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Summary

The analytical report contains SWOT and PESTEL to understand how solutions meet market demands, to identify vulnerabilities, and needs for critical infrastructure that hampers production scaling-up.

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LIST OF ABBREVIATIONS

CBE	Circular Bioeconomy
CBE JU	Circular Bio-based Europe Joint Undertaking
IECS	Innovation Express Call scheme
PLA	Polylactic Acid
SAT	Sustainability Assessment Tool
S3	Smart Specialization Strategy
TRL	Technology Readiness Level
VCG.AI	Value Chain Generator AI



EXECUTIVE SUMMARY

The potential to unlock the circular bioeconomy is mainly due to the possibility of building **value chains** that connect all players, such as primary producers, suppliers of biomass and renewable by-product conversion technologies, brand owners, regulatory and certification agencies and bodies public up-to-end users. However, the **long-term profitability** and **sustainability** of bio-based products depend on several factors that may slow down the increase in bio-based products available on the market and the transition towards green production models, such as continuous and scalable access to biomass, the cost of production and the willingness of consumers to recognise a green premium for products with circularity and sustainability qualities compared to their fossil counterparts.

In this context, the **InnoBioVC project** aims to validate solutions for a circular bioeconomy business model based on interregional cooperation capable of increasing bioproducts' social, economic and environmental impact, overcoming market obstacles. The initiative conducted in the **Alpine area** mobilises the regions that, over the last decades, have implemented policy instruments and financing programs which, to varying degrees, have supported the development of demonstration projects with high innovation potential consistent with the **EU Green Deal**.

Having high innovation capacity and bio-based renewable biomass, Alpine regions strongly support adopting green production models, and a better and more synchronised financing policy based on cross-regional cooperation has great potential to accelerate the development of the circular bioeconomy.

In this context, as a preliminary output of the InnoBioVC project, the **deliverable** aims to understand how bio-based solutions meet **market demands**, identify **vulnerabilities** and frame critical **infrastructure** needs that hinder industrial-scale and sustainable production.

To this end, an integrated strategic PESTEL and SWOT analysis were conducted, dedicated to the in-depth analysis of the internal and external dynamics and strengths of the most significant bioproducts on the market.

PESTEL analysis, which stands for political, economic, social, technological, environmental, and legal analysis, was performed on the market's three most widespread categories of products of biological origin: **plastic polymers**, **platform chemicals** and **amino acids** as identified by J. Cristobal et al.[1].

Going into the specifics of industrial applications, the **SWOT analysis**, a tool for evaluating endogenous and exogenous aspects of a business model, investigates strengths, weaknesses, opportunities and threats for each product of biological origin such as **lactic acid**, **acetic acid**, **adipic, 1, 2 propanediol**, **succinic acid**, **polylactic acid (PLA)**, **glycerol**, **glutamic acid**.

These two analyses are fundamental to help supply chain players jointly develop new circular products considering the main external drivers of change, encouraging them to consider long-term objectives, choose sustainable business innovation and winning investment strategies.

The challenges for implementing bio-based value chains include **selecting raw materials** with the highest added value that do not compete with food production, with the lowest carbon footprint impact throughout the life cycle and sustainable disposal options in which consumers are interested.

Food competition means that raw materials for synthesising bio-based products are commonly used as foods, such as corn, sugar beet and sugar cane. An alternative to this could be replacing food raw materials with residual biomass or lignocellulosic biomass such as forest biomass.

Intending to guide regional authorities in planning actions and financial instruments that can unlock the potential of the circular bioeconomy, the study's results confirm the role of bio-based products in achieving the Nations' 2050 Sustainable Development Goals United.

1. INTRODUCTION

The transition from a fossil-based to a circular bio-based economy is increasingly recognised as a driver for regional competitiveness, playing a crucial role in achieving the objectives outlined in the **European Green Deal** and the **UN Sustainable Development Goals**.

Bio-products and **bio-based value chains** are promising paths to realise a resource-efficient circular economy resilient to climate change and respectful of civil society's demand for greater sustainability and transparency of consumer goods. Bio-based value chains, embracing a "valorisation and value-addition" approach, involve a sophisticated network of processes and stakeholders contributing to industrial competitiveness with environmental and socio-economic benefits at the local and European levels [2].

According to the **EU Circular Economy Strategy**, the circular bioeconomy as systemic thinking aims to "close the loop by becoming resource efficient through development and establishment of industrial symbiosis, to reduce the pressure on EU's natural capital" [3].

The "EU Bioeconomy Strategy Progress Report" published in 2020 by the European Commission states the critical role of the bioeconomy sectors in generating economic wealth across Europe. The manufacturing of bio-based products provides **7.92 million jobs** with a **value-added of EUR 433 billion** in Europe (8.3 % of the European labour force and 4.7 % of its GDP in 2019). Europe's global market share for bio-based chemicals and materials of about 31% is twice as high as that of the fossil-based sectors [4].

