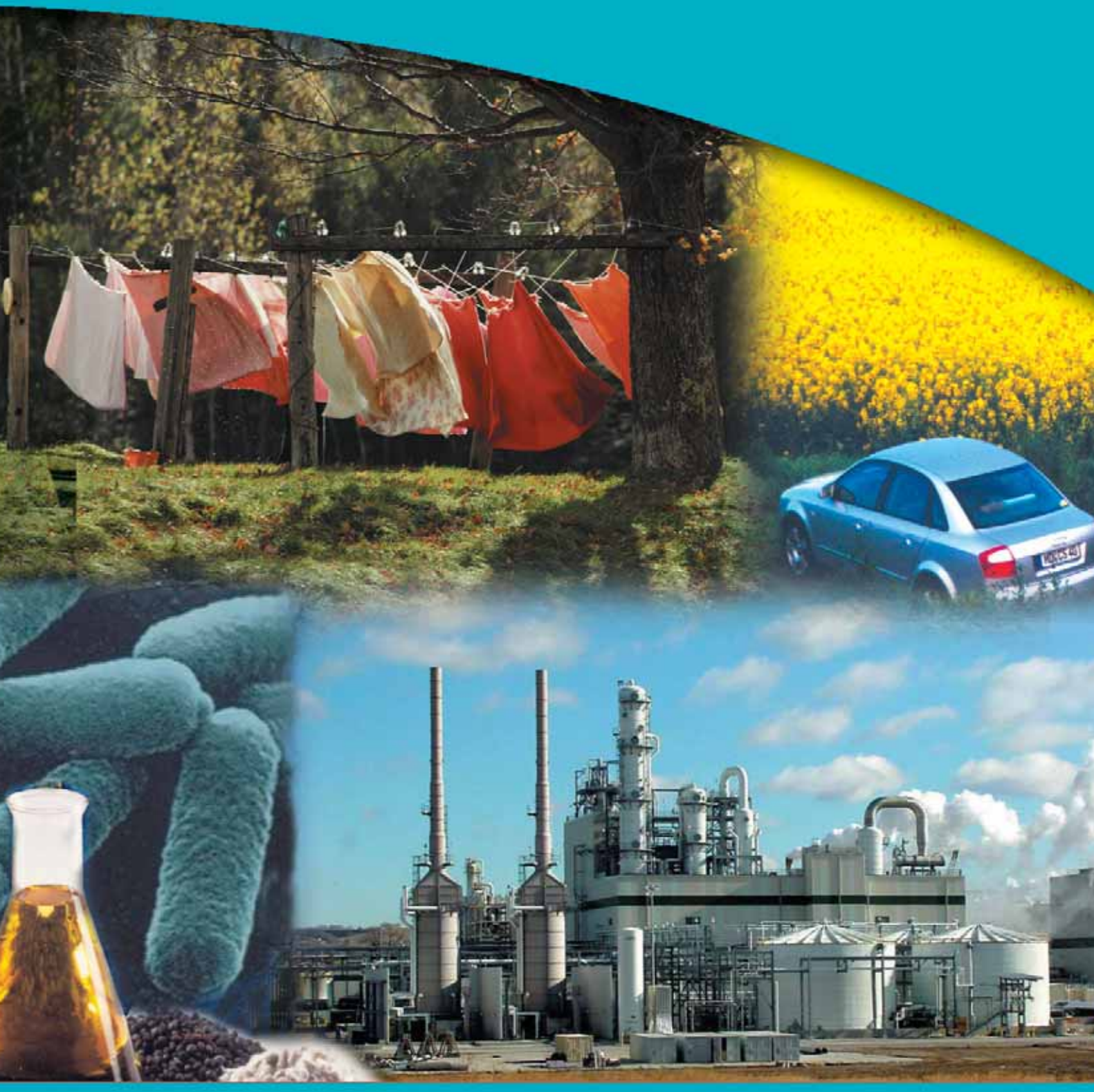
Industrial or White Biotechnology

A Policy Agenda for Europe



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EuropaBio, the European Association for Bioindustries, represents more than 100 corporate and associate members operating worldwide, and 24 national biotechnology associations. Through our associations EuropaBio is also the voice of 1800 small and medium-sized enterprises involved in research, development, testing, manufacturing and commercialization of biotechnology applications. Our corporate members are involved in a wide range of activities: human and animal health care, diagnostics, bio-informatics, chemicals, biofuels, crop protection, agriculture, food and environmental products and services. EuropaBio's main mission is to promote an innovative and dynamic biotechnology based industry in Europe.

ESAB, the European Federation of Biotechnology Section on Applied Biocatalysis, is promoting the development of Applied Biocatalysis - the development through science and engineering of useful biological catalysts and their commercial applications - throughout Europe. The aims of this Section are to take initiatives in areas of growing scientific and industrial interest and importance in the field of applied biocatalysis, and to identify key topics which may be rate-limiting in the development of scientific progress and technological prospects in applied biocatalysis and to take steps to stimulate these areas.

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FOREWORD

Knowledge-Based Bio-Economy a Policy Priority for the EU

Mr. Mauri Pekkarinen
Minister of Trade and Industry, Finland
President of the Competitiveness Council in autumn 2006

The EU is committed through the Lisbon Strategy for Growth and Jobs to a knowledge based and eco-efficient industrial future and consequently to policies conducive to innovation. Industrial biotechnology offers a number of very promising perspectives in form of new products and processes. Equally, new biotechnology based solutions to growing energy and environment policy challenges are most welcome.

Next generations of European citizens will wonder why an integrated use of raw materials, such as biorefinery technology, was not made use of earlier. We need next generation biotechnologies that are based on what we understand today but go much further in efficiency. That alone is a major challenge and an enhanced inter-disciplinary R&D is one of the tools.

We also need next generation policy frameworks. More policy coherence is needed. Government and industry need to work together. Citizens have a right to know the policy premises and their concerns for safety and sustainability will have to be met. Better tools to analyze the energy balance and environmental footprint of products and processes over their life cycle are essential.

This document prepared by EuropaBio offers very useful policy advice with regard to a number of these challenges. I am sure that the document will give EU policy-makers a lot of inspiration when contemplating future measures. The document also demonstrates the value of Technology Platforms which bring together various industrial actors.

Finland gives high priority to innovation, development of renewable energy and consistent policy design. These have also been priorities during the Finnish EU Presidency in autumn 2006. A number of actions such as conferences have been organized together with the European Commission and industry. I welcome the next Presidencies to carry on with this work. The challenge to improve policy co-ordination between various initiatives is a major one. New types of forward planning between the Commission and the Presidency are needed. EuropaBio should be commended for making this point.

