves to be valuable (e.g., where the latter are highly food-soiled), beneficial from an LCA perspective, and consistent with circular economy principles and aspirations derived from other legislative initiatives (infrastructure requirements, additional sorting, contamination issues for recyclers)<sup>4</sup>.
- Support selected uses of biodegradable and compostable products for specific applications.
- Minimum Green Public Procurement (GPP) requirements for biomass-derived products in public procurement, as highlighted in [Cefic's dedicated position paper](#).
- Other market pull measures<sup>5</sup>, such as reduced VAT rates, for biomass-derived products.
- Enabling all business models, including bio-based and bio-attributed, to support the increase of circular carbon<sup>6</sup> sources used by the chemical industry. This includes making incentives available to both bio-based and bio-attributed products and businesses. Additionally, establish a unified term "biomass-derived" to cover both categories across policies.
- Finalising the revision of the PEF/PCF calculation methods and claims to accurately account for biogenic carbon (-1/+1 approach).
- Establishing high-performing bioeconomy clusters throughout the European Union to enable companies across the value chain to collaborate, thereby enhancing opportunities for entering both international and domestic markets and reducing costs.

#### Targeted policy modification to modernize the approach to GMOs

Following the scientific evidence, also highlighted by EFSA, that potential risks associated with a new variety of organisms (plants, microorganisms, ...) are related to the phenotypic traits and not the technique used for the development, Cefic emphasizes the need to focus biotech regulation on the product and not on the process. We call for targeted amendments to the existing policy framework as follows:

- Deliberate Release Directive: clarify requirements and specifications of what a long safety record entails, enabling differentiated (simplified) regulatory procedures for risk assessment and management whenever sufficient experience with a particular GMO has been gained. We propose a product-oriented interpretation: it is not the mutagenesis technique itself that has a long safety record, but rather the products introduced to the market or released into the environment after additional breeding and variety registration. According to this interpretation, additional techniques and methods of genetic modification, such as CRISPR-Cas, should be considered as yielding organisms to be excluded from the directive.

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<sup>3</sup> Bio-attributed products are those for which the use of bio-based feedstocks, substituting part of the raw material needed in the manufacturing process, has been attributed to the product via the mass balance method and is certified according to a third-party certification scheme.

<sup>4</sup> The use of biodegradable and compostable plastics should be targeted to applications where other plastics would get so contaminated with compostable matter that they can no longer be recycled, and incineration would be the fate of the plastic and its compostable contamination otherwise.

<sup>5</sup> An extensive list of market pull measures can be found in the related Cefic's position paper - [Cefic priorities on market pull measures for low-carbon and circular products - cefic](#).

<sup>6</sup> Circular carbon is defined as all carbon sources that are not derived from a virgin fossil feedstock and, which are currently present in the biosphere, atmosphere and anthroposphere. This includes biomass, waste and recycled materials, CO<sub>2</sub> captured from industrial processes or from the atmosphere, even if they originally come from a fossil source.

- Regulation 503/213 and Directive 2018/350: transform the Annexes listing requirements for the execution of risk assessments into implementing acts, to allow quicker adaptation to technological and scientific development.
- Appropriate procedures and guidelines should be available for submitting applications for products containing viable Genetically Modified Microorganisms (GMMs).
- Environmental risk assessment should account for cases of products that require persistence in the environment to yield effects (i.e., bio-fertilizers, bio-remediation).
- “Opt-Out” Directive: should be reformed to an “opt-in” procedure. In such a scenario, whenever a qualified majority is not reached in the standing committee, Member States could still allow for the use of GMOs on their territory.

#### Regulatory Sandboxes and increasing support and funding towards industrialisation

Regulatory sandboxes should be utilized to harmonize regulations for developers of new bioeconomy and biotechnology solutions, especially when involving different and potentially conflicting national regulatory frameworks. They should be leveraged when the legal situation is unclear or meaningful legislation has yet to be created, as they can provide a stopgap solution to determine and impose the relevant rules in real time. The introduction of a dedicated and tailored regulatory sandbox for biomass-derived products would help tackle regulatory uncertainty and fragmentation.