Bio-based products, defined as "wholly or partly derived from materials of biological origin, excluding materials embedded in geological formations and/or fossilised" [5] can be exploited into value chains providing products and/or services by adding value to bulk material (feedstock) through a set of interlinked industrial actors' activities. In the bio-based value chain, feedstocks can be either biomass drawn from an existing primary production route (e.g., agriculture, forestry and livestock) or of a novel route (e.g., microalgae) or secondary origin (e.g., sludge, industrial wastewater, household and organic waste).

The linear production system becomes circular when material and energy disposed of in the primary process becomes further used in a cascade, minimising or eliminating wastes and avoiding food production competition.

Business models built according to the **circular bioeconomy paradigm** must face numerous technological, environmental, and economic **challenges** to preserve the competitive advantage compared to fossil counterparts in the long term. In systems based on the conversion of biological material, feasibility and economic sustainability must simultaneously consider numerous factors, such as continuous and scalable access to biomass, quality and supply costs, and conversion efficiency. The latest bioeconomy report by the JRC center (**Fig.1**) states that biomass's most prominent application in the bioeconomy sector is food and feed, needing more opportunities to valorise it with value-added product manufacture. Biomass for energy (bioenergy) continues to be the leading renewable energy source in the EU, with a share of almost 60%. The heating and cooling sector is the largest end-user, using about 75% of all bioenergy; around 40%



of the land area in the EU is woodlands (forest land and permanent crops). A similar share of the land area is agricultural land, of which 60% is cropland and 40% grasslands [6].

Bio-based products have the potential to contribute to EU objectives of sustainable growth and addressing societal challenges, reducing reliance on fossil fuels. Demand-side developments of bio-based products are also positive; investors and consumers increasingly focus on products' environmental and health aspects, but typically not at the expense of performance.

Studies showed investors consider bio-based barriers and risk as the factors related to feedstock, customer preferences, regulatory concerns and competition aspects vis-à-vis traditional products [4].

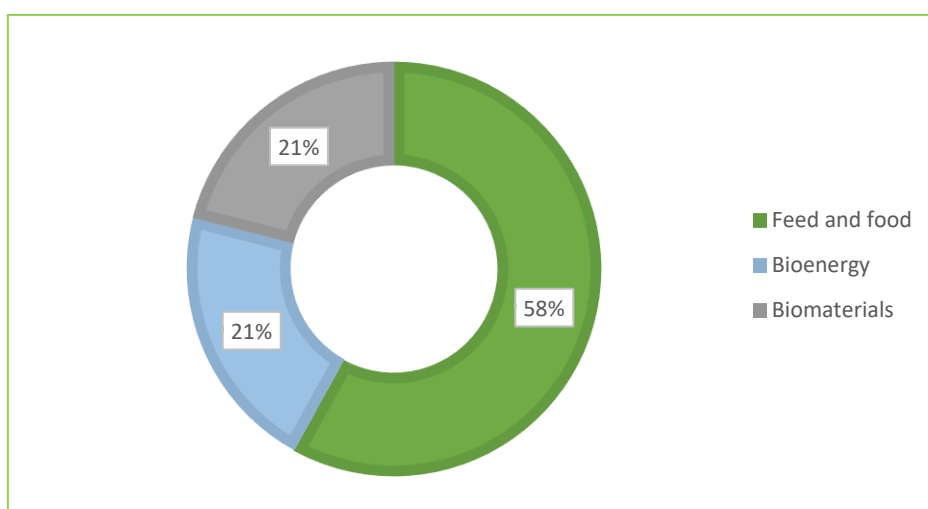


Figure 1 Europe total biomass use, from "How big is the bioeconomy" JRC report, 2020.

Land use, impact on biodiversity and ecosystems, water consumption, greenhouse gas emissions and food competition are just some of the evaluation criteria to consider in the economic decision-making process and the industrial feasibility study [7]. A sustainable bio-based value chain must integrate industrial sectors in a symbiotic logic, where the added value and benefit can be distributed from primary raw material producers to technology providers and brand owners [8].

Considering these characteristics, bio-based value chains are in contrast to the “fossil-based continuous production process”, and a substantial mindset shift in conventional business logic and approaches is required. However, developing a circular added value chain is still challenging (**biomass circularity** is only **11%** across the EU [9]), undermined by potentially risky investments and existing regional support schemes that stop at national borders.

1.1 Circular Bioeconomy in the Alpine area: the INNOBIOVC project

The **Alpine Space** has abundant biomass resources, knowledge, facilities, supply chains and technology to develop sustainable bio-based solutions. With an estimated extension of 27,974,797 hectares of forests (data from InnobioVC project), **lignocellulosic raw materials** represent the most significant resource for developing new bio-based value chains.



