CBE JU Scientific Committee recommendations

We, social and natural scientists and members of the scientific committee of CBE JU, write this recommendation to express our views and concerns with potential forthcoming policy changes and underpinning narrowed definitions or focus that can severely impact European innovation and competitiveness in the circular bioeconomy and bio-based industry development space.

Brussels, 25th November 2024

Executive Summary

Key CBE JU Scientific Committee Recommendations

1. Europe needs to build on its leadership on bioeconomy and decarbonisation goals, but policy siloing and fragmentation threatens Europe's leadership position.

Circular bioeconomy and biobased development models are in demand globally and hold the key for decarbonisation and climate change mitigation. The EU Commission has led in this space and first brought the bioeconomy to prominence as a concept aligned with national development priorities and with international organisations, such as the OECD. Other economies have caught up with Europe's thought leadership. Ongoing policy discussions at European level for the New European Commission are a source of concern as it appears that there is a siloing strategy that would hamper Europe's ability to innovate, an area where other economies are exceling.

2. EU policy should support Key Enabling Technologies (KETs) to build European resilience, autonomy and competitiveness.

Key Enabling Technologies (KETs), such as Biotechnology, cut across multiple parts of the European economy. It has been defined by the Commission as one of the key critical technologies for strategic autonomy and security. Biotechnology is a KET of the European Bioeconomy based on technologies using living organisms and enzymes, and widely used to transform biobased resources into products of value in Biorefineries. Narrowly defining and/or prioritising Biotechnology for development and deployment in one sector such as pharma or medical would be a catastrophic error for the European bioeconomy. KETs such as biotechnology and chemical technologies enable the development, transition, and resilience of the European economy to climate and geopolitical changes. Unified development of strategy and policy for KETs deployment in areas such as Bioeconomy, circular economy, and health (human, animal, environmental) is critical to Europe's future prosperity and agility. Cohesive integrated strategic development in upcoming related EU policies such as the Bioeconomy Strategy 2025, the Biotech and Biomanufacturing Initiative Action Plan and Life Sciences Strategy is critical to Europe's competitiveness.

3. Continued strategic cohesive investment in biomanufacturing is needed to drive innovation, jobs and societal development in Europe.

Biomanufacturing has been well established for over one hundred years but is a recently revived word in the modern policy lexicon. It has evolved through several iterations from simple microbial fermentation producing simple products like organic acids (1.0) using biobased resources (Bioeconomy) to take full advantage of the synthetic biology (bioengineering) era (4.0) to fabricate products for use across a broad range of industries from pharma and medical to food and feed, cosmeceuticals, platform and fine chemicals, biomaterials, and fuels. These are all sectors of the Bioeconomy. Biomanufacturing is the deployment of biotechnology and complementing chemical technologies to produce products of value from biobased resources. The bioeconomy is about the health of humans, animals and environment. Biomanufacturing is a key source

of innovation, job and wealth creation in Europe that needs a holistic strategic plan to maximise its potential to improve the lives of European citizens.

4. **Europe needs to re-examine the competition of non-fuel biobased products with food.**

Food and non-food production are part of a single Bioeconomy system, and they do not operate in isolation. The "food first" principle is critically important. Supporting the development of both food and non-food products in the Bioeconomy is also critically important to unlock the full potential of the Bioeconomy. Considering the full use of biomass and the low volumes of use of biobased chemicals and materials compared to biofuels, we must (re)evaluate the competition that these non-fuel products pose to food production.

5. **Europe needs to re-examine its policy for the circular economy through the lens of the bioeconomy.**

The fossil economy can never be truly circular. Tangent linear inputs from the fossil economy into the circular economy as well as significant leakages from the circular economy drives a large hole in the argument that one can achieve a circular economy when continuing to use fossil resources. Achieving a truly circular economy can only be achieved through use of renewable resources. The use of renewable resources from the bioeconomy is not without environmental risks, as a bioeconomy is not inherently sustainable *per se*, and work is yet needed to develop the bioeconomy to be sustainable. The fossil economy, however, will never be sustainable. Oil and gas are non-renewable depleting resources. Exploration for and use of fossil resources generates GHG emissions and creates water and air pollution.

Introduction - Current context in EU and the world

"Europe is facing a world undergoing dramatic change. World trade is slowing, geopolitics is fracturing, and technological change is accelerating. (...) Long-established business models are being challenged and (...) some key economic dependencies are suddenly turning into geopolitical vulnerabilities. Of all the major economies, Europe is the most exposed to these shifts." (Mario Draghi's address to EU Parliament, 17 of Sept 2024).

