

EuropaBio's input to the EC consultation on the future "EU 2020 Strategy":

Towards a bio-economy in 2020

January 2010

Creating a competitive, connected and greener economy

Introduction to the bio-economy

Faced with global warming and limited fossil fuel resources, the development of new biological processes and the use of renewable raw materials derived from plants, crops and trees has become an increasingly attractive alternative for feedstock. Using these processes and materials to produce fuel, innovative materials and chemicals has enormous potential to enhance quality of life while reducing negative environmental impact.

At the same time, national healthcare systems are facing challenges that put them under unprecedented financial, economic and social strain. For example, a December 2008 report from the European Commission¹ revealed that the number of elderly people (aged 65 and above) will almost double, rising from 85 million in 2008 to 151 million in 2060 in the EU. This will result in a steep rise in health care demand leading to an increase in expenditure and the need for long-term care.

Healthcare biotechnological knowledge, which by 2015 is likely to be used in the discovery and development process for **all** new pharmaceuticals², will provide personalised, innovative, safe, and effective healthcare biotech products which have the potential to improve quality of life whilst supporting the budgetary efforts of national governments.

There is also a need to respond to the growing demand for food without compromising on environmental standards. In a paper³ released in October 2009, the Food and Agriculture Organization of the United Nations (UN FAO) estimated that we will have to produce 70 percent more food for an additional 2.3 billion people by 2050.

Meeting market demands and the growing need for food, whilst at the same time reducing the impact on our climate, is of critical importance to our future. Although in the past, discussions have centred on the causes of climate change, today society, industry, governments and other stakeholders are searching for solutions to mitigate its impact on our health and environment.

In spite of our endeavours so far to reduce greenhouse gas (GHG) emissions, current practices and technologies will most likely be insufficient to achieve the ambitious objectives set by the European Union and other countries to tackle climate change. Regulators must therefore take bold steps towards establishing more sustainable growth and sustainable agriculture through the reduction of our carbon footprint and the mitigation of the impacts of climate change.

Our existing energy infrastructure and industrial production processes are largely based on fossil fuels, which results in high levels of greenhouse gas emissions. However, the **bio-economy** would help enable future generations to no longer be wholly dependant on fossil fuels and

¹ [The 2009 Ageing Report: Underlying Assumptions and Projection Methodologies. European Economy 7|2008](#)

² The Bioeconomy to 2030: designing a policy agenda. OECD. 2009

³ [How to feed the World in 2050: High Level Expert Forum Global Agriculture towards 2050](#)

industrial raw materials. Bio-based products are a substitute for certain fossil fuel-based products, and play a valuable role in contributing to a more sustainable society, with the potential to reduce greenhouse gas emissions, generate less waste, and use less fossil fuels and water⁴. As a result, the potential to improve sustainability in industry is vast and should be among the top technologies considered in any policy discussion.

The bio-economy as part of the solution to mitigate climate change and to break the cycle of resource consumption

One of the fundamental technologies in the bio-based economy is industrial biotechnology. Industrial or white biotechnology uses enzymes and micro-organisms to make biobased products in sectors such as chemicals, food and feed, detergents, paper and pulp, textiles and bioenergy (including biofuels or biogas). Industrial biotechnology is based on renewable resources; it can save energy in production processes, and can significantly reduce CO₂ emissions.

The benefits of biotechnology are repeatedly reaffirmed by scientific studies and reports, such as the OECD's report on the application of biotechnology to industrial sustainability⁵ and, most recently, by the World Wide Fund for Nature (WWF) report on the potential of industrial biotechnology to cut CO₂ emissions and help build a greener economy⁶. The WWF report concludes that the full climate change mitigation potential of biotechnology processes and biobased products ranges from between **1 billion and 2.5 billion tons CO₂ equivalent** per year by 2030. To put this in context, this represents more than Germany's total reported emissions in 1990.

Many low-carbon technologies are already available, and future innovations offer even greater potential. Although forward-thinking companies have already discovered the potential of biotechnology to cut greenhouse gas emissions, to fully realize the potential of biotechnology it will be critical that international policy creates a supportive legislative framework. In a recent Communication⁷, the European Commission recognised industrial biotechnology as a Key Enabling Technology (KET), and believes that combining support for KETs and efforts to tackle climate change would help facilitate the financing of Europe's commitments under international climate change agreements.