Bioeconomy and biomanufacturing-related innovations frequently do not reach industrial scale, which is necessary for making the related products competitive. To tackle this aspect, the EU should:

- Establish a funding instrument tailored to the commercialisation & replication of scaled-up facilities, bridging the gap between innovation and market deployment.
- Continue and increase CBE-JU funding by using the newly dedicated Competitiveness Fund chapter on Health, Biotech, Agriculture & Bioeconomy, the European Scale-up Fund, and updating the scope of the joint undertaking by dedicating it to high-TRL projects ( $\geq$  TRL 6). A detailed proposal is available in [Cefic’s dedicated position paper](#).
- Consider the potential contribution of the European Defence Fund, given the relevance of biomanufacturing for defence applications.
- De-risk the scaling up of new bioeconomy and biomanufacturing innovations by further strengthening and investing in (existing) open-access infrastructures.
- Mobilise EU financial instruments such as the Innovation Fund, European Investment Bank, to support industrial projects, reduce investment risks, and reinforce Europe’s strategic autonomy in biomanufacturing and bioeconomy.
- Ensure a more coordinated and harmonised approach to research and innovation funding at different levels (i.e. regional, national).
- Ensure better and strategic mobility of funding across Europe, especially on a cross-regional basis, by extending the remit of existing regional funding mechanisms.

### **III. Logistics and sustainable feedstock sourcing to support scale-up**

In Europe, in 2023, only 5.5% of the carbon demand for the chemical and derived industries was covered by biomass, while globally, that accounts for about 10%<sup>7 8</sup>. Looking at specific sectors, e.g., plastics, only 1%

<sup>7</sup> (Carus et al. 2025); Carus, M., Porc, O., vom Berg, C., Kempen, M., Schier, F. and Tandetzki, J.: Is there enough biomass to defossilise the chemicals and derived materials sector by 2050. nova-Institut GmbH (Ed.), Hürth, Germany, 2025-02

<sup>8</sup> The lower figure in the EU is a consequence of the easy access to cheap fossil feedstocks from which Europe benefited until recently, and can also be a consequence of tariffs and import barriers on readily available bio-based feedstocks—such as sugar, starches, bioethanol, and organic oils.

derives from biobased feedstock, accounting for just 0.029% of the global biomass demand in 2021<sup>9</sup>. Various studies<sup>10</sup> have indicated that the share of carbon derived from biomass to support the chemical industry is likely to increase in the pursuit of net-zero by 2050. Though the extent of this increase is debated due to the long-term nature of the forecast, sufficient and affordable sustainable biomass must be available and accessible to the chemical industry at competitive prices to enable the scale-up of biomass-derived chemical production. Bioeconomy and biomanufacturing depend significantly on the consistent supply of high-quality raw materials like sugars, whose availability may be limited on the EU market and whose prices can be highly volatile. First-generation feedstocks are often costly due to factors such as trade barriers, while subsequent generations tend to remain more expensive than their fossil-based counterparts due to technological aspects.

Cefic suggests:

- Exploiting synergies related to the utilization of biomass across different sectors
  - Processing in integrated facilities, such as biorefineries, significantly enhances the efficiency of biomass use and maximises its valorisation.
  - Fostering the use of Agritech innovative technologies, including the use of New Genomic Techniques (NGTs), should be fostered and supported, as they are a key instrument that can deliver on the EU bioeconomy objectives by providing higher yields and higher sustainability for crop cultivation.
  - Biomass-derived value chains often stem from agricultural and forestry resources; hence, the implementation of innovative management practices in these sectors is essential for effective climate mitigation and the regeneration of agroecosystems' health. The Common Agricultural Policy (CAP) plays a critical role in achieving this goal and should be integrally connected to the bioeconomy strategy.
- Recognition of the role of primary biomass sources, such as starch, sugars, and natural oils, which are essential feedstocks today and will continue to be significant in the future, even with the advancement of lignocellulosic and waste-based value chains. Therefore, they should be regarded as part of the solution portfolio to enhance the biomass supply for industrial use.
- Establishing a clear set of sustainability criteria for biomass sourcing that apply to all biomass regardless of its final use is essential. It is the first step to reach a level playing field for all sectors using biomass, whether for energy or material uses. Cefic supports using sustainability criteria to define the boundaries for sustainable biomass sourcing, in coherence with Article 29 (2-7) of Directive (EU) 2018/2001 (RED III)<sup>11</sup>.
- Ensuring that biomass is used according to its highest efficiency, following a synergic approach in line with the cascading principle as delineated in the [Cefic paper on biomass-derived plastics](#).
- Trade policy and raw material policies should support access to EU-compliant (sustainable sourcing, production, ...) bio-based raw materials, including sugar, bioethanol, and palm (kernel) oil, and address barriers to their import by introducing dedicated quotas for the chemical industry at reduced or without import duties, e.g., via Free Trade Agreements (FTAs).

