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Efficiency of innovation policies in high technology sectors in Europe (EPOHITE)

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Final Report

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Foreword

In the last decade research and innovation policy in Europe has focused on supporting the development of emerging science and technology fields and the dissemination of the results into the economic and social fabric. In the case of biotechnology, policy-makers in European countries have developed a variety of different policy concepts and instruments with the goal of fostering innovation in this field. The EPOHITE project "Efficiency of innovation policies in high technology sectors in Europe" deepened into the question whether and under which conditions innovation policy has been effective in 14 Member States and explored the practices of policy-making systems that lead to effective public support.

The EPOHITE project was funded as an accompanying measure within the EU STRATA Programme (Strategic Analysis of Specific Political Issues) within the Fifth Framework Programme, under the framework of the specific research and technological development programme "Improving Human research potential and the Socio-Economic Knowledge base". It was carried out between April 2001 and July 2003 by a European research team from Germany, France, United Kingdom and the Netherlands.

With respect to their overall performance in biotechnology European Member States have been grouped into different performance clusters. The main results from the comparison of the biotechnology policies within and between these clusters have provided a sound basis for conclusions on best practices in innovation policies in Europe. From the findings EPOHITE researchers also derived a number of recommendations for the future shaping of innovation policies for biotechnology, which are elaborated in detail in this publication.

I believe that this Report will make an important contribution to the knowledge base concerning public research and innovation policies in Europe and to the discussions on how to further improve their effectiveness.

Jean-François Marchipont
Director

List of contents

List of tables

List of figures

Executive summary

1. Objective

In the last decade innovation policy in Europe has focused on supporting the development of high technology sectors. In the case of biotechnology, policy-makers in European countries have developed a variety of different policy concepts and instruments with the goal of fostering innovation in this field. EPOHITE deepened into the question whether and under which conditions innovation policy has been effective and explored the practices of policy-making systems that lead to effective public support by linking two elements: the national policy approaches implemented (inputs) and the performance of the respective national innovation systems in developing and commercialising biotechnology (outputs). EPOHITE recognised the difficulties in identifying direct links between specific policies and outcomes. For this reason the analysis started from a comprehensive and systematic view of national approaches to support biotechnology rather than focusing on specific policies. Furthermore, the analysis tried to take into account the fact that there are other factors besides policies that influence innovation processes and performance.

2. Methodology

The project combined quantitative and qualitative research tools and explored effectiveness from two different perspectives: from the micro-level through interviews with the actors involved in the innovation process and from the macro-level through national case studies that studied the national performance in biotechnology and the policy-making systems in each country.

In a first step a quantitative analysis of the performance of the national innovation systems in developing the biotechnology knowledge base and commercialising biotechnology was carried out. For that purpose appropriate innovation indicators for our research question were developed for two performance categories: performance related to the knowledge base and performance related to commercialisation. For both types of performance stock indicators have been used to describe the performance status at a fixed time and trend indicators to describe growth.

The performance analysis was combined with a detailed exploration of the biotechnology policy-making systems and the policies implemented since 1994. EPOHITE systematically categorised the national policy-making systems and the policies for supporting biotechnology implemented at the national level between 1994 and 2001. This inventory included policies specifically targeting biotechnology (vertical policies) and those policies with a generic character having an impact on biotechnology (horizontal policies).

The performance analysis and policy assessment were complemented by structured interviews with actors involved in the national innovation systems. The aim of the interviews was to explore the perception of actors of how they use and evaluate policies and how the framework conditions contribute (or not) to their innovation activities. This qualitative analysis covered 144 interviews in 14 Member States with representatives of public sector research organisations (PSRO), biotechnology companies including high performance start-ups (HPSU), successful small and medium-sized enterprises (SME) and Large Firms (LF).

3. Key findings and policy implications

Regarding **methodological issues** EPOHITE shows that there is still a lack of internationally comparable quantitative and qualitative input and output data that are suitable to describe the structure and performance of biotechnology innovation systems. *Additional efforts of the EC to improve data availability and additional research for developing suitable methods for benchmarking biotechnology policies should be initiated. Such approaches should avoid considering specific policy measures in isolation. Rather the specific conditions and the whole set of different policies and their interactions should be taken into account.*

With respect to their overall performance in biotechnology the analysis shows that European Member States can be grouped into four different performance clusters: cluster 1 with the best-performing countries Denmark, Sweden and Finland; cluster 2 with the second-best-performing countries the Netherlands, United Kingdom, Belgium and Germany; cluster 3 with Austria, France and Ireland, representing countries below the European median performance value, and finally cluster 4 with the Mediterranean countries Italy, Spain, Portugal and Greece performing weakly as measured by all indicators. Comparison of biotechnology policies within and between these clusters shows the following:

- National policies for the biotechnology knowledge base and for its commercialisation have a pronounced effect, which can be either positive or negative. In other words policy matters!

- Policies to create and sustain the knowledge base are also crucial for commercialisation but the reverse is not true.

- Countries that have taken a systems perspective and implemented a broad set of policies to promote biotechnology that address all the functions of the innovation system and create an environment conducive to entrepreneurial activity achieve better performances than countries with patchy and fragmented policies.

- Achieving *ex ante* coordination amongst strategic policy decision-makers (public or private) responsible for all the different functions of the innovation system can be extremely beneficial to developments at a national level and in avoiding policy gaps or duplication.

From these findings EPOHITE derives the following recommendations: *The desire to promote the commercialisation of biotechnology should not lead to policies where the sole focus is on support for commercialisation. Rather, it is recommended to implement a* ***balanced mix of instruments*** *that target the creation and sustaining of a competitive biotechnology knowledge base and commercialisation. Moreover, policy-makers should keep a watch on the future development of the performance of biotechnology in European countries. In some countries the first indications of a drying up of the knowledge base are already appearing and policy efforts to support a renewal of the knowledge base are recommended. The design of biotechnology policies should be based on a systems perspective of the innovation process in biotechnology. This implies that policy-makers should be aware of the strong and weak points of their national system and consider the (positive or negative) interactions of all policy measures that have an influence on the development of the biotechnology innovation system.*

The performance analysis indicates that the **specialisation patterns in biotechnology** of most Member States are similar. This result raises several issues. Biotechnology is still at a stage of uncertainty where there are numerous possibilities for its future exploitation. Therefore, diversity of competencies is advantageous for adopting and driving future developments of biotechnology. This leads to the question whether there exists enough diversity across European countries' biotechnology competencies and what impacts on diversity are expected from the forthcoming ERA. Which role should European policy play in relation to Member States' policies? *EPOHITE recommends to initiate further research on the role of diversity*

in specialisation in scientific and commercialisation patterns within Europe for the future competitiveness of European biotechnology.

A further important finding of the project concerns **the influence of the systems to allocate funding**. Public policies have more impact in policy systems that are based on the allocation of grants through a competitive peer-reviewed process (e.g. by research councils or other funding organisations) compared to systems based on the allocation of block grants to research institutes or other PSROs. *Therefore, efforts to increase the effectiveness of policy measures should take into account the need to change the organisation of the research system. In order to improve the effectiveness of the utilisation of funds, competitive funding schemes should be favoured over block grant schemes.*

As concerns the effectiveness of specific policies according to EPOHITE's findings **Technology Transfer Offices (TTOs)** are evaluated negatively. The main reasons for the weak performance of such institutions are the lack of competencies in biotech and IPR and capacities. *EPOHITE recommends to concentrate responsibility for technology transfer activities in TTOs with expertise in both biotechnology and IPR. Professionalism in terms of scientific and regulatory knowledge should be a key qualification of TTO staff. In addition, a critical mass of competencies is required.*

There are still many problems related to **patenting** in addition to the more general harmonisation issue (e.g. the lack of knowledge at universities and technology transfer offices, too costly and too time-consuming procedures, and the absence of incentives for patenting by PSROs and universities). *Improving the conditions for patenting should stay on the political agenda as an important issue. As a first step for improvement a careful analysis of the caveats with respect to patenting at the different institutions is recommended. Furthermore, we recommend to make a benchmark of the various IPR regimes implemented in European countries for handling IPR at universities and PSRO.*

Finally, concerning **company creation** many start-ups have been formed in Europe during recent years and a large share of these are the result of public policy initiatives. Increasingly, such firms are approaching the growth stage and at the same time getting access to the required financial resources is becoming more difficult. This situation raises the question of the attitudes to these firms that should be adopted. It seems evident that a selection phase will arise where only a limited number of firms will be able to move towards sustainable growth. This in turn poses the question of the role of government in this process: should the selection be an independent market-driven process or should policy intervene? *In order to avoid interference with market mechanisms, we do not unequivocally recommend direct support for the growth of firms. However, we do recommend the creation of favourable framework conditions for growing biotech firms. Support to firms for dealing with the recruitment of scientists, regulations in general and IPR issues in particular, ethical issues, consumer issues and conditions for private financing can all have a positive effect on performance, and therefore should form an important component of any policy strategy.*

1. Introduction

In the last decade innovation policy in Europe has focused on supporting the development of high technology sectors. Economic and innovation theories provide us with general rationales for the need of government intervention in innovation processes. These theoretical justifications rely basically on the existence of deficiencies in the mechanisms or institutions responsible for allocating resources for science and technology, for coordinating innovation activities and network formation or for selecting among the potential winners in the innovation processes(1). Rather than searching for empirical evidence to back up a theoretical framework for the need of public support in the development of high technologies, EPOHITE deepens into the question of whether innovation policy has been effective(2) and explores the practices of policy-making systems that lead to effective public support.

There is a long tradition of policy evaluation practices examining the effectiveness and the impact of innovation policy. In the last two decades these practices have developed together with the policy instruments implemented (Papaconstantinou et al. 1997). Accordingly, traditionally innovation policy has focused on the allocation of additional resources for scientific research and the policy evaluation activities in the 1980s focused mostly on the return on investment of the financial resources directed to public promotion programmes. Since the early 1990s innovation policy has adopted a system failure rationale(3) and the implemented instruments include not only financial support, but also measures to improve the framework conditions for innovation and the interaction of the actors involve in the innovation process. In the case of biotechnology, for example, in the last decade policy-makers in European countries have implemented a large set of instruments and have introduced public promotion programmes with the goal of supporting innovation in this field (Enzing et al. 1999). Policies have aimed, for example, at developing the biotechnology knowledge base by supporting public scientific research activities, by promoting the mobility of researchers from academia to industry or by stimulating collaboration. Another policy goal has been the industrial application of biotechnology research results. In this sense measures have been implemented to create incentives for innovation in the industry through tax concessions or legislative measures, to set up incubators for firm creation or to provide favourable framework conditions for venture capital investment. These type of instruments (which go beyond the allocation of additional resources for scientific research) challenge evaluation practices and demand new methodological approaches to examine policy effectiveness.

Focusing on the case of biotechnology the EPOHITE project aims at assessing the effectiveness of innovation policy by linking two elements: on the one hand the national policy approaches implemented (inputs), and on the other hand the performance of the respective national innovation systems in developing and commercialising biotechnology (outputs). EPOHITE recognises the difficulties in identifying direct links between specific policies and outcomes. For this reason the assessment of policy effectiveness focuses on the overall national approaches to support biotechnology rather than on specific policies. Furthermore, the analysis tries to take into account the fact that there are other factors besides policies that influence innovation processes and affect performance.

EPOHITE combines quantitative and qualitative research tools and explores effectiveness from two different levels of analysis: from the micro-

(1) See for example Metcalfe (1995) or Geuna & Nesta (2003)
(2) According to Scriven (1991) *Effectiveness* (in evaluation practices) *is roughly equivalent to "success". Although effectiveness can be constructed more generally as referring to achieving an outcome that may not have been part of the aims of the programme, it always refers to some goal, even if not the original one.*
(3) For a discussion on the system failure rationale of public policy see, for example, Carlsson et al. (1997)

level (trough interviews with the actors involved in the innovation process) and from the macro-level (through national case studies that study the national performance in developing and commercialising biotechnology and the policy-making systems in each country). This final report builds on the results of the qualitative analysis of the interviews and the findings of 14 national case studies in member countries.

The next chapter discusses in detailed EPOHITE's methodological approach. Chapter 3 presents the performance analysis of 14 biotechnology National Systems of Innovation (NSI) in Europe based on quantitative indicators. Next, the exploration of the main characteristics of the 14 national policy-making systems and the policy approaches implemented since 1994 to support biotechnology is presented in chapter 4. Chapter 5 builds on interviews with actors of the different biotechnology NSI and discusses the key issues for the development of biotechnology identified during the interviews. Chapter 6 draws together the overall results of the project and derives conclusions on policy effectiveness. The report concludes by outlining the main findings and by deriving recommendations for policy-makers responsible for the support of innovation processes (chapter 7).

Each chapter of this final report builds on input from all project participants collaborating in EPOHITE. However, for the drafting of the report the division of the work has been as follows: GAEL INRA-UPMF was responsible for drafting chapter 4, Fraunhofer ISI for chapters 1, 2, 3 and 7, SPRU for chapter 6 and TNO-STB for chapter 5. In addition to the report, an annex has been prepared with the 14 national case studies that have been conducted under the responsibility of the different teams(4).

2. Methodological issues

The EPOHITE project aims at assessing the effectiveness of biotechnology policies by exploring the relation between policy approaches towards biotechnology and performance of the respective national innovation systems, taking into account that policy effects need to be differentiated from other influencing factors.

To achieve this goal, EPOHITE assesses the performance of the national biotechnology innovation systems (chapter 3) and explores the policy-making systems promoting the development and commercialisation of biotechnology (chapter 4). Based on these results and on the evaluations and perceptions of the actors involved in the different national innovation systems (chapter 5) EPOHITE draws conclusions on policy effectiveness (chapter 6).

This chapter introduces the main methodological issues concerning EPOHITE's analysis of policy effectiveness.

The chapter is divided into five sections. Section 2.1 summarises the methodological approach and presents the research tools. The definitions used in the project are introduced in section 2.2. Section 2.3 presents the sources for the data used and the definition of the quantitative indicators elaborated. Section 2.4 covers the categorisation and the aspects chosen to explore the biotechnology policy-making systems in Europe. Finally, the main guidelines followed to conduct interviews are summarised in section 2.5.

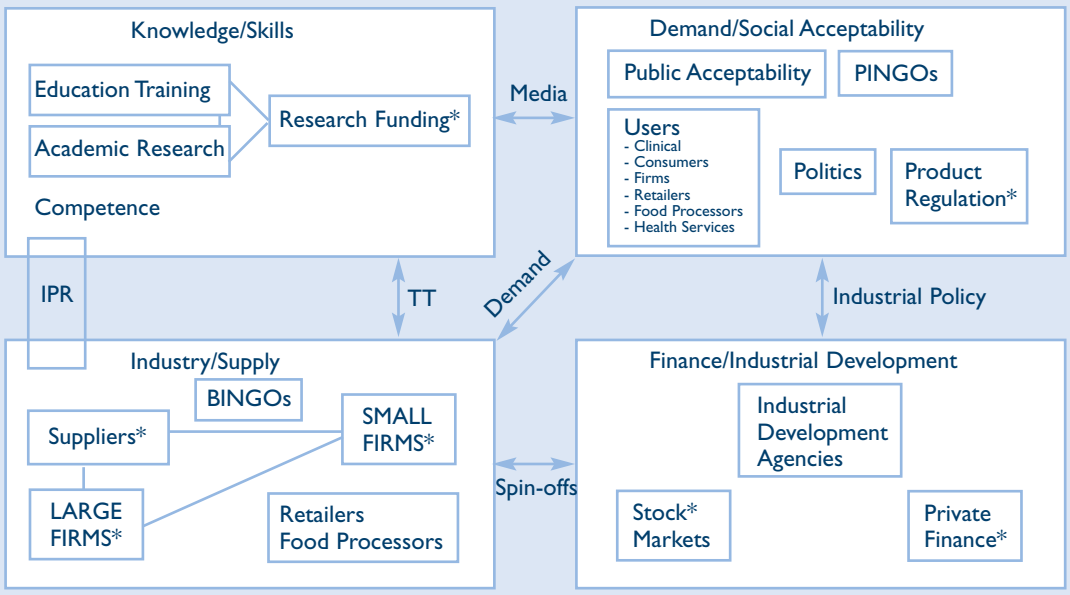
2.1 General approach and research tools

EPOHITE chooses a systemic framework to study the effects of public policy on the performance of the national biotechnology systems of innovation in terms of developing a biotechnology knowledge base and commercialising biotechnology. Figure 2.1, which draws on the EBIS project (Senker et al. 2001), presents this framework with special emphasis on the actors involved, their interactions and other factors influencing innovation.

The figure introduces the organisations and institutions EPOHITE focuses on:

(4) The annex is publicly available as a pdf-document under http://www.epohite.fhg.de or on request as a paper copy from the project coordinator.

Figure 2.1: Biotechnology Actor System of Innovation (ASI) and factors influencing innovation



* International influence

- Public sector research organisations (PSROs) (in the knowledge/skills side);
- Large firms (LFs) and biotechnology companies (BCs) including both high performance start-ups (HPSUs) and successful SMEs (in the industry side);
- Public policy influencing the knowledge base (through research funding), the supply side (through industrial and innovation policy), the demand side and the financial and industrial capabilities (through socio-economic measures and regulations).

The EPOHITE analysis of policy effectiveness combines the following quantitative and qualitative research tools:

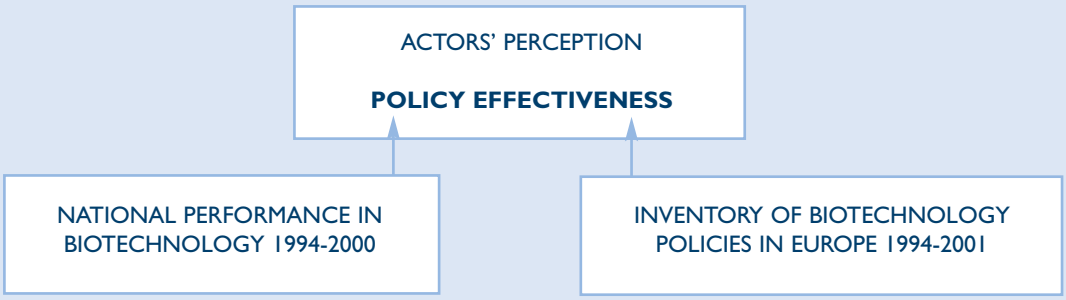
- Performance indicators which provide comparable quantitative information on the performance of biotechnology innovation systems in all Member States;
- Qualitative categorisation of the national funding systems and national policies promoting biotechnology in all Member States in the period 1994-2001;
- Interviews for the qualitative analysis of actor's perception and awareness of public promotion programmes and other relevant policy instruments.

These three research tools were used respectively in the three complementary building blocks that make up EPOHITE's methodological approach (figure 2.2).

EPOHITE carries out a quantitative analysis of the performance of the national innovation systems in developing the biotechnology knowledge base and commercialising it. The quantitative analysis is based on the elaboration of appropriate innovation indicators for our research question (see chapter 3).

The analysis of the performance of the biotechnology national systems of innovation is combined with a detailed exploration of the biotechnology policy-making systems. Drawing on the Inventory project (Enzing et al. 1999), EPOHITE systematically categorises the national policy-making systems and the policies implemented at the national level between 1994 and 2001 for the development and commercialisation of biotechnology (see chapter 4).

Figure 2.2: EPOHITE'S methodological approach



The performance analysis and policy assessment are two major blocks of the EPOHITE project. Complementing them, EPOHITE introduces a qualitative analysis based on structured interviews with actors involved in the national innovation systems considered and sketched in figure 2.1. The aim of the interviews is to explore the perception of actors of how they use and evaluate these policies and how the framework conditions contribute (or not) to their innovation activities.

EPOHITE's methodological approach combines two levels of analysis. On the one side, the interviews with the actors explore the micro level. The interviews are the basis for the identification of key issues for the development of biotechnology and the existence of policy gaps. On the other side, at the level of the national system EPOHITE studies 14 policy-making systems, assesses their national performance in developing and commercialising biotechnology and compares the systems with similar performance according to the policy settings and policy instruments implemented (cluster analysis introduced in chapter 3). EPOHITE combines the results of these two levels to elaborate conclusions on the effectiveness of biotechnology policies.

2.2 Basic Definitions

This section presents the definition of biotechnology applied in the project and the criteria to select the actors included in the qualitative analysis.

2.2.1 Biotechnology definition

There are numerous definitions of biotechnology in the literature. EPOHITE does not apply a theoretical definition, but rather makes use of two list-based pragmatic approaches to define biotechnology activities, which have been developed during two preceding EU projects: the Inventory (Enzing et al. 1999) and EBIS (Senker et al. 2001). In the Inventory a list of biotechnology areas was developed which can be used to check whether any activity can be considered as biotechnological activity or not. The EBIS project developed a list of technologies and products which characterise biotechnology activities, which can be used as a second set of criteria for identifying biotechnology activities.

Accordingly, EPOHITE considers actors that are active in one ore more of the following biotechnology areas:

- Plant biotechnology
- Animal biotechnology
- Environmental biotechnology
- Industrial biotechnology
- Cell factory biotechnology
- Developments of human/veterinary diagnostics, therapeutic systems
- Development of basic biotechnology

Secondly, one or more of the following biotechnology-relevant technologies are employed by the actors:

- Biocatalysis
- Biochemicals for biotechnology
- Biodegradation
- Biofiltration
- Bioinformatics
- Bioprocessing
- Bioremediation
- Cell culture
- Cell fusion
- Cell handling
- Cell therapy
- Chiral synthesis
- Cloning techniques
- Combinatorial chemistry
- DNA probes
- DNA sequencing
- DNA/RNA microarrays
- DNA/RNA synthesis
- Electrophoresis of DNA/RNA
- Electrophoresis of proteins
- Protein Sequencing
- Protein synthesis
- Proteomics
- Protoplast fusion
- Purification/separation of DNA/RNA
- Purification/separation of other biomolecules
- Purification/separation of proteins
- Enzyme technology
- Fermentation technology
- Functional genomics
- Gene amplification/PCR
- Gene therapy
- Genetic fingerprinting
- high throughput screening
- Laboratory robotics
- Mass spectroscopy
- Master technology (DNA, RNA)
- Metabolic engineering
- Micromanipulation
- Micropropagation
- Model animals for tests
- Molecular Biotyping
- Molecular modelling
- Monoclonal antibodies
- NMR spectroscopy
- Protein arrays
- Protein engineering
- Recombinant DNA
- Recombinant DNA
- Somatic hybridisation
- Structural genomics
- tissue culture
- Tissue engineering
- Xenotransplantation

Basically this list-based approach to the definition of biotechnology is comparable to the list-based definition of biotechnology which has recently been developed by the OECD[5].

2.2.2 Actor definition

EPOHITE distinguishes three types of research and development performers:

- The public sector research organisations (PSROs);
- Biotechnology companies (BCs) including both high performance start-ups (HPSUs) and successful SMEs;
- Large firms (LFs).

Public Sector Research Organisations (PSROs)

A PSRO is an organisation performing research of which the source of funds is coming from other public organisations, and which is in public ownership or control. Concerning the level of observation, not whole organisations (such as INRA or the Max-Planck-Society) were

(5) http://www.oecd.org/document/42/0,2340,en_2649_37437_1933994_1_1_1_37437,00.html

considered but individual laboratories. Research organisations of officially recognised charities or foundations, which raise the majority of their funds from the general public, were also considered as PSROs. Hence, the following three groups of PSROs were taken into consideration in the project:

- Research groups in universities and academic hospitals
- Public research institutes
- Charity research organisations

Public research institutes were defined as organisations with significant core government funding (more than 25%), that carry out research in order to develop basic, strategic basic and/or applied knowledge and/or to transfer knowledge to business and other PSROs and/or commercialise knowledge together with clients.

The PSROs selected as interview partners in the project carried out basic or applied research and were active in biotechnology according to the definition given above. We looked for main actors in biotechnology, which means that a considerable part of their research activities (at least 50%) had to be in the field of biotechnology and matched with the technologies considered in the biotechnology definition. The PSROs must have a history of research activities in biotechnology of at least five years and have to have a programme/plan of future biotechnology activities in order to underline the continuity of their biotechnology activities. Finally, the project considered only PSROs receiving at least 25% of their budget from public funding organisations.

Biotechnology companies

EPOHITE focuses on two different types of biotechnology companies:

- Successful small and medium enterprises (SMEs)
- High performance start-ups (HPSUs)

SMEs and HPSUs are biotechnology companies whose core activities fall within at least one of the biotechnology areas described in section 2.2.1, and which apply one ore more of the technologies mentioned. The differentiation between high-performance start-ups (HPSUs) and successful biotechnology small and medium-sized enterprises (SMEs) is made mainly according to the criteria growth in terms of

Table 2.1: Definition of SMEs and HPSUs

Criteria	*HPSUs*	*SMEs*
Engaged in biotechnology	Yes	Yes
Staff	< 50	50 – 500 (or smaller if they fulfil other conditions)
Foundation year	1996 or after	before 1996 (or after if other conditions met)
moved off incubator site	Yes	Yes
tranche of investment received	Second	Third
Self financing	Yes	Yes
Growth	At least double since creation	> 100 employees or recent rapid growth (100% since 1998)
R&D activities	Yes	Yes
R&D collaboration with other firms	Yes	Yes
Independent	Yes	Yes

employment, stage of financing and types of activities. Respective criteria and definitions of both types of companies are summarised in table 2.1.

Both types of actors present a different stage of development of a biotechnology company. Therefore, they have different goals and are potentially targets of different policies: HPSUs are mainly dealing with the management of the start-up process while SMEs have to manage consolidation and growth.

Large Firms (LFs)

Large firms (LF) include both, national firms and multinationals. They differ in so far from successful SMEs (which also became large and international as e.g. Amgen in the USA) as that they existed before the discovery and development of biotechnology. The following characteristics are specific for LFs:

(1) They have developed also technological competencies in other fields than biotechnology. They are not dedicated to biotechnology but are users of biotechnology development. At the same time they may perform R&D activities at the frontier of biotechnological knowledge;
(2) They embody marketing, distribution, production and/or manufacturing competencies that prove central for other small firms lacking such competencies;
(3) Thus, their role is to commercialise new knowledge in biotechnology, embodied in new products.