Agricultural biotechnology also offers tremendous opportunities across key European public policy goals including among others improved sustainability, CO₂ mitigation and sequestration, higher resource and energy efficiency and increased productivity when compared to traditional farming practices. Biotechnology is being exploited at an accelerating rate by Europe's competitors. When allowed to flourish in the EU, it can improve environmental sustainability and competitiveness and would help to **ensure that world food production keeps up with rising demand**.

Advances in agricultural biotechnology are already providing solutions to enhance food production and lessen the impact of agriculture on the environment, including the reduction of greenhouse gases (see also our factsheet "[Green biotechnology and climate change](#)").

GM crops are able to⁸

- Increase yields by 6% - 30% on the same amount of land, thereby avoiding the need to plough up extra land;
- Result in permanent reductions in fuel use and CO₂ emissions due to less tillage; in 2007 this led to global emissions reductions of 14.2 billion kg of CO₂, equivalent to 6.3 million fewer cars on the road for one year;
- Increase the economic viability of biofuels and bio-based products by reducing production costs of raw materials;

⁴ See also the JRC "Biotech for Europe" report (2007) and the Case studies report "[The impact of industrial biotechnology applications](#)"

⁵ [The application of biotechnology to industrial sustainability – OECD \(2002\)](#)

⁶ WWF report: "[Biotechnology - More than green fuel in a dirty economy?](#)", September 2009

⁷ [Preparing for our future: Developing a common strategy for key enabling technologies in the EU](#) - SEC(2009) 1257

⁸ [ISAAA Executive Summary 2008 – page 13](#)

The development of bio-based products leads to a competitive, knowledge-based and sustainable economy

In a bio-economy, carbon is stored and recycled, resulting in much lower GHG emissions and reduced waste. There are many examples of **bio-based products** already on the market, such as biopolymer fibres for construction and household applications, biodegradable plastics, biofuels, lubricants and industrial enzymes such as those used in detergents and in the paper and food processing industries. These bio-based products are already made from agricultural and forestry feedstocks that provide a sustainable resource for manufacture. Biotechnological processes also form the basis for the manufacture of some antibiotics, vitamins, amino acids and other fine chemicals. However, significantly, recent advances in the biosciences and associated technologies are resulting in major new opportunities for farmers, foresters, commodity processors, chemical, pulp, paper and energy companies. New opportunities are also opening up for those authorities and agencies interested in the environmental and economic benefits of renewable resources for production of high-value industrial and consumer products.

To achieve a competitive, knowledge-based bio-economy in Europe

- Renewable raw materials must be available in sufficient quantity, consistent quality, diversity, and at competitive prices without the need of long-term government subsidies. Key to success is the establishment of commercially viable and robust supply chains to ensure the renewable feedstocks are both available and efficiently and cost effectively used by industry;
- The adequate renewable raw materials and appropriate conversion methods complying to the specific European possibilities and needs have to be developed and optimised,
- Adequate research should be supported in order to develop the right technologies and make them economically viable;
- An encouraging and enabling political and economical framework must be created to grow the market of bio-based products;
- Needs for information must be fulfilled in order to enable consumers to make informed choices about bio-based products.

A sustained innovation in healthcare biotech has the potential to address major societal challenges

Europe's demographics, and more specifically our ageing populations, are a major long-term challenge, where biotech innovation will play an important role. Investment in healthcare innovation will be essential in securing the economic future of Europe, by both helping to ensure an able population with a lower burden of disease and by providing a valuable, leading high tech industry sector within Europe. As highlighted in the 2007 'Competitiveness of the European biotechnology industry' report from DG Enterprise⁹, whilst the biotech sector is not, in itself, currently a major employer in Europe, the industry sectors that biotechnology feed into are very sizeable. Thus, biotechnology is a very important part of a chain of research, development and innovation activities which generate novel products or production processes in many industrial sectors. Furthermore, the jobs created within the industry are exactly those that Europe is targeting: highly skilled and high value-added.

Healthcare innovation is crucial in ensuring that Europe capitalises on its existing strength in human resources whilst at the same time improving the quality of life of EU citizens for the future.

So far, designing EU policy to foster innovation in biotechnology has not been an easy task. However, because of the uniqueness of the healthcare biotech industry, in terms of the long product development phases, the high costs of innovation, and the novelty of many of the treatments, EU and national strategies, as well as adequate patent and data exclusivity regimes, are crucial to fostering and sustaining innovation efforts.