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<sup>9</sup> Pia Skoczinski, Michael Carus, Gillian Tweddle, Pauline Ruiz, Nicolas Hark, Ann Zhang, Doris de Guzman, Jan Ravenstijn, Harald Käb and Achim Raschka (March 2024) - *Biomass utilization worldwide*. [Biomass Utilisation Worldwide \(PNG\) | Renewable Carbon Publications \(renewable-carbon.eu\)](#) – Last viewed April 2025

<sup>10</sup> Among others: «The Carbon Managers » report by Cefic, Page 97-98 - Ibid 9

<sup>11</sup> Directive (EU) 2018/2001 “on the promotion of the use of energy from renewable sources”

- An analysis of the existing supply chain pathways should be conducted, and suggestions for enhancing efficiency should be provided. EU-funded initiatives that address the issue of fragmented and disorganized local biomass markets are available and could be utilized (see <sup>12,13</sup>).
- A study about the necessity of additional transportation infrastructure in function of biomass availability and the location of industry should be executed. Extensive mapping of resources, (potential) production facilities, transportation routes, etc., is already available at the EU level. See, among others, the JRC biomass report<sup>14</sup>, the mapping of biorefineries<sup>15</sup>, and the mapping of rail/road infrastructure (part of TEN/t<sup>16</sup>). The mapping of biomass should be integrated with other existing maps to gather additional valuable information and inform policy.

## The enablers: skills, data, and Artificial Intelligence

### Skills and consumer engagement

Developing EU-wide bioeconomy and biotech competencies and education pathways from secondary education through university, as well as supporting programs offering on-the-job training and experiential learning opportunities, are crucial for public support for these technologies. Cefic proposes that the Commission ensure the following actions under the European Research Act (2026):

- In collaboration with Member States, **promote inclusion** of bioeconomy, biotech, and biomanufacturing principles already at the high school level.
- Establish a European **minimum framework of competencies** in bioeconomy, biotechnology, and biomanufacturing to serve as a basis for the creation of EU-harmonized university-level courses.
- Overcome sectoral competition for talent and brain drain: The EU is experiencing a loss of top scientific talent to countries like the US, Canada, and China, driven by better funding, salaries, and research opportunities. Nature reports that 90% of German academics are on temporary contracts, and countries like Spain and Italy face hiring freezes, pushing young researchers abroad.
- Offer **specialized European master's degrees** focused on bioeconomy, biotech, and biomanufacturing by leveraging the European university alliances, and include bioeconomy, biotech, and biomanufacturing as a key technological domain for innovative joint European study programs.
- To improve consumer engagement, develop a detailed action plan to **effectively communicate the nature of bioeconomy, biotechnology, biomanufacturing, and their products**, highlight their benefits, and demonstrate how they can address EU climate challenges while building public confidence and acceptance of these technologies and products.

### Use of data and artificial intelligence

To speed up innovation, Cefic asks for the establishment of a “data initiative”, which would allow biotechnology and biomanufacturing developers **access to high-quality, secure, and wide-ranging datasets** that can drive biomanufacturing development, together with AI-enhanced design facilitating in-silico metabolic engineering strategies. Such an initiative should build on existing platforms and systems and could speed up dramatically the design and selection of promising pathways leading to the development of new strains and the related process development (e.g., by AI-based literature mining and enzyme library design).

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<sup>12</sup> [AGROinLOG - Demonstration of innovative integrated biomass logistics centres for the Agro-industry sector in Europe | EU CAP Network](#) – Last viewed April 2025

<sup>13</sup> [Sustainable Regional Supply Chains for Woody Bioenergy | BioRES | Projekt | Fact Sheet | H2020 | CORDIS | European Commission](#) – Last viewed April 2025

<sup>14</sup> Avitabile et. Al (2023) – Biomass production, supply, uses and flows in the EU – European Commission - Joint Research Centre

<sup>15</sup> Parisi, C. (2018). Research Brief: Biorefineries distribution in the EU. European Commission - Joint Research Centre

<sup>16</sup> [TENtec Map Viewers - Explore the TEN-T Network | European Transport Infrastructure](#) – Last viewed April 2025

In addition, we call for creating a **secure collaborative EU data space that pools datasets and resources together** (following the example of the Health Data Research UK sandbox). Hosted by one entity and allowing access to others, it would serve new combinations and uses of data, allow regulators or government agencies to test capabilities on actual datasets, and enable coalitions of actors to pool resources together through technologically enabled decentralised approaches (e.g., data collaboratives, fiduciaries, commons).

