# Valuing Biotechnology Innovation

*the invisible revolution for sustainability & quality of life; offering new solutions for old problems*

## Annual report 2007

Highlighting achievements

The Chairman of EuropaBio Dr. Hans Kast and members of the EuropaBio Board met with EU Commission President José Manuel Barroso.

EUROPABIO

The European Association for Bioindustries

The Chairman of EuropaBio - the European Association for Bioindustries - Dr Hans Kast and members of the EuropaBio Board met this year with Commission President José Manuel Barroso to underline how the biotechnology industry, being an unequivocal cornerstone of the knowledge based bio-economy, is committed to achieving this and enabling Europe meet its Lisbon targets.

President Barroso acknowledged the importance of Biotechnology as a key technology in the innovation strategy, supporting the Growth and Jobs program. He said: "I want to be kept informed about all the important issues faced by biotechnology because I am aware that Europe needs innovation from new technologies such as biotechnology to fulfil the Lisbon target".

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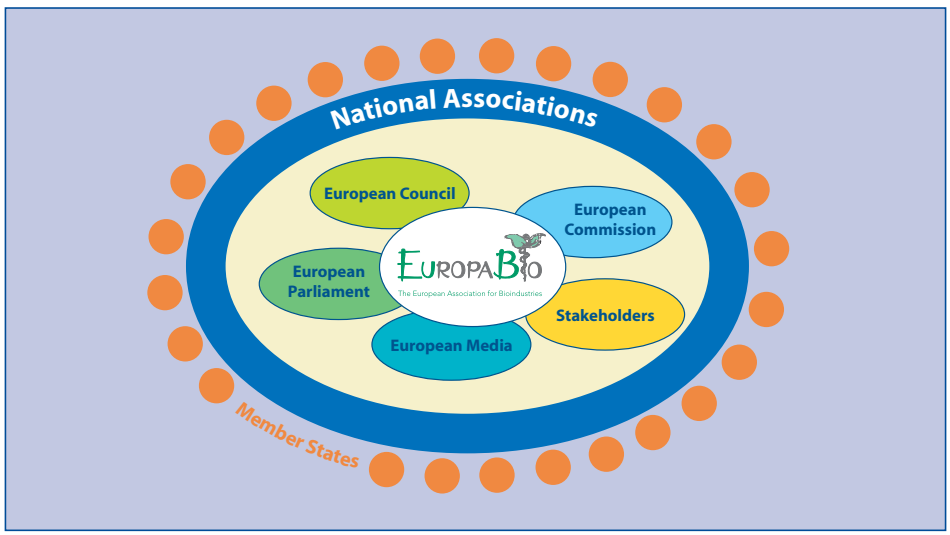
# EuropaBio is the voice of the European biotech industry

Over 80% of legislation affecting biotechnology companies in Europe originates in Brussels, with a proposal from the European Commission which is voted and agreed upon by the Member States acting through the Council of Ministers and the European Parliament of 748 directly elected Members.

EuropaBio represents the interests of the industry towards the European institutions so that legislation encourages and enables biotechnology companies in Europe to innovate and provide for our society's unmet needs.

## EuropaBio's role




*EuropaBio - Sharing alliances, building across policy blocks*

The European Association for Bioindustries, was created in 1996 and represents 83 corporate members operating worldwide, 11 associate members including 5 BioRegions and 25 national biotechnology associations. Through our national associations, EuropaBio is also the voice of over 1800 small and medium-sized enterprises involved in research, development, testing, manufacturing and commercialisation of biotechnology applications.

Our corporate members are involved in a wide range of activities: human and animal healthcare, diagnostics, bioinformatics, chemicals, biofuels, crop production, agriculture, food and environmental products and services. EuropaBio also welcomes associate members such as international commercial, financial, asset management and other service-providing companies, regional biotechnology development organisations and scientific institutes. The common denominator among all our members is the use of biotechnology at any stage of research, development or manufacturing.

"The EU has recognised biotechnology as a key technology of the 21st century by a number of important political initiatives. In this regard, EuropaBio is dedicated to helping create a better political, regulatory and legal framework to foster a competitive biotechnology industry in Europe,"

Dr. Hans Kast, President and CEO of BASF Plant Science and EuropaBio Chairman

# What is your European association doing for you?

## National associations – a formidable lobbying force across Europe

EuropaBio is a formidable lobbying force for the biotechnology industry both in Brussels and in the capitals of the European Union's Member States, thanks to our 25 different member national associations. Collectively we are the voice of more than 1800 biotech companies, that makes us a strong European partner and counterpart to important EU level institutions, organisations and stakeholder groups. This year following a survey of National Associations, a new communications and lobby strategy for the National Associations Council in support of EuropaBio was agreed. A major lobby outreach "Brussels Day" was a top class lobbying event which brought 10 national delegations of company CEOs and senior executives to Brussels to meet with over 50 national representatives from the European Parliament, European Commission and the Council over one day. The National Associations led the first Biotech SME day at the the European Medecines Agency EMEA and contributed to EuropaBio's lobbying work on the Paediatrics Regulation, Tissues and Cells Directive and Advanced Therapies Regulation, helping to secure positive votes in the two European Decision Making bodies – the European Parliament and the Council.

Aisling Burnand, Chief Executive Officer, UK Bio Industry Association (BIA) and Chair of the National Associations Council said that Brussels Day gave a good opportunity to National Associations to bring their messages to EU decision makers:

"I believe strongly that by acting together – through organisations such as EuropaBio and events like Brussels Day – we strengthen those national voices rather than diminish them."

The National Associations Council at EuropaBio brings together heads of Association and provides a coordination role in EU wide lobbying on EU policies and regulations and is chaired by Aisling Burnand, CEO,BIA.