LFs are at the interface of new biotechnology knowledge and commercially viable products. An important role of LFs is that they provide a market for small and medium-sized biotechnology companies (through collaborations and alliances) and also become a substantial source of supplementary funds for public sector research organisations (through research contracts).

The population of LFs included in EPOHITE meets the following criteria:

- Their research facilities must be located in at least one of the countries considered in EPOHITE. They are eligible regardless of their type (parent company or subsidiary) and their nationality (European, non European).
- LFs must both have biotechnological competencies according to the technology list given in section 2.2.1 and be present in the biopharmaceutical, agro-food sector and/or other sectors.

When selecting LFs for a specific country, the main product groups of the country have been considered. The analysis tries to achieve representation of the relevant (from the country's perspective) sectors. In some cases a strict distinction between LFs affiliated to a specific economic sector is not possible because their activities are dispersed over several sectors. In this context also the so-called life sciences companies which are active not only in biopharmaceuticals, but also in agro-food applications of biotechnology are relevant and should be considered.

2.3 The assessment of the policy systems and national policy implemented in the period 1994-2001

The assessment of policy effectiveness in the EPOHITE project goes through the detailed analysis of (i) the national biotechnology policy-making systems from an institutional point of view and (ii) the national policy implemented (that is the promotion programmes and other policy instruments introduced).

2.3.1 The national biotechnology policy-making systems

EPOHITE draws on a categorisation of the biotechnology policy-making systems in Europe introduced in the previous Inventory project (Enzing et al. 1999). In this section we briefly introduce this categorisation which is based on six main aspects of the biotechnology policy-making systems and the R&D infrastructure at the national level.

Governance of the national funding systems: multiplicity of actors and number of interactions among actors.

According to Enzing et al. (1999) the key players in the biotechnology policy-making systems are:

I) National government bodies
- National ministries of education, science, research (or similar)
- Sectoral ministries (agriculture, health or environment)
- Ministries of economic affairs or of trade and industry

II) Regional government bodies
- Regional ministries

III) Intermediary actors
- Research councils
- Charities
- National research institutions and funding support organisations
- Industry

Based on the variety of agents involved in policy-making and on the intensity of interactions between them, Enzing et al. (1999) present a qualitative characterisation of the biotechnology policy-making systems. Accordingly, a policy system can be more or less pluralistic depending on the multiplicity of players in the system or more or less concentrated depending on the level of coordination between actors.

Industrial involvement

One important aspect of the policy-making systems is the extent to which industry actors get involved in the design of public R&D promotion programmes and in the identification of needs for public intervention. Based on the analysis of Enzing et al. (1999) EPOHITE considers this aspect in the analysis of policy effectiveness.

Focus on biotechnology

EPOHITE considers the extent to which biotechnology is a funding priority in the different national policy-making systems and since when.

Total funding of biotechnology 1994-1998 in MEUR

To measure the national public effort for the promotion of biotechnology EPOHITE draws on the data collected in the Inventory project. Enzing et al. (1999) present data for 17 European countries on the total national funding of biotechnology in the period 1994-1998. It was not intended to update this data in the framework of the EPOHITE project. Due to the time lag between the implementation and the possible effectiveness of policies and considering that the EPOHITE analysis takes place between 2001 and 2003, from a methodological point of view the update of the funding figures was not required for the analysis of policy effectiveness.

Total investment in R&D in 1994 and in 2001 (GERD/GDP)

EPOHITE uses the national Gross Expenditure on Research and Development (GERD) as a percentage of the Gross Domestic Product (GDP) as an indicator for the national public efforts for the promotion of research and development. For the year 1994 the source was the Inventory project. For the most recent year (if available 2001) national sources from each country were used.

Balance of public/private R&D expenditures in 2001

The balance between public and private R&D indicates the sources of investments in R&D and the share of private firms and institutions that are investing in R&D. The source used is the OECD Main Science and Technology Indicators (MSTI) database(6).

Characterisation of the system for R&D

Enzing et al. (1999) present a characterisation of the R&D performing infrastructure. They identify three types of systems:
- The national research institution (NRI)-based systems
- The research council-based systems
- The support funding organisation-based systems

This aspect is considered in the policy effectiveness analysis as well.

(6) http://www.oecd.org/document/26/0,2340,en_2649_34409_1901082_1_1_1_37461,00.html

2.3.2 Policy implemented at the national level

Due to the multidisciplinary, high technology character of biotechnology and the plurality of actors involved in the biotechnology industry, a rather broad set of different policies could be effective in the promotion of biotechnology. One way of structuring this complex set of policies is to differentiate between those policies targeting biotechnology and those with a generic character, having an impact on it without being biotechnology specific. Accordingly, EPOHITE distinguishes between vertical and horizontal policies.

Vertical policies refer to those policy measures which specifically focus on the promotion of biotechnology. These can be directed to promote the creation of the biotechnology knowledge base (policy type A in table 2.2.), to encourage networking activities among the actors involved in the innovation process or to facilitate commercialisation (policy type B). Policies implemented to promote biotechnology may be also relevant for other technologies. We will consider the instrument as *vertical* if the development or commercialisation of biotechnology was an explicit objective in the policy design.

Policies with a socio-economic dimension dealing with public consciousness or ethical aspects are relevant for the demand and for the supply side since they also influence the attitude of investors, industrial players and scientists and their engagement in the development of biotechnology. These types of policies are included in the vertical policies of the type C.

Table 2.2 National Biotechnology Policy Profile

Policy Types	***Importance***	
	Trend 1994-2001	2001
Vertical Policies		
A. Policies for knowledge base support 1. Instruments to encourage basic research 2. Instruments to encourage industry-oriented (and applied) research in PSROs 3. Instruments for strengthening academic cooperation among PSROs and disciplines		
B. Policies for commercialisation support 1. Instruments to build up technological capabilities for the industry 2. Instruments to encourage the commercialisation of scientific results from public research institutions 3. Instruments to encourage the collaboration between public and industrial research.		
C. Policies with a socio-economic and ethical dimension		
Horizontal Policies		
D. Science and technology policies 1. Instruments to support the knowledge base, including mobility of researchers 2. Instruments to support the commercialisation of technologies 3. Instruments to support firm creation		
E. Regulation matters for the biotechnology industry		
F. Legislation on Intellectual Property Rights (IPR)		
G. Measures to assure the availability of financial capital in high growth sectors		

On the other side, policies that were not specifically designed to promote biotechnology but still contribute to its development and commercialisation are considered as **horizontal policies**. Those policies, which aim at promoting scientific and technological development per se, and to improve the conditions for innovation will be referred to as science and technology policies (type D). Relevant legal matters (like measures to regulate the intellectual property) or regulations concerning stock market or product quality and labelling which indirectly have an effect on biotechnology innovation are also considered as horizontal policies (type F and E, respectively). Finally, horizontal policies include measures to assure the availability of financial capital in high growth sectors (horizontal policy type G).

In order to understand the national policy systems, their organisation, their priorities, their instruments to promote biotechnology and their evolution between 1994 and 2001, the project teams conducted desk research to gather the relevant information. The goal was to collect information on national public promotion programmes, funding activities and policy instruments that belong to the classification described above. The desk research covered publicly available information from the national institutions responsible for promoting science and technology in the different countries. Besides, documentation from other research projects and publications on promotion activities in the biotechnology field or in innovation activities in general were also taken into account(7).

Apart from gathering information on horizontal and vertical policies at the national level the EPOHITE project team has evaluated the importance of the different policy instruments according to their relevance in the national policy system. Accordingly, the policy measures in each country were evaluated with an ascending scale from 1 to 5 based on a subjective analysis of the emphasis given by the policy system to the specific instruments. To evaluate the change between 1994 and 2001 a "0" was awarded to those instruments that have not experienced significant change in the emphasis received from the policy system since 1994, "+" and "-" indicated increasing or decreasing significance.

Table 2.2 presents the framework used to assess the importance of the different policy instruments within each funding system.

2.4 The assessment of the national performance

To assess the performance of the European Member States in developing and commercialising biotechnology EPOHITE chooses a quantitative approach based on indicators. Two types of data were used for constructing indicators: firstly, publicly available data on commercial biotechnology activities such as number of firms, venture capital investment and initial public offerings (IPO); secondly, data on publication and patenting activity that were generated during the EPOHITE project using various online databases. Table 2.3 presents the type of indicators and its sources.

Two performance categories were considered for the analysis: performance related to the knowledge base in biotechnology and performance related to commercialisation of biotechnology. It is assumed that knowledge-base-related performance reflects mainly the activities of public sector research organisations (PSROs), while commercialisation performance represents the activities of small and medium-sized biotechnology firms and large firms. For both types of performance two sets of indicators were used: stock indicators which describe the performance status at a fixed time and trend indicators which describe growth.

Knowledge base indicators are based on scientific publications, which were analysed by

(7) The following material was especially valuable:
– Enzing, C. M.; Benedictus, J. N.; Engelen-Smeets, E. et al. (1999): Inventory of Public Biotechnology R&D Programmes in Europe. Luxembourg: Office for Official Publications of the European Communities.
– European Trend Chart on Innovation: Country Reports European Commission. http://trendchart.cordis.lu/

various bibliometric methods. Bibliometric data was collected using the online version of the Science Citation Index (SCI), produced by the Institute of Scientific Information in Philadelphia and offered by the host STN. Publication data was collected for the period 1991-2000. The starting point for the bibliometric work was the definition of the field under analysis. A set of keywords as well as subject codes, which are provided by the SCI, were used for delimiting the field 'biotechnology' and the biotechnology sub-fields considered[8].

EPOHITE's analysis used different knowledge indicators to measure scientific performance:

- Share of biotechnology publications to all scientific publications: this indicator gives an impression of the significance of biotechnology within all scientific activities in a country.
- Development of total biotechnology publications over time: this measure indicates general trends in terms of biotechnology-related scientific output.
- Total biotechnology publications per capita, stock and growth: using these indicators, scientific output in biotechnology is related to the country size resulting in relative indicators which allow a better comparison of the performance of countries with different sizes.

Table 2.3. National performance indicators and their sources

National indicators	**Sources**
Knowledge base indicators	
Indicators to measure the scientific output	
Share of biotechnology publications to all scientific publications	Own calculations using SCI[9] data
Total biotechnology publications over time	Own calculations using SCI data
Total biotechnology publications per capita	Own calculations using SCI and GFS[10] population data
Relation of basic-research-oriented publications to all publications	Own calculations using SCI data
Indicators to measure the scientific impact	
Citations to biotechnology publications	Own calculations using SCI data
Indicators to measure international scientific collaboration	
Share of internationally co-authored biotechnology papers	Own calculations using SCI data
Commercialisation indicators	
Number of biotechnology companies per capita	Ernst & Young[11]
Amount of venture capital invested in biotechnology per capita	EVCA[12]
The number of initial public offerings (IPOs) per capita	Ernst & Young, websites by Nasdaq, Neuer Markt, London Stock Exchange, Euronext
Patent applications in biotechnology per capita	Own calculations using EPO data[13]

(8) EPOHITE considers 7 biotechnology (BT) sub-fields: Plant BT, Animal BT, Environmental BT, Bioprocessing, Diagnostics/Therapeutics, Platform Technologies, Cell factory (see section 2.2.1)
(9) SCI stands for Science Citation Index. SCI was gathered through STN international, a private provider of scientific and technical information. http://www.stn-international.com
(10) GFS stands for the German Federal Statistical Office, Statistical yearbook 1999, 2000, 2001
(11) Ernst & Young European biotechnology annual reports. Several years
(12) European Venture Capital Association, Venture Capital in Europe Annual Reports 1992 – 2001
(13) Data on patent applications at the European patent office (EPO) was retrieved through Questel Orbit, a private provider of intellectual property information. http://www.questel.orbit.com/

- Scientific profile of publications: in order to obtain an impression of the specialisation of the different countries in various sub-areas of biotechnology and possible changes in specialisation patterns, publication output is also analysed for different sub-fields of biotechnology.
- Relation of basic-oriented publications to all publications: since biotechnology is rooted strongly in basic research, the significance of publications oriented towards basic research among all biotechnology publications can be used as an indication for the relative performance of the basic research base of a country.
- Indicators to measure the scientific impact: Publication intensity alone does not take into account the fact that the value of publications and thus the significance of the underlying scientific activities may be quite different. Therefore, as an additional indicator citations to biotechnology publications were used as an impact indicator.
- Indicators to measure international scientific collaboration: The degree of internationalisation in biotechnology is an important measure for the integration of national activities into international networks. For measuring this process the share of internationally co-authored biotechnology papers is analysed.

In order to measure the **commercialisation performance** of the various countries, four different indicators were used: the number of companies per capita, the amount of venture capital invested in biotechnology per capita, the number of initial public offerings per capita and the number of patent applications in biotechnology per capita.

The first indicator, the relative number of biotechnology companies, is used as a proxy for the extent of commercialisation of biotechnology in a country. In order to take account of different sizes of the considered economies, the indicator is related to the population size of each country.

The amount of venture capital invested in biotechnology per capita is an indicator which integrates two types of information. Firstly, since venture capital is invested mainly in promising start-up biotech firms, the amount of invested venture capital mirrors the intensity of start-up activities in a country. The second type of information relates to the process of providing venture capital. Before doing so venture capital firms carry out careful evaluations of the potential receiver company according to strict criteria. Therefore, venture capital investment could also be interpreted as a quality indicator reflecting the quality of biotechnology start-up activities as assessed by venture capital companies.

The venture capital indicator is biased to some extent towards start-up activities. Therefore, as additional indicator reflecting the commercial maturity of a national biotechnology universe, the number of initial public offerings (IPO) is used.

In order to describe innovation activities in biotechnology, patent applications in biotechnology at the European Patent Office (EPO) are used as an indicator. Patent data was collected for the period 1991-2000 using the online version of the European Patent Office (EPO) database offered by the host Questel. To select the patent records related to biotechnology and the selected biotechnology sub-fields a search strategy based on codes from the International Patent Classification (IPC) was elaborated. Accordingly selected IPC codes were the basis for the definition of biotechnology and the seven biotechnology sub-fields considered. The national assignment of a patent record was given according to the country of the inventor. The year of application considered was the first priority year, that is the year of the first application for a patent to a patent office.

The indicators presented were built to assess the performance of the different national systems. In order to compare the performance of the different countries, EPOHITE uses a scaling system, which transfers the scores of each indicator to a 100-point scale. 100 points represent the sum of the indicator values of all countries. For comparison the median value of the 100-point scores is calculated (see section 3.4).

2.5 Actors' Perception

Like already introduced in section 2.1, a major building block of EPOHITE's methodological approach is the qualitative analysis of the policy effectiveness from the perspective of the actors involved in the innovation process. This qualitative analysis covers 144 interviews in 14 countries with representatives of public sector research organisations (PSROs), biotechnology companies including high performance start-ups (HPSUs), successful small and medium enterprises SMEs and large firms (LFs).

Three actor-specific interview guidelines with a common structure were designed (one for each type actor interviewed) to carry out the interviews. The interview-guidelines include open-ended and closed-ended structured questions to explore the actors' characteristics and their needs. The goal is to capture their assessment of the effectiveness of the policies implemented in their countries of location since 1994 and to identify policy gaps. The following paragraphs describe the content of the interview-guidelines.

Fact sheet with general information about the actor

Actors are supposed to complete a fact sheet with general information on the actor and their research and development activities.

Part I: Assessment of policy effectiveness: selected issues

The actors are interviewed about the effectiveness of public programmes in supporting their R&D activities and in creating the necessary framework conditions for successful activities in developing and commercialising biotechnology.

The aim of this part of the interview is to explore:

- The need for public promotion programmes in selected activities of the actors
- The awareness of the actors about existing policy instruments or promotion programmes
- The experiences of the actors with the policy instruments and their propositions for improvement

Part I covered the following aspects of the innovation process and the innovation system:

1. Strategies followed by the actors to acquire knowledge and to get access to external capabilities.
   Recruitment.
   Collaboration.
2. Strategies followed by the actors to finance their innovation activities.
3. Intellectual Property Rights (IPRs).
   Importance/ role of IPRs.
   Effects from the European harmonisation on IPR related to Biotechnology.
4. Socio-economic and ethical aspects.
   Extent to which actors take into account any socio-economic/ethical issues when designing and performing biotechnology research activities.
   Extent to which actors organise or participate in activities concerned with the socio-economic/ethical issues of biotechnology.
   Influence of socio-economic/ethical issues in the biotechnology research activities of the actors.
   Collaboration with NGOs.
5. Regulation.
   Importance/role of regulation.
   Main regulations affecting the R&D activities.
   The need for European harmonisation.

Part II: Assessment of policy effectiveness: policy profiles

From the policy profile presented in table 2.2 the actors identify the public programmes and promotion measures that were most relevant for their activities. In general terms and according an ascending scale from 1 to 4 the actors evaluate how the national policies included in the policy profiles are supporting their activities and how the support has changed since 1994.

Part III: Assessment of policy effectiveness: actor-specific general issues

PSROs

1. Factors influencing the quality and the amount of scientific output of a research unit and their relevance.
   Special focus on the influence of the size of a research unit on the scientific quality and output of the unit.
   Special focus on the role of the degree of interdisciplinarity of the research for the quality and the success or research projects.
2. Factors influencing the commercialisation of scientific results and their relevance.

Biotechnology Companies (HPSUs and SMEs)

1. Factors influencing the creation and the creation and development of biotechnology companies and their relevance.
2. Factors influencing the location of biotechnology companies and their relevance.
3. The rationales for collaboration with PSROs.
4. Identification of gaps in public policy.

LFs

1. Location of facilities for research and development.
2. Factors influencing location and their relevance.
3. Assessment of the factors influencing location in the home country.
4. Identification of gaps in public policy.

3. Performance of European Member States in biotechnology

3.1 Introduction

The main objective of the EPOHITE project is to explore the relation between policy approaches towards biotechnology and performance of the respective national innovation systems, taking into account that policy effects need to be differentiated from other influencing factors. Therefore, the assessment of the performance of European Member States in biotechnology is a key element of the EPOHITE project.

In this chapter we will first assess the performance of European Member States in biotechnology, by using different indicators for scientific activities (section 3.2) and activities related to the commercialisation of biotechnology (section 3.3). Based on the results of these performance analyses we will present the identification of clusters of countries with similar performance in terms of their scientific and/or commercialisation activities (section 3.4). Comparisons within and between such performance clusters will be carried out in detail in the following chapters 4, 5 and 6 of this report.

Even though there is a wide-spread policy interest in biotechnology in Europe (see e.g. European Commission 2002), there is a surprising lack of systematic internationally comparable data on the performance of various national or sectoral biotechnology innovation systems, which was not only detected during EPOHITE research but also by other recent studies (e.g. European Commission 2003a).

On a national level the few available recent studies include an analysis of the development of the biotech industry in France with a focus on identifying business models (Mangematin et al. 2003). The Swedish Agency for Innovation Systems (VINNOVA) has published an analysis of the Swedish performance in biotechnology using various science, technology and economic indicators (Sandström & Norgren 2003). Another recent study on Sweden has a focus on the analysis of formal knowledge collaboration in the Swedish biotechnology-pharmaceutical sector, addressing the theoretical question about the relative importance of co-location for formal knowledge collaboration (McKelvey et al. 2003). A survey of Finnish biotechnology firms was performed in 2002 in the context of the international evaluation of Finnish biotechnology. Within this survey a broad set of commercialisation indicators for biotechnology in Finland has been compiled (Hermans & Luukkonen 2002). Commercial development and academic activities in the Life Sciences in the Netherlands were analysed recently by Enzing et al. (2002). They found, for example, that compared to other European countries commercial development of biotechnology in the Netherlands occurred at a slower rate. For most other European Member States up-to-date information on performance in biotechnology is scarce. It should be noted, however, that there are biotechnology reports from various consultancy firms[14]. Unfortunately, in most cases underlying data and information about the used methodology are not accessible publicly.

On a European level the biotechnology innovation score board (European Commission 2003a) is the most recent attempt to fill the information gap on biotechnology performance. The biotechnology innovation score board was produced under the "European Trend Chart on Innovation" and highlights as a benchmarking exercise strengths and weaknesses of the EU Member States in biotechnology innovation. A second recent European analysis is a background report for the European competitiveness report (European Commission 2001), which presents some patent data in biotechnology, but mainly provides an analysis of the European biotechnology industry based on an internal database which is not accessible to the public (Allansdottir et al. 2002). In addition, the consultancy company Ernst & Young provides yearly reports on the European biotechnology industry with a strong focus on firm creation and economic performance. However, as mentioned it is difficult to assess such surveys because data accessibility is limited.

(14) For example, Annual European Life Sciences Reports of Ernst & Young (e.g. Ernst & Young 2001a).

A main reason for this scarcity of information seems to be a general lack of statistical data on biotechnology in Europe, which could be used for the calculation of performance indicators. Despite recent efforts of the OECD to improve this situation (OECD 2002), basic innovation indicators giving information on the level of R&D, employment, output of biotechnology innovative activities or collaboration between public and private organisations are still not available.

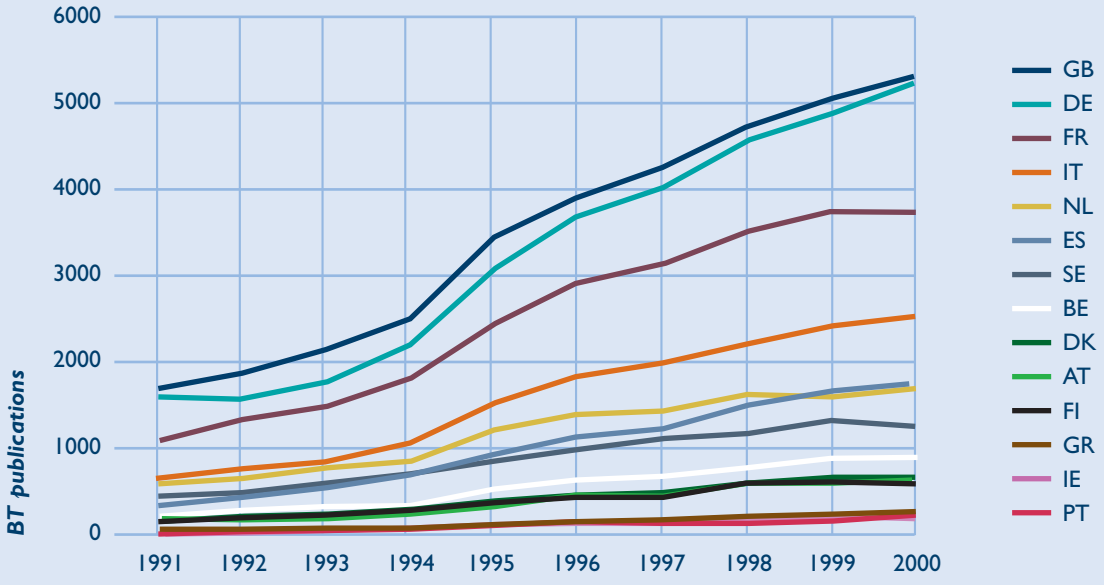
For this reason the performance analysis of EPOHITE had to focus on a limited set of indicators. Two performance categories were considered for the analysis: performance related to the knowledge base in biotechnology and performance related to commercialisation of biotechnology (see chapter 2). The following sections present a cross-country analysis of the performance of the European biotechnology systems of innovation. The same data and set of indicators have been used for the assessment of policy effectiveness at the national level presented in the EPOHITE national reports[15].

3.2 Performance of European countries in generating and sustaining a biotechnology knowledge base

The analysis of publication activities in biotechnology in the EU Member States indicates a strong growth of the scientific output in biotechnology between 1991 and 2000 in all countries (figure 3.1). The larger countries United Kingdom, France and Germany contribute by far with the highest number of publications. Interestingly, the relative position of most countries remains stable throughout the 1990s. Only Spain seems to have improved its relative position by getting ahead of Sweden and the Netherlands at the end of the 1990s.

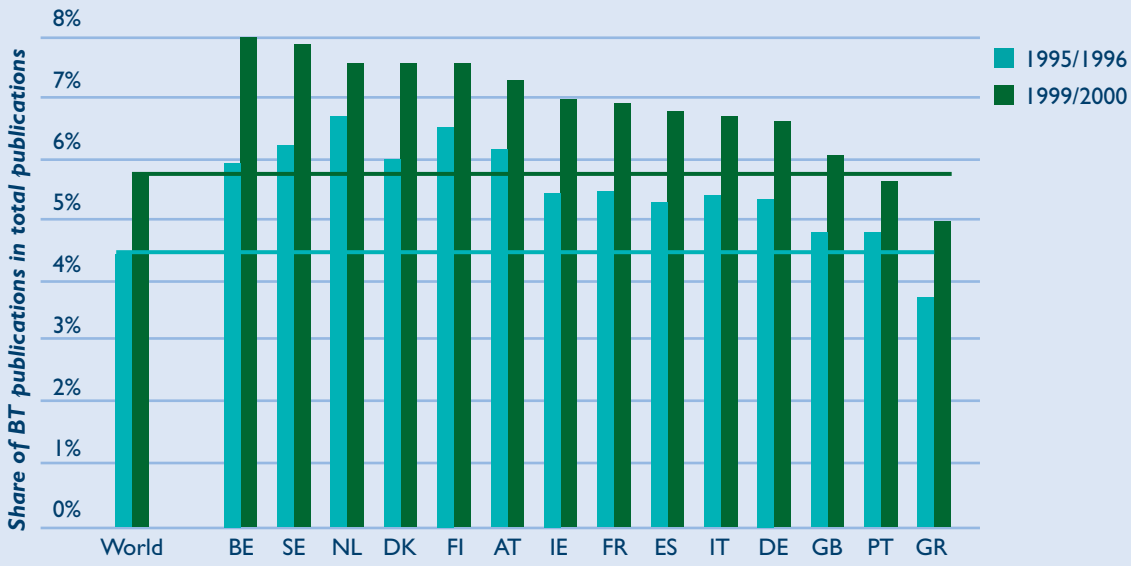
Publication intensity in biotechnology increased not only in absolute terms but also in relative terms as shown by the ratio of biotechnology publications to all publications calculated for each Member State (figure 3.2). In other words, the significance of biotechnology among all scientific activities in the Member States

Figure 3.1: Development of biotechnology publications in EU Member States between 1991 and 2000 (source: EPOHITE research[16], data: SCI via host STN)



(15) See http://www.epohite.fhg.de
(16) Reiss et al. (2003): Efficiency of innovation policies in high technology sectors in Europe (EPOHITE) (HPV1-CT-2001-00005)

Figure 3.2: Share of biotechnology publications in total publications in the EU Member States (source: EPOHITE research, data: SCI via host STN)



increased. Most European countries performed above the world average with respect to this indicator. In the smaller countries the significance of biotechnology seems to be even higher. For example, Belgium, Sweden, the Netherlands, Denmark, Finland and Austria achieved a share of between 7% and 8% of biotechnology publications to all publications for the period 1999 and 2000.