Although conditions differ within the EU, the policy measures proposed in the document are applicable in all the Member States. In Finland, we attach particular attention to forest based raw materials as well as pulp and paper industry. Fields and oceans and chemical industry are more important for others. Still, there is a lot of room for co-operation and best practice exchange on all aspects of the knowledge-based bio-economy.

With the common goal in mind and with joint policy efforts, the European knowledge-based bio-economy has every opportunity to emerge to a leading position.

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Executive summary

Industrial or white biotechnology has the potential to form the basis of a future EU knowledge-based bioeconomy and make European society both more sustainable and more competitive. But to realise the potential, a number of policy steps must be taken. This report puts forward concrete policy proposals to encourage the development of a Knowledge-Based Bio-Economy (KBBE).

Of primary importance is the need **to develop policy coherently across the EU**, and to coordinate its implementation. There are many policy strands and activities which relate to biotechnology – biofuels, research and innovation, climate change, sustainable development, CAP reform, ETAP etc – and they must be harmonised for consistency and efficiency. Appointment of a KBBE coordinator by the Commission to bring together activities in the various DGs is essential. At the same time, a KBBE task force is needed to coordinate Member State programmes.

It is equally important that the policy should be based on sound evidence. This makes **data gathering, collation and analysis** the task which underpins the whole process: good policy cannot be formulated without good data. At the other end of the policy making process, **a comprehensive roadmap is needed** to chart the way towards the bio-based economy and allow both coherent implementation and good impact evaluation.

With the enabling policy framework in place, full support then has to be given to **innovation in biotechnology** in general, and white biotechnology in particular. This is a research-driven activity, and Europe must build upon its undoubted strengths in the area. This means in particular ensuring that the various relevant Strategic Research Agendas from the KBBE related Technology Platforms (particularly Sustainable Chemistry, Plants for the Future, Forestry and Biofuels) are properly planned, funded and implemented within the Framework 7 programme and at Member State level via for instance ERA-Net.

Within this context, it is important to foster the synergies between the various participating sectors, for example by stimulating public-private partnership and industry participation in general, promoting inter-disciplinary research and striving to avoid fragmentation and even duplication of programmes. This cooperation must also extend downstream to demonstration projects, in particular to enable the development of **flexible, research-oriented pilot plants to validate the concept of integrated and diversified bio-refineries**. Appropriate funding schemes will be needed to allow multi-company consortia to collaborate in such pre-competitive activities ("first of a kind" biorefineries).

Moving beyond the research phase, there are practical steps which can be taken to facilitate the move towards bio-processing in manufacturing. A necessary prerequisite is the assurance of **a secure and affordable supply of biomass**, for which a combination of policy, innovation and financial incentives will be needed.

With the supply of feedstock assured, the **conversion of existing industrial processes to bio-based ones** can be encouraged via streamlined regulatory processes (akin to the "fast track" system used by the American EPA), assessing the opportunities for biobased processes and products to contribute and benefit from the EU's Climate Change Policy, and providing market-based mechanisms to overcome investment hurdles. This manufacturing push can be further enhanced via market pull effects. Demand can be raised in a number of ways: for example by setting appropriate **public-sector procurement standards, short-term positive price discrimination or promotional labelling** (eg "bio-based").

While all these actions will have a positive effect, they will be more effective if supported by **a coherent communications plan to raise awareness** of the potential of industrial biotechnology, the use of renewable resources and the benefits the Knowledge-Based Bio-Economy will bring. The plan should take account of all major stakeholders, including industry, policy makers, consumers, farmers and the investment community, but early stage ("upstream") open engagement with the general public is particularly important.

Smaller companies make up an important part of this relatively young biotechnology sector, and it is they who will provide much of the necessary innovation. Because of their early stage of development, there are a number of hurdles they find more difficult to overcome than larger companies do. SMEs need help in particular to **reduce the cost of Intellectual Property protection**. Ultimately, a single European Community patent will provide the answer, but in the meantime a specific SME application process is needed at the EPO. Early stage search costs could also be reduced by introducing a searchable database flagged for industrial biotechnology applications.

While intellectual property forms the basis of innovation, finance is needed to derive value from it. "Proof of concept" work is often funded by grants for start-up companies, and SMEs could benefit from a similar grant system for work on environmentally friendly technologies.

More generally, **greater awareness of the potential of the industrial biotechnology sector is needed among the investment community** in order for funds to be made available more easily. The necessary communications programme is a vital part of the overall stakeholder outreach effort. But this in itself will not be sufficient. Because of the particular difficulties of raising capital for SMEs, **a new investment model** will be needed which sits between loans and conventional private equity, to provide finance along with equitable risk sharing. As the industrial biotechnology sector becomes increasingly successful, venture capital will become more available.

In conclusion, to establish a sustainable and knowledge-based bioeconomy in Europe, efforts are needed:

- To establish a coherent European Policy Agenda for Industrial Biotechnology and the Knowledge-based Bioeconomy (KBBE),
- To stimulate and support innovation in plant science and industrial biotechnology,
- To promote production and use of bio-based products and processes,
- To create awareness amongst all stakeholders, and
- To improve investment in KBBE-related SMEs

1. Biotechnology: Key to the Knowledge-Based Economy in Europe

The introduction of new key technologies has fundamentally changed societies. The enormous impact of inventions like steam power, the internal combustion engine and mains electricity is well known. Information technology (IT) and biotechnology are the two most recent waves of innovation which are reshaping the way we live. Unfortunately, Europe allowed other regions to take the lead and initiative in IT. Biotechnology, probably more than any other technology, offers full or partial solutions to major societal problems like healthcare, environmental degradation, food security and safety, and energy supply. Biotechnology has the potential both to allow truly sustainable development and contribute to value creation in all sectors of society.

The European Union is at a crucial stage of development. It is committed to becoming a globally-competitive knowledge-based economy, while also moving towards a more sustainable model for industry. It has also recently undergone a period of major enlargement – from 15 to 25 Member States – and significant reforms are in the air, including for the Common Agricultural Policy. Against this backdrop of challenge and change, biotechnology is set to play an important part in the future success of the European economy and society generally.

Biotechnology is indeed in the vanguard of industrial development. It has a unique capacity to enable the European economy to contribute to the key policy objectives of increasing competitiveness, employment and sustainable development. In 2005, the European Commission reinvigorated the Lisbon Strategy[1] aimed at making Europe an attractive place for industrial development, creating jobs and a clean environment via a competitive, knowledge-based economy. It is an ongoing process aimed at securing Europe's future as a high productivity, high value-added, high employment and eco-efficient economy. To achieve these goals, a series of interconnected reform policies is being implemented within a wider macroeconomic framework supporting growth, demand and employment.