According to Draghi's report **"The future of European competitiveness: A competitiveness strategy for Europe"**, Europe is the most open economy in the world, the most dependent one, importing over 80% of its digital technologies and lagging behind in development of new technologies and world leading companies. This report sets an anxiety scenario for Europe's future and questions its capacity to perpetuate its values and remain competitive in a fast pace changing world. Within this document, 3 main areas for action are presented, focusing on i) closing the innovation gap with the USA and China, increasing spending and speeding up the pace of innovation scale up, but most importantly, diversifying and being more open to promote new technologies and markets; ii) making a joint plan for decarbonisation and competitiveness, taking advantage of the European leadership and last years' investments in these topics to tackle the carbon-neutral goals of 2050; and iii) increasing security and reducing dependencies, guaranteeing that Europe secures internally key strategic technologies and maintains autonomy in tactical resources.

A new paradigm shift is needed for human development on this planet. Circular bioeconomy and biobased development models are in demand and hold the key for decarbonisation and climate change mitigation. A transition from a fossil fuel-based economy to a bio-based one also brings a new set of geopolitical implications. The dominance and power that comes with ownership, control and access to in-demand resources and technology can shift from current large oil and fossil fuels majors to new players with different bio-related endowments. This shift is, however, set against a backdrop of current world turbulence and uncertainty. Sustainable technological advancements are proceeding at a great pace and rapidly altering businesses, societies and national priorities. The extent of climate impacts is also likely to affect the abilities of nations to transition to a bioeconomy development model.

1. Europe needs to build on its leadership on bioeconomy and decarbonisation goals, but policy siloing and fragmentation threaten Europe's leadership position.

The bioeconomy provides sustainable alternatives to fossil fuel-based goods, and new products with no fossil equivalent spurring innovations that boost the economy, develop new greener jobs, while tackling global climate impacts. The EU Commission has led in this space and first brought the bioeconomy to prominence as a concept aligned with national development priorities and with international organisations, such as the OECD, that have a long track record of identifying and analysing different bioeconomy archetypes.

At EU level, the development of the **European bioeconomy strategy** in 2012 recognised that a number of interdependent challenges existed in the world such as food security, sustainable biomass supply, climate change, biodiversity, and the sustainable production of everyday products. This strategy has evolved to incorporate circularity, biodiversity, just transition and has been further influenced by the **EC Missions** on soil, oceans and waters, and adaptation to climate change. Central to the development of the bio-based sector in the EU was CBE JU and its predecessor (BBI JU), where the actors could stimulate the advancement and implementation of novel technologies that could diversify business activity and boost decarbonisation efforts across industries and sectors. The Strategic Research and Innovation Agenda (SRIA) identified key gaps and needs in biobased industries that should be addressed to develop the bioeconomy in Europe. R&D funding has been heavily deployed in these, and other programmes in the EU, to foster connected areas and technologies like biotech and biomanufacturing, but also agro- and food-tech, clean-tech, green chemistry and industrial processes technologies to name a few.

2. EU policy should support Key Enabling Technologies (KETs) to build European resilience, autonomy and competitiveness.

Biotechnology is an important cornerstone of the bioeconomy. It has been defined by the Commission as one of the key critical technologies for strategic autonomy and security (alongside advanced semiconductors, artificial intelligence and quantum technologies) and innovation within biotechnology is very relevant to the EU Bioeconomy.

Biomanufacturing, on the other hand, has been around for hundreds of years and has evolved through several iterations from simple microbial production of beverages such as beer and wine and primary metabolites such as organic acids (1.0) to take full advantage of the synthetic biology (bioengineering) era (4.0) to fabricate products for use across a large number of industries from pharma and medical to food and feed, cosmeceuticals, chemicals and biomaterials, and fuels. The Commission has recognized the relevance of these technologies and has launched the **Biotechnology and Biomanufacturing Initiative** in 2024, to give emphasis to various biotechnologies and promote industrial scale production of biotech products through biomanufacturing. Nations like USA, Brazil and China have since followed and acknowledged that the bioeconomy is an important instrument for future security, innovation, tackling climate change, and promoting biodiversity. These nations have launched bioeconomy as well as biotech and biomanufacturing related acts and initiatives that aim to bolster their power and capacity to speed up development and R&D in these fields.