## Emerging Enterprises

The discovery of DNA and harnessing the knowledge to uncover nature's secrets leads to discoveries everyday like those listed in this brochure. Remarkably such discoveries have also led to the creation of some 2000 small and medium sized companies in Europe that have founded companies based on the exploitation of this new knowledge. The vast majority of these companies did not exist 20 years ago. They are leading today in some of the world's most innovative products in healthcare, food, feed industries as well as new processes that revolutionise the way we manufacture products.

Most of these companies are healthcare based developing methods to detect, to treat, to cure and even to prevent diseases and conditions that have been neglected up until now or simply cast aside as being intractable.

But these companies are still fragile, needing lots of support and finance to enable them to turn research results into products for you and me to use. That is why EuropaBio has a special group focussing on policies to increase access to capital for these emerging, often small biotech companies.

The Emerging Enterprise Council at EuropaBio that advocates for an improved financial environment in Europe for European biotechs brings together senior industry figures to help develop a better finance environment for biotech in Europe and is chaired by Philippe Archinard, CEO, Transgene.

Also, the Emerging Enterprise Council is the driving force for simplification of European legislation and reduction of bureaucracy.

## The Sector Councils

EuropaBio has three sector Councils each with a special mandate to develop their policy and that are the ultimate arbiters and gatekeepers of the association's sector positions that are developed by specialised working groups reporting into each Council.

The Healthcare Council drives the healthcare policy agenda that our association is advocating and is where industry representatives work together to iron out policies that are needed to deliver a strong healthcare biotech agenda for Europe. The Council is chaired by Andrea Rappagliosi, Merck Serono International.

### Healthcare biotech today

- More than 325 million patients have benefited from biotech medicines treating heart attacks, stroke, multiple sclerosis, breast cancer, cystic fibrosis, leukaemia, hepatitis, diabetes and many other diseases.
- Today, 418 new biotech medicines and vaccines are being tested for more than 100 diseases, among which 210 to treat cancer, 50 to treat infectious diseases and 44 to treat autoimmune disorders. Biotech medicines are estimated to account for approximately 20% of all marketed medicines and represent 50% of all medicines in the pipeline.

The Agri-Food Council groups together leading industries to develop policy on biotech crops and agri-food products in Europe and is made up of representatives of companies and national associations with an interest in plant biotechnology applications. It is chaired by Dr Bernward Garthoff of Bayer CropScience and Chairman of the German Biotechnology Industry Association (DIB).

## Agri-food and crop biotechnology today

Agricultural or "green" biotechnology is being adopted at record speed around the world. In 2006, 10.3 million farmers in 22 countries cultivated genetically modified (biotech) crops on 102 million hectares. The adoption rate has seen double-digit annual growth since 1996. Ninety percent of farmers who benefited from biotech crops in 2006 were resource poor farmers from developing countries, whose increased income from these crops contributed to the alleviation of poverty.

Planting in Europe has been much slower, but is accelerating as farmers start realizing the benefits of biotech crops. In 2006, six European countries (Portugal, Spain, Germany, France, Czech Republic, Slovakia) grew biotech crops as opposed to only one a few years ago. The number of hectares of biotech crops in Europe, although modest, is also growing significantly. The technology is safe and regulatory systems, if applied correctly in the countries of the European Union, guarantee consumers and farmers the choice of whether or not to consume and plant biotech crops.

The Industrial Biotech Council provides a political forum to develop policies for white biotechnology and the bio-based economy. It is chaired by Jack Huttner, Vice President, Biorefinery Business Development, Genencor International - A Danisco Company.

## Industrial Biotech

This is a sector of biotech that is growing exponentially. Industrial or white biotechnology is the application of biotechnology for the processing and production of chemicals, materials and energy. It uses enzymes and micro-organisms to make biodegradable products in sectors such as chemistry, food and feed, paper and pulp, textiles and energy. Industrial or white biotechnology is making an increasingly important contribution to the development of a sustainable, bio-based economy, and has a considerable impact by using biomass as an alternative to fossil resources for the production of biochemicals such as biofuels and biopolymers.

The campaign to raise awareness of the sector is resulting in major support at EU level and at national level to use more biological processes and encourage more companies to adopt these new greener, manufacturing processes. The EU is a leader in this sector. According to the latest EU Commission report by the JRC, in industrial biotech the EU produces about 75% of the world's enzymes and about 45% of all manufacturing sectors, for example textiles, pulp & paper use modern biotechnology.

According to Jack Huttner, Chairman of EuropaBio's Industrial Biotech Council:

"Having done the hard preparatory work, we now have to go out and spread the messages about Industrial Biotechnology. At the same time, we need to make sure that we develop a coherent overall policy framework. If policy makers get it right, biotechnology can be the key which unlocks the door to a sustainable and competitive future for Europe. The objectives of the Lisbon agenda are still within reach."

## The Board

All EuropaBio's Councils report to the EuropaBio Board that has set the association seven policy goals. In this report we will present the highlights of what has been achieved over the last year to achieve these policy goals.

## EuropaBio's seven policy goals

- **The Policy Coherence Goal**
  - Building policy consistency and predictable rules for all biotech sectors.
- **The Regulatory Goal**
  - Improving the European regulatory environment for biotechnology.
- **The IPR Goal**
  - Protecting Europe's intellectual property – promoting a robust regime.
- **The Finance Goal**
  - Funding the future – ensuring financing for Young Innovative Companies.
- **The Awareness Goal**
  - Bridging the gap – building public awareness of the benefits of biotech.
- **The Research Goal**
  - Supporting research excellence.
- **The Access Goal**
  - patients and consumers have the right to fair and equitable access to the products and services issued from biotechnology.

Commissioner Janez Potočnik, responsible for research and development, said:

"Life sciences and biotechnologies are playing a vital role for the competitiveness of our industry but I see it also playing an important role in facing challenges such as the perils of oil dependence, global warming, food security and population health. The FP7 has been designed to address these challenges and to support the development of a European Knowledge Based Bio-Economy, that among others will play a crucial role for achieving the EU goal of reaching the minimum level of 10% biofuels for vehicle fuel by 2020."