If we consider the relative publication intensities measured as biotechnology publications per million capita, it becomes obvious again, that all Member States increased their relative performance throughout the 1990s.

Focusing on the most recent period (1999/2000) the best performing countries were the Nordic countries Sweden, Denmark and Finland. Among the established large players (United Kingdom, Germany and France) the United Kingdom performed best in terms of publications per capita. The Southern countries show up at the end of this performance scale. However, with the exception of Italy these countries (Portugal, Greece and Spain) exhibit the highest growth rates of the per capita publications if we compare the periods 1995/96 and 1999/2000.

The analysis of the number of citations to biotechnology publications indicates that the scientific impact increased in all Member States between 1995 and 2000 (figure 3.4). For both periods the highest impact value is observed for publications originating from the United Kingdom. On the contrary, the impact of publications from Southern countries seems to be relatively low. The highest improvement of impact rates could be detected for publications from Ireland, Denmark, Spain, Austria and France.

The evaluation of internationally co-authored biotechnology papers reveals that the international orientation increased in all Member States between 1995 and 2000 (figure 3.5). Strongest growth in internationalisation could be observed for Finland, France, Sweden and Portugal. Portugal also presents itself as the country with the largest number of internationally co-authored papers per biotechnology publications in the most recent period. In more general terms, smaller countries seem to have a stronger international orientation. This "small-countries effect" is well-known from other research activities and is mainly due to the fact that it is more difficult for research units in small countries to find domestic partners compared

Figure 3.3: Relative biotechnology publication activities in EU Member States (source: EPOHITE research, data: SCI via host STN)

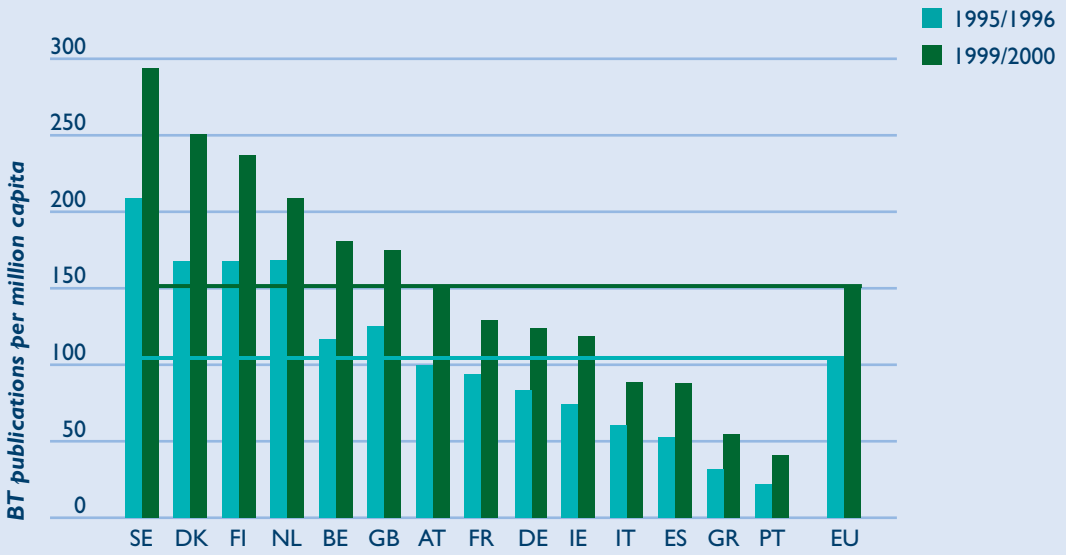
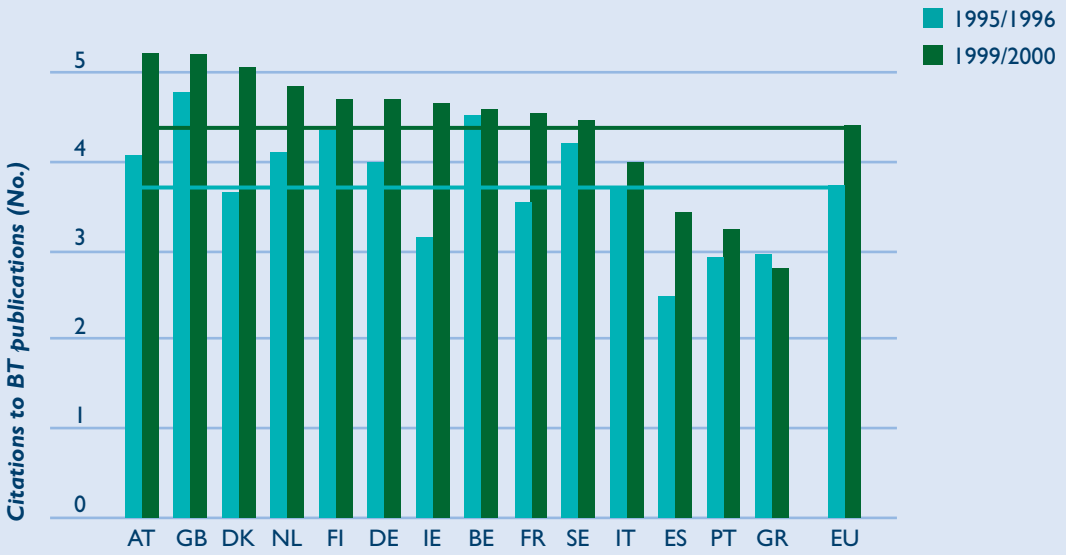


Figure 3.4: Citations to biotechnology publications of EU Member States during the 1990s (source: EPOHITE research, data: SCI via host STN)



to larger countries. Therefore, looking abroad for cooperation is probably driven by lack of domestic capacities.

The orientation of research activities towards basic research, as indicated by the share of basic research publications to all publications, turns out to be similar in all analysed countries (figure 3.6). Approximately 30% of all publications present research results drawing on basic research. Obviously, the significance of basic research activities in generating a biotechnology knowledge base is acknowledged by all national innovation systems to a similar extent. Greece

Figure 3.5: Internationally co-authored publications of European Member States (source: EPOHITE research, data: SCI via host STN)

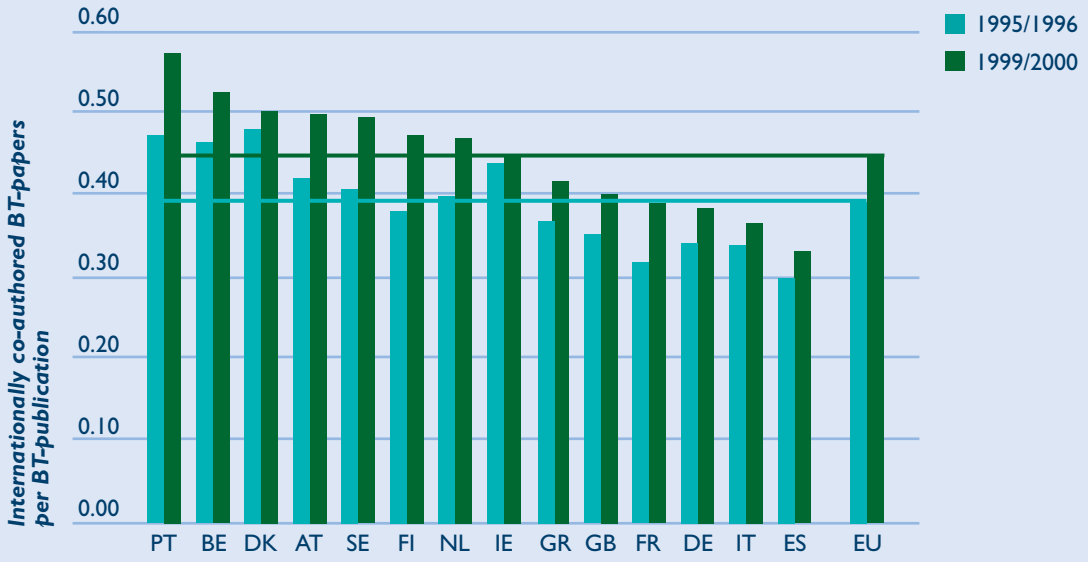
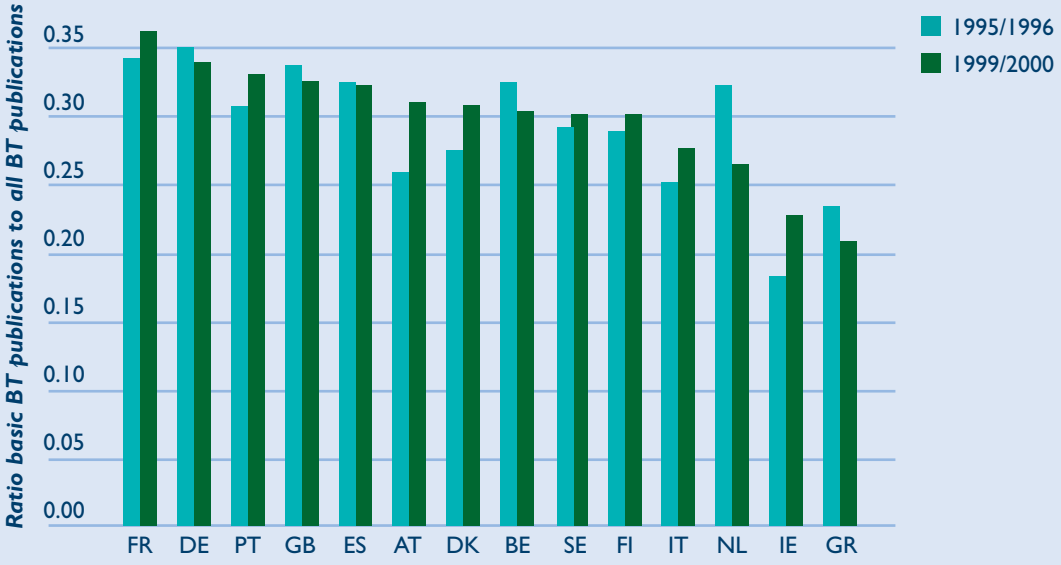


Figure 3.6: Ratio of basic research-oriented publications in biotechnology to all biotechnology publications in EU Member States (source: EPOHITE research, data: SCI via host STN)



and Ireland do not fit to this general observation by their rather low share of basic research orientation.

The specialisation analysis indicates on the one hand that the specialisation patterns are very similar across all European Member States. Diagnostics and therapeutics based on biotechnology is the most important field in terms of publications followed by the areas cell factory and plant biotechnology (figure 3.7). Interesting deviations from this general pattern are Ireland with a rather strong focus on animal biotechnology and Portugal with strong emphasis on

Figure 3.7: Specialisation pattern of European Member States in various sub-areas of biotechnology. The figure shows the ratio of publications in sub-fields of biotechnology to all biotechnology publications for the period 1995 to 1996. For comparison, the European average value is also given. (source: EPOHITE research, data: SCI via host STN)

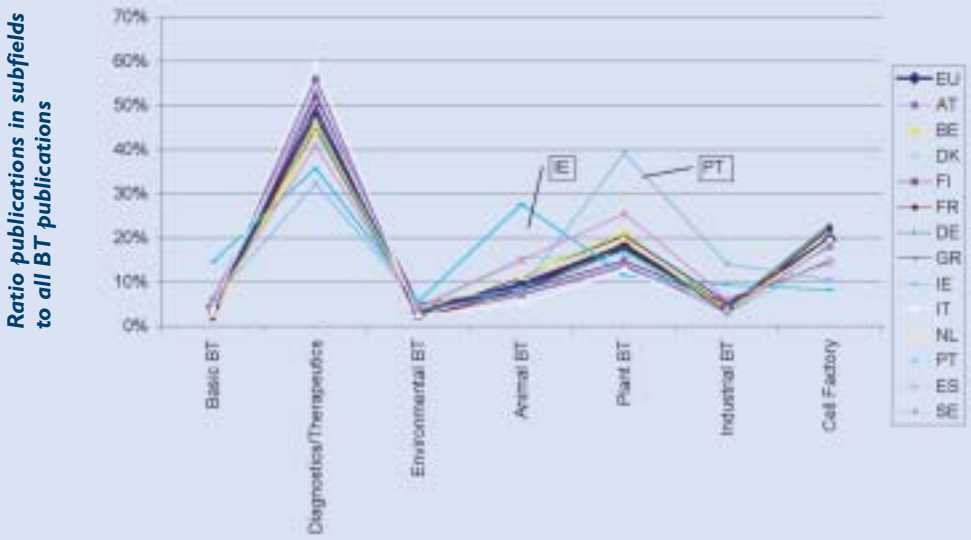
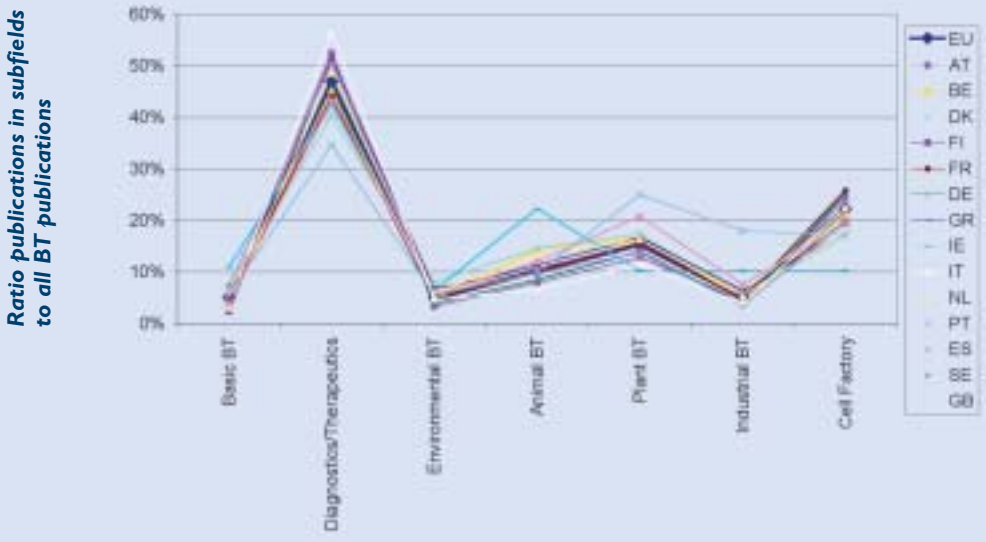
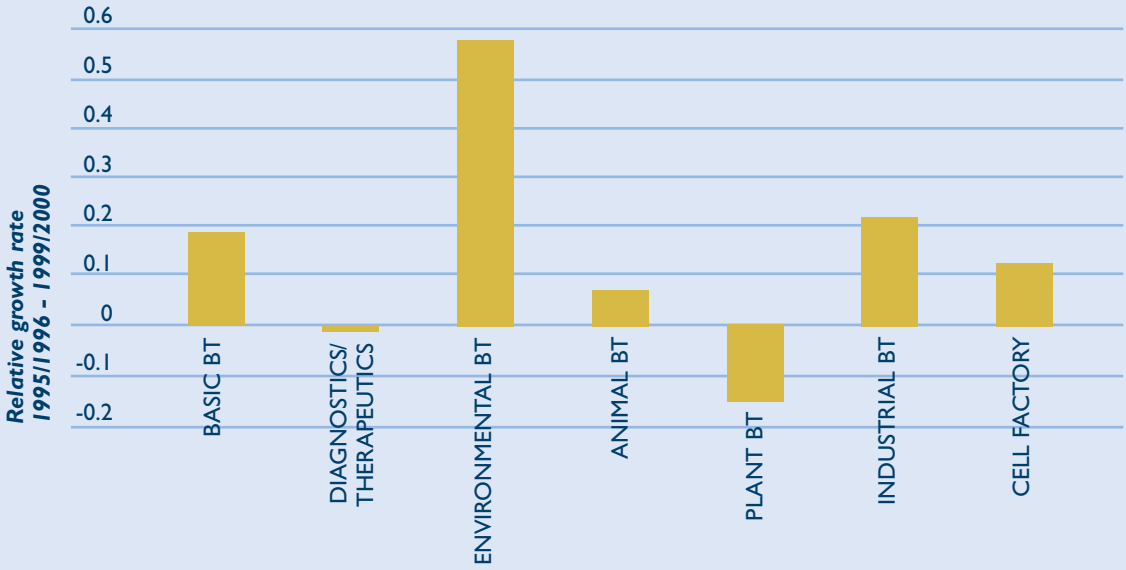


Figure 3.8: Specialisation pattern of European Member States in various sub-areas of biotechnology. The figure shows the ratio of publications in sub-fields of biotechnology to all biotechnology publications for the period 1999 to 2000. For comparison, the European average value is also given. (source: EPOHITE research, data: SCI via host STN)



plant biotechnology. On the other hand, the analysis of the dynamics of specialisation patterns (figures 3.8, 3.9) indicates a few remarkable changes: some small areas, such as environmental biotechnology and industrial biotechnology, are becoming more important. The only medium-sized area, which gained significant growth is research related to the cell factory. Finally, there is one area, which is losing significance considerably in the period 1995 to 2000: the area of plant biotechnology.

Figure 3.9: Specialisation trends in biotechnology across European Member States between 1995 and 2000 (source: EPOHITE research, data: SCI via host STN)



3.3 Performance of European countries in commercialising biotechnology

The biotechnology industry in all Member States has grown considerably in terms of number of biotechnology firms per capita in the period 1996 to 2000. While in absolute figures the United Kingdom and Germany host by far the largest number of biotechnology companies in Europe, a different picture emerges if the different country sizes are taken into account (figure 3.10): the three Nordic nations – Denmark, Finland and in particular Sweden – show the best performance. The three large European countries United Kingdom, Germany and France perform below the European average for both periods. The Mediterranean countries are placed at the end of the performance scale[17]. The three leading Nordic countries and in addition Germany are also the countries where the strongest growth of the biotechnology industry in relative terms took place throughout the 1990s.

Measuring commercialisation performance of European countries by the amount of invested venture capital into biotechnology per population reveals an increasing flow of venture capital into almost all European countries during the 1990s (figure 3.11). Denmark, Germany and Belgium are performing best during the years 1999 and 2000. Finland, the Netherlands, France and to a lesser extent Sweden take a medium position. All other countries were not able to attract sizeable amounts of venture capital for biotechnology. Considering the growth rates of venture capital investment in biotechnology the strongest dynamics can be observed in Spain and Sweden, however, starting from a rather low absolute level. Looking at those countries were venture capital was invested already in the middle of the 1990s the strongest growth took place in Germany were the amount of venture capital per million capita invested increased during this period almost tenfold.

Two of the countries under consideration – Belgium and United Kingdom – started already at a rather high level of venture capital investment at the middle of the 1990s. Both countries succeeded in increasing venture capital investment from this high level towards the end of the 1990s. In summary, the analysis of venture

(17) There are no comparable data available from the Ernst & Young reports for Greece and Portugal.

Figure 3.10: Development of the biotechnology industry in EU Member States (source: Ernst & Young European Life Sciences Reports: e.g. Ernst & Young 2001a)

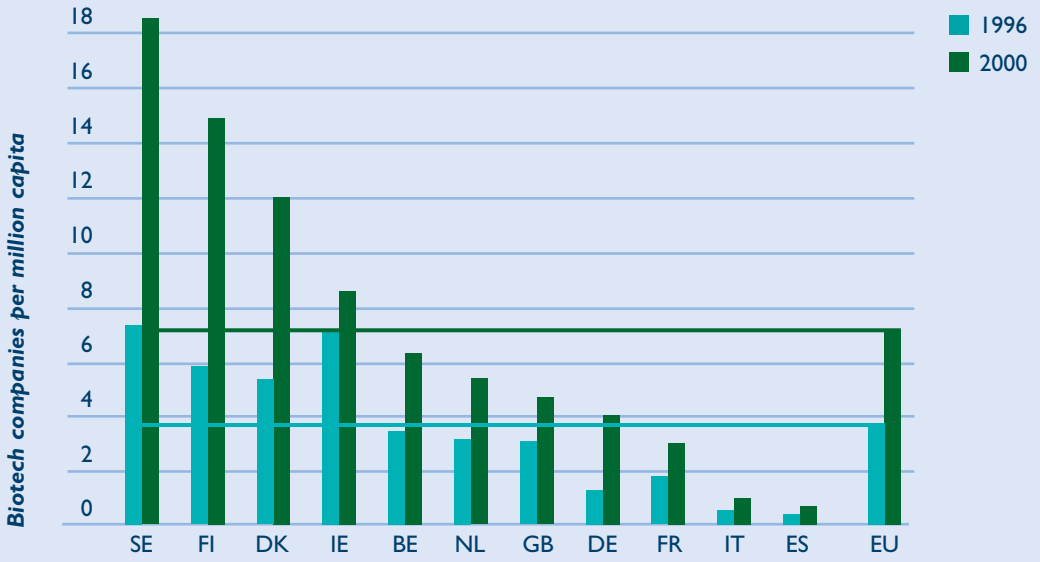
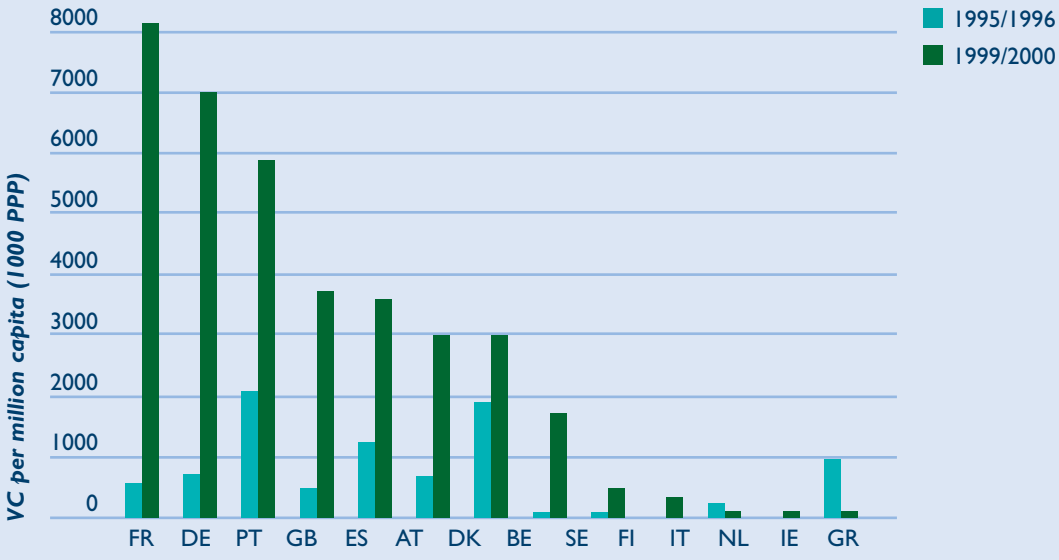


Figure 3.11: Investment of venture capital in biotechnology in European countries related to the size of the population (source: EVCA 2002)



capital investment in biotechnology in European countries indicates that venture capital investors increasingly trust the European biotechnology industry, which could be considered as an indication of improving quantity *and* quality of the industry.

The number of initial public offerings (IPOs) placed in the periods 1995 to 1997 and 1998 to 2000 gives an indication of the development stages of the biotechnology industry in the Member States. Accordingly, Denmark, the United Kingdom and Germany are the countries with the most mature industries (figure

3.12). United Kingdom has been given signals of a more advanced development stage compared to its European neighbours already since 1995. Germany presents a rather strong growth of IPOs between the two periods considered. In general it should be mentioned, however, that most of the European Member States have placed only a very low number of IPOs during the time analysed, indicating still a rather early stage of development of the industry, in particular, if the European situation is compared to the one in the United States. For example, in the year 2000 in the USA 58 IPOs by biotechnology firms were counted (Ernst & Young 2001b) corresponding to an IPO to a million population ratio of 0.206, compared to a total of 29 IPOs in the EU Member States, which corresponds to an IPO to population indicator of 0.077 IPOs per million population.

In terms of patenting activities indicating technology generation for biotechnology Denmark performs exceptionally (figure 3.13). Already in the middle of the 1990s Denmark was far ahead of the other countries. This lead could be sustained until the end of the 1990s. Belgium, the Netherlands, Sweden and Germany come next to Denmark in their patenting performance. Again at the lower end of the scale the Mediterranean countries show up.