2. Industrial Biotechnology: a cornerstone of the Knowledge-Based Bioeconomy

The bio-based economy is a term encompassing a future society no longer wholly dependent on fossil fuels for energy and industrial raw materials. Currently, most of our power comes from burning coal, oil or gas: once extracted and used, we have to find and exploit new resources. We don't know when they will begin to run out, but as demand increases rising prices are focusing attention on alternatives. It is crucial for industries to secure abundant, competitively priced and stable resources. And natural renewable resources constitute an interesting and reliable set of feedstocks.

Bio-fuels made directly from agricultural crops, are becoming increasingly competitive with conventional fuels, and provide at minimum a sustainable fuel supply until hydrogen generated using non-fossil fuels becomes a viable alternative. But a lot of fossil fuels are actually used as industrial feedstocks, to produce for instance chemicals and plastics. A large part of this use could, over time, be replaced by biomass – sugar and starch, straw, or even agricultural waste – fermented and converted to a vast range of materials using enzymes or micro-organisms developed specially for the task. And for this we need Industrial Biotechnology …

Industrial Biotechnology, in Europe also known as White Biotechnology, is the modern use and application of biotechnology for the sustainable processing and production of chemicals, materials and fuels. Biotechnological processing uses enzymes, micro-organisms and plants to make products in a wide range of industrial sectors including chemicals, pharmaceuticals, food and feed, paper and

pulp, textiles, energy, materials and polymers. Mankind has already benefited from biotech for a long time, but with the evolution of new technologies and a much deeper understanding of cell metabolism and materials science, many new opportunities have been identified, and others are continuing to emerge.

A renewed interest in the sustainability of industrial processes has also contributed to biotechnology's attractiveness. All major facets of European society and economic activity, including agriculture, environmental protection and manufacturing industry, are being challenged to demonstrate their sustainability. Industrial Biotechnology can make a major contribution. It can, for example:

- make agriculture[2] more competitive and sustainable by creating new non-food markets for crops;
- improve the quality of life of European citizens while reducing environmental impact by developing innovative products at affordable costs; and
- help industry increase its economic and environmental efficiency (eco-efficiency) and sustainability, while maintaining or improving its competitive advantage and ability to generate growth.

There are many examples of products already on the market, such as biopolymer fibres for household applications (e.g. carpeting), biodegradable plastics made from corn, biofuels, lubricants and industrial enzymes used in detergents and in the paper and food processing industries. Biotechnology also forms the basis for the manufacture of some antibiotics, vitamins, amino acids and other fine chemicals. European companies are world leaders in a number of Industrial Biotechnology sectors. For example, they lead the development and production of industrial enzymes. Some of these enzymes are used in detergents, allowing lower washing temperatures and reducing the consumption of water and energy, and others are creating new opportunities for the production of fine chemicals via biotechnological processes. Other examples include using plant-based renewable resources to produce biofuels such as bioethanol or biogas, which helps to reduce carbon emissions from the transport sector.

3. The overall impact of Industrial Biotechnology

The Lisbon Strategy for Growth and Employment Report from the High Level Group chaired by Wim Kok[3] identified promotion of eco-efficient innovations, such as those derived from Industrial Biotechnology, as a win-win opportunity that should be fully exploited in order to reach the Lisbon goals. By bringing together academia, industry and other stakeholders, the emerging research opportunities can be effectively exploited to address social, environmental and economic challenges. In key eco-industrial markets Europe can build on home-grown innovations that can lead to reduced pollution, less resource-intensive products and more efficiently managed resources. These technologies will meet the growing public demand for sustainable production and use of renewable resources.

Biotechnology in general, and Industrial Biotechnology more specifically, has tremendous potential to improve industrial production along all dimensions of sustainable development: Society, the Environment, and the Economy[4,5]. It has also a specific impact on agriculture.

- **Impact on Society**
  As White Biotechnology makes industry more sustainable, it is expected that the benefits will be seen across a range of critical social dimensions: creation of knowledge driven and attractive jobs, development of new technology platforms as a basis for innovation, and a reduction of society's dependence on valuable fossil resources, thus conserving them for future generations.

- **Impact on the Environment**
  We have a responsibility to leave a clean and productive environment and healthy eco-systems for future generations.

Biotechnology offers new ways to improve the environmental performance of industrial processes in various sectors. It can contribute to reducing energy consumption and waste and to achieving sustainable industrial and societal development. Biomass can be exploited as a novel feedstock for efficient conversion into high added-value products such as complex intermediates for the pharmaceutical industry. Industrial biotechnology can maximise the economic value of current waste and by-product streams through new and potentially energy-saving bio-processes, at the same time reducing net carbon emissions. The wide production and use of bioproducts can therefore make a considerable impact on industry's GHG emissions. Biotechnology also has the potential to detect, monitor, prevent, treat and remove pollution.

In addition, more local integrated biorefineries using the by-products and residues or wastes from agriculture and other industries, such as food industry, for production of biochemicals, biomaterials and/or biofuels, could result in an additional benefit for the environment and reduce the emission of greenhouse gases. As the distance between producers and consumers is reduced, also the needs for transportation of raw materials should decrease compared to current long-distance transportation of fossil fuels.

- **Impact on the Economy**

In parallel, the economy will benefit as biotechnology enables the introduction of more efficient, less energy-intensive processes. Already, fermentation and enzymatic processes are commonly used in the fine chemicals sector, to produce for example vitamins, pharmaceutical intermediates and flavours. They are also making their first inroads into larger volume segments such as polymers, bulk chemicals and bio-fuels, and many other industrial sectors.
Some recent reports (such as those by BCC Inc[6] and Freedonia[7]) predict annual growth rates of nearly 5% for fermentation products (compared to 2-3% for overall chemical production) in the coming years, while others (such as the one by McKinsey & Company[8]) predict that by 2010 biobased products (products made from biobased feedstocks or through fermentation or enzymatic conversion) will account for 10 percent of sales within the chemical industry, accounting for $125 billion in value. Although numbers may differ, all studies agree that industrial biotechnology will play an increasingly significant role in the chemical and other manufacturing industries in the future.

- **Impact on Agriculture**

All major facets of European society and economic activity - including agriculture - are being challenged to demonstrate their sustainability. Industrial Biotechnology can make a major contribution by for example make agriculture more competitive and sustainable by creating new non-food markets for crops. The farmland of the future could produce not only sufficient food and feed as it does currently, but also chemicals, industrial raw materials and fuels. Over time, this could transform the farming and rural economies.