Policy highlights from this year…

# The Policy Coherence Goal

## Building policy consistency and predictable rules for all biotech sectors.

*MAJOR ACHIEVEMENT:*

### BIOTECHNOLOGY IS NOW PART OF THE INNOVATION STRATEGY FOR GROWTH AND JOBS!!!

### Success in Mid Term Review of EU Biotech Strategy

In April 2007, the EU Commission issued a major communication on biotechnology – the Mid-Term Policy Review of the EU's Life Science and Biotechnology Strategy. The strategy which was first published in January 2002, has been subject to re-examination over the last two years by Member States and the EU Commission who have consulted interested stakeholders to get their input including through an open consultation via the internet. The Review assesses what needs to change in the strategy, what new policies are required, what has worked and what has not worked so well in developing the biotechnology environment in Europe.

EuropaBio has collaborated in a constructive way with the EU Commission and the Member States to ensure that the review is extensive and refocused towards building the bio-economy. However we still regret the lack of implementation of the EU biotech strategy by a number of Member States and would like to see both the Review and the new action plan for biotechnology being implemented throughout Europe without a biased pick and choose approach so as to obtain a coherent policy in favour of biotechnology in Europe.

"Europe is great in science and knowledge generation but when it comes to translating that science and knowledge into products – the innovation part – the fragmented European legal, financial and regulatory environment is not as fertile as other regions."

Johan Vanhemelrijck,
EuropaBio Secretary General.

**The Biotech revolution …..**

**Biotech opens path to Regenerative medicine – a new medical era dawns**
Advanced Therapies is an umbrella term that covers three new biotechnology techniques that are revolutionising modern medicine: cell therapy, gene therapy and tissue engineering. Examples include skin therapies for burns victims, cell therapies to treat stroke and new tissue engineering treatments that can actually replace cartilage.

### EuropaBio updates Healthcare Biotech Manifesto 2007

The EuropaBio Healthcare Council updated its policy agenda for Healthcare Biotechnology in Europe, with the launch of our second Healthcare Manifesto (www.healthcare-manifesto.org). In it we announced new policy priorities for 2007 and promoted Patient Centred Healthcare Systems.

### Representing the healthcare biotech voice at the Pharmaceutical Forum

We continue to represent the bio-healthcare industry on the High Level Pharmaceutical Forum – EuropaBio is a full member of this high profile process. We are seeking to lobby Commission and

Member States to recognise a role for the innovative bio-healthcare sector in providing important information to patients on these new therapies. In addition, non-harmonised reimbursement and health technology assessment decisions continue to hamper the industry's development in Europe - meaning long and uncertain delays in drugs making it onto market in Member States - despite receiving central approval - due to budget (and not patient) - centered policies. We will continue to use the Forum to push for harmonised recognition and definitions of the value of innovation in reimbursement decisions in order to improve this situation.

## Green biotech – a new manifesto

The Green biotech industry reorganised its unit inside EuropaBio this year and launched a Green Biotechnology Manifesto (www.greenbiotech-manifesto.org) at BioVision where industry, politicians and NGOs were gathering to discuss how biotechnologies can meet the Millennium Development Goals and the needs of Developing Countries. The 'Green Biotechnology Europe' Manifesto advocates five main policies for green biotech addressed to the EU Commission, to the Presidencies and key Member States so that the European Union as a whole nurtures and promotes coherent pro-development policy that does not discriminate against promising technology. The industry calls on Europe's political leadership to openly communicate its support for the policies it has agreed and to correctly reflect the trust it has in its own regulatory system and the products approved through this system.

## Launch of new policy agenda for industrial biotech and the bio-based economy

After almost one year of intensive brainstorming with industry leaders, EuropaBio members have worked out a set of practical steps to realise the vision of a Knowledge-Based Bio-Economy (KBBE), where biotechnology's new, clean, energy-efficient processes and innovative bio-based products create a sustainable industrial base to ensure Europe's future prosperity. The European Policy Agenda for Industrial Biotechnology and the KBBE, sets out five goals. Of primary importance is the need to develop policy coherently across the EU, and to coordinate its implementation. 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 must be extended 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. Additionally, demand for biobased products 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. 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 and the benefits of industrial biotechnology and the use of renewable resources. And finally, 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 policies were endorsed by the Finnish Presidency and have now been incorporated in the Commission's Mid Term Policy Review of the European Biotechnology Strategy.

Dr. Bernward Garthoff, Bayer CropScience, Chairman of the German Biotechnology Industry Association (DIB) and Chair of EuropaBio's Agri-food Council said:

"The application of biotechnology to plant breeding has yielded benefits to farmers, the economy and the environment which are simply not possible with the more traditional approaches. These new possibilities are making an essential contribution not only to the food and animal feed security of a growing and increasingly prosperous global population, but also to the sustainable supply of renewable raw materials for industry and energy such as transport fuels. We need harmonised policies that are coherent and consistently implemented so that benefits get through to society."

"We at DuPont have a mission to bring sustainable solutions to the market place while reducing our own environmental footprint. Green and White Biotechnology are key to achieving that mission, and we believe EuropaBio is best placed to ensure that European Policy makers are aware of the needs of companies involved in these areas and to ensure the development of stimulating biotech policies in Europe."

