



European
Commission



European
Patent Office








































Life Sciences & Biotechnology



for Europe



European countries

		European Union	European Patent Organisation
Albania			⊗ ²
Austria		⊗	⊗
Belgium		⊗	⊗
Bosnia-Herzegovina			⊗ ²
Bulgaria		⊗ ¹	⊗
Croatia		⊗ ¹	⊗ ²
Cyprus		⊗	⊗
Czech Republic		⊗	⊗
Denmark		⊗	⊗
Estonia		⊗	⊗
Finland		⊗	⊗
Former Yugoslav Rep. of Macedonia			⊗ ²
France		⊗	⊗
Germany		⊗	⊗
Greece		⊗	⊗
Hungary		⊗	⊗
Iceland			⊗
Ireland		⊗	⊗
Italy		⊗	⊗
Latvia		⊗	⊗
Liechtenstein			⊗
Lithuania		⊗	⊗
Luxembourg		⊗	⊗
Malta		⊗	
Monaco			⊗
Netherlands		⊗	⊗
Poland		⊗	⊗
Portugal		⊗	⊗
Romania		⊗ ¹	⊗
Serbia and Montenegro			⊗ ²
Slovakia		⊗	⊗
Slovenia		⊗	⊗
Spain		⊗	⊗
Sweden		⊗	⊗
Switzerland			⊗
Turkey		⊗ ¹	⊗
United Kingdom		⊗	⊗

¹ candidate for the European Union

² extension state of the European Patent Organisation

overview

Opportunities in life sciences and biotechnology

The European Commission, which is the executive arm of the European Union [EU], the European Patent Office [EPO] and the European Medicines Agency [EMA] are working closely together to support the development of life sciences and biotechnology in Europe. In this role they present themselves as a “one-stop shop” for anybody who is interested in research and business opportunities in Europe. These include joint presentations at international events like the annual BIO convention. The European Union supports research and innovation in life sciences and biotechnology and offers opportunities for research, partnering and business in Europe.

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DOING BUSINESS IN EUROPE

Facts and figures

Since the late 1990s, Europe's biotechnology sector has rapidly expanded. In 2003, there were nearly 2 000 companies in this sector, employing over 94 000 people, of which 35 000 were involved in R&D. These companies spent about €6 billion in R&D and generated nearly €19 billion revenue.¹ It is envisaged that the European biotechnology sector will mature in the next few years by going through a period of consolidation and integration.

The United States and the European Union share the largest bilateral trade and investment relationship in the world, accounting for over €1.5 trillion [\$1.8 trillion]. The top 500 companies in the EU invested a total of \$119 billion in R&D in 2003. In 2000, European-owned firms invested \$18.6 billion in research and development in the US, while spending by US firms in Europe amounted to \$12.9 billion.²

The European Union

The European Union [EU] presently has 25 member states which represent 455 million people, making the EU the world's largest common market and leading exporter.

- **Pharmaceuticals** – Europe produces more than 37.5% of the world's pharmaceutical output, worth some €160 billion [\$208 billion], making it the world's leading manufacturing location.³
- **Chemicals** – Europe is the world's largest producer of chemicals, with a turnover of €580 billion [\$ 750 billion] accounting for more than one third of their production.
- **Agrifood** – with a turnover close to €600 billion [\$780 billion] Europe is the world's largest food producer. The US is the largest trade partner in this sector, importing €9 billion [\$11.7 billion] worth of food from the EU and being a large supplier of agricultural raw materials for the EU food and feed industries.⁴

¹ 2003 figures taken from the Critical I report, produced on behalf of EuropaBIO

² US State Department

³ Data from EFPIA.org

⁴ Data from CIAA.be

DOING RESEARCH IN EUROPE

Top quality research

Europe educates over 3 million graduates and PhDs per year, of which more than 25% graduate in science and engineering disciplines.⁵

European Research Area: towards a European knowledge market

The **European Research Area [ERA]** is the vision for research in Europe, based on better coordination, more cooperation and complementary policies and programmes of all relevant actors and institutions.

To reach the ERA objectives significant resources are mobilised through multi-annual research framework programmes. Although these R&D funds provided by the EU account for only around 5% of the overall public research funds in Europe, it is a major instrument to encourage R&D collaborations in Europe and beyond.