According to the report “Gross value added of the environmental goods and services sector”, published by the European Environmental Agency in 2023, the added value of the environmental or green economy to the overall EU economy increased from 2.1% in 2010 to 2.5% in 2020, when it reached just over 300 billion euros (2010 prices). Substantial investments in producing renewable energy, energy efficiency and waste management have been the factors driving growth and are also crucial for the actions underway to achieve the climate neutrality objectives of the EU Green Deal [10]. In the Alpine area, Italy and Germany drive the most significant growth (from 1.86 and 1.82 to 2.46 and 2.39 respectively), followed by France (from 1.79 to 2), while Austria and Slovenia show stable data (4.3 and 1.77 on average) [11].

Being one of the most innovative technological hubs in Europe, the Alpine Area has a high potential innovation capacity driven by a rich ecosystem of research centres, universities and companies firmly committed to valorising biological resources in products with high added value capable of counteracting the challenges of climate change. In this context, regional policy instruments and financial investments are essential in facilitating the green transition, accelerating the development of biological value chains and placing bio-based products on the market. Over the last decades, Alpine regions have strengthened this commitment by including objectives and action plans in their regional strategies, such as the **Smart Specialization Strategy (S3)**, and by funding research and innovation in sectors consistent with the EU Green Deal. International partnerships and cross-regional cooperation programs have helped develop demonstration projects and jobs that have significantly contributed to developing sustainable solutions in the circular bioeconomy sector. However, although it has high potential, better and more effective synchronisation of circular business models would allow substantial growth in competitiveness in all regions of the Alpine area.

The INNOBIOVC project [6], funded by the **Interreg Alpine Space Program**, aims to combine two tools previously developed by the AlpLnkBioEco and ARDIA-NET projects: the Value chain generator (VCG.AI) and the **Innovation Express Call scheme (IECS)**. The first is an artificial intelligence platform supporting companies to find partners along the circular bioeconomy value chain. At the same time, the IECS is a financial measure to facilitate cross-border cooperation by existing regional funding schemes.

Thanks to the synergistic use of these tools, INNOBIOVC’s mission is to focus on those value chains with a high Technology Readiness Level (TRL) compared to bio-based products already on the market, overcoming the barriers that hinder incremental production. Existing solutions IECS and VCG are combined with the **Sustainability Assessment Tool (SAT)**, measuring the circular bio-based value chain and scalability by assessing the environmental, social and economic impacts.

INNOBIOVC implements IECS in all Alpine regions, focusing on interregional financing for developing circular bioeconomy value chains across regions. The results will demonstrate to policymakers in the Alpine Space that interregional financing is possible and creates the desired impact.

2. MATERIAL AND METHODS

2.1. Market analysis and literature review

In this study, a market analysis was carried out to identify the bio-based products with the most significant potential impact on the growth of competitiveness in the Alpine area.



It contributed to highlighting the current development trends in the production of bio-based products, the costs of the raw material, the conversion technologies, the leading market players and the development prospects in the medium-long term. An analysis of the global competitive landscape and market dynamics has been combined with an extensive literature review on mature technologies and challenges of the bio-based industry. Bio-based products represent approximately €57 billion in annual revenue and involve 300,000 jobs [5].

Global bio-based chemical and polymer production is estimated at around 90 million tons [4]. According to J. Cristobal et al. the ten bio-based products most present on the market and with the highest value are listed below.

1. **Bio-based lactic acid.** It is a key product in cosmetics as a skin exfoliator and moisturiser in drug manufacturing because of its antibacterial properties and PLA synthesis.
2. **Bio-based acetic acid.** It is commonly exploited in paints, plastics and glues as a pH regulator and in food industries as a sour agent.
3. **Bio-based 1,2 propanediol.** It is suitable for insulators with antifreeze properties, and, in the food industry, is employed as a humectant and preservative agent.
4. **Bio-based succinic acid.** It is exploited as a green and bio-based solvent in various chemical processes, such as in the production of resins and coatings and the cosmetics field as an exfoliating and skin-conditioning agent.
5. **Polylactic Acid (PLA).** It is used to produce filaments for extrusion, disposable tableware, soil fabrics and household products (toys, reusable bags, garbage bags).
6. **Bio-based glycerol.** It is a key ingredient in food, used as a humectant and sweetener, medical as an excipient, paints and coating applications.
7. **Bio-based glutamic acid.** It is produced from biomass through fermentative pathways. It is used in medical applications in treating neurological conditions and neurodegenerative diseases, in the food industry as a flavour enhancer and in the animal feed industry.
8. **Polyhydroxyalkanoate (PHA).** It is used in the plastic industry because of its biodegradability and compostability.
9. **Bio-based adipic acid.** Used mainly for nylon production and as a food additive.
10. **Bio-based lysine.** It is produced from biomass through fermentative pathways. It is a common additive in animal feed, especially for livestock, poultry and hair care industries.

Those products have been further analysed according to the **TRL level**, technology relevance in the Alpine space and current **market value** (selling price, market dynamics prospects). Based on those criteria, the analysis has not considered adipic acid, PHAs and Lysine.

The remaining products have been grouped into three categories: bio-based platform chemicals (intermediates between raw materials and final products and used to link different biorefinery concepts), bio-based plastic polymers and bio-based proteins.