Ian Hudson, President, DuPont Europe, Middle East and Africa

## The Biotech revolution …..

**Bioplastics**

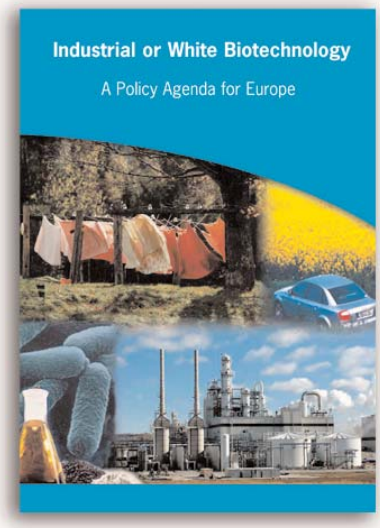
Plastics are one of the most common products in our daily life. New biological processes allow the production of bioplastics from renewable resources thus reducing the dependency on fossil resources and the impact on the environment. Several companies have started to produce and commercialise bioplastics. As an example, today at least six companies produce lactic acid in Europe (mainly used to produce the plastic polylactic acid (PLA), with a total production volume of 148,000 tons/year. Other examples are poly-hydroxybutyrate (PHB), polyamide- or nylon- type, bioplastics based on propanediol, or starch based plastics.

## Stimulating a European lead market initiative for sustainable bio-based products

EuropaBio brought together the main European stakeholders (industry, several Technology Platforms, European Commission, European Investment Bank, etc.) to stimulate the development of integrated diversified biorefineries and is coordinating the activities to develop a European-wide "Lead Market Initiative for eco-efficient biobased products". The purpose of the Lead Market Initiative is to enable future technology to emerge and come to market. In order to ensure success, an integrated effort is needed across all services, policy areas, and between public authorities and industry.

## Defining a biofuels agenda for Europe

In 2006, EuropaBio set up a Biofuels Task Force, representing the biotechnology based biofuels industry and related companies at European level. It is a cross sector group that covers the complete chain of companies: from biomass to biofuel. Its mission is to advocate coherently favourable policies, strategies, regulations and their implementation for research, finance, and market access of biofuels as one of the pillars of the competitive and sustainable European Knowledge Based Bio-Economy (KBBE), increasing the value of plants and renewable materials of agricultural origin. EuropaBio is a member of BIOFRAC (the Biofuels Research Advisory Council) and is a member of the Steering Committee of the European Biofuels Technology Platform. The Task Force published an industry position paper with specific recommendations for biofuels in Europe. We also published the "Status and Comparative Study - Cellulosic bioethanol production in the US, EU and China".




*EuropaBio's policy agenda for White Biotech*

### *Still to be resolved:*

- Coherence in policies and implementation of the clinical trial directive.
- Awareness of the need of harmonised transition periods.
- European simplification of regulations and national reduction of administrative burden.
- Quick and economical market access for innovative products.
- Functioning approval system for biotech crops.
- Coherent application of green biotech policies at national level.

# The Regulatory Goal

## Improving the European regulatory environment for biotechnology

### *MAJOR ACHIEVEMENT:*
### NEW ADVANCED THERAPIES RULES ADOPTED EARLY

Following a five year campaign by EuropaBio for an Advanced Therapies Regulation for Europe, the landmark European Parliament vote, and its subsequent approval by the EU Council of Ministers, means that the Regulation will pave the way for truly innovative, safe regenerative medicines for patients. It will also provide a regulatory framework that offers certainty and predictability for Europe's biotechnology-based companies that are developing these revolutionary treatments. The new rules aim to put an end to the bewildering patchwork of guidelines, regulations and procedures that exist today, where some countries have no specific framework at all.

"EuropaBio has been responsive, well-prepared and – most important – consistent in proactively leading a successful lobbying campaign to get the Advanced Therapies Regulation on fast track."

Wills Hughes Wilson, Genzyme
and Chair of EuropaBio's Advanced
Therapies Working Group.

### Seeking workable implementation of biosimilar medicines regulation

This year, the Association has lobbied for harmonised and immediate implementation of the EU's biosimilars regulatory framework in Member States, in order to fully recognise the uniqueness of this new generation of products. Biosimilars cannot be classified or treated as "generics" in the same way that chemical compounds may be, due to the differences stemming from the variability of the active biotechnological substance and its manufacturing process. EuropaBio is also directly participating in an industry consortium engaged in the World Health Organisation (WHO) review of the nomenclature of biologicals and biotechnology products, including biosimilars, in order to ensure the same goal.

Thomas Bols, Director Government Affairs, Europe – Amgen International and Chair of EuropaBio's Biosimilars Working Group:

"EuropaBio has seized the opportunity presented by the WHO and the international community to discuss and debate the issues related to the naming of biologicals and biosimilar medicines.
This is necessary to ensure that with the arrival of biosimilar medicines, the traceability, substitution and pharmacovigilance of biosimilar and biological products are harmonised and guaranteed throughout all regions of the world."

**The Biotech revolution …..**

**Breast Cancer and biotech**

The incidence of breast cancer has significantly increased in the last 20 years. There are now more than 360,000 new cases a year in Europe. Biotech has developed cancer cell "busting" agents called monoclonal antibodies which only attack the cancer cells and present few side effects. Trastuzumab (Herceptin®), in use since 1998, was the first such antibody directed at an altered gene in breast cancer. About a quarter of breast cancer patients carry this altered gene - HER2.

### Full implementation of the biotech crop authorization process

EuropaBio has provided detailed comments for the Review of Regulations on Genetically Modified (GM) Food and Feed and GM Traceability and Labelling, specifically concerning mechanisms to manage the Adventitious Presence (AP) of GM products approved in 3rd countries but not yet in the EU. The association is also working with the institutions and Member States on coexistence rules in Europe which give farmers a real choice to use the technology.

## The Biotech revolution …..

**Biotech sugar beet controls greenhouse gas**

A new biotech application called Nitrogen Use Efficiency (NUE) technology is now underway in commercial sugar beet production, which is nitrogen use-intensive. Nitrogen fertilizer is one of the largest production costs incurred by sugar beet farmers. As is the case with most crops, sugar beets typically absorb less than one-half of applied nitrogen. Unutilized nitrogen can be transformed into a highly potent greenhouse gas. NUE sugar beets under development would require less nitrogen fertilizer for production, and farmers could expect to benefit from reduced costs, enhanced yields, and improved profitability - making them more globally competitive. At the same time, benefits to the environment are expected from reduced nitrogen run off into waterways and into groundwater. Field tests conducted over five growing seasons in various U.S. regions demonstrate that NUE crops achieve higher yields than the control variety, while using as much as two-thirds less nitrogen fertilizer.