Figure 3.12: Placement of initial public offerings (IPOs) by biotechnology firms in relation to the national population (sources: Ernst & Young annual European life sciences reports, websites of NASTAQ, Neuer Markt, London Stock Exchange, Euronext)

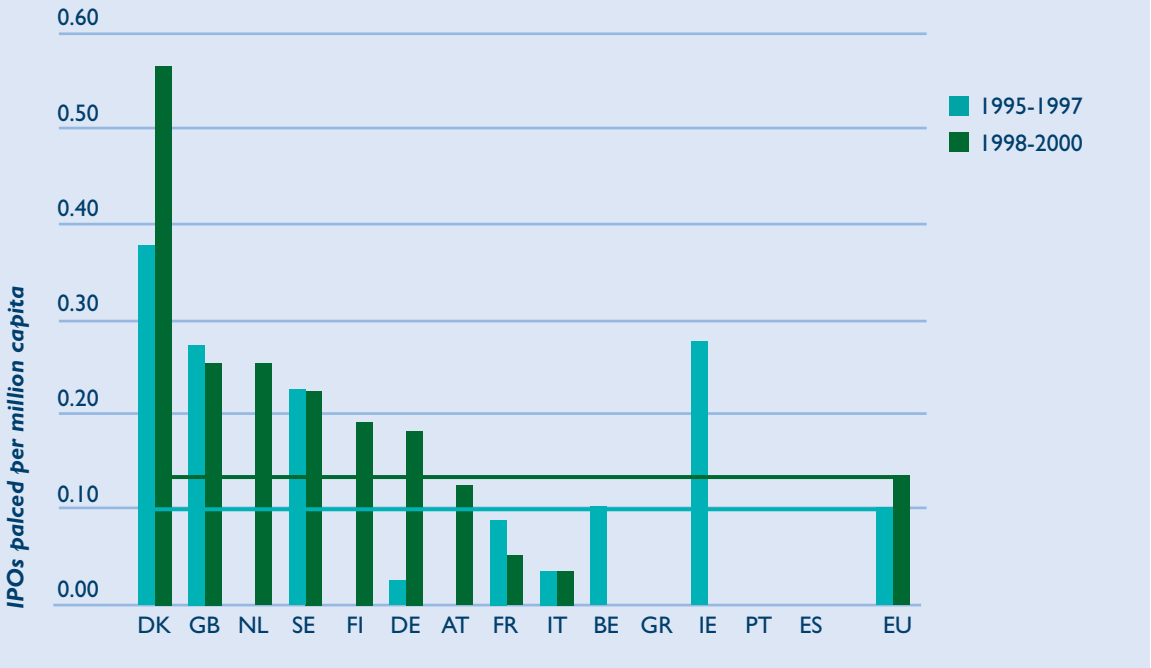
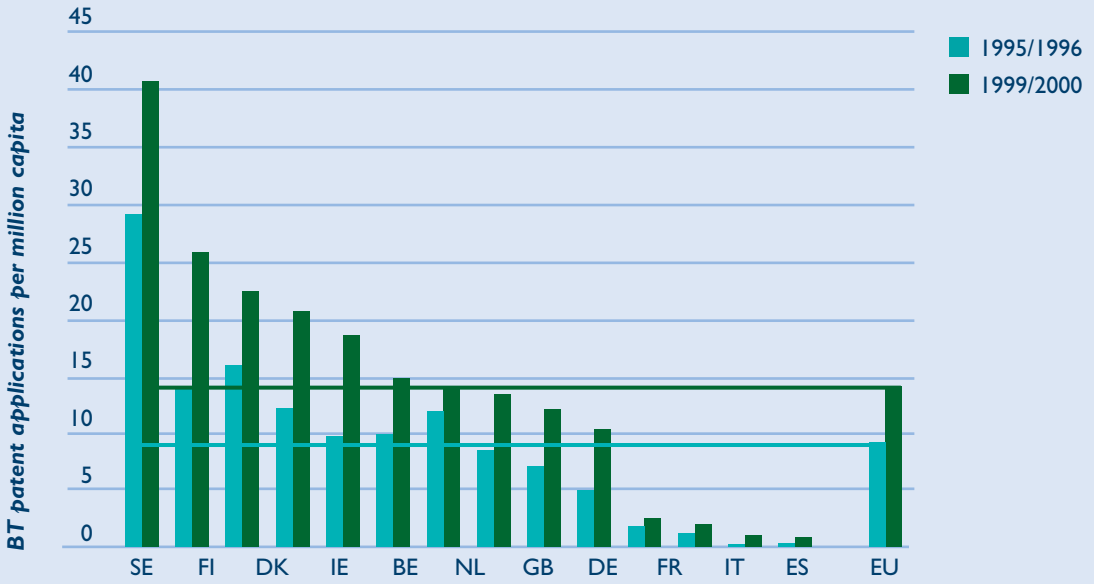


Figure 3.13: Biotechnology patent applications per million capita during the 1990s (source: EPOHITE research, Data: EPO via Quastel Orbit)



3.4 Identification and comparison of country clusters with similar performance in biotechnology

In order to identify clusters of countries with similar performance, index values for the individual indicators were constructed (see chapter 2), which allow to calculate a combined indicator for each performance type. For comparison, the European median value was also calculated for the combined indicators.

Tables 3.1 and 3.2 summarise the index values for both indicator types – the knowledge base indicators and the commercialisation indicators. In addition, the last columns of each table contain the average commercialisation indicator for each performance type.

Table 3.1: Index values of knowledge base indicators used for performance clustering[18].

	BT publications per million capita		*citations per BT publications*		*basic BT publications per total BT publications*		*average knowledge base indicator*	
	1995/1996	1999/2000	1995/1996	1999/2000	1995/1996	1999/2000	1995/1996	1999/2000
Austria	6.78	7.03	7.78	8.50	6.32	7.41	6.96	7.65
Belgium	7.92	8.49	8.62	7.44	7.94	7.28	8.16	7.74
Denmark	11.49	11.83	6.95	8.26	6.76	7.39	8.40	9.16
Finland	11.50	11.10	8.30	7.65	7.03	7.21	8.94	8.65
France	6.34	6.01	6.74	7.36	8.36	8.64	7.15	7.34
Germany	5.66	5.77	7.59	7.64	8.56	8.11	7.27	7.17
Greece	1.92	2.42	5.67	4.59	5.74	4.99	4.44	4.00
Ireland	5.06	5.48	6.02	7.62	4.45	5.45	5.17	6.18
Italy	4.02	4.08	7.03	6.49	6.16	6.58	5.74	5.72
Netherlands	11.58	9.85	7.80	7.90	7.86	6.31	9.08	8.02
Portugal	1.33	1.87	5.59	5.25	7.51	7.92	4.81	5.01
Spain	3.54	4.04	4.73	5.59	7.96	7.73	5.41	5.79
Sweden	14.31	13.83	8.05	7.24	7.13	7.21	9.83	9.43
United Kingdom	8.55	8.22	9.14	8.47	8.23	7.76	8.64	8.15
						European median	*7.14*	*7.49*

(18) For sources of the data and definition of the indicators used in tables 3.1 and 3.2 see section 2.4 and table 2.3 in chapter 2.

Table 3.2: Index values of commercialisation indicators used for performance clustering

	venture capital per million capita		*BT companies per million capita*		*IPO per million capita*		*average commercialisation indicator*	
	1995/1996	1999/2000	1996	2000	1995-1997	1998-2000	1995/1996	1999/2000
Austria	0.00	0.24	n.a.	n.a.	0.00	6.55	2.25	4.51
Belgium	23.18	15.92	8.75	8.05	7.07	0.00	12.49	9.25
Denmark	6.54	21.94	13.52	15.27	27.00	30.07	17.53	21.95
Finland	5.66	10.01	14.87	18.88	0.00	10.30	7.47	11.51
France	7.74	8.07	4.39	3.80	6.14	2.70	5.96	5.16
Germany	7.90	18.90	3.23	5.04	1.75	9.63	5.14	10.72
Greece	0.00	0.00	n.a.	n.a.	0.00	0.00	0.05	0.12
Ireland	10.68	0.21	18.21	10.86	19.72	0.00	13.14	4.07
Italy	0.42	1.20	1.42	1.15	2.50	1.85	1.44	1.38
Netherlands	13.99	9.69	8.18	6.80	0.00	13.46	8.71	10.32
Portugal	2.67	0.26	n.a.	n.a.	0.00	0.00	0.92	0.25
Spain	0.01	0.85	0.97	0.80	0.00	0.00	0.46	0.66
Sweden	0.37	4.65	18.68	23.46	16.25	11.94	11.22	12.60
United Kingdom	20.84	8.05	7.79	5.89	19.55	13.49	14.01	8.72
						European median	*6.71*	*6.94*

Considering the average indicators summarised in the last columns we can differentiate between two clusters of countries: those performing above the European median and those performing below this value. In order to explore the relations between knowledge-based performance and commercialisation performance, in a second step the two performance categories were combined resulting in the performance portfolio shown in table 3.3.

This analysis indicates that there is a relation between knowledge base performance and commercialisation performance. For both periods almost all countries are located either in the "weak quadrant" with respect to both performance types or in the "strong quadrant". Therefore, it seems justified to define clusters of countries for the further analysis based on a combination of both types of performance. The results of the combined performance ranking are shown in figure 3.14.

Table 3.3: Combined performance clustering of European Member States in the period 1999/2000. Arrows indicate changing positions compared to the situation in the period 1995/1996

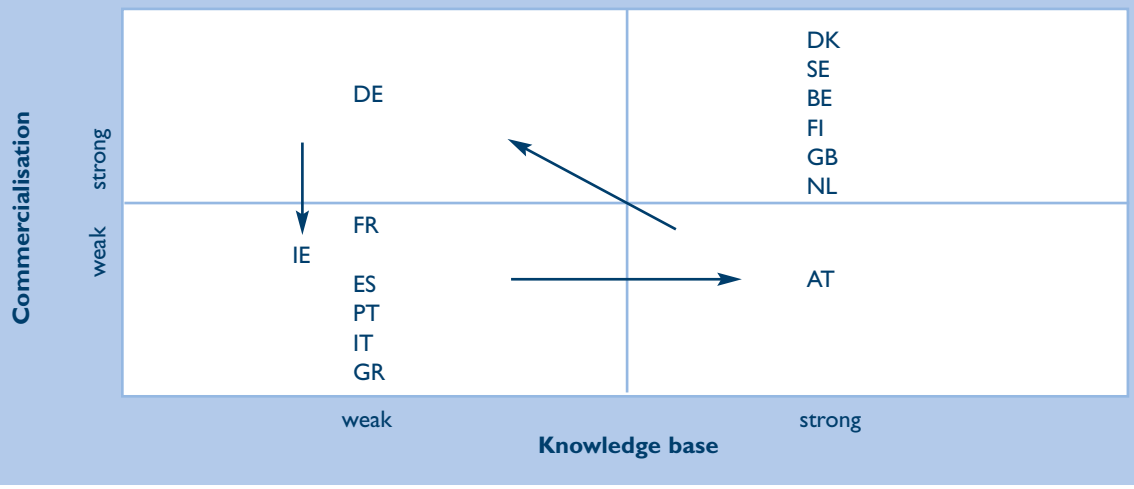
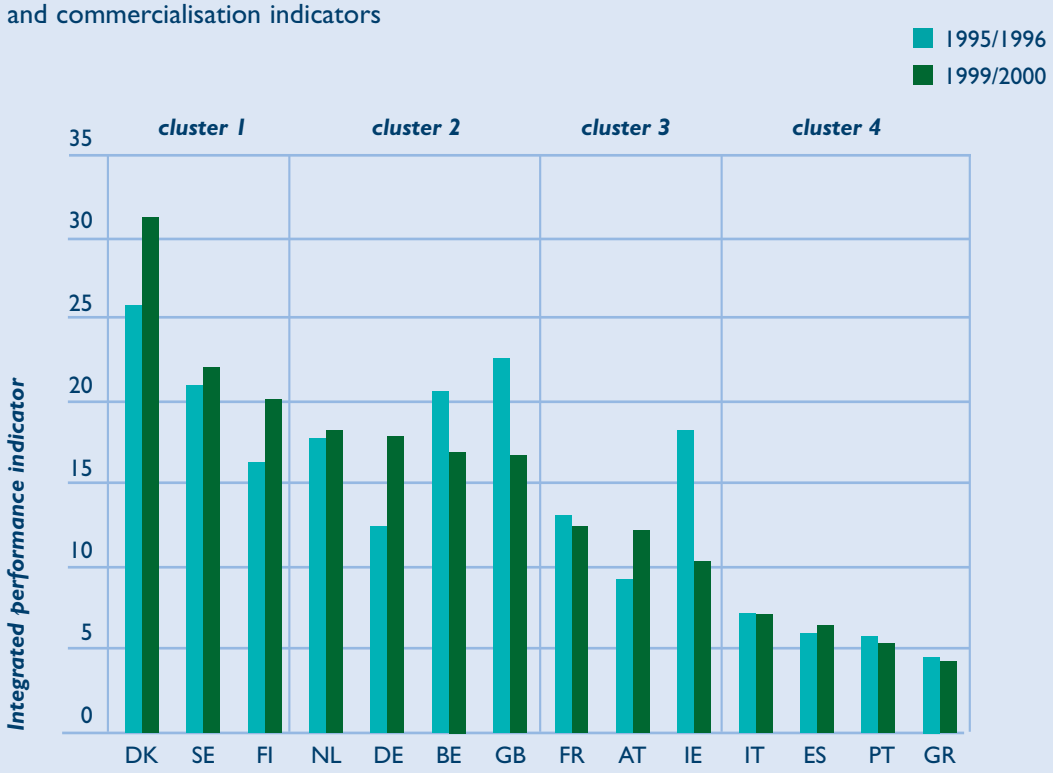


Figure 3.14: Combined performance ranking adding indexed knowledge base and commercialisation indicators



Of the two rankings shown in figure 3.14 the ranking of the most recent period 1999/2000 is crucial for our analysis because we can assume that policy activities during the 1990s will most likely show effects (if any) at the end of this period. Considering these performance data it becomes obvious that it is possible to identify groups of countries, which perform very similar and other groups presenting a more heterogeneous performance. In order to obtain additional evidence of possible clusters we performed a cluster analysis according to the Ward-linkage method using SPSS and based on the individual indicators for commercial and scientific performance. The cluster analysis reveals the following results:

- Denmark is different from all other countries
- Finland and Sweden are very similar
- the Netherlands, Germany, Belgium and the United Kingdom form another rather homogeneous cluster
- the remaining seven countries (France, Austria, Ireland, Italy, Spain, Portugal and Greece) form another cluster, which however is rather heterogeneous.

The exercise of combining this information with the ranking shown in figure 3.14 suggests that the countries can be divided into the following four clusters:

Cluster 1: Denmark, Sweden and Finland representing the best performing cluster.

Cluster 2: the Netherlands, the United Kingdom, Belgium and Germany, representing the second best performers.

Cluster 3: Austria, France and Ireland representing countries performing below the European median performance value.

Cluster 4: Italy, Spain, Portugal and Greece representing the weakly performing cluster.

3.5 Summary and conclusions

The performance analysis indicates that there is an increasing significance of biotechnology in all 14 European Member States which were considered during EPOHITE. Biotechnology-related research activities led to an increasing output of biotechnology publications, not only in quantitative but also in qualitative terms as measured by the improved citation rates and the growing internationalisation of European biotechnology research. The assessment of the overall performance of European Member States with respect to providing a knowledge base for biotechnology in the years 1999 and 2000 reveals the following ranking: the three Nordic countries Sweden, Denmark and Finland present the best performance followed by the United Kingdom, the Netherlands, Belgium and Austria. All these countries are performing above the European average. France, Germany, Ireland, Spain, Italy, Portugal and Greece comprise in this order the second half of the ranking list which contains countries performing below the European average.

Comparing the situation in the years 1999 and 2000 with the middle of the 1990s indicates that Denmark, Austria, Ireland and Spain were able to improve their knowledge-base-related position in the performance scale, while the Netherlands, Germany and Italy lost places in the ranking list. All other countries could keep their positions. These results of EPOHITE are supported by the recently published biotechnology innovation score board of the European Commission (European Commission 2003a), which also found that Sweden, Denmark and Finland followed by the United Kingdom, the Netherlands and Belgium are the countries producing the highest output of scientific publications in biotechnology in the year 2000. Interestingly, ahead of all these countries Switzerland is producing the highest number of biotechnology publications related to population among all European countries and also compared to the United States and Canada which are ranked between the Netherlands and Belgium. The European biotechnology score board also finds a rather weak position of the Mediterranean countries.

The specialisation analysis of scientific activities in biotechnology shows that most Member States can be characterised by a more or less similar specialisation pattern, in a sense that publications related to pharmaceutical biotechnology comprise almost 50% of all publications. Other important areas are plant biotechnology and biotechnology related to the exploration of the cell factory. The evaluation of changes in specialisation over time reveals some minor shifts between the different areas with the exception of plant biotechnology. This area lost its significance considerably between 1995 and 2000.

During the same period the legal environment for commercial activities with genetically modified organisms in the agro-food sector became more difficult due to the de facto moratorium on a European level on the authorisation for marketing genetically modified organisms (GMOs) issued in June 1999. Against this background recent research explored possible consequences on commercial and scientific activities. Lheureux et al. (2003) found that almost 39% of European institutions (large firms, small and medium-sized enterprises, public sector research organisations and universities), which are doing research with GMOs cancelled at least one of such projects between 1998 and the beginning of 2002. This conclusion is based on a survey of 165 European institutions. As a main reason for cancelling GMO projects the unclear legal situation was mentioned. Universities and research institutions also cited limited financial resources as a main constraint. Combining the findings of Lheureux et al. (2003) with the EPOHITE performance analysis provides evidence that the unclear legal situation with respect to the commercialisation of genetically modified organisms which emerged in the second half of the 1990s led to the cutting down of research activities in plant biotechnology which can be measured as decreasing scientific output. In more general terms, the unclear legal situation related to GMO on the commercial side seems to have a negative feedback on the science base. This could give reason for concern that once the legal environment would become more stable and/or more favourable for commerciali-

sation of GMO research, the knowledge base would be less prepared to provide the required know-how. We should like to point out that these data just give some first evidence for such a relation. In order to confirm this observation, it would be necessary to establish a direct relation between cutting projects due to unfavourable framework conditions and reducing scientific output, by getting more information on the behaviour of individual scientists.

The analysis of commercial performance of European Member States in biotechnology reveals that the biotechnology industry has grown considerably in all Member States in the period 1996 to 2000. The strongest growth dynamics can be observed in Germany and in the Nordic countries. Indicators related to the developmental stage of the biotech industry show that the industry still is at a rather early stage. Considering the generation of technological know-how for biotechnology as measured by patent applications Denmark is showing by far the best performance followed by Belgium, the Netherlands, Sweden, Germany and the United Kingdom. These countries are above the European average, while Finland, Austria, France, Ireland and the Mediterranean countries in this order form the second half of the ranking list. Similar results have also been obtained by the biotechnology innovation score board 2003 (European Commission 2003a).

Combining the two performance rankings, the one for creating a knowledge base for biotechnology and the other one indicating commercialisation of biotechnology, suggests that there is a tight relation between scientific performance and commercialisation performance: almost all countries are performing either weakly or strongly in both categories. The only exceptions are Germany and Austria. Austria has a strong position related to knowledge base performance, while commercialisation performance is rather weak. Germany on the other hand, is strong in commercialisation and below average in its knowledge-base-related performance. Due to this relation, it seems justified to combine both types of performance into an combined ranking index which allows to identify four different performance clusters: cluster 1 with the best-performing countries Denmark, Sweden and Finland; cluster 2 with the second-best-performing countries the Netherlands, the United Kingdom, Belgium and Germany; cluster 3 with Austria, France and Ireland, representing countries below the European median performance value, and finally cluster 4 with the Mediterranean countries Italy, Spain, Portugal and Greece performing weakly as measured by all indicators.

The observed strong relation between scientific and commercial performance implies that it is important to consider the whole innovation process and take a systemic perspective when designing and evaluating policy instruments for supporting biotechnology.

4. Policy approaches to biotechnology and their evolution in European Member States

4.1 Introduction: from national and sectoral systems of innovation to instruments of public policies

Biotechnology is a priority of all Member States and of the European Union (European Commission 2003a). Throughout Europe, hundreds of policy measures and support schemes aiming at encouraging the development of biotechnology have been implemented or are under preparation (Enzing et al. 1999). The diversity of the measures and schemes reflects the diversity of the framework conditions, cultural preferences and political priorities in the Member States. In some countries, priority has been given to research, in others, to commercialisation. In some countries, incentives schemes and support policies are dedicated to biotechnology, in others research and innovation as a whole are targeted.

The main **objective** of this chapter is to describe the evolution of biotechnology policies in the Member States. In order to achieve this goal, we describe the different national biotechnology policy-making systems and follow their evolution between 1994 and 2001. The respective biotechnology policies (taking into account non-policy influencing factors) are thus linked to the performance information for each country (or cluster) based on quantitative indicators as presented in the previous chapter.

The description of the evolution of national biotechnology policies is mainly based on two existing reports: Inventory (Enzing et al. 1999) and EBIS (Senker et al. 2001) and on the national case studies performed within the EPOHITE project. Qualitative data as well as economic and performance indicators have been used to describe public policies and the economic situation. Both sets of data complement each other and should help to provide a rather comprehensive picture of the performance of different national biotechnology innovation systems.

The evolution of public policies promoting *high technology* sectors can be analysed from two different perspectives: the national and the sectoral perspective. On the one hand, the national and cultural features can be stressed to analyse the fit between public policy and national features. On the other hand, the sectoral specificities can be considered to identify the public policies that best fit with them. Accordingly, national public policies suppose that the development of biotechnology in Europe is mainly determined by the institutional features of a particular 'national system of innovation' (NSI). While in contrast public policies dedicated to the biotechnology sector assume that the biotechnology development takes place at the sectoral level. Findings of the EBIS project (Senker et al. 2001), which explores the European biotechnology NSI, reveal great differences in the innovation patterns between countries and the three sectors studied (bio-pharmaceutical, agro-food and instrumentation). Partial explanations for these differences are provided by the NSI conceptual framework. EBIS national case studies confirm that the R&D system, the role of the public sector including public policy, interfirm relationships, the financial system, and the national education and training system are important elements of a NSI. These elements are all influenced by public policies. Although some of the differences in national innovation performance in biotechnology could be related to public policies for developing the science base (and the date when policy was introduced), the differences can also be explained by the mechanisms in each system responsible for linking the science base to the industry and by the cultural traditions at universities which influenced the commercialisation activities and small firm creation. Finally, the NSI concept also suggests that the national industry structure influences the innovation patterns as well.

However, the characteristics of the biotechnology sector transcend the national context. Some characteristics of the innovation process (science push, network as the locus of innovation, role of public sector research organisations and universities, SMEs, and the existence of mainly business to business markets) are common for all NSI. In other words, the sector is quite similar in all developed countries

(Allansdottir et al. 2002). The concept of a sectoral innovation system (SIS), introduced by Breschi & Malerba (1997), clearly accounts for the specific dynamics of the biotechnology sector. A sectoral innovation system is defined as a "system (group) of firms active in developing and making a sector's products and in generating and utilising a sector's technologies; such a system of firms is related in two different ways: through processes of interaction and cooperation in artefact-technology development, and through processes of competition and selection in innovative and market activities" (Breschi & Malerba 1997). The key actors of a SIS are the private firms. Breschi & Malerba (1997) emphasise the fact that competition and selection processes involve firms with different capabilities, capacities to mobilise other actors – large firms, universities, research institutes – and innovative performances.

The approach in terms of sectoral innovation systems highlights the key role of firms in the dynamics of innovation. For fast growing SMEs, critical resources are access to scientific competencies and techniques developed by academic research, and to capital markets. Their development relies on signals of these scientific competencies, i. e. patent applications, new products and researchers involved in the firm or in its scientific advisory board. Patents, collaborations with the academic world and partnerships with pharmaceutical firms appear to be positive signals of competences for potential investors when the firm enters into the stock market. Researchers with a high level of scientific visibility often create these firms. The connection with the scientific network is a condition for growth. It is not sufficient, however, for firms must not only develop high-tech research but also transfer and commercialise their results. This often involves research or development contracts with a large company, in which the SME undertakes to provide its partner with specific materials, technologies, know-how or expertise. Relations are formed on the basis of a specific competency recognised by the large firm. The SME's technological lead depends on the quality of its research, and the launching of the activity relies on capital input for the development of the product or process.

However, the development of the biotechnology sector is based on the coexistence of two types of firms, fast growing ones which will form the elite of European industrial biotechnology leaders on which the sector could grow and compete with that of the US and a large number of small firms mainly involved in providing biotechnology services for the whole life science sector and which are not expected to become worldwide leaders (Mangematin et al. 2003).

4.2 General features of the biotechnology policy-making systems

The following section describes the general economic features related to research and innovation, thereby analysing the conditions for effectiveness of public policies in the national context. It pictures the national system of innovation i. e. the process of production of innovation within a national economy as well as the production and distribution, of knowledge. The national system of innovation concept (NSI) provides a comparative method that can be used for policy purposes in order to identify problems or weaknesses that may be addressed in public policy. The NSI deals with the set of actors related to innovation processes and the way they interact. According to Edquist & Johnson (1997), organisations (actors) are formal structures with an explicit purpose.

NSI approaches give a broad overview relevant to understand the development of biotechnology. However, several questions remain open and it is important, at the European level, to analyse the extent to which national evolution and European evolution in terms of leading sectors such as biotechnology are correlated. The first set of questions relates to the relationship between the national context, i. e. how countries deal with globalisation and to the mechanisms of creation of wealth through innovation. Innovations are created locally but they circulate, as well as knowledge, product, funds, etc. at the world level. Such a remark may induce that the way by which innovation is produced and diffused is quite similar from one country to another. However, Europe appears to be a patchwork of national public policies that

focus on the strengths and weaknesses of each national system. However, to what extent are these public policies similar?

In the framework of the NSI approach we explored two different facets of the biotechnology policy-making systems. Firstly, by using macro-economic indicators we asses the importance of research activities in each national system and the context in which public policies targeting biotechnology are implemented. Secondly, to get an idea of the relative importance of biotechnology for the national policy-making systems, we asses the priority given to biotechnology.