- The annual budget for the current **Sixth Research Framework Programme [FP6, 2002-2006]** is around €5 billion [\$6.5 billion].
- The European Commission has proposed the key elements of the **Seventh Research Framework Programme [FP7, 2007-2013]**, which includes a significant increase in the budget available for biotechnology and life sciences research.

More info: www.cordis.lu

⁵ key figures 2003 –2004 [EUR 20735]





THE EUROPEAN COMMISSION

The European Commission is the executive arm of the European Union and largely responsible for managing the EU's common policies, such as research, agriculture, trade, development aid, etc. The Commission also manages the budget for these policies.

More info:

www.europa.eu.int/comm/index_en.htm

EU strategy for life sciences and biotechnology

In 2002 the EU adopted a major policy initiative for the development of life sciences and biotechnology in Europe. Since then, annual progress reports have also focused on the competitiveness of the sector, the completion of an EU regulatory framework for GMOs and initiatives to boost research and increase the number of scientists in the biotech sector.

More info:

www.europa.eu.int/comm/biotechnology

EU support for research in the life sciences

The European Union annually provides about €770 million [\$1 billion] in public funds for life sciences research through its research funding programmes. These funds are allocated mainly through competitive calls inviting proposals for collaborative R&D projects in a variety of areas, including genomics, biotechnology and agro-food applications.

More info on thematic priorities:

- **food quality & safety:** www.cordis.lu/food
- **life sciences, genomics & biotechnology for health:** www.cordis.lu/lifescihealth

DOING RESEARCH WITH EUROPE

International R&D cooperation

Organisations [companies, research institutions and researchers] from all over the world are welcome to participate in EU-funded research consortia with Europe-based partners. Participation from industry [small and large companies] is highly encouraged.

The EU member states link up their research activities with associated countries like Switzerland, Iceland, Norway, Turkey and Israel, as well as countries with science and technology [S&T] cooperation agreements, such as the US and Canada.

Human resources and mobility

Funds are available for fellowships [Marie Curie action program], companies and multidisciplinary research activities such as nanobiotechnology and information technology.

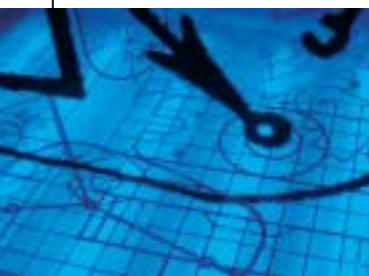
Mobility portal: www.europa.eu.int/eracareers

ERA-Link – a network for EU researchers in the US

ERA-Link is a networking tool for European researchers in the US. It provides information about research in Europe, the European Research Area, opportunities for career development, for research funding, for international collaboration and for transnational mobility. ERA-Link is expected to be fully operational by the end of 2005.

More info:

www.eurunion.org/legislat/STE/ERALink.htm





THE EUROPEAN PATENT OFFICE

The task of the EPO is to grant European patents for inventions in all fields of technology. The EPO has its headquarters in Munich and offices in Berlin, the Netherlands, Austria and Belgium. With its workforce of nearly 6 500, the EPO is also one of the largest international organisations.

Reaching a market of 540 million people

The EPO is the executive body of the [European Patent Organisation](#). It operates on the basis of the [European Patent Convention \[EPC\]](#) which has been ratified by the 31 member states of the Organisation. The Convention provides the legal basis for all activities of the Office and establishes standards and rules governing the treatment of patents granted by the EPO. It makes it possible to obtain patent protection in several or all member states – depending on the choice made by the applicant – by filing a single patent application with the EPO in English, French or German.

As the European Union and European Patent Organisation are largely identical in terms of member states, it is possible to obtain EU-wide patent protection with the help of a [European patent](#), although “EU patents” as such do not yet exist and the EPO is not an EU authority. A number of other European countries also recognise European patents for their territory. As a result, the European patent now covers a market of more than 540 million inhabitants.

Since its creation in 1977, the EPO has received more than 2 million patent applications and granted over 750 000 European patents. Moreover, the Office has established itself as the leading authority for international procedures under the [Patent Cooperation Treaty](#) that makes it possible to file for patent protection in more than 100 countries on the basis of a single patent application.