BIO-BASED PRODUCTS	MARKET VALUE
Lactic acid	1,100 million
Acetic acid	206.3 million

Legend

Platform Chemical
Plastic polymers



INNOBIOVC

1,2 propanediol	375.1 million
Succinic acid	110.4 million
Glycerol	2,400 million
PLA	624.97 million
Glutamic acid	9,540 million

Proteins

2.2. The PESTEL analysis

A PESTEL analysis is the acronym for a tool used in corporate, institutional, and research contexts to analyse and monitor macro-environmental (external) factors affecting an organisation, company, or industry. By examining political, economic, social, technological, environmental and legal factors in the external environment, as well as threats and weaknesses, the analysis allows us to organise in a summary framework the significant forces at play in the development of an industry or organisational model, supporting the decision-making process, the definition of development priorities and the planning of short-term objectives aimed at overcoming challenges and barriers.

A summary description of the factors is given below.

- **Political factors** include government and foreign trade policies, domestic political issues and trends, tax policy, and regulatory and deregulation trends.
- **Economic factors** include current and expected economic growth, inflation and interest rates, employment and unemployment rates, raw material and labour costs, the impact of globalisation, margins and utility for businesses and consumers, and the probable changes in the economic context.
- **Social factors** include demographics (age, gender, race, family size), consumer purchasing choices, opinions, population growth rate, employment patterns, socio-cultural changes, ethnic and religious tendencies, and standard of living.
- **Technological factors** influence marketing in new ways of producing goods and services, new ways of distributing goods and services, and new ways of communicating with target markets.
- **Environmental factors** include considerations on access and availability of raw materials, pollution objectives, ethical and sustainability values, and carbon footprint objectives.
- **Legal factors** include health and safety, equal opportunities, advertising standards, consumer rights and laws, labelling and product safety.

This analysis is based mainly on scientific literature, market analysis reports and policies from the European Commission website (Fig. 2).



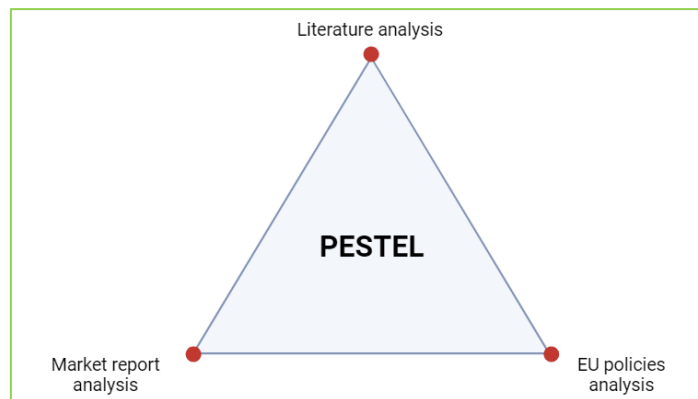


Figure 2 PESTEL analysis sources.

2.3. The SWOT analysis

SWOT Analysis has been used in strategic management over the last fifty years as a valuable technique for planning and decision-making. Over the years, SWOT has been widely used in analysing internal and external environments to support strategic decision situations. The technique has been employed in many areas demanding strategic analysis for an industry, an organisation, a product, a person, a project, a city and so on[12]. The SWOT analysis aims to analyse four aspects of, in this case, a bio-based product; SWOT stands for Strengths, Weaknesses, Opportunities, and Threats [12]. A summary description of the four aspects is given below.

- **Strengths.** It describes what a product/industry excels at and what separates it from its fossil counterpart.
- **Weaknesses.** It describes what stops a product/industry from performing at its optimum level;
- **Opportunities.** It refers to favourable external factors that could give a competitive advantage, such as increasing sales or market share;
- **Threats.** It refers to what could harm the product business [13].

This a tool to analyse how the product’s business can be improved in the future and what is holding the product back from being widely available and successful. A SWOT analysis examines internal and external factors, meaning some can be managed [14].

This SWOT analysis is based on three primary sources: the European Commission report “Environmental Sustainability Assessment of Bioeconomy Products and Processes”, online literature and market surveys (Fig. 3).



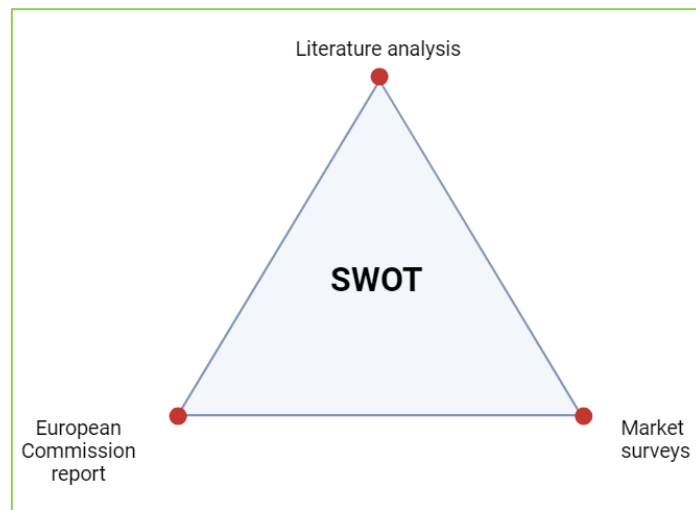


Figure 3 SWOT analysis sources.



