

Competitiveness of the European biotechnology industry

Contact:

Tomas Jonsson

European Commission, Enterprise and Industry DG

Unit F5: Competitiveness in the Pharmaceuticals Industry and Biotechnology

Telephone: +32 (0)2 - 296 05 51

E-mail: tomas.jonsson@ec.europa.eu

This is a working document prepared as part of the input material for the 2007 mid-term review of the Commission's biotechnology Strategy and Action Plan. It may be subject to further changes or amendments. The contents do not necessarily represent the Commission's official position.

Table of contents

1	Introduction and sources	2
2	Overall figures on the biotechnology industry	3
2.1	Definition	3
2.2	Employment	3
2.3	Number of firms and geographical distribution	5
2.4	Biotechnology patents	5
2.5	New EU Member States	6
3	European competitiveness at the aggregate level.....	7
4	New company formation.....	8
5	The knowledge base: R&D, innovation and product development	8
5.1	Healthcare biotechnology.....	9
5.2	Agricultural biotechnology	11
5.3	Industrial biotechnology.....	13
5.4	Energy and environment	16
5.5	Marine biotechnology	17
6	Access to finance.....	18
7	R&D funding and expenditure	21
7.1	Private R&D expenditure	21
7.2	Public R&D funding and a comparison of national performance.....	21
8	Cooperation between company clusters and regional networks	24
9	Consumers.....	26

1 Introduction and sources

The purpose of this note is to present the state of competitiveness of the European biotechnology industry. Analysing competitiveness can be done in different ways and the approach depends on the kind of data that is available. This analysis has been made by using various sources of biotechnology statistics. However, standardised data sets from Eurostat are not available. The focus of the analysis is not on providing as much statistics as possible but on analysing the factors behind the concept “competitiveness”. The text also attempts to identify what obstacles may exist and the influence this has on the competitiveness of European biotechnology companies and research centres.

Data on the economic impact of biotechnology has been made available through the publication of the Bio4EU study by the European Commission’s Joint Research Centre/IPTS in April 2007.

The sources used for the competitiveness analysis include:

- Annual report of the European Medicines Agency 2005
- Best practices of public support for early-stage equity finance, European Commission, September 2005
- Beyond borders – Global biotechnology report 2006 and 2007, Ernst & Young
- Bio4EU study by JRC/IPTS (<http://bio4eu.jrc.es/>)
- BioPolis – Inventory and analysis of national public policies that stimulate biotechnology research, its exploitation and commercialisation by industry in Europe in the period 2002–2005, June 2007
- Biotechnology in Europe: 2006 comparative study, Critical I and EuropaBio
- Commission Communication “European Industry: A Sectoral Overview” - SEC(2005) 1216 final of 5.10.2005, and “Technical Update – 2006”
- Commission Communication “on the mid term review of the Strategy on Life Sciences and Biotechnology” – COM(2007)175 of 10/04/2007
- Compendium of patent statistics 2006, OECD
- Competitiveness in Biotechnology Advisory Group (CBAG) - 2006 Report
- Eurobarometer 64.3 “Europeans and Biotechnology in 2005: Patterns and Trends”, May 2006
- European Federation of Pharmaceutical Industries and Associations: “Pharmaceutical Industry in Figures”, 2006 edition
- Genetic Engineering News, Dec 2006
- Green Paper Towards A Future Maritime Policy For The Union: A European Vision For The Oceans And Seas, European Commission, COM(2006) 275 final, 7 June 2006; and Background Paper No. 10 on Marine Biotechnology
- ISAAA Brief 35, 2006: Global Status of Commercialized Biotech/GM Crops: 2006
- OECD biotechnology statistics – 2006, Brigitte van Beuzekom and Anthony Arundel
- Private biotech 2004 – the numbers, Nature Biotechnology 6/2006
- Public biotechnology 2005 – the numbers, Nature Biotechnology 6/2006
- Recommendations from the Contact Network with Member States’ Ministries with Responsibility for Competitiveness in Biotechnology, 2006
- Statistiques en bref 10/2006, European Communities (KS-NS-06-010-FR-N)
- “The Prospects for Marine Biotechnology Development in the UK”, Foresight Marine Panel, 2005
- U.S. Dept. of Agriculture, National Agricultural Statistics Service (NASS), Acreage. June 29, 2007

2 Overall figures on the biotechnology industry

2.1 Definition

In this note, the definition of “biotechnology” is given by the OECD definition (updated in 2005). The definition of a “biotechnology company” below may exclude certain companies whose activities are at least partly in the field of “biotechnology”. Even if the available statistics may exclude certain companies, the policy proposals aims to take into account all companies involved in biotechnology-related activities.

The figures in this chapter are based on the definition of what constitutes a biotechnology company given by Critical I and by OECD. According to Critical I’s definition, only the dedicated biotechnology industry is represented, whose primary commercial activity depends on the application of biological organisms, systems or processes. Suppliers and research organisations, that are only partly involved in biotech, are excluded. Big corporations for which biotechnology is only a minor part of their activities are also excluded. Dedicated biotech subsidiaries are considered as entities and are thus included. The OECD definition is comparable to that of Critical I.

Note: Critical I data for “Europe” presented below include Norway and Switzerland.

It should be kept in mind that the economic contribution of biotechnology goes way beyond the dedicated biotech companies. Their inventions, methods or ready products are used in other sectors and create a larger value added than that recorded in the biotech firms themselves.

2.2 Employment

The European dedicated biotechnology industry employs 96 500 people in total, mostly in SMEs. The industry is highly research-intensive with 44% of employees (42 500) involved in research and development functions. The typical European company (as defined by Critical I) at the age of 6-10 years has 28 employees, and at 11-15 years it has 41 employees¹.

In itself, the dedicated biotech industry is not big, but its inventions are used in other industries both in terms of novel products and improved production methods. It is difficult to get exact data to describe the impact, but the industry sectors that may pick up biotech inventions are very sizeable²:

- The pharmaceutical industry employs 615 000 people³ (year 2005) and accounts for 3.5% of EU manufacturing GVA. According to Bio4EU, the manufacturing GVA share of the pharmaceuticals industry was 4% in 2002⁴. Modern biotechnology-based products

¹ Critical I, 2006

² Commission Communication "European Industry: A Sectoral Overview" - SEC(2005) 1216 final of 5.10.2005, and “Technical Update – 2006” available at:
http://ec.europa.eu/enterprise/enterprise_policy/industry/com_2005/sec_2005_1216.pdf
http://ec.europa.eu/enterprise/enterprise_policy/industry/doc/sec_overview_update06.pdf

³ EU25+Switzerland+Norway. European Federation of Pharmaceutical Industries and Associations: “Pharmaceutical Industry in Figures”, 2006 edition.

⁴ Bio4EU study, JRC/IPTS 2007

including biopharmaceuticals, vaccines and diagnostics contributed about 0.25% to the manufacturing GVA.

- The chemicals industry employs 1.2 million people directly (and twice that number indirectly) and has 27 000 enterprises. It accounts for 12% of gross value added in EU manufacturing and for 1.9% of GDP.
- The plastic industry has 1.5 million employees and 37 000 enterprises.
- The pulp and paper industry employs 740 000 people and makes up 3% of EU manufacturing value-added.
- The textile industry employs 2.3 million workers in 70 000 companies. The textile finishing segment contributes 0.28% of manufacturing GVA and 121 000 jobs; the share of biotechnology being 0.13% of manufacturing GVA and 48 000 jobs in textile finishing with enzymes⁵.
- 14.4% of *all industrial manufacturing sub-sectors* (excl. pharmaceuticals) use biotechnology in their processes, measured in contribution to EU25 gross value added (GVA). Of a total of 4.9 million employees in manufacturing sectors (excluding pharmaceuticals and chemicals) 1.5 million or 30% are active in processes based on modern biotechnology (food processing, detergents and textile finishing, etc)⁶.
- In agricultural primary production and food production, biotech is estimated to make an economic contribution of €3.0-5.6 billion, or 13-23% of the input sectors' turnover, mainly from food enzymes, veterinary products, feed additives, and diagnostics⁷. Figures on its contribution to employment are missing.

Thus, biotechnology is a very important part of a chain of research, development and innovation activities which generate novel products or production processes in many industrial sectors.

When looking at private biotechnology companies (not listed on the stock market) only, the median number of employees is 12 in Europe and 28 in the US. This is probably related to the lower median age of European private companies (10 years compared to 12 in the US), but also to the weaker supply of investment capital⁸.