⁹ http://ec.europa.eu/enterprise/phabiocom/docs/biotech_analysis_competitiveness.pdf

The value of an innovation in healthcare tends to be split into three categories:

1. breakthrough innovation
2. incremental innovation
3. marginally innovative and/or “me-too” innovation

However, not only breakthrough innovation is ‘real’ innovation. Innovation can also be the bringing together of many different small incremental improvements such as, in the case of healthcare biotech, the mode of application of a medicine as opposed to just the medicine itself. Such increments may ultimately be just as important for a patient. Failure to also recognize and reward incremental innovation will undermine a vital part of the innovation process.

Today, many EU Member States have established health technology assessment (HTA) systems to systematically determine the relative “value for money” provided by new technologies – including biotech medicines – to, ultimately, support decision-makers in their coverage, pricing and reimbursement decisions. These HTA systems give providers and patients information with which to make treatment choices and have the positive effect of encouraging the efficient and effective use of health technologies and of supporting innovation by identifying and rewarding high-value products.

However, HTA evaluations have a potentially critical impact on patient access and on the rate of innovation by its misuse as a tool of cost-containment/rationing policies in healthcare. Awards for innovation should be appropriately and fairly granted based on holistic assessments of new and existing technologies. Such assessment should recognise key elements such as value to society and economy, ethical views of disease management, impact on productivity and quality of life, value not only to patients but also families, caregivers and employers. Current EU efforts to provide a common methodological framework to HTA systems such as the Joint Action on HTA should be given the right consideration and further integrated into a wider EU innovation policy to ensure consistency of approaches.

Fully exploiting the single market

In the area of healthcare, competence lies at Member State level. Nevertheless, the EU can contribute towards encouraging the development and implementation of innovation-friendly procurement practices. Today, within Europe, the market for biotech medicines is highly fragmented. National demand for medicinal products is affected by the size of the country, per capita expenditure on pharmaceutical products and the public procurement regime. Strong commitments by governments to purchase innovative biotech medicines can provide incentives for companies to continue and/or increase their innovation efforts.

In recognising the competence of Member States to manage their own healthcare system budget, the European Commission needs to further encourage the development and implementation of procurement practices which spur innovation. This can be achieved by promoting procurement practices based on three pillars:

- (i) identifying what patients need through involvement of all relevant stakeholders (e.g. patients, clinicians);
- (ii) developing and implementing innovation-friendly criteria (e.g. focus on the outcomes of the innovation process, not the process itself); and
- (iii) ensuring competition throughout the entire procurement process (including through incentives to increase the number of potential suppliers).

By being more demanding on the innovative nature of their healthcare purchases, national governments will not only get higher value for their investments but they will also indirectly foster innovation and, at the same time, greatly improve their patients’ outcomes through access to highly innovative therapeutic solutions.

SMEs are the backbone of European business and innovation

In the EU, SMEs comprise approximately 99% of all firms and employ about 75 million people. Globally, SMEs account for 40% to 50% of GDP. Biotech SMEs are knowledge-based enterprises and provide the high value-added jobs that will help the EU achieve its goal of becoming the foremost knowledge-based economy in the world. At the same time, some of the best innovation happens in SMEs and these companies form what is described as a symbiotic relationship with large, multi-national companies across the healthcare, energy and agricultural sectors, paving the way for improved healthcare, clean energy and sustainable farming for Europe's citizens.

Therefore, special attention to the needs of the SMEs is vital in any forward-looking strategy. For biotechnology SMEs, specifically, there is a need to attract more venture capital, to work towards making the European Research Area a reality, and for commitment of funding at an EU level. In addition, it will be essential to ensure that the process of applying for funding under FP7 and structural funds becomes simpler, faster and less resource intensive. This is particularly critical for the biotech industry for two reasons:

- (i) Biotechnology innovation involves high-cost, high-risk long term investment. As a result many biotech companies remain non-profit for quite some time – in fact, today, around 87% of biotech SMEs worldwide are in the pre-profit phase as a natural consequence of their business model. This means that they are often perceived as being too high-risk for external investment or that they simply cannot fulfil the criteria to sign financing contracts offered through various funds.
- (ii) A significant amount of innovation in the biotech sector results from the work of SMEs (EuropaBio counts 1800 SMEs amongst its members through 26 national associations.). Many of these organisations are micro-enterprises consisting of 10 or fewer employees and the administrative burden of participation is therefore often beyond their capacity.