This initiative should be further compiled or integrated on a platform like the European Genomic Data Infrastructure, which could benefit from the announced Commission investment of EUR 25 million from the Digital Europe work program 2026 to boost the European genomic data infrastructure.

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**About Cefic**

Cefic, the European Chemical Industry Council, is the forum of large, medium and small chemical companies across Europe, accounting for 1.2 million jobs and 13% of world chemicals production.

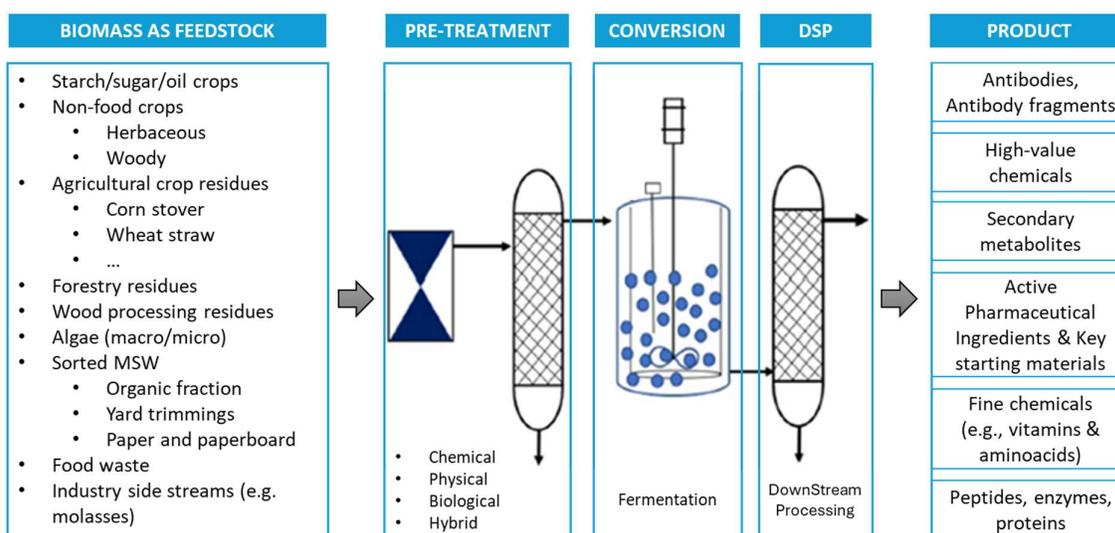
## Annex 1 – Why a Biotech Act II extended to the whole bioeconomy?

To illustrate the use of biotechnology across sectors and the integration of biotechnology and biomanufacturing within the broader bioeconomy, fermentation-based processes are a good example. Here, biotechnologically optimized microorganisms, designed to efficiently produce specific products, facilitate the generation of vital bio-based chemicals, enzymes, vitamins, amino acids, and Active Pharmaceutical Ingredients (APIs). These products have diverse applications such as home and personal care products, agrochemicals, pharmaceuticals, textiles, food & feed, and packaging.

Such a process can be summarized in a series of interconnected blocks, as shown in **Figure 1**.

While the fermentation in itself can be considered the biotechnological core of the process, it cannot be carried out without a feedstock to feed the microorganisms. The latter needs to be fed with a feedstock they find “palatable” to properly work. To this end, the biomass, coming from a variety of different sources, needs to be pre-treated and broken down to make its components accessible for microbial fermentation or other (bio)chemical processes, thus also showing the link with the broader bioeconomy.

The pre-treatment process is an example in which biotechnology can be again the protagonist, but can also be carried out using more conventional technologies like solvent extraction.



**Figure 1** - Schematic representation of a typical bioprocess. Different types of feedstocks that can be used and different types of products resulting from such a process are reported to highlight the diversity of sectors covered by bioeconomy, biotechnology, and biomanufacturing.