The number of employees is the highest in Denmark, France, Germany and the UK with between 10 000 and 20 000 but considerably lower in the other Member States. Employment data depend on the definition of a “biotech company”⁹.

According to OECD statistics covering some EU Member States, e.g. the UK has 9 644 biotechnology R&D employees and Germany 8 024, which can be compared with 73 520 in the USA.

Admittedly, the exclusion of big pharmaceutical or chemical companies from the company definition means that the figures above are not entirely representative. To compensate for this, OECD statistics include a broader definition for biotechnology-related activities, according to which there are 24 131 employees in biotechnology-related activities in Germany and 22 405 in the UK, while the USA has 172 391. The figures relate to year 2003 and 2004 and are unfortunately not complete for the EU.

⁵ Bio4EU study, JRC/IPTS 2007

⁶ Bio4EU study, JRC/IPTS 2007

⁷ Bio4EU study, JRC/IPTS 2007

⁸ Nature Biotechnology 6/2006

⁹ Critical I, 2006

2.3 Number of firms and geographical distribution

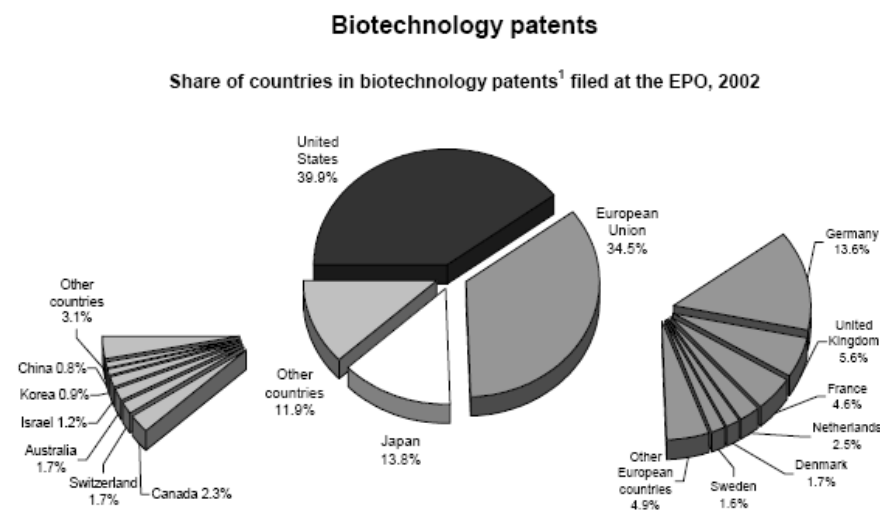
In terms of number of companies the leading European countries in biotechnology are Denmark, France, Germany, Netherlands, Sweden and the UK. The number of firms doubled during the mid-90s amid a surge in discoveries and investments in biotechnology. In contrast, the years after 2001 have been characterized by consolidation through company acquisitions and mergers. In 2004, Europe had 2 163 biotech companies compared to 1 991 companies in the USA, but the European companies are generally smaller in size¹⁰.

The data may differ depending on the methodology (some businesses are active in several sectors). According to OECD statistics there were 3 154 companies in Europe at least partially active in biotechnology, but the figure may be higher in reality since not all Member States are covered by this survey.

It is possible to identify several company clusters and regional networks in Europe¹¹, which play a role in connecting people and resources in the sector. As for geographical distribution, biotech companies are present across the whole continent but often concentrated to existing clusters.

2.4 Biotechnology patents

Europe has a strong technological basis when measured in the number of patent filings. The European Union accounts for 34.5% of all biotechnology patent applications at the European Patent Office (EPO) as compared to 39.9% for the US (see the pie chart below). No figures on granted patents are available.



Source: OECD Biotechnology Statistics - 2006

¹⁰ Critical I, 2006

¹¹ Examples of biotech clusters and regional networks: Scanbalt BioRegion (Denmark, Estonia, Finland, Germany, Iceland, Latvia, Lithuania, Norway, Poland, Russia and Sweden), BioTech-Region München (Germany), Medicon Valley Academy (Sweden, Denmark), BioValley (France, Germany, Switzerland), ERBI (UK), Atlantpole (France), Lyon Rhone Alps Life Science Network (France), Parc Científic de Barcelona (Spain), EuroBioCluster South (Spain, France, Switzerland, Italy and South Germany), Transalpine BioCluster (France, Italy and Switzerland), etc.

The table below depicts the 10 most active European regions in filing biotechnology patent applications at the EPO. In absolute terms (number of patents) regions in France, Germany and the UK are most active. In relative terms (number of patents per million capita) some of the small(er) Member States' regions have a leading position: Belgium, Netherlands, Sweden and Denmark¹².

par million d'habitants		Nombre total	
Prov. Brabant Wallon (BE)	54	Île de France (FR)	145
Oberbayern (DE)	34	Oberbayern (DE)	139
Karlsruhe (DE)	33	Denmark (DK)	139
Berlin (DE)	32	Berlin (DE)	108
Utrecht (NL)	28	Köln (DE)	97
Braunschweig (DE)	28	Berkshire, Buckinghamshire & Oxfordshire (UK)	93
Stockholm (SE)	27	Düsseldorf (DE)	93
Denmark (DK)	26	Karlsruhe (DE)	88
Hamburg (DE)	24	Inner London (UK)	86
Sydsverige (SE)	23	East Anglia (UK)	73

Publication : Statistiques en bref 10/2006, European Communities (KS-NS-06-010-FR-N)

The regional concentration in biotechnology is lower than for high technology in general. The 10 most active regions still account for less than 30% of the total number of patent requests in EU-25.

Statistics on the number of patents filed under the Patent Co-operation Treaty (PCT)¹³ in 2003 show a similar picture with the US at a 43.3% share, the EU at 27.8% and Japan at 14.1%. Over the period 1995-2003, the growth in biotechnology patent applications to EPO is strongest in China (+49%), New Zealand (+42%), India (+30%), Taipei (+26%), Korea (+22%) and Brazil (+22%), whereas the EU increased by 7% and the US by 1.5%. The level of internationalisation in biotech patents¹⁴ is high in several European countries including Switzerland and low in the US, Korea and Japan¹⁵.

2.5 New EU Member States

The available data for the twelve latest EU members are still fragmented and incomplete, and not always comparable because they come from different sources. Estonia has 12 biotech companies with 192 employees, Hungary has 16 companies with 394 employees, and the Czech Republic has around 65 companies. Poland has 13 companies with 946 employees, but only 11.5% of the employees are active in R&D (the world average is 42%), with most being employed in production. Many of the companies in the new EU countries have been founded rather recently but some date back to the early 1990s. It is notable that there is already a diversification of research and development into several biotech branches in the twelve new Member States. E.g. Poland has a focus on healthcare but also on industrial-environmental applications. The industry is still in its infancy and revenues are modest, but several new

¹² Eurostat figures from 2002 ("Statistiques en bref", 10/2006)

¹³ The Patent Co-operation Treaty (PCT) makes it possible to seek patent rights in a large number of countries by filing a single international application.

¹⁴ Internationalisation as measured in foreign ownership of domestic patents, domestic ownership of patents filed abroad, or patents with foreign co-inventors.

¹⁵ "Compendium of patent statistics 2006", OECD

Member States governments have recognised biotechnology as a key economic area, and state funding of R&D is steadily growing¹⁶.

3 European competitiveness at the aggregate level

In general Europe entered the field of biotechnology later than the US. Since a long time is necessary to develop biotech products, sales or trade do not seem to be good indicators to measure the competitiveness of the European biotech industry. If research expenditure is a measure of future success, then the current state of biotech research can be assessed by the number of companies, people employed, expenditure on R&D, and products in the pipeline. Also the venture capital and equity finance raised are measures of the current activity that could lead to productive results in the future.

The majority of biotech companies are small and generate (yet) very low revenues. In Europe and the USA, 95% of the revenues come from 530 public companies and 650 larger private companies. Some 2200 small private companies (with less than 40 employees) generate only 5% of the revenues, account for less than 10% of R&D spending and just under 20% of the R&D employees¹⁷.

Most European biotech companies are micro or small, research-intensive firms, smaller than their US counterparts, partly due to the significantly greater availability of risk capital and debt provision in the USA. At the aggregate level, the US biotech industry consists of roughly the same number of companies as the European industry, but the difference is clear (based on 2003 figures):

- the US biotech industry employs twice as many people as Europe's,
- spends three times more on R&D,
- raises more than twice as much venture capital,
- raises more than twice as much through equity,
- raises more than three times as much through debt financing,
- generates twice as much revenue in total,

By comparing the R&D expenditure per R&D employee, we find that European companies spend on average €179 000/R&D employee, while the US figure is €264 000 (47% higher). R&D spending in relation to all employees gives €79 000/employee in Europe and €110 000 in the US (39% higher). These differences are smaller than in the examples above, but the reader should bear in mind that R&D spending and employment may be causally linked to the amount of capital raised (or in other words: they can only spend the money they have been able to find).