Setting EU 2020 in a global context

A growing market for sustainable biotech products benefits the agricultural, rural and healthcare economies, and will create new skilled and green jobs

The production of bio-based products via integrated biorefineries has tremendous potential to improve industrial processes with sustainable benefits for society, the environment, and the economy. In addition, it also has a specific impact on agriculture, including the forestry sector. It can, for example:

- Make agriculture more competitive and sustainable by creating new non-food markets for crops and by providing a diversified local supply of renewable raw materials for the biobased economy;
- Contribute to rural development by providing alternative economies for farmers, e.g. by providing diversified supplies of renewable raw materials for the bioeconomy;
- Create extra income for farmers by creating value in local agricultural waste.

Bio-based products can help industry to increase its economic and environmental efficiency (eco-efficiency), while maintaining or improving competitive advantage and creating new jobs and wealth.

In additions, biotech medicines are estimated to account for more than 20% of all marketed medicines and about half of all medicines in the pipeline. This proportion grows when it comes to the most innovative treatments such as growth hormones, recombinant growth factors, vaccines, monoclonal antibodies for the treatment of cancers, inflammatory and infectious diseases and cell

therapy. In addition, the OECD reports that by 2015 healthcare biotechnological knowledge will be used in the discovery and development process for **all** new pharmaceuticals¹⁰.

For example, it is estimated that, thanks to the incentives provided by the 2000 EU Regulation on orphan medicinal products¹¹, employment in all departments working on orphan drugs increased by 158 % between 2000 and 2008¹².

Existing isolated policy supporting the bio-economy and innovation which could be further integrated include initiatives by

- **DG RTD:** Research in the area of industrial biotechnology and bio-based products is promoted and financed in Europe via the Commission's Framework Programme 7 (e.g. the KBBE-related calls¹³) and Member State initiatives (often collaborating via ERA-nets). Several Technology Platforms (such as SusChem) have developed over the last few years a strategic research agenda, and are now joining forces in the area of biorefineries¹⁴.
- **DG ENT (Policy Unit):** The Commission published an action plan on Key Enabling Technologies (KETs)¹⁵, as part of the preparation for the new European plan for innovation. KETs are knowledge intensive and associated with high R&D intensity, rapid innovation cycles, high capital expenditure and highly-skilled employment. KETs are of systemic relevance as they enable the restructuring of industrial processes needed to modernise EU industry and secure the research, development and innovation base in Europe. Mastering these technologies means being at the forefront of managing the shift to a low carbon, knowledge-based economy, and is vital if the EU is to address challenges such as climate change. Industrial biotechnology is one of the five technologies selected by the Commission. The purpose is to develop an action plan with measures to remove obstacles hindering the further development and to fully exploit the results of research (such as demo projects, and better coordination of the activities between EU and Member States for example through joint calls or joint programming).
- **DG ENT (Biotechnology Unit):** The European Commission's **Lead Market Initiative**¹⁶ aims to facilitate an early adoption of technological innovation on various markets. By removing barriers and introducing new ideas to facilitate market entry, it will be possible to build early markets of sufficient scale that help to justify costly investments, bring down unit production costs, generate higher returns on investment, and reduce risks for investors and entrepreneurs. In the case of bio-based products, research and innovation have reached a stage where products are ready for market introduction. However, renewable raw materials are only used in certain product categories and mostly manufactured in small volumes. An Ad-hoc Advisory group has developed a series of concrete recommendations and actions, ranging from improving the implementation of the present targets for bio-based products over standardisation, labelling and certification to ensure the quality and consumer information on the new products.

Furthermore, in 2002, in the context of the Lisbon growth and jobs strategy, the Commission drew up a strategic vision for life sciences and biotechnology up to 2010. It outlines 30 Actions, including both general actions around the strengthening of a broad education and understanding of life sciences, and the development and training of a skilled workforce in life sciences, as well as specific actions on biotech medicines and GMOs. The 2007 Mid-Term Review re-emphasised that whilst some Actions have been addressed, others still need further attention, not least at Member State level.