A recent OECD report[9] came to the conclusion that plant and animal wastes could become viable alternatives to fossil fuels as raw materials. As the Industrial Biotechnology sector grows, increasing amounts of biomass will be needed as a fermentation source, and more sophisticated technologies will be developed to handle materials such as straw and other agricultural residues, which are currently largely wasted. At the same time, novel crops may be grown to supply bio-refineries with feedstocks to produce new and value-added products. Such developments will clearly, over time, have the potential to make the best use of the crops we grow, and to utilise all the agricultural waste which currently has no economic value. This could transform the lives of farmers by making their businesses more profitable and creating new opportunities, while reducing dependency on subsidies.

The other transforming factor will be the need to site bio-refineries in rural areas, to avoid transporting bulky agricultural products long distances. This would not only improve the economics of the biological production processes by providing raw materials at lowest cost, but also provide much-needed jobs in a generally depressed rural economy.

Further technical advances in industrial biotechnology will make important contributions to the formulation and implementation of Community policies and legislative projects by addressing socio-economic, agronomic, environmental and consumer issues. Creating industrial demand for agricultural biomass as a feedstock will facilitate the ongoing reform of the Common Agriculture Policy (CAP). In the future, and especially for non-food uses, Green Biotechnology could make a substantial contribution to the efficient production of agricultural raw materials such as cereals which, in contrast to oil, have become cheaper as farming yields have increased. New safe, affordable, eco-efficient and competitive products from agricultural resources (including aquaculture and forestry) will enhance the opportunities for rural economies to deliver on the EU's sustainable development objectives.

Application of biotechnologies throughout the supply chain will make it easier to achieve the full potential of the bio-refinery approach to make industrial sectors such as transport, energy and chemistry more sustainable. Biotechnology can also play a considerable role in enabling developing countries and emerging economies to reach certain Millennium Development Goals (MDGs) such as "ensuring environmental sustainability" and "developing a global partnership for development". There will also be new possibilities to fulfil the EU's international commitments on security and safety of food and drinking water, global spread of diseases, equitable use of biodiversity, and poverty reduction.

4. Opportunities for Industrial Biotechnology in Europe

The first applications of Industrial Biotechnology in the largest volume segments – polymers, bulk chemicals and bio-fuels – have already been commercialised. However, in these largely cost-driven segments, the future commercial success of bio-products and -processes depends on scientific, technological and environmental innovation and on a supportive regulatory framework. Nevertheless, Europe is currently well placed to develop good products for the market, building on its established strengths:

- Europe has a solid chemical and biotechnology industry infrastructure and knowledge base;
- Europe is still the world leader in key industrial biotechnologies such as enzyme technologies, and both small- and large-scale fermentation. The key enzyme-business players are heavily concentrated in Europe;
- Europe is very strong in the development and production of bio-specialities (such as food ingredients, pharmaceuticals, and fine chemicals);
- Renewable raw materials are widely available in Europe;
- Europe has an essentially high performance education system which provides an extremely highly skilled workforce for the biotech sector.

Several political achievements are already paying off and, together with a societal consensus on the importance of environmental issues, will further drive the development of industrial biotechnology in the near future:

- Research policy in Europe is delivering scientists who are currently leaders in the field of Industrial Biotechnology;
- The recent expansion of the EU provides a large increase in agricultural biomass suitable as an industrial raw material;
- Established Industrial Biotechnology products (such as detergent enzymes, vitamins, antibiotics, bioplastics, etc.) have been generally accepted and welcomed by society;

- Emerging public-private partnerships exist in almost all European Member States. Bringing together these partnerships via the Technology Platforms, Framework Programme 7, and the ERA-Net will be key to Europe's success in Industrial Biotechnology;
- Last but not least, Europe has a real culture of respect for sustainable development, and the political concept of sustainable development is more advanced in Europe than elsewhere

Industrial Biotechnology could become an important cornerstone for both industry and transport in efforts to achieve current and future greenhouse gas reductions. The first reduction period of the Kyoto Protocol ending by 2012 may be followed by future post-2012 strategies and targets which may be even more challenging with respect to reductions in global emissions. These targets may be reached partly by continuous improvements, but will also require some technology shifts.

5. Towards a European policy for Industrial Biotechnology and the Knowledge-Based Bioeconomy

Policy plays an important role in the development of many new technologies and policy measures are seen as a way innovation can be driven in a direction to benefit society as a whole, by maximising social, environmental and economic goods. The Commission, Council and Member States should devise a clear political strategy to promote the development and adoption of eco-innovations which support business growth and competitiveness. There is an urgent need for policy support to build and develop a European Knowledge-Based Bio-Economy (KBBE), as envisaged in the Lisbon agenda. The Environmental Technology Action Plan (ETAP)[10] has identified several market barriers which need to be overcome if Europe is to fully tap the potential of eco-efficient innovations. Member States have produced national roadmaps for the implementation of concrete measures and deadlines within the ETAP, in particular the research dimension (particularly Technology Platforms) and support for SMEs in general and Young Innovative Companies in particular (encouraging investment).

The development and implementation of a properly-functioning, science-based regulatory framework is essential to foster widespread and effective market take-up of biotechnology applications. This also requires political incentives to encourage investors and consumers to participate, without creating unnecessary burdens on industry.

Even more pressing for companies active in the field of biotechnology-based innovations is limited access to finance. At present, investments in environmental technologies carry relatively high risks for investors since payback times are long. However, we should remember the simple fact that investment money flows where reasonable returns can be expected. Therefore clear, science-based regulations are essential to reduce uncertainty for investors.

Industrial applications of advances in biotechnology touch almost the whole of society through their influence on the food chain, renewable energy, environmental improvement and sustainable development. Biotech has already started to make what will be a major contribution to building a sustainable, post-fossil resource industrial society. It will continue to shape our future society for decades to come. It will also contribute in a major way to Europe's food and energy security, in an environmentally sustainable way. The scope of future legislation has to take into account the potential economic consequences of Industrial Biotechnology across the many industrial sectors where it can play a role. Biotech innovation in one industrial sector can often have positive spill-over effects in other sectors. Novel – even revolutionary – products and processing will lead to long-term and sustained improvements in productivity. These spill-over effects of biotechnology innovation pose both challenges and opportunities for other sectors of manufacturing. Because of its interdisciplinary scope, the EU could benefit from appointing a 'KBBE coordinator' who would ensure a coherent policy for IB across all relevant sectors.