An estimation of the biotechnology industry's contribution to Europe's current economic wealth is best made on the basis of companies that have grown larger, generate higher revenues and can sustain their R&D. The most successful biotech companies have much higher productivity as measured by revenues per employee than small firms do, which shows that an economically productive size really matters. As an illustration, Critical I has identified 33 "European Elite Companies" that display significant growth, R&D spending and revenues.

¹⁶ Various sources

¹⁷ Nature Biotechnology 6/2006

From this perspective, the number of successful European biotech companies is still low. However, many of the small companies should be able to grow significantly and generate many new jobs as they succeed in putting new products on the market. In that sense, the biggest growth possibilities are perhaps presented by today's tiny biotech research labs.

4 New company formation

Europe excels at new company formation and even after the 2001 crunch new company formation in 2003-2004 was as high as 18-25% in several Member States (ES, IT, AT, GR, NL, PT) while reaching appr. 15% in some countries with a mature biotech industry (DK, UK, CH, SE, IE, FR). As said earlier, the rate of start-ups is a poor measure of success and the growth problems of European SMEs are a sign of warning. Fewer but stronger companies is a preferable path although national authorities might be tempted to boost new company formation by offering grants and incentives. This may be ill-advised if the necessary financial resources cannot be mobilised to make existing businesses grow.

As companies faced harsh economic realities in 2001-2004, mergers & acquisitions and insolvencies made the total number of companies fall somewhat to 2 163 in 2004. The resulting business consolidation will hopefully mean that more companies can realistically expect to go through the difficult stages of product development, clinical trials (in the case of medical biotech) and marketing.

Unavoidably, some European companies leave Europe to get a home base on the American market (it has not been possible to get figures). EU and national policy makers urgently need to identify and implement policy measures that would encourage more companies to stay in Europe.

5 The knowledge base: R&D, innovation and product development

Overall, Europe's basic research and knowledge-building are world class, but Europe does not excel in turning research into commercial applications on a broad front, as evidenced by the relative weakness of European biotech companies to their US competitors.

The level of activity in biotechnology among the EU countries depends largely on the research and business environment in each Member State. Some Member States have developed advanced pharma and biotech sectors whereas others are lagging behind. This may be the result of a poor focus on innovation and poor funding schemes, among other factors.

Europe's competitive edge lies mainly in healthcare applications and in industrial biotechnology including the chemical industry. The major competitors today are the USA, Canada and Japan, but new competitors emerge quickly, particularly in the Asia-Pacific region (China, India, Korea, Australia, New Zealand, etc) and there are justified concerns as to the long-term competitiveness of the European biotech industry.

In the following section, Europe's R&D strengths and the prevalent obstacles to development for each of the main branches of biotechnology will be analysed.

5.1 Healthcare biotechnology

Healthcare biotechnology accounts for the largest number of biotech companies in Europe as well as in the USA. More than 250 million patients have benefited from the 142 biopharmaceuticals approved since 1982 (treatment of heart attacks, multiple sclerosis, breast cancer, cystic fibrosis, leukaemia, etc).

The economic contribution of healthcare biotechnology

Biopharmaceuticals, diagnostics and recombinant vaccines in EU25 had a turnover of appr. €bn in 2002 and the gross value added was €3.1bn, representing 0.25% of total manufacturing gross value added in 2002¹⁸.

Over the period 1996-2005, 9% of the pharmaceuticals launched in EU25 were biopharmaceutical products (11% in the US). The growth in turnover for biopharmaceuticals is twice as high as for pharmaceuticals (23% to 11%)¹⁹, making this a more profitable segment.

Although most of Europe's biotech companies focus on healthcare, EU25 still has a weak position in the development and marketing of biopharmaceuticals, with only 15% of products developed by EU companies, compared to 10% by Switzerland and 54% by the USA. Among the *ten most sold biopharmaceuticals* (representing half the world market), seven are US products, two Swiss and only one EU25 (by Sanofi-Aventis, France)²⁰.

In the discovery of new medicines, diagnostics and the understanding of diseases, biotechnology provides new R&D tools. A great part of all innovative medicines, whether traditional small molecule pharmaceuticals or biopharmaceutical proteins, are made available by applying biotechnology processes. Both large corporations (e.g. GSK, Serono, and Innogenetics) and SMEs are investing heavily in their knowledge base, which is why biotech should be regarded as a key enabling technology that will contribute to an advanced knowledge-based economy. However, R&D projects often involve high risks of failure, but the successful ones can generate substantial economic returns.

Regulation should give predictable and stable conditions for industry and consumers. Healthcare biotechnology is already regulated to a large extent, offering a coherent legislative framework for authorisation and marketing. All biotechnology medicinal products follow a centralised European procedure for marketing authorisation. The recent introduction at the European Medicines Agency of the new SME services and fee reductions are an important element in helping biotech companies (most are SMEs) to get marketing authorisation.

“Advanced therapies” is a new, booming industry in the field of gene, cell and tissue-based products. The Commission proposed new harmonised EU legislation in November 2005 that would provide a centralised marketing authorisation system for these products. Arguably such a system would be the best to provide stable conditions and encourage companies to invest in R&D. The European Parliament and the Council of Ministers adopted the Regulation in the first reading in May-June 2007.

¹⁸ Bio4EU study, JRC/IPTS 2007

¹⁹ Bio4EU study, JRC/IPTS 2007

²⁰ Bio4EU study, JRC/IPTS 2007

Generic biotech drugs, so-called “biosimilars”, will become an interesting business opportunity. The EU has introduced a regulatory pathway for the assessment, authorisation and monitoring of similar biological medicinal products (i.e. biosimilars, also called “follow-on biologics” in the US). By closing this gap in the legislation, the EU is set to gain a competitive advantage over the US.

In the coming years, the patent protection of many biotech medicines will expire, opening up for generic producers, increasing competition and putting more pressure on prices. Research on and the development of biosimilars is an R&D-intensive activity, unlike the production of generic pharmaceuticals (small molecule drugs). Company growth in biosimilars may lead to positive effects on the knowledge base and stimulate research and novel product development.

The prevalent obstacle faced by businesses developing healthcare applications is a financing gap occurring in later-stage development. The limited availability of additional rounds of risk capital coincides with a need for greater financial resources to go through clinical trials. This could motivate a policy intervention to correct the market failure.

The difference between *market authorisation* and *real access to markets* (reimbursement decisions) may hamper the development of innovative biotech medicines by SMEs in Europe. As the issue is of economic importance, it deserves to be addressed at both EU and national level.

Another issue of concern mostly to SMEs is the relatively high cost and heavy administration of filing and defending patents. Directive 98/44/EC on the legal protection of biotechnological inventions has been implemented by all Member States in 2006. However, resolving the issue of a consistent, effective and affordable Community Patent is a precondition for strengthening the competitiveness base.

Biopharmaceutical product development and clinical trials

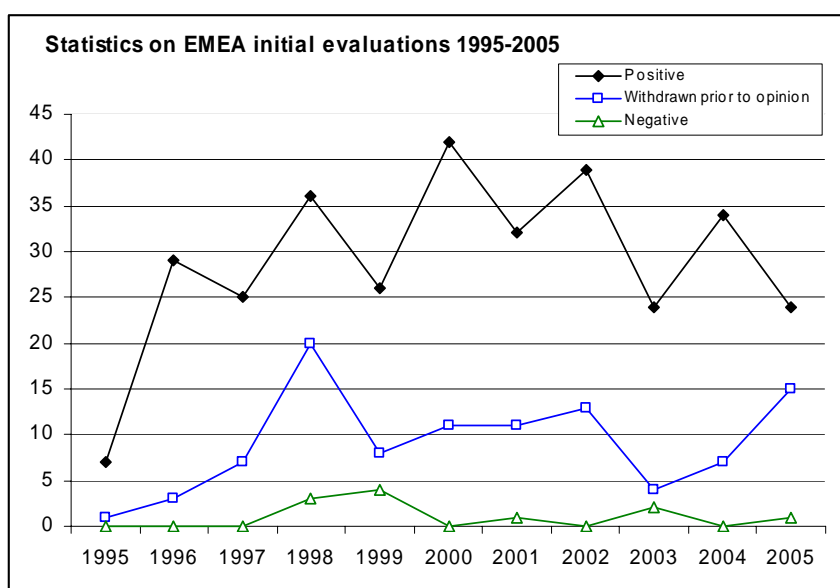
Biopharmaceuticals is an important source of innovative healthcare products, as described in the Bio4EU study.