3. PESTEL ANALYSES

In Europe, the **Bioeconomy Strategy** is considered the primary **policy** tool influencing the growth and acceleration of bio-based products on the market and the green transition of fossil-based manufacturing processes. It outlined the EU's vision for a sustainable and circular bioeconomy by encouraging the sustainable production of bio-based products, including chemicals, materials, and energy, to reduce dependence on fossil resources [15].

Driving market adoption of bio-based products as well as the sustainability and profitability of new **business models** based on them, in Europe, the primary funding measure to support the implementation of bio-based products is found in the **Horizon Europe** program and, in particular, in the **Circular Bio-based Europe Joint Undertaking** (CBE JU), a public-private partnership between the EU and the Biobased Industries Consortium (BIC). It supports research and innovation projects in the bio-based sector to accelerate innovation toward large-scale demonstration plants, develop new bio-based solutions, accelerate the market deployment of existing, mature, and new bio-based solutions, and ensure high environmental performance [16]. Among the applications playing an increasingly significant role in the latest EU programming, the search for alternative sources of proteins and the sustainable production of bio-based proteins play a growing role. Under Horizon Europe, the European Commission invested 70 million euros in 15 projects investigating the potential of plant-, insect-, microalgae- and microbial-based technologies to produce protein sources [33].

3.1. Bio-based platform chemicals

The European policy context of bio-based chemical platforms is supported by related policies and action plans listed below.

- **Renewable Energy Directive** (RED II): the RED II directive set targets for renewable energy use in the EU and promoted using renewable resources for energy and fuel production, including bio-based feedstocks [17].
- **Circular Economy Action Plan**: Part of the European Green Deal, this action plan promotes the circular use of resources, including bio-based materials and chemicals, to reduce waste and environmental impact [18].
- **Chemicals Strategy for Sustainability**: This strategy, part of the European Green Deal, aims to make chemicals safer and more sustainable, promoting bio-based and biodegradable chemicals as alternatives to traditional, potentially harmful chemicals [19].
- **European Chemicals Agency** (ECHA): ECHA oversees the regulation of chemicals in the EU and assesses the safety and environmental impact of chemicals, including bio-based chemicals, to ensure their compliance with EU regulations (<https://echa.europa.eu/>).

In Europe, representing approximately **10.6 billion euros** in annual revenue and **98,700 K jobs** [20] bio-based platform chemicals help shape a more sustainable economy and lower its dependence on fossil fuels. Although they have the same characteristics as their fossil counterparts and, in some specific cases, can carry out additional activities, their **market share** still needs to be higher, representing **only 0.3%**, mainly due to production technologies that could be better competitive with conventional fossil-based



applications. Potentials and limitations constantly stimulate investments in research and development (R&D) in biochemical production by both private and public actors [21], [22].

The primary environmental benefit surrounding the development of bio-based platform chemicals is based on the proven climate change mitigation potential of biotechnological processes, which is expected to range from 1 billion to 2.5 billion tonnes of CO₂ equivalent annually by 2030 [23].

By saving non-renewable energy, the manufacturing industry can replace part of its fossil fuel- or mineral-based raw materials with renewable raw materials [24].

Bio-based materials generally exert lower environmental impacts than conventional materials in the climate change category, neglecting greenhouse gas emissions resulting from indirect land use change [24]. Furthermore, they can exert higher environmental impacts than their conventional counterparts in the eutrophication and stratospheric ozone depletion categories. These impacts can be reduced by improving fertiliser management and employing extensive agricultural practices [24].

The biggest issue with bio-based chemicals is the availability of sustainably produced biomass and related issues of land availability and use [25].

The contexts and legal bases that regulate the production of bio-based platform chemicals are the following:

- **REACH Regulation** (EC) No. 1907/2006. REACH is a comprehensive regulation that governs the EU's registration, evaluation, authorisation, and restriction of chemical substances. Companies must register the chemical substances they manufacture or import, provide safety data, and manage the associated risks. REACH aims to ensure the safe use of chemicals while promoting substituting hazardous substances with safer alternatives [26].
- **CLP Regulation** (EC) No. 1272/2008. The Classification, Labeling, and Packaging (CLP) Regulation harmonises the classification and labelling of chemicals across the EU. It aligns with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). It ensures that chemicals are labelled and classified consistently, making it easier for users to understand their hazards [27].
- **Biocidal Products Regulation** (BPR) (EU) No. 528/2012. BPR regulates the placement of biocidal products (substances and preparations intended to control pests) on the EU market. It requires assessing and approving active biocide substances before they can be marketed in the EU [28].