6. Concrete policy recommendations to implement the Knowledge-Based Bioeconomy in Europe

6.1 Establish a coherent European Policy Agenda for Industrial Biotechnology and the Knowledge-Based Bioeconomy (KBBE)

Today, we see many political, environmental and scientific initiatives in Europe where industrial biotechnology is involved, but in an uncoordinated way (environmental technologies and innovation programmes such as ETAP[11], different Technology Platforms[12], Framework Programme 7[13], the EU strategy for Biofuels[14] and the Biomass Action Plan[15], European Strategy for Life Sciences and Biotechnology[16], CAP reform[17], strategy on Climate Change[18], waste management[19], Sustainable Development strategy[20], etc.). If European and national authorities want to develop a competitive and sustainable IB industry and bio-based economy in Europe, we need real integration and coordination of these existing individual policies.

To achieve this, a specific coordinating office at EC and EU Presidency level should be established – with representatives from different DGs and Ministries such as industry/competitiveness, innovation/research, agriculture, environment, energy, etc. - to develop and coordinate the implementation of the "knowledge-based bio-economy" at European and Member State level.

There is also a need for long-term policy and regulatory certainty to support the continuous development of IB as a clean and sustainable technology. Harmonisation of regulatory policy and coordination focussed on Industrial Biotechnology and the KBBE is necessary between Member States and at the EU level. However, beyond a harmonised implementation of EU initiatives, there should be some space for Member States to "compete" to be the major supporter of Industrial Biotechnology and the bio-based economy. This could stimulate other Member States to develop additional initiatives.

Finally, coherent and evidence-based regulations and policy measures are at the heart of responsible development of industrial biotechnology. This requires a shared vision on future developments and a long term, detailed strategy to achieve that vision. Currently dispersed data needs to be compiled and additional data generated to facilitate a comprehensive assessment of the long term effects of the move towards bio-based products. This should include assessing potential impacts on the environment and land use, employment, occupational safety and mobility, and economic competitiveness, in comparison with existing products and processes.

Recommendations:

- Development of a coherent policy, and coordination of its implementation:
  - At EC level, nominate a "KBBE Coordinator" of all competencies involved in implementing KBBE (Research, Agriculture, Environment, Energy, etc.)
  - At Presidency and Member State level, set up a KBBE task force
  - Ensure consistency and certainty among current EU policies and strategies involved (KBBE, Biofuels, EU Climate Change Policy, GM food/feed regulation, Sustainable development, Eco-innovation and ETAP, etc.)

- Coherent, evidence-based policy development:
  - Collect and provide sufficient data to help decision makers and other stakeholders making realistic decisions, evidence-based regulations, strategy building and long-term planning
  - Develop a comprehensive roadmap towards the bio-based economy for coherent implementation and impact evaluation

6.2 Stimulate and support innovation in plant science and Industrial Biotechnology

6.2.1. Long-term planning and continuity of research funding

Industrial biotechnology is a relatively new discipline and therefore immature: there are major areas of knowledge still to be explored. This presents a bottleneck to greater exploitation, but also offers tremendous opportunities for further research and break-through innovation. Both basic and applied sciences are essential: basic to develop our fundamental knowledge base, and applied to introduce innovative products and processes based on this knowledge. If White Biotechnology is to fulfil its promised contribution to Europe's future global competitiveness and industrial sustainability, the commitment to underpinning R&D in all relevant science fields must be long-term and guaranteed. Scientific expertise has to be built up and nurtured; it cannot be turned on and off at will.

To define the content, a clear link has to be made with the activities of the SusChem Technology Platform. In 2004, the European Technology Platform for Sustainable Chemistry (SusChem) was set up, with Industrial Biotechnology as one of its three pillars. All stakeholders – industry, academia, interest groups and Member States – have jointly developed a long-term Vision and a Strategic Research Agenda (SRA). The SusChem section on Industrial Biotechnology - coordinated by EuropaBio and the EFB section on Applied Biocatalysis, with European Commission funding - is putting forward the stakeholders' strategy for Industrial Biotechnology as a cornerstone of the knowledge-based bio-economy. The overall goal of Industrial Biotechnology is to develop new bio-based technologies to convert renewable raw materials into chemicals, materials and bio-energy.

The key commercial objectives for an R&D programme are:

- The development and production of novel, innovative products and processes in a cost- and eco-efficient manner, increasingly using renewable raw materials.
- The discovery and optimisation of improved microbial strains and biocatalysts.

To achieve these, seven major areas of research and technology have been jointly identified by the stakeholders:

1. Novel enzymes and micro-organisms
2. Microbial genomics and bio-informatics
3. Metabolic engineering and modelling
4. Biocatalyst function and optimisation
5. Biocatalytic process design
6. Fermentation science and engineering
7. Innovative downstream processing

It is important to see these as inter-connected components in a cohesive and integrated overall programme of work. Many individual disciplines need to be developed to meet the challenges offered by Industrial Biotechnology, but they can only provide effective solutions if they are properly coordinated both at EC level (via Framework Programme 7) and at Member State level (via national research programmes).

It is also likely to be worthwhile and productive to combine different Technology Platforms in a virtual KBBE cluster (IB section of SusChem[21], Plants for the Future[22], Forestry[23], Biofuels[24])

6.2.2. Promote inter-disciplinary cooperation, overcome fragmentation and stimulate industry participation

Industrial Biotechnology is by nature a multi-disciplinary area, comprising biology, microbiology, plant sciences, biochemistry, molecular biotechnology, chemistry, bioinformatics, engineering etc.

Good contacts and coordination, including the formation of multi-disciplinary project teams, are therefore crucial to create synergies to unleash Industrial Biotechnology's true potential and allow it to become a real driver of innovation and sustainability in Europe. Combining knowledge from different scientific disciplines can indeed create unexpected synergies.

Many Member States have research programmes in the area of Industrial Biotechnology and plant science, but this research is currently carried out by these countries in virtual isolation. If we are to achieve the maximum return on research funds without duplicating efforts, national programmes should take into account the over-arching European Strategic Research Agenda. Good coordination of the ERA-Net (European Research Area Networks) on Industrial Biotechnology - with a strong link to the European Framework Programme and the Technology Platforms - is therefore necessary.

Today, industry participation in European research programmes is at a rather low level. This should be increased by making application and participation less burdensome, for example introducing simpler participation procedures, solving the problem of access by consortium members to background and side knowledge, better access for SMEs, etc.

Research is important to create knowledge. But industry will only continue to invest in research if this knowledge can be exploited, meaning that this should result in processes and products – in this case bioprocesses and bioproducts – that can be brought on the market and commercialised. Therefore, technology transfer should be facilitated: high quality research is of little value if it does not contribute to innovation and economic growth. All possible steps should be taken to facilitate good working partnerships between universities and industry, including the setting up of public-private partnerships.