## A European single market in seeds draws closer

EuropaBio is campaigning with the European Seed Association to ask the Commission to put in place workable and economically viable seed labelling thresholds for genetically enhanced seeds in non GM seeds. Together we lobby the Commission services to draft a proposal establishing labelling thresholds for seeds approved by the EU authorities.

## Adventitious presence threshold agreed for discontinued products

Earlier this year, the EU agreed a 0.9% threshold for the low level adventitious presence of five GM products that are no longer commercially available as they have been superceded by better products. EuropaBio has previously proposed the establishment of adventitious presence thresholds for such GMOs in food and feed products and is very pleased to see that this proposal marks a decisive step in the right direction.

## *Still on the agenda:*

- Implementation of the strategy for biotechnology in all the Member States.
- Reduction of the administrative burden and contradictions in important issues such as clinical trials.
- Simplification of the regulations.
- The animal welfare directive review.
- Workable and economically viable thresholds for the adventitious presence of GM seeds in non GM seeds.
- Practical solutions to resolve the issue of GM material approved outside the EU, entering the EU at low level traces in traded commodities.

# The IPR Goal

## Protecting Europe's intellectual property – promoting a robust regime

*MAJOR ACHIEVEMENT:*
## IP COSTS CAN BE REIMBURSED UNDER NEW STATE AID RULES FOR SMEs

### New State Aid rules support research intensive biotech companies

The industry was delighted with the new EU State Aid rules that entered into force in January 2007 and which provide Member States with lots of new opportunities to support their innovative companies and encourage the private sector to spend more on Research and Development. That is very good news indeed for our research intensive biotech sector. One of the elements in the new rules will allow Member State Governments to help companies out with their IPR costs. The challenge now is to encourage governments to use their budgets to provide this kind of support.

### EuropaBio agrees principles to access genetic resources

The long North-South debate over access to genetic resources has moved a step closer to resolution with a commitment from the European biotechnology industry to promote the international United Nations Convention on Biological Diversity (CBD) to protect biological resources. The 'EuropaBio principles for accessing genetic resources' adopted by the Board this year set out some guidelines on how European companies should behave if engaging in bioprospecting activities.

The EuropaBio principles acknowledge the importance of biological resources, and underline the rights of each State to protect them. The European biotech industry will work towards agreeing contracts with authorities that define commercial rights in advance and include appropriate terms and conditions on intellectual property rights, royalties, technology transfer and other means of benefit sharing.

EuropaBio is also encouraging all countries to put in place the mechanisms necessary for the system to function fully – including authorities officially designated to negotiate and agree contracts.

"The biotech industry knows how valuable biological resources are, and wants to protect the trade in them – both for its own sake and for the sake of the countries where they are found. Our members are undertaking to operate under terms of fair trade. But they are going further than that. They are also committed to helping source countries put in place effective protection mechanisms, and they are committing themselves to help stamp out pirate trade in unauthorised material".

Johan Vanhemelrijck,
EuropaBio Secretary General.

**The Biotech revolution …..**

**Enzymes**

The EU is the leading producer of enzymes (75% worldwide), the prerequisite for many industrial biotechnology processes. Enzymes are very versatile tools, each of which can be applied in different industrial processes. Most of these enzymes are used in the food sector (30%-45%) and the detergents sector (33%). The textile and pulp and paper industries account for about 8%-14% and 1%-3%, respectively. As an example, the advantages of using enzymes in detergents are the ability to reduce washing time and temperature, thus reducing energy consumption, improving cleaning performance, and reducing the environmental impact.

## EuropaBio reflecions on Marine Genetic Ressources

EuropaBio organised a meeting with the European Commission on “Marine genetic resources”. The aim of this meeting was to collect input from industry and related stakeholders for the establishment of an EU position in international discussions such as the United Nations. The Commission wanted to obtain a clearer picture of the stakes involved for the European biotechnology industries in this debate, and listen to views on what kind of international legal framework could best provide for the sustainable development of the sector

A EuropaBio working group came up with some reflections on the management of genetic resources in areas beyond national jurisdiction (deep sea). This position has also been used as input for the Green paper consultation process on the future marine policy of the EU.

### *Still on the agenda:*

- Real reduction of the cost of patents in Europe.
- The European patent.
- The signature of the London protocol.
- The European patent litigation act.
- Clarification of Biotech patents involving stem cell research.
- Supplementary patent certificate.

# The Finance Goal

Funding the future – ensuring financing for Young Innovative Companies.

*MAJOR ACHIEVEMENT:*
## COMMISSION TO FINANCE A GUARANTEE FUND TO MAKE MORE RISK CAPITAL AVAILABLE TO SMEs

### Special tax status granted to SME biotech companies in new State Aid rules

This year the EuropaBio campaign for tax incentives for Young Innovative Companies was given a major boost when the European Commission acknowledged this special status under the new State Aid rules which came into force in January 2007. Now Member States have no excuse – Europe allows governments to help their emerging innovative biotech companies and stay clear of Europe's tough competition rules. A signed cheque of 1 million euros can be a starting point that all Young Innovative Enterprises could have access to if national governments make the budgets available.

### Access to EMEA for SMEs

Just over one year after the EMEA announced new services, and reduced fees to benefit Small and Medium-sized Enterprises that use the EMEA for review and approval of new medicinal products, the agency held its first ever SME day. EuropaBio was instrumental in making the authorities aware that SMEs needed special help. We are very pleased to see that the Agency's new 'SME Office' which is dedicated to addressing the particular needs of smaller companies has had an overwhelming response: 136 companies have to date submitted SME declarations to the agency to obtain the SME status and 108 of these have been assigned SME status by EMEA. EuropaBio is encouraging companies to register with the EMEA and be assigned the SME status to benefit from the generous reductions in fees, deferral of payments, and the free translation and administrative assistance offered by the Agency.