The number of biotech drugs in late stage clinical trials is increasing: among European public companies including Switzerland (private companies not included), the product pipeline increased by 28% from 409 to 523 products in 2005, 84 of which are in late-stage development²¹, according to Ernst&Young. The Bio4EU study indicates that EU25 companies had 109 biopharmaceutical products in clinical trials in 2005, an increase of 40% since 1996, but much less than the 190 products tested by US companies. The EU share of biopharmaceuticals in clinical trials is stable at 11%, while the US share has declined from 18% to 12% since 1996 because growth in traditional pharmaceuticals in clinical trials was even higher: 80%²². Over the last five years, there is a clear move towards late-stage (phase II and III) development as a proportion of all products in clinical trials. This is a result of a strong focus on product development and, according to Ernst&Young’s estimate, will lead to a surge in drug approvals in 2006 and on. Altogether, the improvement in market prospects amounts to a strengthening of the competitiveness of the European biotech industry.

²¹ “Beyond borders – Global biotechnology report 2006”, Ernst & Young

²² Bio4EU study, JRC/IPTS 2007

The number of applications for marketing authorisation at EMEA²³ has fluctuated between 25 and 40 each year since 1996 and there is not yet any sign of an increasing trend²⁴, as shown by the chart to the right.



Judging by the product pipeline, EU companies will be able to gain marketing authorisation for a number of innovative biopharmaceuticals in the next years. Ideally, these products will generate substantial revenues and make the companies self-sustainable so they can carry out new R&D projects. Such a consolidation is necessary to keep the large number of European start-ups that are so far relying on external financing to survive.

5.2 Agricultural biotechnology

Modern biotechnology is applied in a variety of ways in agriculture, forestry, horticulture and fishery. In primary production, biotechnology is used for the breeding and propagation of plants and animals, and indirectly, through the production of feed additives, veterinary pharmaceuticals and diagnostics. Biotech is also used to produce enzymes used as inputs for food processing, traceability of food ingredients, and assurance of food safety²⁵.

Marker assisted selection is a technique used to select new plant, animal and fish varieties for agriculture, horticulture and forestry, livestock and fish production in Europe²⁶ with the help of molecular markers. It therefore differs from the technique used in genetically modified organisms. These applications have so far not given rise to much public controversy. With the rapid development of plant and animal science, modern biotechnology is anticipated to play an increasing role in the plant, animal and fish breeding industry and will affect the competitiveness of the European food industry in general.

²³ Applications for new medicines are reviewed by the European Medicines Agency (EMA) through the Committee for Medicinal Products for Human Use (CHMP). The Committee assesses the quality, safety and efficacy of a medicine and, based on an overall balance of the benefits and risks of the medicine, gives its opinion on whether or not the European Commission should grant a Community-wide marketing authorisation.

²⁴ Annual reports of the European Medicines Agency, 1995-2005

²⁵ Bio4EU study, JRC/IPTS 2007

²⁶ Bio4EU study, JRC/IPTS 2007

The market for genetically modified crops has grown quickly worldwide. 102 million hectares of GM crops were grown in 22 countries in 2006²⁷, equivalent to appr. 6% of cultivated land worldwide. In the EU, the uptake has been so far limited, where GM crops are cultivated only in 6 Member States (maize). Only in Spain GM maize has a significant share of maize cultivation with 13% of the acreage (less than 1% of EU maize acreage), compared to 61% of the acreage in the USA²⁸ (52% in 2005, 61% in 2006 and 73% in 2007) and 20% worldwide²⁹ (17.8% in 2005 and 20.1% in 2006).

The economic contribution of agro-biotechnology

- The combined economic contributions from biotech in agriculture are estimated to €3.0–5.6bn, or 13-23% of the input sector's turnover³⁰.
- The most common applications in Europe in primary production include veterinary products (30%), feed additives (28%), food enzymes (13%), and diagnostics (10%).
- The indirect impact of biotechnology is stronger than the figures show. The scientific advances from biotechnology benefit the "user sectors" in agriculture and improve their economic performance³¹.

Public and private investments into agro-biotechnology research have decreased in the EU during the past decade and there has been a delocalisation of private R&D to countries outside Europe. US companies are market leading in agro-biotech but new competitors are emerging, particularly in the Asia-Pacific and South American regions.

The fact that the knowledge base has been eroded is alarming since plant science discoveries are also key to developing industrial-environmental applications. In the light of recent international developments, i.e. the increase in global food demand and the development of biofuel industries worldwide, it is expected that increased agricultural productivity will become an important issue again. Genetic engineering may contribute to higher productivity but can also be used to develop crops with specific traits for industrial processing and provide raw material for various (non-food) bio-based products. Plants and/or farm animals can be used for producing bio-pharmaceuticals: so-called "molecular farming" is already being pursued on a small experimental scale in the USA and Europe. Molecular farming in plants and animals has several benefits over synthetic molecules, but its cost-effectiveness has not yet been clarified, although it will likely be case-specific.

²⁷ Bio4EU study, JRC/IPTS 2007

²⁸ USDA-ERS, 2007: <http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm>

²⁹ ISAAA, 2006: <http://www.isaaa.org/resources/publications/briefs/35/ppts/slides/default.html>

³⁰ Bio4EU study, JRC/IPTS 2007

³¹ Bio4EU study, JRC/IPTS 2007

The regulatory framework

A stringent regulatory framework on genetically modified organisms (GMOs) exists at the European level. The EU started legislating on GMOs in the early 1990s. The main legal acts are Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, Regulation (EC) No 1829/2003 on genetically modified food and feed, and Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms; both of the European Parliament and of the Council of 22 September 2003.³² Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms as amended by Council Directive 98/81/EC of 26 October 1998, complements the series of basic acts regulating GMOs. All these basic acts above have been supplemented by several Decisions which, either in a legally binding way or in the form of guidelines, contribute to the implementation of policy objectives such as risk assessments, monitoring, traceability, labelling, inspections and controls.

In line with the conclusions of the mid-term review of the Strategy on Life Sciences and Biotechnology, a necessary precondition for realising the economic potential of plant science is a correct and uniform application across the EU of the regulatory framework for the authorisation of GMOs. This would provide stable conditions for plant science R&D projects, for farmers who choose to cultivate GM crops and for distributors. A second precondition is to have an informed debate with the public and explain the functioning of the rigorous GMO framework and the safety assessments carried out.

Yet another precondition is to give adequate support to research in plant science and especially *technology transfer* to related areas, notably industrial-environmental applications, but also pharmaceuticals.

5.3 Industrial biotechnology

Biotechnology is today being used in manifold industrial manufacturing processes. The use of isolated enzymes or non-growing cells is called *biocatalysis* and the use of growing micro-organisms is called *fermentation*. Biotechnological processes have advantages over traditional chemical processes because they contribute to a reduced environmental impact, improved process efficiency and fewer purification steps, and lower production costs. In addition, end products can be given improved or novel characteristics³³.

Products

There are many examples that biotechnology is applied in various products already on the market, such as fibrous polymers from biomaterial for household applications (e.g. carpeting), biodegradable plastics made from maize, lubricants, cooling fluids, pulp and paper, and in mining (extraction of metals from ore using micro-organisms). Enzymes are used for food processing and to manufacture antibiotics, vaccines, vitamins, detergents, bulk chemicals and fine chemicals³⁴.

³² For more details on regulation, see “User Guide to European Regulation in Biotechnology” on http://ec.europa.eu/enterprise/phabiocom/comp_biotech_intro.htm

³³ Bio4EU study, JRC/IPTS 2007

³⁴ Bio4EU study, JRC/IPTS 2007

European companies are world leading both in the production of enzymes and in the use of enzymes to manufacture chemicals, such as eco-efficient enzymes in washing powder which allow washing at lower temperatures. Tailor-made enzymes may reduce the consumption of water, raw materials and energy in industrial processes. The enzymes are not necessarily produced from genetically modified micro-organisms, but can also use naturally existing ones to start biocatalytical processes.

The production of biogas, biofuel (ethanol) and chemicals from biomass are other examples where biotechnology is being used to improve the ecological sustainability of industrial processes and transportation³⁵.