USA and China have gone one step further in encompassing measures in their programmes to bolster a wide range of technologies, industries and applications for deployment that can foster a holistic development of bioeconomy. Also recently, G20 members outlined the G20 High-Level Principles on the Bioeconomy adopted in Rio de Janeiro (September 11, 2024). This new G20 Initiative on Bioeconomy is focused on advancing a bioeconomy that is equitable, regenerative of biodiversity, supportive of climate action and an enabler of the sustainable transition of the current fossil economy to a bioeconomy through cross cutting holistic approaches. However, recent developments in the formation of the new EU commission, raise questions about

possible growth constraints for the bio-based industries and bioeconomy as a whole, especially if the circular bioeconomy and connected technologies are not jointly recognised and strategically positioned as a force for both economic and environmental advancement across sectors and industries. This can harm Europe's competitiveness, autonomy and resilience.

3. Continued strategic cohesive investment in biomanufacturing is needed to drive innovation, jobs and societal development in Europe.

Since its inception Biomanufacturing and Biotechnology have pervaded the SRIA and its predecessor (SIRA) but have not been overtly coined in such terms.
P. Michels and J. Rosazza 2009 or Zhang et al. 2017, amongst others gave a definition of biomanufacturing as the "type of manufacturing that utilises biological systems (e.g., living microorganisms, resting cells, animal cells, plant cells, tissues, enzymes, or *in vitro* synthetic (enzymatic) systems) to produce commercially important biomolecules for use in the agricultural, food, material, energy, and pharmaceutical industries". The evolution of the biomanufacturing concept from 1.0 to today's 4.0 has rather expanded the portfolio of products that can be made out of it, instead of narrowing it to usage in a certain group of applications (like health and biomedical for example).

Biotechnology is an underpinning technology of biomanufacturing as it uses living organisms and the molecular mechanism of biology to make diverse products. The great advances in life sciences over recent decades can be directly applied through biotechnology, to create novel innovations. For example, genome sequencing and the data generated from it is available for designing new biotechnological production organisms and processes as part of the biomanufacturing 4.0 era, which combines computational design of biological systems and the use of robotics and automation for their fast development in special laboratories called biofoundries. The integration of biology, AI and automation is a powerful combination that will revolutionise biotechnology in the coming 10-20 years. Often considered in connection to medical applications, e.g. production of drugs such as antibiotics, vaccines and antibodies, as well as development of tissue engineering and gene therapy technologies, biotechnology is much broader and vastly enabling. e.g. production of bioactive compounds, food and feed ingredients, platform chemicals (chemical building blocks), specialty chemicals with complex structures difficult to synthesise with chemical technologies, to various materials such as bioplastics (e.g. PLA, PHA), and enzymes which we use in so many everyday items/activities (e.g. detergents, food processing, healthcare and personal care) and as biorefinery processing aids. Most of the applications can directly contribute to sustainable industrial, medical, pharmaceutical, environmental, and agricultural developments.

Chemical technologies also play a role in biomanufacturing, alongside, and in conjunction with, biotechnology. These enabling technologies can be deployed in specialist small scale manufacturing facilities but also in larger scale biorefineries to sustainably produce products of value. Furthermore, chemical technologies and biotechnologies will not develop in isolation but rather with Information technology and Artificial intelligence which will enrich biomanufacturing approaches in the Bioeconomy.

Furthermore, biotechnology can be deployed to enable society to achieve a **circular bioeconomy**. Living organisms can utilise a variety of feedstocks such as heterogeneous waste and CO2, as raw materials to synthesise new complex molecules and materials. It differs from other technologies in not being dependent on the existing chemistry and structures of the feedstock in product manufacture but can - in principle - turn any feedstock to any product using the mechanisms found in nature. Thus, biotechnology has a significant potential to diversify the feedstock and product range in bioeconomy and contribute to a wise and resource efficient way to use renewable raw materials. This calls for systematic evaluation of the available raw material streams and consideration of how biotechnology processes can be integrated into the value chains to bring new possibilities on EU's autonomous strategy and security as well as economic value. However, due to the richness of the options and rapidly developing technologies, significant efforts are still needed to unlock biotechnology's potential so that it can be competitive against technologies that have prevailed much longer.