The distribution of the 14 countries under review is highly skewed in terms of economic wealth and R&D intensity. Table 4.1 provides some basic data presented in a comparable form. The table presents four sets of variables:

- The intensity of R&D efforts in 1994 and in 2001. France, the United Kingdom, Italy and Ireland have a decreasing ratio GERD/GDP between 1994 and 2001. In all other countries, the proportion of wealth dedicated to R&D is increasing. This is especially the case of Sweden and Finland which started from a high level of R&D expenditures. Public policy indicates a high priority to R&D in both countries.

- The balance between public and private R&D indicates the sources of investments in R&D and the share of private firms and institutions that are investing in R&D. In low intensive R&D countries, public R&D is dominating. In high R&D intensive countries, the proportion is only between 24% to 38%. France and Denmark have the highest shares of public investments. Low R&D intensity countries mainly rely on public sector to invest in R&D, like in Italy, Portugal, Greece and Spain.

- The third indicator underlines the R&D expenditures in each country. Germany, the United Kingdom and France show a high priority for biotechnology. Large-sized countries with high R&D intensity represent more than 85% of national biotechnology R&D expenditures in Europe. Small-sized countries with high R&D intensity represent less than 4% of the total expenditures.

- The last column indicates the clusters of effectiveness. As pointed out in chapter 3, cluster 1 is the best performing cluster, cluster 2 the 2nd best, both in terms of renewal of the knowledge base and commercialisation, and the 3rd and 4th ones are those of countries, which present lower performances.

These general economic features set the general frame within which each country can define its R&D and innovation policy. The data draws on the findings of the Inventory report (Enzing et al. 1999) and we can highlight the following issues relevant for our analysis:

- Countries of large economic size with high R&D intensity are the big players on the European scientific scene. This is especially the case for Germany, the United Kingdom and France with almost 80% of the biotechnology R&D expenditures of the Member States. They all benefit from a national knowledge base, a good and quality higher education system and a set of institutions devoted to R&D and innovation. They also benefit from large internal markets with large leading firms and dynamic start-ups. However, as Trend Chart reports (European Commission 2003a) point out, the effectiveness of these inputs are not obvious, as these countries have to face with important problems of coordination.

- Countries of large economic size with low R&D intensity do not benefit from long-term investment in R&D and higher education. They have fairly poor local markets and a weak industrial sector.

- Small economic size with high R&D intensity countries benefit from a long tradition of investment in higher education and R&D that appears to be very important in the knowledge-based economy. They have developed a strategy to build absorptive capacities on a limited set of strategic areas. Therefore, strong internal coordination amongst actors has been developed.

Table 4.1: General features about biotechnology public policies

	GERD/GDP 1994 (Inventory: Enzing et al. 1999)	GERD/GDP 2000 (source: national reports)	Balance of public/ private R&D expenditures (Source: OECD, MSTI database, 2001)	Biotechnology R&D expenditures 1994-1998 (source: Inventory: Enzing et al. 1999) MEUR	Clusters (see chapter 3)
Large countries, high R&D intensity					
Germany	2.3	2.45 2000	33.0	3021	2
France	2.4	2.15 1999	37.3	2115	3
United Kingdom	2.2	1.86 1999	27.9	2572	2
Large countries, low R&D intensity					
Italy	1.2	1.04 1999	51.1	207	4
Spain	0.8	0.94 1999	40.8	47	4
Small countries, high R&D intensity					
Finland	2.3	3.19 1999	29.2	248	1
Denmark	1.8	2.0 1999	36.1	138	1
Netherlands	2.0	2.02 1999	37.9	314	2
Sweden	3.3	3.8 1999	24.5	271	1
Small countries, low R&D intensity					
Belgium	1.6	2.0 1999	24.9	551	2
Austria	1.5	1.63 1998	39.3	49	3
Ireland	1.4	1.37 1997	22.2	46	3
Portugal	0.6	0.77 1999	69.7	73	4
Greece	0.5	0.57 1997	53.5	20	4

- Countries of small economic size with low R&D intensity represent those countries that do not prioritise R&D and innovation as key mechanisms for wealth creation.

4.3 The configuration of biotechnology policy-making systems in Europe

As a result of the pervasive nature of biotechnology, policy-making faces problems of coordination which influence the effectiveness of public policy. This section explores the organisation of the biotechnology policy-making systems, the actors involved in the decision-making process and the influence of these aspects on the effectiveness of policies.

In all countries, government bodies, ministries and institutes play a key role in organising biotechnology policy strategy and implementation. The Inventory report characterised biotechnology policy-making system according to two dimensions (Enzing et al. 1999):

- the intensity of the interactions between key players and the multiplicity of policy players and
- the organisation of the research system.

This categorisation is used for describing the biotechnology policy-making systems in the EPOHITE countries.

4.3.1 The intensity of the interactions between key players and the multiplicity of policy players

The intensity of interactions is interpreted as an indicator for the degree of coordination amongst actors. Accordingly, a country with weak interactions is fragmented: actors define strategies with high degree of independence. The reverse situation is a country where interactions amongst actors are strong and coordinated. The criterion of multiplicity of policy players defining their own strategy takes into account the importance of the policy-making population as well as the relative influence of governmental bodies, charities, foundations and industry in each country. Accordingly we

differentiate between pluralistic countries and monolithic ones. For this dimension, the main criterion is the *ex ante* coordination of strategic decision. When countries are pluralistic with a fragmented system, there is a large number of actors who can promote their own objectives with specific assessment criteria. There is no *ex ante* coordination and public policies thus have to coordinate independent decisions *ex post*. The decision-making process is divergent. In contrast, countries in which the number of decision-makers is low with high interactions amongst each other have a rather concentrated decision-making process with *ex ante* coordination. Decision-making process is convergent. While the former system encourages diversity, the latter is more targeted.

Table 4.2 presents the characterisation of each country under review based on the Inventory report (Enzing et al. 1999) and the national case studies performed during the EPOHITE project.

Most of low R&D intensity countries are monolithic. The number of actors is reduced. However, they do not *ex ante* coordinate their research and innovation strategies leading a fragmenting system. Convergent systems appear in high R&D intensity countries when their research and innovation system is based on research councils or funding organisation, like Denmark, the Netherlands, the United Kingdom, Finland and to a smaller extent Ireland. High R&D intensive countries which do not perform *ex ante* coordination are France and Germany.

4.3.2 The organisation of the research system

In order to better understand the national system of innovation, it is necessary to picture the interactions between the different levels of decisions. The scientific community defines its goals considering scientific advances and problems to solve. Public authorities define their priorities. Three different systems have been depicted according to two dimensions: the way in which funds are allocated and complementarities between institutions[19]:

- National systems based on public research institutes: those institutions define priorities and research programmes, fund and coordinate their own research infrastructures and incentive schemes.
- National systems based on research councils: the characteristic of these countries is their strong programme orientation and their

Table 4.2: Coordination of decision-making process

	Qualitative characterisation of the biotechnology policy		
Qualitative Characterisation of biotechnology policy systems		Fragmented	Concentrated
	Pluralistic	DK 1994 •••••► SE 1994-2001 BE 1994-2001 PT 1994-2001 FR 1994-2001 DE 1994-2001 **DIVERGENT**	DK 2001 GB 1994-2001 NL 1994-2001 **CONVERGENT**
	Monolithic	AT 1994-2001 GR 1994-2001 IT 1994-2001 ES 1994-2001 **DIVERGENT**	FI 1994-2001 IE 1994-2001 **HIGHLY CONVERGENT**

(19) This is only a rough classification to portray the global evolution of each national system and public policy. It should not imply that the complete system in a country follows the classification presented.

Table 4.3: Evolution of the coordination of the decision-making process

Qualitative characterisation of the biotechnology policy-making systems			
Qualitative Characterisation of biotechnology research systems		DIVERGENT	CONVERGENT
	System based on funding organisation	AT 1994-2001 BE 1994-2001 GR 1994-2001 PT 1994 – 2001	FI 1994-2001 IE 1994-2001
	System based on research councils	DK 1994 •••••► SE 1994-2001	DK 2001 GB 1994-2001 NL 1994-2001
	System based on public research institutes	FR 1994-2001 DE 1994-2001 IT 1994-2001 ES 1994-2001	

Source: Inventory report (Enzing et al. 1999, Epohite research)

flexibility in subjects and themes of research. Allocation is based on competition, mainly scientific competition. Ministries are not closely involved and research councils have autonomy.

- National systems based on funding organisation: most of these countries adopted a two-head organisation: one tool for basic research and the second for applied research and interactions with industry.

Table 4.3 presents the relative position of each country according to these dimensions.

According to table 4.3 the following observations on the evolution of the decision-making processes in biotechnology policy are made:

(1) Most of the countries show a real stability in their structures during the past ten years. Only Denmark has changed from a divergent framework to a more convergent system in which the number of actors involved is diminishing or more interrelated.

(2) The second comment is to underline the diversity of organisation and its stability.

(3) Except for the United Kingdom, most of the convergent R&D systems are found in small countries with high R&D intensity like Finland, Denmark, the Netherlands and to a smaller extent Ireland. In what concerns science policy Sweden is also moving towards a convergent system. Systems based on public research institutes group large countries with high R&D intensity (Germany and France) and with a low R&D intensity (Italy and Spain).

(4) Systems based on research councils appear to be those that are able to change more easily from divergent to convergent. It appears to be the more flexible system, as the funding organisation is more flexible than systems based on public institutes.

4.4 From vertical to horizontal public policy

While structures are rather stable, public policies have changed radically since 2001. Policy profiles have been defined according to detailed items for each theme. The importance of public policies during the period has been assessed on an ordinary scale from 1 to 5 for the periods 1994-98 and 1998-2002 (see section 2.3.2). The scores of each category (knowledge base, commercialisation, horizontal and infrastructure) have been added (see table 2.2 in chapter 2). Thus the highest mark that could be achieved in each category is 15, indicating that where national public authorities have given the highest priority to that category.

The four categories of table 4.4 cover the following items:

Vertical policies for knowledge-based support

These instruments aim at supporting the creation and renewal of the knowledge base i. e. instruments to encourage basic research such as funding for basic research and for supporting scientists, instruments to encourage industry-oriented (and applied) research in PSROs (research programmes targeting industry-oriented research, funding of PSROs-industry joint research, support for patenting activities in PSROs) and instruments for strengthening academic cooperation among PSROs and disciplines (support for centres of excellence and programmes for interdisciplinary research, encouragement of the mobility of researchers, establishment of and support for research networks).

Vertical policies for commercialisation support

These instruments represent tools to stimulate the economic valorisation of the knowledge base and scientific results. The category includes instruments to build up technological capabilities for the industry (creation of research institutes and technology centres of industrial interest, grants for industrial research), instruments to encourage the commercialisation of scientific results from public research institutions (spin-off formation in biotechnology, start-up companies and establishment of biotechnology-specific public venture funds, establishment of BT science parks and incubators) and instruments to encourage the collaboration between public and industrial research (research programmes requiring industry involvement, support of temporary personal exchange between industry and PSROs).

Horizontal science and technology policies

These instruments cover tools to stimulate R&D and innovation regardless to the targeted sector. These instruments can be applied for all sectors, especially high-tech sectors. It includes instruments to support the knowledge base, including mobility of researchers (open call systems of research councils, block grants to research institutes, funding of research institutes), instruments to support the commercialisation of technologies, including mobility of researchers (Technology Transfer Offices, support for network formation and collaboration between industry and PSROs). Grants for industrial research, industry involvement in decisions concerning public sector research, advisory and consulting services for the industry regarding grant application, legislation, IPR etc.) and firm creation (firm creation, establishment of science parks and incubators).

Framework policies

These instruments cover regulation tools (harmonisation with European legislation for drugs, GMO release, labelling), legislation on property rights (legal protection of inventions and share of IPR between scientists and institutions) and measures to assure the availability of financial capital in high growth sectors (Establishment of attractive credit market conditions for technology-based firms, venture capital market support, stock exchange markets for small companies).

Table 4.4 presents an overview of the evolution of public policies for 14 countries in Europe by giving the mean score in each time period for each public policy category. The third row indicates the general trend.

Drawing on table 4.4. we can highlight the following issues:

(1) The creation and renewal of the knowledge base in general (horizontal) and in biotechnology (vertical) has been the main priority of public authorities during the period 1994-98 for UK, the Netherlands, Denmark, Sweden, Portugal, Belgium, France and Germany. After 1998, priority of the creation and renewal of the knowledge base has decreased in France and increased in Finland.

(2) Vertical policies to support the creation and renewal of the knowledge base are the tools, which slightly increase during the period.

(3) Vertical policies in favour of commercialisation have been supportive in Finland, UK, the Netherlands, Ireland, Germany, Sweden and Denmark during the first period as well as stable and highly supportive for the second

Table 4.4: The Evolution of public policies[20]

	Emphasis on knowledge base	Emphasis on commercialisation	Horizontal policies	Framework policies
1994-1998	8,1	7,2	8,3	4,7
1998-2002	8,7	8,5	10,1	6,6
Trend	ε	+	++	+++

period. They increase in importance for Austria, France and Belgium in the second period. Vertical policies supporting commercialisation are rather weak for Italy, Spain, Greece and Portugal.

(4) Horizontal policies appear to have been one of the main tools during the periods under review. In the second period, public policy emphasised horizontal policies more than vertical ones. Instruments to support the knowledge base and those to support commercialisation are equally important. The growing importance of horizontal instruments may be due to the transversal nature of biotechnology. Instruments in favour of firm creation and start-ups have been created and reinforced in Denmark, Germany, France, Ireland and the Netherlands.

(5) Infrastructures policies appear to be of growing importance. Rather than directly stimulating knowledge or commercialisation, these policy tools are dedicated to the creation of a favourable environment in terms of IPR, availability of venture capital and stock exchange for high-tech SMEs.

To sum up, it appears that most of the countries define and implement public policies to support biotechnology, R&D and innovation. Except for Greece, Portugal, Italy and Spain, European countries have given strongly support to biotechnology during the last ten years. Tools were quite similar i. e. funding for basic research, support for researcher mobility, instruments to support PSROs and industry cooperation, science parks and incubators, tax credit for R&D, technology transfer offices and creation of a favourable environment for innovation and research. The main differences are based on the relative emphasise on vertical and horizontal policies on the one side and knowledge base renewal and commercialisation on the other.

The general evolution of public policies is heterogeneous in Europe. Highly intensive R&D countries and large R&D countries have a balanced policy, which combines support for the knowledge base and commercialisation. Over time, support for commercialisation has increased in the United Kingdom and France, the support for both commercialisation and knowledge base has increased in Austria, Belgium, Ireland, and the priority for knowledge base support has increased only in Germany and the Netherlands. Vertical public policies for supporting commercialisation and the knowledge base seem to be substitutable rather than complementary.

Regarding the balance between vertical and horizontal public policies, table 4.5 emphasises the increasing importance of horizontal policies compared to vertical ones. It shows that the relative importance between horizontal and vertical policies has changed for only few countries (Ireland, Sweden and Belgium).

(20) The assessment of the weight of vertical and horizontal policies has been made for each country separately on a comparable basis.

Table 4.5: Intensity of vertical and horizontal policies

		Vertical policies: Weak	Vertical policies: Strong
Horizontal policies	Weak	PT 1994-01 IT 1994-01 SP 1994-01 FR 1994-01	SE 1998-01
	Strong	GR 1994-01 AT 1994-01 IE 1994-98 BE 1994-98 NL 1994-01	GE 1994-01 SE 1994-98 IE 1998-01 FL 1994-01 GB 1994-01 BE 1998-01 DE 1998-01

4.5 Effectiveness: combination of performance assessment, R&D structures and policy approaches

As already introduced in chapter 2, EPOHITE's assessment of policy effectiveness draws on the analysis of the performance of the biotechnology national systems of innovation which is combined with the detailed exploration of the biotechnology policy-making systems. In this section we firstly introduce the clusters and their main characteristic from the policy perspective. Next, the analysis links the performance assessment to the features of the national policy-making systems discussed.

4.5.1 Performance clusters from a policy perspective

The cluster analysis introduced in chapter 3 suggests that the countries can be divided into the following four clusters:

Cluster 1: Denmark, Sweden and Finland representing the best performing cluster.

Cluster 2: the Netherlands, the United Kingdom, Belgium and Germany, representing the second best performers.

Cluster 3: Austria, France and Ireland representing countries performing below the European median performance value.

Cluster 4: Italy, Spain, Portugal and Greece representing the weakly performing cluster.

Cluster 1 with the best performing countries Denmark, Sweden and Finland combines countries where all aspects of the innovation process are considered by the various funding systems for biotechnology. In addition, in these countries a considerable amount of funding has been devoted for biotechnology in the period 1994 to 1998. However, they are not among the countries with the highest biotechnology budget in the European Union. In all of these countries there is a search for and support of research units with recognised scientific excellence. Further, there is a long tradition of industry-academia collaboration and a broad set of instruments supporting such interactions. We also observe a rather strong emphasis, which is given to the direct support of the biotechnology industry especially in Finland. All three countries have made increasing efforts to supply loans and credits for the creation of biotechnology companies.

The second cluster integrates two large (United Kingdom, Germany) and two small countries (Belgium, the Netherlands) each with their specific framework conditions, so that we in general observe a rather strong heterogeneity in these conditions. Except for the Netherlands all these countries had larger budgets for biotechnology throughout the 1990s compared to the best performing countries, but fewer sources for R&D across all fields. In all these countries

biotechnology has been a funding priority at least during the period 1994 to 2001. Similar to cluster 1 policy instruments have been implemented targeting the whole innovation process. Policies devoted to the development of the knowledge base seem to have a stronger focus on industry-oriented research compared to basic research. In some of the member countries of this cluster, in particular in Germany and Belgium, a strong emphasis has been given to the support of small and medium-sized enterprises in the biotechnology industry.

The third cluster of intermediate performing countries, Austria, France and Ireland, combines countries with rather different framework conditions in terms of size, tradition of life sciences, research, budgets for biotechnology and characteristics of the funding systems. Surprisingly, Ireland appears as a rather successful late entrant, while France performs behind the other two traditional big players the United Kingdom and Germany. The French experience seems to show that the organisation of research at public sector research organisations and universities matters and seems to be more important than the mere value of research budgets. In France the research system is highly fragmented and the vast majority of academics are civil servants with tenure positions. The whole research system is thus organised around heterogeneous research institutions whose budgets come from block grants. *A priori*, it could be assumed that research projects are complementary within research institutions. As academics have tenure positions, competition between national research institutions (and also at an international level) remains low because academics have little incentive to perform well in order to remain in academia. This leads to the conclusion that structural deficiencies in the national system of innovation that affect every area of technology contribute to the poor performance of France in biotechnology. Another observation relates to the emphasis, which is given to commercialisation. This seems to be more important than the development of the science base, particularly in France and Austria. For technology transfer and commercialisation different approaches can be observed in the members of this cluster. Technology transfer measures seem to be more centralised and more professional in Ireland. Ireland is also the country which had tried to achieve commercialisation by attracting large multinationals, while France had put more emphasis on company creation and Austria on commercialisation via technology transfer from public sector research organisations.

The weakly performing cluster with the countries Greece, Italy, Portugal and Spain is first of all characterised by very low budgets for biotechnology in the period 1994 to 1998. Further, in these countries there seems to be a certain neglect of the broad range of policy instruments applied in other countries. In particular, there is only little support for the commercialisation of scientific results from public research institutions and public private research collaborations. Further, regulations of biotechnology and legislation on IPRs have been neglected or paid little attention to. Finally, with the exception of Greece until the beginning of the year 2000 nothing was done to create incentives for private and venture capital investment in new firms.

4.5.2 Establishing the link between performance, the organisation of the national research system and the features of the national biotechnology policy-making systems.

In this section the organisation of the national research systems and the features of the national biotechnology policy-making systems will be related to performance. Accordingly, tables 4.7 and 4.8 present the links between R&D structures, coordination amongst actors, the type of public policies implemented and the performance of each biotechnology NSI under consideration.

In table 4.6 convergent or divergent refer to the coordination amongst actors as regards the strategic decision-making process. The table assesses the relationship between the convergence of strategic decision-making processes and the performance of the biotechnology NSI. It highlights that a convergent decision-making process seems to lead to better performance of the innovation system. For all countries, even large ones, fragmentation of actors seems to be a weakness. We could argue that the concentration of the strategic decision process in a few actors allows for a visible, stable and coherent policy-making process, even with specific institutions for basic and applied research.

Table 4.6: Convergence versus divergence policy-making systems and performance

		Qualitative Characterisation of biotechnology research systems		
Performance cluster		System based on funding organisation	System based on research councils	System based on public research institutes
Cluster 1	FI	Convergent		
	SE		Convergent	
	DK		Convergent	
Cluster 2	GB		Convergent	
	DE			Divergent
	BE	Divergent		
	NL		Convergent	
Cluster 3	FR			Divergent
	AT	Divergent		
	IE	Convergent		
Cluster 4	IT			Divergent
	GR	Divergent		
	ES			Divergent
	PT	Divergent		

Table 4.6 also reveals that convergent systems (*ex ante* coordination of strategic decisions) appear to better perform than divergent ones. Moreover, research systems based on research institutes seem to be more divergent than systems based on research councils or funding organisations. One of the explanations can be found in basic models of sociology of organisation, which emphasise that the strategy of organisations is to compete to survive (Crozier 1963). To do so, they have to differentiate themselves from the closest. Thus, it is difficult to coordinate *ex ante* the strategies of public institutes. In contrast, funding organisations and research councils appear to be two mechanisms of more flexible and effective coordination.

Table 4.7: Horizontal versus vertical public policies

Performance cluster		Vertical policies	Horizontal policies	
Cluster 1	FI	Strong	Strong	
	SE	Strong	Strong (94-98) to weak (98-01)	
	DK	Strong	Strong	
Cluster 2	GB	Strong	Strong	
	DE	Strong	Strong	
	BE	Weak (94-98) to strong (98-01)	Strong	
	NL	Weak (94-98) to strong (98-01)	Strong	
Cluster 3	FR	Weak	Weak	
	AT	Weak	Strong	
	IE	Weak (94-98) to strong (98-01)	Strong	
Cluster 4	IT	Weak	Weak	
	GR	Weak	Weak	
	ES	Weak	Weak	
	PT	Weak	Weak	

Table 4.7 compares the performance of the various biotechnology NSI with the national policy approaches in terms of the policy type implemented (vertical versus horizontal) and the intensity (weak i. e. below the average for the period – strong i. e. above average). Table 4.7 shows that public policies play a role. Countries that invest the most in R&D (GERD/GPD) are also those that belong to the best performing clusters (except for France). In all of these countries, except Sweden for the second period, R&D and biotechnology have been strongly supported through both horizontal and vertical public policies.

To sum up, the empirical findings of EPOHITE suggest that strong support could lead to better performances and that concentration can have a positive effect on performance. Countries in which strategic decisions regarding public policies are concentrated belong to the better performing clusters. Actually, concentrated versus fragmented policy reveals more about *ex ante* versus *ex post* coordination. In countries in which strategic decisions are concentrated, coordination is more effective because it is done *ex ante*, before the implementation of strategic decision. In reverse, if strategic decision is fragmented and split between independent actors, coordination has to be done *ex post. Ex ante* coordination appears to be more effective. It could be one of the reasons why no system based on research institutes appears amongst the most effective. Institutes have their own autonomy and they are not coordinated *ex ante*. Moreover, in large size countries, the research councils system appears to be one of the ways to encourage concentration, like in the United Kingdom. It is also a means to reinforce effectiveness through competitive funding to support both the knowledge base and commercialisation.

4.6 Summary and conclusions

This chapter emphasises the fit between national contexts or innovation systems and public policies. The biotechnology policy-making systems in Europe present similarities in the organisation of the research and funding systems across countries. At the same time, the biotechnology NSI have reached different stages of development in what concerns the knowledge base and the structure and dynamics of the industry (number of firms, presence of national leaders, presence of large firms, rate of growth, etc.). The process of designing and implementing policy measures for the promotion of biotechnology at the national level has to consider, on the one side, the specificities of the national innovation system and on the other side the stage of development of the sectoral system within the relevant geographical boundaries.

Focused on national public policies and instruments, the analysis does not integrate the growing role of some regional public authorities in large countries like Germany or France. Thus, neither coordination amongst national and regional policies are analysed, nor complementarities with EC measures, which are especially important for Ireland or Portugal during this period.

From 1994 to 2001, support for biotechnology research and development has increased in the 14 European countries under review. Despite of a large variety of public policies and measures, priorities can be identified as follows:

- Reinforcement of commercialisation.
- A move from vertical to horizontal public policies. This shift from vertical to horizontal and framework-oriented public policies may also reflect the evolution of the biotechnology sector, which matures during the last ten years. The emergence phase is characterised by radical and rapid technical change. The emergence of a new technological paradigm may potentially destroy the traditional barriers to entry, representing a threat to incumbents using the old set of technologies as well as opportunities for new entrants. The second phase reveals technological consolidation and stabilisation around a dominant design (Anderson & Tushman 1990). New firms are created on the basis of the differentiated knowledge as to test, refine and exploit opportunities. The exploitation phase also represents the diffusion of biotechnology and its use by a large set of users, from biotechnology firms to the whole life sectors. It induces an evolution of the actors involved in the biotechnology sector as well as a modification of patterns of

collaboration (Nesta & Mangematin 2002). Thus dedicated public policies to biotechnology may be less adapted than they previously were.

- Higher attention paid to the creation of a favourable environment, which stabilises the rules of the game and promotes private investments through the reduction of uncertainty.

- Public policies in favour of technology transfer from university or PSROs to industry.

The performance of the national systems (which may be a result of the effectiveness of public policies) seems to be higher when:

- Public policies are coordinated *ex ante* rather than *ex post*. That means that strategic decisions have to be designed and implemented by actors that are continuously interacting with each other,

- The allocation of resources is determined through competitive funding mechanisms coordinated by research councils or supporting funding organisations,

- The policy-making systems target the promotion of favourable framework conditions for innovation (regulation issues, IPR, etc.). A favourable environment for innovation seems to coordinate innovation activities more effectively than the direct coordination through promotion programmes for specific goals.