### A new SME office at the EPO

EuropaBio started to lobby actively to develop a similar initiative at the European Patent Office (EPO). 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 do larger companies. 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.

"EMEA SME status not only provides the direct fee reduction incentive, which is greatly appreciated especially in the early stages of start-up of a small company but is much appreciated for the actual help that is provided as well (regulatory information, translation work ….) ."

Gil Beyen, CEO, Tigenix - a company awarded the EMEA SME status.

## EuropaBio co-organises the Industrial Biotech & Finance Forum (IBFF)

For the 2nd time only, this unique initiative in Europe, the Industrial Biotech & Finance Forum (IBFF) has been organised by Europe Unlimited and EuropaBio.

As the only key initiative of it's kind in Europe, the IBFF is designed to source and present the most innovative private industrial biotech companies to invest in, acquire, partner with or license from. Its mission is to foster dynamic industrial biotech entrepreneurship, innovation and growth, by providing a unique and exclusive deal-making platform for Venture Capitalists (VCs), strategic investors, corporate decision-makers, and leading industrial biotech CEO-entrepreneurs.

### *Still on the agenda:*

- The implementation of the much appreciated new State Aid rules.
- Include evaluation fees for the 1st product of a SME as part of state aid.
- Data mining on the state of biotechnology industry over the whole European Union including the new accession countries.

# The Awareness Goal

Bridging the gap – building public awareness of the benefits of biotech.

## *MAJOR ACHIEVEMENT:* BIOTECHNOLOGY AS A WHOLE GETTING POSITIVE SUPPORT FROM A LARGER PUBLIC

### Public opinion more favourable to biotech

According to the latest Eurobarometer, in the period 1999 to 2005, with the exception of Austria, all the EU15 countries showed an upward trend in optimism about biotechnology, with marked increases in Denmark, UK, Italy and Ireland.

Trust in university and industry scientists, and in industry itself showed substantial improvements since 1999 while environmental groups declined. Healthcare biotech continues to receive overwhelming popular support with the European public. Industrial applications of biotechnology in biofuels, bioplastics and biopharming for pharmaceuticals are widely supported in Europe, with over 70 per cent of respondents supporting incentives to develop biofuels and plastics. More people than not say they would pay more for a vehicle that runs on biofuels and pay more for bioplastics.

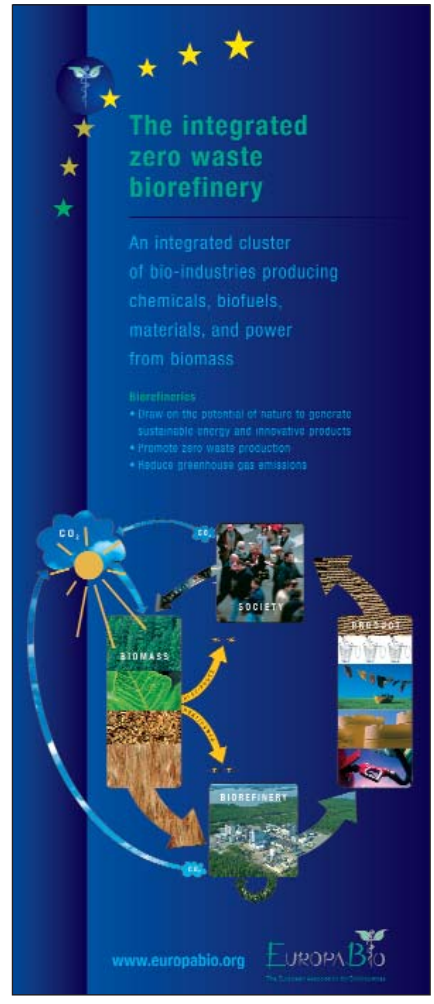
**The Biotech revolution …..**

**Biofuels**

Biotechnology is used to make biofuels like bioethanol. While it will reduce the world's fossil fuel dependency, it is also a sustainable energy source that reduces $CO_2$ emissions substantially, and can act to stimulate the economic development of the agricultural/rural areas. Although the European bioethanol market is still in its infancy compared to Brazil or the USA, the progress is extraordinary. Compared to the year before, in 2005 the bioethanol sales increased by 122 %, the production volume by almost 80 %, and the EU share in world ethanol production by 24 %.

### One million euro study highlights biotech benefits

EuropaBio and members have worked hard over the last year to provide input into the Commission's Joint Research Centre's (JRC's) study "Consequences, Opportunities and Challenges of Modern Biotechnology for Europe", better known as the Biotech for Europe (Bio4EU) study. Released in April 2007 it is the largest study ever of its kind in Europe. The Bio4EU study shows the pervasiveness of biotechnology across all major economic sectors in Europe. The study's figures are compelling: they confirm that life sciences and biotechnology have grown to be central to several industrial sectors of the EU economy. They also confirm the dramatic contribution of biotechnology to progress in medicine for the benefit of patients despite the continuous rationing of healthcare practiced by Member States.



Some key facts and figures emerging from the 'BIO4EU' study:

- Modern biotechnology and its applications generate almost 2% of EU gross value added, indicating that its importance is comparable to Europe's largest industry sectors.
- The European dedicated biotechnology industry directly employs 96,500 people, mostly in SMEs; however given biotechnology's "enabling effect", employment in industries using biotechnology products is many times higher.
- The number of biopharmaceutical companies rose from 37 (1996) to 143 (2005).
- The number of biopharmaceuticals on the market has more than doubled in the last 10 years.
- 30% of all in vitro diagnostics (IVD) in the EU in 2005 were biotech.
- Revenues for biotech vaccines jumped from EUR 65 million in 1996 to EUR 259 million.
- In the agroindustry, up to 20% of the input sector's turnover is now related to biotech.
- In Spain, studies show a 12% increase in gross margin for GM maize over conventional production.
- In industrial biotech the EU produces about 75% of the world's enzymes.
- About 45% of all manufacturing sectors, for example textiles, pulp & paper use modern biotechnology.
- Industrial biotech increases labour productivity by 10-20% over conventional processes.