3.2. Bio-based plastic polymers

The political context affecting the bio-based plastic polymers business is as follows:

- **EU's Directive on single-use plastics** [29]. It seeks to reduce single-use plastics by promoting alternative materials, including bio-based plastics.
- **Directive (EU) 2015/720** of the European Parliament and of the Council of 29 April 2015 amending Directive 94/62/EC regarding reducing the consumption of lightweight plastic carrier bags [30].
- **European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste**. The priorities of the Directive are preventing the creation of packaging waste mainly by reducing the overall volume and managing it to allow its reuse and other forms of recovery. Compostable and biodegradable plastic packaging is considered preferable concerning environmental impact [30].



- **New EU Circular Economy Action Plan** (2020). The new action plan announces initiatives along the entire life cycle of products. It targets how products are designed, promotes circular economy processes, encourages sustainable consumption, and aims to prevent waste and ensure the resources used are kept in the EU economy for as long as possible [18].
- **Waste Framework Directive** [31]. It lays down some basic waste management principles, prioritising waste re-usage and recycling, explaining when wastes become secondary raw material, and how to distinguish between waste and by-products. It supports mainly industries active in businesses based on residual biomass as raw material.

In Europe, bio-based plastic polymers represent approximately **3.4 billion euros in annual turnover**[20]and **60,510 thousand jobs** [20], the demand for which is expected to grow due to the increase in prices of crude oil[32] [33] and fossil-based plastic products [34].

The economic factor that most influences their profitability is production costs dependent on fluctuating **raw material prices**. Currently, bioplastics are mainly produced from corn starch or sucrose derived from sugarcane, meaning their prices may increase due to their dependence on general agro-economic factors such as drought, trends in seed prices and fertilisers and the labour shortage in harvesting. This could increase the production costs of bioplastics, leading to a decline in demand for bioplastics [35].

A further factor slowing the development of the bio-based polymer market is connected to the considerable amount of **energy** required for production, both in the form of electricity and process heat. In particular, the fermentation phase is closely related to the temperature of the process. Therefore, industrial electricity and natural gas price fluctuations can significantly impact the total manufacturing expenses associated with bioplastic polymers [36].

Finally, the disposal of waste plastic polymers of biological origin requires considerable efforts on the part of users (collection of products, assignment to appropriate treatment channels), increasing the overall cost burden of a life cycle. Without transparent rules and frameworks for the collection of bioplastics, cost competition develops with conventional plastics, characterised by established waste management systems [37].

Although studies have shown that most consumers recognise the need to accelerate the green transition of the packaging sector by showing an awareness of the related environmental advantages, purchasing choices are still dependent on the product's cost-effectiveness compared to its fossil counterpart [38]. Correct end-of-life management remains one of the significant challenges to ensuring complete sustainability of the supply chain [39]. Therefore, technological investments and public awareness represent two key factors to unlock the potential of bio-based polymers.



3.3. Bio-based proteins

In Europe, the Renewable Energy Directive (RED II), the central supporting policy, affects bio-based protein production. It set targets for renewable energy use and promoted the use of renewable resources for energy and fuel production, including bio-based feedstocks [17].

Although bio-based proteins produced through fermentative organisms starting from bio-based feedstocks raise consumer concerns, the trend in demand is constantly growing [40].

The global plant-based protein market, in terms of revenue, was estimated to be worth **12.2 million US dollars** in 2022 and expected to reach **17.4 billion US dollars** by 2027 linked to the rise of veganism and health concerns related to the consumption of animal proteins [41].

One of the main technological challenges in bio-based protein production is reducing the allergenic potential of the final product to make it suitable for marketing according to Regulation (EU) No 1169/2011. Production costs are strictly related to fermentation processes that require rigorous control and aseptic techniques to avoid contamination by unwanted microorganisms; therefore, to satisfy the growing food demand, the new frontier of fermentation technologies focuses on optimising processes to guarantee a high yield and food safety [42]. With the potential to reduce land consumption by 38%–91%, water consumption by 53%–95 % and carbon emissions by 69%–92%, plant-based proteins qualify as a crucial alternative to meat-based [43].


The laws regarding bio-based proteins are:

- **General Food Law (Regulation (EC) No 178/2002):** it establishes the general principles and requirements of food law, including provisions related to food safety, traceability, and consumer information.
- **Novel Foods Regulation (Regulation (EU) 2015/2283):** This regulation governs the authorisation and safety assessment of novel foods and ingredients, including novel protein sources. It ensures that new protein sources, such as insect-based or lab-grown proteins, meet safety standards before commercialising them.
- **Food Information to Consumers Regulation (Regulation (EU) No 1169/2011):** This regulation sets out rules for the labelling and presentation of food products, including requirements for ingredient labelling, allergen declarations, nutritional information and claims related to protein content.
- **Food Safety Regulations:** various regulations and directives related to food safety and hygiene apply to protein production and commercialisation.
- **Genetically Modified Organisms (GMOs) Directive 2001/18/EC and Regulation (EC) No 1829/2003:** these regulations require safety assessments, labelling, and traceability for GMO-derived proteins.
- **Allergen Labelling Regulation (EU) No 1169/2011:** Protein products must adhere to strict allergen labelling requirements.