6.2.3. Set up European research-oriented demonstration or pilot projects: Integrated and diversified bio-refineries

In order to turn research into products, a crucial step is to establish a proof of concept and test it under industrial conditions. Because often full-scale manufacturing facilities or even pilot plants are not accessible to researchers, the concepts developed in R&D are not immediately applicable nor necessarily economically feasible on a larger scale. It is therefore necessary to have access to scale-up and pilot infrastructures during the research and development stage to develop and test industrial processes, so reducing both lead time and investment. This can also facilitate the establishment of stronger academia and industry cooperation to facilitate the translation of research into industrial innovation.

The integrated and diversified bio-refinery is an overall concept of a processing plant where biomass feedstocks are converted into a wide range of valuable products. Biorefineries combine and integrate the technologies necessary to convert biological raw materials into industrial intermediates and final products of use to society, thus covering the whole industrial biotechnology value chain. Considering the current state of knowledge of biomass conversion, the technological approach will initially focus on improving and developing techniques for the processing of readily available and easily convertible standardised feedstocks such as starch, glucose, vegetable oils and proteins to produce intermediate and final products (ideally novel bio-products).

- **Support the development of flexible research-oriented pilot plants**
  Lessons learnt from existing biorefineries teach us that the construction of pilot plant facilities and demonstration activities are crucial steps towards developing a fully fledged biorefining industry. Pilot plants and demonstration activities are able to close a critical gap between scientific feasibility and industrial application. They enable us to measure actual operating costs, and specific strengths and weaknesses of technological processes before costly, large-scale facilities are built. While pilot plants are not profitable ventures by themselves, they dramatically reduce the risk of introducing new technology on an industrial scale and therefore make a biorefinery venture much less risky for investors. Stimulating the construction of pilot plants is therefore one of the most important measures that can be taken in the development of the bio-economy.

The initial construction of biorefinery pilot plants is, however, a costly undertaking. Hence, specific scenarios for developing and funding flexible research-oriented pilot-scale activities need to be developed in Europe. These flexible pilot plants should allow large-scale research, testing, and optimising processes to produce a wide range of products. This will fulfil the dual aims of testing various feedstock and pre-treatment processes, and exploiting their potential to produce the highest value possible from all fractions of biomass in an eco-efficient way. Such projects will allow both feasibility and eco-efficiency studies and demonstration of the benefits of the new technology in relation to the three pillars of sustainability: People, Planet, and Profit.

- **Develop funding schemes in Europe for "multiple company consortia" to build "first of a kind" small scale production biorefineries**
  Companies often hesitate to invest in small scale plants, especially if they have to co-invest with other industrial partners. Therefore, developing specific funding schemes to encourage investment in some "first of a kind" bioproduction facilities would provide tangible proof-of-concepts and test facilities for new technological processes, and benefit all partners. These funding schemes should encourage value chain coalitions with multiple companies (public-private partnership consortia) to build small-scale projects and to form and create integrated system-level solutions. Similar incentives have been developed in the US[25].

Recommendations:

- Full implementation of the KBBE-related SRAs (Industrial Biotechnology, Plants for the Future, Forestry, Biofuels, etc.) at EC (FP7) and Member State (via ERA-Net) level
  - Ensuring long-term planning and continuity of research funding
  - Increasing industry participation and stimulating public-private partnership
  - Promoting inter-disciplinary cooperation
  - Overcoming fragmentation and duplication of research
- Set up European research-oriented demonstration or pilot projects: Integrated and diversified bio-refineries
  - Support the development of flexible research-oriented pilot plants
  - Develop funding schemes in Europe for "multiple company consortia" to build small scale plants (first of a kind biorefineries)

6.3 Promote production and use of bio-based products and processes

6.3.1. Ensure secure and affordable supply of biomass feedstock

Issues such as the need to establish a reliable, large-scale supply of raw materials and the lack of a EU-wide implemented resource policy[26] should be tackled if we want to establish a sustainable and competitive bio-based economy in Europe. There is indeed uncertainty about resource availability in Europe: both over the potential of biomass feedstock to deliver sufficient raw material for all future applications (chemicals, bioplastics, bioenergy, etc), as well as over its long-term price. Existing biomass such as starch and glucose is expensive and supply is limited (and there is of course competition with other applications), and the future potential biomass such as lignocellulose and agricultural waste has still to be developed to be competitive and commercially available.

So there is need both for concrete, accepted statistics and a feasibility study on feedstock availability and logistics in the EU, both from dedicated crop production and from agricultural and industrial waste, including market surveys on bio-based products. Political initiatives such as reform of the sugar regime and revision of the CAP should be carried out with the needs of he bio-economy in mind, to increase and assure the supply of biomass at a competitive cost. Of course, such an EU-wide agreement on a common framework should still allow Member States to develop their own

specific approaches and determine individual goals and balances between energy and non-energy uses of biomass, and environmental considerations tailored to specific national or regional requirements. Also the type(s) of biomass and energy crops and the sectors in which biomass is used should be defined in the context of a balanced approach regarding domestic production and imports of biomass, taking into account aspects such as competitiveness, security of supply and rural development. In addition, the feasibility of building new processing plants in the vicinity of biomass sources to lower transport cost should be studied in Europe.

While security of feedstock supply is a major concern, it is important to note that, especially in the case of imported feedstock from developing countries, increase in production to satisfy demand should not have a negative impact on natural resources and diversity in these countries. Initiatives such as the Round Table on Sustainable Palm Oil, which brings together all stakeholders to discuss and promote a sustainable value chain, are welcomed and supported[27].

6.3.2. Help convert conventional industrial processes into bio-based ones

Industrial Biotechnology processes and products already coexist with conventional ones and will continue to do so. Conventional processes are also being redeveloped to become increasingly sustainable and have lower environmental impact, which of course should be supported. However, greater use of renewable materials and Industrial Biotechnology processes has the potential to speed up and facilitate the establishment of a sustainable industrial base, through break-through innovations. Therefore, as technologies improve, specific support should be dedicated to promote the conversion to processes and products that are clearly more eco-efficient than existing ones. The versatility of Industrial Biotechnology has been recognised by the European Commission, which made it one of the priority issues of the European Environmental Technology Action Plan (ETAP).