The environmental effects of industrial applications are striking: the change from chemical to biotechnological methods for the production of a widespread category of antibiotics showed a reduction in the use of electricity by 37%, of solvents of almost 100% and a reduction in wastewater by 90%. Other industrial applications, such as biodegradable plastics and packaging, could bring similar benefits.

http://bio4eu.jrc.es/

## Communicating benefits of healthcare biotech

A big priority for us is to galvanise support from - and to inform - decision makers to better understand what biotechnology is and how it is contributing to a radical breakthrough in medical sciences and innovative treatments for patients. That is why EuropaBio in partnership with France Biotech and the BIA have updated a recent study BioImpact© to help policy makers and journalists discover how healthcare biotechnology is saving lives, helping patients and serving society. The study shows that the top performing medicines treating major diseases for breast cancer, heart disease and inflammatory diseases like rheumatoid arthritis are biotech medicines.

## Bringing our messages to the media

Hardly a day goes by without EuropaBio messages being featured in the press commenting on important issues impacting the industry. More than 350 articles have reached millions of readers and online visits to the EuropaBio web site have jumped to 1000 unique visitors a day - making it one of the most widely visited European trade association web sites.

## Media partnerships

EuropaBio continues to work with magazines like European Biotechnology News http://www. european-biotechnology-news.com/ and Science Business www.sciencebusiness.net/ to enable them to send these excellent magazines and news sources direct to EU policy makers, providing independent news streams that touch on all of biotech's hot topics. Also this year we partnered BioLife TV http://www.biolifetv.com – a brand new online channel – showing latest biotech news and views.

## Promoting responsible bioethics

As representative of the biotech industry we believe that it is our responsibility to elaborate and anticipate the implications of our practices. In fact many of the "hot" ethical topics presented in the media are issues with which the association is engaged. These topics invariably involve ethicists, lawyers and philosophers but it is also the industry's obligation to review "practical" ethics and how they are being applied in industry. Under the leadership of France Biotech, EuropaBio and partners are undertaking to address the issue of how ethics are applied in practice by the industry by undertaking a survey of daily bioethical practices of European biotech industries and we aim to establish a European Observatory of Good Bioethical practices as well as a set of bioethical guidelines for the industry and recommendations for European and national legislators. This project launched this year has the financial support of the EU Commission and will report on the survey results and impact on EU policies in 2008.

## The Invisible Revolution

EuropaBio's short film of "The Invisible Revolution" shows policy makers, the media and stakeholders what biotechnology is and where it appears in our everyday lives and has been shown to audiences of up to 5000 policy makers and industry at events in Brussels and used by National Associations across Europe. The film is now showing on Youtube with a five star rating.

## EuropaBio at BioVision (Lyon) and at BIO2007 (Boston)

EuropaBio has been involved in many events this year, but it was at BioVision where industry, science and society gathers that EuropaBio launched its revamped bioimpact study, where GBE published is green biotech manifesto and enabled a discussion between BioVision participants and agriculture researchers and farmers around their choice to research and grow beneficial GM crops. At BIO the industry organised a number of panels to give a horizon scan of the latest EU policy developments that will impact the biotech industry to the largely European biotech companies that are at BIO each year.

Commission Vice-President Günter Verheugen, responsible for enterprise and industry policy, said:

"Biotechnology is an important means to promote growth, jobs and competitiveness in the EU. The use of biotechnology is however not without controversy and the enhanced use of biotechnology needs to be accompanied by a broad societal debate about the potential risks and benefits of biotechnology including its ethical dimension."

# The Research Goal

## Supporting research excellence.

*MAJOR ACHIEVEMENT:*

### 2 MAJOR EUROPEAN PROJECTS STIMULATING TECHNOLOGY AND INNOVATION GRANTED TO EUROPABIO (LifeCompetence & Match2BIOSME)

### EuropaBio helps make the EU's research programme more SME friendly

This year also saw the culmination of a 2 year long lobbying campaign by EuropaBio to make FP7 more useable, and accessible to biotech companies. Major funds are now allocated for healthcare, agriculture, the knowledge-based bioeconomy. And there are big changes to the rules - giving SMEs 75% funding up from 50% in previous programmes.

### Ensuring continued support for biotech companies to develop and research medicines for rare disorders

The active lobbying, completion and publication by EuropaBio of the first study on the economic impact of the European Union's Regulation on Orphan Medicinal Products has ensured the continued supportive environment for healthcare biotech companies researching and developing treatments for the forgotten communities of patients suffering from rare diseases. The European Commission has subsequently confirmed that they would continue their policy to provide a full ten year market exclusivity for rare disease treatments being developed by our companies - this is good news for patients and means companies can avoid potential losses that could have amounted to millions of euros and would have discouraged them from pursuing this type of specialised research.

**The Biotech revolution …..**

**Down the road …..Drought Tolerance**

Biotech corn with improved tolerance to heat and drought — one of the world's leading causes of famine — can provide a more consistent, reliable food supply and reduce agricultural use of valuable ground water resources (agriculture uses the majority of the world's freshwater resources).

## EuropaBio promotes alternatives to animal testing

As a founding member of the European Platform for Alternatives to Animal Testing (EPPA), EuropaBio has successfully promoted biotech companies researching and providing alternatives to animal testing. The biotechnology revolution of recent years has triggered a wave of innovation creating new solutions to supplant animal testing, not to mention the added turnover it has meant for small- and medium-sized enterprises (SMEs). For example, a recent study jointly undertaken by the European Commission's Research Department and the JRC has reported that four new biotech testing methods can reduce the need for animals and cut validation times in half. These newly discovered assays for bacterial contamination detection (known as pyrogens) have the potential to reduce animal tests in Europe by 200,000 rabbits each year. Most interestingly, they can also be used for new cell therapies, where no appropriate test had previously been available.