- The implemented policy instruments aim at supporting both: the commercialisation activities and the development of the knowledge base. The commercialisation of research results and the development of the knowledge base appear to be complementary rather than substitutable goals.

5. Key Issues for Biotechnology Development in Europe

5.1 Introduction

Like already introduced in chapter 2, a key tool for EPOHITE's assessment of policy effectiveness is the qualitative analysis based on structured interviews with actors of the different biotechnology national systems of innovation. The aim of the interviews is to explore the perception of actors of how they use and evaluate public policies and how the framework conditions contribute (or not) to their innovation activities. In total 144 persons in 14 EU Member States were interviewed. First, the interviews gave a good picture of the use of the national policy instruments. Second – and these outcomes were sometimes rather surprising – the interviews also led, in some cases, to sharp assessments of national policies and policy effectiveness and some instruments in particular.

On the basis of the interviews – and the 14 EPOHITE national case studies – a set of issues was formulated that are essential to the further development of biotechnology in Europe. These issues concern:

- Public policies for stimulating the biotechnology knowledge base;
- Public policies for commercialisation of biotechnology research;
- Public support for collaborative biotech R&D;
- Intellectual property rights and support for academics;
- Laws & regulations on biotechnology development;
- Availability of human resources;
- Socio-economic and ethical aspects of biotechnology R&D.

Of course, next to these issues, also other issues can be mentioned that deal with conditions that influence the future development and success-rate of European biotechnology. However, these seven issues were often stressed by the interviewees as of utmost importance for the continuity of their own activities and also for the general state of European biotechnology in the years to come. Although the time frame under investigation concerns 1994-2001, all respondents also reported on and made assessments about the current situation.

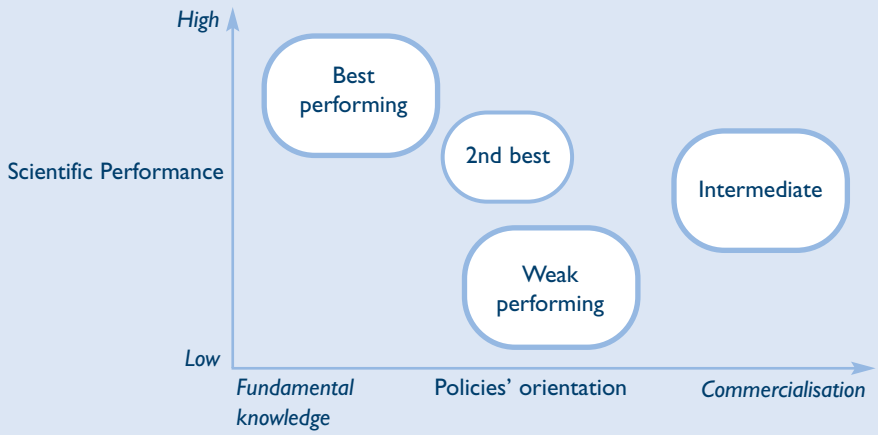
In this chapter for each issue, we discuss the availability of national policies and instruments, the use of these instruments by the respondents and their assessment. We conclude this chapter by discussing the issues that are – according to our analysis – most important for future biotechnology development in Europe.

5.2 Public policies for stimulating the biotechnology knowledge base

Because of the science-driven character of biotechnology, the development and renewal of the biotech knowledge base is an important source for new product development. Hence, from a policy perspective a key issue for the development of biotechnology in Europe is the extent to which national policies support the existence of high level biotech research groups and infrastructure.

Considering the four clusters (see chapter 3) we can observe that EU Member States have different policy approaches in this respect (figure 5.1). In general, a distinction can be made between the well performing clusters (cluster 1 and 2) and the weak performing clusters (cluster 3 and 4). The countries in cluster 1 (Denmark, Finland, Sweden) and cluster 2 (Belgium, Germany, Netherlands and United Kingdom) seem to be aware of the importance of supporting the development of the knowledge base. In Sweden and Finland this is mainly done through horizontal instruments, although there is a trend towards calls concerning well-defined research fields of biotechnology. Vertical instruments play a strong role in Denmark; since 1996 the efforts to support research in biotechnology have been increased considerably in this country. Vertical instruments have also been running during the period 1994-2001 in Germany, the United Kingdom and Belgium (i. e. Flanders). In the Netherlands vertical instruments (concerning genomics research) have been present since 2000.

Figure 5.1. The relation between policies' orientation and knowledge base performance



With exception of France (cluster 3) and Portugal (cluster 4), all other countries in clusters 3 and 4 gave less priority to the support of the biotechnology knowledge base in the period 1994-2001. In Ireland and Austria (cluster 3), and Greece, Italy and Spain (cluster 4) the emphasis was more on stimulating commercialisation than on stimulating the renewal of the knowledge base. Ireland mainly had vertical instruments, whereas Austria particularly used horizontal instruments. Since 2001, in Italy and Spain the allocation of funds for basic research has been increased.

It can be concluded that countries with a relatively strong policy focus on the development of the biotechnology knowledge base are strong in both scientific and commercial performance. Countries focusing only on the support of commercialisation activities show relatively lower performance levels for both indicators.

Nevertheless, one should keep in mind, that also the best-performing countries in the period 1994-2001 placed an increasing policy emphasis on applied research, the industrial orientation of the research base and commercialisation. However, the distinguishing characteristic of the best-performing countries vis-à-vis the intermediate and weak performing countries is that they have sets of policy instruments that address all stages of the innovation chain.

Assessment of policy instruments

The shift in innovation policies to more applied and industry-oriented research programmes is criticised by interviewees from both public research organisations and firms in many countries, except from Germany. Respondents feared that this emphasis on the commercialisation part of the innovation chain would be at the expense of budgets for fundamental, non-targeted biotech research. Both public research organisations and firms emphasised that strong support for fundamental research is absolutely needed: without fundamental research there is no basis for further biotechnology development. Additionally, many respondents argued that budgets for supporting the knowledge base are too limited and too fragmented and that funding is available for only a very short period.

Especially in Portugal, the Netherlands, Denmark and the United Kingdom interviewees from public research organisations and firms argued that public policies lack coordination, strategy and vision. According to them, national public policies should follow one national strategy, focusing on a few specific, well-defined research areas with clear targets. In addition, the various funding organisations in a country should better cooperate and coordinate their funding activities. Furthermore, German interviewees from public research organisations fear the concentration of resources in a few core research centres.

Another finding concerning knowledge base instruments is the criticism on the administrative procedures: application procedures lack transparency and are very time-consuming. Especially public research organisations and firms in the countries of cluster 4 heavily criticised these bureaucratic burdens. Dutch interviewees also complained about the increasing demands for detailed reporting on intermediary and final results, and on the results of financial monitoring when research projects are still running.

The respondents also commented on the EU programmes, although they were not the main focus of the EPOHITE project. Mostly, EU programmes were considered as important for the support of biotechnology research; in some countries these programmes are even the most important means for research funding (e.g. Greece). Also here criticism was brought forward on the large amount of administrative work that is needed when applying for EU programmes. However, in Portugal these administrative procedures were considered rather simple compared to the national application procedures; for them a problem with EU funding is the long time gap between the structural funds.

5.3 Biotech commercialisation policies

The support for the commercialisation of biotechnology is mainly implemented through three types of policy instruments:

- Specific programmes that support the commercialisation of results of public sector research;
- Specific programmes that stimulate firm creation and support young, small and medium-sized biotech firms;
- Policy programmes and initiatives that deal with the availability of financial capital and private investment in biotechnology firms.

Commercialisation of public sector research

The main goal of this first type of instruments is to encourage researchers in public research organisations to exploit their research results by patenting, licensing out and/or by creating a spin-off company. These instruments are available in all Member States, most as horizontal and in some countries also as vertical instruments.

Especially the interviewees in the public research organisations in the countries of clusters 1 and 2, and Ireland, Austria and Portugal have actively pursued the commercialisation of their research, mainly by patenting and licensing. Although some specific instruments are available in France, Greece, Italy and Spain, researchers in public research organisations in these countries gave less priority to the commercialisation of their research results. Although commercialisation is becoming an issue in their countries, according to the French and Greece interviewees, incentives to patent are still lacking.

Public sector researchers throughout Europe did not evaluate the support for commercialisation of their research – if available – as very positive. The most prominent problem mentioned is the lack of professional support for dealing with patenting and technology transfer questions. Scientists ask for professional support in patenting. Patent applications procedures are rather complex and public sector researchers indicated that writing a publication is quite different from writing a patent application. As one interviewee noted:

> "Writing a patent is the opposite of writing a scientific paper. In the latter, you always try to narrow your results and to show the limits of your results, while in a patent, you must write all the potential applications of your results that cross your mind. You must enlarge the scope of your invention."

According to the interviewees, most technology transfer offices are not equipped for providing professional support. Researchers in Flanders (Belgium) and to some extent in Ireland do not agree with this negative evaluation. It seems that the Flanders Inter-university Institute for Biotechnology (VIB) and BioResearch Ireland can be held responsible for this positive assessment.

Firm creation and support for young firms

The second type of instruments deals with direct financial support to start-ups, project funding, incubator facilities, and office/lab space. In most countries these are horizontal instruments. Only the United Kingdom, Belgium and Germany had explicit biotechnology specific and horizontal policies during the period 1994 – 2001. For Germany and Belgium most of these initiatives were integrated in the larger schemes like BIOTECH 2000 and the Flanders Interuniversity Institute for Biotechnology (VIB). The United Kingdom had in this period (and still has) measures specifically aiming at promoting the use of biotechnology by SMEs; e.g. the 'Biotechnology Means Business' programme (since 1999: BioWise) and the 'Manufacturing for Biotechnology' initiative. Spain used to have horizontal policies on this; at the end of the period 1994-2001 it shifted to vertical policies. Recently, Austria, France, Ireland and the Netherlands have implemented biotechnology-specific support measures.

In general, these public support schemes are evaluated by the respondents as rather relevant for the creation and further development of high-technology firms. Especially small companies mentioned that they could use all extra support they can get. 'Larger' SMEs mainly used public funds to finance high-risk research projects, to enter high-risk partnerships with new partners, or to finance research activities that do not belong to their core research focus.

The companies interviewed had several recommendations concerning the improvement of these instruments:

- They wanted more simple and short-track application procedures;
- These applications should not ask that first costs have to be made before they can be returned. It seemed that in some countries (e.g. Ireland), SME programmes existed of which funds could only be received after the activity had taken place and costs had been made. This has led in some cases to serious cash flow problems. A number of SMEs throughout Europe even had decided not to make use of public support anymore due to the costs and the time involved when applying for specific schemes;
- Public support is also needed after the seed and start-up phases, when firms seek opportunities for their second round of financing or need to expand their operations and look for production and extra lab facilities. Most public business-support programmes focus on the creation of new biotechnology companies and very young companies that are still in an early stage of business development;
- As IPR and regulations are crucial elements in the development of biotechnology business, small companies need easily available and cheap support from professional special services on IPR and regulation matters. At the moment these services are relatively expensive.

Availability of instruments that facilitate access to financial capital

Most European countries – except Austria, Italy, Spain and Portugal – have installed instruments that support and/or improve the availability of financial capital in the biotechnology industry. Public instruments include:

- Instruments that give direct financial support (through seed capital, R&D-programmes, soft loans, etc);
- Instruments that facilitate SMEs to enter the private capital market and also stimulate companies and private investors to invest in SME's (VC, investment funds, Business Angels, stock market entry);
- Tax instruments.

Austria, Italy, Spain and Portugal have only recently installed their first instruments to ensure the availability of financial capital. In the United Kingdom, Germany and Denmark, special attention was given to the stock market entry. This included relaxation of criteria for listing on the stock market and the creation of new stock markets for high-tech firms.

Almost all interviewed start-ups and SMEs indicated that they have made use of external financial capital to create and/or further develop their company. Firms in Finland, Denmark, Germany, Belgium, the Netherlands, Ireland,

Austria and Spain have used public instruments. In general they were positive about these instruments. Especially start-ups seem highly dependent on external financing. Some SMEs had already been able to generate a substantial turnover providing them with internal financial sources for their R&D.

Almost all respondents pointed at the possible benefits of specific taxation measures for SMEs. Such measures include:

- Decreasing the costs for hiring R&D employees;
- Providing start-up companies substantial tax credits in their first years of operation;
- Stimulating private investors to invest into high-technology firms by offering them tax reductions.

All firms considered tax measures as welcome additional money that is received rather easily, i. e. without complex application procedures.

In some countries negative assessment were made in the interviews:

- Small Swedish firms complained that there is not enough financial support for them and that the Swedish system of taxation makes it relatively unattractive for private investors to invest in young high-tech firms;
- In the United Kingdom none of the small firms interviewed used public schemes for financing. The main reason for them was that they considered public programmes as too time-consuming and as having too limited budgets;
- An Irish small firm "would prefer some type of public development funding to grow. If government bodies maintained interest in the firms they helped to found by providing second rounds of finance, companies could develop their plans more quickly". However, another Irish SME stated that if a state institution is too supportive then you may support things which will never be successful;
- Although small French firms had relatively easy access to financial capital – at least before the stock market crisis – they mentioned as one of their problems the homogeneity of venture capitalists in France: more diversity would be welcome;
- Small Italian firms indicated that they are missing public support for financing their activities. Although the Italian government installed several initiatives in the past, they find these funds too much oriented towards large firms. There is also a serious mismatch between the public funding and the company time schedule;
- Portuguese small firms say there is no 'real' venture capital available in their country: it proves very difficult for them to attract risk capital. One reason for this is that Portuguese venture capitalists have almost no knowledge of biotechnology and are rather risk-averse. The early involvement of large firms in the start-ups' and SME's activities could provide a guarantee to investors. However, Portuguese large firms are considered to be unaware of the importance of innovation; they are not willing to invest in R&D;
- There was a general complaint – especially in Sweden, Finland, the Netherlands, Belgium and Ireland – that public financial capital is mainly provided for firm creation and the first stage of business development, while support for the consecutive stages is merely lacking. This – combined with the actual economic situation, which makes it almost impossible for a large number of young high-tech firms to attract new venture capital – is more or less killing for a number of grown-up start-ups.

5.4 Policies supporting collaboration

Policies and programmes that stimulate collaborative research and networking are very popular in Europe: over the period 1994 to 2001 they have been present in all 14 Member States. Most countries from clusters 1, 2 and 3 have installed vertical and horizontal instruments to support collaboration and networking. In cluster 4, i. e. mainly in Greece and Spain, most horizontal instruments are at stake.

There are two types of collaboration and networking instruments:

- Instruments that financially support collaborative research projects and the formation of research consortia.
- Instruments for the creation of special research institutions or centres for industry relevant research, in which industry is heavily involved. This is especially the case in most of the countries in clusters 1 and 2 and in Ireland where institutes are set up with the mission to support industry.

In general, both firms and public research organisations consider collaborative research as of utmost importance. Respondents from large firms indicated that between 10-30% of the research activities is being carried out in collaboration. This amount varies for SMEs and the start-ups; the majority of start-ups perform 80-100% of their research in collaboration. The most preferred research partners of firms are public research organisations.

Collaborative research is also quite substantial for the public research organisations as they indicated performing between 50-100% of all their research together with partners. Most of their partners are other public research organisations, especially universities. A considerable number are also engaged in collaborative projects with large and small firms.

Collaborative research of public research organisations

Almost all public research organisations interviewed reported to use public support for their collaborative research projects with both firms and academia. Moreover, most respondents highly appreciated this support. Especially in Finland, Denmark, and Ireland public research organisations considered this as very supportive.

In other European countries, research organisations assessed this type of support as more or less supportive, but with some important shortcomings:

- Extensive administrative procedures;
- Lack of transparency in procedures of selection and approval;
- Lack of proper peer review;
- Lack of flexibility and freedom in performing the collaborative research;
- Too small budgets for performing large and long-running biotechnology research projects or to acquire research equipment.

Although most of the public research organisations indicated that public cooperative programmes indeed provide additional funding, their main incentive for cooperation was not to enlarge their research budgets but rather to share knowledge and continuation of working on 'their' research subjects (see table 5.1).

Table 5.1 Main reasons for collaborative R&D of public research organisations

Reasons for cooperation with other public research organisations:

- Sharing of complementary knowledge and expertise (synergy);
- Additional research budgets.

Reasons for cooperation with firms:

- Use opportunity to continue the development of their knowledge and technologies (development of new applications, up-scaling and production activities);
- Additional research budgets.

Table 5.2 Main reasons for firms to collaborate with public research organisations

- Access to specific, complementary expertise (basic and applied);
- Enter new research areas and low financial risk;
- Access to facilities, tools and research materials;
- Access to additional funds;
- Testing and validation of biotechnology concepts, processes and products;
- Access to source of new skilled employees;
- Performing pre-clinical and clinical trials;
- Reputation.

Table 5.3 Main reasons for firms to collaborate with other firms

Small firms collaborate with large firms for:

- Access to markets;
- Use skills in commercialisation such as marketing, sales;
- Use of skills in product development, manufacturing up-scaling of production;
- Expertise in regulatory and legal affairs.

Large firms collaborate with small firms for:

- Access to specific knowledge (also through contract research) and platform technologies for existing R&D;
- Quick and relatively low-cost access to new research areas.

Most interviewees from public research organisations also participate in EU collaborative research projects (EU framework programmes, Marie Curie fellowships). In some cases, e.g. in Greece, EU programmes were even more important than national programmes. Among academia there is a general agreement on the extent to which these programmes support collaborative research: they provide excellent opportunities for networking and meeting other interesting researchers. However, respondents also indicated some major disadvantages; these are merely in line with the criticism of the national programmes.

Collaborative research of firms

Throughout Europe, firms use public support for collaborative R&D on a large scale, especially small firms. Small firms in Finland, the Netherlands, Belgium (i. e. Flanders), Austria and Ireland considered these programmes as very relevant and supportive. However, the interviewees from small firms in France, Germany, Greece, Italy, Spain, Portugal and the United Kingdom were less positive in their evaluation and expressed a number of shortcomings that have been listed already in a number of places in this chapter. Moreover, interviewees from a number of start-ups – mainly in the Netherlands, Denmark, the United Kingdom, Spain, Austria and Finland – even indicated that they do no longer apply for public support for collaborative research. Given the firms' limited resources, the disadvantages outweigh the advantages of public support programmes.

Large firms use less public support for collaborative research projects. They mainly use public funding for research projects in non-strategic areas. The use of public funding often implies openness about research results and also special IPR arrangements; this is especially what they want to avoid in strategic research collaborations. Collaborative agreements are not just initiated for R&D-projects, but also for manufacturing, sales and distribution.

Large firms, mainly in the Netherlands, Belgium and Germany evaluate these public programmes as supportive, while large firms in Italy, Portugal and Spain are rather negative about them.

The main criticism of large firms on these programmes is more or less similar as that expressed by the interviewees of the small firms and public research organisations.

There is no difference between the reasoning of small firms and large firms for engaging into collaborative research projects with public research organisations (see table 5.2).

Young biotechnology firms and SMEs have various reasons to collaborate with large firms. Most of these reasons address the capabilities needed for activities downstream the innovation chain. For large firms the reasons to collaborate with small firms are somewhat different; they collaborate with small firms for more upstream innovation activities (see table 5.3).

Both partners have complementary skills, knowledge or facilities and by performing joint R&D, new technologies and applications can be further developed.

Finding research partners

Neither firms nor public research organisations encountered major problems in finding new research partners, although they all acknowledged the fact that networking remains time-consuming and very demanding. Only a few firms and research organisations considered it difficult to find partners, especially when they wanted to expand their activities in a new research area. Moreover, the sober economic situation makes it now more difficult to attract industry partners. In Portugal, Greece, and Spain public research organisations and firms mentioned specific difficulties with finding industry partners. In these countries the size of the biotechnology industry is very modest and therefore the number of potential research partners is very limited. As it was mentioned before, especially in Portugal the industry is reluctant in investing in R&D. In Greece it was reported that this has led to a paradoxical situation as public support schemes increasingly require the involvement of industrial research partners. However, there are hardly firms available that are qualified for this.

In general, firms and research organisations do not use nor need public support for finding research partners. They do not believe that external public agencies can help them sufficiently; their own networks are more efficient and effective. In a few cases, small firms used external public support: the services of a special agency or the Cordis database. This support in finding partners is evaluated as positive, especially when entering a new research area.

5.5 Intellectual Property Rights

Intellectual property rights (IPRs) play a key role in the dissemination of knowledge. Interviewees from both public research organisations and firms had applied for patents and also tried to exploit them commercially. Firms indicated that the main reason to patent is to protect their research results. In addition, patents and their trading are used to be able to operate, to acquire a favourable negotiation position, to realise turnover, but also for strategic reasons, such as to confuse competitors. Because of this important role in the biotechnology innovation process, over the recent years national governments have aimed at creating favourable framework conditions to encourage and support patenting and licensing of biotechnology.

Three issues are relevant in this respect:

- The institutional regimes handling IPRs of university inventions;
- The support to ease the complex patenting and licensing process;
- The harmonisation of national patent procedures.

IPR regimes for handling university inventions

The regimes assigning IPRs of the research results from public research organisations have important influence on the incentive systems and the framework conditions for patenting. Two regimes in the EU Member States (table 5.4) can be identified. These regimes represent the legal basis or most common practice in these countries in 2003. In most countries, scientists and research institutions have the possibility to agree otherwise by individual contracts.

In the period 1994-2001 some countries changed their IPR regimes:

- Before 1999, Belgian law granted all ownership of research at public research institutions to the scientist;
- Until October 2001, inventions at public research institutions in Italy were automatically assigned to the institutions. The Italian government introduced in 2001 the new Law 383/2001 that assigns the ownership to the individual scientists and made the scientists more or less independent from the public administration;
- Denmark and Germany have established the regimes of 'shared benefits' only since respectively 2000 and 2001. In both countries, it replaced a regime where IPRs were directly assigned to the inventor. In Germany, all inventions made by the scientists now have to be reported to the research institution, which has to decide within four months whether it wants to apply for patent protection or leave them to the inventor for application. If the IPRs are assigned to the research institution, the inventor receives up to 30% of the compensation profits. In Denmark, the ownership is shared between the researcher and institution and the researcher is granted with one third of the patent revenues.

The assessment of these regimes is not simple: no clear picture of pros and cons is available. As most countries have chosen for the second regime in which the research organisation is the owner, one could easily conclude that this one should be the best. However, the examples of Finland and Sweden – countries that belong to the best-performing cluster – tell us that systems in which the inventor is the prime proprietor can be quite successful, especially for the creation of university spin-offs.

In a number of countries and especially in Germany, interviewees from public research organisations and firms mentioned some specific problems related to IPR in public-private research collaborations. Public research organisations indicated that they lacked sufficient support in the negotiating process on IPR with firms. Firms complained that public research organisations tend to have an unrealistic idea of the value of the patents (mostly they over-value patents) and that they lack professionalism in dealing with IPR issues.

Institutional support and technology transfer offices

In the 1980s and 1990s policies have supported institutions for the technology transfer and commercialisation of university research. Many science parks with technology transfer bureaux were settled. Technology transfer offices have several tasks; providing support in IPR matters is considered as one of the most important ones.

Scientist and companies generally assessed the functioning of these offices as non-efficient and non-effective. Two main reasons for this were mentioned:

Table 5.4 Regimes in Europe for assigning IPRs at public research organisations

Regime	*Basic principle*	*Countries**
1. Scientist is the owner	All revenues to the scientist	Italy, Spain, Finland and Sweden
2. Research organisation is the owner	2.a. All revenues to the research organisation	The Netherlands, France, the United Kingdom, Ireland, Portugal, Austria and Belgium
	2.b. Ownership and revenues are shared between the scientist and the organisation	Denmark and Germany

** In Greece, no national regime for assigning academic IPRs exists; each individual university and research institute has its own rules.*

- A combination of expertise of both legal and biotechnological is crucial for providing support in IPRs and technology transfer in the field of biotechnology. Most technology transfer offices lack this expertise;
- Technology transfer offices have a serious lack of commercial expertise and professionalism. Accordingly, firms as well as scientists at public research organisations use external private agencies to support them in their patenting activities.

Positive assessments were given in Belgium and Ireland, where the Flanders Inter-university Institute for Biotechnology (VIB) and BioResearch Ireland perform important tasks regarding IPR support and technology transfer. Most of the Belgian and Irish respondents evaluated their services as satisfactory and efficient. The services of two specialist IPR offices in the United Kingdom (at a research funding organisation and at a specific university) were also positively evaluated. This suggests that the main reason for positive evaluation is specialisation in biotechnology and IPR. Concentrating these support capabilities in one specialised organisation may be important for small countries.

Harmonisation of patent systems

Most respondents indicated that they experience problems with the existing IPR regulation that concern the complex, time-consuming and expensive procedures, the lack of professionals with accurate knowledge of patenting in biotechnology and last but not least the lack of harmonisation between the European and the American systems.

Interviewees from both firms and public research organisations in most countries pleaded for harmonisation of national patent procedures within Europe. They expected that harmonisation will simplify procedures and lead to lower application (i. e. translation) cost. However, several respondents pointed out that real harmonisation within Europe still had not been realised. The 'European Patent' is too much of a compromise, as there are still six official languages.

When discussing the issue of harmonisation at European level, many times respondents referred to harmonisation with the system of the United States. They believed that harmonisation at the global level would help; although they indicated that the USPTO procedure had benefits but also some shortcomings. Benefits of the USPTO system mentioned were the grace period for publishing the results, the relatively simple procedures, the low costs, and the broader technological and geographical coverage. However, important disadvantages mentioned were the larger amount of 'junk patents' because the USPTO grants patents rather easily, and the lack of transparency when trying to invalidate a patent claim.