Europe has a strong knowledge base in industrial biotechnology at the onset, with many established companies active in this area, not least the big chemical companies, e.g. Novozymes, Danisco, Chr. Hansen (Denmark), BASF, AB Enzymes GmbH, DIREVO Biotech AG (Germany), DSM (Netherlands). Denmark is the leading enzyme producer with 47% of world production in 2001. The established companies are joined by new entrants, mostly SMEs. There are recent examples of European companies acquiring US-based companies, thereby strengthening their knowledge base and innovation potential, e.g. the Danish food ingredients producer Danisco that acquired Genencor in 2005.

The economic contribution of industrial biotechnology

- There are 117 enzyme producing companies worldwide, with 75 (64%) located in EU25 and 21 (18%) in the USA. France, Spain and Germany have more than 10 companies each. Denmark has fewer companies but accounts for as much as half of the world enzyme production.
- The world enzyme production amounted to 53 000 tons/year in 2001, and was estimated to 65 000 tons/year in 2005, of which European companies had a 75% share.
- With a world enzyme market value of €1,8bn European companies are estimated to account for €1.3bn or 0.05% of GVA (Gross Value Added) in EU manufacturing³⁶.
- In food production, enzymes are used for dairy, starch and sugar, bakery, fruit juice, wine, brewing and dietary supplements. Food production makes an economic contribution of €70bn or 4.6% of GVA in EU manufacturing. It accounts for 4.2% of employment in the manufacturing sector.
- The EU pulp and paper sector (€75bn turnover) makes use of enzymes with a GVA of appr. €300m. The cost of enzymes is relatively low, but it is nonetheless an essential component for 15% of pulp manufacturing. Environmental benefits from enzymes lead to lower chlorine emissions (90%), lower energy use (32%), less GHG³⁷, additives, etc.
- Textile finishing includes bleaching, printing, dyeing and other treatments of the contributed €4.3bn or 12% to the GVA of the textile industry in 2002, which amounted to 0.28% of total manufacturing GVA and 121 000 employment opportunities. With an adoption rate of 40% in textile finishing, biotechnology contributed €2bn and 48 000 jobs.
- Bio-based polymers as a replacement for plastic from fossil oil are still not widely used, but the EU accounts for a production of 148 000 tonnes a year, equivalent to an EU market value of €5m. The world production is 390 000 tonnes a year, but is expected to

³⁵ Bio4EU study, JRC/IPTS 2007

³⁶ Bio4EU study, JRC/IPTS 2007.

³⁷ Various green house gases

rise rapidly in the near future. Poly lactic acid (PLA) already today has a **cost advantage** to Polyethylene terephthalate (PET) even if the oil price drops to \$27 per barrel.

- Bio-ethanol world production is appr. 30 m tonnes, of which the EU has a 2.6% share. Bio-ethanol production in the EU and US can be made competitive at today's oil price of appr. \$60 per barrel, provided that subsidies/tax exemptions are given in the transition phase. In a few years, when second generation biofuels can be produced through enzymatic hydrolysis of entire plants, production costs become competitive with fossil fuel.

To optimise the plant material needed for industrial biotechnology processes, it is advantageous to use genetically modified organisms. One example is BASF's Amflora Potato that contains mainly amylopectin-type starch, not amylose. Amylopectin is well suited for processing because of its low viscosity (liquid), unlike amylose which is rather like a gel. With high water solubility and bonding capacity, amylopectin can be used as raw material for paper, textile, glue, and lubricants. Compared to the mixed starch content obtained from a conventional potato, amylopectin will save energy and simplify the production process.

A central competitiveness issue is the uptake of industrial biotech methods in the economy³⁸. An efficient uptake depends on both demand and supply side factors. To realise the full potential of industrial biotech, necessary preconditions would include: a **clear political strategy** at both EU and national level, **favourable economic and regulatory conditions**, and a **demand-side stimulation of key technological capabilities**. The coherence of EU and national policies (initiatives, programmes, financial instruments, etc) is of particular importance. Concrete steps have been taken in this direction with the Commission's adoption of the Communication on the mid-term review of the Strategy on Life Sciences and Biotechnology, which was supported by Member States in the Conclusions of the Competitiveness Council of May 2007.

A second precondition for increased competitiveness is to demonstrate the usefulness of white biotech by setting up **integrated bio-refineries**³⁹, which are flexible installations at pilot or industrial scale for the production of biofuels and other biomaterials, based on a variety of feedstock (biomass). See section 5.4 for more details.

A third precondition for making bio-based products or processes competitive in relation to conventional (e.g. chemical or fossil-based) methods, is to ensure an adequate supply of biomass (renewable resources derived either from crops, wood or biowaste)⁴⁰. The supply of raw material from natural resources, secondary raw materials and recyclable waste needs to be cost-effective, reliable and environmentally friendly. A coherent policy approach for raw materials supply will need to build on all relevant policy areas, including research and innovation, environment, agriculture, development, trade, etc.

³⁸ Recommendations from the Contact Network with Member States' Ministries with Responsibility for Competitiveness in Biotechnology, 2006

³⁹ Recommendations from the Contact Network with Member States' Ministries with Responsibility for Competitiveness in Biotechnology, 2006

⁴⁰ Recommendations from the Contact Network with Member States' Ministries with Responsibility for Competitiveness in Biotechnology, 2006

5.4 Energy and environment

Energy and environment are two very central policy areas for the coming decades. Biotechnology is part of the solution to the challenges we are facing in trying to secure a reliable and sustainable energy supply and in protecting our environment.

Biotechnological processes can contribute to energy savings, reductions in water consumption, waste reductions, as compared to conventional (chemical) production processes. Such applications are already available and have had a significant impact on European industry⁴¹. An early adoption of new environmentally-friendly techniques may give Europe a competitive edge – in addition to the environmental benefits.

However, **the transition to eco-efficient technologies will be slow and difficult unless given adequate political support** from the EU and Member States. The importance of **stimulating eco-innovation** was emphasized in a 2006 report from the *Independent Expert Group on R&D and Innovation* headed by Esko Aho, and in a 2004 report from the *High Level Group* headed by Wim Kok. The Commission recognises Europe's potential to make industrial biotechnology an important eco-industry, and has supported the launch of the "Industrial Biotechnology Platform".

Examples of policy measures to facilitate the transition to sustainable industrial processes or products include:

- One EU initiative to start the transition from fossil fuels to bio-based ones is the adoption of Directive 2003/30/EC of the European Parliament and of the Council of 8 May 2003 on the promotion of the use of biofuels or other renewable fuels for transport. In addition, the Commission has adopted a Biomass Action Plan⁴² which also includes biofuels. A progress report on biofuels⁴³ from January 2007 points at increasing sales of biofuels but estimates that the 5,75% target for 2010 in the biofuels directive will not be met. Instead, the March 2007 European Council has set a new *10% binding minimum target to be achieved by all Member States* for the share of biofuels in overall EU transport petrol and diesel consumption *by 2020*⁴⁴. Biofuels is a typical illustration of the need for coherent policies to promote the transition to eco-efficient technologies.
- As the uptake of new technologies is a central issue, the setting up of **research-oriented demonstration or pilot projects** would be a competitiveness showcase to support the emergence of new bio-based products and methods. EU and Member State could support this field in order to reduce the disadvantage of emerging technologies compared to established technologies. Common disadvantages include large investment needs and not-yet-obtained economies of scale for the emerging technologies, and the possible negligence of externalities (negative environmental effects) of established technologies.
- A strategic EU policy could help to incentivise the conversion of conventional industrial processes into bio-based ones. Examples: by developing a faster regulatory

⁴¹ Bio4EU study, JRC/IPTS 2007.

⁴² Communication from the Commission of 7 December 2005, COM (2005) 628 final

⁴³ Communication from the Commission of 10 January 2007, COM (2006) 845 final

⁴⁴ http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/envir/92864.pdf

procedure for sustainable processes and products, by making a link with EU's "Green house gases emission trading" project, by developing a trade scheme under which bio-based products and processes are considered for carbon credits if they produce less CO₂ and other GHG, or by providing alternative incentives to overcome the high investment needs.

- Initiatives to boost the demand side could help the uptake of bio-based products and stimulate their commercialisation on a broader scale, such as public procurement standards, temporary pricing measures, specific labelling, etc. Such measures need to comply with European competition law.

5.5 Marine biotechnology

Marine biotechnology encompasses the applications of biotechnology techniques, such as bioprocessing, bioharvesting; bioprospecting, bioremediation, or in general molecular-based techniques, on marine organisms, to provide solutions in the fields of healthcare, food, cosmetics, adhesives, paints, aquaculture, fisheries, agriculture, environmental remediation, biofilms and corrosion, biomaterials, research tools, and so on.