*New Biotech tests can reduce the numbers of rabbits used in tests by almost a quarter of a million each year.*

## Finally a coherent research programme for Industrial Biotechnology in Europe

One of the main achievements of EuropaBio was the development of the Strategic Research Agenda (SRA) for industrial biotechnology. The research priorities were provided to the EC and some are included in the first call of the 7th Framework Programme, especially in the "Food, Agriculture & Biotechnology" and the "Renewable Energy" area. In addition, the ERA-Net on Industrial Biotechnology – a network with 16 Member States - is carrying out a detailed overview of the national research programmes, and preparing a first joint call based on the Strategic Research Agenda.

## Plants for the future technology Platform

EuropaBio is also a member of the "Plants for the Future" Technology Platform that has already identified the need for basic research into plants that will be developed as efficient primary feedstocks in the production of renewable resources, including biofuels, in its Strategic Research Agenda. Some of these research areas were already part of the final call for proposals in the 6th Framework Programme and are included in the first call of the 7th Framework.

"EuropaBio's membership in the EPAA has enabled a small biotech company like Straticell to show how we are meeting the big challenge of reducing the need for animal testing thanks to the alternatives we are developing. For instance we see this initiative as an excellent platform to voice our concerns as a small company to develop a suitable regulatory framework ensuring that these tests can be validated and accepted in all member states at an affordable cost".

Michel Salmon, CEO, StratiCELL

# The Access Goal

## Supporting research excellence.

*MAJOR ACHIEVEMENT:*

### PATIENT CHARTER OPENS DOOR TO COLLABORATION FOR THE RIGHT TO FAIR AND EQUITABLE ACCESS TO THE PRODUCTS AND SERVICES ISSUED FROM BIOTECHNOLOGY

### EuropaBio publishes patient charter to put patients first

"This new Patient Charter is necessary to ensure that biotechnological advancements in healthcare meet patient needs. It will ensure that patients and EuropaBio can work together within a clearly defined framework that is based on openness and integrity."

Andrea Rappagliosi,
Chairman of the HealthCare Council,
Merck Serono International

More than 325 million patients to date have benefited from medicines derived from biotechnology. In our fight to reverse the budget driven – cost containment paradigm of the current healthcare systems in Europe and to put patients at the centre of modern policy making, this year EuropaBio published its first ever Patient Charter - setting out a clear framework to ensure the integrity and independence of both patient groups and industry working in partnerships. As the ultimate consumer of bio-healthcare products, patients are our natural allies and we are committed to working with them.

**The Biotech revolution …..**

**Rheumatoid arthritis and biotech**

The total number of cases of inflammatory diseases in the European Union is thought to be around 3 million adults (including 2 million with rheumatoid arthritis) and 50,000 children. There are an estimated 90,000 new cases of rheumatoid arthritis each year in the European Union. The Biotech revolution has brought understanding of the role that TNF $\alpha$ (tumour necrosis factor, a protein produced by numerous cells in the body) plays in chronic inflammatory joint disease which has enabled the emergence of new drugs. These new biological agents, whose role is to prevent TNF $\alpha$ from acting to excess, have shown themselves to be very effective in slowing the progression of the disease. Other biological agents acting through different mechanisms are also effective.

### Green biotech - Promoting policies that respect developing countries

EuropaBio is working with the international industry (CropLife International Global Industry Coalition, Traders, etc.) to develop common positions, and papers on key issues of the BioSafety Protocol implementation and the Codex Alimentarius.

## Respect freedom to trade in commodities

The industry calls on EU decision makers to respect other countries' freedom to trade in biotech crop commodities and EuropaBio has built alliances with food chain representatives to exchange information and keep trading associations up to date on GM approvals. The association continues to work with the food chain to raise awareness of the need and the urgency for a solution to low level presence of GM material, approved outside the EU, which may enter the EU in traded commodities.

### The Biotech revolution …..

**Correcting Iron deficiencies with plants**

Scientists at Aachen University in Germany claim that GM maize could be used to tackle iron deficiency in developing countries. Nearly two billion people in developing countries, mainly women and children, do not have enough iron in their diet. This can lead to anaemia, and can stunt children's development, as well as causing chronic fatigue in adults. The Aachen University team have modified maize by adding genes to its DNA from both soybean and the Aspergillus niger fungus. Working together, the two genes are able to retain iron from the soil, and to make it available in a form that can be absorbed by humans.

# EuropaBio Members

## Membership gives you a strong voice within Europe

### National Associations

ABI (Austria)
APBio (Portugal)
ASEBIO (Spain)
Assobiotec (Italy)
Barabas Zoltan Federation of Biotechnology (Hungary)
BIA (United Kingdom)
BIO.be (Belgium)
BIO Deutschland (Germany)
BioFarmind (The Netherlands)
Bionova (Greece)
BioteknikForum (Sweden)
DIB (Germany)
Estonian Biotech Association (Estonia)
Dansk Biotek (Denmark)
FIB (Finland)
France Biotech (France)
Hungarian Biotech Association (Hungary)
IBIA (Ireland)
Norwegian Bioindustry Association (Norway)
Niaba (The Netherlands)
Organibio (France)
SSCI (Switzerland)
SwedenBio (Sweden)
Swiss Biotech Association (Switzerland)
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EuropaBio is the European Association for Bioindustries.
We represent 83 corporate members operating worldwide,
11 associate members including 5 BioRegions and 25 national
biotechnology associations.

Through our national associations EuropaBio is also the voice of
over 1800 small and medium-sized enterprises.


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