With more than 56 million documents, the [EPO's patent databases](#) are among the largest in the world. They can be accessed on the Internet using the Office's free esp@cenet server:

www.espacenet.com

High quality patents

The EPO examines European patent applications originating from countries all over the world in all fields of technology, including biotechnology and life sciences.

In carrying out its task the EPO strictly applies the European Patent Convention and other relevant European law, such as the EU's [Directive on the legal protection of biotechnological inventions](#). European patents are granted only after a thorough examination procedure, carried out by three patent examiners specialised in the respective technology. This ensures high quality and legal certainty standards for European patents.

The EPC also provides legal procedures for centrally opposing European patents within nine months from grant. Moreover, all decisions reached by the EPO and its instances can be challenged by an appeal before the EPO's independent judiciary, the [Boards of Appeal](#).

Disputes concerning the validity and infringement of a European patent are subject to national law, and the final decision rests with national courts.

Validity of patents

As in other patent systems, the grant of a European patent does not confer a positive right to use the invention without complying with all applicable rules of the legal system. The EPO has no regulatory competence, and permission to commercialise patented inventions may have to be obtained from the respective national and European authorities. Generally, the term of a European patent is limited to 20 years from the date of first filing [priority date].

More info: www.epo.org



JOINT RESEARCH CENTRE

The European Commission's Joint Research Centre [JRC] provides customer-driven scientific and technical support for the conception, development, implementation and monitoring of EU policies. It functions as a reference centre of sciences and technology for the European Union. Close to the policy-making process it serves the common interest of the Member States, while being independent of special interests, whether private or national.

The JRC is carrying out a comprehensive study on the [consequences, opportunities and challenges of modern biotechnology](#) for Europe and its contributions to the achievement of major EU policy goals.

Further activities in the field of biotechnology cover the following areas:

Food, Feed and Agriculture

The JRC has been identified as the [Community Reference Laboratory \[CRL\] for Genetically Modified \[GM\] food and feed](#) which is involved in the authorisation of GM products and the detection of adventitious GM in non-GM material.

Further, the JRC provides [quality assurance tools](#) for the detection, identification and quantification of GMOs. The JRC supports EU policies on the [coexistence of GM with non-GM crops](#) and carries out studies on emerging biotechnological applications in food production.

Nanotechnology

The JRC develops [biological/ non-biological interfaces](#) and [new sensing techniques](#) which are integrated into systems for applications in environment and health. Supporting EU policies on [nanotoxicity](#), the JRC contributes to the development and standardisation of methods and metrology as well as to the characterisation and toxicity testing of nanoparticles.

Health-related aspects

Promoting the EU-wide coordination of efforts to ensure the highest quality possible of [genome-based diagnostic technologies](#), the JRC gives scientific advice for policy actions in this area and delivers [quality assurance tools](#) for bioanalysis.

More info: www.jrc.ec.eu.int

EUROPEAN MEDICINES AGENCY

The European Medicines Agency [EMA] contributes to the protection of public and animal health by ensuring that medicines for human and veterinary medicines are safe, effective and of high quality. Established as an executive agency of the European Union it took up operations in 1995.

The EMA coordinates the [evaluation and supervision of medicines](#) throughout the EU, bringing together the scientific resources of the EU and EEA-EFTA Member States in a network of more than 40 national competent authorities. The Agency cooperates closely with international partners, reinforcing the EU contribution to global harmonization.

The scientific opinions of the Agency are prepared by four committees: the [Committee for Medicinal Products for Human Use \[CHMP\]](#), the [Committee for Medicinal Products for Veterinary use \[CVMP\]](#), the [Committee on Orphan Medicinal Products \[COMP\]](#), responsible for the designation of "orphan" medicines for rare diseases, and the [Committee on Herbal Medicinal Products \[HMPC\]](#) responsible for the formulation of scientific opinions on traditional herbal medicines. A network of more than 3 500 European experts underpins the scientific work of the EMA and its committees.

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MORE INFORMATION ...



...about us:

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European Commission:

www.europa.eu.int

European Patent Office:

www.epo.org

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