¹⁰ The Bioeconomy to 2030: designing a policy agenda. OECD. 2009

¹¹ Regulation (EC) No 141/2000 - http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2000_141/reg_2000_141_en.pdf

¹² Office of Health Economics – unpublished data

¹³ http://cordis.europa.eu/fp7/kbbe/home_en.html

¹⁴ <http://www.star-colibri.eu/>

¹⁵ COM(2009) 512/3 : "Preparing for our future: Developing a common strategy for key enabling technologies in the EU",

¹⁶ http://ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/biobased-products/index_en.htm

As the timeframe of the present Strategy expires in 2010, a second Strategy is due to be launched for 2011. EuropaBio would therefore strongly recommend ensuring a close synergy between the 2nd EU Life Science and Biotechnology Strategy and the 'EU 2020 Strategy' in terms of actions and goals, and that key learnings from the first EU Life Science and Biotechnology Strategy are taken into consideration when shaping the 'EU 2020 Strategy'.

“Creating a competitive, connected and greener economy”

Europe needs to develop an integrated policy and strategy to support the development of a competitive and sustainable bio-economy by 2020

The development of a bio-economy is fully aligned with the strategic aims of the European Recovery Plan¹⁷ to support innovation, build a knowledge-based economy and to speed up the shift towards a low carbon economy. But in order to develop a sustainable and competitive bio-economy in Europe, and to utilize the full potential of Europe's resources and academic and industrial capabilities, there is a need for an integrated, holistic approach by the Commission and the Member States. Europe is at the forefront of this field which should enable us to develop and implement a clear strategy for the deployment of a world leading bio-economy by 2020, where renewable resources will be used not only for energy and biofuels but also for the chemicals and materials industry, and where innovative healthcare biotech products will be accessible in a timely manner.

Furthermore, an integrated holistic approach by the European Commission and the Member States is needed because a successful bio-economy would need a supportive policy framework in numerous areas. This includes the sectors of climate change, energy security, renewable feedstock supplies, research and innovation, healthcare, agriculture, the environment and trade.

An integrated strategy for a bio-based economy should be pragmatic, long-term and offer real partnerships between businesses – including the agricultural and forestry sectors, the pharmaceutical industry, civil society including patient advocacy groups, national governments, the scientific community and consumers within the EU as well as between the EU and less industrialised nations.

Key elements of such a strategy are:

- Targeted research, training and innovation programmes with clear objectives (e.g. bio refineries);
- Development of technology, and bridge building between research and market (hence shortening time to market);
- Fair reward system such as patents and data exclusivity regimes, supporting innovation and encouraging more investments into biotechnological research and development;
- Stimulating market demand and market development of bio-based products;
- Improving and securing access to renewable raw material for industrial use (future agricultural policy);
- Clear and transparent multilateral frameworks on sustainability for all stakeholders concerned;
- Supporting SMEs in their efforts to innovate;
- Listening to, and supporting more vocally. European farmers to help them benefit from the economic and environmental advantages of green biotechnology;
- Publicly acknowledging agricultural biotechnology as a key tool in the challenge to respond to the growing demand for food without compromising on environmental standards;
- Proposing draft decisions for the placing on the market of biotech products in a timely manner as required by EU legislation;
- Nurturing and promoting coherent pro-growth and predevelopment policies that do not discriminate against these promising technologies;

¹⁷ http://ec.europa.eu/commission_barroso/president/pdf/Comm_20081126.pdf

- Contributing more effectively toward informing citizens about the technology, its safety, its advantages and the existing regulatory framework;

Therefore a fully harmonised strategy is required in order for all biotech products – and by extension the bio-economy – to develop in a sustainable manner with a strong focus on economic, ecological and social opportunities.

EuropaBio is the European Association for Bioindustries. EuropaBio's mission is to promote an innovative and dynamic biotechnology-based industry in Europe. EuropaBio has 69 corporate and 8 associate members operating worldwide, 4 Bioregions and 26 national biotechnology associations representing some 1800 small and medium sized enterprises. Members of EuropaBio are involved in research, development, testing, manufacturing and commercialisation of biotechnology products and processes. Our corporate members have a wide range of activities: human and animal health care, diagnostics, bio-informatics, chemicals, crop protection, agriculture, food and environmental products and services.

For more information on EuropaBio: www.europabio.org

For more information on the bio-based economy: www.bio-economy.net