The barriers preventing the establishment of a European bio-based economy (different technology, logistics and business models, high investment costs, different reglementations, etc.) are not likely to disappear in the short term, even with the forecast increased prices of oil and petroleum-based raw materials. Supplementary measures and incentives are therefore needed. Today, high levels of investment are needed to replace more conventional production plants or industrial processes by bio-based ones. The real costs for a transition to sustainable processes need to be reduced and the long-term cost/benefit ratio of a move to biotechnological processing has to be more transparent to motivate companies in different industrial sectors. And finally, the full extent of the benefits has to be made clear: better products and processes, lower production cost, less impact on the environment and creation of new jobs.

Industrial users and consumers could be supported to use more sustainable and economically beneficial bioprocesses using renewable resources via, for instance, seeding economic incentives (e.g. tax breaks, in accordance to EU state aid) based on scientifically-derived environmental and sustainability metrics.

Other major incentives or removal of existing barriers to increase the use of biotechnology in traditional industry could also be effective. A good incentive would be a preferential approval system, such as a faster and/or cheaper regulatory procedure at European level for products produced by bioprocesses or from biomass (like the “fast track” regulatory procedure at the EPA in the USA).

The potential contribution of white biotechnology and biobased products to different policy objectives of the European Union also covers climate change mitigation, as replacement of fossil fuel based raw materials by biomass feedstock could help to reduce CO_2 emissions substantially. The current EU’s Climate Change Policy is already positive for the adoption of renewable resources. In the long-term incentives for the use of renewable raw material in lowering CO_2 emissions could be achieved by capturing the value of carbon gain in the production process or product itself. However, this would have to be studied more closely with the different industries and policy makers concerned in order to develop appropriate instrument to capture the environmental value of using renewable raw materials for products and processes.

As the scientific, technological, economic and ecological considerations relevant to a specific process will determine the best available technology, a high quality life cycle analysis (LCA) of competing processes is needed. In order to develop these important incentives further, international harmonisation of criteria to measure eco-efficiency and life-cycle assessment and methodology is necessary. This would both increase transparency and stimulate adoption and implementation of bio-processes.

6.3.3. Provide market incentives to stimulate the commercialisation of bio-based products

The products of bio-processes are often similar to "conventional" products (bioplastic is plastic, biofuel is fuel, biochemicals are chemicals, etc.), and although they can be produced in a more sustainable way, in many cases the consumer is unaware of this invisible benefit. In addition, the market price does not reflect the real benefits for society and the environment. So communicating to consumers about the technology or production process and specific and/or temporary incentives could help to change consumer behaviour, which will create a market pull for such products.

Public Procurement Policy (such as the EU Green Public Procurement[28], the "Bioproducts Guidebook for Greener Procurements[29] "edited by the French Environment Agency, or the "Federal Biobased Products Preferred Procurement Program"[30] (FB4P) launched by the Farm Security and Rural Investment Act of 2002 (FSRIA) in the USA) could have a crucial role in stimulating the use of bioproducts. This they do by tools such as biotech product lists, setting-up minimum requirements to claim a product "sustainable", and by developing international standards for biotech products. Green public procurement policies should not only focus on the product but on the whole system (production process, application, waste management, etc.), in keeping with the principles of Life Cycle Analysis.

It is also worth considering the **labelling** of products and/or processes according to energy and water consumption efficiency. Existing information on bioprocesses and bioproducts could also be edited as a basis for consumer information (for example, bioplastics could be labelled "bio-based" and "biodegradable" for short life products, or "bio-based" for long life product). These and similar labelling terms could give some visibility to the sustainability benefits of these products. Another type of action in certain sectors could be the establishment of **temporary positive discrimination measures**, for instance VAT reduction on bio-products if it is shown they are more sustainable, or the establishment of a minimum market share (e.g. for biodegradable supermarket plastic-bags). This could help to develop a market for new biobased products and to reach a critical volume so the production of these products can become competitive and sustainable also without these temporary pricing measures.

Recommendations:

- Secure and assure an affordable supply of biomass feedstock through
  - Supportive innovation programmes,
  - Agricultural policies,
  - Further clarification of certain elements of sugar policies which are relevant for the fermentation industry, and
  - Price incentives

- Help convert conventional industrial processes into bio-based ones:
  - Via the approval system: develop faster regulatory procedures and preferential treatment (like the "fast track" regulatory process at EPA in the USA).
  - To assess the opportunities for biobased processes and products to contribute and benefit from the EU's Climate Change Policy.
  - To provide market incentives to overcome the hurdle of high investments.

- Provide market incentives to stimulate the commercialisation of bio-based products, via:
  - Public procurement standards
  - Temporary pricing measures
  - Labelling (e.g. "biobased", "biodegradable" , etc.)

6.4 Create awareness amongst stakeholders

Industrial Biotechnology is one of the key enabling technologies necessary to secure a sustainable future for European society based on the knowledge based bio-economy (KBBE). In general, there is a lack of awareness of Industrial Biotechnology's potential in manufacturing industry and among policy makers, consumers and even investors. Furthermore technological developments often carry unexpected consequences in their wake. Forecasting the potential contribution of Industrial Biotechnology to society should therefore include economic, environmental and broader social impact assessments. Some answers can be provided by additional scientific data on the implementation and impact of the technologies. However, to facilitate smooth long-term development and implementation of the technologies, a strategy for communication and stakeholder involvement is necessary not only to raise awareness and provide information, but also to reflect upon long-term developments and applications with a broad stakeholder base and society in general.

To raise stakeholder awareness, they have to be involved. Stakeholders' awareness requires the demonstration of the benefits of the technologies via concrete examples. These could include the establishment of biorefineries which provide a demonstration of the potential applications and evaluate their results and impact. An appropriate coordinated communication strategy, together with a series of round-tables with a broad stakeholder base to put technological developments and implementation in perspective, is a must.

It is clear from previous experience that information and communication are not synonymous with public acceptance. A long-term process has to be set up by industry and governmental organisations to build trust through **a transparent process of engagement on values, appropriate risk-management and critical self-evaluation.** Sustainability – characterised by the triple bottom line of People, Planet and Profit, and a key element of Industrial Biotechnology - should be made more visible in the core values driving the development process. Finally, **upstream public engagement** can be used as a valuable indicator in the development of technologies, and should be used where feasible in the development of technology or policy strategies.

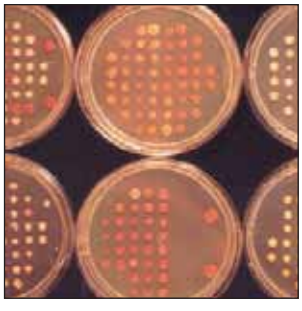
Recommendations:

- Develop an action plan and communication strategy to raise awareness of the potential of Industrial Biotechnology and the KBBE, involving the main stakeholders (Industry, Policy makers, Consumers, Investors, Farmers, etc.)
- Take into account public perception though direct engagement and interaction with the public (trust building, innovative communication activities, etc.)