5.6 Regulation

Most regulations concerning biotechnological activities in the EU Member States is conform the EC directives, such as Good Laboratory Practices, Good Manufacturing Practices, safety of working conditions, labelling of GMO-products and for those in the pharmaceutical sector the regulations of the US Food and Drug Agency. However, there are still important national differences, for instance on clinical trials (United Kingdom and the Netherlands), the use of transgenic animals in biotech research (the Netherlands), stem cells (Germany) and GMO field trials (the Netherlands). Moreover, the Netherlands has taken an isolated position concerning the implementation of the EC biotechnology patent directive.

For years, the Netherlands and the United Kingdom have been attractive locations to perform clinical studies not only because of a high quality research infrastructure. It also proved to be relatively easy in these countries to start already with clinical studies before having completely finalised the pre-clinical research. Therefore, the development process of a new drug or treatment could significantly be shortened. However, the new EC directive on Good Clinical Practice is expected to level the Dutch and British situation with the rest of Europe.

There is a general agreement among the actors on the necessity of a regulatory framework: to assure standardised procedures for safety conditions for research, to improve the work practices and to facilitate contracts with suppliers. The interviewees also mentioned that a regulatory framework would support the social acceptance of biotechnology-related activities. Interviewees from both firms and public research organisations in Portugal, Greece and Belgium called for even stricter regulation as this would help to improve safety and quality in their countries. However, both firms and research organisations also mentioned some major disadvantages of the regulatory system. The extensive administrative procedures and increasing complexity of regulation make the application process time-consuming, very costly and slows down the research activities, especially for small companies. In addition, firms and public research organisations in Belgium, Germany and the Netherlands complained about the inconsistency between regulations and the lack of coordination between responsible authorities.

However, the major complaints refer to the lack of European harmonisation and the differences in national practices of implementing EU regulations. New directives are not implemented in all Member States at the same time and the way directives are implemented also differs. For example in the case of gene therapy, clinical trials are regulated differently among Member States: some regulate clinical trials under the contained use directive, others regulate it under the deliberate release directive. In addition, the evaluation procedures for the design and the conduct of these clinical trials differ throughout the EU (Kampmeijer & Van der Zanden 2003). Another example is the implementation of Directive 2001/18/EC for field trials with genetically modified organisms (GMOs): the United Kingdom has already fully implemented this directive, while Germany, France and the Netherlands are expected to do so in 2003 (Kampmeijer & Van der Zanden 2003). These differences in regulation lead to extra costs due to duplication and extra regulatory affairs staff in firms. It is argued that they will also contribute to higher costs for R&D and innovation in Europe, compared to the USA. These complaints were put forward by respondents in each country, but relatively less in the countries of cluster 1 and in Greece and Portugal. European harmonisation is especially called for in relation to clinical research, animal testing, novel foods, stem cell legislation and GMOs.

Especially in Belgium and Germany, small firms and public research organisation indicated that they lacked sufficient regulatory expertise. They pleaded for (more) public support in understanding the regulatory framework as the complexity of biotechnology regulation increases constantly over time. Public support for dealing with regulation issues is used by some interviewees in Austria, Spain, Portugal, Denmark, Germany, Belgium and Italy.

However, in most cases firms rely on their own experiences, on firm resources and on external support from specialist companies to be kept informed about the regulatory framework, while public research organisations rely on personal networks.

5.7 Human Resources

Especially in Finland the availability of human resources for biotechnology research and development is a serious problem: companies and public research organisations reported that they needed to recruit foreign staff (US, Estonia and Rumania among other nationalities). Also, public research organisations in Germany, the United Kingdom, France and Greece had problems in hiring young researchers like post-docs and PhD students. In general there is a specific deficit of skilled researchers in bioinformatics, followed by chemistry disciplines like combinatorial chemistry, medicinal chemistry, and computational chemistry. In addition, there is a lack of technical assistants, mainly in Germany, Belgium and Austria. However, it was reported that in Spain, Portugal and also in Greece there is a serious lack of jobs for young researchers; this might lead to a brain drain to other European countries and to the USA.

Although in general, firms had no serious problems in finding high qualified research staff, a number of interviewees from small firms mentioned problems with finding personnel

with a combination of scientific and business skills. Firms in Denmark, Belgium, Ireland, and Italy also mentioned the lack of multidisciplinary background of young researchers. There is no overall consensus on this, but it was mentioned regularly by small firms that "… an excellent scientist can become a good manager, but an excellent manager can never become a good scientist". For that reason, small firms believed that natural sciences studies at universities also should include management and business courses.

Interviewees from public research organisations reported that it was increasingly difficult to attract young researchers, and above all to retain outstanding researchers. They said that universities and research institutes were considered as an unattractive employer. Compared to companies, universities are not able to offer attractive working conditions, high salaries and status.

Finally, in some countries bureaucratic and legal barriers made it difficult to hire foreign scientists, especially non-EU citizens. Even though some EU-members have introduced special conditions to support and to ease the hiring of foreign scientists, there is still a need for more explicit policies in the area of mobility of human resources. Respondents in Denmark and Sweden mentioned the 'heavy tax burden'-image of their country as an important barrier for foreign researchers to settle in their countries.

5.8 Socio-economic and ethical aspects of biotechnology

Government programmes to support activities that deal with socio-economic and ethical aspects are mostly non-existent in the 14 EU Member States or scarcely used by the scientists of public research organisations and firms.

In those countries where government initiatives regarding socio-economic and ethical aspects of biotech existed, there was no general consensus in the assessment of the interviewees. Only in Germany, Sweden and Finland most of the respondents from both public research organisations and firms considered these initiatives as supportive. Dutch public research organisations and firms were rather critical about the public initiatives (mainly public debates). They argued that these initiatives were not sufficient and also that the organisations that wanted to communicate with the public have not been supported and rewarded enough. Portuguese interviewees mentioned that the public is not very responsive to biotech issues. This is mainly because they are not informed about biotechnology and thus are not interested in public debates. According to them education of the public should become a higher priority in government policies.

Across Europe, respondents from both firms and public research organisations considered the socio-economic aspects of their biotech activities as very relevant. Several large firms and public research organisations (mainly active in medical research) reported to have internal ethics committees that assess research plans. Most actors that took into account the socio-economic and/or ethical aspects when planning research and designing production processes, reported that they did this because of existing regulations and procedures that obliged them to do so. Another, rather different argument was getting a positive reputation. Several public research organisations also said to deal with socio-economic aspects of their research because they felt some responsibility for this.

However, those firms and public research organisations that did not take socio-economic aspects into account, said that this was because they were involved in biotechnology research areas that had no important ethical or socio-economic considerations. These considerations are mostly related to biotech activities such as animal testing, clinical research, cloning, and use of stem cells and genetically modification techniques, and they were not active in these fields.

The socio-economic and ethical issues – although considered as relevant and important – had hardly any effect on the research or production activities of firms and public research organisations. Only in a few cases public research organisations and firms had decided to stop specific activities (e.g. plant biotechnology projects), to move specific research abroad (e.g. animal testing, or to adjust their R&D programme). Main

reasons to do this were the low public acceptance of the technology or the high costs due to tight regulations.

Only a limited number of respondents were actively involved in discussing and communication activities with the public, such as participation in special committees (e.g. on ethics), organisation and participation in public debates and roundtables, give lectures, attend conferences, and write articles for the popular press. For those organisations that did participate this was mostly on an individual basis of an interested employee. Especially large firms and public research organisations were actively committed to these kinds of activities, while small firms showed to be more reluctant in this.

For the majority that was not engaged in these activities, the main reasons for this were that they are not active in areas with possible controversial issues and, above all, that they want to keep a low profile in order to avoid attention from pressure groups. Only in Denmark and Austria non-governmental organisations like pressure groups, churches and consumer organisations were engaged in activities of some firms and public research organisations.

None of the firms or the public research organisations did perform research on socio-economic and ethical aspects themselves. Most important reason: it did not fit into the overall mission of the organisation. However, some firms had ordered specific socio-economic and ethics research to be done by other specialised organisations. The results were used as an input to the firms' strategic planning.

5.9 Summary and conclusions

In this chapter we discussed a number of issues that emerged from the interviews and national case studies as very relevant for the future development of European biotechnology. From a policy-making perspective we believe that especially three issues should receive a high priority in national and European biotechnology innovation policies.

The three key issues are:
- The renewal of the knowledge base;
- The stimulation of business development;
- The framework conditions for IPRs at public research organisations.

Not another European paradox

The EPOHITE findings point out the importance of the knowledge base policies for the development of biotechnology. Those countries that have emphasised in their national policies the support and renewal of the biotechnology knowledge base during the period 1994-2001, appear among the best performing countries in biotechnology in Europe, both in terms of scientific and commercial performance. Moreover, among the best performing clusters, no single country is present that has mainly concentrated on the commercialisation of biotechnology and more or less neglected the knowledge base. This shows the need of a continuous focus in innovation policies on creating and improving outstanding and excellent scientific research in biotechnology. Without a cutting-edge biotechnology knowledge base European countries will not only be limited in their scientific production but also in their capacities of absorbing and exploiting and thus commercialising new scientific developments. Allansdotir et al. (2002) also emphasised the importance of a strong science base by pointing out the high correlation between R&D productivity as well as the rates of firm creation with the strengths of universities and research institutions in biotechnology.

The Third European Report on Science and Technology Indicators (European Commission 2003b) – but earlier also other reports – highlighted Europe's very high numbers of graduates and publications, higher than the United States. This is a relative strength of the European S&T-

system, including biotech. However, the disability of Europe in turning this strength into innovative and commercial viable applications was reported in many European policy studies in the beginning of this century and was generally referred to as the European Paradox (among others: Allansdotir et al. 2002 and European Commission 2003). As a reaction to this, European countries have introduced instruments to support applied, industry relevant research and the valorisation of it.

We observed in a significant number of countries that the focus in biotech R&D policies is shifting from basic research programmes to more applied and industry driven research programmes. Allansdotir et al. (2002) noticed the same trend; the most important focus in innovation policy in the recent years was on science-industry relationships and entrepreneurial professors. They interpreted this as a reflection of an understanding of the innovation process based on transfer of knowledge, instead of a more integrated approach. On the short term this trend may lead to a rapid growth in the commercialisation of biotech in Europe. However, on the long term this could lead to a new paradoxical situation where Europe will have improved its capabilities for exploiting the results of scientific research but will no longer be able to play a leading role in (basic) scientific research in biotechnology. The pool of cutting-edge biotech research could run dry, making the European biotech innovation system dependent upon scientific research produced elsewhere. As biotech is a science driven industry, national governments and the EU should include instruments that support the continuous renewal of the biotech science base, including both fundamental and applied research, as an important part of their biotech innovation policies.

Stimulating entrepreneurship and business development

National biotech firm creation programmes in Europe have been rather successful. The number of new biotech firms has almost doubled since mid 1990s; in 2001 the growth stabilised. Nevertheless, there certainly is a future for biotechnology as an industry, but the actual economic crisis has changed the perspective of many young start-ups considerably. Business models solely based on patent positions and their promises are no longer accepted; venture capitalist also request products that could guarantee an income.

In most of the 14 Member States the support for high tech biotech firms is mainly emphasising the first stages of development. Another observation is that business growth instruments for SMEs seemed, at least in a number of countries, to favour more the larger than the smaller and medium sized firms(21). It was also noticed that small companies had very serious problems with public programmes. In some countries, none of the start-ups and small firms interviewed used public support for financing innovation. The most important reason was the relatively heavy administrative and also financial load of public R&D programmes.

The European biotech industry is moving to a new development stage; after the start-ups programmes of the late 1990s the need for support is shifting. In those countries where the biotech industry moves towards more mature development stages, a differentiated set of instruments is required that address the specific needs of these companies and that facilitate a creative environment in which market forces can operate. Ernst & Young (2003) reported a trend away from direct state support toward changes in tax systems and the legal framework to encourage entrepreneur ship. This gives in to wishes of a considerable number of firms we interviewed who qualified tax measures as very attractive (presumably also because they demand relatively less administrative procedures).

In developing these new business support programmes, national policy-makers have to take into account the specific characteristics of their national industry profiles: industrial base, development stage of biotech industry, strength in sciences base and other national resources, etc.

(21) Tait et al. (2002) mentioned also that support for SMEs is indirect support for large firms, as the small firms strongly depend on the large firms for commercialisation their techniques and products. So support for SMEs is "*de facto*" supporting the development costs of large firms.

Intellectual property rights

The demand for a uniform patent regime in Europe was expressed several times during our interviews. Uniform implementation throughout Europe was considered as one of the most important conditions for the future development of the European biotech business sector. However, the implementation of the Biotechnology Patent Directive in the EU Member States still has not been completed in a number of countries.

Our interviews also brought forward some other very relevant IPR issues concerning the incentive and the support systems. There is quite a variety in treatment of IPR at public research organisations across Europe. The OECD has made a first, experimental attempt at benchmarking the various systems in OECD countries and recommends that the experiment be repeated (OECD 2003). This report also shows that there is an international trend to assign IPR ownership to the research institute. This is also the case for a number of European countries. In some countries, this regime is complemented with a principle of 'shared benefits' for both scientist and institution like in Germany and Denmark. However, there are still some countries in which the inventor is the prime proprietor. There are pros and cons to both of these systems. In case the researcher becomes the legal owner of IPR the research organisations will not always be willing to provide appropriate and expensive support. On the other hand, when the research institute becomes the IP owner, the scientist will lack the motivation and incentives to patent.

Effective IPR policies need both an incentive and a support part. The key question is how to combine these two. Possibly the regime where the research institute becomes the owner with a system of 'shared benefits' could inhibit such a combination. However, the regimes are quite young and their effects on commercialisation are not clear yet. Moreover, Sweden and Finland are two examples of countries that have not followed the international trend and they show very good results in terms of commercialisation performance. A benchmark through in-depth case studies of these different systems in which pros and cons are analysed in relation to their performance, could lead to a list of specifications, to which an ideal system should comply. On the basis of this, European countries could develop incentive systems according to a more uniform model.

A second important issue is the lack of qualified IPR service systems. In most countries researchers and industry complained about the support systems that are at place in universities and public research institutes. This mainly regards the missing capabilities in these research organisations in handling IPR. At the core of these problems is the serious lack of both legal and biotechnological expertise in the responsible service centres. Moreover, these centres – most technology transfer offices – work too bureaucratically and have insufficient knowledge of their clients' needs. This is especially true for general technology transfer offices, in contrast to the specialised organisations in biotechnology, like BioResearch Ireland and the Flanders Inter-university Institute for Biotechnology. Additionally, it appears that very often IPR management and planning are not part of the research management plans at public research organisations. Finally, companies throughout Europe complained that research organisations often make unrealistic assessments of the commercial value of patents.

National governments could investigate in detail the effectiveness of the present support systems at universities and research institutes in stimulating and supporting researchers to patent and industrial partners to acquire academic IPRs. Moreover, policy-makers could investigate the important advantages, but also possible disadvantages, of support systems that are highly specialised into a specific technology area, such as biotechnology.

Other relevant framework conditions

The other four issues are also relevant framework conditions for future development of biotech in Europe, but we would argue that these issues do not seem to cause immediate major barriers to the development of biotechnology and therefore policy initiatives are expected to be less urgent:

- Regarding the support of **R&D collaboration**, our analysis shows that public research organisations and firms use the support instruments frequently and assess them in a rather positive way. However, public policies seem to be more effective in sustaining existing R&D partnerships than in stimulating firms and research organisations into new networks and quite a number of firms had serious problems with administrative procedures and specific conditions concerning financing. Future policy-making could be directed to solve these problems and shape lower entrance levels to these programmes.

- **Laws and regulations** for biotechnology are increasingly set at the European level. Differences among European Member States are the result of national differences in implementation and application of these laws and regulations. Removing these national differences should be an issue for national and especially European policy-makers.

- Concerning the **availability of human resources** in biotechnology, the analysis showed shortage of personnel (in specific areas)in the Nordic countries and a shortage of jobs in the Mediterranean countries.

- Finally, the acknowledgement by governments, scientists and firms of the importance of **socio-economic and ethical aspects** concerning biotech has not led to many coordinated initiatives in this area so far. Public policies can play an important role by providing information on biotech and by initiating open and constructive dialogues involving representatives from industry, research organisations and the public. Moreover, public policies should also be aimed at stimulating industry and academia to take up their own responsibility in communicating with the public.

6. Effectiveness of Biotechnology Policies

6.1 Introduction

In order to assess the effectiveness of a broad range of policies to promote the biotechnology science base and its commercialisation, this chapter draws together the results of the analysis of indicators to assess the performance of European countries in biotechnology (chapter 3), national policy approaches to biotechnology (chapter 4) and the views of key actors about the relevance of national policies (chapter 5). It will also use these sources to identify problems connected with some policies.

The assessment of effectiveness presented in this chapter fully recognises that there is great difficulty in identifying direct links between specific policies and outcomes. In the first place, there are limitations in the statistical indicators used to measure national performance. Systematic data for biotechnology is scarce (see table 1 in European Commission 2003) and as indicators cover a limited set of activities only, they may not fully reflect the performance of a specific country. Confidence in our results, however, is provided by the results of another study (European Commission 2003) which arrived at a very similar ranking of national performance in biotechnology although it used a different range of indicators. A second problem relates to the fact that there is a time lag between the date at which a policy is introduced and its results. This has been dealt with by mainly covering policy activities for the 1990s and using performance indicators for the period 1999/2000. Thirdly, national economic, institutional, cultural or legal conditions may hinder the fulfilment of policy objectives. Finally, some policies may only achieve the desired outcomes in conjunction with other complementary policies. Specific examples of the two latter problems are included in this chapter.

The next section discusses macro-level policies and in particular the effect of overall government policies for science and technology, including the proportion of funds allocated to R&D and the way in which funds are allocated. Section 3 discusses the effectiveness of a range of specific policies that aim to promote the biotechnology both in terms of the knowledge base and of its commercialisation and the key issues affecting biotechnology development in Europe. Gaps in policy coverage are identified in section 5 and the chapter concludes by considering the wider implications for policy effectiveness that have emerged from this study.

6.2 Macro-level policy approaches and effectiveness

It is important to recognise that path-dependence has a strong influence on the development of biotechnology in a specific country. As pointed out in chapter 4, the potential for biotechnology development is strongly influenced by the size and strength of the national economy, the structure of existing industry and the intensity of R&D. Large R&D intensive countries that have strong firms in sectors that can benefit from the application of biotechnology and a large internal market would appear to have a major advantage over both small and large countries with low R&D intensity or firms in relevant sectors. The results of our analysis, however, show that small countries with high R&D intensity out-perform the large, high R&D intensity countries. Partial explanations for this anomaly are related to two aspects of national science and technology policy at the macro level which are discussed in the followed sections: (a) the method used to allocate research funds and policy coordination and (b) the range and type of policy instruments.

6.2.1 Methods for allocating research funds and coordination

The analysis shows that the number of policy actors involved in supporting biotechnology differs from country to country, but the degree of pluralism does not of itself affect performance. Countries with many policy actors appear both in the high performance cluster (Denmark and Sweden) and well as in the weak cluster (Portugal). A better explanation is provided by looking at both the research funding system and the extent to which it is coordinated.

Chapter 4 groups countries according to their system for allocating research funds, and changes in these systems over time. It notes that systems based on public research institutes, tend to be rather fragmented(22) (e.g. France, Germany, Italy and Spain). Research funds are allocated in the form of a block grant and this gives public research institutes great autonomy to control their research agendas. Systems based on research councils have a strong programme orientation and funds are allocated in the form of peer-reviewed competitive grants. Research council systems appear to have the capability for cooperative working to achieve a coherent strategy for research and for diminishing the number of policy actors over time. This can lead to policy concentration (e.g. Denmark and Sweden in the case of the organisation of the research councils). The third system is based on funding organisations. The organisation funding basic research is usually separate from that responsible for applied research and interactions with industry. There is no clear pattern of either fragmented or concentrated policy in the countries following this system.

Countries with a concentrated policy-making system mainly cluster in the best and second best performing clusters. Most of these countries are small countries with high R&D intensity (Finland, Denmark, and the Netherlands), but the United Kingdom also falls into this group. Ireland, the sixth country with a concentrated policy system, also has a relatively good performance in terms of its rather low investment in R&D and its low starting point. Policy concentration therefore appears to have a positive effect on performance.

The analysis in chapter 4 also indicates that higher performance is related to *ex ante* coordination, before the implementation of strategic decisions. Coordination can be achieved in a large country with numerous actors supporting biotechnology research. However, this appears to be mainly connected with the research council system of funding (e.g. the United Kingdom). In contrast, fragmented decision-making has a negative effect on performance, particularly in large countries with systems based on autonomous public research institutes (Germany, France, Italy and Spain), where coordination can only be carried out *ex post*. Competitive funding by research councils or funding organisations may lead to more effective performance than the provision of block grants to public research institutes because it is a flexible system benefiting from peer review procedures. The organisation of competition between actors therefore appears to be a more effective method to achieve high scientific performance than direct control of funds by research institutions.

6.2.2 Range and Type of Policy Instruments

Countries have used three types of policy instrument to support biotechnology research: biotechnology-specific or "vertical" policies, broad science and technology or "horizontal" policies and policies to build a supportive environment to facilitate biotechnology development. Chapter 4 discussed the evolution over time from vertical to horizontal policy. It may be appropriate for countries with strong biotechnology performance to make this shift. However, some countries with poor scientific performance, such as Greece, Italy and Spain, have provided either low or no support through vertical policies for the biotechnology knowledge base. One consequence of this may be that the relevant actors might have been too weak to gain funds from horizontal instruments in competition with other technologies. Horizontal policy may be ineffective at supporting the biotechnology knowledge base unless it is preceded by vertical policy or some other method to strengthen national scientific capabilities. Finland, for instance, although traditionally placing more reliance on horizontal than vertical policy to build up the knowledge base, concentrated in the mid 1990s its resources for basic research in biocentres and is now introducing a growing number of biotechnology-specific programmes.

(22) As discussed in chapter 4, a fragmented system is one where there is little coordination of strategy amongst actors and actors define strategy with high independence.

Some of the weaker countries have also tended to focus on either supporting the knowledge base (e.g. Portugal) or commercialisation (Greece). Evidence from the more successful countries suggests that these types of policies are complementary and cannot be used as substitutes for each other. Moreover, the stronger countries have also supplemented vertical and horizontal policies with a range of instruments to provide a favourable environment for the commercial exploitation of biotechnology research (discussed in more detail in section 6.3.2 below). Policy effectiveness therefore seems to derive from policy breadth in vertical and horizontal instruments – introducing policies to encourage activity in every part of the biotechnology innovation system.

6.3 Effectiveness of specific policies

6.3.1 Knowledge base

The significance of scientific knowledge to the biotechnology innovation system heightens the importance of developing and renewing the science base. The extent to which national policy approaches are effective in supporting the knowledge base (both basic and applied research) is therefore a key issue. The analysis of the four clusters of Member States shows diversity in the policy approaches adopted: the countries with good or excellent performance (clusters 1 and 2) support the knowledge base, but the weaker countries appear to give it too little priority (e.g. Austria, Italy) or insufficient resources (e.g. Portugal). The scientific performance of most of the countries in the higher two clusters confirms the importance of giving priority to policies to support the knowledge base (see table 6.1), and particularly the support of basic research.

Table 6.1: Knowledge base score and biotech research expenditure

Country	***Score (2000)*** (Source: EPOHITE[23])	***Per capita expenditure 1994-98 (MEUR)*** (Source: Enzing et al, 1999)
High Performance		
Sweden	9.43	30.6
Denmark	9.16	26.0
Finland	8.65	48.1
2nd Best		
United Kingdom	8.15	43.5
Netherlands	8.02	20.0
Belgium	7.74	54.0
Germany	7.17	36.8
Intermediate		
Austria	7.65	6.1
France	7.34	35.9
Ireland	6.18	12.4
Weak		
Spain	5.8	1.8
Italy	5.7	3.6
Portugal	5.0	7.3
Greece	4.0	1.9
Correlation coefficient = 0.68		

(23) See table 3.1 in chapter 3.

However, as table 6.1 also shows there is only weak correlation between national knowledge base scores as presented in table 3.1 (section 3.4) and per capita expenditure on research. For instance, Belgium has the highest per capita expenditure but achieves sixth place only in terms of its performance. Finland has more than twice the per capita expenditure of the Netherlands, but only a slightly higher score. Denmark also achieves a very high score, from rather modest per capita expenditure. Italy and Spain achieve a similar score, although Italian expenditure is twice that of Spain. This indicates that high expenditure does not necessarily lead to high scientific output and that other factors also affect scientific performance.

In terms of the intermediate cluster of countries, Austria and Ireland, are both small countries with a weak knowledge base in term of scientific production, but their knowledge base performance reflects the high visibility of both knowledge bases (in terms of citations) and their international character (in terms of internationally co-authored papers). France benefited from a large knowledge base in 1995-96. By 1999-2000 there was only a small increase in French publications and citations despite a rather large amount of money being dedicated to R&D, highlighting the inefficiency in the organisation of French research. The poor performance of France could be explained by the organisation of funding (allocation of block grants to PSROs), lack of international evaluation for researchers and PSRO researchers competing with each other rather than with international colleagues. Spanish researchers also used to receive a high proportion of their research funds from block grants. There have been recent changes to the system of research funding in Spain with a higher proportion of funds now being allocated through a competitive, peer-reviewed, response-mode approach. The new approach may explain recent improvements to the Spanish knowledge base.

Allocating research funds through a competitive, response-mode approach therefore seems more effective than institutional funding in the form of block grants. It could be argued that the response mode facilitates the support of unconventional ideas that are not necessarily covered by policy directed instruments. It also works well when there are strict and clear selection criteria, and international evaluation of research proposals also exerts a positive influence, especially in small countries. Block grants seem to lead to poorer performance, because they provide only limited incentives to stimulate researchers' performance. They may also lead to duplication in the research work being undertaken. Any coordination should not be taken too far, however, but recognise that competition between research groups seeking to solve the same problem in different ways can be beneficial.