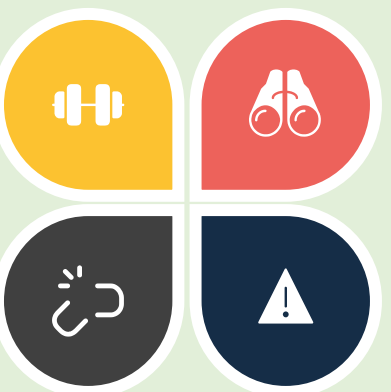


4. SWOT ANALYSES

4.1. Lactic acid

<p>STRENGTH</p> <ul style="list-style-type: none"> • It has an established value chain and a mature market [33] for various food, chemical and medical applications [and is a building block of PLA. • The bio-based production route is cheaper than the other chemicals counterparts [4] and allows 100% organic products. <p>WEAKNESS</p> <p>Due to the high separation and purification costs, the selling price is double that of traditional polymers.</p>		<p>OPPORTUNITY</p> <ul style="list-style-type: none"> • Growing demand for PLA can boost production [44]. • EU's Directive on single-use plastics [27] aimed at reducing single-use plastics and promoting them as an alternative to fossil-based plastic. <p>THREATS</p> <ul style="list-style-type: none"> • Food and land use competition (primary PLA feedstock is corn) and the consequent impact on food prices becoming higher [45]. • Lack of specific regulation on bioplastics.
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4.2. Acetic acid


<p>STRENGTH</p> <ul style="list-style-type: none"> • It enables various applications from lignocellulosic biomass conversion [46] with low toxicity and high biodegradability [4]. • It is compatible with bacterial strains with a greater yield of acetic acid. <p>WEAKNESS</p> <ul style="list-style-type: none"> • The biological route has a low yield [4] related to issues in separating the acetic acid from the fermentation broth [43] and distillation to glacial purity (99.8% acetic acid), 		<p>OPPORTUNITY</p> <ul style="list-style-type: none"> • The “Chemicals Strategy for Sustainability” of the EU Green Deal promotes its production among those of biological origin [19]. <p>THREATS</p> <ul style="list-style-type: none"> • Competition with food production for the starting feedstocks (Starch and sugar crop) [4].
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hindering commercial viability [47].

4.3. 1,2 propandiol (PDO)


<p>STRENGTH</p> <ul style="list-style-type: none"> • The bio-based production route is at full commercial scale[48] and new routes for purification are increasing efficiency and sustainability [45]. • It is easily turned into glycerol with higher market demand [4]. <p>WEAKNESS</p> <ul style="list-style-type: none"> • It is difficult to recover it from fermentation broth [4], resulting in an equivalent low yield [4] and high energy consumption during PDO purification [4]. 		<p>OPPORTUNITY</p> <ul style="list-style-type: none"> • The increased market demand boosts the greener fermentation pathway development [4]. • The EU Green Deal’s “Chemicals Strategy for Sustainability” promotes its large-scale production [16]. <p>THREATS</p> <ul style="list-style-type: none"> • Low biomass availability (Sugar, starch and oil crops) due to food competition [4]. • Until its production is not optimised, there is a strong price competition with fossil-based counterpart which are cheaper [4].
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4.4. Succinic acid

<p>STRENGTH</p> <ul style="list-style-type: none"> • It can replace several fossil-based chemicals in various applications [4]. <p>WEAKNESS</p> <ul style="list-style-type: none"> • The complex purification affects the large-scale production[4]. • Bio based succinic acid has still a relatively small world market[49]. 		<p>OPPORTUNITY</p> <ul style="list-style-type: none"> • “Chemicals Strategy for Sustainability” part of the European Green deal promotes bio-based chemicals production [16]. <p>THREATS</p> <ul style="list-style-type: none"> • Sugar and starch crops are the main feedstock for the production of bio based succinic acid leading to biomass competition with food [4].
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4.5. Polylactic acid (PLA)

<p>STRENGTH</p> <ul style="list-style-type: none"> • It is a biodegradable and biocompatible polymer used in high-added-value applications (medical field) [50]. • It has a good moisture barrier properties, comparable to fossil-based plastics [51]. • The ability to produce PLA from waste/ residues could decrease production costs. <p>WEAKNESS</p> <ul style="list-style-type: none"> • It has high production costs compared to its fossil counterparts [51]. • It has low thermal and gas permeability compared to fossil polymers and a low shelf life [51]. • It has biodegradability properties only under certain conditions (as high Temperatures and specific PH conditions) [51]. 		<p>OPPORTUNITY</p> <ul style="list-style-type: none"> • The EU's Directive on single-use plastics [27] promotes alternative materials to single-use plastics. • The European Parliament and Council Directive 94/62/EC on packaging and packaging waste promoting compostable and biodegradable plastic packaging. <p>THREATS</p> <ul style="list-style-type: none"> • Starch crops being the main feedstock lead to biomass competition with food [4]. • Issues related to end-of-life disposal and proper biodegradation of the material [52]. • Lack of specific regulation on bioplastics.
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4.6. Glycerol