6.5 Improve investment in KBBE-related SMEs

6.5.1. Lower the cost of Intellectual Property protection for SMEs

Critical issues in the successful development and growth of SMEs are the establishment of Intellectual Property Rights (IPR), demonstration of "proof of concept", laboratory experiments, and scale up to commercialisation via pilot plant. Fee reductions will go a long way to assist SMEs in the creation and maintenance of their IP portfolio, and yet the legal costs involved are still considerable. There is certainly an urgent need for a European Community Patent, with one single granting agency and one language. As a temporary measure and until a viable European Community Patent is in place, a specific SME-initiative could be developed at the European Patent Office (EPO). In addition, any initiative to assist the EPO in producing a searchable database of patents flagged for applications in IB would help to mitigate the cost of searches in the earliest stages.



6.5.2. Develop grants for "Proof of Concept" studies for environmental friendly technologies

"Proof of concept" studies may be simple or complex depending on the technology and the types of reaction involved. Costs of this kind of study are often covered by University grants or specific grant structures in start-up companies. This kind of grant however is not as readily available for SMEs developing innovative products once they are no longer under the umbrella of a university or institute. Consideration could be given to the creation of a grant foundation with a mandate to give preference to industrial applications listed in a regularly reviewed hierarchy of industrial "hot spots" relating to key enabling technologies for maximum economic, social and environmental impact.

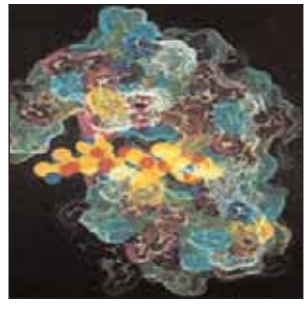
6.5.3. Attract new investors

Compared to the more established life science areas such as healthcare biotechnology, in the Industrial Biotechnology sector the investment and finance community is only in its infancy, and business models still need to be proven. Today mainly larger companies are investing in industrial biotech start-ups, and there is also a need for more private investors with knowledge of the sector. So there is a specific need to raise awareness among the investment community. This can be done by a specific communication campaign showing some examples, good results and the possibilities for return on investment. Building up and publishing a track record for the sector could help to attract new investors. Also a list of IB SMEs in Europe with brief descriptions could be put on the EuropaBio website.

6.5.4. Increase risk capital and facilitate funding for Industrial Biotech SMEs

In order for an SME to develop it must have a product and a market and, in order for a market to be accessed, production capacity must be able to satisfy demand at an acceptable cost. A **pilot scale production facility** may be as small as a 5L bench process or for bulk products it may need to be in much larger quantities. This step will therefore present different hurdles to be cleared for Industrial Biotechnology SMEs depending on their sector and their level of development as a company. For larger applications this step has, in the past, often only been possible with the involvement of a large industrial partner. As these industrial partners have their own investment constraints and portfolio limitations this has been a major limiting factor on innovation and, as a consequence, on SME proliferation worldwide. In Europe, investment is required particularly at this point in the development process because of the limited number of industrial sponsorship opportunities.

While **loan guarantees** are one approach to bridging this gap in the absence of collateral, this still falls short of the funding requirement in terms both of the limited sources of such funds and the administrative requirements to qualify for the guarantees. There is thus a need for further levels of risk capital to be deployed beyond the normal risk tolerance of lenders. **Venture capital** has the highest level of tolerance to risk because it uses portfolio theory to allow for failures by making exceptional returns on a small number of total investments. In order for this asymmetric investment model to be successful, however, an exit strategy that can provide exceptional returns needs to be present. In the healthcare biotechnology sector, this has largely been through public offering of shares in the company at much higher value than the original investment or by competitive bidding in a trade sale of the company. As yet Industrial Biotechnology has the disadvantage of a lower profile for its activities and so little interest in its stock as it lacks a 'bell-weather' success story to attract investors. Also valuation techniques relying on sales multiples are not very useful due to the as yet undeveloped nature of the market, with few examples of companies having significant cash flows from Industrial Biotechnology activities. The sector is thus not yet ready for the traditional venture capital approach to investment to be a source of funds on a wide scale.



An **investment model that sits between loans and pure private equity** is required to break the impasse for the market. An investment model that has a risk sharing component yet avoids the risk of an equity-only exit is that of securitisation of future (projected) cash flows. A similar model is the norm in property markets where future rental income is pledged to raise the capital for building offices or housing. The approach has been pioneered in the pharmaceutical sector with considerable success and will be well suited also to the Industrial Biotech sector. The nature of these investments is related to income generated by products. In the area of White Biotechnology most companies will have a limited initial focus and this may be restricted to the development of one product or product family alone due to financial constraints.

In Industrial Biotech, following proof of concept there is relatively little scientific or regulatory risk, unlike the situation for medicines. For example an enzyme used for cleaning does not have to be tested in clinical trials over a number of years and then approved for use by a risk assessment board such as the EMEA. Scale-up to production capacity is largely a technical issue which will generally be successful. The value of the product in the market place can be assessed by relatively simple techniques and the likelihood of commercial success predicted with reasonable confidence. As a consequence this financing method can be adapted and blended with equity components to provide a flexible and suitable method to opening the Industrial Biotechnology market to a wider investor base.

A fund is in creation which will address these issues. In association with other sources of finance, this can address the gap in funding which is currently restricting the growth of Industrial Biotechnology in Europe. The present situation is limiting the competitiveness of SMEs and preventing them from taking leading positions in world markets for innovative white biotech products. **A coordinated approach to public and private funding** will provide an environment where SMEs can thrive in a competitive market without becoming dependent on public funds for subsidies and yet deliver innovation to the market through licences, alliances and product sales. Larger organisations in he European Industrial Biotechnology sector will also benefit from the broader investment in innovation which can extend their portfolios without requiring a level of research spending which would make them uncompetitive in the world market. This too will stimulate the economy through the Industrial Biotechnology sector, creating jobs and supporting other industries in Europe.

Recommendations:

- Reduce the cost of Intellectual Property protection for SMEs:
    - Develop a European Community Patent, with one single granting agency and one language
    - Introduce a specific SME-initiative at the European Patent Office (EPO)
    - Develop a searchable database of patents flagged for applications in IB
- Develop specific grants for “Proof of Concept” studies for environmental friendly technologies
- Attract new public and private investors by creating awareness among the whole investment community via a specific communication programme, by publishing a track record, etc.
- Increase risk capital and facilitate funding for Industrial Biotech SMEs by developing an investment model that sits between loans and pure private equity (risk sharing).

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