While this type of application is not new, the concept of marine biotechnology per se is relatively young and research into this field has entered a very dynamic phase. The potential of marine biotechnology relies on the rich marine biodiversity coupled with the fact that it is at a rather early phase of development⁴⁵.

One study⁴⁶ estimated the global market for marine biotechnology at \$2.4bn in 2002, and a predicted growth rate exceeding 10% per annum over the next three years. Marine biotechnology could contribute to nearly every industry sector, such as pharmaceuticals (e.g. anti-cancer compounds), bioremediation, cosmetics, and so-called "nutraceuticals" or "functional foods" with a beneficial effect on human health.

Marine bio-resources are a source for pharmaceuticals: so far there are four marine-based drugs on the market and about 40 in clinical or preclinical development⁴⁷.

Two preconditions for reaping these benefits are to invest in research capabilities and to increase the public understanding and acceptance.

Research in marine bioscience and marine biotechnology already involves universities, research centres and companies worldwide. In the EU, financial support is given through the research framework programmes (FP3 to FP6), under themes such as marine biotechnology, ecology, and biodiversity. Examples of projects are "Network of Excellence in Marine Genomics" and "ERA-NET MarinERA".

A precondition for strengthening European research in marine biotechnology is to firmly establish it in the 7th Framework Programme. The aim would be to enlarge the knowledge

⁴⁵ Green Paper Towards A Future Maritime Policy For The Union: A European Vision For The Oceans And Seas, Sec(2006) 689; and Background Paper No. 10 on Marine Biotechnology. [http://ec.europa.eu/maritimeaffairs/pdf/SEC\(2006\)_689%20_10.pdf](http://ec.europa.eu/maritimeaffairs/pdf/SEC(2006)_689%20_10.pdf)

⁴⁶ "The Prospects for Marine Biotechnology Development in the UK", Foresight Marine Panel, 2005 <http://www.dti.gov.uk/sectors/biotech/agribusiness/biosciencemarine/page10522.html>

⁴⁷ Genetic Engineering News, Dec 2006

base on marine life, focus on marine biology and biotechnological applications, and upgrade the networking of European marine stations and centres. Industrial involvement in marine biotechnology projects is crucial for their further development and commercialisation. The entire field would thus benefit from increased stakeholder participation encouraged by the Commission and Member States. Furthermore, a better public understanding and acceptance of the use of marine organisms are preconditions for avoiding a skewed debate similar to that on GMOs during the past decade.

6 Access to finance

A general problem for Europe is to provide adequate access to finance, especially for SMEs. An underdeveloped European venture capital market and the fragmentation of financial markets are two likely causes.

Though the financial picture improved in 2005, it may be a cyclical improvement. The financing gap for biotech companies occurs both in the **start-up phase** (pre-seed and seed capital) and in the **growth phase** after 3-8 years (venture capital, and later the initial public offering on the stock market). There is clear evidence of this gap: the typical European company grows much slower than the typical US company (that has twice the number of staff and spends three times more on R&D). In every age group, the US companies are ahead of the EU.

Early-stage finance⁴⁸: Judging by the empirical data, the start-up capital may be less of a problem since we still record many new start-ups. However, saying this may be controversial as it still seems tricky for start-ups to collect the first moneybag in order to carry out the “industrial proof of concept”. Without a convincing proof of concept, it is not possible to acquire venture capital for the new-born company. Secondly, the amount of money raised at the early stage is mostly too small to give the company a good start, thus limiting its research capabilities.

Studies on the capital base show that there is a long-standing market failure in early-stage equity finance (generally, not only in biotechnology) warranting public sector action. This early-stage market failure is due to problems both in the supply of, and in the demand for risk capital⁴⁹. To address the early-stage market failure, the best results could be achieved when the public sector works in partnership with the private sector and creates incentives for funds to improve performance.

A strengthening of business incubator services and seed funds would seem necessary to secure the creation of new biotech companies in the future. A more advanced version of the incubator, which basically provides customised laboratory and business space, is the business accelerator. The accelerator concept has been tried with success in the USA and offers additional business support including venture capital and committed technical, clinical and market expertise. European biotechnology industry could benefit from accelerators being set up in existing clusters as a way to reduce investment risks and increase the attractiveness of the companies.

⁴⁸ Recommendations from the Contact Network with Member States' Ministries with Responsibility for Competitiveness in Biotechnology, 2006

⁴⁹ “Best practices of public support for early-stage equity finance”, European Commission, Sep 2005.

Late-stage finance⁵⁰: The obstacle to real biotech company growth seems to be linked with getting adequate financing for expensive clinical trials and the marketing of pharmaceuticals. In this phase 3-8 years after start-up, the companies do not seem to be able to attract a sufficient amount of financing to enable them to take charge of the product development themselves. Instead, they seem forced to licence out their invention to e.g. a large pharmaceutical company, merge with a bigger company, or move to the United States. The consequence is that Europe gets hardly any self-sustainable, larger biotech companies. Insofar as this is a market failure, there is a justification for public authority intervention to correct the problem. If action is not taken, many European companies will move to the American market where they can raise more risk capital, thus depriving Europe of business opportunities, employment and future research capability.

Progress since 2002:

a) The European Investment Bank (EIB) has launched its **Innovation 2010 Initiative (i2i)** which aims to help increase the spending on research, development & innovation in Europe by providing €10bn in loans until 2010. More than €750m in loans has been granted to the biotech & pharma sectors.

b) The EIB loan facility has been strengthened by introducing a new financing instrument, the “**risk-sharing finance facility**”, which will provide loans for larger research and infrastructure projects. It also aims to fund projects with higher risks. This facility is a joint loan instrument between the European Commission and the EIB, is managed by the EIB, and can provide finance for research in high technology areas by private companies and institutions, for which the risk cannot properly be assessed by classical banks and are therefore considered too risky.

c) The European Investment Fund (EIF) has launched **venture capital instruments** consisting of **equity investments in venture capital funds** that support SMEs, particularly those that are in their early stages of development and those that are technology-oriented. The EIF's venture capital activity is backed by two sources of funding: (1) capital from the EIB Group (EIB and EIF) that forms the bulk of the EIF's investments, and (2) capital from the European Commission that is allocated under three different programmes: the ETF Start-up Facility, the EIF-ERP Dachfonds, and the Competitiveness and Innovation Programme (CIP).

d) A “**Technology Transfer Accelerator**” was launched in 2006 after the Commission and the European Investment Fund (EIF) had carried out a feasibility study on a new type of risk capital and technology transfer investment vehicle. It aims to link different centres of excellence and universities in European countries. The TTA should bridge the finance gap between university/spin-off research and early stage investment, a sector currently not favoured by VC investors. The Commission is also financing entrepreneurship training courses with particular focus on scientists in the New Member States.

⁵⁰ Recommendations from the Contact Network with Member States' Ministries with Responsibility for Competitiveness in Biotechnology, 2006

Policy measures to improve access to finance: A combination of policy measures to facilitate companies' access to finance would seem the most efficient solution in the medium term. A little simplified, such measures would aim at improving the framework conditions in two ways:

1. *Making companies more attractive for early- and late-stage investors.* Framework conditions that affect companies include the costs of obtaining and enforcing patents, the coherence of patent systems, the administrative burden of marketing authorisation procedures, the fees levied on applications for authorisation, advice offered by agencies to SMEs, tax systems and social charges, employment regulation, et cetera.

A concrete example of improving framework conditions is to introduce fiscal incentives for Young Innovative Companies in order to reduce the tax wedge (including social charges) for innovative companies during a limited period of time (e.g. 6 years), allowing them to devote more resources to research and hire more research staff. Such measures would have to comply with the newly revised EU framework for state aid to innovation and state aid to risk capital. The Young Innovative Company scheme has already been introduced in France and Belgium.

To improve the companies' attractiveness and future business potential, experienced investors should take an active part in developing human skills, management skills, business plans, product development pipelines, and so on. Creating good market value will facilitate the companies' access to capital.

2. *Increasing the overall availability of investment capital for European biotechnology companies.* The finance instruments to be analysed include e.g. seed capital, venture capital, initial public offering, debt financing, et cetera. In addition, the framework conditions can be improved by using public funding instruments in the right way to leverage more private investment capital.

The financial markets are volatile and especially biotechnology ventures are subject to cyclical changes in the supply of capital. The Commission should follow the developments on the financial markets closely to identify the shortcomings of the capital base, by analysing each stage of development that biotech companies usually go through. This could help formulating adequate recommendations to remedy *possible sectoral problems* with the capital base.