<p>STRENGTH</p> <ul style="list-style-type: none"> • It represents 10% of biodiesel production meaning it becomes a secondary income source, making the production of “green” fuels economically sustainable in the long term [53]. • It has a broad versatility in producing <u>value-added</u> products due to its low cost [51], as products for medical and food applications, industrial protective coatings and paints. 		<p>OPPORTUNITY</p> <ul style="list-style-type: none"> • Several EU policy recommendations are promoting its production, such as the “Circular Economy” action plan, the “EU Bioeconomy Strategy” and the “Chemicals Strategy for Sustainability” of the EU Green Deal [13], [16].
<p>WEAKNESS</p> <ul style="list-style-type: none"> • The conventional production process has significant environmental drawbacks due to the purification step [54]. • Glycerol purification via greener routes is an expensive process mainly due to the purification step [54]. 		<p>THREATS</p> <ul style="list-style-type: none"> • Increased production of glycerol as a by-product of biodiesel has lowered its market price due to the high amounts of it produced and available on the market [53].



4.7. Glutamic acid

<p>STRENGTH</p> <ul style="list-style-type: none"> • It enables various applications (food additives, feed supplements, therapeutic agents and agricultural chemicals) [4]. • It can be produced by fermentation from residual biomass [53], preferred to chemical synthesis for forming racemic mixture. • Production usually relies on cheap carbon substrates, including waste, available in large quantities [55]. 		<p>OPPORTUNITY</p> <ul style="list-style-type: none"> • Amino acids' market doubles every decade [56]. • Microbial proteins (MPs) are promising alternatives to animal- and plant-based ones for food safety and environmental impact [54].
<p>WEAKNESS</p> <ul style="list-style-type: none"> • Bacteria make production highly sensitive to pH, temperature and other factors[4]. • Downstream high-purity separation and purification are significant obstacles to cost-effective production [4]. 		<p>THREATS</p> <ul style="list-style-type: none"> • Increasing awareness of Monosodium Glutamate (the main final product of glutamic acid synthesis) harms human health[55].



5. CONCLUSIONS

The biorefinery and bio-based economy concepts promote biomass and residues to produce bio-based products and create more value from plant production chains [57]. Sustainability calls for contributions from all countries in the evaluation of all its components: nations and regions should invest in research and development, prioritising the use of green and circular resources, facilitating actors of regional markets to know each other across borders to collaborate and speed up the transition towards a sustainable business [58], [59].

Based merely on the market value of the analysed products, it is clear that the products with the highest value are:

- **Glycerol.** Since the late 1990s, biodiesel production has created an abundance of crude glycerol, significantly impacting its market and resulting in a price decline [60]. Because of the economic viability, its renewability and attractive pricing make glycerol an appealing platform chemical. Examples of chemicals which can be synthesised from glycerol are 1,2-propanediol, commonly used in the pharmaceutical industry as a solvent, as a stabilising agent and as a plasticiser; Acrolein, a versatile intermediate for the chemical industry used in the preparation of polyester resin polyurethanes [61].
- **Glutamic acid (or glutamate).** It is an important amino acid used widely in the fields of food, as a flavour enhancer in processed food products, and in medicine to treat nervous system disease, using *Corynebacterium glutamicum* and starting from different sugar biomasses (as wheat, corn, lignocellulosic biomasses). The global demand for glutamic acid is projected to increase at a CAGR 4.7% during the forecast period between 2023 and 2033 [59]. Moreover, glutamic acid can potentially be used as a platform chemical, leading to an increase in its value; some examples are: N-methylpyrrolidone (NMP), a solvent used in paints industries, N-vinylpyrrolidone (NVP) used as a binder in many pharmaceutical tablets or as a lubricant in eye drops, succinonitrile used in the production of plastics and nitron fibers. Currently, those processes show very high costs to the possible gains, meaning further optimisation is necessary.
- **Lactic acid** is a very valuable compound in the context of “circular bioeconomy”, in fact is nowadays commonly polymerised into PLA, a biodegradable and compostable plastic polymer. Furthermore, lactic acid finds application in food, pharmaceuticals, cosmetics, and polymer industries.

The SWOT and PESTEL analysis performed aimed to highlight the current challenges for the production and commercialisation of bio-based products in Europe, specifically in the Alpine region.

To sum up this study, it is clear the main challenge is overcoming the competition for biomass between food and non-food applications. Most bio-based marketed products are produced starting from biomasses such as corn or sugarcane, hindering the UN Sustainable Development Goal of overcoming hunger by 2025 and making those feedstocks a lot more expensive. Instead, areas like the alpine region have hectares of alternative non-food biomasses, such as forestry with biomasses rich in sugars that can be fermented and turned into valuable bio-based products. This will allow industries to have environmentally, socially, and economically sustainable products.



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