Biomanufacturing is, thus, part of the Bioeconomy's offering to society to transition away from fossil resources, using virgin and 2nd and 3rd generation biomass to reduce GHG emissions, increase nitrogen cycle efficiency, produce food and feed ingredients, biomaterials and bioactives for human, animal, soil and marine health. These **intertwined technologies** create new biobased value chains, address the interconnected challenges society faces, create green jobs and can drive rural and coastal development where the majority of biorefineries are, or will be, built (close to the biomass to ensure the sustainability loop). To demonstrate its diversity Biotechnology has been grouped to Green (agricultural), Blue Marine), Red (pharma, medical), White (industrial), Yellow (food), Grey (environmental), Gold (bioinformatics) etc. **Biotechnology should not be viewed through a narrow lens of pharma as this will significantly disadvantage Europe's competitiveness and resilience**. Some would argue that the use of biotechnology (e.g. enzymes/microbial cells) to transform fossil-based resources is also biomanufacturing. Thus, this term could be manipulated (green washing). As an example, such logic is akin to attributing biobased carbon credits to a fossil feedstock-based product if biofuel is used as an energy source in its production. As such, caution and solid scientific grounding in application of these concepts is key to maintain credibility and spur innovation into the desired direction. Cohesive policy for development and deployment of key enabling technologies can supercharge Biomanufacturing. Policy cohesion is required to promote a more open cross-fertilising and competitive circular European (bio)economy.

4. Europe needs to re-examine the competition of non-fuel/energy biobased products with food.

Food and non-food production are part of a single **Bioeconomy system**, and they do not operate in isolation. The competition between biofuel production and food has been correctly identified as an issue and the "food first" principle is critically important. Supporting the development of both food and non-food products in the Bioeconomy is also critically important to **unlock the full potential of the Bioeconomy**. We must (re)evaluate whether the emerging biobased chemicals and materials, that are produced in lower volumes than biofuels, pose a competition to food production, taking into account the upcycling of residues from food production and current food trends, like

decreasing animal protein consumption. Using data based on projected volumes of production of biobased products over a 10-20-year time frame should create a realistic picture and avoid the creation of barriers to sustainable innovation in the European bioeconomy.

5. **Europe needs to re-examine its policy for the circular economy through the lens of the bioeconomy.**

The **Bioeconomy is the renewable part of the Circular economy**. Yet, only the technical part of the circular economy is seen as the solution to resource efficiency through the fossil economy lens and not the bioeconomy. **The fossil economy can never be truly circular**. Tangent inputs from the fossil economy combined with leakage from the circular economy operations (technical cycle) into nature drives a large hole in the argument that one can achieve a circular economy when continuing to use fossil resources. Accomplishing a truly circular economy can only be achieved through use of renewable resources. The use of renewable resources from the bioeconomy is not without environmental risks, as a bioeconomy is not inherently sustainable, and work is yet needed to develop the bioeconomy to be sustainable. The fossil economy, however, will never be sustainable. Oil and gas are non-renewable depleting resources and exploration for and of fossil resources generates GHG emissions and creates water and air pollution. The idea that European policy supports a circular economy based on fossil-based materials over biobased and biodegradable materials is Orwellian and puts at risk Europe's reputation and leadership role in greening the economy.

Closing remarks

The world is fast changing and global geo-political uncertainty challenges Europe's economy and society. Cohesive policy and integration of technologies that cut across sectors such as pharma, food, feed, chemicals and materials are needed as we transition to the next European Commission. **The major developments in the last decade in the European Bioeconomy are in danger of being eroded as a result of policy siloing and through narrowing of definitions such as biomanufacturing being linked to pharmaceuticals only.** The recognition of the crucial roles of biotechnology and biomanufacturing to foster the paradigm shift in the European economy is needed. The **Circular Bioeconomy** can be a reality in the near future, and it will help deliver successful endeavours in Europe in the next 20 years, but Europe must have a policy strategy that will continue to aid and accelerate the transition to it. To maintain conformity with international norms and strengthen Europe's position as a leader in the sector, **the EU must include similar principles and concepts as its international counterparts and competitors, in its upcoming relevant policies such as the Bioeconomy Strategy 2025, the Biotech and Biomanufacturing Initiative Action Plan and its Life Sciences Strategy as they are undeniably intertwined**. Abandoning narrow narratives and silos approaches is crucial to maintain EU leadership and, more importantly, to continue being the front runner determining the pace and direction of future Bioeconomy endeavours by setting the example. Furthermore, the openness needed and claimed in the 2024 Draghi's report is crucial to keep in mind when drafting these new policies and frameworks in the EU.