7 R&D funding and expenditure

7.1 Private R&D expenditure

European biotechnology companies spent in total €7.6bn in R&D in 2004. As the typical European company of 6-10 years of age is rather small, it spent an average of €3.3m on R&D activities. For the 11-15 years category the average R&D spending was €4.0m. The corresponding typical US companies spent €8.7m and €13.3m respectively. This is evidence that the US financial markets generally offer higher funding than European markets, but it could also relate to a higher valuation of the business prospects of American companies.

It should be noted that a significant amount of R&D spending by (mainly) large US companies in Europe, and diversified European companies active in several sectors, is likely not included in the statistics. These companies contribute to expanding Europe's R&D capability and to raise economic growth. Whereas the lack of complete statistics for all companies somehow active in life sciences and biotechnology is indeed a weakness, it does not mean that the analysis of the dedicated biotech companies is wrong. We can still draw useful conclusions about the competitiveness situation.

7.2 Public R&D funding and a comparison of national performance

This section features a comparison of public funding of biotechnology R&D across EU Member States, and how well these countries have succeeded in nurturing their biotech industries.

Grants are an important funding instrument for European biotechnology companies. Two-thirds of surveyed European companies plan to raise capital through grants in the next two years, compared to only 38% of US companies. Venture capital remains the most common way of raising capital (80%), but grants qualify in second place, way ahead of other sources, such as alliances, debt, PIPE⁵¹ and initial or follow-on offerings on the stock market⁵².

With this strong reliance on public funding, a positive development in the biotech industry depends much on coherent European and national R&D funding policies. According to the BioPolis study⁵³, public funding of 32 European countries surveyed amounted to US\$4.1bn (€3.54m) (all amounts in PPP, adjusted for purchasing power parity) in 2005. Looking only at EU15 and Iceland, Switzerland and Norway, the public spending amounted to US\$3.8bn PPP.

⁵¹ Private investment in public equity

⁵² Ernst & Young 2007

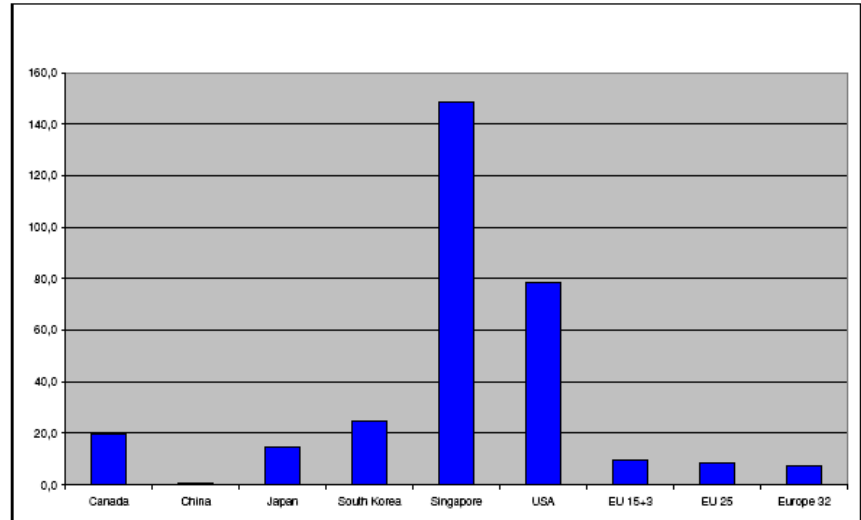
⁵³ BioPolis – Inventory and analysis of national public policies that stimulate biotechnology research, its exploitation and commercialisation by industry in Europe in the period 2002–2005, June 2007

A quick comparison with major competitors shows that the US spend six times more, US\$23.2 bn PPP, Japan 1.9 bn, Korea 1.2 bn, Canada and Singapore 0.6 bn and China 0.5 bn⁵⁴.

Total public funding of biotechnology of the EU15+3, EU25 and EU32, USA, Canada, China, Japan, South Korea and Singapore in \$PPP pMC, 2005

A comparison of the *spending per million capita (pMC)* gives a different picture, with the EU lagging far behind all competitors except China. For instance, the US spends 8 times more than the EU.

Source: BioPolis – Inventory and analysis of national public policies that stimulate biotechnology research, its exploitation and commercialisation by industry in Europe in the period 2002–2005, March 2007



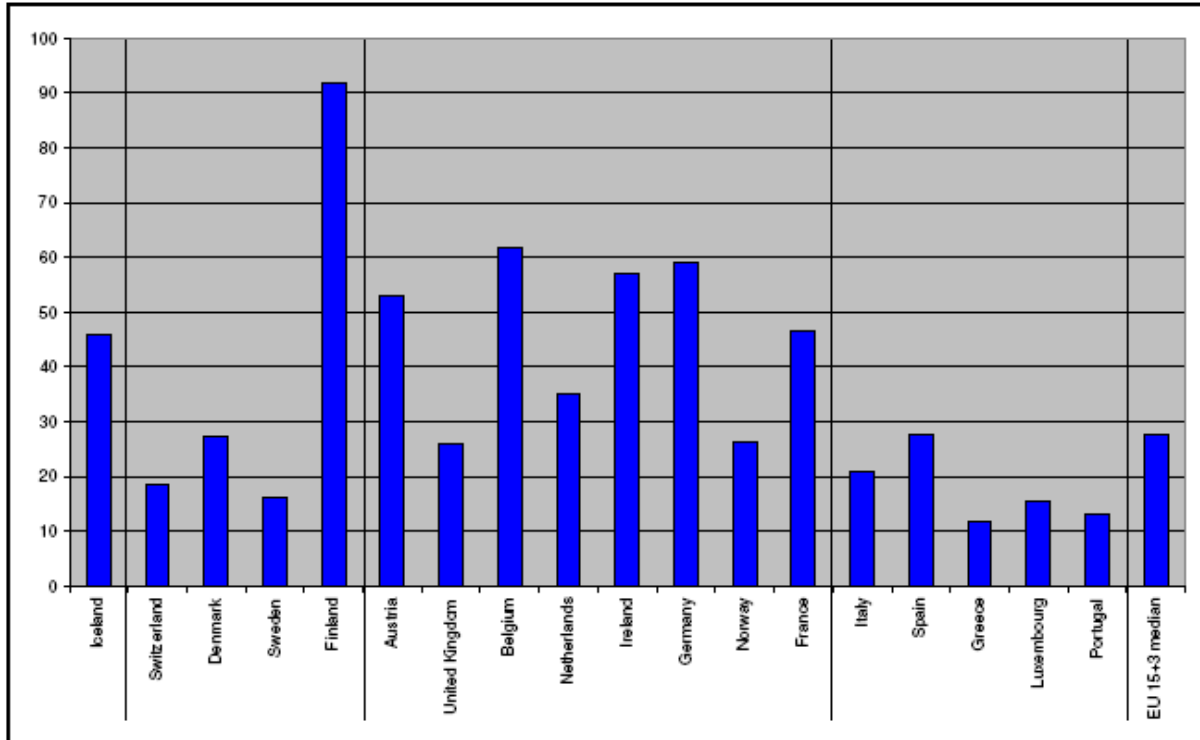
In absolute figures, the biggest biotech budgets are found in Germany, France and the UK. A comparison of the EU15 and three EFTA countries shows that the highest public *spending per million capita* is recorded in Finland, followed by Belgium, Germany, Ireland, Austria, France and Iceland.

By contrast, some countries with well-developed biotech industries rely much more on private R&D money and spend relatively little public money per million capita, notably Sweden, Switzerland and the UK.

⁵⁴

A comparison is difficult because different definitions are used in various countries. In the USA and Canada, for instance, only federal funding is included, leaving out state funding. The figures should therefore be treated with caution.