The international biotechnology knowledge base is expanding rapidly, creating a plethora of new sub-disciplines, e.g. bio-informatics and functional genomics, all of which can contribute to the conduct of research. Countries that allocate low resources to research, especially those in the weak sector, may suffer from lack of "critical mass". In Portugal, for instance, where funds are allocated on the basis of competitive, peer-reviewed grants, many PSROs complain that their researchers can experience long gaps between grants. Several small countries have a policy to concentrate resources into a small number of research groups (e.g. Ireland) and this may be an appropriate development strategy for small countries with limited resources for research. As mentioned in section 2.2 above, Finland, a small high-performance country, in the mid 1990s concentrates funds by allocating them to biocentres.

The lower knowledge base scores of the large research-intensive Member States (e.g. France, Germany and the United Kingdom) compared with their smaller counterparts may be an effect of the rapidly expanding science base, particularly when large countries attempt to progress every area of research. Another cause of underperformance could be high cost involvement in large international programmes like the Human Genome Project, that initially relied on very large teams of researchers to undertake sequencing, without a commensurate increase in publications or citations.

Analysis of national science performance and policy does not suggest that there is any relationship between scientific performance and higher priority for basic than applied or industry-oriented research. However, the analysis of policy approaches reveals a recent shift in policy, away from fundamental and towards more applied and industry-driven research programmes. In the short term this may have the potential to aid the growth of European industry. However, in the long-term, this could lead to a depletion of the European knowledge pool and failure to keep up with the rapidly expanding knowledge frontier. As biotechnology is based on science and drives a science-based commercial sector, failing to invest sufficiently in fundamental research so as to renew the knowledge base could be detrimental to European firms. In this connection, it is relevant to note that Ireland, which originally allocated most funds to industry-oriented or applied research, has recently invested significant funds in basic research, after realising that this was important for the development of new industry. Firms of all sizes anticipate benefit from the new policy.

Finally it is important to recognise effective knowledge base performance may depend on introducing policies to change adherence to outdated procedures in the universities. For instance during interviews in Italy several companies mentioned that they cannot recruit scientists with relevant biotechnology skills. They thought that fragmented, disciplinary training in the university sector is having a negative effect on the biotechnology skills of its scientists.

6.3.2 Commercialisation

There is a wide variety of direct policies to encourage the commercialisation of biotechnology in Member States. These include the commercialisation of the results of public sector research, the application of biotechnology to new products and processes by existing firms (both in high-tech and traditional sectors) and the creation of new firms. In recognition of the significance of scientific knowledge to biotechnology innovation, an important arm of policy for commercialisation are instruments to encourage collaboration between public and industrial research (discussed in detail in section 6.3.3). General policy on intellectual property and its ownership, for regulating biotechnology and for making investment capital available for high-tech sectors has also been addressed with the aim of creating a favourable environment for innovation (each of these issues is also discussed in detail in subsequent sections of this chapter). This section provides an overview of the mix of policies that appears to be most effective in stimulating the commercialisation of biotechnology.

Analysis of national policy and performance indicates that success in commercialisation is achieved by countries with a broad set of policies that target all the elements of the innovation system and the links between them. The differentiation between direct and indirect instruments is not that relevant, nor the priority given to basic or applied research. In addition, it is not sufficient for commercialisation policies to concentrate only on funding applications-oriented research or supporting firm creation. Commercialisation is best promoted by having a mixture of instruments to encourage all potential actors to contribute to the commercial exploitation of biotechnology knowledge.

It seems self evident that policies for commercialisation cannot work in the absence of a strong science base but some countries with poor commercialisation performance (Greece and Austria) have given priority to policies for commercialisation but not paid sufficient attention to developing the knowledge base. Other poor performers have prioritised basic research, but neglected commercialisation (e.g. Portugal). This finding highlights the fact that policies to support the knowledge base or to promote commercialisation are complementary rather than substitutes for each other.

It is also necessary to introduce policies to create a favourable environment for both knowledge creation and commercialisation. This may include advice and support about how to conform to biotechnology regulations, or protect intellectual property, the provision of finance for start-up firms and policies to encourage existing firms to apply biotechnology to their products and

processes. It is significant that most countries in the two weaker clusters have paid insufficient attention to these policies for creating a supportive environment for innovation.

In some countries, the achievement of effective commercialisation may demand that policies are introduced to change institutional norms or cultural attitudes in PSROs that inhibit entrepreneurial activity. In France, for example, academics used to be reluctant to create spin-off companies, or work in industry, because of the risk of losing permanent academic positions. Mobility between academia and industry has been promoted by allowing academics who work in firms to resume their academic posts if not more than six years have elapsed. Another barrier to commercialisation within the university system could be the training given to doctoral students. Many firms that were very satisfied with the scientific knowledge provided by doctoral training, mentioned the need to broaden this training to include more about industrial practice, needs and entrepreneurship, so as to create a larger population of entrepreneurial people. In other words, effective commercialisation performance depends not only on appropriate policies for creating knowledge and commercialising it, but also on stabilising the environment for innovation by reducing some of uncertainties and difficulties that face would-be entrepreneurs.

In terms of promoting commercialisation of the science base, it may be important to tailor investment in the knowledge base to areas which are relevant to strong economic sectors within a country. Some countries do this by involving industry policy formulation, especially Denmark, Sweden, Finland, Germany, the United Kingdom and France. These countries have performed better than countries like Portugal, Greece or Spain where industry has no chance to influence policy formulation; indeed in Portugal, such involvement is prohibited by law. Industrial involvement in policy formulation can raise industrial awareness of the potential benefits of research, knowledge of the work of national researchers and research on topics of relevance to national industry.

The general results suggest that commercialisation performance is related to a wide range of factors. In small countries or those with limited resources for research the concentration of resources can play an important role. Commercialisation and science base performance both appear to benefit from policy to concentrate resources. Ireland, for example, has had a long-running strategy to concentrate resources on six PSRO centres only, each in a different area of biotechnology relevant to the Irish economy, and to commercialise the results. This has created a biotechnology sector in Ireland and led on to the funding of basic research. The agriculture and the food industry are important economic activities in other countries with weak performance (Spain, Portugal and Greece), suggesting that priority should be given to concentrating research support relevant to these sectors in a small number of PSROs. Research to be undertaken by these PSROs needs to be subject to prior peer review, to maintain scientific standards.

The national reports suggest that a wide variety of factors account for the number of biotechnology companies in a given country, such as its existing industrial structure, the attractiveness of a country for foreign investment or supporting measures to stimulate the creation of new firms (e.g. making venture capital available or providing incubators). The employment conditions of academics, ownership of intellectual property in PSROs or lack of entrepreneurial attitude by academics (as in Portugal) may hinder the creation of firms. Knowledge about the factors supporting commercialisation may be drawn from Spain, whose performance now seems to be improving. Recent changes in policy which may contribute to improved performance do not concern shifting priorities for basic or applied research. They are to do with increasing the allocation of research funds through peer-reviewed assessment and reducing block grants, encouraging firms to hire qualified scientists and engineers, and introducing instruments to support firm creation together with assuring the availability of financial capital.

6.3.3 Collaboration

Policies aiming to promote collaboration and networking between academic and industrial research are probably amongst the most prevalent in biotechnology programmes in Europe. According to the actor's assessment summarised in chapter 5, public programmes promoting collaborative research have wide acceptance among the actors involved in innovation activities, specially in the northern European countries and among PSROs. However, due to the following difficulties, these promotion programmes are not always effective, especially in southern European countries:

- Bureaucratic procedures are a major barrier that reduce the number of applications to collaborative programmes specially in Greece, Portugal, Italy and Spain.
- Delays in grant payments lead to a negative perception of grants after completion of the projects in collaboration. Policy effectiveness is limited because firms have no incentives to apply for further project grants.
- In Greece collaborative programmes are hindered by the limited number of firms involved in biotechnology. These programmes can therefore have a limited effect only on creating public-private networks in biotechnology.

The preceding points lead us to question the effectiveness of these policy instruments in southern European countries. The problem is that programmes linking public researchers with private organisations are not based on a long-standing collaborative tradition. Rather, these programmes aim at building the tradition. Poor effectiveness is explained by factors far beyond the scope of these programmes. It is connected to lack of trust in national initiatives, lack of understanding between the two communities that share a mutual interest in biotechnology but for different reasons, and policy-makers' failure to understand the incentives that may stimulate researchers and firms to work together.

The fact that there is a sketchy, yet significant differences in the assessment of these programmes by southern and northern countries leads us to question the uniform replication of these programmes across Europe. It is of concern that policy-makers assume that financial incentives will be sufficient to link the different communities. However, when communities are not stimulated by similar incentives, and when they do not have a long standing tradition of collaboration, as tends to be the case in southern countries, the implementation of collaborative programme may not fulfil their promise, especially when they are coupled with demanding bureaucratic procedures and poor organisational backing. It is noticeable, however, that private researchers know beforehand with whom they want to collaborate, i. e. the specific PSRO and, if necessary, they do not hesitate to bypass public programmes. What is also evident is that public researchers are ready to assist and learn from industry when they perceive that there is a need for it. In the latter case, the benefits of self-organisation seem to prevail over public intervention.

The cost of linking different communities with highly divergent incentive structures may outweigh the potential benefits that can arise from these collaborations. EPOHITE findings point out that public programmes aiming at developing public-private networks have failed in countries where there is little tradition of interaction between PSROs and industry. This does not question public support. Rather, it is the form of its support (its organisation) as well as its philosophy (its aims and views), which demand a thorough rethinking.

6.3.4 Intellectual property rights

Intellectual property rights (IPRs) are thought to play a key role in knowledge dissemination. For this reason, policy approaches need to promote the appropriate framework conditions to provide the incentives that support patenting and licensing in biotechnology. Three issues are relevant for policy design: the IPR regimes for university inventions, institutional support to ease the complex patenting and licensing process and harmonisation of IPR regimes.

Concerning the first issue, it is extremely difficult to assess the impact of IPR on academic research because our understanding of the phenomenon remains very limited (Geuna & Nesta 2003). However, the view of technology

transfer (TT) activities has shifted from being seen mainly in the area of managing research agreements with firms, to one in which the primary task of TT is to 'assess and protect IP and make it available to industry'. According to the European Commission report on the causes of publication failure (2002), the level of scientific expertise and codification experience required for patent applications is far less than that required for scientific publication. Thus learning both how and when to patent should be a minor cost for scientists and for academic research as a whole. However, changes in IPR policies in universities are likely to have limited effects because researchers are not trained to write patents. Policies that try to enforce university patenting must allow for additional costs, i. e. sunk costs, inherent in learning how to write patent applications.

The regimes for assigning the IPR from PSROs' scientific research can influence the incentive system and framework conditions for patenting. EPOHITE has identified three regimes in the EU Member States (see chapter 5). However, we still know little about the impact of these different regimes on academic patenting. It is often argued that PSROs are not always willing to provide appropriate and expensive support to the scientist in the patenting process where the scientist/inventor is the legal owner of the IPR. On the other hand, when the PSROs are the owners of the IPR, the scientist has no clear incentive to protect the research results. Effective IPR policies need to do both, to offer incentives and to support the scientist in the patent application process. The key question is how to combine these two goals. Benchmarking – by making in-depth case studies of both regimes – is needed to analyse the differences between the systems, and assess the costs and benefits in relation to their performance.

Most, if not all European countries have strongly promoted the creation of institutions to support the patenting of university research results. Today, technology transfer organisations (TTOs) can be found in most universities. EPOHITE interviews point to one TTO model where respondents evaluated the services as satisfactory and effective. Its key characteristic is the concentration of expertise for biotechnology IPR in a few key institutions responsible for technology transfer.

Questions arise as to whether these different sets of instruments for patenting academic IPR are consistent with the general missions of the university, i. e. the generation of new knowledge and its dissemination to wider society through scientific publication, teaching and training. We know little in Europe about the effects of university patenting on the nature and conduct of university research, while in the US, evidence about the effect of the Bayh-Dole act on universities remains inconsistent (Mowery et al. 2001, Jensen & Thursby 2001).

6.3.5 Human capital

Policy effectiveness either in scientific performance or commercialisation is intimately linked to the availability of skilled scientists. In successful countries, high demand leads to shortage of skilled recruits, whereas in weaker countries lack of employment opportunities leads to a brain drain. The latter is an example of extreme policy ineffectiveness because there are enormous costs for society, which bears most of the cost of producing human capital but does not or cannot seize the opportunity to enjoy the benefits of its initial investment. In addition, the disciplinary organisation of education, especially for a multidisciplinary area like biotechnology, seems to hamper the employability of young researchers in biotechnology research, be it public or private.

Most biotechnology programmes tend to assume the quality of scientists and young students instead of aiming to reinforce it. A notable exception is programmes favouring the mobility of scientists to industry, and, to a limited extent, *vice versa*. Although our results show very limited evidence as to their effectiveness, these programmes both enhance knowledge or technology transfer while being very intense in terms of learning. Learning here has many facets, ranging from scientific and technological to managerial and commercial learning. On the whole, biotechnology programmes are likely to prove more effective if they rely on a more solid pool of research, both in terms of quality and quantity.

6.4 Gaps in Policy

Policies that have addressed biotechnology as a key element for innovation and economic growth have relied on a particular view of biotechnology development: biotechnology is interdisciplinary and must combine several bodies of knowledge and/or heterogeneous actors or communities. In this respect, this view is confirmed by one of the main conclusions of this EPOHITE study: biotechnology development must rest on a strong knowledge base and on the capability of programmes to address both scientific and commercial purposes. This leads us to identify four gaps in policy that appear as necessary, though not sufficient conditions for the successful development of biotechnology. These are gaps in supporting firm growth; gaps in sustaining the strength of the science base; gaps in management knowledge and skills; and structural gaps in the national system of innovation.

6.4.1 Gaps in Supporting Firm Growth

The analysis of policy instruments in Member States and interviews with companies revealed that public support available to firms mainly supports the creation and first stage of small companies, but support for the growth and further development of these companies is lacking. Managing company growth is a key entrepreneurial task which does not require policy intervention. The need for policy intervention arises from the need to capitalise on the large amount of public investment dedicated to company formation which could be in danger of being wasted when companies fail. Among the problems faced by growing biotechnology companies is securing new rounds of finance, finding premises to rent with specialised laboratory facilities and, in the better performing countries, recruiting qualified scientific personnel.

To enable the maturation and consolidation of these emerging biotechnology companies, there is need for a differentiated set of instruments to meet their specific needs:

> "Public authorities should finance small firms with pre-commercialised ideas or prototype so they can develop their ideas. Our jobs is to develop, [but] we do not succeed in going to the industry (sic). "

Instruments supporting biotechnology R&D in firms should be based on a better allocation of funds between research, the "R", and development, the "D". Notably, the scarcity of the funds allocated to the development from prototypes to the later stages of industrial production inhibits the embodiment of knowledge outputs into marketable artefacts. Of importance should be the role of public institutions supporting this stage. It is noticeable that most government efforts support the firm creation phase while providing few policy instruments to support firm growth.

6.4.2 Scientific Gaps

Another strong EPOHITE observation is that nurturing biotechnology implies the *sine qua non* condition of nurturing science and renewing the biotechnology knowledge base as successive waves of new research areas are being generated. Countries lagging behind are those that fail to adequately sustain a strong science base in biotechnology, creating caveats in the breadth of what one could call the national knowledge base. It is not clear that the implications for effective policy are similar if one looks at small countries or concentrates on larger ones.

Smaller countries should have a specialisation advantage. They could benefit from research specialisation in areas which best fit national strengths and needs. Larger countries should have a size advantage. First, larger countries are in the position to establish large research centres and concentrate a substantial amount of facilities in biotechnology research at a time where biotechnology equipment is becoming more costly to acquire and manage. Examples of large research centres are the Genopole in Evry, France, which acts as a catalyser of resource utilisation in the realm of genomics. Second, large countries are in the position to support a sufficient critical mass in a broader range of new areas. The United Kingdom, Germany, and France provide evidence of research activities in a wider range of research areas than smaller countries. This, it should be noted, comes at a cost: the division of labour and that of knowledge do not neatly and naturally overlap, leading to the duplication of R&D efforts in biotechnology. Policy-making systems should explicitly address the issue of division of

labour in biotechnology research, the allocation of resources and the coordination between institutions. A similar issue arises at the European level particularly in view of the imminent European Research Area. There seems to be a need for stronger coordination between European and national programmes in the sense of achieving more complementarity rather than substitution.

6.4.3 Gaps in Management Knowledge and Skills

Firms in many countries commented that the training given to doctoral students lacked any component that could provide them with understanding about industrial practice, needs and entrepreneurship or, indeed, with management skills. This pointed to a gap in policy relating to scientific training and curriculum development. National biotechnology developments could be promoted by making "entrepreneurial" training a small, but integral part of all scientific doctoral programmes.

6.4.4 Systemic Gaps

The previous point leads to the final observation on policy gaps, which relates to systemic gaps. Systemic gaps in public biotechnology programmes are those gaps that are due to addressing biotechnology objectives irrespective of the whole national system of innovation. Let us take the case of France, with a poor performance in research while investing in biotechnology at comparable levels to the United Kingdom or Germany. It appears that the problem is not due to deficiencies in biotechnology programmes per se. Rather, the deficiencies are structural in the sense that that they appear to be generated by shortcomings in the organisation of research as the whole, i. e. the national system of innovation (see chapter 4 on the structural deficiencies of the French NSI).

Systemic gaps in biotechnology occur when an isolated policy instrument is at odds with the structure of the national system of innovation. Biotechnology as a research field and as a promising source of economic growth must not be thought of as being divorced from the entire system of innovation. Therefore, we shall stress the fact that addressing policies in biotechnology is strongly connected with the national incentive structures, the reward systems and the practices within and across communities, such as academics, private researchers, entrepreneurs and firms. Policies that seek to provide temporary solutions to deficiencies in the knowledge base have been adopted recently in some countries, e.g. France, Italy, Spain. These are unlikely to succeed unless significant changes are also made to overcome structural deficiencies in the national innovation system. The same is true for policies imported or replicated from other countries where they have proved successful.

The aim of EPOHITE was not to address general issues of what constitutes a well-balanced national system of innovation. Economists have devoted substantial efforts in depicting these characteristics, but no clear picture has yet emerged. We should like to stress, however, that issues regarding the incentive structures for public and private scientists seem particularly important in understanding the performance of countries in biotechnology in particular, and in research in general (Dasgupta & David 1994).

7. EPOHITE conclusions and recommendations

In this concluding chapter we summarise the main findings of EPOHITE and on this basis present our recommendations for policy-makers. The recommendations are structured along the following aspects: methodological issues, performance of Member States in biotechnology, improving policy effectiveness.

Methodology

Findings

There is still a lack of internationally comparable quantitative and qualitative input and output data that are suitable to describe the structure and performance of biotechnology innovation systems. This contributes to the more general difficulty of establishing causal relationships between policy measures (input) and performance (output).

Recommendations

(1) Additional efforts of the EC to improve data availability by supporting activities aiming at generating a set of agreed upon input and output indicators for describing biotechnology innovation systems are strongly recommended.

(2) Additional research into developing suitable methods for benchmarking biotechnology policies should be initiated. Such approaches should avoid considering specific policy measures in isolation. Rather the specific conditions of a country (e.g. economic specialisation, legal situation, culture, traditions at universities and PSRO) and the whole set of different policies and their interactions should be taken into account.

Performance and policy implications

Findings

There exists a close relationship between scientific and commercial performance: almost all countries are performing either weakly or strongly in both categories.

With respect to their overall performance in biotechnology European Member States can be grouped into four different performance clusters: cluster 1 with the best-performing countries Denmark, Sweden and Finland; cluster 2 with the second-best-performing countries the Netherlands, the United Kingdom, Belgium and Germany; cluster 3 with Austria, France and Ireland, representing countries below the European median performance value, and finally cluster 4 with the Mediterranean countries Italy, Spain, Portugal and Greece performing weakly as measured by all indicators. Comparison of biotechnology policies within and between these clusters shows the following:

- National policies for the biotechnology knowledge base and for its commercialisation have a pronounced effect, which can be either positive or negative. In other words policy matters!
- Policies to create and sustain the knowledge base are also crucial for commercialisation but the reverse is not true.
- Countries that have taken a systems perspective and implemented a broad set of policies to promote biotechnology that address all the functions of the innovation system and create an environment conducive to entrepreneurial activity achieve better performances than countries with patchy and fragmented policies.
- Achieving *ex ante* coordination amongst strategic policy decision-makers (public or private) responsible for all the different functions of the innovation system can be extremely beneficial to developments at a national level and in avoiding policy gaps or duplication.

Recommendations

(3) The desire to promote the commercialisation of biotechnology should not lead to policies where the sole focus is on support for commercialisation. Rather, it is recommended to implement a balanced mix of instruments that target the creation and sustaining of a competitive biotechnology knowledge base and commercialisation. In countries with weak scientific performance and low research expenditure special emphasis should be given to vertical policies because these are essential to building up scientific capabilities.

(4) The exploitation of biotechnology in the EC would be enhanced by providing management and entrepreneurship training to postgraduate scientists in biotechnology.

(5) Policy-makers should keep a watch on the future development of the performance of biotechnology in European countries. In some countries the first indications of a drying up of the knowledge base are already appearing and policy efforts to support a renewal of the knowledge base are recommended.

(6) The design of biotechnology policies should be based on a systems perspective of the innovation process in biotechnology. This implies that policy-makers should be aware of the strong and weak points of their national system and consider the (positive or negative) interactions of all policy measures that have an influence on the development of the biotechnology innovation system.

(7) We recommend policy-makers to review the results of policy initiatives from time to time, including discussions with targeted actors, so as to improve policy design and better achieve intended objectives.

Findings

The specialisation patterns in biotechnology of most Member States are similar. This observation raises several questions:

- Biotechnology is still at a stage of uncertainty where there are numerous possibilities for its future exploitation. Therefore diversity of competencies is advantageous for adopting and driving future developments of biotechnology. This leads to the question whether there exists enough diversity across European countries' biotechnology competencies.
- What impacts on diversity are expected from the forthcoming ERA? Which role should European policy play in relation to Member States' policies?

Recommendations:

(8) Further research on the role of diversity in specialisation in scientific and commercialisation patterns within Europe for the future competitiveness of European biotechnology should be initiated.

Effectiveness in relation to the organisation of the research system

Findings

Public policies have more impact in policy systems that are based on the allocation of grants through a competitive peer-reviewed process (e.g. by research councils or other funding organisations) compared to systems based on the allocation of block grants to research institutes or other PSROs. Competitive peer-reviewed systems are characterised by higher flexibility, stronger competition between research performing actors and a stronger international orientation. In addition, the response mode component of such systems facilitates the support of unconventional ideas that are not necessarily covered by directed policy.

Recommendations

(9) Efforts to increase the effectiveness of policy measures should take into account the need to change the organisation of the research system.

(10) In order to improve the effectiveness of the utilisation of funds, competitive funding schemes should be favoured over block grant schemes.

Effectiveness of specific policies

Findings

Due to the strong dependency of biotechnology on science, cooperation between industry and research institutions is important. In line with this fact we find many policy instruments in all countries aimed at supporting such cooperation. However, the value added by such policy initiatives can be questioned as they are mainly used for non-strategic research. This seems to be related to the fact that relevant policies usually are formulated from a supply-side (science) perspective, and neglect the demand side.

Recommendation

(11) In order to improve the effectiveness of policy instruments supporting cooperation programmes the demand perspective should be strengthened in the sense that support for cooperation should be given only after such a demand has been expressed.

Findings

Technology transfer offices (TTOs) are evaluated negatively. The main reasons for the weak performance of such institutions are the lack of competencies in biotech and IPR and capacities.

Recommendation

(12) Concentrate responsibility for technology transfer activities in TTOs with expertise in both biotechnology and IPR. Professionalism in terms of scientific and regulatory knowledge should be a key qualification of TTO staff. In addition, a critical mass of competencies is required.

Findings

There are still many problems related to patenting in addition to the more general harmonisation issue (e.g. the lack of knowledge at universities and technology transfer offices, too costly and too time-consuming procedures, and the absence of incentives for patenting by PSROs and universities).

Recommendations

(13) Improving the conditions for patenting should stay on the political agenda as an important issue. As a first step for improvement a careful analysis of the caveats with respect to patenting at the different institutions is recommended.

(14) We recommend to make a benchmark of the various IPR regimes implemented in European countries for handling IPR at universities and PSRO. Performing in-depth case studies of these systems to analyse their pros and cons in relation to their performance should lead to a description of 'best practice' cases and specifications to which an ideal system should comply. On the basis of this, European countries could develop incentive systems according to a more uniform model.

Findings

Many start ups have been formed in Europe during recent years and a large share of these are the result of public policy initiatives. Increasingly such firms are approaching the growth stage and at the same time getting access to the required financial resources is becoming more difficult. This situation raises the question of the attitudes to these firms that should be adopted. It seems evident that a selection phase will arise where only a limited number of firms will be able to move towards sustainable growth. This in turn poses the question of the role of government in this process: should the selection be an independent market driven process or should policy intervene?(24)

Recommendations

(15) In order to avoid interference with market mechanisms, we do not unequivocally recommend direct support for the growth stage of firms. However, we do recommend

(24) It is important to note that the US provides public venture capital, particularly for small technology-based firms, because "growth in our economy and employment has come from small business and much of this growth arises from advancement in technology. Because of a shortfall of funds, there is often a gap… between what technology entrepreneurs can and cannot do to bring new technology to the market after a prototype is developed." (Etzkowitz et al. 2000).

the creation of favourable framework conditions for growing biotech firms. Support to firms for dealing with the recruitment of scientists, regulations in general and IPR issues in particular, ethical issues, consumer issues and conditions for private financing can all have a positive effect on performance, and therefore should form an important component of any policy strategy. This recommendation is in line with the observed trend of biotechnology policies across Europe to develop beyond vertical or horizontal specific policies to framework-oriented policies.

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