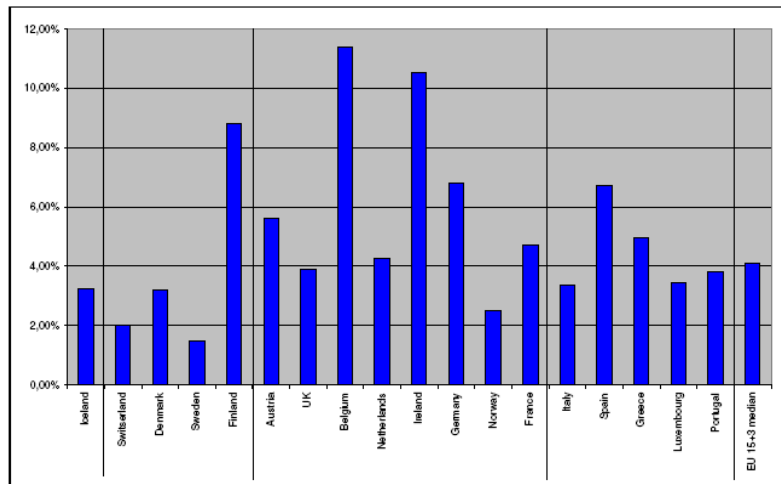
Total public funding of biotechnology in the EU15+3, in \$PPP pMC, 2002-2005



Source: BioPolis

The focus on biotechnology, measured as *the share of biotech funding of the total public funding of R&D* (all sectors) is particularly *high* in Belgium, Ireland and Finland, but very *low* in Sweden, Switzerland and Denmark.

This is evidence that certain European countries have given a much higher priority to biotech R&D.

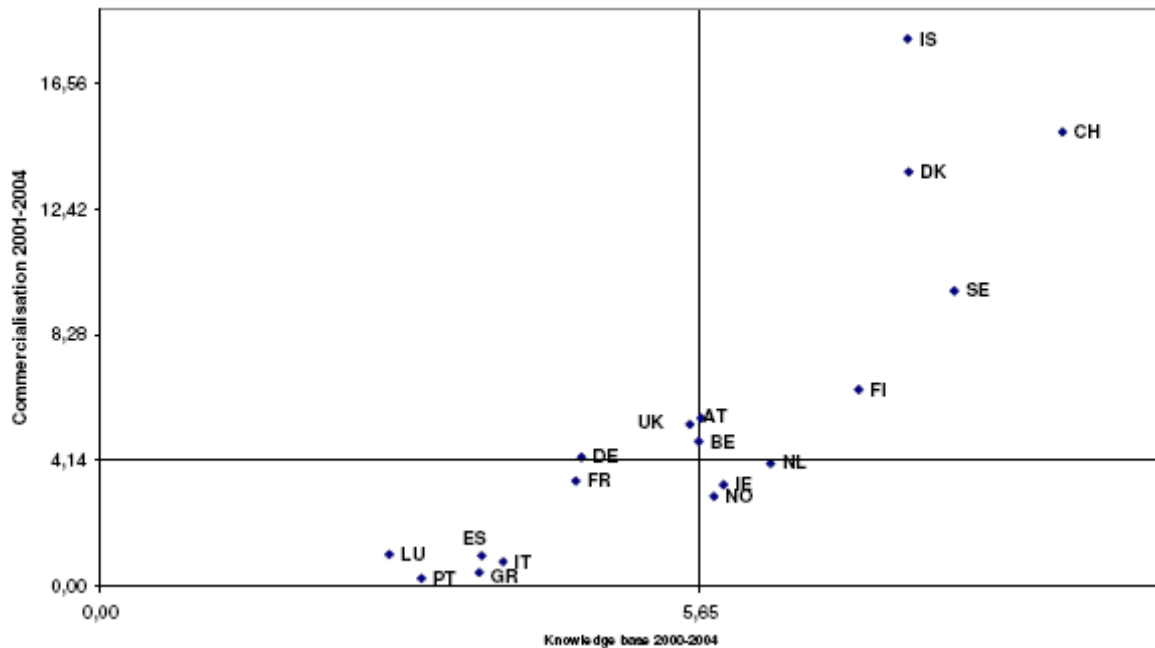


Source: BioPolis

The BioPolis study has attempted to find a link between how Member States organise their funding system and their performance, but there is no clear link, mainly because becoming successful in biotechnology depends on a combination of favourable measures. This includes creating a solid knowledge base, transferring knowledge between academia and business, encouraging innovation and product development, providing adequate access to finance, and coordinating activities at national and regional levels. One single measure is simply not enough to succeed.

There is however a clear correlation between the number of scientific publications and the number of biotech firms: the higher the publication activity, the higher the number of firms in a country. Consequently, public support to scientific performance should logically help achieve a better commercial performance. The prominent countries in this respect are Iceland, Switzerland, Denmark, Sweden and Finland.

Correlation between the knowledge base (publications) and commercialisation (2000-2004)



Source: BioPolis

The analytical difficulties in establishing a link between public policies and performance notwithstanding, it remains important for public authorities to support biotech R&D through a combination of **public funding** and facilitating **access to finance** (see chapter 5).

In several of the analyses above, the European performance surpasses even the US, particularly among the Nordic countries and Switzerland. The main problem seems to lie in the fact that Europe's biotech industry is less mature than the US and that Europe has a long-standing problem with turning scientific discoveries into marketable products in order to generate revenue streams.

8 Cooperation between company clusters and regional networks

The 2002 biotechnology strategy and action plan identified the development of stronger networks in European biotechnology as a key component to improve our competitiveness. This was reiterated in the 2007 mid-term review of the Strategy.

Many company clusters have been formed in Europe with the aim of bringing together the resources of the life sciences industry, hospitals, universities, public research institutions, and investors. Although progress has been made, Europe is still very much a fragmented in terms of the research communities, the business communities, and the capital markets. The

Commission and the Member States need to act together to pool our scientific and financial resources better. Stronger clusters may provide more possibilities for small firms to get financial backing from bigger, established firms, or to link up scientific expertise.

In the USA, biotechnology is characterised by a high degree of concentration of firms in a restricted number of regions, where the beneficial effects of company clusters reinforce both cooperation and competition. A similar process of clustering has taken place across Europe, with examples such as the BioTech-Region München and the Medicon Valley between Sweden and Denmark. In comparison with the US company structure, Europe has a lack of critical mass, not only at the individual company level but also at the cluster level. The majority of European biotechnology clusters do not seem big enough to compete effectively with those in the US.

It is desirable to support politically and financially a better integration between clusters of biotech companies into “mega-clusters” and an increased European-wide cooperation between bio-clusters and regional networks. At the moment, the co-operation between companies in the EU and USA seems more intensive than intra-European co-operation. The Council of European Bio Regions was launched in 2006 and will enable better networking between bio-clusters and regional associations in Europe.

Networks of bio-regions and biotech clusters would need to develop their role and activities, e.g. by identifying and exploiting the added value of specific cooperative actions between bio-regions. While “exchange of best practise” used to be the most common activity, the networks of bio-regions and clusters will now need to develop common strategies and activities with the objective of increasing the overall competitiveness of the network and its members. Support for such initiatives could be given through 7th Research Framework Programme (FP7) or the Competitiveness and Innovation Framework Programme (CIP).

Technology transfer from academia to industry is also a field where Community support is important. A “Technology Transfer Accelerator” was launched in 2006 by the EIF to link centres of excellence and universities in the EU and provide capital for early-stage projects. Supporting similar initiatives would help exploit the knowledge base and presumably increase the growth potential of European companies.

Regions have a key role in the development of the European Research Area (ERA), which is an internal market for science and knowledge. More initiatives to support technological development, foster co-operation between universities, and encourage research at a regional level, are a precondition for strengthening the ERA. An example is the "Regions of Knowledge" initiative. Continued financial support from the Commission to such proposals would seem necessary to obtain the objectives.

9 Consumers

The attitude of the public is crucial for the acceptance of new technologies and products, which in turn has a major impact on the investment and marketing decisions of companies. Consumers can therefore be regarded as a factor directly affecting competitiveness. The difficulties with communicating – in a balanced way – the benefits and potential risks of genetically modified organisms led to decreasing public support for biotechnology in the 1990s.

The Eurobarometer 64.3 released in May 2006 shows rising public support for biotechnology, with 52% of the respondents believing that biotechnology will improve our way of life, compared to only 20% in 1999. This is almost the same percentage as those believing that mobile phones will improve our way of life (58%).

All fields of biotechnology generally enjoy a high level of public support with the exception of GM food, where there is more public opposition. Interestingly though, 50% or more say they would buy GM food if it is healthier, if it contains less pesticide residues, or if it is more environmentally friendly, and the supporters outnumber the opponents. This indicates that public support would rise if the benefits are demonstrated to the consumers, but also that public awareness of GMOs currently is linked with negative perceptions. This tends to show that the European public has limited knowledge about the crucial role of agriculture production in the development of bio-based industries, including for biofuel production.

In the area of biotechnology, EU authorities, Member State authorities, companies, the research community, consumer organisations, and other stakeholders, would need to increase their efforts to improve the communication with the public and aim at providing well-balanced information about biotechnology applications including the functioning of the existing EU regulatory framework.